Quality Enhancement and Assurance in Abdominal Surgery

A multimedia approach

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Chapter 1

General introduction

Since the dawn of civilization, physicians around the globe have been captivated by the possibility of visualizing human's concealed body cavities. From the first ever documented endoscopic inspection of an internal organ by Arabian physician Abu al-Qasim (936-1013 CE), followed by Avicenna's (980-1037) fundamental addition of reflective light to the method, it has taken generations before the framework of modern endoscopy was built.[1,2] It's origin however, can be traced back to the industrial revolution and the technical advancements made in that era, which paved the way for the rapid innovation we have witnessed in endoscopic surgery so far. It was not until the year 1901 that the first endoscopic visualization of the peritoneal cavity was performed by Dresden based surgeon and gastroenterologist Georg Kelling (1866–1945), dubbing the procedure as "*koelioscopie*" (derived from Ancient Greek: *κοιλιά*, meaning "abdomen", and *σκοπέω* meaning "to see").[3] The presently more common name for this technique "*laparoscopy*" (of which the first part is derived from the Ancient Greek word *λαπάρα*, meaning 'flank' or 'side') was coined by his Swedish contemporary Hans Christian Jakobæus.[4] From that moment on, endoscopy has increasingly been used for diagnostic and later on also therapeutic purposes.

Still, performing endoscopic surgery in those days was an awkward and uncomfortable task, given the fact that the procedure had to be carried out by directly peering through the endoscope's eyepiece whilst passing verbal instructions, often ineffectively, to the operating assistant burdened with the task of blindly navigating the surgeon's field of view. To address this problem, several surgeons experimented with the use of video cameras – often intended for commercial use – combining these with their endoscopy equipment on their own initiative. The first in this regard to mention the two together was George Berci in his 1962 article "*Endoscopy and television*".[5] The main focus of his research however, was to provide improved documentation methods and novel teaching capabilities, not necessarily to alter the mode of operation. The first to recognize not only the physical constraints of this traditional approach, but also its impedance in performing more advanced surgical procedures, was Camran Nezhat. From the late 1970's and onward, Nezhat started to routinely perform laparoscopic procedures directly from a video monitor.[6,7] However, like the pioneers of endoscopy during its implementation encountered resistance amongst their peers, Nezhat faced the same fate as his predecessors in his transition to performing endoscopic surgery "*off the monitor*". Nevertheless, many physicians eventually embraced the possibilities of this method, preluding the mass implementation of endoscopic surgery we know today.

In the 1980's, the endoscopic revolution started to take form. Gynecologist Kurt Semm, by many considered as the father of modern endoscopic surgery, invented the automatic electronic insufflator and further developed endocoagulation.[8] In 1980, he performed the first laparoscopic appendectomy, after which he was subject to outrage from both surgeons and gynecologists. Surgeon Erich Mühe however was fascinated by Semm's technique, not affronted by it, as the rest of his colleagues were. Using Semm's instruments and technique, Erich Mühe perfomed the first laparoscopic cholecystectomy in 1985.[9] Shortly after in 1987, Philippe Mouret performed the first ever *video-assisted* laparoscopic cholecystectomy.[10] These events prelude the drastic increase in procedures using a minimally invasive method, with laparoscopic cholecystectomy as prime example; a mere five years after introduction, approximately three quarters of all cholecystectomy cases were performed using a minimally invasive approach.[11-13] Due to this rapid increase, a large number of surgeons found themselves in unchartered waters. Formal training was not yet widely available and the transition from open surgery proved difficult for many.[14] This became particularly apparent in the incidence of one of the most dreaded complications of cholecystectomy: bile duct injury. In the first few years, the incidence of this potentially life-threatening complication rose significantly among patients operated by this method, with reports suggesting a two- to four-fold increase compared to the traditional open cholecystectomy.[15-20] However, as operator experience and cumulative case load increased, the incidence of BDI remained high.[21-23] Therefore, a common explanation for this problem has become that misidentification of biliary structures, rather than the novelty of the approach, is the major cause of biliary injury in laparoscopic cholecystectomy. Specifically local operative risk factors, e.g. active or chronic cholecystitis and obesity, as well as the presence of aberrant anatomy, might engender the operator to misinterpret the biliary structures, potentially causing erroneous clipping and transection of a major bile duct.[24] In an attempt to correctly identify the cystic duct, surgeons started using a technique later dubbed as '*infundibular technique*'. The essence of this technique is that a ductal structure is identified as the cystic duct by visualizing the traditional '*flare*' or '*funnel*' shape at the junction of the gallbladder infundibulum and the cystic duct. This technique was popularized because of the need of identification measures, as fundus first resection traditionally done in open cholecystectomy – in which the cystic duct is exposed by the natural flow of the surgery – was awkward to perform in a laparoscopic approach. However, this technique has been judged to be a hazardous method of identifying the cystic duct.[25]

It was not until 1995 that an anatomically well-defined method was introduced in response to the drastic increase of bile duct injury and the immense morbidity that accompanies it. In their critical review of the problem, Strasberg et al. proposed a number of criteria to abide by in order to decisively identify the structures entering the gallbladder.[26,27] No structure should be transected before that. The moment of this conclusive identification was dubbed as "*the critical view of safety*". In order to reach the critical view of safety, one has to achieve the following: 1) Calot's hepatobiliary triangle must be dissected free of fat, fibrous, and areolar tissue (it does not require the common bile duct to be exposed). 2) The lower end of the gallbladder must be dissected off the liver bed. 3) Only two structures should be seen entering the gallbladder. Being a crucial step in the procedure, it has been recommended by the Association of Surgeons of the Netherlands (*Nederlandse Vereniging voor Heelkunde - NVvH*), as well by the Society of American Gastrointestinal and Endoscopic Surgeons (*SAGES*) in the United States of America, to record the critical view of safety on photo or video before transection of structures.[28,29] This way, it is properly documented whether the identification of structures was indeed decisive.

For years, creating a photographic record of an operative event, rather than a videographic one, had been the most feasible method. This despite the fact that videographic representation is significantly superior to its photographic or written counterparts.[30-32] For a long time, the main reason for this has been that a photograph took fewer actions to create and was easier to implement in the patient record. The last decade however have seen many technical advancements, along with hospitals making the switch from paper-based to electronic patient records. Because of this, video documentation has become less challenging to accomplish, prompting a whole new dimension in research focussing on education and quality of care.

A major benefit of intraoperative video documentation is the fact that it provides an objective source of technical procedural information, especially in endoscopic surgery, as the video is a one on one representation of the surgeon's vision during the procedure. This in contrast to the currently implemented method of operative reporting by way of the narrative, i.e. written or dictated, operative report. This source is, by definition, subjective and proved to be lacking necessary information on a regular basis.[32] A different method of improving the flaws of the traditional narrative operative report is the synoptic operative report. With a synoptic operative report a concise summarization of the surgical procedure is made using predefined leading criteria, which can be produced with ease using a computerized template. Furthermore, by the addition of quality of care indicators in this reporting method, these factors can be monitored efficiently, avoiding the need for double entry in a separate report.

An excellent example of what video can provide for quality improvement in surgery is the study conducted by the Michigan Bariatric Surgery Collaborative.[33] using peer-rated procedural video of laparoscopic gastric bypass surgery to assess participating bariatric surgeons' technical skills, the authors demonstrated the relationship between technical skills and postoperative outcomes. Overall, the study determined that greater technical skills do indeed result in significantly fewer postoperative complications.

Taking it a step further, Theodor Grantcharov, professor of surgery at the University of Toronto, wanted to initiate a switch from the traditional "reactive" management of adverse events, to a "proactive" approach. In order to achieve this, he developed the surgical 'black box'. Like its namesake in aviation, this recording device registers multiple inputs, i.e. sound (speech), videos from several angles (surgical site and surroundings), and patient's vital signs. This is all recorded in real-time over the course of the surgical procedure.[34]

Outline of this thesis

The aim of this thesis is to evaluate the main quality factors in abdominal surgery, in particular laparoscopic colorectal surgery and laparoscopic cholecystectomy, that could be enhanced by use of intraoperative video and audio recording and investigate barriers for implementation. It consist of three parts:

In Part 1, different modalities of multimedia recording and subsequent utilization are delineated.

In Part 2, the use of intraoperative systematic video recording for quality assurance in colorectal cancer surgery is covered.

In Part 3, quality and safety methods for laparoscopic cholecystectomy and notably the relevance of intraoperative systematic video and audio recording are reported.

PART 1 – Multimedia as a quality improvement tool in surgery

Chapter 2 provides an overview of the several advantages, as well as some significant barriers in medico-legal, ethical and technical fields. Due address the fact that many surgical parameters deemed important by surgical practitioners are omitted or inaccurately represented in the traditional operative report, synoptic operative reporting might be of assistance.

In **Chapter 3** a systematic review comparing the synoptic operative report with the narrative operative report in surgical treatment is reported. Despite the rapid developments in video recording in the operation room, the views of medical professionals having to deal with this have been poorly know.

In **Chapter 4** the results of a nationwide survey of these key players regarding the use of intraoperative multimedia recording are presented.

In **Chapter 5** the effects of segmentation in video-based learning of a surgical procedure (i.e. open inguinal hernia repair) are assessed.

PART 2 – Quality assurance in colorectal cancer surgery

In **Chapters 6 and 7**, the added value of intraoperative systematic video recording in laparoscopic colorectal cancer surgery are reported in a pilot study and a subsequent multicenter, prospective, observational cohort study, respectively.

PART 3 – Quality and safety in laparoscopic cholecystectomy

Chapter 8 provides a comprehensive review on several methods of bile duct visualization to reduce the most dreaded complication in laparoscopic cholecystectomy: bile duct injury.

In **Chapter 9** the results of a nationwide survey among surgeons and residents in training are reported regarding their current methods of executing laparoscopic cholecystectomy and their knowledge regarding the critical view of safety method in this procedure.

For **chapter 10 and 11**, the roles of intra-operative audio and video recording in terms of operative reporting are defined.

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Part 1

Multimedia as a quality improvement tool in surgery

Chapter 2

An image says more than a thousand words: Standardising video registration in the operating theatre

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ABSTRACT

Today, video imaging is a major part of laparoscopic surgery. Despite continuous efforts to improve or innovate laparoscopic techniques, the registration of laparoscopic imaging for quality of care purposes remains an afterthought. By recording the essential steps of a surgical procedure, it is possible to inquire in more detail about what actually occurred in the operating theatre. However, it is necessary to take the legal framework into account. Questions concerning patient consent, permission from healthcare providers, whether video documentation should enter the patient record, and the length of the period it is retained must be answered. Also, the prevention of the misuse of information is important and therefore the purpose of documentation needs to be put on record beforehand. Video documentation is a promising method of registering surgical quality. However, the first priority is to demonstrate the actual quality improvement of video documentation and the formulation of precise guidelines.

INTRODUCTION

In recent years, recording surgical procedures on video has become increasingly accessible. Originally intended for educational purposes, these video images were later on also used for quality improvement in surgery. The prime example is found in laparoscopic cholecystectomy, in which the 'critical view of safety' is documented on image as adjunct to the operative report, to demonstrate that the transection of structures was done without any anatomical misidentification. Meanwhile, this method is standard practice in the Netherlands.[1]

Despite the ongoing innovation and improvement in image quality, it seems that documenting laparoscopic images for quality of care purposes, aside from this example of laparoscopic cholecystectomy, remains an afterthought. In aviation, the police sector, and even in top-class sport, video is currently being used as a quality improvement tool. Furthermore, all events in aviation are recorded in real-time during flight by a so called 'black box', something that is still not a prerequisite in surgery. It is self-explanatory that the events which transpire during the surgical procedure have a major impact on postoperative outcomes. Not documenting these crucial events is therefore a missed opportunity.

In this article we discuss the pros and cons of peroperative video registration as a method of documenting the care provided and improving its quality, as well as the legal aspects that accompany it.

Background

The outcomes of a certain treatment could differ immensely among similar patients. This is notably the case in complex surgical procedures, such as rectal surgery. For instance, after rectal surgery the majority of patients suffer from potentially avoidable functional disorders, e.g. urogenital dysfunction and faecal incontinence.[2-4] Also due to this variability the importance of quality control policies are widely endorsed.

The chief example of quality control in surgery is the addition of the 'time-out'-procedure to the guideline regarding the peroperative phase. This procedure implies that the 'surgical safety checklist' is run down in the presence of all attending the surgical procedure, including the patient, before the start of the procedure.[5] However, this checklist mainly focusses on the preoperative factors, whilst peroperative factors are also defining for the eventual prognosis. The applied surgical techniques could not be analysed in this way and additionally this checklist does not guarantee that essential operative steps are executed in a correct manner.

Currently, the traditional and often subjective operative report is the only source of information of what transpired during surgery, especially in absence of the primary surgeon. The operative report does indeed provide a textual outline regarding the general course of the procedure, yet prior research has demonstrated that operative reports lack critical components at times.[6] In a recent study, we have determined that video documentation of surgical procedures provides a more detailed and objective representation of peroperative events.[7]

Quality improvement and control

Purposeful and systematic application of video documentation in surgery could lead to quality improvement in several ways. For instance, it is possible to compare distinct surgical techniques among each other or optimise a certain approach. Using video-analysis, a number of peroperative causes of sexual dysfunction were identified in patients that underwent radical prostatectomy.[8] In a similar way, an operating team could review footage of the procedure as a form of self-reflection, for example after a complication has occurred.

The development of a 'black box' in surgery, of which recently a version was brought into service in the Academic Medical Center Amsterdam, follows this ideal. Comparable to an airplane equipped with a flight data recorder, the operating theatre is prepped with recording equipment which continuously registers video and sound of the surgical procedure and operating theatre surroundings, as well as data regarding the patients' vital signs. The goal is to document all technical and non-technical actions (i.e. communication) of the operating team in real time, so that causes of possible adverse events could be identified upon review of the black box data.[9] In theory, the mere realisation that the surgical procedure is recorded on video could potentially improve outcomes, the so called 'Hawthorne-effect'.

Is consent necessary?

The act of documenting this kind of personal data is bound by legislation. The primary rights that patients are granted in their relation to a treatment provider are written in the Medical Treatment Agreement Act (Wet op de Geneeskundige Behandelingsovereenkomst – WGBO).[10]The management of patient data is recorded in the Personal Data Protection Act (Wet Bescherming Persoonsgegevens – WBP).[11]

In the process of creating peroperative video, three situations can be distinguished.[12] In situation I, video is an integral part of the treatment provided, for instance in the case of laparoscopic surgery. In situation II, the images are not an indispensable part of the treatment but are an added value in, for example, quality improvement, such is the case with the black box. Situation III concerns the use of images that are used for a different purpose than was initially intended, such as for education.

Article 8 of the WBP states that unambiguous consent is a prerequisite for the processing of data which can be traced back to a person. Naturally, in all previous situations consent from both patient and treatment provider is necessary. Yet in theory, certain types of video documentation will not be traceable to the person in question, for instance endoscopic images. To use these types of video documentation in practice however, e.g. as documentation method or for quality improvement, requires patient identifiers. Therefore, video documentation in principle will be covered by the WBP.

Situation I is a noteworthy case. In this, the creation and processing of images is interwoven in such a manner with the treatment, that its justification lays in the accomplishment of the medical treatment agreement. Given the fact that this agreement already is based on patient consent, the images may be processed, if only for documentation purposes. In the cases of situation II and III, patient consent is indeed necessary. In addition, it is not unthinkable that in the case of situation II, recorded video images could potentially become such an integral part of the treatment, that these eventually appertain to situation I.

Moreover, it is plausible that for the use of images such as in the case situation III 'assumed consent' is applicable, as is described in KNMG-guideline 'Handling medical data' and article 7 and 9 of the Healthcare Quality, Complaints and Disputes Act (Wet Kwaliteit, Klachten en Geschillen Zorg – Wkkgz).[13,14] This is then exclusively applicable to the use of images for internal quality improvement purposes, of which the patient has to be informed about.

Storage and retention period

How should these video images be stored? In situation I, in which the creation of these images is an essential part of the treatment, addition to the patient file is recommended.[12] In that case, the documentation will be covered by the WGBO and the images, with a few exeptions, will be stored 15 years from the moment of creation.[10]

In situation II the images, which are not essential for the treatment, would not necessarily have to be stored in the patient file. These are then covered by the WBP, of which article 10 states that a retention period has to be defined beforehand.[11] As of yet, no concensus regarding this exists.

Drawback of video documentation

Documenting peroperative video does pose some risks. If the purpose for which data may be examined and by whom is not properly documented beforehand, information could then be used for a different goal that was formerly intended, which in turn might lead to exposure of not only the patient, but also the members of the operating team. This is undesirable. All members of the treatment team must be able to open up for improvement, whilst care is being taken to maintain a 'no-blame'-culture. The WGBO allready states who is able to review patient data, including video images, for what purposes.[10] For images covered by the WBP, this should clearly be formulated in advance.[11]

A different fact of great significance is that the medical disciplinary committee and the public prosecuter is allowed access, under strict circumstances, to the stored video documentation for use as evidence.[12,13] The objective representation that video documentation provides does not necessarily have to discredit the healthcare professional. It might just as well speak in favor of the defendant.

Future perspectives

Changes in healthcare practice are often received with hesitance. Implementing peroperative video documentation will be accompanied with challenges on legal and technical areas. For instance, at this moment only endoscopic procedures are reasonably suitable for video documentation. Recording video using the current IT envrironment in operating theatres is often complicated to achieve, let alone the storage of the great amount of data in the case of the surgical black box. It is also important to realise that video documentation is not destined to replace the written operative report. Many healthcare providers are not able to interpret the video images and also the considerations of the operator are less adequately documented using video alone.

Conclusion

Video documentation is a promising method to record surgical quality. We consider that it is a question of time before this method will take a prominent place in the operating theatre. Until that time, the priority is to demonstrate actual quality improvement through video documentation and the development of clear guideline regarding documentation and use of video images. In 2016, an international prospective multicenter trial has been initiated from the Erasmus University Medical Center to evaluate the process and results of systematic video- and sound registration in the face of documentation and quality improvement.

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Chapter 3

A systematic review on the synoptic operative report versus the narrative operative report in surgery

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ABSTRACT

Background

Proper documentation is an essential part of patient safety and quality of care in the surgical field. Surgical procedures are traditionally documented in narrative operative reports which are subjective by nature and often lack essential information. This systematic review will analyze the added value of the newly emerged synoptic reporting technique in the surgical setting.

Methods

A systematic review was conducted to compare the completeness and the user-friendliness of the synoptic operative report to the narrative operative report. A literature search was performed in EMBASE, Ovid MEDLINE, Web of Science, Cochrane CENTRAL, and Google Scholar for studies published up to April 6, 2018. The Newcastle–Ottawa Scale was utilized for the risk of bias assessment of the included articles. PROSPERO registration number was: CRD42018093770.

Results

Overall and subsection completion of the operative report was higher in the synoptic operative report. The time until completion of the operative report and the data extraction time were shorter in the synoptic report. One exception was the specific details section concerning the operative procedure, as this was generally reported more frequently in the narrative report. The use of mandatory fields in the synoptic report resulted in more completely reported operative outcomes with completion percentages close to 100%.

Conclusions

The synoptic operative report generally demonstrated a higher completion rate and a much lower time until completion compared to the traditional narrative operative report. A hybrid approach to the synoptic operative report will potentially yield better completion rates and higher physician satisfaction.

INTRODUCTION

In the current medicine, all healthcare providers are obliged to properly document the care services provided. Within this requirement lays the composition of the operative note, comprising the essence of a surgical intervention and an imperative part in the continuity of care.[1] For decades, the narrative operative report (NR) has been used in this manner. This reporting method, however, is subjective by nature and often lacks essential information.[2] Given the fact that proper documentation is an essential part of patient safety and quality of care, many in the surgical field have experimented with or even have implemented synoptic reporting (SR) as a substitute. The word synopsis is derived from two ancient Greek words: σύν (sún, "with or whole") and ὄψις (ópsis, "view") and can be interpreted as a concise description of—in this case—a surgical procedure. An SR provides summarized documentation containing predefined leading criteria of the surgical procedure, which can effortlessly be completed in computerized templates. This synoptic way of reporting can also be achieved by providing easily comprehensible aide-mémoires. By adding quality of care indicators to this documentation method, these factors can be monitored efficiently without the need for double entries in a separate report. A good example of an electronically stored SR can be found in a study by Vergis et al. focusing on Roux-en-Y gastric bypass.[3]

Worldwide, over seven million patients suffer major complications following surgery every year. One million of these patients will die during or immediately after surgery as a result. Around half of these adverse events are potentially preventable.[4] Checklist usage in surgery results in thousands of patients' lives being saved each year. One of the best-known examples is the 19-item WHO Surgical Safety Checklist which was developed to decrease errors and adverse events and increase teamwork and communication.[5] This checklist reduced morbidity and mortality rates by more than one-third across all participating hospitals.

Earlier publications determined the lack of available information in the traditional reports. Wauben et al. demonstrated that NRs in laparoscopic cholecystectomy contained fewer essential procedural steps compared to what could be seen on operative video recordings.[2] Another study on laparoscopic cholecystectomy concluded that cases with bile duct injury contained fewer key elements of the report than those without bile duct injury, a phenomenon likely caused by surgeons tending to focus more on reporting unusual events rather than reporting the essential steps of the operation.[6] Apart from this explanation, it is plausible that, due to medicolegal concerns and fear of litigation, surgeons may, consciously or not, omit some part of the operative report when intraoperative complications occur. Furthermore, several studies reported improved efficiency,[7] higher patient acuity level,[8] higher physician satisfaction,[9] and reduced administrative costs [10] in SRs. However, the extent of the superiority of SR and the ideal construction of the operative report remain unknown.

This systematic review evaluates the completeness and user-friendliness of the SR and the NR in the surgical setting.

Material and methods

The study protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO, http://www.crd.york.ac.uk/prospero), prior to the start of the systematic review, with registration number CRD42018093770.

Systematic literature search

A systematic search was performed in EMBASE, Ovid MEDLINE, Web of Science, Cochrane CENTRAL, and Google Scholar for studies published up to April 6, 2018, comparing SRs to NRs. There was no limit in date of publication. The search was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and limited to manuscripts written in English.[11] The complete search strategy is shown in the *Appendices*

Article selection and data extraction

Two investigators (ÖE and FWvdG) independently reviewed articles using a standardized extraction form (Microsoft Excel—Microsoft Corp., Redmond, WA, USA). Disagreements were resolved through consensus or by consulting a third investigator (JFL). Studies were excluded if no comparison was made between SR and NR or when the intervention was used in a non-surgical setting. Specific types of articles were excluded: no available full-text, non-original articles, surveys, case reports, animal or cadaveric studies, guidelines, protocols, conference abstracts, letters to the editor, replies, and editorials. Study parameters included: first author, publication year, study design, comparison method, surgery type, NR type, SR type, use of mandatory fields in the SR, number of cases, completeness of reporting, and time until completion and extraction of the report.

Risk of bias assessment

We utilized the Newcastle–Ottawa Scale (NOS) to grade the risk of bias of each included article [12] The NOS comprises eight items, categorized into three groups: selection of study groups, comparability of groups, and ascertainment of the outcome of interest. A maximum of four points can be assigned to "Selection," two points to "Comparability," and three points to "Outcome." Stars were awarded for each item to depict the quality of each study. Studies of the highest quality can be awarded up to nine stars.

Outcomes

The primary outcome was reporting completeness with respect to the total number of reported variables in SRs and NRs. The secondary outcome was user-friendliness which was divided into time until completion and readability of the report.

RESULTS

Literature search

The initial search resulted in 4120 articles. After deduplication, 2101 studies were screened based on title and abstract. A total of 2059 articles were not relevant for the reviewed question. The eligibility of the remaining 42 articles was assessed based on full-text review, of which 16 met the inclusion criteria.[13-28] The study selection process is depicted in Figure 1.

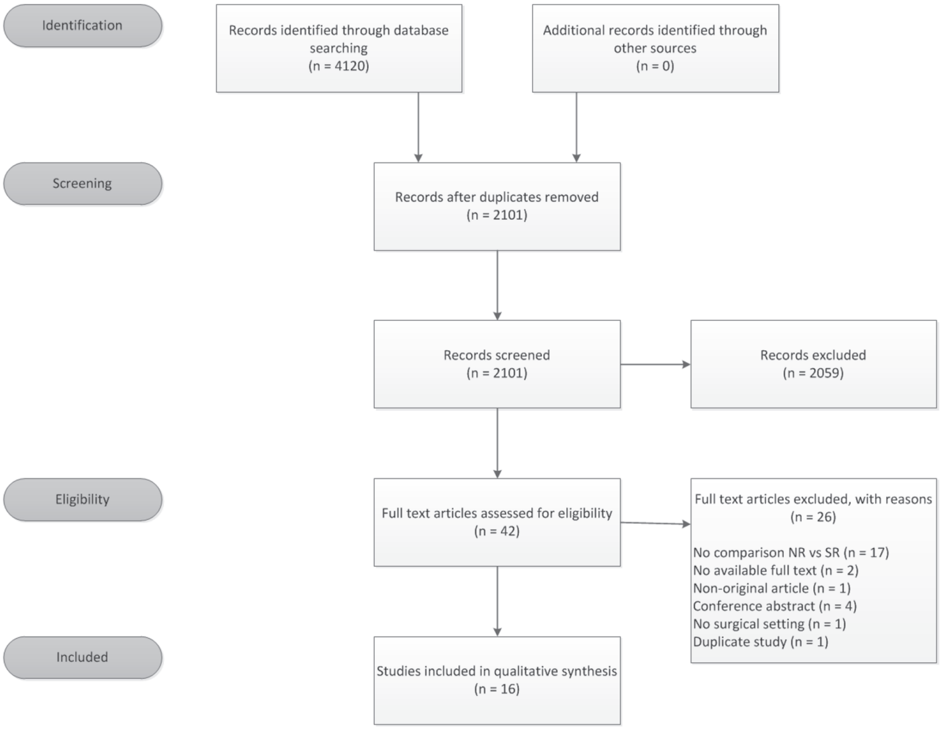

Figure 1. PRISMA flow diagram of the study selection process.

Study characteristics

Table 1 summarizes the study characteristics, and **Table 2** reports the study results. In total, 2496 cases were present in the NR group and 1688 cases in the SR group. Eight studies compared retrospective cohorts to prospective cohorts, five studies compared prospective cohorts, and three studies compared retrospective cohorts. NRs were predominantly dictated (56.3%), whereas SRs were primarily available as electronic template (68.8%). Two studies utilized mandatory fields in their SRs.

Table 1. Study characteristics.

Author	Year	Study design	Comparison method	Surgery type	Type of narrative operative report	Type of synoptic operative report	Mandatory fields in SR	Number of cases (control)	Number of cases (intervention)
Abbas et al.	2016	Before–after	Retrospective versus prospective	Laparoscopic appendectomy	Typed	Other	No	43	57
Anderson et al.	2016	Before–after	Retrospective versus prospective	Transurethral resection of bladder tumor	Not described	Other	No	428	325
Chambers et al.	2009	Before–after	Retrospective versus prospective	Thyroidectomy	Dictated	Electronic template	Yes	271	133
Edhemovic et al.	2004	Before–after	Retrospective versus prospective	Rectal cancer surgery	Dictated	Electronic template	Yes	40	40
Eng et al.	2018	Retrospective	Retrospectively	Breast cancer surgery	Dictated	Hardcopy template	No	772	110
Gur et al.	2012	Prospective	Prospectively	Breast cancer surgery	Dictated	Electronic template	No	60	60
Harvey et al.	2007	Retrospective	Retrospectively	Laparoscopic cholecystectomy	Dictated	Hardcopy template	No	102	119
Hoffer et al.	2012	Prospective	Prospectively	Kidney cancer surgery	Dictated	Electronic template	Yes	97	158
Hussien et al.	2015	Prospective	Prospectively	Trauma surgery	Typed	Hardcopy template	No	50	50
Maniar et al.	2014	Before–after	Retrospective versus prospective	Colon cancer surgery	Dictated	Electronic template	No	80	80
Maniar et al.	2015	Before–after	Retrospective versus prospective	Rectal cancer surgery	Dictated	Electronic template	No	97	97
Park et al.	2010	Before–after	Retrospective versus prospective	Pancreatic resection	Dictated	Electronic template	No	102	107
Rudra et al.	2015	Retrospective	Retrospectively	Trauma surgery	Not described	Hardcopy template	No	24	24
Shayah et al.	2007	Prospective	Prospectively	Otorhinolaryngology	Not described	Hardcopy template	No	100	100
Stogryn et al.	2018	Prospective	Prospectively	Roux-en-Y gastric bypass	Not described	Electronic template	No	100	100
Thomson et al.	2016	Before–after	Retrospective versus Prospective	Laparoscopic cholecystectomy	Not described	Electronic template	No	130	128

Table 2. Study results.

Study parameters[a]	Author	Year	Narrative report (mean %)	Synoptic report (mean %)
Overall completeness	Abbas et al.	2016	66%	94%
	Edhemovic et al.	2004	45.9%	99%
	Eng et al.	2018	45%	60%
	Gur et al.	2012	66%	94.7%
	Hoffer et al.	2012	68%	92%
	Hussien et al.	2015	After introducing a standardized printed proforma, an overall significant improvement in the studied parameters was noticed ($p < .0134$)	
	Maniar et al.	2014	31.7%	64.6%
	Maniar et al.	2015	32.2%	71.1%
	Park et al.	2010	59.6%	88.8%
	Stogryn et al.	2018	64.0%	99.8%
Identifiers	Hussien et al.	2015	Range 18–100%	Range 26–100%
	Rudra et al.	2015	Range 0–100%	Range 20.8–100%
	Shayah et al.	2007	Range 46–98%	100%
Perioperative information	Gur et al.	2012	General and preoperative sections underreported in NR compared to SR ($p = .004$) also for intraoperative sections ($p = .001$)	
	Harvey et al.	2007	Range 95–100%	Range 14–100%
	Maniar et al.	2014	Significantly higher scores on the patient–provider discussion and laparoscopic cases sections	Significantly higher scores on both preoperative evaluation and operative care data
Operative details	Eng et al.	2018	57%	59%
	Harvey et al.[c]	2007	The use of a gallbladder retrieval bag (63.0%)	The use of a gallbladder retrieval bag (57.8%)
			The size of the operative trocars (58.0%)	The size of the operative trocars (55.9%)
Postoperative recommendations	Abbas et al.	2016	95%	100%
	Hussien et al.	2015	100%	100%
	Rudra et al.	2015	Range 25–100%	Range 83.3–100%
	Shayah et al.	2007	94%	100%
	Thomson et al.	2016	95%	100%
Time until completion[b]	Edhemovic et al.	2004	–	5:59
	Hoffer et al.	2012	2:36	2:04
	Park et al.	2010	–	4:00 ± 1:36 SD
	Stogryn et al.	2018	4:50 ± 0:50 SD	3:55 ± 1:26 SD
Time until extraction[b]	Harvey et al.	2007	2:36	2:04
	Maniar et al.	2014	4:01 ± 1:14 SD	2:32 ± 0:44 SD
	Maniar et al.	2015	4:48 ± 1:32 SD	2:45 ± 1:36 SD

[a]Mean percentages unless otherwise specified
[b]Time values are given in mean time (minutes:seconds)
[c]No statistically significant difference

Table 3. Newcastle-Ottawa Scale.

Author (Year)	Selection							
	Representativeness of exposed cohort		Selection of non-exposed cohort		Ascertainment of exposure		Outcome not present at baseline	
Abbas et al. (2016)	A	★	A	★	A	★	A	★
Anderson et al. (2016)	A	★	A	★	A	★	A	★
Chambers et al. (2009)	A	★	A	★	A	★	A	★
Edhemovic et al. (2004)	A	★	A	★	A	★	A	★
Eng et al. (2018)	A	★	A	★	A	★	A	★
Gur et al. (2012)	C		A	★	A	★	A	★
Harvey et al. (2007)	A	★	A	★	A	★	A	★
Hoffer et al. (2012)	A	★	A	★	A	★	A	★
Hussien et al. (2015)	A	★	A	★	A	★	A	★
Maniar et al. (2014)	A	★	A	★	A	★	A	★
Maniar et al. (2015)	A	★	A	★	A	★	A	★
Park et al. (2010)	A	★	A	★	A	★	A	★
Rudra et al. (2015)	B	★	A	★	A	★	A	★
Shayah et al. (2007)	D		D		A	★	A	★
Stogryn et al. (2016)	A	★	B		A	★	A	★
Thomson et al. (2016)	A	★	A	★	A	★	A	★

Score interpretation:
1–3 stars: low quality, 4–6 stars: moderate quality, 7–9 stars: high quality.
The complete interpretation of the letters (A–D) can be found on http://www.ohri.ca/programs/clinical_epidemiology/nos_manual.pdf

Quality of the included studies

The NOS demonstrated that 93.8% of the studies earned above two stars for the Selection item, 18.8% of the studies earned above one star for the Comparability item, and 37.5% of the studies earned above two stars for the Outcome item (Table 3). These results suggest that nine studies [16,17,19-24,28] could be considered of good quality and seven studies [13-15,18,25-27] of moderate quality.

Completeness of reporting

Overall completeness

Studies focusing on rectal and colon cancer surgery demonstrated that the range of retrieved information from SRs was 64.6–99.0% compared to 31.7–45.9% from NRs.[16,22,23] Breast cancer surgery showed similar results ranging from 60 to 94.7% for SRs and 45 to 66%

Comparability of cohorts (adjusted for confounders)		Outcome						
		Assessment of outcome		Sufficient follow-up duration		Adequate follow-up		Total Score
C		D		A	★	A	★	6
C		D		A	★	A	★	6
C		D		A	★	A	★	6
A (operator function) B (procedure type)	★ ★	B	★	A	★	A	★	9
A (operator function) B (procedure type and n reports)	★ ★	B	★	A	★	A	★	9
C		D		A	★	A	★	5
B (procedure type)	★	A	★	A	★	A	★	8
B (operator who used both NR and SR)	★	D		A	★	A	★	7
A (operator function)	★	D		A	★	A	★	7
A (surgeon matched)	★	A	★	A	★	A	★	8
A (surgeon matched)	★	A	★	A	★	A	★	8
A (resection matched) B (procedure type)	★ ★	C		A	★	A	★	8
C		C		A	★	A	★	6
C		C		A	★	A	★	4
B (procedure type)	★	C		A	★	A	★	6
C		A	★	A	★	A	★	7

for NRs.[17,18] Studies covering laparoscopic appendectomy, kidney cancer surgery, pancreatic resection, and Roux-en-Y gastric bypass presented rates ranging from 88.8 to 99.8% for SRs and 59.6 to 68% for NRs.[13,20,24,27] Necessary reporting items concerning transurethral bladder tumor resection significantly improved from .5 to 27% when surgeons were directed to consult a 10-item checklist before surgery and while entering the operative report ($p<.001$).[14] Reporting compliance in laparoscopic cholecystectomy showed an improvement from 53% compliance in the first month of SR implementation to 67% compliance over the final two months of their study period.[19] Overall NRs in oncological thyroidectomies documented the presence/absence of tumor invasion in 27% of the cases, completeness of resection in 3%, and tumor size in 29%, whereas these were recorded in 100% of the cases in SRs ($p<.001$).[15] Other studies consistently showed higher overall completion rates in SRs.[21,25,26,28]

Completeness of subsections

Patient and surgeon identification, operation time and date, and operative diagnosis are examples of identifiers. One study demonstrated that prior to implementation of an operative note template, median completeness of identifiers was 81.65% (range 0–100%).[25] After implementation, a median completeness of 100% (range 20.8–100%) was obtained. Surgeons performed suboptimally at recording the assistant's name (82%), the operative diagnosis (46%), the incision type (87%), and the type of wound closure (83%).[26] 100% compliance in most identifiers was observed after provision of a printed aide-mémoire of a "Good Surgical Practice" guideline. An exception was that 18% of surgeons reported the surgery time and that surgeons were tended to report the surgery type in an emergency setting, but not when the procedure was performed electively.

The perioperative phase is the time period describing the duration of a patient's surgical procedure. In laparoscopic cholecystectomies, most perioperative and operative data were more completely reported in the SR (range 95–100% in SR vs. range 14–100% in NR).[19] In colon cancer surgery, SRs were associated with significantly higher scores on both preoperative evaluation and operative care data.[22] NRs were also associated with significantly higher scores on the patient–provider discussion and laparoscopic cases sections. A prospective study to breast cancer operations concluded that surgeons underreported general and preoperative sections of the dictated report compared to the same items in the SR ($p = .004$). This was also the case for intraoperative sections ($p = .001$).[18] This study also stated that the least frequent (0% - 25%) retrieved data were related to preoperative comorbidity, local and metastatic assessment, carcinoembryonic antigen levels and preoperative treatment.

In breast cancer surgery, technical operative details were completely reported in 59% of SRs and in 57% of NRs.[17]These technical details were divided into important and less important details. This division in subgroups showed that important technical details were completely reported in 69% of SRs versus 58% of NRs. Contrarily, less important technical details were reported less frequently in SRs (44% SR vs. 55% NR). Furthermore, non-technical operative details showed a larger difference between both groups, favoring SR (61% SR vs. 29% NR). Consistent to latter study, NRs of thyroidectomies routinely included nonessential information.[15] In laparoscopic cholecystectomy, operative details were more completely reported in the SR. Two exceptions were the use of a gallbladder retrieval bag (57.8% vs. 63.0%, p = .45) and the size of the operative trocars (55.9% vs. 58.0%, p = .75).[19]

Improvements in the recording of postoperative instructions after laparoscopic appendectomy in the SR were not significant.[13] Prospectively reviewed trauma surgery reports also showed no completion rate differences in the postoperative plan sections for both SR (100%) and NR (100%).[21] In a retrospective trauma surgery study, SRs yielded a median overall completion rate for postoperative instructions of 95.8% (range 83.3–100%), whereas NRs had a median completion rate of 54.2% (range 25–100%).[25] In otorhinolaryngology, postoperative instructions were recorded in 94% of NRs. After the introduction of an aide-mémoire, 100% completion of this section was detected.[26]

User-friendliness

The time until completion for SRs in rectal cancer surgery was approximately 6 min.[16] SRs for pancreatic resections took 4 min ± 1.6 min SD to complete per case.[24] In an electronic SR used in kidney cancer surgery, a mean completion time (mean time (minutes:seconds)) of 2:04 was found in SRs and 2:36 in NRs.[20] SR completion times after Roux-en-Y gastric bypass were significantly shorter than NR completion times (mean time (minutes:seconds) ± SD; SR 3:55 ± 1:26 SD and NR 4:50 ± 0:50 SD, $p = .007$).[27] Three studies focusing on the readability of the operative report recorded shorter mean data extraction times in SRs compared to NRs in colon cancer surgery (mean time (minutes:seconds) SR 2:32 ± 0:44 SD and NR 4:01 ± 1:14 SD, $p < .01$), rectal cancer surgery (mean time (minutes:seconds); SR 2:45 ± 1:36 SD and NR 4:48 ± 1:32 SD, $p < .001$), and laparoscopic cholecystectomy (SR 124 s and NR 156 s).[19,22,23]

DISCUSSION

In this review, we compared the completeness and user-friendliness of two surgical reporting techniques (SR and NR). All published studies comparing the two reporting designs have consistent conclusions. Overall completion and completion of subsections of the operative report were higher in SR. Subsequently, the time until completion and extraction of the operative report was shorter in SR. One exception to our findings was the specific details concerning the operative procedure, as this was reported generally higher in NRs. The main reason for this occurrence is most likely the lack of an extra comments section in most SR templates, in which the operator is able to report nonstandard, yet important events that have occurred during surgery.

Synoptic reporting methods were developed as a result of the lack of essential information in the NR. Despite the fact that new reporting techniques are being used more frequently, obtainment of scientific evidence regarding the extent of the added value and advantages of the SR was needed to promote further incorporation of synoptic reporting methods.

In 1994, a study was conducted on medical record keeping in which 70% of notes written by consultants were indecipherable in its present form by the nurse or junior doctor collecting the data.[29] To make usage of these poorly dictated or typed operative reports redundant, hospitals have implemented new reporting methods of which the Web-based reporting technique is the most commonly used computerized SR. It is designed to be user-friendly, and it can save data much faster and easier than the NR. Web-based reports, such as WebSMR (Surgical Medical Record), allow surgeons to securely access reports in the operating room or any other place connected to the Internet. It contains questions with drop-down menus and other functionalities, such as risk factor calculators and mandatory response fields for essential operative steps, to achieve a most comprehensive overview of the surgical procedure.[30]

Limitations

The included articles focus on a diversity of surgical specialties, and just a few of these studies had similar surgical specialties.[17-19,21,25,28] This could complicate the generalizability of the study outcomes. Seven articles were of moderate quality, which means that a proper understanding and comparability of these non-randomized studies are not fully ascertained. This could affect the interpretation and the quality of the data as presented.[13-15,18,25-27] Furthermore, we noticed that most articles compared a retrospective NR group to a prospective SR group. This way, it could be more difficult to accurately compare the two reporting methods, which might subsequently result in selection and information biases. Only a few articles were included with prospective comparisons of both reporting methods.

The analyzed data were not detailed enough to perform a pooled analysis. The previously mentioned differing surgical settings and comparison methods were also reasons not to pool the low number of studies. Each article utilized its own definitions for the different subsections in the operative reports, and these were not consistent between all studies.

Furthermore, it should be discussed that not all quality improvement projects on SR are published, which could result in higher risk of publication bias.

In general, all included studies favored SR. Nevertheless, advantages of NR and disadvantages of the current form of SR were also extensively reported. The use of mandatory fields in SRs resulted in more complete reporting with completion rates close to 100%. The use of these fields is most likely the major contributor to the high disparity in completion rates between NRs and SRs. We noticed that SRs *without* mandatory fields showed a reduced yet still considerable difference between the two types of operative reports. Thus, the overall difference in completion rates favoring the SR can be detected in both SRs with and without mandatory fields.

Importantly, physicians could feel "forced" to use mandatory tools in this Web-based approach. This mindset might consequently result in less accurate reporting. However, feeling "forced" is not a physician's main mode of thought. New implementations are not easy to get accepted by physicians due to the idea that there could be an increased workload related to data entry and a big impact on current surgeon practices which could eventually affect timely patient care.[31] This impact is, in reality, minimal and, as this review demonstrates, the time until completion and extraction of the reports is shorter. It is thus important to inform physicians about the advantages of SR.

Recommendations

Our review demonstrates that the current form of the NR lacks much information and that there is still much room for improvement in the SR. The included studies contain a wealth of information on pitfalls of and tricks for the implementation method of a new operative report. Having evaluated all recommendations, we can strongly emphasize that for the purposes of education, for dealing with any unintended consequences of surgery, and for those faced with carrying out a subsequent operation, the description of exactly what was found, any unexpected findings such as anatomic variants, and any deviations from the planned procedure are all absolutely key to providing high-quality ongoing care to patients.

Taking into account the benefits and limitations of both reporting methods, a hybrid approach should be aimed for in which the SR and NR complement each other. In this approach, information can be stored without the use of mandatory fields for nonessential information with an additional narrative and/or video description of the procedure if possible. As mentioned before, it could be beneficial to implement an extra comments box for specific details and unusual observations as a standard section. By minimizing the variability of reporting across surgeons and by adding these important details to the current SR in a standardized way, abnormalities during surgery can be seen at a glance in this more extensive version of the SR.

Conclusions

Overall completeness of the SR is higher compared to the traditional NR. Likewise, subsections of the operative report show higher completion rates in the synoptic method. Furthermore, a much shorter time until completion and time until extraction was found in SRs, which could indicate higher user-friendliness. The narrative method generally demonstrated higher completion in specific details regarding the surgical procedure. A hybrid approach to the SR could give better completion rates and higher physician satisfaction.

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Chapter 4

Current perspectives on video and audio recording inside the surgical operating room - results of a nationwide survey

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ABSTRACT

Introduction

Intraoperative multimedia recording is increasingly available. As an addition to reporting adequacy, aid in quality control and considering the growing call for physicians' accountability, it is inevitable that multimedia will play an important role. However, the perspectives of medical professionals on this matter is poorly known. In this nationwide survey, we aimed to investigate the current viewpoints concerning the use of multimedia recording in the operating room.

Material and Methods

We conducted an electronic survey among all affiliated members of the Association of Surgeons of the Netherlands, Dutch Urological Association and the Dutch Society of Obstetrics and Gynecology containing questions regarding current use of intraoperative recording and the level of likelihood or objection for certain scenarios.

Results

The response rate was 27.8%. The survey encompasses 370 (54.5%) surgeons, 71 (10.5%) urologists, 80 (11.8%) gynecologists and 158 (23.3%) residents in training. 52.4% of respondents feel that the operative report currently used is insufficient for future quality requirements. 58.5% think it is unlikely they would behave differently during surgery when intra-operative video recording is applied. 82.8% think it is unlikely that their surgical methods would be altered. 63.8% of respondents preferred only video registration when intraoperative recording is implemented.

Discussion

The majority of respondents find the current method of operative reporting insufficient for future quality requirements. There is support for intraoperative video recording, however, legal transparency is needed before either intraoperative video or audio recording could be implemented to protect not only the patients, but also the healthcare providers.

INTRODUCTION

During the last decade, the use of multimedia in the context of the operating room has increased rapidly. Capturing video, still images or sound have become an essential part of daily practice in many surgical disciplines, with the potential to benefit either individual patient care or treatment as a whole. In addition to photo-documentation of laparoscopic female sterilization probably the best-known example is the documentation of the critical view of safety (CVS) on photo or video in laparoscopic cholecystectomy as an auxiliary to the narrative operative report.[1] This approach has become an essential part in laparoscopic cholecystectomy procedures in the Netherlands and is also recommended in the USA.[2,3] Prior research demonstrated that the traditional narrative operative report does not adequately reflect reality in laparoscopic cholecystectomy.[4-6] One method to ameliorate the accuracy of these reports could be the use of synoptic reporting, utilizing a structured template to construct an operative report, diminishing the amount of data omitted and effectively increasing its integrity.[7-13] Utilizing intraoperative video recording in synergy with a written operative report also proved to be feasible and furthermore superior to the classic narrative operative report alone.[5,6]

In addition to a boost in reporting quality, use of multimedia documentation could also be invaluable for other purposes, for instance, in the case of surgical quality control and quality assurance. In a study by the Michigan Bariatric Surgery Collaborative, peer-rating of procedural videos of laparoscopic gastric bypass surgery was performed to assess participating bariatric surgeons' technical skills.[14] The authors reported a relationship between the technical skill quantified on video and postoperative outcomes, confirming that greater technical skill does indeed result in significantly fewer postoperative complications. Taking it a step further, Toronto based surgeon Dr. Theodor Grantcharov developed the surgical 'black box'. This recording device, much like its equivalent in aviation, registers data in real time from multiple inputs, i.e. sound (speech), videos from several angles (surgical site and surroundings), and patient's vital signs, in order to discern the origins of adverse events.[15]

Considering the growing call for physicians' accountability, it is inevitable that multimedia will play an important role in the foreseeable future and that it will indeed contribute to quality of care. Nonetheless, the views of key players are of great importance in this evolution, and the perspectives of medical professionals in the current surgical climate are poorly known. Therefore, in this nationwide survey it was aimed to investigate the current viewpoints of surgical specialists and residents in training concerning the use of multimedia recording in the operating room. Inquiries were made regarding their current practice in documenting surgical procedures, their views in regard to the added value and the exact composition of multimedia recordings, and their perspective on possible privacy issues in this context.

METHODS

On 20 December 2018, members affiliated to the Association of Surgeons of the Netherlands, Dutch Urological Association and the Dutch Society of Obstetrics and Gynecology were approached by e-mail to engage in a web-based survey (LimeSurvey, LimeSurvey GmbH. Hamburg, Germany). Respondents not wanting to participate in the survey were provided with an opt-out option. Three reminders were sent to non-responders after initial invitation, with an interval of four weeks. Retired surgeons, urologists or gynecologists, approached persons with other functions than surgeons, urologists, gynecologists or residents of the corresponding disciplines, and partial responses were excluded from analysis.

Questionnaire design

This questionnaire consists of 16 questions. Questions 1 through 4 covered respondents' demographics. Questions 5 through 9 were multiple choice questions regarding the current use of operative reporting. Questions 10 through 16 were 5-point Likert type scales for likelihood or level of objection concerning the use of multimedia in the operating room. The full survey can be found in the *Appendices*.

Statistical considerations

Data was analyzed with IBM SPSS Statistics for Windows, version 25.0 (IBM Corp. Armonk, NY) and Microsoft Excel (Microsoft Corp., Redmond, WA). Data are presented as numbers and percentages. A *p*-value of less than .05 was considered statistically significant. Groups were compared using Chi-square test or Fisher's exact test. When responses of two categories were compared within the same group, McNemar's test was used.

RESULTS

Invitations to a total number of 3151 e-mail addresses were sent, of which 3056 were successfully delivered. The overall response rate was 876 (27.8%). Replies of 197 respondents were excluded from this survey (112 (56.9%) retired or other function than surgeon, urologist, gynecologist or resident; 85 (43.1%) partial responses). After exclusion, a total number of 679 complete questionnaires were analyzed.

Among the respondents, 370 (54.5%) were surgeons, 71 (10.5%) were urologists, 80 (11.8%) were gynecologists and 158 (23.3) were residents in training of the corresponding disciplines.

Of the respondents, 147 (21.6%) currently practice their trade in university hospitals, whereas 428 (63.0%) and 82 (12.1%) work in general teaching and general non-teaching hospitals, respectively. Respondents' demographics can be found in Table 1.

Table 1. Respondent demographics.

	Specialists (n=521)
	N (%)
Years practicing	
<5 years	109 (20.0)
5 - 10 years	129 (25.1)
10 - 15 years	102 (18.9)
15 - 20 years	88 (16.2)
>20 years	90 (18.9)

	Residents (n=158)
	N (%)
Year of training	
Year 1	24 (15.2)
Year 2	19 (12.0)
Year 3	27 (17.1)
Year 4	28 (17.7)
Year 5	37 (23.4)
Year 6	23 (14.6)

Perspectives on the current operative report

Overall, 356 (52.4%) respondents feel that the currently used narrative operative report – without video and/or sound – is insufficient for future quality requirements (183 (49.5%) surgeons, 47 (58.8%) gynecologists, 41 (57.7%) urologists and 85 (53.8%) residents). There was no significant difference in responses among specialists and between specialists and residents (p = 0.267 and 0.850, respectively).

Current use of intraoperative multimedia recording

Table 2 delineates the different techniques which respondents reported to be present in their institution. 630 (92.8%) of respondents reported the use of endoscopic camera recording. Respectively, 179 (26.4%) and 85 (12.5%) of respondents indicated that an external camera to record the surgical site, such as a lamp mounted camera, or a camera dedicated to film the surroundings of the operating room, as is the case with the surgical black box among others, is used. A mobile phone is stated to be used to record intraoperative events by 288 (42.4%).

Overall, 621 (91.5%) of respondents stated that routine video recording of conventional procedures was not common practice in their department. For endoscopic procedures, this number was 186 (27.4%). There was no significant difference within departments (p = 0.791 and 0.640 for conventional and endoscopic setting respectively). Data of all separate specialties is delineated in Table 3.

Table 2. Reported techniques used in institutions.

	Respondents (n=679)
	N (%)*
Endoscopic camera feed	630 (92.8)
External camera filming the surroundings of the operating room	85 (12.5)
External camera dedicated to fil the surgical site (e.g. lamp camera)	179 (26.4)
Surgical black box	25 (3.7)
Mobile phone	288 (42.4)
Sound recorder (microphone)	25 (3.7)
None of the above	23 (3.4)
Other	33 (4.9)

Values represent the number and percentage of respondents answering "yes"

Table 3. Routine use of intra-operative video recordings, per department.

	Surgery (n=486)	Obstetrics and Gynecology (n=112)	Urology (n=81)	Total (n=679)
	N (%)	*N* (%)	*N* (%)	*N* (%)
Routine use of video recordings during conventional surgery				
Yes	16 (3.3)	2 (1.8)	1 (1.2)	19 (2.8)
No	445 (91.6)	103 (92.0)	73 (90.1)	621 (91.5)
Don't know	10 (2.1)	3 (2.7)	2 (2.5)	15 (2.2)
Missing	15 (3.1)	4 (3.6)	5 (6.2)	24 (3.5)
Routine use of video recordings during endoscopic surgery				
Yes	317 (65.2)	73 (65.2)	47 (58.0)	437 (64.4)
No	128 (26.3)	32 (28.6)	26 (32.1)	186 (27.4)
Don't know	24 (4.9)	3 (2.7)	4 (4.9)	31 (4.6)
Missing	17 (3.5)	4 (3.6)	4 (4.9)	25 (3.7)

Retention period

423 (62.3%) respondents did not know the retention period their institution upholds for video recordings of surgical procedures. Residents know the retention period significantly less often than specialists (120 (75.9%) vs. 303 (58.2%); $p = <.001$). There was no significant difference among specialists (surgeons 217 (58.6) vs. gynecologists 44 (55.0%) vs. urologists 42 (59.2%); $p = 0.821$). Of the respondents who do know the retention period in their institution, 20 (2.9%) reported a retention period of less than 30 days, 109 (16.1%) between 30 and 90 days, 40 (5.9%) 90 days and up to a year and lastly 87 (12.8%) reported a period of more than a year.

Frequency of intraoperative recording

Overall, the number of respondents answering 'never' or 'almost never' regarding intraoperative video recording was 130 (19.1%) for endoscopic procedures, and 483 (71.1%) for conventional procedures. For specialists only, these numbers were 104 (20.1%) for endoscopic procedures and 421 (81.3%) for conventional procedures. When comparing specialists in terms of experience level, there was no significant difference (p = 0.710 and p = 0.605 for endoscopic and conventional procedures, respectively). Surgeons significantly more often utilize video recording in open procedures than gynecologists and urologists (p = 0.002). There was no significant difference among specialists in regard of work experience (less than 5 years, 5 – 10 years, 10 – 15 years, 15 – 20 years or more than 20 years of work experience; p = 0.639 and p = 0.612 for endoscopic and conventional, respectively).

Purposes of video recording

Respondents from the surgical department include video in the patient file significantly less often than those from gynecology or urology (41.4% vs. 55.4% vs 49.4% respectively; p = 0.018). There was no significant difference within departments in respondents recording video files for quality control purposes, educational purposes or in the context of proctoring (overall percentage 50.5%, p = 0.070; 48.5%, p = 0.341; 9.7%, p = 0.066, respectively). Respondents from the surgical department record video to provide information for patients and their family or for colleagues significantly less often than those from gynecology or urology (23.9% vs. 33.0% vs. 35.8%, respectively; p = 0.021).

All purposes for intraoperative video recording reported by respondents are delineated in Table 4.

Table 4. Purposes of video recording.

	Surgery (n=486)	Obstetrics and Gynecology (n=112)	Urology (n=81)	Total (n=679)
	N (%)	*N* (%)	*N* (%)	*N* (%)
Addition to patient file	201 (41.4)	62 (55.4)	40 (49.4)	303 (44.6)
For quality control purposes	232 (47.7)	65 (58.0)	46 (56.8)	343 (50.5)
For educational purposes	238 (49.0)	48 (42.9)	43 (53.1)	329 (48.5)
In the context of proctoring	55 (11.3)	5 (4.5)	6 (7.4)	66 (9.7)
To provide information for patients, family and/or colleagues	116 (23.9)	37 (33.0)	29 (35.8)	182 (26.8)
Other	32 (6.6)	5 (4.5)	5 (6.2)	42 (6.2)

Values represent the number of respondents selecting the given purposes as a reason for video recording

Behavior in the operating room

Among all respondents, 397 (58,5%) responded that it would be "unlikely" or "very unlikely" that they would behave differently during surgery when intra-operative video recording is applied. 562 (82.8%) responded that it would be "unlikely" or "very unlikely" that their surgical methods would be altered by the presence of intra-operative video recording. When intra-operative video *and* audio recording is implemented, respondents reported they would significantly be more likely to behave differently and/or would alter their surgical methods (reports of "unlikely" or "very unlikely": 232 (34.2%) $p < 0.001$ and 512 (75.4%) $p < 0.001$, respectively). Responses by residents indicated that they would behave differently in the operating room significantly more likely when intraoperative video recording is applied in comparison to responses by specialist (39.7% vs. 30.2%; $p = 0.047$, respectively). When inquired about the effect of video and audio recording, this significant difference increases to 71.0% vs. 56.5% ($p = 0.003$), respectively. Crohnbach's alpha of internal consistency for 5-point Likert type scale questions in this section was 0.871.

Privacy and legal concerns

In the context of the recognizability of the respondent in the situation of intraoperative video recording, 252 (37.1%) of respondents find this either "objectionable" or "very objectionable". 358 (52.7%) find it either "objectionable" or "very objectionable" to be recorded on intra-operative video in regards of medical liability. Finally, 241 (35.5%) find it either "objectionable" or "very objectionable" to be recorded on intra-operative video in the context of quality of surgical care. Crohnbach's alpha of internal consistency for these questions was 0.726.

Added value of intra-operative video and sound recording

409 (60.2%) and 222 (32.7%) respondents recognized the added value of intraoperative video and intraoperative video with sound as either "likely" or "very likely". 602 (88.7%) and 419 (61.7%) deemed this for educational purposes. 302 (44.5) and 148 (21.8%) respectively found intraoperative video and intraoperative video with sound useful in providing information for patients, family and/or colleagues. 411 (60.5%) and 269 (39.6%) saw potential in use of these respective modalities for quality control purposes. 453 (66.7%) and 312 (45.9%) deemed it likely that intraoperative video and intraoperative video with sound respectively would be an addition in the context of proctoring. Finally, 378 (55.7%) and 282 (41.5%) of respondents found it likely that intraoperative video and intraoperative video with sound could play a supportive role in medicolegal proceedings.

Crohnbach's alpha of internal consistency for these questions was 0.84.

Preferred recording method for intraoperative registration

Table 5 lists an overview of preferred recording methods. 433 (63.8%) of respondents preferred only video if registration of the surgical procedure was implemented. 144 (21.2%) preferred video *and* audio recording. 84 (12.4%) would rather not have any recording at all. 18 (2.7) did not submit any preference.

Table 5. Preferred recording method for intraoperative registration.

	All respondents (n=679)
Statements	N (%)
Video recordings of the entire surgical procedure	211 (31.1)
Video recordings of only the essential steps of the surgical procedure	222 (32.7)
Video and audio recordings of the entire surgical procedure	77 (11.3)
Video and audio recordings of only the essential steps of the surgical procedure	67 (9.9)
No video and audio recordings	84 (12.4)
No preference	18 (2.7)

DISCUSSION

An increasing number of studies are exploring the values of multimedia recording in the surgical setting today. Some are exploring its role in surgical quality analysis and control.[4-6,16,17] Some assess its part in the amelioration of operative reporting [6]. Others examine its part in surgical education.[18-20] While each an addition to the growing knowledge on this matter, none are currently implemented in a widespread manner. End users, in this case the surgical specialists, have yet to voice themselves regarding their viewpoint in intraoperative video and audio recording. To our knowledge, this study has been the first to do so.

About half of the respondents agree with the statement that the currently used narrative operative report, without the addition of intraoperative video and/or sound, is lacking for future quality requirements. Today, the majority of institutions utilize either dictation devices, typed reports or modified pre-written concept reports. This method of reporting however, is subjective by nature and often lacks essential information.[4]

As expected, endoscopic procedures are far more often recorded by respondents compared to conventional (“open”) procedures. This is mostly due to the fact that the endoscope’s camera function is essential to conduct minimally invasive surgery. Video recording could then be implemented at the press of a button. Therefore, far less use a different, dedicated modality to record surgical procedures on video, such as a camera mounted to the surgical lamp (26.4%) or a fixed camera in the operating room (12.5%). Often, the quality is lacking, or the operator’s head and body are in its line of sight. Furthermore, for dynamic procedures, such as in orthopedic surgery or vascular surgery, it is virtually impossible to capture the essential moments through this method. Noteworthy is the use of mobile phones to record certain aspects of the surgery; About half of respondents have stated to use their mobile phone. This is probably due to the ease of use and the possibility to utilize the phone's video call function to consult colleagues or other specialists.

More than half of respondents did not know the duration of the retention period for intraoperative video recordings in their institution. Most that did know, reported a retention period between 30 and 90 days. Rules regarding the production and handling of medical documentation have been laid down in the Health Insurance Portability and Accountability Act (HIPAA) for the United States and the European General Data Protection Regulation for the European Union.[21,22] However, a specific time period is stipulated in neither and referral to local legislation is made.

The majority (58.5%) would think it is unlikely they would behave differently during surgery when intra-operative video recording is applied. Even more (82.8%) think it is unlikely that their surgical methods would be altered. An important finding is the fact that residents among respondents find it significantly less unlikely that their behavior or surgical method would be altered (34.2% and 75.4% respectively). Being in specialist training, it is important for residents to feel at ease and to be able to perform their surgery with as less additional pressure as possible. However, as our previous study has demonstrated, the role of intraoperative video recording in behavioral modification, also known as the "Hawthorn effect", is negligible.[6]

A major concern related to the recording of intraoperative video (and audio) is the risks regarding the privacy of the patient and the operating room personnel alike. This is illustrated by the fact that over a third of respondents find it objectionable to be recognized on intraoperative video recording. Regarding possible medico-legal liability, over half of respondents find it objectionable.

At this moment it is unclear when and for what purposes and by whom these recordings could be accessed. International legal texts mainly focus on the individual's privacy, and are yet to incorporate specific situations for the surgical setting.[21-23]

Overall, the majority of respondents consider the added value of intraoperative video recording for multiple uses. This is far less for intraoperative audio recording. The main sentiment in this regard is about significant loss of privacy. For instance, many respondents commented that in the operating room it is of great importance to be able to talk about non work-related issues for an adequate balance between focus and being at ease. Sometimes these topics can be of intimate nature. Without the proper delineation of who is able to access such audio recordings, most fear for their privacy and current job satisfaction.

55.7% and 41.5% of respondents recognized the benefit of intraoperative video recording and combined video- and audio recording respectively in regard to its supportive role in medicolegal proceedings. In contrary of what is often feared, intraoperative recording could aid in medicolegal proceedings, instead of merely posing risk for medical negligence.[24] The importance of an intraoperative event is often not able to be appraised by an operator during the procedure. Therefore, in this scenario, systematic recording of a procedure in its entirety is necessary, not merely of a selection of procedures or at certain moments when the surgeon "feels like it".

This survey yielded a response rate of 27.8%, a rate similar to other surveys having approached a comparable number of possible respondents.[25] Also, due to the larger number of invitations, this survey included a high number of replies. With this response rate however, there is risk for possible imbalance among respondents, e.g. respondents more interested in laparoscopic surgery, in which video recording is already operational, might be more outspoken concerning intraoperative video, compared to respondents of which the majority of procedures are "open surgery" (e.g. transplant surgery, vascular surgery or trauma surgery).

As the results of this study suggest, the surgical landscape is still divided in terms of intraoperative multimedia recording. Whilst the majority of respondents feel the current method of surgical reporting is insufficient and a large portion are open to the idea of documenting the operative phase on video or audio, there are still certain issues to be sorted out before implementation could even be considered. First of all, a significant portion of respondents expressed their concern in regard to potential privacy infringement. Currently no specific law is in effect to shield healthcare providers for their exposure when being recorded during practice. Furthermore, the issue in terms of ownership not yet been cleared. Up to now, all documentation in healthcare, albeit written, photographed or recorded, are incorporated in the patient file, rendering it patient property by law. In this case, no protection for the healthcare provider is specifically implemented. It is therefore imperative that specific legislation will be developed for these specific methods of intraoperative documentation to adequately protect all subjects in the recordings as well as securing ease of use and harnessing its potential in quality and safety procurement.

In conclusion, The majority of respondents find the current method of operative recording insufficient for future quality requirements. There is support for intraoperative video recording, however most respondents fear privacy infringement. These concerns are greater for audio recording compared to video recording only. Legislation is necessary before either intraoperative video or audio recording could be implemented to protect not only the patients, but also the healthcare providers.

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Chapter 5

One step at a time: step by step versus continuous video-based learning to prepare medical students for performing surgical procedures

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ABSTRACT

Objective

The objective of this study was to compare the effects of cognitive load and surgical performance in medical students that performed the open inguinal hernia repair after preparation with step-by-step video-demonstration versus continuous video-demonstration. Hypothetically, the step-by-step group will perceive lower extraneous load during the preparation of the surgical procedure compared to the continuous group. Subsequently, fewer errors will be made in the surgical performance assessment by the step-by-step group, resulting in better surgical performance.

Design

In this prospective study, participants were randomly assigned to the step-by-step or continuous video-demonstration. They completed questionnaires regarding perceived cognitive load during preparation (10-point Likert scale). Their surgical performance was assessed on a simulation hernia model using the Observational Clinical Human Reliability Assessment.

Setting

Erasmus University Medical Center, Rotterdam, the Netherlands.

Participants

Participants included medical students who were enrolled in extracurricular anatomy courses.

Results

Forty-three students participated; 23 students in the step-by-step group and 20 in the continuous group. As expected, the step-by-step group perceived a lower extraneous cognitive load (2.92 ± 1.21) compared to the continuous group (3.91 ± 1.67, $p = 0.030$). The surgical performance was not statistically significantly different between both groups; however, in subanalyses on a selection of students that prepared for 1 to 2 hours, the step-by-step group made less procedural errors, 1.67 ± 1.11, compared to the continuous group, 3.06 ± 1.91, $p = 0.018$.

Conclusions

Our results suggest that preparation using step-by-step video-based learning results in lower extraneous cognitive load and subsequently fewer procedural errors during the surgical performance. For learning purposes, demonstration videos of surgical procedures should be presented in a segmented format.

INTRODUCTION

Since the dawn of the digital age, surgical education has undergone an immense evolution, from its initial "master and apprentice" model in which apprentices learned from observing in the operating room to a time in which the 21st-century learner has the availability to learn by observing a multitude of online resources, for example, medical apps, books and videos.[1] Online videos are used frequently by medical students and residents and are known to be excellent tools to build anatomical and surgical knowledge.[1-3]

To understand how a trainee learns surgical procedures from observing videos, the limited cognitive capacity of the human brain must be taken into account. The cognitive capacity can be burdened when new and complex information is presented in a dynamic and transient format, as in a video-demonstration of a surgical procedure. To grasp the entire surgical procedure video-demonstration, the cognitive load can be high as disappearing information from the video needs to be retained and processed in working memory to understand the information that is presented in the video later.[4]Novices tend to learn better when this complex and transient information is presented in learner-paced segments, rather than as one continuous unit.[5] The learner-paced chunks result in lower perceived cognitive load and, subsequently, in potentially better learning.[5,6] In cognitive learning theory, this is referred to as the segmentation principle.[7]

The segmentation principle is an approach to prevent cognitive overload.[5] As shown in Figure 1, 3 types of cognitive load can be distinguished: intrinsic, germane, and extraneous cognitive load.[8,9] The complexity of new information determines intrinsic cognitive load. This type of cognitive load is higher for novices, and as the learner advances, the intrinsic cognitive load decreases. Germane cognitive load is determined by the construction and automation of cognitive schemas and is often categorized together with the intrinsic load.[10] Finally, extraneous cognitive load is determined by the suboptimal presentation of new information.[11,12]

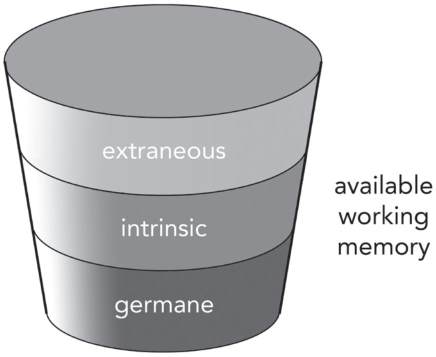

Figure 1. Cognitive load types.

While processing new information, the total load of these 3 types of cognitive load cannot exceed the working memory available as the bucket in Figure 1 will overflow.[8] During simple tasks that yield low intrinsic cognitive load, the learner will be able to manage the task even if the extraneous cognitive load is high. On the contrary, during complex tasks, such as closely observing or performing a surgical procedure, the intrinsic load will be high. Therefore, the extraneous cognitive load should be reduced as much as possible so that learning and the corresponding germane load can still occur. Theoretically, as shown in Figure 2, unsegmented surgical procedure video-demonstration demands high extraneous load (Figure 2a). The application of the segmentation principle on video-based learning of surgical procedures would reduce the extraneous cognitive load because it provides additional processing time (Figure 2b). This extraneous load reduction gives more opportunity for germane processing (construction of cognitive schemas; Figure 2c), and subsequently improve the performance of the surgical procedure.[13]

Figure 2. Optimizing cognitive capacity: lowering extraneous load and providing opportunity for germane processing (adapted from Sweller 1998).

Segmenting surgical procedures into steps and substeps can be done in a standardized approach using our developed step-by-step framework.[14] A step is defined as a surgical goal that needs to be reached and evaluated before proceeding to the next step. A step consists of one or more substeps, a combination of anatomical structure with an action (for example, incise, transect, dissect, et cetera).

Surgical performance can be assessed using various methods. For a stepwise assessment, a validated option is the Observational Clinical Human Reliability Assessment (OCHRA).[15] The OCHRA is a systematic assessment checklist assessing errors on a substep level. Each substep could be assessed as “correct,” “procedural error,” or “executional error.” A substep is assessed as a “procedural error” when a substep was not performed, partially performed, repeated, or done out of sequence. Executional errors concern a substep performed with too much or too little force, speed, depth, or distance, or a substep executed in the wrong direction or on a wrong structure.

To investigate the effects of segmentation in video-based learning, the Lichtenstein open inguinal hernia repair (LOIHR) was chosen as an example surgical procedure as it is a complex procedure with multiple steps. Medical students prepared themselves using either a step-by-step video-demonstration or a continuous video-demonstration to perform the LOIHR surgery in a controlled environment using an open inguinal hernia repair simulation model.[16] The hypotheses are that the step-by-step group will perceive lower extraneous load during the preparation of the surgical procedure compared to the continuous group. Subsequently, fewer errors will be made in the surgical performance assessment by the step-by-step group, resulting in better surgical performance.

MATERIAL AND METHODS

Participants, Setting and Design

Medical students of Erasmus University Medical Center, Rotterdam, the Netherlands who were enrolled in extracurricular anatomy research courses, were approached for participation. The extracurricular anatomy research courses at Erasmus University Medical Center select their students on the grounds of significant interest and knowledge of surgical anatomy. Participation was voluntary, and written consent was gathered before the study. This study among medical students did not require institutional board review according to Dutch law.

During this prospective randomized trial, the participating medical students were randomly assigned to 2 groups; the step-by-step group (n = 23) or the continuous group (n = 20). Randomization was stratified per study year. Figure 3 shows the study design.

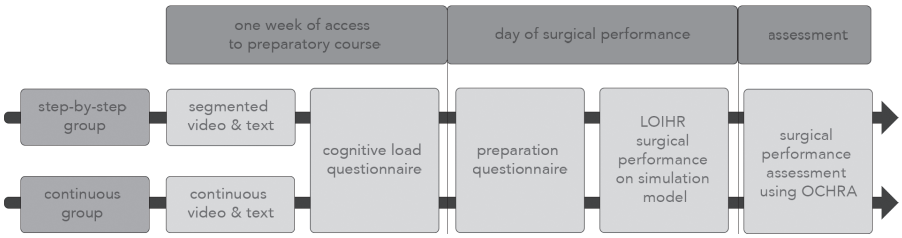

Figure 3. Study design.

Step-by-Step Versus Continuous Preparatory Course

Before the participants performed the surgical procedure, they were granted 1 week of access to their assigned online preparatory course: the step-by-step or continuous online preparatory course.

The step-by-step group had access to the segmented video-demonstration alongside the associated textual description. The segmentation of the LOIHR video-demonstration and description consisted of 6 steps and 25 substeps, which were constructed using the step-by-step framework.[14] In this step-by-step course, the student was presented the video-demonstration one step at a time. After viewing the video-demonstration of one step (Figure 4a), the student had to press on the "next" button to continue to the next webpage to view the associated textual description of this step (Figure 4b). This process was repeated for all 6 steps (Table 1).

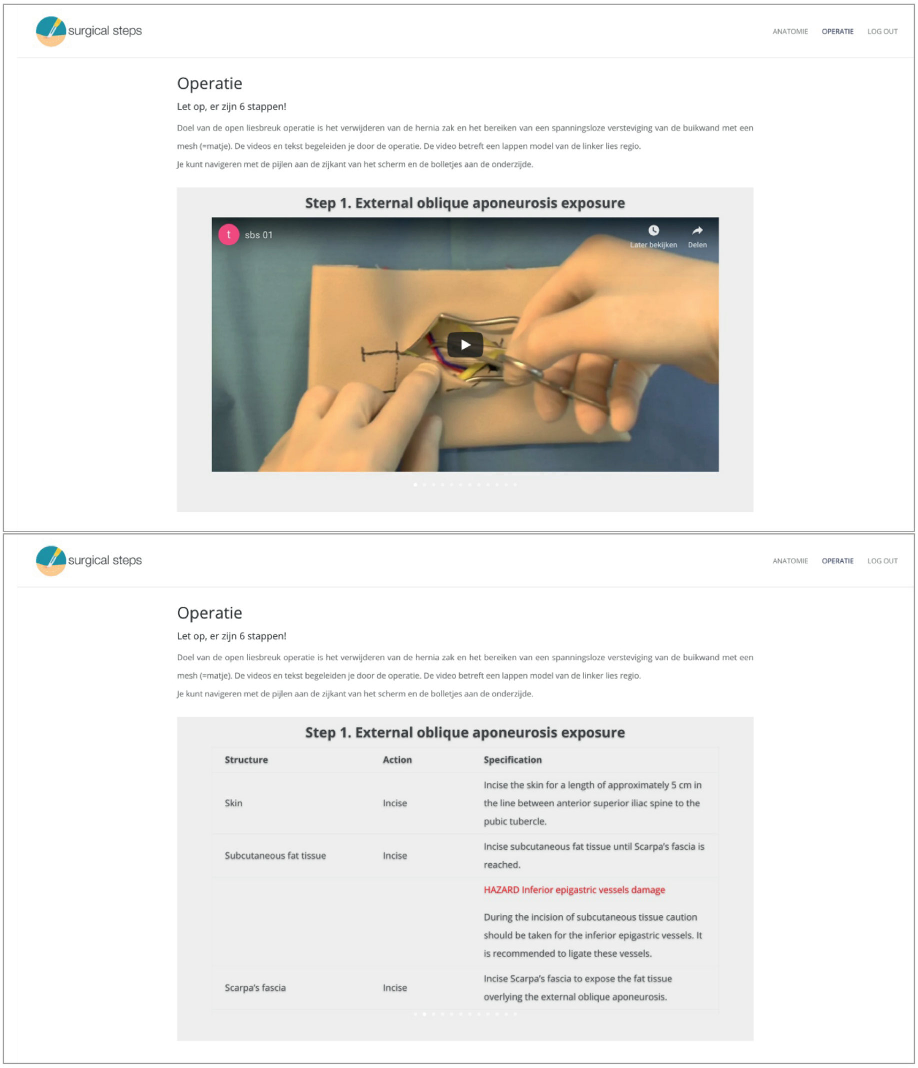

Figure 4. (a) Step by step video-demonstration and (b) textual description on the website.

Table 1. Duration Video-Demonstrations

Step-by-Step Video-Demonstration	Duration (mm:ss)
Step 1 External oblique aponeurosis exposure	01:38
Step 2 Inguinal canal exposure	00:30
Step 3 Spermatic cord mobilization	00:24
Step 4 Hernia sac removal	00:52
Step 5 Mesh placement	03:22
Step 6 Wound closure	01:02
Total duration	07:48

Continuous video-demonstration	Duration (mm:ss)
Total duration	07:30

The continuous group had access to a continuous video-demonstration of the LOIHR procedure and its associated textual description without segmentation. The continuous video-demonstration and textual description were displayed on separate webpages. After viewing the video-demonstration, the students could access the textual description of the procedure on a separate webpage in the online course by pressing on the "next" button.

The participants were allowed to study the online preparatory course at their own pace. The students could pause and rewatch the videos on demand. The content of the online courses (video-demonstrations and textual descriptions) were identical in both groups, with segmentation being the only difference.

Cognitive Load Questionnaire

At the end of the online preparatory course, students were requested to fill out a questionnaire on their perceived cognitive load during the entire online course. A modified version of an existing questionnaire was used, composed of 12 statements assessing the intrinsic/germane cognitive load (8 statements) and the extraneous cognitive load (4 statements).[11] All statements were rated on a 10-point Likert type scale, ranging from 1 = totally disagree to 10 = totally agree.

On the day of the surgical assessment, students were asked to fill out a questionnaire regarding their preparation (time spent on self-study during the online course in hours, use of other sources for self-study, and satisfaction during online preparation on a 10-point Likert scale, ranging from 1 = not at all to 10 = completely liking the teaching method).

LOIHR Surgical Performance

All students performed the LOIHR surgical procedure on a simulation model.[16] This model mimicked the human abdominal wall anatomy, as each textile layer corresponded with a layer of the abdominal wall. The blood vessels, nerves (ilioinguinal, iliohypogastric, and genital branch of the genitofemoral nerve), the spermatic cord, and an indirect hernia sac were placed in the correct anatomical position within the textile layers. The simulation model used in the surgical performance assessment was identical to the model used in the preparatory video-demonstration.

To perform the LOIHR surgical procedure, each student received the necessary instruments and materials, such as a scalpel, forceps, scissors, retractor, mesh, needle driver, sutures, ligatures, marker, and a Penrose drain (Figure 5). The students had a maximum of 30 minutes to perform the LOIHR surgical procedure. The students were allowed to ask for help. Each time a student requested help regarding the execution or the correct order of the steps, this was flagged by one of the experimenters (TN or FvdG) as "requiring help." Requests for an extra pair of hands by the students, such as cutting threads or holding retractors, were provided but not flagged as "requiring help."

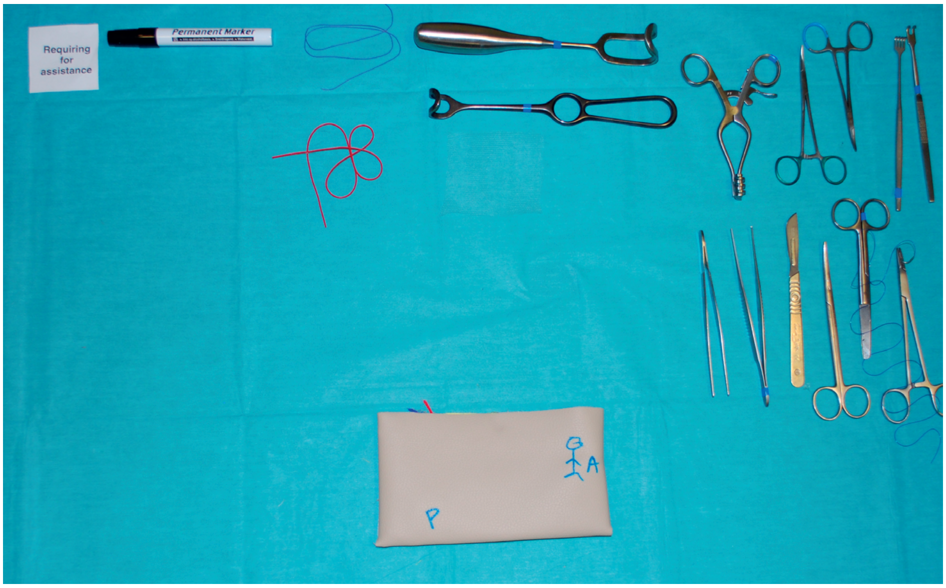

Figure 5. Set up operating table

Surgical Performance Assessment

The LOIHR surgical procedures were video recorded using a head-mounted GoPro Hero 5 Black (GoPro Inc. San Mateo, California), with the following settings: resolution 720p, 60 frames per second; FOV: Narrow; White Balance 4000k; Locked exposure. The video recordings were anonymized and stored. Two trained assessors (TN, FvdG) were blinded for the randomization and reviewed the video recordings independently. Any discrepancies were discussed and reviewed by the 2 assessors and resolved through consensus. The assessment was done according to the principles of OCHRA.[15] As shown in Figure 6, a performed substep could be assessed as "correct," "procedural error" or "executional error." When the substep was not performed, this could be categorized as a "procedural error" if the students skipped this substep, or as "due to time" if it was caused by time constraints. The number of errors was registered for each medical student.

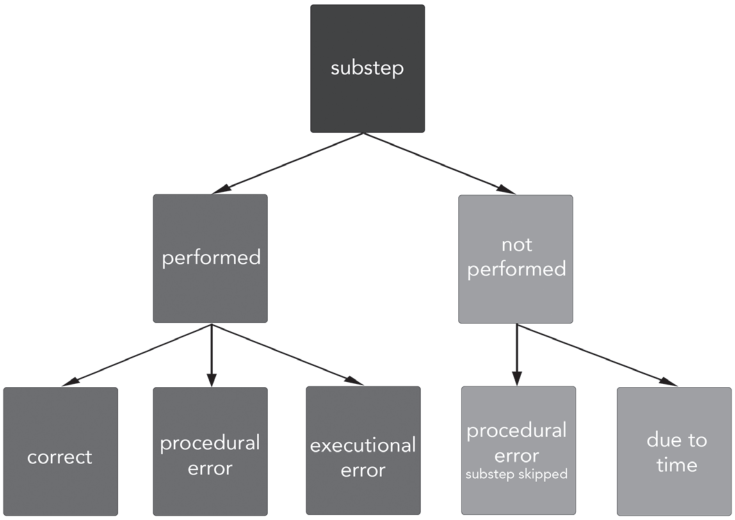

Figure 6. Assessment of a substep using observational clinical human reliability assessment.

Statistical Analysis

Data were tested for normality using the Shapiro-Wilk test and presented as means and standard deviations, or as medians and interquartile ranges [Q1-Q3], according to their normality of distribution. If normal distribution was present, an independent samples *t*-test was used; otherwise, the Mann-Whitney *U* test was conducted. Categorical data were presented as numbers and percentages and compared using the Chi-square test. For the performance assessed by the OCHRA checklist, the mean of each category was presented. Subanalyses were performed on comparable subgroups of participants that spent 1 to 2 hours preparing the online course. A p-value of less than 0.05 was considered statistically significant.

Effect sizes were calculated using Cohen's delta (d). Different formulas were used for parametric and nonparametric data.[17] Effect sizes of 0.20 were considered small, ≥0.50 were considered medium, and ≥0.80 were considered large.[18] The internal consistency was determined using Cronbach's alpha (α). Data were analyzed with IBM SPSS Statistics for Windows (IBM Corp. Version 24.0, Armonk, New York).

RESULTS

A total of 43 students participated in this study, of which 23 students were randomly assigned to the step-by-step group and 20 students to the continuous group. There were no statistically significant differences between the 2 groups regarding time spent during preparation, satisfaction during the preparation, and usage of other resources (Table 2).

Table 2. Total Group of Students – Demographics and Preparation

		Step by step (n=23)	Continuous (n=20)	*p*-value
Gender (n)	Female	13	9	.451[a]
	Male	10	11	
Age in years (median [IQR])		20 [19-21]	20 [19-21]	.805[b]
Year of study (n)	Year 1	6	5	.744[a]
	Year 2	6	6	
	Year 3	8	7	
	Year 4	3	1	
	Year 5	0	1	
Time spent during preparation				
How much time did you spend studying the online course? (n)	0 - 1 hour(s)	5	2	.326[a]
	1 - 2 hours	15	16	
	2 - 3 hours	1	2	
	3 - 4 hours	2	0	
Satisfaction during the preparation				
Over all, I appreciated the way the procedure was taught (median [IQR])	Scale 1-10	8 [7-9]	8 [6.25-8]	.053[b]
I felt well prepared after watching the video and studying the text (median [IQR])	Scale 1-10	7 [6-8]	7 [4.50-8]	.487[b]
Usage of other learning resources				
Did you, besides the online course, use other resources or materials to prepare for the surgery? (n)	Yes	12	12	.606[a]
	No	11	8	
Which other different resources or materials did you use? (n)	Books	3	2	.758[a]
	Other websites	4	6	
	Other videos	3	3	
	Other…	1 anatomy images	1 Google	
How much time did you spend studying other resources or materials? (n)	0 - 1 hour(s)	10	12	.286[a]
	1 - 2 hours	1	0	

IQR interquartile range [Q1 – Q3]
[a] analyzed using Chi square test
[b] analyzed using Mann Whitney U test

The perceived cognitive load and surgical performance are shown in Table 3. The mean (SD) extraneous cognitive load was perceived lower by the step-by-step group, 2.92 (1.21), than by the continuous group, 3.91 (1.67), with a medium effect size (t (41) = −2.24, p = 0.030, *d* = 0.68, Cronbach α = 0.836). The surgical performance was not significantly different between both groups on any of the measures. The median [Q1-Q3] satisfaction during preparation tended to be higher in the step-by-step group, 8 [7-9], than in the continuous group, 8 [6.25-8], with a small effect size (*U* = 153.00, p = 0.053, *d* = 0.09).

Additional subanalyses were run on comparable subgroups that spent the same amount of time studying the preparatory course (1-2 hours). In this selection, gender, age, years of study, satisfaction during the preparation, and usage of other sources for preparation were not statistically significantly different between the groups (Table 4). As shown in Table 5, in the subanalyses, the step-by-step group perceived a lower level of extraneous cognitive load than the continuous group, with a medium effect size (t (29) = −2.091, p = 0.045, *d* = 0.75, Cronbach α = 0.827). Furthermore, the step-by-step group made less "performed – procedural errors," mean (SD) of 0.33(0.49), than the continuous group, 1.13 (1.09), with a small effect size (*U* = 65.00, p = 0.018, *d* = 0.15).

Table 3. Total group of students – Performance and cognitive load

	Step by step (n=23)	Continuous (n=20)	*p* - value
	Mean (SD)	Mean (SD)	
Performance			
Total performed - correct	7.30 (2.80)	7.75 (2.31)	.531[b]
Total performed - incorrect	6.43 (2.00)	6.25 (1.91)	.759[a]
Total performed - procedural error	0.39 (0.50)	0.90 (1.07)	.109[b]
Total performed - executional error	6.00 (2.00)	5.25 (1.89)	.215[a]
Total performed - procedural and executional error	0.04 (0.21)	0.10 (0.31)	.473[b]
Total not performed	11.04 (3.23)	10.85 (2.13)	.763[a]
Total not performed - due to procedural error (skipped)	1.48 (1.31)	1.70 (1.46)	.644[b]
Total not performed - due to time	9.52 (3.18)	9.05 (2.31)	.109[b]
Total procedural error combined (total performed – procedural error and tot not performed – procedural error)	1.87 (1.39)	2.60 (1.98)	.223[b]
Total times asked for help	1.26 (1.57)	1.30 (1.63)	.868[b]
Cognitive load			
Intrinsic/germane cognitive load Cronbach α = .807	6.10 (1.17)	6.43 (1.10)	.351[a]
Extraneous cognitive load Cronbach α = .836	2.92 (1.21)	3.91 (1.67)	.030[a,*]

[a] analyzed using independent samples t-test
[b] analyzed using Mann Whitney U test
* statistically significant

Table 4. Students with 1-2 hours preparation – Demographics and preparation

		Step by step (n=15)	Continuous (n=16)	*p*-value
Gender (n)	Female	10	7	.200[a]
	Male	5	9	
Age in years (median [IQR])		20 [19-21]	20 [19-21]	.896[b]
Year of study (n)	Year 1	4	3	.764[a]
	Year 2	4	6	
	Year 3	5	5	
	Year 4	2	1	
	Year 5	0	1	
Satisfaction during the preparation				
Over all, I appreciated the way the procedure was taught (median [IQR])	Scale 1-10	9 [8-9]	8 [7-8.75]	.090[b]
I felt well prepared after watching the video and studying the text (median [IQR])	Scale 1-10	7 [7-8]	7 [4-8.75]	.340[b]
Usage of other learning resources				
Did you, besides the online course, use other resources or materials to prepare for the surgery? (n)	Yes	7	10	.376[a]
	No	8	6	
Which other different resources or materials did you use? (n)	Books	2	2	.752[a]
	Other websites	2	4	
	Other videos	1	3	
	Other…	1 anatomy images	1 Google	
How much time did you spend studying other resources or materials? (n)	0 - 1 hour(s)	5	10	.182[a]
	1 - 2 hours	1	0	

IQR interquartile range [Q1 – Q3]
[a] analyzed using Chi square test
[b] analyzed using Mann Whitney U test

DISCUSSION

Video-demonstrations create high extraneous cognitive load for managing the transiency of information as relevant information disappears quickly from the screen.[6,9] Segmentation provides smaller portions of information with pauses in between to reduce the extraneous load. In our study, this theory was affirmed as

the segmented step-by-step group showed a lower extraneous cognitive load compared to the continuous group. The intrinsic cognitive load was not statistically significantly different between the groups, as was expected since the complexity of the new information – the LOIHR surgical procedure for the medical students – was similar in both groups.

Table 5. Students with 1-2 hours preparation – Performance and cognitive load

	Step by step (n=15)		Continuous (n=16)		*p*-value
	Mean	SD	Mean	SD	
Performance					
Total performed - correct	7.80	2.43	7.19	2.20	.460[b]
Total performed - incorrect	6.33	2.06	6.63	1.63	.667[a]
Total performed - procedural error	0.33	0.49	1.13	1.09	.018[b,*]
Total performed - executional error	6.00	2.17	5.44	1.63	.425[a]
Total performed - procedural and executional error	0.00	0.00	0.06	0.25	.333[b]
Total not performed	10.67	2.92	10.88	1.82	.815[a]
Total not performed - procedural error (skipped)	1.33	1.18	1.94	1.48	.247[b]
Total not performed - due to time	9.33	3.29	8.94	2.18	.286[b]
Total procedural error combined (total performed – procedural error and tot not performed – procedural error)	1.67	1.11	3.06	1.91	.018[b,*]
Total times asked for help	1.00	1.36	1.44	1.78	.531[b]
Cognitive load					
Intrinsic/germane cognitive load Cronbach α = .827	6.53	1.08	6.59	1.10	.879[a]
Extraneous cognitive load Cronbach α = .827	2.87	0.92	3.92	1.74	.045[a,*]

[a] analyzed using independent samples T-test
[b] analyzed using Mann Whitney U test
* statistically significant

When comparing students in our study with the same preparation time (1-2 hours), the step-by-step group made fewer procedural errors than the continuous group. Procedural errors are errors concerning the performance of the surgical procedure in the correct order and are determined by a trainee's procedural knowledge. A likely explanation for fewer procedural errors in the step-by-step group is that surgical knowledge was better learned while watching the segmented video leading to higher surgical performance compared to the continuous group. The executional errors were not significantly different between both groups. The executional errors concern surgical skills, such as knotting and suturing. Surgical skills are determined by repetitive practice and are therefore not solely dependable on video-based preparation.

To our knowledge, this is the first study to demonstrate the effects of segmentation of video-based surgical procedure learning on cognitive load and surgical performance. The findings of this study need to be viewed in light of several limitations. First, our prospective experimental design allowed students in both groups to pause and rewatch the video-demonstration on demand, similar to reality. The option to pause continuous videos effectively segments videos by providing smaller portions of information at a time. The continuous group had thus the option to compensate for potential suboptimal teaching in this condition by investing more study time in preparation for the surgery (e.g., by pausing or rewatching the video, consulting other resources, et cetera). Additional subanalyses were therefore performed on the selection of students with the same preparation time of 1 to 2 hours in order to correct for potential compensation. This selection concerned the majority of the students, 31 of the 43 participating students.

In this study, the effects of segmentation were investigated in medical students as they form a homogeneous group with similar surgical experience and are more readily available compared to surgical residents. The next step is to investigate the segmentation effect in surgical residents. Finally, the segmentation in this study was performed using the step-by-step framework.[14] Further research is needed to investigate if the step-by-step framework offers the best way to define these segments.

Conclusions

This study compared the effects of a step-by-step versus a continuous video-demonstration of a surgical procedure on perceived cognitive load and surgical performance. The step-by-step group perceived a lower extraneous cognitive load compared to the continuous group. Among students with the same preparation time (1-2 hours), the step-by-step group showed a lower extraneous cognitive load and higher performance, specifically, fewer procedural errors. Based on the findings in our study, we suggest presenting surgical video-demonstrations in a segmented format.

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Part 2

Quality assurance in colorectal surgery

Chapter 6

Imaging for quality control: comparison of systematic video recording to the operative note in colorectal cancer

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ABSTRACT

Background

Oncological and functional results after colorectal cancer surgery vary considerably between hospitals and surgeons. At present, the only source of technical information about the surgical procedure is the operative note, which is subjective and omits critical information. This study aimed to evaluate the feasibility of operative video recording in demonstrating both objective information concerning the surgical procedure and surgical quality, as using a systematic approach might improve surgical performance.

Methods

From July 2015 through November 2015, patients aged ≥18 years undergoing elective colorectal cancer surgery were prospectively included in a single-institution trial. Video recording of key moments was performed peroperatively and analyzed for adequacy. The study cases were compared with a historic cohort. Video was compared with the operative note using the amount of adequate steps and a scoring system.

Results

This study compared 15 cases to 32 cases from the historic control group. Compared to the written operative note alone, significant differences in availability of information were seen in favor of video as well as using a combination of video plus the operative note (N adequate steps p = .024; p = <.001. Adequacy score: p = .039; p = <.001, both respectively).

Conclusions

Systematic video registration is feasible and seems to improve the availability of essential information after colorectal cancer surgery. In this respect, combining video with a traditional operative note would be the best option. A multicenter international study is being organized to further evaluate the effect of operative video capture on surgical outcomes.

INTRODUCTION

Over the past several years, laparoscopic surgery has become standard of care in the treatment of colorectal malignancies, resulting in similar oncological outcomes and improved short-term results compared with conventional open surgery.[1,2]

Although colorectal cancer treatment has improved dramatically, short- and long-term oncological and functional results in colorectal cancer patients with similar stage disease vary widely between different hospitals and surgeons.[3] Operative mortality in colorectal cancer patients ranges from 0.5 to 6 %, while operative morbidity ranges from 15 to 25 %, mainly as a result of avoidable surgical complications.[1,4-6] Regarding oncological outcome, disease recurrence is reported in 5–50 % of patients and 5-year survival rates vary between 32 and 64 %.[7-10]. Long-term pelvic organ dysfunction after rectal cancer surgery, mainly attributed to avoidable surgical (nerve) damage, occurs in the majority of patients[10-14]. In this respect surgical performance in colorectal cancer surgery still has room for improvement, especially with regard to reducing variability among surgeons.

The importance of quality improvement programs to decrease operative variability is widely supported at this time. In 2009, Haynes et al. introduced the surgical safety checklist, used in the "Time-out-procedure," cutting mortality in half after implementation.[15] However, this checklist addresses only preoperative anesthesiological and nursing concerns and not so much the surgical technique used during surgery. Furthermore, surgical quality is an important prognostic factor, especially in colorectal cancer treatment, but is poorly captured. During complex surgical procedures, such as total mesorectal excision (TME) for rectal cancer, essential steps might be skipped or inadequately performed (such as the identification of nerves and the ureter). However, postoperatively, it cannot be clearly reproduced what exactly occurred during the surgical procedure. Currently, the only source of technical information about the surgical procedure is the operative note, which has been shown to be subjective and lacking in critical information.[16] Systematic video registration of the procedure might be a solution, adding objective information to the traditional operative note.

The aim of this study was to investigate the feasibility of operative video recording with the hypothesis that this may (1) increase the amount of critical information from the surgical procedure and (2) improve surgical quality due to a systematic approach using a checklist.

METHODS

All patients aged 18 years or older undergoing elective laparoscopic colorectal cancer resection (right hemicolectomy, transverse colectomy, left hemicolectomy, sigmoid colectomy, or anterior resection) in Havenziekenhuis (Rotterdam, The Netherlands) were included from July 2015 through November 2015. During each surgical procedure, intraoperative video recordings of about 10 s length were made of predefined key moments, initiated and ceased by the primary surgeon. Patients with metastatic disease, unresectable tumor, or incomplete video recordings due to technical difficulties in the recording software were excluded from analysis. The primary and secondary outcomes were compared with a historical cohort, treated 1 year before implementation of the checklist, to avoid bias induced by the use of the checklist. The medical research and ethics committee of the Erasmus Medical Centre exempted this study from the Research Involving Human Subjects Act (WMO).

Predefined Checklist and Reviewing

Key moments in the studied surgical procedures were defined by experts in this field (J.M., J.L., M.L.). A surgical checklist was compiled from these key moments and further transcribed into a case report form (CRF). During surgery, video fragments under direction of the leading surgeon were recorded according to the surgical checklist, and the corresponding steps were checked off on the CRF afterward. If a step was not relevant in a particular procedure, "n/a" was added next to the step in the CRF.

Before reviewing the video recordings, requirements for adequacy were dictated (F.vdG., J.M., A.M., J.L.). Then, the completed CRFs along with operative recordings and the operative notes were reviewed for adequacy (F.vdG., M.L.). The CRFs and the requirements for an adequate recording can be found in the *Appendices*. Failure to comply with these requirements, or absence of a recording resulted in a step being labeled "not adequate." In reviewing the operative note, a step would be labeled "not adequate" if there were either an incomplete description or a lack of description altogether.

Primary Outcome

With respect to the primary outcome, the availability of essential information, according to the predefined checklist, was evaluated. This information was collected from the operative video recording of the study group and from the operative note from both the study group and historic control group. Subsequently, the availability of the essential information was compared between the video recordings alone vs the operative note of the historic control group, and between the combination of the video recordings and the operative note coming from the study group vs the operative note of the historic control.

To assess the availability of information, two methods were used: (1) The adequacy of steps with adequate information was compared. (2) A scoring system was utilized. For the maximum amount of information, according to the critical steps described in the CRF, a maximum of 100 points could be obtained. These 100 points were divided by the number of applicable steps in that specific procedure, resulting in the amount of points per step. Finally, the factor of the amount of adequate steps and the amount of points per step was calculated, resulting in the total score for that specific procedure.

Secondary Outcome

With respect to the secondary outcome, surgical complications within 30 postoperative days were analyzed to assess any improvement in surgical quality, which was expected with the use of a predefined checklist according to our hypothesis. Surgical complications were graded according to the Clavien-Dindo classification. The following complications were included in analysis: surgical wound infection, intra-abdominal abscess, urinary tract infection, respiratory tract infection, cardiologic complication, neurologic complication (including delirium), postoperative ileus, postoperative bleeding, and anastomotic leakage. Furthermore, the postoperative length of stay was measured.

Video Recording and Video Data Management

High-definition images were captured using EndoEYE 30° videoscope connected to an EVIS EXERA II CLV-180 xenon light source and subsequently an EVIS EXERA II CV-180 video processor (Olympus Europa SE & Co., Hamburg, Germany). The video feed was then recorded on a Microsoft Windows based computer system in MPEG-4 format using image storage software (Clinical Assistant 6 [RVC Ltd., Baarn, The Netherlands]).

Statistical Analysis

Data was analyzed with IBM SPSS version 23.0 for Mac. Categorical data were presented as numbers and percentages. Continuous data were described by mean and standard deviation. Study population and historical control were compared using chi-square test or Fisher exact test in case of categorical data. Continuous data was tested for normality using the Shapiro-Wilk Test, and if normal distribution was present, an independent samples t test was used. Otherwise, the Mann-Whitney U test was conducted. In analyzing the adequacy per step, the sum of all adequate steps was calculated, converting the range to continuous data. Subsequently the Mann-Whitney U test was used for comparison. A p value of less than .05 was considered statistically significant.

RESULTS

Study Population

From July 2015 through November 2015, 20 patients meeting inclusion criteria were included in this study. All 20 patients underwent elective surgery for colorectal cancer with operative video recording according to the predefined checklist. A total of five patients were excluded from further analysis: two patients because of technical difficulties in the recording software resulting in loss of video fragments, two patients because of absence of malignancy, and one patient because of disseminated disease. As a result, the study population concerned 15 patients, who were was compared with 32 patients meeting inclusion criteria, which were retrospectively included in the period of July 2014 through January 2015. Patient characteristics are presented in Table 1. There were no significant demographic differences found between the study and the historic control group.

Table 1. Patient characteristics

Parameter	Study Cases (n=15)		Historic control (n=32)		P-value
Age (years)	67.87	± 8.31	69.34	± 14.16	0.355
Sex					0.758
Male	9	(60.0)	17	(53.1)	
Female	6	(40.0)	15	(49.6)	
Height (cm)	173.33	± 11.60	171.94	± 11.48	0.654
Weight (kg)	85.69	± 17.22	78.51	± 15.98	0.153
BMI (kg/m^2)	28.49	± 5.46	26.41	± 4.13	0.147
ASA class					0.845
ASA I	1	(6.7)	4	(12.5)	
ASA II	6	(40.0)	18	(56.3)	
ASA III	2	(13. 3)	10	(31.3)	
Missing	6	(40.0)	0		
Charlston Comorbidity Index	2.79	± 1.05	2.72	± 0.99	0.864
Diabetes Mellitus	5	(33.3)	5	(15.6)	0.242
Hypertension	8	(53.3)	20	(62.5)	0.753
History of cardiac disease	2	(13.3)	7	(21.9)	0.701
History of pulmonary disease	1	(6.7)	6	(18.8)	0.413
History of renal disease	2	(13.3)	1	(3.1)	0.216
Prior abdominal and/or pelvic surgery	6	(40.0)	13	(40.6)	1.000
Type of laparoscopic surgery					0.369
Right hemicolectomy	3	(20.0)	11	(34.4)	
Transverse colectomy	1	(6.7)	0	(0)	
Left hemicolectomy	1	(6.7)	1	(3.1)	
Sigmoidectomy	7	(46.7)	10	(31.3)	
LAR / APR	3	(20.0)	10	(31.3)	

Data are presented as N (%) or mean ± SD
ASA American Society of Anesthesiologists, BMI body mass index, LAR low anterior resection, APR abdominoperineal resection

Primary Outcome

The number of adequate and inadequate steps was compared between the two groups. Two comparisons were made: firstly, the video recordings of the study group versus the operative notes of the historic control group, and secondly, the video recordings and operative notes of the study cases combined versus the operative notes of the historic control cases (Table 2).

Respectively, significant differences in favor of the study population were found regarding availability of information on the introduction of trocars under vision, overall exploration of the abdominal cavity, inspection of the liver, mobilization and resection, exploration of the resection specimen, and the accumulative steps. Information on vascular control was significantly more often available in the operative notes compared with the video recordings.

The average score for the amount of available information was 54.29 points (±15.42 SD) for the operative notes in the control group, 67.08 points (±13.81 SD) for the video recording alone, and 80.53 points (±11.72 SD) for the combination of video recording and operative note. Video recording alone and the combination of video recording and operative note scored significantly higher compared with the operative notes in the historic control group (p = .039; p = <.001, respectively).

When comparing the operative notes of the historic control cases to the operative notes of the study cases, the overall number of adequate steps were 185 (53.9 %) and 84 (53.2 %) (p = .648), respectively, and the average score for the amount of available information was 54.29 points (±15.42 SD) and 53.24 points (±13.26 SD) (p = .705) respectively.

Table 2. Amount of adequate steps.

	Study cases (n=15)						Historic control (n=32)	
	Video recording			Video recording and operative note combined				
	Adequate		P-value	Adequate		P-value	Adequate	
Step 1 - Introduction of trocars under vision	12	(80.0)	0.004	14	(93.3)	<0.001	10	(31.3)
Step 2 - Exploration	35	(77.8)	0.014	40	(88.9)	<0.001	57	(60.6)
Inspection of the liver	14	(93.3)	<0.001	14	(93.3)	<0.001	10	(31.3)
Inspection of the tumor	8	(53.3)	0.599	12	(80.0)	0.182	17	(53.1)
Inspection of the peritoneum	13	(86.7)	0.583	14	(93.3)	1.000	30	(93.8)
Step 3 - Vascular control	8	(40.0)	0.006	13	(65.0)	0.371	32	(72.7)
Step 4 - Mobilization and resection	24	(72.7)	<0.001	24	(72.7)	<0.001	26	(35.6)
Exploration of resection specimen	9	(60.0)	<0.001	9	(60.0)	<0.001	1	(3.1)
Identification of left ureter	11	(100)	0.534	11	(100)	0.534	18	(85.7)
Step 5 - Creation of Anastomosis	16	(53.3)	0.376	23	(76.7)	0.354	41	(60.3)
Anastomosis	10	(66.7)	0.481	14	(93.3)	0.406	25	(78.1)
Step 6 - Closure	10	(66.7)	0.753	12	(80.0)	0.202	19	(59.4)
Accumulative steps	105	(66.5)	0.024	126	(79.7)	<0.001	185	(53.9)

Data are presented as N (%). P-value obtained from comparison with Historic control group.

Secondary Outcome

Postoperative outcomes within 30 days after surgery are summarized in Table 3. Aside from a significant difference in the postoperative length of stay in favor of the study group (8.80 ±

9.01 vs. 10.44 ± 6.44 SD; p = .016), there was no significant difference found between the study cases and the historic control.

Table 3. Postoperative outcomes ≤30 days

Parameter	Study Cases (n=15)		Historic control (n=32)		P-value
Duration of surgery (min.)	141.89	± 79.14	143.84	± 37.70	0.257
Blood loss (ml) [a]	131.82	± 78.34	104.69	± 26.52	0.284
Clavien-Dindo [b]					0.292
Grade I	10	(66.7)	13	(40.6)	
Grade II	3	(20.0)	15	(46.9)	
Grade III	1	(6.7)	3	(9.4)	
Grade IV	1	(6.7)	1	(3.1)	
Surgical wound infection	1	(6.7)	4	(12.5)	0.545
Intra-abdominal abcess	0	(0.0)	2	(6.3)	0.322
Urinary tract infection	0	(0.0)	4	(12.5)	0.152
Respiratory tract infection	1	(6.7)	6	(18.8)	0.278
Cardiological complication	1	(6.7)	1	(3.1)	0.575
Neurological complication	2	(13.3)	1	(3.1)	0.182
Postoperative Ileus	0	(0.0)	6	(18.8)	0.073
Postoperative bleeding	0	(0.0)	1	(3.1)	1.000
Anastomotic leakage	2	(13.2)	1	(3.1)	0.235
Postoperative length of stay (days)	8.80	± 9.01	10.44	± 6.44	0.016

Data are presented as N (%) or mean ± SD
[a] Minimal blood loss set at ≤100ml
[b] Postoperative morbidity and mortality according to Clavien-Dindo classification
DVT: Deep Venous Thrombosis, PE: Pulmonary Embolism

DISCUSSION

Very few published studies analyzed the possible advantages of operative video recording prospectively. This pilot study is the first study evaluating operative video recording during colorectal cancer surgery. Our findings confirm the feasibility of systematic video registration in colorectal cancer surgery, as is shown in prior research.[17] It also demonstrates the improved availability of essential information. The best results are obtained by combining video recording with the traditional operative note. This improvement might also be caused by the more stepwise approach during systematic video registration and the Hawthorne effect – improved performance due to the subject's awareness that it is being recorded.

About half of the steps in the operative note were described in an adequate manner, which is in accordance with similar published findings in different fields of surgery.[18-21] According to our results, adding systematic video recording to the traditional operative note would increase the total amount of available adequate information by almost 50 %. The most contributing steps to this increment are: introduction of trocars under vision, exploration of the abdomen, inspection of the surgical specimen, and, although not significant, the creation of the anastomosis. All these steps contain important information regarding either the procedure or further management of patient care. It is important to introduce the trocars under vision, because this otherwise poses risk to intra-abdominal injuries.[22,23] The importance of an adequate inspection of the abdomen, including the liver and its surrounding ligaments, the parietal peritoneum, and the tumor, is to determine the operability of the patient and whether or not it is necessary to convert to open surgery. The surgical specimen should be inspected to make sure the tumor has been removed and the resection margin is sufficient. If flawed, the surgeon can then still act on these findings.

With regard to operative vascular control, a difference was found favoring the operative note over video. This is mainly due to atypical resections such as resection of the splenic flexure in which vascular control is at the level of peripheral vessels. Furthermore, especially in typical left-sided resections with central vascular control, it was sometimes difficult to assess the anatomy in the video without the explanation of the surgeon.

There was no significant difference found between the operative notes of the historic control group and those of the study cases in both the number of adequate steps and the average score for the amount of available information, which would suggest that participation of the study and the knowledge of the checklist by the surgeons do not bias the increase in available information when operative note and video registration are combined.

No significant difference was found in postoperative outcomes within 30 days, apart from postoperative length of stay. Because of the small sample size in the study group, this result should be considered thoughtfully.

Although video recording during laparoscopy has minimal impact on the surgical procedure, it might be considered impractical if recording could only be started and stopped outside the sterile area (e.g., on the laparoscopy tower, handled by an operating room assistant). This problem can be avoided by using a laparoscope with a dedicated recording button, or by using a recording remote inside the sterile environment, thus giving complete control to the surgeon's team.

The video recordings in this study are fragments, aimed to capture the specific key moments in the surgical procedure instead of using a full-length recording. This results in a manageable amount of content and minimizes the required digital storage space. However, because of the fragmentation, it is sometimes difficult for reviewers to recognize certain structures in that particular fragment. A great improvement to this matter could be the addition of audio to the video recording, where the surgeon can verbally annotate the given procedure.

In addition to the improvement in available operative information and possibly surgical outcomes, video recording might also be useful for patient and family information and education and research purposes regarding effects of specific surgical techniques, as well as situational team awareness in the operating room. Also, it can result in improved communication between physicians from the treating team (e.g., surgeon and oncologist).[24]

In conclusion, peroperative systematic video registration in colorectal cancer surgery is feasible and early results regarding an increase in available intraoperative information are promising. An international multicenter study is currently being organized to evaluate the effect of video capture on surgical quality and patient outcomes.

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Chapter 7

Systematic video documentation is superior to the narrative operative report in colorectal cancer surgery. Results of the IQ-Trial

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ABSTRACT

Importance

Despite ongoing advances in the field of colorectal surgery, the quality of surgical treatment is still variable. As an intrinsic part of surgical quality, the technical information regarding the surgical procedure is reflected only by the narrative operative report (NR), which has been found to be subjective and regularly omits important information.

Objective

To investigate systematic video recording (SVR) as a potential improvement in quality and safety with regard to important information in colorectal cancer surgery.

Design, Setting, and Participants

The Imaging for Quality Control Trial was a prospective, observational cohort study conducted between January 12, 2016, and October 30, 2017, at 3 centers in the Netherlands. The study group consisted of 113 patients 18 years or older undergoing elective laparoscopic surgery for colorectal cancer. These patients were case matched and compared with cases from a historical cohort that received only an NR.

Interventions

Among study cases, participating surgeons were requested to systematically capture predefined key steps of the surgical procedure intraoperatively on video in short clips.

Main Outcomes and Measures

The SVRs and NRs were analyzed for adequacy with respect to the availability of important information regarding the predefined key steps. Adequacy of the reported information was defined as the proportion of key steps with available and sufficient information in the report. Adequacy of the SVR and NR was compared between the study and control groups, with the SVR alone and as an adjunct to the NR in the study group vs NR alone in the control group.

Results

Of the 113 study patients, 69 women (61.1%) were included; mean (SD) age was 66.3 (9.8) years. In the control group, a mean (SD) of 52.5% (18.3%) of 631 steps were adequately described in the NR. In the study group, the adequacy of both the SVR (78.5% [16.5%], $P < .001$) and a combination of the SVR with NR (85.1% [14.6%], $P < .001$) was significantly superior to NR alone. The only significant difference between the study and historical control groups regarding postoperative and pathologic outcomes was a shorter postoperative mean (SD) length of stay in favor of the study group (8.0 [7.7] vs 8.6 [6.8] days; $P = .03$).

Concusions and Relevance

Use of SVR in laparoscopic colorectal cancer surgery as an adjunct to the NR might be superior in documenting important steps of the operation compared with NR alone, adding to the overall availability of necessary intraoperative information and contributing to quality control and objectivity.

INTRODUCTION

During the past decades, colorectal cancer treatment has been subject to some of the most successful developments in modern medicine, constantly improving its quality and outcome. Laparoscopic surgery is now the standard of colorectal cancer treatment, resulting in similar oncologic outcomes and improved short-term results compared with conventional open surgery.[1,2] Also, 5-year survival rates of colon and rectal cancer are rising, and the incidence has been decreased owing to the establishment of preventive measures.[3,4] Despite these positive developments, the quality of surgical treatment, possibly the most significant factor in short- and long-term outcomes, remains variable. This variability is not only evident in postoperative mortality and morbidity, ranging from 0.5% to 6% and 15% to 25%, respectively,[1,5-7] but also in oncologic outcomes, with disease recurrence varying from 5% to 50% of patients and 5-year survival rates ranging from 32% to 64%.[8-11] The importance of quality assurance to reduce this variability is recognized and several quality improvement programs have already been established, such as the implementation of the surgical safety checklist used in the time-out procedure, effectively reducing perioperative mortality.[12,13] In addition, different clinical audits have been developed in the pursuit of quality improvement. These programs, however, focus on either preoperative or postoperative concerns. The essential steps during the surgical procedure are not specifically examined, and might be skipped or inadequately performed. Currently, the only source of information regarding the essential intraoperative surgical steps is represented by the narrative operative report (NR). This source is, however, subjective by definition and proved to be lacking necessary information on a regular basis.[14] A lack of clear description of actual intraoperative events could affect the patient's postoperative therapeutic management and delay diagnosis of complications.[15,16]

Using systematic video recording (SVR), it is possible to capture all important intraoperative steps in more detail and provide a source of objective information. In a pilot study, we have evaluated the use of SVR in laparoscopic colorectal cancer surgery.[17]

In this study we aimed to investigate SVR as a potential improvement in quality and safety with focus on the availability of important information in colorectal cancer surgery.

METHODS

The Imaging for Quality Control Trial is a multicenter, prospective, observational cohort study conducted at 3 centers in the Netherlands (Havenziekenhuis–Erasmus University Medical Center, Rotterdam; Jeroen Bosch Hospital, 's-Hertogenbosch; and University Medical Center Utrecht). The medical research and ethics committee of the Erasmus University Medical Center exempted this study from the Research Involving Human Subjects Act. Institutional review boards of the participating centers provided separate approval of this study prior to local initiation. Informed consent was waived by the medical research and ethics committee. Patients provided oral consent for use of video footage.

Patients

Patients 18 years or older who planned to undergo elective laparoscopic surgery for colorectal cancer were eligible for inclusion. Surgical procedures were defined as right hemicolectomy, transverse colectomy, left hemicolectomy, sigmoid colectomy, or low anterior resection or abdominoperineal resection. Patients who underwent treatment without curative intent, unresectable tumor, or absence of video data owing to technical malfunctioning of recording equipment or failure in data retrieval were excluded from the study. The study was conducted from January 12, 2016, to October 30, 2017.

Predefined Checklist

Surgical checklists compiled from the key moments of the aforementioned surgical procedures were previously defined and feasibility of the process was confirmed.[17] These surgical checklists were subsequently transcribed into a case report form (CRF); printable versions of the study CRFs are presented in the *Appendices*). The intraoperative video clips were then recorded according to the surgical checklist under the direction of the primary surgeon and the corresponding steps were marked on the CRF after completion of the procedure. If a step was not relevant in a particular procedure, not applicable or n/a was added next to the step on the CRF.

Data Collection

During each procedure, the primary surgeon was requested to capture the predefined key moments intraoperatively on video in short clips. The recordings of the different steps were initiated and ceased at the judgment of the primary surgeon. High-definition images were obtained using the available endoscopy equipment in each institution. Subsequently, the video files were retrieved and anonymized for further analysis.

Patient data regarding baseline characteristics, comorbidities, oncologic outcomes, and postoperative complications were gathered from the patients' medical records and anonymously entered into a Good Clinical Practice–compliant electronic data capture system (OpenClinica Community, version 3.12, OpenClinica LLC and collaborators, http://www.OpenClinica.com)

Review for Adequacy

The video clips of the recorded procedures, as well as the corresponding NRs, were reviewed for adequacy according to the predefined key steps. Adequacy was defined as the competent depiction of a surgical step and expressed as the amount or percentage of adequate steps of the total applicable steps for each case. Requirements for adequacy of each step were formulated for both the SVR and NR to aid in the review process (Requirements for adequacy are presented in the *Appendices*). Steps in the CRF were classified as adequate, not adequate, or not applicable. For the review of the SVR, not meeting these requirements or any absence of a recording resulted in a not adequate classification. In reviewing the NR, a step would be labeled not adequate if there was either an incomplete description or a lack of description.

Outcomes

For the primary and secondary outcomes, cases from the study group were matched on an institutional level in a 1:1 ratio with cases from a historical cohort. Patients in this historical cohort had undergone surgery before the start of the study period to most accurately represent the standard situation in operative reporting by avoiding any bias related to the systematic use of the surgical checklists. Case matching was done based on the procedure performed (exact) and the American Society of Anesthesiologists score (tolerance of 1 American Society of Anesthesiologists class).

The primary outcome was the availability of essential information of the performed surgical procedure according to the predefined checklist. Accordingly, the amount of adequate information as provided by SVR of the study group and NR from both the study and control groups was obtained. To assess the added value of SVR to the current situation in which only NR is composed, 2 comparisons were made: SVR of the study group vs NR of the control group and SVR as an adjunct to NR of the study group vs NR of the control group alone.

For the secondary outcome, surgical quality was evaluated. Adverse events associated with the surgical procedure within 30 days postoperatively were analyzed. Surgical complications were graded according to the Clavien-Dindo classification.[18] Furthermore, surgical wound infection, intra-abdominal abscess, urinary tract infection, respiratory tract infection, cardiologic complication, neurologic complication (including delirium), postoperative ileus, postoperative bleeding, and anastomotic leakage were separately documented. In addition, the postoperative length of stay and readmissions within the first 30 postoperative days were obtained.

Statistical Analysis

Categorical data are presented as numbers and percentages. Continuous data are described by mean (SD). Study cases and control cases were compared using $\chi2$ test or Fisher exact test in case of categorical data. Continuous data were tested for normality using the Shapiro-Wilk test and, if normally distributed, analyzed using an independent-samples, 2-tailed t test. Otherwise, the Mann-Whitney test was conducted. In comparing the adequacy of reporting between the different modalities within the study group, a paired-samples t test or Wilcoxon signed rank test was used, depending on normality. A P value <.05 was considered statistically significant.

Based on pilot data,[17] the expected percentage of total adequate steps for NR was approximated at 50%. This percentage was expected to rise to approximately 80% by the addition of SVR. We anticipated minimal improvement in reporting adequacy of 15 percentage points between the study and control groups ($\delta=0.15$). With $\alpha=.05$ and $\beta=.20$, the calculated sample size resulted in 113 cases for both the study and control groups. In the pilot study, 5 of 20 cases were excluded from further analysis. To account for this loss of data, 142 patients were intended to be included in this trial. Data were analyzed with IBM SPSS Statistics for Windows, version 21.0 (IBM Corp) and Microsoft Excel (Microsoft Corp).

RESULTS

Study Population

Between January 12, 2016, and October 30, 2017, a total of 141 patients meeting inclusion criteria underwent operations in participating centers and were included in this study. Subsequently, 28 patients were excluded from the analysis: 25 owing to technical malfunctioning of the recording equipment or problems in data storage, 2 because of the absence of curative intent, and 1 because of an unresectable tumor. Hence, 113 patients (69 women [61.1%]) were included for further analysis. Mean (SD) age was 66.3 (9.8) years. The control group was assembled from an equal number of case-matched patients from each institution who underwent an operation between February 2013 and December 2016. Patient and surgery characteristics of study and control cases are presented in Table 1 and Table 2. In the study group, 17 primary surgeons conducted the procedures, with a mean number of 7 cases (range, 1-38). For the control group, 15 primary surgeons were identified, with a mean number of 8 cases (range, 1-28).

Quantitative Technical Data

In the study group, a total of 59 hours 3 minutes of footage was recorded. The mean (SD) duration of 1 case recording was 31 (46) minutes. The total number of digital storage space occupied was 107 029 megabytes, with a mean (SD) size per case of 964 (1119) megabytes per case.

Primary Outcome

The number of adequate steps for the control and study groups is depicted in Table 3. Among the control cases overall, NR reflected the key moments adequately in mean (SD) 52.5% (18.3%) of procedure steps (631 of 1206). The adequacy of NR in the study group did not significantly improve after implementation of SVR, with an adequacy of 58.3% (19.9%) ($P=.07$). In the control group, the percentage of adequate steps for NR were as follows: introduction of trocars under vision, 42.2%; exploration, 62.9%; vascular control, 67.3%;

Table 1. Patient characteristics

Characteristic	No. (%) Study Cases (n= 113)	Historic control (n= 113)	*p* value
Age, mean (SD), y	66.30 (9.8)	67.80 (10.1)	.29
Women	35 (40.2)	34 (39.1)	.88
Height, mean (SD), cm	173.4 (10.0)	172.1 (9.7)	.32
Weight, mean (SD), kg	77.6 (14.8)	79.2 (15.2)	.48
BMI, mean (SD)	25.8 (4.0)	26.8 (4.5)	.14
ASA class			.78
ASA I	11 (12.6)	12 (13.8)	
ASA II	50 (57.5)	49 (56.3)	
ASA III	24 (27.6)	23 (26.4)	
ASA IV	2 (2.3)	1 (1.1)	
Missing	2 (2.3)	0	
Charlston Comorbidity Index			.72
None (0)	35 (40.2)	41 (47.7)	
Low (1-2)	42 (48.3)	35 (40.7)	
Moderate (3-4)	7 (8.0)	6 (7.0)	
High (≥5)	3 (3.4)	4 (4.7)	
Diabetes Mellitus	18 (15.9)	16 (14.2)	.85
Hypertension	48 (42.5)	52 (46.0)	.69
History of			
Cardiac disease	22 (19.5)	31 (27.4)	.21
Pulmonary disease	24 (21.2)	17 (15.0)	.30
Renal disease	9 (8.0)	8 (7.1)	1.00
Prior abdominal and/or pelvic surgery	28 (24.8)	37 (32.7)	.24
Metastasic disease	4 (3.5)	5 (4.4)	.90

ASA American Society of Anesthesiologists, *BMI* Body Mass Index (calculated as weight in kilograms divided by height in meters squared)

mobilization and resection, 35.1%; creation of anastomosis, 49.2%; and closure, 57.9%. For the study group, surgeons recorded a mean of 85.5% (16.0%) of the relevant key moments during surgery. After review, these recorded key moments were considered adequate in 78.5% (16.5%) of the cases, significantly higher than the NR of both control and study groups (52.5% [18.3%], P<.001 and 58.3% [19.9%], P<.001, respectively). In the study group, the percentage of adequate steps for SVR and SVR combined with NR, respectively, were as follows: introduction of trocars under vision, 84.5% and 85.5%; exploration, 79.4% and 88.5%; vascular control, 74.8% and 83.7%; mobilization and resection, 79.7% and 84.2%; creation of anastomosis, 76.1% and 83.0%; and closure, 79.0% and 85.7%. With these findings, the adequacy of the reviewed SVR was significantly higher than that of NR

Table 2. Surgery characteristics

Characteristic	No. (%) Study Cases (n= 113)	Historic control (n= 113)	*p* value
Type of laparoscopic surgery			
Right hemicolectomy	40 (35.4)	40 (35.4)	>.99
Transverse colectomy	1 (0.9)	1 (0.9)	
Left hemicolectomy	11 (9.7)	11 (9.7)	
Sigmoidectomy	28 (24.8)	28 (24.8)	
LAR / APR	33 (29.2)	33 (29.2)	
Surgery duration, mean (SD), min	147 (62.7)	146 (62.4)	.95
Operator function			.004
Surgeon	85 (75.2)	79 (69.9)	.46
Fellow	17 (15.0)	32 (28.3)	.02
Resident	11 (9.7)	2 (1.8)	.02
Stoma	21 (20.0)	26 (23.0)	.51
Stoma type			
Loop ileostomy	12 (57.1)	15 (57.7)	<.99
End colostomy	8 (38.1)	10 (38.5)	
Other	1 (4.8)	1 (3.8)	
Anastomosis type			
Side-to-side	59 (56.7)	46 (43.4)	.19
Side-to-end	30 (28.8)	36 (34.0)	
End-to-side	0	3 (2.8)	
End-to-end	7 (6.7)	10 (9.4)	
None	8 (7.7)	11 (10.4)	
Missing	9 (8.0)	7 (6.2)	

LAR Low Anterior Resection, APR Abdominoperineal Resection

of both study and control cases (58.3% [19.9%] and 52.5% [18.3%], respectively; both P<.001 with Wilcoxon signed-rank test).

When SVR was combined with NR, a mean percentage of adequate steps of 85.1% (14.6%) was achieved, which was a significant increase from both the NR and the reviewed SVR (P<.001 for both). Figure 1 delineates the reporting adequacy for each of the key moments per documentation method.

A total of 1213 applicable steps among the procedures of the study group could be documented on SVR or NR. Overall, 97 steps (8.0%) were checked on the CRF as having been recorded, yet they were not adequately perceived. Furthermore, 80 steps (6.6%) were described on the NR but were not observed on SVR. A total of 322 steps (26.5%) were adequately seen on the SVR, but were inadequately described on the NR. This disparity

Table 3. Number of Adequate Steps

Procedure steps	No. Adequate steps/No. Total steps (%)							
	Historic control, NR		Study Cases					
			SVR		SVR and NR		*p* value[a]	*p* value[b]
Step 1. Introduction of trocars under vision	46/109	(42.2)	93/110	(84.5)	94/110	(85.5)	< .001	< .001
Step 2. Exploration	205/326	(62.9)	255/321	(79.4)	284/321	(88.5)	< .001	< .001
Step 3. Vascular control	103/153	(67.3)	110/147	(74.8)	123/147	(83.7)	.69	.045
Step 4. Mobilization and resection	91/259	(35.1)	212/266	(79.7)	224/266	(84.2)	< .001	< .001
Step 5. Creation of Anastomosis	124/252	(49.2)	201/264	(76.1)	219/264	(83.0)	< .001	< .001
Step 6. Closure	62/107	(57.9)	83/105	(79.0)	90/105	(85.7)	.009	< .001
Total	631/1206	(52.3)	954/1213	(78.6)	1034/1213	(85.2)	< .001	< .001

NR narrative operative report; *SVR* systematic video recording

[a] Control group; NR vs study group SVR

[b] Control group; NR vs study group NR with SVR

Table 4. Discrepancies between video recordings, video review and narrative operative report within 113 study group cases

Procedure steps of study cases (n=113)	Total steps	Recorded but not seen[a]		Described but not seen[b]		Seen but not described[c]	
Step 1 - Introduction of trocars	110	8	(7.3)	1	(0.9)	45	(40.9)
Step 2 - Exploration	321	37	(11.5)	29	(9.0)	65	(20.2)
Step 3 - Vascular control	147	10	(6.8)	13	(8.8)	20	(13.6)
Step 4 - Mobilization and resection	266	14	(5.3)	12	(4.5)	103	(38.7)
Step 5 - Anastomosis	264	17	(6.4)	18	(6.8)	71	(26.9)
Step 6 - Closure	105	11	(10.5)	7	(6.7)	18	(17.1)
Total steps	1213	97	(8.0)	80	(6.6)	322	(26.5)

Data are presented as *N* (%) of adequate steps.

[a] Steps stated to have been recorded by primary surgeon, but not seen upon video review.

[b] Steps adequately described in the narrative operative report, but not adequately seen upon video review.

[c] Steps adequately seen upon video review, but not adequately described in the narrative operative report

predominantly comprised the steps regarding introduction of trocars and mobilization and resection (40.9% and 38.7%, respectively). The full list of discrepancies can be found in Table 4.

Secondary Outcome

Postoperative outcomes and pathologic outcomes are summarized in Table 5 and Table 6. Aside from a significant difference regarding the postoperative length of stay in favor of the study group (8.0 [7.7] vs 8.6 [6.8] days; P = .03), no significant differences were found

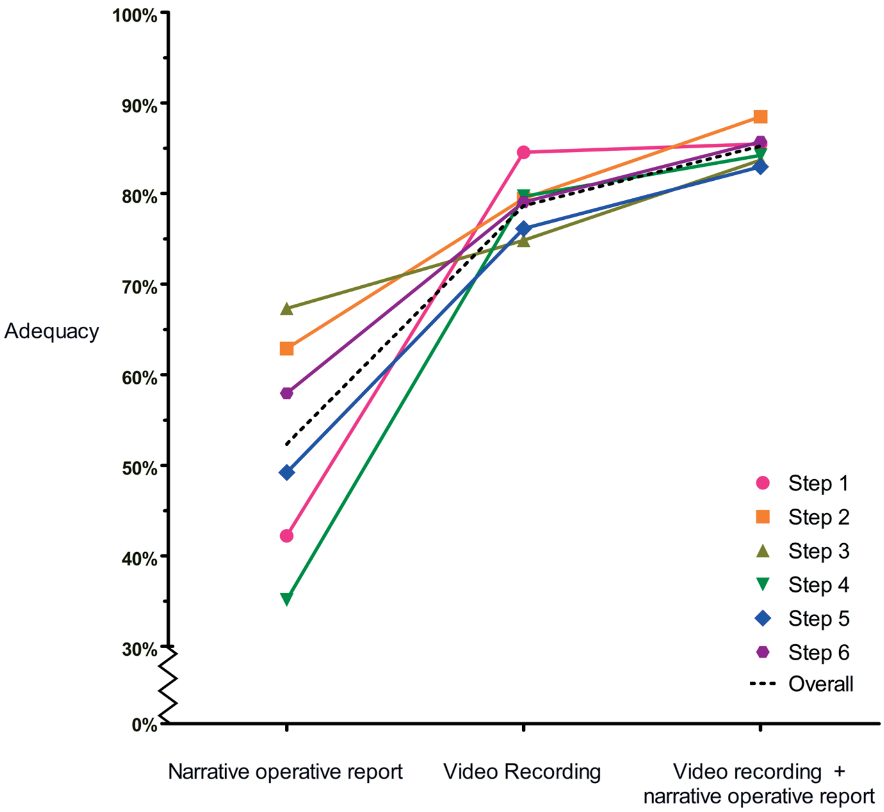

Figure 1. Reporting adequacy per documentation method among study cases
Adequacy is defined as the percentage of adequate steps per total number of applicable steps
Step 1: Introduction of trocars under vision
Step 2: Exploration
Step 3: Vascular control
Step 4: Mobilization and resection
Step 5: Creation of Anastomosis
Step 6: Closure

between the study and historical control groups regarding postoperative and pathologic outcomes.

DISCUSSION

Ever since George Berci, as early as 1962, created the foundation for video-assisted endoscopic surgery, technological advancements have made it increasingly practical for health

Table 5. Postoperative outcomes

Outcome	No. (%) Study Cases (n= 113)	Historic control (n= 113)	*p* value
Postoperative complication[a]	49 (43.4)	45 (39.8)	.69
Clavien-Dindo[a]			.20
I	11 (22.4)	8 (17.8)	
II	26 (53.1)	24 (53.3)	
III	8 (16.3)	8 (17.8)	
IV	1 (2.0)	5 (11.1)	
V	3 (6.1)	0	
Surgical wound infection	9 (8.0)	6 (5.3)	.60
Intra-abdominal abscess	8 (7.1)	3 (2.7)	.22
Urinary tract infection	6 (5.3)	6 (5.3)	>.99
Respiratory tract infection	9 (8.0)	8 (7.1)	>.99
Cardiological complication	4 (3.5)	3 (2.7)	>.99
Neurological complication	4 (3.5)	9 (8.0)	.25
Thrombotic complication[b]	2 (1.8)	0	.50
Prolonged Postoperative Ileus	23 (20.4)	14 (12.4)	.15
Postoperative bleeding	1 (0.9)	2 (1.8)	>.99
Anastomotic leakage	2 (1.8)	6 (5.3)	.28
Hospital admission, median (IQR), d	8.0 (7.7)	8.6 (6.8)	.03
Readmittance ≤30 d postoperatively	9 (8.1)	4 (3.5)	.16

IQR Interquartile range.
[a] Grading according to Clavien-Dindo classification
[b] Deep venous thrombosis or Pulmonary embolism

care professionals to display and record multimedia of intraoperative surgical events.[19,20] These events are known to significantly affect surgical quality, and inadequate reporting has previously been linked to several unfavorable effects on postoperative care.[15,16] Despite its ever-growing availability, and taking into consideration that the current method of documenting surgical care is substandard in most cases, use of video documentation in the surgical setting is still limited. To our knowledge, this trial, along with the preceding pilot study, has been the first to prospectively investigate the benefits of SVR relevant to quality and safety in colorectal cancer surgery.

In this study, we demonstrated a significant increase in reporting quality regarding the intraoperative key moments of laparoscopic colorectal oncologic surgery by using intraoperative SVR. Only 52.5% of the steps reported in NR were adequately described. This finding is consistent with our pilot study and earlier published findings in surgery.[17,21-24] The steps that were most adequately described in NR were vascular control (67.3%), followed by explora-

Table 6. Pathologic outcomes

Outcome	No. (%) Study Cases (n= 113)	Historic control (n= 113)	*p* value
Tumor type			
Benign	2 (1.8)	1 (0.9)	.85
Pre-malignant	2 (1.8)	2 (1.8)	
Malignant	108 (96.4)	109 (97.3)	
Resection margin, mm			
<5	7 (7.1)	9 (9.6)	.73
6-9	3 (3.0)	4 (4.3)	
≥10	89 (89.9)	81 (86.2)	
Tumor size, median (IQR), cm	3.7 (1.9)	3.5 (1.9)	.59
Total lymph node yield, median (IQR), No.	17.7 (10.1)	16.8 (7.4)	.94
Tumor-positive lymph nodes, median (IQR), No.	0.9 (2.2)	1.0 (2.0)	.28
pT-category[a]			
pT0	3 (2.8)	2 (1.9)	.87
pT1	16 (14.7)	24 (13.0)	
pT2	30 (27.5)	29 (26.9)	
pT3	53 (48.6)	52 (48.1)	
pT4	7 (6.4)	11 (10.2)	
pN-category[b]			
pN0	80 (72.7)	74 (66.7)	.44
pN1	23 (20.9)	25 (22.5)	
pN2	7 (6.4)	12 (10.8)	

IQR Interquartile range; *pN* pathologic evaluation of regional lymph nodes; *pT* pathologic evaluation of primary tumor

[a] For pT categories, T0 indicates no evidence of primary tumor; T1, tumor invades submucosa; T2, tumor invades muscularis propria; T3, tumor invades through the muscularis propria into pericolorectal tissues; and T4, tumor penetrates to the surface of the visceral peritoneum or directly invades or is adherent to other organs or structures

[b] For pN categories, N0 indicates no regional lymph node metastasis; N1, metastasis in 1 to 3 regional lymph nodes; and N2, metastasis in 4 or more regional lymph nodes.

tion (62.9%). The least adequately reported step was mobilization and resection (35.1%). This step included the substeps regarding the description of the resection specimen and the identification of the left ureter in left-sided resections. A possible explanation of why this step is only adequately reported in one-third of the cases might be owing to the custom to not include a remark regarding the quality of the resection specimen in NR. This suggestion is supported by the fact that 38.7% of the steps regarding the mobilization and resection is seen on SVR, yet not adequately described on NR within the study group. Almost all NRs included the statement, “resection specimen sent to pathology,” or similar phrasing. Undeniably an important step, the addition of this sole phrase to NR is nugatory, as the only information it provides regarding the resection specimen is that it has been sent for pathologic evaluation. Whether the specimen has been investigated before hand-off is unknown. It is necessary to inspect the surgical specimen after resection, determining whether the tumor has been completely removed and with a sufficient resection margin. If the resection margin is deemed to be compromised on inspection, the surgeon can still act on this discovery perioperatively, thereby preventing the patient from having to undergo reintervention.

The most adequately recorded step among SVR in the study group was introduction of trocars under vision (84.5%), followed by exploration (88.5%). The least adequately recorded step was vascular control (79.4%) followed by creation of the anastomosis (76.1%). Although significantly higher in adequacy than was documented in NR, 21.5% of all cases remained inadequately recorded by SVR alone. No significant difference was found between the adequacy of NR and SVR for the vascular control step. It was not until the 2 methods were combined that a significant difference between the control and study group was achieved. A possible explanation of this result is the fact that in most cases, resections were endoscopically assisted (extracorporeal resection, including transection of vascular structures). Therefore, only the phase in which the transection of the central vasculature occurred intracorporally was often recorded on the endoscopic camera.

In this study, it appears that SVR is superior to NR in laparoscopic colorectal surgery, with an overall improvement of 26.3 percentage points compared with NR alone. However, NR and SVR provided the best results when complementing each other. In this combination, the reporting adequacy increased to 85.2% of the total relevant key moments—an increment of 32.9 percentage points. The best contribution of NR to the documenting adequacy of SVR was done by the exploration and vascular control phases, enhancing the adequacy with an absolute difference of 9.0% and 8.8%, respectively, compared with SVR alone. Furthermore, 26.5% of all possible steps were adequately documented by SVR, but were not adequately described in the NOR, of which the steps regarding introduction of trocars and mobilization and resection contained the most disparity (40.9% and 38.7%, respectively). The percentage of the former is comparable to the result found in the study conducted by Wauben et al.[14]

Before the start of the study, it was expected that the participating surgeons' knowledge of the key moments that were to be recorded and the corresponding checklist was a risk of bias, resulting in a more complete NR. However, the introduction of the systematic approach and procedural recording using a checklist did not seem to have a significant association with NR adequacy. Therefore, the amount of bias caused by this knowledge seems negligible.

We decided to record video fragments aimed to capture the essence of the surgical procedure in contrast to full-length video encompassing the entire operation. This method was chosen so that surgeons were committed to consciously start and stop the process of recording these essential steps, with the potential of improving quality, also by way of the Hawthorne effect: an increase in performance owing to the individual's awareness that it is being recorded. Furthermore, the recording of video fragments diminishes the digital storage space necessary, allowing for manageable content.

Regarding the secondary outcomes, SVR does not seem to significantly alter short-term postoperative and pathologic outcomes. It is plausible that the fact that parts of the surgery were videotaped did not influence the surgical approach in such a manner that a significant change in postoperative outcomes occurs. Conversely, the fact that short-term postoperative and pathologic outcomes do not differ between study and control settings might also indicate that SVR does not impair surgeons in their performance. The significant difference of length of stay can be explained by other improvements in patient care since the inclusion period of the historical control group, which is outside the scope of this study.

As this study suggests, SVR is able to document surgical procedures in a more complete manner than NR, which adds to the overall availability of essential intraoperative information, in turn contributing to quality control and objectivity. On evaluation, any given reviewer is able to observe how and when certain events happened, instead of reading another's perception of the procedure (eg, the exact positioning, size, and relative anatomy of vascular structures ligated, rather than merely the phrase ligation of arterial supply). Even the surgeon who was present during surgery is able to benefit from this technique. For instance, a surgeon who is notified of tumor-positive resection margins may review the SVR to evaluate whether this inadequate resection was unavoidable or the particular dissection technique used during the surgery was suboptimal. When only an operative note is obtained, further evaluation of the technical aspects is impossible. But with SVR, one is able to reflect on his or her actions more thoroughly than during or directly after surgery.[25]

We foresee video documentation of surgical procedures becoming an essential part of surgery in the near future. Use of SVR is, however, intended as an extension to the written operative report—not a substitute. Surgeons' considerations to perform or omit certain steps during the surgical procedure are difficult to capture using only video. Also, for sake of practicality in daily practice, a written record should still be available.

Limitations

This study has limitations. Because the operative steps were consciously recorded in a number of short clips, a considerable amount of information, which, according to the intraoperative checklist is deemed nonessential, was not recorded. With this method, adverse events that might occur in these parts of the procedure are not recorded. Furthermore, this method of documentation is prone to human error, with a probability of missing data that could range from insignificant details (eg, starting the recording too late or stopping the recording too early) to entire procedures in which recording has been omitted. Ultimately, full-length video recording of surgical procedures would be more informative, as it will also encompass the possible adverse events that would have been disregarded otherwise and will be able to provide for thorough analysis of technical performance data.[26] However, regarding user convenience, the density of valuable information of full-length surgical recordings is low, often necessitating arduous review processes, particularly in major surgery. To address this inconvenience and make review of the surgical procedure more convenient for daily practice, real-time annotation of these key moments might be a solution for easier retrieval and incorporation in the operative report. Furthermore, owing to staff changes in the participating centers, predominantly fellowship positions, continuity of the primary surgeons between the study and control group is limited, making direct comparison between surgeons difficult.

Conclusions

Intraoperative SVR in laparoscopic colorectal cancer surgery as an adjunct to the NR appeared to be associated with better documentation of intraoperative essential steps of the procedure compared with the traditional NR alone. For the use SVR combined with NR in surgical practice, implementation studies are necessary to provide the most adequate and convenient manner of recording and using these images.

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Part 3

Quality and safety in laparoscopic cholecystectomy

Chapter 8

Safe laparoscopic cholecystectomy: a systematic review of bile duct injury prevention

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ABSTRACT

Background

Since the introduction of laparoscopic cholecystectomy (LC), a substantial increase in bile duct injury (BDI) incidence was noted. Multiple methods to prevent this complication have been developed and investigated. The most suitable method however is subject to debate. In this systematic review, the different modalities to aid in the safe performance of LC and prevent BDI are delineated.

Materials and methods

A systematic search for articles describing methods for the prevention of BDI in LC was conducted using EMBASE, Medline, Web of science, Cochrane CENTRAL and Google scholar databases from inception to 11 June 2018.

Results

90 studies were included in this systematic review. Overall, BDI preventive techniques can be categorized as dedicated surgical approaches (Critical View of Safety (CVS), fundus first, partial laparoscopic cholecystectomy), supporting imaging techniques (intraoperative radiologic cholangiography, intraoperative ultrasonography, fluorescence imaging) and others. Dedicated surgical approaches demonstrate promising results, yet limited research is provided. Intraoperative radiologic cholangiography and ultrasonography demonstrate beneficial effects in BDI prevention, however the available evidence is low. Fluorescence imaging is in its infancy, yet this technique is demonstrated to be feasible and larger trials are in preparation.

Conclusion

Given the low sample sizes and suboptimal study designs of the studies available, it is not possible to recommend a preferred method to prevent BDI. Surgeons should primarily focus on proper dissection techniques, of which CVS is most suitable. Additionally, recognition of hazardous circumstances and knowledge of alternative techniques is critical to complete surgery with minimal risk of injury to the patient.

INTRODUCTION

With a number of 150–200 procedures per 100,000 inhabitants in Europe and the United States each year, cholecystectomy is one of the most common abdominal surgical procedures today, of which over 80% is performed laparoscopically.[1,2] Since the introduction of laparoscopic cholecystectomy (LC) its superiority compared to open cholecystectomy (OC), e.g. decreased postoperative pain and shorter length of stay, was cause of its rapid and widespread implementation. Accompanying this however, was an upsurge in the occurrence of bile duct injury (BDI), a potentially life threatening complication. Compared to an average of 0.2% in OC,[3,4] the incidence of BDI encountered a drastic increase after the introduction of LC, with reported rates of up to 1.5%%.[5-11] At first, this aggravation was attributed to the learning curve surgeons had to deal with.[10] Yet, higher patient numbers and operator experience did not significantly decrease the incidence of BDI.[12] Since then, considerable effort has been made to improve safety in LC with a variety of methods described in literature, reducing the incidence of BDI to around 0.23% and 0.30%.[13,14] To date however, it is unclear what contribution the different methods make in the prevention of BDI, therefore rendering it difficult to identify the most suitable method.

In this systematic review, the different modalities that might aid in the realization of safe LC are outlined with emphasis on the available evidence with regard to the prevention of BDI.

MATERIAL AND METHODS

Search strategy

EMBASE, Medline, Web of science, Cochrane CENTRAL and Google scholar databases were systematically searched from inception up to 11 June 2018 for articles describing possible methods to avoid BDI in LC. With the assistance of an information specialist, the search was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and limited to manuscripts written in the English language. The complete search strategy can be found in the *Appendices*.

The work has been reported in line with AMSTAR (Assessing the methodological quality of systematic reviews) Guidelines.

Article selection and data extraction

Potentially eligible articles were reviewed by two investigators independently (IZ and FvdG). Exclusion criteria included: no description of role in BDI prevention, technical reports without study population, no full text available, non-original articles, surveys, case reports, animal or cadaveric studies, guidelines or protocols, no distinction between OC and LC, and other hepatopancreaticobiliary surgery. Discrepancies between the two investigators were resolved through consensus.

The following data were extracted from the included articles:

- Study period
- Study type
- Described method of BDI prevention
- Number of included cases
- BDI rate (number of BDIs per total number of cases)
- Bile leak rate (number of bile leaks per total number of cases)
- Success rate (successful execution of the described method per total number of cases)
- Conversion rate (the number cases converted top open resection per total number of cases)
- Authors' conclusion
- Authors' viewpoint regarding the described method

The level of evidence (according to the Oxford Centre of Evidence-Based Medicine[15]) was appraised for each inclusion. Articles were categorized according to the following BDI prevention methods:

1. Dedicated surgical approaches
   - *Critical view of safety (CVS)*; the technique proposed by Strasberg et al. in 1995 to conclusively identify the cystic duct and the cystic artery and minimize misidentification.[16]
   - *Fundus first laparoscopic cholecystectomy (FFLC)*; The act of clamping the gallbladder at the fundus to facilitate traction during dissection alongside the liver bed towards the liver hilum. Through the natural course of dissection, the cystic duct emerges from the infundibulum and is thereby identified.
   - *Laparoscopic subtotal cholecystectomy (LSC)*; Partial resection of the gallbladder, most often by transection proximal to the cystic duct. This technique makes it possible to avoid dissection in Calot's hepatobiliary triangle in case of precarious conditions.
2. Supporting imaging techniques
   - *Intraoperative radiologic cholangiography (IOC)*; The practice in which a radiographic image of the biliary tree is acquired during surgical intervention by cannulating a bile duct and subsequently administering a radiographic contrast agent. In general, three different policies towards the use of IOC can be distinguished: *routine* use, *selective* use or *total omission*. Routine IOC implies that all patients planned for LC are expected to have IOC performed during the procedure. In selective use, IOC is only performed in certain circumstances, according to protocol or upon surgeons' request.

- o *Intraoperative ultrasonography (IOUS)*; The visualization of transverse and longitudinal planes of not only biliary structures, but also other critical structures, such as the portal and caval veins, and the hepatic arteries by introducing a linear ultrasonography probe.
- o *Fluorescence cholangiography*; The method of using a fluorescence agent to illuminate the biliary system. The best known fluorescence agent currently used is Indocyanine green (ICG), which becomes fluorescent once excited with specific wavelength light in the near infra-red (NIR) spectrum (approximately 800-825 nm).[17] Once injected into the blood stream, ICG is excreted via the liver into bile almost exclusively.[18]

3. Other BDI prevention methods

Data analysis

Due to the presence of conceptual heterogeneity among the included studies a quantitative synthesis is not realized. Therefore, a narrative synthesis is performed. Microsoft Excel (Microsoft Corp., Redmond, WA, USA) was used for the analysis of data. Values are represented as median and interquartile range (IQR) or mean and range

RESULTS

The initial database search resulted in 2,309 articles. After removal of duplicate studies, 1,429 potentially relevant articles were screened based on title and abstract, resulting in 318 records eligible for full-text review. After thorough assessment, an additional 228 articles were excluded, resulting in 90 studies to be included in this systematic review. The PRISMA flowchart presented in Figure 1. depicts the detailed selection of studies.

Among the 90 studies, 20 covered dedicated surgical approaches (CVS in 7 studies,[19-25] FFLC in 6,[26-31] LSC in 7[32-38]). Supporting imaging techniques were investigated in 69 (IOC in 45 studies,[39-83] IOUS in 8 studies,[76-78,84-88] fluorescence imaging in 16 studies[79,89-103]). Other methods were described in 5 studies.[104-108] Detailed characteristics of these studies are represented in the *Appendices*. Overall, the results of 203,368 patients in total were presented in the included articles (with an average per article of 2,285 patients (range 12 – 51,041). 68 studies reported BDI rates, a total of 1,104 incidents. The mean reported BDI rate was 0.23% (range 0% – 3.1%).

Figure 2 depicts the studies included in this systematic review in order of publication date and the time periods of inclusion. Note that the primary method investigated before the turn of the century was IOC. Thereafter, other modalities of BDI prevention were starting to be explored.

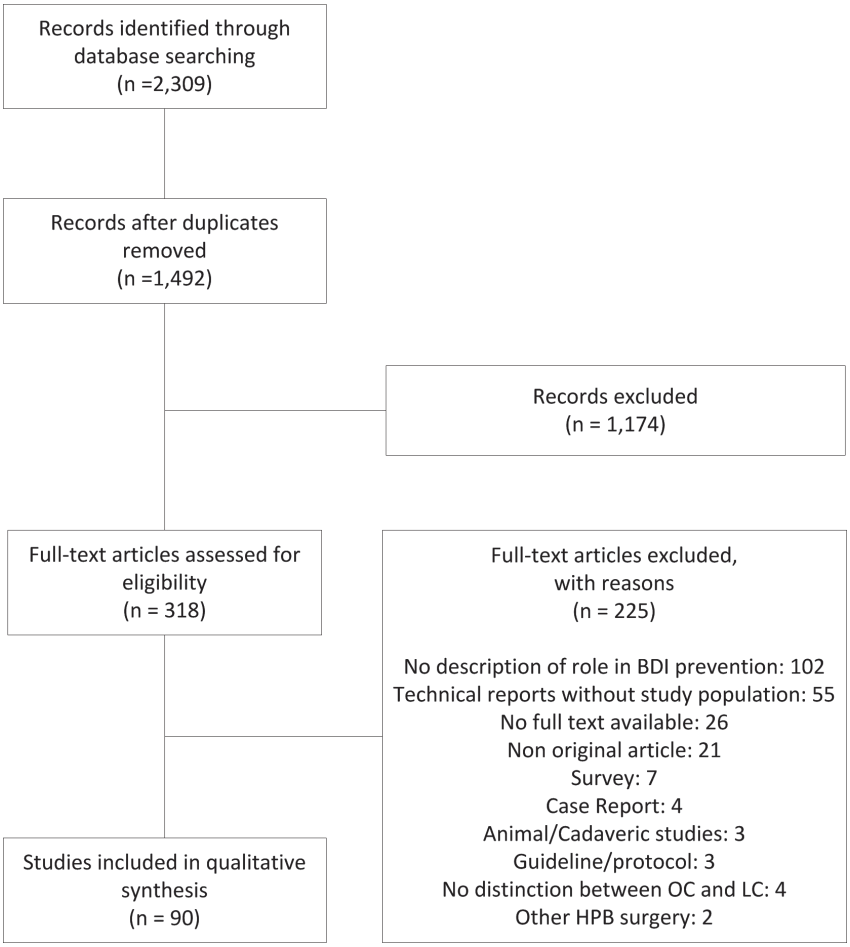

Figure 1. PRISMA Flow-chart

Dedicated surgical approaches

A summary of findings of the articles covering dedicated surgical approaches is presented in Table 1.

Table 1. Dedicated surgical approaches – summary of findings

BDI prevention technique	*N* Studies	N Cases		Median Success rate
		Total	Average per study	
Critical View of Safety	7	5,728	818 (54 - 3,042)	95.8% (95.4 - 100)
Fundus First Laparoscopic Cholecystectomy	6	3,094	516 (16 - 53)	89% (84.5 – 93.5)
Subtotal Laparoscopic Cholecystectomy	7	6,196	885 (23 - 60)	90.2% (85.3- 95.1)

Values represent total, average (range) or median (interquartile range) of reported outcomes among included studies

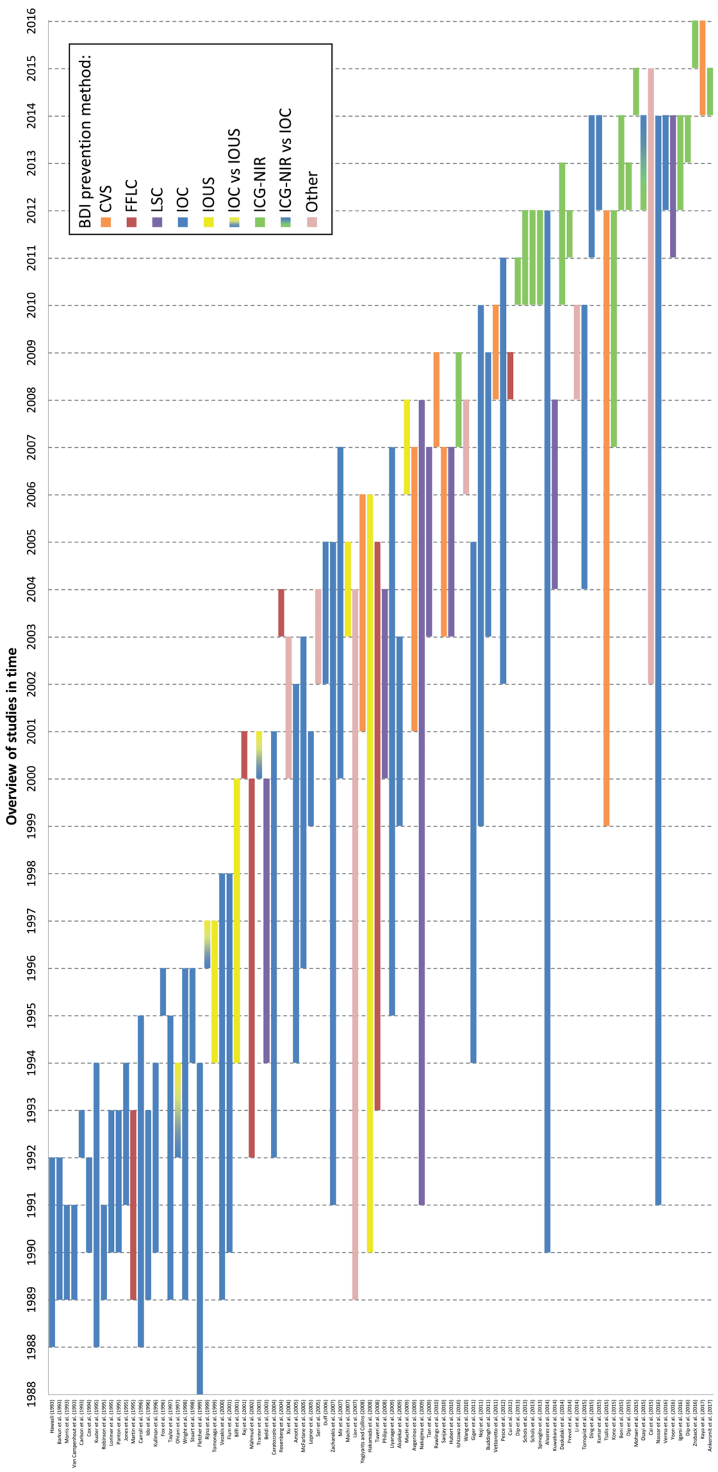

Figure 2. Overview of studies in time

Critical view of safety

Seven studies were included in this systematic review covering the use of CVS.[19-25] Within these articles, encompassing over 5,000 cases in total (average of 818 patients per study; range 54 – 3,042), one BDI was reported by Yegiyants et al. among 3,042 cases (incidence 0.03%).[25] Overall, the median reported success rate of CVS was 95.8% (IQR 95.4%–100%). The median reported conversion rate was 0.95% (IQR 0–2.4%)

Fundus first laparoscopic cholecystectomy

Six studies described FFLC.[26-31] A median of 32 FFLC procedures were performed (IQR 22 – 46). The conversion rate in these series was lower than the general conversion rate in LC, with a median of 0.3% (IQR 0 – 1.2%). Mahmud et al. described a conversion rate of 1.2% among 710 LCs, of which 35 by way of FFLC.[27] The authors also reported that, without the use of FFLC in this study, conversion would have been necessary in 28 cases having received FFLC, what would have resulted in a potential conversion rate of 5.2%. Tuveri et al. conducted a large retrospective study (1,965 LCs; 29 FFLCs), in which two BDIs occurred (none in the FFLCS group).[31] It was also noted that a significantly larger amount of complications occurred in the FFLC group than in the conventional LC group (20% vs. 1.4% respectively). Both the studies by Mahmud et al. and Tuveri et al. respectively reported dense adhesions (40% and 51%), followed by impacted stones in Hartmann's pouch (29% and 17%) and a short dilated CD (17% and 14%) as most common indications of resorting to FFLC.

Laparoscopic subtotal cholecystectomy

7 articles covered LSC.[32-38] A median of 39 LSC procedures have been performed (IQR 26 – 47), accounting for a median of 9.1% of LC cases in these articles (IQR 6.3% – 10.3%). The median reported number of bile leaks was 6.3% (IQR 0.85% – 12.5%). Beldi et al. compared their institution's experience in LSC with a national database, reporting a significantly lower conversion rate in cases with acute cholecystitis (9.7% to 23.2% respectively).[32] LSC was attempted in 46 of 345 cases (13.3%) with subsequent conversion deemed necessary in approximately one fifth of the patients. The posterior wall was left in situ in all LSC patients and the infundibulum in 26.1% of the cases. No bile duct injury was reported. Nakajima et al. compared two periods: before and after the introduction of LSC in their institution.[35] Before introduction, the BDI incidence was reported to be 1.6% with a conversion rate of 2.5%. after introduction LSC was performed in 10.3% of the LC cases with both BDI incidence and conversion rate significantly dropping to 0.3% each.

Supporting imaging techniques

Intraoperative radiologic cholangiography

The key findings of articles covering IOC are summarized in Table 2.

Table 2. Intraoperative Radiologic Cholangiography and Intraoperative Ultrasonography – summary of findings

BDI prevention technique		*N* Studies	N Cases		Median success rate	Median BDI \ Incidence
			Total	Average per study		
Intraoperative Radiologic Chol-angiography	*Overall*	45	155,105	4,432 (50 - 51,041)	89% (78.5 – 94)	0.18% (0 - 0.38)
	Routine	15	76,894	5,126 (100 - 51,041)	94% (88.5– 96.3)	0.025% (0 - 0.29)
	Selective	4	33,455	8,364 (75 - 31,838)	76.3% (75.7 – 85.2)	0.15% (0 - 0.3)
	Omission	10	9,935	994 (82 - 2,038)	X	0.28% (0.02 - 0.53)
Intraoperative Ultrasonography		8	3,360	420 (43 - 1,381)	88.8% (78.5 - 94)	0% (0 – 0.6)

Values represent total, average (range) or median (interquartile range) of reported outcomes among included studies

One RCT was included in this systematic review.[41] The authors of this study randomized 404 patients to either conventional LC or LC combined with routine IOC. No significant differences were reported between the two groups in regards to BDI rate, conversion rate or bile leaks. Therefore the authors concluded that IOC as an adjunctive to LC had no significant effect on the reported success rates of LC or BDIs. In a retrospective study performed by Flum et al. covering 30,630 LCs, a significant reduction in BDI rate was observed with concurrent IOC use, about 40% less (2.0 vs. 3.3 per 1,000 cases).[43] It was thereby noted that the majority of BDIs occurred in earlier parts of the learning curve. Fletcher et al. reviewed cases of BDI to assess possible risk factors.[42] The authors concluded that approximately one third of BDI cases could be prevented by performing IOC.

Routine and selective use of IOC

Fifteen articles primarily addressed the *routine* use of IOC. [44-58] Among an average of 5,126 patients per study (range 100 - 51,041), the median reported BDI incidence was 0.025% (IQR 0 – 0.285%).

Tornqvist et al. obtained the data of 51,041 patients operated between 2005 and 2010 from the national Swedish Registry for Gallstone Surgery (GallRiks).[56] In this retrospective cohort study, 747 BDIs – graded according to the Hannover criteria[109] – were identified (incidence 1.5%). In patients suffering from concurrent cholecystitis, a significant protective effect was demonstrated by applying IOC. Alvarez et al. retrospectively evaluated the routine use of IOC (successfully performing cholangiography in over 95% of the cases) in 11,423 consecutive LCs.[44] Twenty patients suffered from BDI (0.17%) of which 18 were diagnosed and managed peroperatively. The sensitivity and specificity for the detection of BDI in this study was 79% and 100% respectively.

Four articles addressed the *selective* use of IOC.[59-62] With an average of 8,364 patients per study, the median reported BDI incidence was 0.15% (IQR 0 – 0.3%). IOC was attempted in a median of 29% of the cases (IQR 11.8% – 34.6%). Giger et al. performed a retrospective analysis of 31,838 LC cases entered in a prospectively maintained nationwide database.[59] 101 BDIs (0.3%) were observed among these cases. IOC was performed in 36.6% of LCs, among which 39.6% of BDIs were observed. IOC did not seem to reduce the amount of BDIs in this study, as no significant differences were found between the groups. The amount of BDIs that were missed during surgery also did not show a significant difference (10% and 8% - IOC and no IOC respectively).

Three other studies directly compared a routine IOC policy with selective use of IOC.[63-65] One of these studies (n=835) concluded that routine IOC was superior in comparison with a selective approach,[64] while two studies (n=334 and 319 respectively) found no superiority in a routine policy considering BDI rates.[63,65]

Omission of IOC

Ten studies were included in this systematic review that evaluated the safety of LC *without* the use of IOC.[66-75] In these studies any specific surgical techniques as described above were not mentioned. The median reported BDI incidence without the use of IOC was 0.28% (IQR 0.02 – 0.53%). Comparing the reported rates of conversion among the included studies in this review, the median conversion rate of the articles without IOC was 3.1% (IQR 2.5% - 5.1%), versus a median of 3.5% (IQR 1.8% to 5.8%) reported by studies employing either *routine* or *selective* IOC. The prospective study by Mir et al. demonstrated that, in rural hospitals in a developing country, where a minimalistic setting applies and costly interventions like IOC are undesirable or even unavailable, safe LC was also possible.[70] Despite their restrictions, the authors report a BDI incidence of 0.08% and conversion rates of 1.8%, all having been acquired through application of safe dissection techniques. In 1993, Barkun et al. reported a BDI incidence of 0.38% while employing a very low IOC rate (4.2%), achieving a rate similar as has been reported elsewhere in literature.[66] Taylor et al. reported the outcomes of 2,038 LC cases without the use of IOC after retrospective review.[73] BDI was reported in 1.1%, of which 18.2% required additional surgery postoperatively. Zacharakis et al. reported a BDI rate of 0.37% in 1,851 patients who underwent LC without an IOC, which were found to be comparable with the reported rates after an LC with routine use of an IOC.[75]

Other applications of IOC

Three articles reported results of performing IOC through the gallbladder (cholecystocholangiography).[80-82] All three studies agreed that cholecystocholangiography is a simpler method of employing IOC compared to the CD method. Noji et al. and Liyanage et al. addressed a method of preoperative endoscopic placement of an endo-nasal biliary drainage tube (ENBD), through which cholangiography could be performed, avoiding the chance of BDI as a consequence of the cannulation process.[52,83] Both recommended the use of ENBD, particularly in cases in which the patient is to undergo preoperative ERCP.

Intraoperative ultrasonography

A summary of findings regarding IOUS are delineated in Table 2.

The largest study was performed by Machi et al., investigating 1,381 LC cases with routine IOUS.[86] In this article, successful imaging using IOUS was reported in 98% of the cases. Overall, the reported accuracy among the studies was similarly high, with a median reported overall identification rate of biliary structures of 97% (IQR 95.9% - 97%).[76-78,85-88] Five studies reported BDI incidence.[76,84-87] Of these five, the studies of Biffl et al. and Hakamada et al. had occurrences of BDI (0.6% and 1.1% respectively).[84,85] The other three reported none. When explored in more detail, the reported BDIs in these two articles all occurred in the group in which IOUS was not used.

Fluorescence imaging

The main findings of fluorescence imaging are summarized in Table 3.

The primary focus of the studies covering fluorescence cholangiography is the evaluation of feasibility and the biliary detection rates. No BDIs were reported in any of these studies. For the extrahepatic biliary system, the studies investigating ICG-NIR reported the following median detection rates of biliary structures: 75.7% for the CHD (IQR 62.4% - 93.8%); 87.8% for the CD-CHD confluence (IQR 77.8% - 97.8%); 100% for the CD (range 97.8% - 100%); 87.3% for the CBD (83% - 98.5%). While the majority of the articles utilize ICG-NIR to map the biliary tree, Mohsen et al. achieved fluorescence imaging of biliary structures through administration of a fluorescein solution and subsequent exposure to UV-A, visualizing the bile ducts in 82.5% of the time whilst demonstrating true negative results for other tissue in all cases.[98]

Table 3. Fluorescence Cholangiography - summary of findings

N Studies on Fluorescence Cholangiography	N Cases		Median identification rate			
	Total	Average per study	*CHD*	*CD-CHD Confluence*	*CD*	*CBD*
16	863	54 (12 - 184)	75.7% (62.4 - 93.8)	87.8% (77.8 - 97.8)	100% (97.8 - 100)	87.3% (83 - 98.5)

Values represent total, average (range) or median (interquartile range) of reported outcomes among included studies

Comparison of techniques and other preventive measures

Comparison of techniques

Three articles compared IOC with the use of IOUS.[76-78] IOUS was favored over IOC in all, on account of technical availability, success rate in the examination of the biliary tree and the absence of radiation and contrast solution. In the study by Osayi et al. both ICG-NIR and routine IOC were performed during the same procedure, comparing their measurements.[79] The main study focus was safety and the role of ICG-NIR in the identification of biliary anatomy. CD detection rates were superior compared to IOC (95.1% vs. 72.0% respectively). Furthermore, IOC was unobtainable in 24.4% of the IOC cases compared to an inability to visualize biliary structures in 4.9% using the ICG-NIR technique.

Other preventive measures

Apart from the main techniques mentioned above, several other methods have been investigated. Cai et al. reported over a decade's experience with hydrodissection combined with blunt dissection using the suction tube to expose Calot's hepatobiliary triangle, having applied this technique in 21,497 patients.[104] In this series BDI incidence was reported to be 0.09%, with a conversion rate of 1.1%. Li et al. introduced a 4-point grading system to evaluate intraoperative unfavorable factors (IUF) as a decision aid for the use of IOC and/or conversion to OC.[105] The purpose of this study was to validate this tool by comparing safety of LC before (n=384) and after introduction (n=396). After implementation, a significant increase in conversion rate was observed (1.6% to 5.4%), while the BDI rate dropped from 1.3% to zero. No significant differences in postoperative morbidity and mortality were observed.

Three articles reported alternative methods to directly visualize the biliary system, either by way of methylene blue dye injection or light cholangiography.[106-108] Xu et al. compared methylene blue cholangiography with light cholangiography, favoring the latter, demonstrating clear images of the biliary tree using an optic fiber introduced via duodenoscopy.[108]

DISCUSSION

As a much dreaded complication of LC, BDI has been widely researched. In this systematic review, the largest to date within this topic, we have provided a critical analysis of the different modalities currently employed for its prevention. We have noted however that research yielding a high level of evidence is difficult to perform and consequently scarce. In a recent perspective written by Strasberg and Brunt it was emphasized that, despite the numerous major BDIs that still occur, the amount of injuries per number of LCs is relatively low.[110] This makes it incredibly difficult to organize a proper RCT. Therefore, low sample size is a recurrent problem in the search for valid literature. A different problem we encountered is the inconsistency of BDI reporting. For instance, different BDI classification systems are currently in use.[111] Some studies report BDI according to one of these classification systems, for instance Tornqvist et al.[56] employing the Hannover classification,[109] whilst others report terms like 'major BDI' or 'common bile duct injury'. The nature of these unclassified injuries are frequently unclear, making the the true incidence of BDI caused by iatrogenic damage difficult to estimate.

Despite the aforementioned problem involving low power among studies, the articles describing CVS report just one BDI in over 5,000 cases, the lowest reported incidence of BDI in literature with regard to a specific technique for prevention of BDI. This might suggest that CVS would be a capable method to conduct safe LC. However, CVS requires a thorough knowledge of biliary surgical anatomy with special reference that Calot's hepatobiliary triangle has to be unfolded completely and overseen correctly after mobilization of the gallbladder neck from the liver. A recent survey has demonstrated that, despite the fact that CVS was well-known overall, many respondents, senior surgeons in particular, were not able to adequately discern the essential steps of this technique.[112] In an effort to create awareness among the practicing surgeons, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has implemented CVS in its SAGES Safe Cholecystectomy Program, as part of their general culture of safety program.[113]

CVS is more likely to function well in uncomplicated LCs, while in case of acute inflammation, fibrosis, or adhesions, a safe dissection within Calot's hepatobiliary triangle is often impeded. In these cases a different approach should be considered. Conversion to open cholecystectomy might come to mind in these situations. Conversion does not necessarily facilitate easier operation however, as conditions do not change and visibility might be equally poor. FFLC or LSC are techniques that could be employed in these circumstances instead of conversion.

Bile leak rates were higher among LSC cases in this review. The median reported number of bile leaks was 6.3%, compared to the 0.35% reported in standard LC.[114] This could probably be attributed to the incomplete resection of the gallbladder and incomplete closure of the residual infundibulum. The morbidity associated with these bile leaks however is moderate: only 1.4% – 15% of bile leaks require an (endoscopic) intervention.[32,115]

IOC has been a comprehensively investigated, yet highly debated method in both conventional and laparoscopic cholecystectomy. Ever since the moment it was first described by Mirizzi in 1931.[116] IOC has demonstrated to be a helpful tool in both prevention and intraoperative recognition of BDI. However, definitive recommendation to employ this technique routinely, selectively or not at all cannot be given because of the low evidence available studies are coping with. Due to the same reason, a review by Ford et al. made a similar conclusion: no robust evidence currently exists to either support or abandon the use of IOC in the prevention of BDI.[117] Also, IOC use is highly variable across the world. For example, IOC use is customary in the UK and the USA; two surveys among surgeons demonstrated mass use of IOC in these countries, with 93% to 99% of surgeons reported to use IOC – among which 24% to 27% used the technique routinely.[118,119] In contrast, IOC is rarely used outside these parts of the world.[120,121] Moreover, since the wide availability of endoscopic retrograde cholangiopancreatography (ERCP) and magnetic resonance cholangiopancreatography (MRCP), the necessity to perform IOC has been diminished greatly.[122] This development has already led to surgical trainees lacking exposure to IOC, which is unfavorable if this technique is to be incorporated in surgical practice.[112] Furthermore, IOC is prone to failure. The median reported success rate was 89% among the included studies and none established a perfect record. Even if a successful IOC is achieved, i.e. successful cannulation and mapping of the biliary tree on a radiological image, this does not equal correct interpretation. Advocates for omission of IOC also state that proper dissection techniques in favorable circumstances do not necessarily call for IOC and this technique might even be harmful to the patients due to the additional operative time and the risk of iatrogenic major BDI. [50,61,66]

IOUS is another method to identify biliary structures, yet less invasive than IOC. It has the potential to achieve high accuracy, with reports of completely visualizing the biliary tract in 92% to 100% of cases, with a failure rate that is lower than IOC.[123] Furthermore, in theory IOUS could be repeated an infinite amount of times with negligible harm to the patient on account of its non-invasive nature, without the need of radiologic contrast solutions or cannulation of a ductal structure. An apparent disadvantage is the learning curve in the performance and interpretation of the ultrasonogram, which has previously been described as ten or even up to thirty cases.[124,125] Despite these advantages, the evidence in support of IOUS as a preventive measure of BDI is scarce and therefore decisive recommendation cannot be given.

Upcoming modalities such as fluorescence imaging could function as a minimally invasive and easy to perform extension to conventional LC. ICG-NIR allows for repeatable and real time exploration of the biliary system, something that is not possible with radiological IOC due to safety limits in radiation exposure and iodine contrast administration and that is difficult to achieve with IOUS. ICG-NIR provides good detection rates of biliary structures, with specifically high detection rates of the cystic duct. Furthermore, new methods within the field of fluorescence cholangiography are currently being developed, of which in particular direct intragallbladder injection of ICG is promising, providing higher contrast due to the reduced ICG accumulation in the liver as seen after systemic administration.[126]

A limitation to the articles evaluating fluorescence cholangiography is that the moments when biliary structures are detected are quite inconsistent; some measurements are made before dissection of Calot's hepatobiliary triangle, whilst some are made thereafter. A recent review evaluating the utility of ICG-NIR cholangiography reported similar results in terms of for the intraoperative visualization of the biliary system.[127] Important deficiencies of the technique however were also noted. Mainly, the limited tissue penetration of light prohibited the deeper intrahepatic ducts, as well as extrahepatic ducts obscured by (inflamed) tissue to be adequately visualized.

In the current systematic review, the primary aim of the studies investigating fluorescence imaging was to obtain information regarding the feasibility and safety. From the results provided it can be concluded that the technique of ICG-NIR imaging is indeed feasible and safe. The following step is to properly study the benefits of fluorescence imaging on a larger scale. Hence a multicenter randomized controlled trial comparing LC assisted by ICG-NIR cholangiography with conventional LC is initiated in the Netherlands.[128]

Conclusion

Many methods used in the prevention of BDI have demonstrated promising results, yet lack sufficient power. To execute a high volume multicenter study providing the high level of evidence necessary however is very challenging. Furthermore, there is great need for consensus regarding a systematic reporting system of BDI to adequately determine the true incidence of BDI and, not in the least, discern between the severity of injuries. For the time being, it is advisable to focus on proper dissection techniques while following the basic principles of biliary surgery, of which CVS seems arguably the preferred method. Moreover, when conventional dissection proves to be too hazardous, a sufficient attention to alternative techniques should be apprehended.

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Chapter 9

Lacunar implementation of the Critical View of Safety technique for laparoscopic cholecystectomy. Results of a Nationwide Survey

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ABSTRACT

Background

Bile duct injury remains a dilemma in laparoscopic cholecystectomy, with an incidence still higher than in conventional cholecystectomy. The Critical View of Safety technique is used as one of the important operating technique to reduce bile duct injury incidence. The objective of this study was to determine current practices in laparoscopic cholecystectomy and the use of the Critical View of Safety technique among surgeons and residents in surgical training.

Methods

We conducted an electronic survey among all affiliated members of the Association of Surgeons of the Netherlands containing questions regarding the current practice of laparoscopic cholecystectomy, essential steps of the Critical View of Safety technique, reasons for conversion to open cholecystectomy, and the use of other safety techniques.

Results

The response rate was 37% (766/2,055). In the study, 610 completed surveys were analyzed. Of the respondents, 410 (67.2%) were surgeons and 200 (32.8%) were residents in surgical training. Furthermore, 98.2% of the respondents indicated incorporating the Critical View of Safety technique into current practice. However, only 72% of respondents performed the essential steps of the Critical View of Safety technique frequently. Subsequently, half of respondents were able to identify the corresponding steps of the Critical View of Safety technique, and only 16.9% were able to distinguish these adequately from possible harmful steps. Furthermore, 74.9% selected ≥1 possible harmful steps as part of this technique. Residents significantly performed and selected the essential steps of the Critical View of Safety technique more often than surgeons. Intraoperative cholangiography, intraoperative ultrasound, and fluorescence cholangiography are seldom used. Bail-out techniques such as subtotal cholecystectomy, fundus first dissection, and leaving the gallbladder in situ are familiar to the majority of respondents.

Conclusion

Responses indicate that practically all Dutch surgeons and residents claim to use the Critical View of Safety technique. The majority of surgeons and residents are unable to discern correctly the essential steps of the Critical View of Safety technique from actions not part of the technique and even potentially harmful. Residents' current knowledge regarding the Critical View of Safety technique is superior to those of surgeons.

INTRODUCTION

Laparoscopic cholecystectomy (LC) has taken the medical world by storm since its debut by Eric Mühe in 1985 and widespread implementation shortly thereafter.[1] Currently, cholecystectomy is the most performed abdominal surgical procedure in the world, with one in 500 inhabitants in Europe and the United States receiving this procedure annually, of which >80% is performed laparoscopically.[2,3] Despite the superiority in outcomes, such as decreased postoperative pain and reduced duration of stay, a disquieting increase in the number of bile duct injuries (BDI), a potentially life-threatening complication, was detected. Compared to the average BDI incidence of 0.2% in open cholecystectomy (OC), rates between 0.32% and 1.33% were reported after introduction of LC.[4-8] The current incidence of BDI is reported to be 0.23% to 0.47%.[9,10] At first, due to the novelty of the minimally invasive approach and the inexperience in the technique among the majority of surgeons, this aggravation was attributed to the learning curve. It is indeed noted that in the early cases of a surgeon's career the risk is increased; however, accumulated case load and operator experience have not decreased the incidence of BDI.[11-13] Therefore, misidentification of biliary structures, rather than the laparoscopic approach in itself, is commonly considered the main cause of BDI.

To reduce the risk of misidentification, several methods have been used, such as intraoperative cholangiography (IOC), near-infrared fluorescence cholangiography with indocyanine green, and intraoperative ultrasound (IOUS) to identify (aberrant) anatomy. A well-known method is represented by the critical view of safety technique (CVS) as proposed by Strasberg et al. in 1995.[14] This technique was initially a revision of the safe identification of biliary structures in open cholecystectomy and one of the first attempting to transfer these basic principles to the laparoscopic approach. This is in contrast to the historically first promoted technique, which has been around since the implementation of laparoscopic cholecystectomy and is currently known as the "infundibular technique" (IT). The essence of the latter technique is that a ductal structure is identified as the cystic duct (CD) when the traditional "flare" or "funnel" shape is visualized at the infundibulum-CD junction. Despite the potential of CVS, Daly et al have demonstrated that more than half of surgeons still preferred using IT, compared to 27% preferring CVS.[15] Furthermore, >20% of surgeons could not identify CVS on an intraoperative image, and 65% were not able to properly reproduce the description of CVS, despite the fact that this technique has been incorporated in resident training since its introduction. In the Netherlands, the use of CVS among surgeons is estimated to be >90%, and it is currently included in the national guideline for LC.[16,17] However, the extent to which surgeons and surgical residents properly utilize CVS is unknown. In this study, we aimed to determine current practices and perceptions in the performance of safe LC and how CVS is implemented, along with what safety measures are currently performed among practicing surgeons and residents in surgical training.

Methods

On June 20, 2017, all members affiliated to the Association of Surgeons of the Netherlands were approached by E-mail to participate in a Web-based survey (LimeSurvey, LimeSurvey GmbH. Hamburg, Germany). An opt-out option was provided for respondents not wishing to participate in the survey. After initial invitations, 3 reminders were sent to nonresponders with an interval of 4 weeks. Retired surgeons, approached persons with other functions than surgeons or residents, and partial responses were excluded from analysis.

This survey was composed of 14 questions. The full survey can be found in the *Appendices*. Questions 1 through 6 covered current function, subspecialization, years of practice or year of surgical training, number of laparoscopic cholecystectomies during career, number of laparoscopic cholecystectomies in the past 12 months, and workplace (by type of institution). Questions 7 through 10 focused on the current use of CVS. In question 11, 9 statements regarding the certain moments in LC were presented in random order. To evaluate the current practice in LC, respondents were requested to grade each statement according to the frequency with which they would apply it in daily practice on a 5-point Likert-type scale of 1 (never) to 5 (always). Question 12 was designed to evaluate the current knowledge of CVS and intentionally placed after question 11 to not bias the responses regarding the current practice in LC. Six statements were provided in random order; the respondents were asked to select the steps (multiple selections were allowed) which are, in their opinion, essential to CVS. Half of these 6 statements are not considered part of CVS and have been determined previously to even be potentially hazardous techniques ("identification of the cystic duct–common hepatic duct junction," "the cystic duct is transected after the funnel-shaped junction between the infundibulum and the cystic duct is recognized," and "to identify corresponding structures, Calot's hepatobiliary triangle [cystic duct—common hepatic duct—liver] has to be cleared entirely from fat and fibrous tissue").[14,18] Question 13 focused on the situations in which the respondent would convert to OC. Lastly, in question 14 respondents were asked with what frequency certain imaging and safety techniques were utilized on a 5-point Likert-type scale of 1 (never) to 5 (always). All responses were anonymous. Respondents were able to leave additional remarks.

Statistical analysis

Data was analyzed with IBM SPSS Statistics for Windows, version 21.0 (IBM Corp. Armonk, NY) and Microsoft Excel (Microsoft Corp., Redmond, WA). Data are presented as numbers and percentages. Data derived from Likert-type scales were grouped in 2 categories: 1 through 3 ("never," "rarely," "sometimes") and 4 with 5 ("regularly" and "always"). Groups were compared using $\chi 2$ test or Fisher exact test. In case of ≥ 2 categories, post hoc testing was performed using the standardized residual method, followed by Bonferroni adjustment to the Z critical of 1.96 corresponding to an α of 0.05, to determine the categories with disparity. Figures were created with GraphPad Prism for Windows version 5.0 (GraphPad Software, La Jolla, CA).

RESULTS

Invitations were sent to 2,102 E-mail addresses and successfully delivered in 2,055 cases. In total, 207 respondents chose not to participate. Overall, the response rate was 766 (37%). In addition, 156 responses were excluded (retired surgeons 28%; functions other than surgeons or residents 3%; partial responses 69%). Finally, 610 completed surveys were included for further analysis. Of the included respondents, 410 (67.2%) were surgeons and 200 (32.8%) were residents in surgical training. Among the surgeons, the most reported subspecialization was gastrointestinal surgery (56.1%), followed by surgical oncology (45.6%) and trauma surgery (22.9%). For the residents, the majority (52%) reported not having differentiated as yet, followed by a differentiation toward gastrointestinal surgery (18.0%) and surgical oncology (16.5%). The majority of surgeons and residents were employed in general teaching hospitals (58.5% and 72.0%, respectively). Detailed respondent information can be found in Table 1.

Regarding the LC caseload, more than two-thirds of responding surgeons had performed >300 LCs during their career. For residents, 45% had performed or assisted in >100 LCs in total. In the past year, ≈60% of the surgeons and half of the residents had performed >25 LCs. Overall 21.5% performed >50 LCs in the past 12 months. The detailed experience of respondents is delineated in Table 2.

Table 1. Respondent information

	Surgeons (n=410)		Resident in surgical training (n=200)	
	N	(%)	*N*	(%)
Subspecialization				
Surgical oncology	187	(45.6)	33	(16.5)
GI surgery	230	(56.1)	36	(18.0)
HPB surgery	31	(7.6)	3	(1.5)
Pediatric surgery	20	(4.9)	3	(1.5)
Pulmonary surgery	32	(7.8)	6	(3.0)
Trauma surgery	94	(22.9)	20	(10.0)
Vascular surgery	49	(12.0)	16	(8.0)
No specialization	2	(0.5)	104	(52.0)
Workplace				
University hospital	68	(16.6)	55	(27.5)
General teaching hospital	240	(58.5)	144	(72.0)
General non-teaching hospital	91	(22.2)	-	

GI Gastrointestinal, *HPB* Hepatopancreaticobiliary

Table 2. Experience of respondents

	Surgeons (n=410)	
	N	(%)
Total years practicing		
<5 years	100	(24.4)
5 - 10 years	104	(25.4)
10 - 15 years	100	(24.4)
>15 years	106	(25.9)
LC during career		
<100	17	(4.1)
100-300	104	(25.4)
301-500	127	(31.0)
>500	162	(39.5)
LC in the past 12 months		
<10	62	(15.1)
10-25	97	(23.7)
26-50	151	(36.8)
>50	100	(24.4)

	Residents (n=200)	
	N	(%)
Year of training		
Year 1	17	(8.5)
Year 2	28	(14.0)
Year 3	44	(22.0)
Year 4	33	(16.5)
Year 5	42	(21.0)
Year 6	36	(18.0)
LC during career		
<50	47	(23.5)
50-100	62	(31.0)
101-200	66	(33.0)
>200	25	(12.5)
LC in the past 12 months		
<10	40	(20.0)
10-25	61	(30.5)

Critical view of safety

In total, 99% of respondents indicated familiarity with CVS and 98.2% of respondents indicated that they use CVS in practice. Of the latter, 87.1% replied using CVS "always," and 10.5% using it "regularly." The respondents who reported not knowing CVS were all surgeons, practicing >15 years, with an oncological or vascular subspecialization. In these surgeons, the lifetime caseload of LC and that of the past year were low (<100 and <10 LCs, respectively). Of the respondents who reported using CVS, two-thirds selected "because I was trained this way" as a reason for using the technique. Residents selected this option significantly more often than surgeons (88.0% vs 56.3%, respectively; $P<.001$). Among responding surgeons, this option was significantly selected more often by those practicing ≤10 years (85.3%) compared to surgeons practicing ≥10 years (27.7%; $P\leq.001$). The reason "this is the most trustworthy method of preventing BDI" was selected by 73.5% of respondents and equally often by residents as by surgeons (73.5% vs 73.4%; $P=.982$). Other reasoning provided for use of CVS by the respondents was "due to current guidelines" or "for training purposes." Eleven respondents stated that they did not use CVS, of whom 4 replied that they used a method they deem more reliable.

Current practice of laparoscopic cholecystectomy

With regard to the identification of Rouvière's sulcus, the majority of respondents (72.1%) did so "always" or "regularly." Residents did this significantly more often than surgeons (78.2% vs 68.8%; $P=.017$). Opening of the peritoneal envelope as far as possible from the liver hilum was done "always" or "regularly" by the vast majority of respondents (94.5%), with no significant difference between the residents and surgeons ($P=.813$). The responses were divided regarding the statement in which the full dissection of Calot's hepatobiliary triangle (consisting of the CD, the common hepatic duct [CHD], and the liver) free from fat and fibrous tissue was described: Half of the respondents indicated clearing Calot's triangle completely on a regular basis, whereas a third responded that they did so rarely or never. Groups did not differ significantly in this respect ($P=.227$).

Circumferential overview of the junction of the CD and the cystic artery (CA) at the level of the gallbladder was frequently done by the majority of respondents (95.6% and 82.6%, respectively) and was done just as often by residents and surgeons ($P=.158$ and $P=.758$, respectively). In addition, 92.8% of respondents completely dissect the infundibulum free from the liver bed "regularly" or "always," with no significant difference between residents and surgeons ($P=.481$). Residents report clipping the CA *before* the CD "regularly" or "always" significantly more often than surgeons (76.5% vs 66.8%; $P=.016$). Conversely, clipping of the CD *before* the CA was replied "regularly" or "always" by one-third of the respondents and significantly more often by surgeons (36.5% vs 21.9%; $P<.001$). Within the surgeons group, responding surgeons with the least amount of practicing years (<5 years and 5–10 years) first clip the CA significantly more often than responding surgeons with more experience (10–15 years and >15 years). The fundus first approach of LC is done rarely (overall, 80.9% "sometimes" or less). However, according to the responses, this approach is done significantly more often by residents than by surgeons ("regularly" or "always" by 24.6% vs 16.4%; $P=.017$). In addition, 72% of respondents performed all 3 steps constituting CVS (circumferential overview of the junction of both CD and CA at the level of the gallbladder by dissecting the infundibulum free of the liver) either “regularly” or “always.” Although no significant difference existed between residents and surgeons (74% vs 71%; P=.851), among surgeons, the group with the most years practicing (>15 years) performed the 3 steps of CVS significantly less often than those practicing ≤15 years. A detailed representation of the frequency in which these techniques are used by residents and surgeons can be seen in Table 3 and Figure 1.

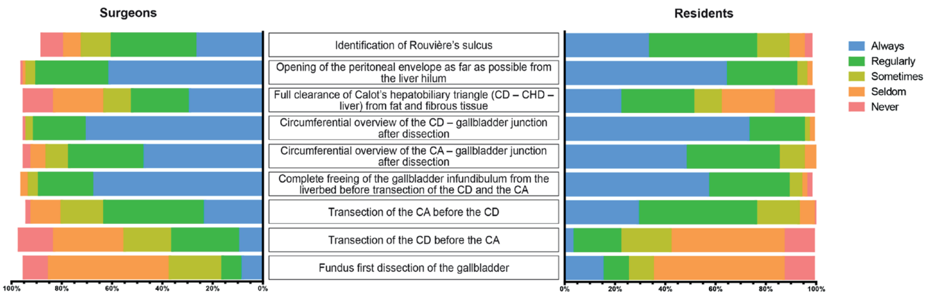

Figure 1. Comparison of current use of laparoscopic cholecystectomy techniques between surgeons and residents.

Aspects of the critical view of safety

The statements presented to the respondents in question 12 and the number of respondents who selected these as essential steps of CVS are presented in Table 4. Among the 3 statements that are not considered part of CVS, overall 8.5% of respondents selected the identification of the CD-CHD junction as part of CVS. The statement describing IT for recognition of the CD was selected by 51.3% of respondents. The third statement covering the entire clearance of Calot’s hepatobiliary triangle including the CHD was selected by 38.2% of respondents. Within all these 3 statements, no significant difference was found between residents and surgeons (P=.988, P=.073, and P=.256, respectively). Among surgeons, identification of the of the CD-CHD junction was selected significantly more often by surgeons practicing over 15 years compared to those with less working years (P=.001).

Regarding the 3 statements that are considered an essential part of CVS, the vast majority (86.1%) selected the statement concerning the dissection of the entry point of the CD into the gallbladder until circumferential overview is achieved. This statement was selected significantly more often by residents than by surgeons (92.5% vs 82.9%; P=.001). The corresponding statement regarding the CA was selected by 67.4% of the respondents and again was selected significantly more often by residents than by surgeons (78.5% vs 62.0%; P<.001). The final essential part of CVS, dissecting the gallbladder infundibulum free from the liver for approximately one-third, was selected by 79.3%, significantly more by residents compared to surgeons (84.5% vs 76.8%; P=.028).

Table 3. Current execution of laparoscopic cholecystectomy by respondents

		Surgeons (*N*=410)											Residents (*N*=200)			All Respondents (*n*=610)	
		<5 years (*N*=100)		5 - 10 years (*N*=104)		10 - 15 years (N=100)		>15 years (*N*=106)			Overall						
	Statements	*N*	(%)	*N*	(%)	*N*	(%)	*N*	(%)	*p*-value[a]	*N*	(%)	*N*	(%)	*p*-value[b]	*N*	(%)
Q1	Identification of Rouvière's sulcus	79	(79.0)	69	(66.3)	*43	(43.0)	54	(50.9)	.003	245	(59.8)	151	(75.5)	.019	396	(64.9)
Q2	Opening of the peritoneal envelope as far as possible from the liver hilum	95	(95.0)	91	(87.5)	89	(89.0)	94	(88.7)	.607	369	(90.0)	184	(92.0)	.813	553	(90.7)
Q3	Full clearance of Calot's hepatobiliary triangle (CD-CHD-liver) from fat and fibrous tissue	52	(52.0)	51	(49.0)	56	(56.0)	54	(50.9)	.797	213	(52.0)	102	(51.0)	.494	315	(51.6)
Q4	Circumferential overview of the CD-gallbladder junction after dissection	97	(97.0)	92	(88.5)	91	(91.0)	92	(86.8)	.202	372	(90.7)	189	(94.5)	.758	561	(92.0)
Q5	Circumferential overview of the CA-gallbladder junction after dissection	87	(87.0)	78	(75.0)	79	(79.0)	72	(67.9)	.031	316	(77.1)	168	(84.0)	.158	484	(79.3)
Q6	Complete freeing of the gallbladder infundibulum from the liver bed before transection of the CD and the CA	94	(94.0)	89	(85.6)	93	(93.0)	89	(84.0)	.142	365	(89.0)	178	(89.0)	.481	543	(89.0)
Q7	Transection of the CA before the CD	*87	(87.0)	*77	(74.0)	*51	(51.0)	*45	(42.5)	<.001	260	(63.4)	150	(75.0)	.016	410	(67.2)
Q8	Transection of the CD before the CA	*16	(16.0)	*24	(23.1)	43	(43.0)	*61	(57.5)	<.001	144	(35.1)	43	(21.5)	<.001	187	(30.7)
Q9	Fundus first dissection of the gallbladder	12	(12.0)	13	(12.5)	19	(19.0)	20	(18.9)	.234	64	(15.6)	48	(24.0)	.017	112	(18.4)
	Execution of CVS (Q4, Q5, Q6)	80	(80.0)	69	(66.3)	77	(77.0)	*65	(61.3)	.010	291	(71.0)	148	(74.0)	.851	439	(72.0)

Values represent the amount of responses on the Likert type scale containing 'regularly' or 'always'.
CA Cystic artery, *CD* Cystic duct, *CHD* Common hepatic duct, *CVS* Critical View of Safety
[a] *p* value for difference among surgeons' experience level
[b] *p* value for difference between surgeons overall and residents
* Significant difference according to the standardized residual method

Table 4. Aspects of the Critical View of Safety technique among respondents.

	Surgeons (*N*=410)											Residents (*N*=200)			All Respondents (*n*=610)	
	<5 years (*N*=100)		5 - 10 years (*N*=104)		10 - 15 years (*N*=100)		>15 years (*N*=106)			Surgeons overall						
Possible statements	*N*	(%)	*N*	(%)	*N*	(%)	*N*	(%)	*p*-value[a]	*N*	(%)	*N*	(%)	*p*-value[b]	*N*	(%)
Identification of the CD-CHD junction	2	(2.0)	7	(6.7)	8	(8.0)	*18	(17.0)	.001	35	(8.5)	17	(8.5)	.988	52	(8.5)
The CD is transected after the funnel-shaped junction between the infundibulum and the cystic duct is recognized	46	(46.0)	59	(56.7)	48	(48.0)	47	(44.3)	.284	200	(48.8)	113	(56.5)	.073	313	(51.3)
To identify corresponding structures, Calot's hepatobiliary triangle (CD-CHD-liver) has to be cleared entirely from fat and fibrous tissue	39	(39.0)	39	(37.5)	41	(41.0)	44	(41.5)	.931	163	(39.8)	70	(35.0)	.256	233	(38.2)
Dissection of the entry point of the CD into the gallbladder until circumferential overview is achieved	*93	(93.0)	84	(80.8)	85	(85.0)	*78	(73.6)	.002	340	(82.9)	185	(92.5)	.001	525	(86.1)
Dissection of the entry point of the CA until circumferential overview is achieved	73	(73.0)	68	(65.4)	67	(67.0)	*46	(43.4)	.000	254	(62.0)	157	(78.5)	<.001	411	(67.4)
Dissection of the infundibulum free from the liver bed for approximately one third	*90	(90.0)	90	(86.5)	73	(73.0)	*62	(58.5)	.000	315	(76.8)	169	(84.5)	.028	484	(79.3)
All statements regarding CVS, none of the other	*25	(25.0)	13	(12.5)	15	(15.0)	9	(8.5)	.008	62	(15.1)	41	(20.5)	.096	103	(16.9)
Any statement not regarding CVS	72	(72.0)	82	(78.8)	72	(72.0)	80	(75.5)	.627	306	(74.6)	151	(75.5)	.817	457	(74.9)

Values represent number of responses selecting the given statement as essential step of the Critical View of Safety technique.
CA Cystic artery, *CD* Cystic duct, *CHD* Common hepatic duct
[a] *p* value for difference among surgeons' experience level
[b] *p* value for difference between surgeons and residents overall
* Significant difference according to the standardized residual method

Surgeons practicing >15 years selected all 3 statements considered to be essential to CVS significantly less often than those practicing ≤15 years. The statements concerning the dissection of the entry point of the CD into the gallbladder until circumferential overview is achieved and the dissection of the infundibulum free from the liver for approximately one-third were chosen significantly more often as an essential part of CVS by the group of surgeons practicing <5 years as compared to the other groups of surgeons.

Overall, the percentage of respondents who selected only and all 3 statements in line with CVS was 16.9%. Residents and surgeons did not differ significantly. Surgeons practicing <5 years selected all 3 of the statements in accordance with CVS and none of the disagreeing statements significantly more often than those with >5 years of practice. Three-quarters of the respondents selected at least one of the statements not related to CVS. No significant difference between surgeons and residents or among surgeons was found. The respondents who performed >50 LCs in the past 12 months did not select the statements associated with CVS significantly more often (19.1% vs 16.3%; $P=.448$) or select the unrelated statements less often (75.6% vs 74.7%; $P=.845$) compared with those who performed fewer LCs. Gastrointestinal surgeons selected only the statements attributed to CVS significantly more often than nongastrointestinal surgeons (18.3% vs 11.1%; $P=.045$) and selected the statement describing IT significantly less often (44.3% vs 54.4%; $P=.042$).

Conversion to open cholecystectomy

The respondents' considerations in converting to OC are delineated in Table 5. Overall, the most common reason for converting to OC was "in case of severe bleeding" (65.4%), followed by "when the Critical View of Safety is not achieved" (58.0%) and "extensive adhesions involving the surrounding structures and organs" (44.9%). The reasons for conversion chosen least often were "spillage of gallstones due to gallbladder damage," "spillage of bile due to gallbladder damage," and "in case of shrunken gallbladder" (none, 0.2%, and 5.2%, respectively). Surgeons would convert to OC when CVS was not achieved significantly more often than residents in training (61.2% vs 51.5%; $P=.022$).

Use of other techniques to perform safe laparoscopic cholecystectomy

IOC is never performed by 57.9% of respondents. In addition, 73.0% of the residents never perform IOC, in contrast to 50.5% of the surgeons ($P<.001$). The majority of respondents never perform near-infrared fluorescence cholangiography with indocyanine green and IOUS (86.1% and 84.8%, respectively) during LC. Bail-out procedures such as laparoscopic subtotal cholecystectomy and leaving the gallbladder in situ are performed by the majority of respondents (60.7% and 55.7%, respectively). Of the respondents, 12.3% never performed the first technique and 30.0% never performed the latter. The current use of other safety techniques during LC is delineated by Figure 2.

Table 5. Respondents' considerations to convert to open cholecystectomy

	Surgeons (*N*=410)		Residents (*N*=200)			Overall (*n*=610)	
Reason to convert to open cholecystectomy	*N*	(%)	*N*	(%)	*p*-value	*N*	(%)
In case of shrunken gallbladder	24	(5.9)	8	(4.0)	.335	32	(5.2)
When the Critical View of Safety is not achieved	251	(61.2)	103	(51.5)	.022	354	(58.0)
Extensive adhesions involving the surrounding structures and organs	173	(42.2)	101	(50.5)	.053	274	(44.9)
Bile leakage (with an intact gallbladder)	73	(17.8)	43	(21.5)	.275	116	(19.0)
Spillage of bile due to gallbladder damage	1	(0.2)	0		.485	1	(0.2)
Spillage of gallstones due to gallbladder damage	0		0		-	0	
In case of severe bleeding	259	(63.2)	140	(70.0)	.096	399	(65.4)

Values represent number of responses of each case in which the respondent would convert to open cholecystectomy.

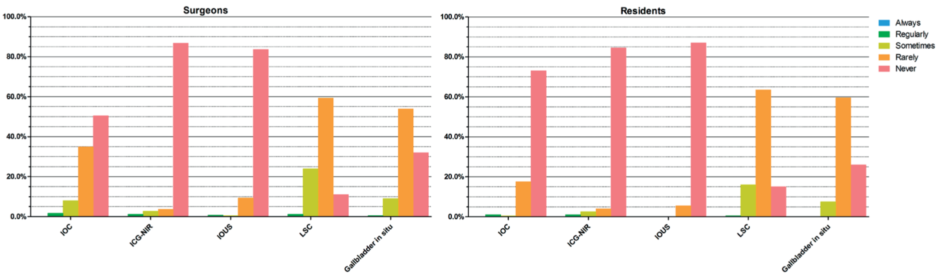

Figure 2. Use of other safety techniques during laparoscopic cholecystectomy by surgeons and residents. IOC intraoperative (radiologic) cholangiography, ICG-NIR near infrared fluorescence cholangiography with indocyanine green, IOUS intraoperative ultrasound, LSC Laparoscopic Subtotal Cholecystectomy

DISCUSSION

Since its introduction by Strasberg et al. over two decades ago, CVS as both a safety technique and an educational tool to prevent BDI in LC has received considerable acclaim. This is illustrated by the implementation of CVS by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) in their guidelines for the clinical application of laparoscopic biliary tract surgery, and by the inclusions of a "best practice laparoscopic cholecystectomy" chapter utilizing CVS in the guideline "gallstone disease" by the Association of Surgeons of the Netherlands.[19,20] Furthermore, a recent Delphi study as part of the Tokyo Guideline 2018 formation reported consensus regarding the use of CVS whenever possible.[21]

In a previous survey, responses by Dutch surgeons already demonstrated that CVS is widely accepted and implemented in the Netherlands.[16] The fact that this survey yields a comparable percentage of CVS use (98.2%) among responses confirms that this technique remains the standard of care in the Netherlands. The most common reason for its use given in the present survey is due to the implementation of CVS in surgical training, as is illustrated by the vast majority of residents who chose this response. Just over half of the surgeons selected this reason. Not unexpectedly, the group of surgeons practicing for ≤10 years selected this reason significantly more often, since their surgical education began after the implementation of CVS 20 years ago. Three-quarters of respondents used CVS because they find it the most trustworthy technique to prevent BDI in LC.

Regarding the current practices in LC, all 3 essential components belonging to CVS are performed either "regularly" or "always" by 72% of respondents. This is done significantly less often by experienced surgeons (>15 years of experience). When subsequently asked for the definition of CVS, only 57.4% selected these statements as essential parts of CVS. The discrepancy in replies that exists among 1) residents and surgeons reporting use of CVS in daily practice, 2) respondents actually performing the fundamental elements of the technique, and 3) those indeed able to correctly define the definition of CVS is peculiar. Respondents clearly indicated that they use CVS on a regular basis, yet the results of this survey seem to indicate that they are not consistent in specifying which steps are essential to the technique. Even though this survey has been conducted anonymously, social desirability bias might still be present, specifically regarding the initial question concerning the use of CVS in practice. Nijssen et al. reported a similar inconsistency.[22] In their study, operative reports and video reviews of complicated LCs were compared. CVS was described in 80% of the operative reports, yet was correctly reached in only 10.8% of the cases.

In addition, 16.9% of all respondents selected *only* the statements most accurately corresponding with CVS (i.e., without selecting *any* other statement not associated with the definition of CVS). Conversely, three-quarters of the respondents selected at least one of the 3 statements not describing elements of CVS as being a component of CVS. The techniques portrayed by these statements are possible harmful actions. For instance, more than half of respondents incorrectly selected the statement describing IT as an essential aspect of CVS. In a previous study critically analyzing 21 patients being referred with common bile duct (CBD) injury after LC, it was noted that in a majority of cases a technique was described matching IT. Particularly in difficult conditions such as inflammation and fibrosis, the CD could be hidden from sight by shortening and thickening. This might lead to erroneous interpretation of the CBD or other structures as a "false infundibulum," thereby provoking BDI, when using IT.[18] Furthermore, two-fifths of the respondents selected the statements concerning the full dissection of Calot's hepatobiliary triangle, including the CHD, from fat and fibrous tissue as part of CVS. In their original article describing CVS, Strasberg et al did indeed state that for unequivocal identification of the CD and CA, essentially the structures to be divided, Calot's hepatobiliary triangle must be cleared of fat and fibrous tissue. The key components of the critical view are that the infundibulum is dissected free from the liver surface and that 2 structures, the CD and the CA, are observed entering the gallbladder. It was explicitly noted that visualization of the CBD is unnecessary, even undesirable, with regard to CVS due to risk of iatrogenic damage. In this survey, this step was therefore not implied among the essential components of CVS. However, it is still a possibility that this statement is interpreted differently by the respondents. A separate analysis excluding this statement was therefore conducted, which did not cause any change in the resulting significance.

Residents prove to have superior knowledge over surgeons regarding the essential steps of CVS, selecting the correct statements significantly more often than surgeons, as do surgeons with the least amount of years practicing as compared to those practicing for a longer period. The most obvious explanation is because of the implementation of CVS in current surgical education and in laparoscopic skills courses. Gastrointestinal surgeons grasp the essence of CVS better than those with a different subspecialization.

Still, in some cases with aberrant anatomy or gross fibrosis caused by, for example, chronic cholecystitis, it is not possible or is even detrimental to (continue to) perform LC using CVS. These situations therefore call for a different approach. Fortunately, these bail-out techniques (i.e., laparoscopic subtotal cholecystectomy, fundus-first dissection, and leaving the gallbladder in situ) are performed by the majority of respondents: only 12.3%, 7%, and 30%, respectively replied that they never utilized these techniques. This indicates that alternatives to standard LC are well established. This survey however did not evaluate the considerations regarding whether or when to use these bail-out techniques.

Regarding conversion to open surgery, surgeons seem to convert more often than residents. This might be due to increased reluctance of residents, resulting from decreased exposure of residents to OC as compared to practicing surgeons. However, these results are also representative of current practice: An important decision like conversion is a major event in LC and is often not made by residents alone without consulting a superior.

Other considerations for conversion to OC were: insufficient progression and/or overview and when malignancy is suspected. Also, some respondents rightfully added that conversion to open surgery does not necessarily facilitate an easier operation as conditions do not change and the magnification of the surgical area as provided by the endoscope is lost.

The use of IOC during LC is highly variable across the world. Initially the main purpose of performing this procedure was to diagnose CBD stones, but because of the wide availability of endoscopic retrograde cholangiopancreatography and magnetic resonance cholangiopancreatography, its necessity has been greatly diminished. Previous surveys have demonstrated that IOC is still customary in the United Kingdom and the United States, with 93% to 99% of surgeons reporting its use, 24% to 27% on a routine basis.[23,24] In contrast to these countries, IOC is rarely used outside these parts of the world.[16,25] In the present survey, half of surgeons and almost three-quarters of residents in surgical training state that they never perform IOC during LC. With these numbers, it is not inconceivable that a large portion of these residents have never performed or even witnessed IOC at all, considering the duration of their career so far. Also, IOUS, once a promising and minimally invasive alternative to IOC, is never performed by the vast majority of either group. Because the use of these supporting imaging techniques is declining and infrequent use has already led to inadequate exposure among surgical trainees, incorporation of these techniques in standard surgical practice seems unfavorable.

The response rate of this survey was 37%, a rate comparable to other surveys approaching a similar wide range of possible respondents. Partly due to the large number of invited participants, this survey yielded a high number of replies. A possible limitation is the possibility of imbalance among respondents. Surgeons more proficient in laparoscopic surgery, such as those with gastrointestinal or oncologic subspecialization in the Netherlands, might be more inclined to respond to the survey. Furthermore, no selection was made based on whether surgeons still perform LC. This is slightly compensated by the question regarding the number of LCs in the past year and the fact that most surgeons who, because of differentiation or other reasons, do not perform LC were not motivated to respond to the survey. This is illustrated by the many replies from respondents no longer performing LC among the opt-outs.

In conclusion, the responses to this survey indicate that CVS is well known among Dutch surgeons and residents in surgical training, nearly utilized by all in daily practice. However, the percentage of respondents who actually perform CVS and furthermore recognize all correct steps of CVS is lower. It is therefore probable that CVS as a safety technique and educational tool for residents is less frequently used and more poorly understood in the Dutch surgical field than is suggested by its incorporation in national guidelines and skills courses. Residents and younger surgeons have better understanding of this topic, which is in line with the fact that courses with regard to CVS were structurally installed only a decade ago. Considering that these findings originate from a country like the Netherlands in which CVS is widely implemented, it is conceivable that the proficiency regarding CVS in other countries utilizing this technique could be equal or less. As a useful method to prevent BDI in noncomplex LC and to teach residents the basic principles of cholecystectomy, we suggest that the essential steps and pitfalls of CVS, as well as when not to perform CVS, should be featured more thoroughly in the present curriculum for residents in surgical training with special regard to surgical anatomy, preferably “before the job.”

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Chapter 10

Association of video completed by audio in laparoscopic cholecystectomy with improvements in operative reporting

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ABSTRACT

Importance

All events that transpire during laparoscopic cholecystectomy (LC) cannot be adequately reproduced in the operative note. Video recording is already known to add important information regarding this operation.

Objective

It is hypothesized that additional audio recordings can provide an even better procedural understanding by capturing the surgeons' considerations.

Design, Setting, and Participants

The Simultaneous Video and Audio Recording of Laparoscopic Cholecystectomy Procedures (SONAR) trial is a multicenter prospective observational trial conducted in the Netherlands in which operators were requested to dictate essential steps of LC. Elective LCs of patients 18 years and older were eligible for inclusion. Data collection occurred from September 18, 2018, to November 13, 2018.

Main Outcomes and Measures

Adequacy rates for video recordings and operative note were compared. Adequacy was defined as the competent depiction of a surgical step and expressed as the number of adequate steps divided by the total applicable steps for all cases. In case of discrepancies, in which a step was adequately observed in the video recording but inadequately reported in the operative note, an expert panel analyzed the added value of the audio recording to resolve the discrepancy.

Results

A total of 79 patients (49 women [62.0%]; mean [SD] age, 54.3 [15.9] years) were included. Video recordings resulted in higher adequacy for the inspection of the gallbladder (note, 39 of 79 cases [49.4%] vs video, 79 of 79 cases [100%]; $P<.001$), the inspection of the liver condition (note, 17 of 79 [21.5%] vs video, 78 of 79 cases [98.7%]; $P<.001$), and the circumferential dissection of the cystic duct and the cystic artery (note, 25 of 77 [32.5%] vs video, 62 of 77 [80.5%]; $P<.001$). The total adequacy was higher for the video recordings (note, 849 of 1089 observations [78.0%] vs video, 1005 of 1089 observations [92.3%]; $P<.001$). In the cases of discrepancies between video and note, additional audio recordings lowered discrepancy rates for the inspection of the gallbladder (without audio, 40 of 79 cases [50.6%] vs with audio, 17 of 79 cases [21.5%]; $P<.001$), the inspection of the liver condition (without audio, 61 of 79 [77.2%] vs with audio, 37 of 79 [46.8%]; $P<.001$), the circumferential dissection of the cystic duct and the cystic artery (without audio, 43 of

77 cases [55.8%] vs with audio, 17 of 77 cases [22.1%]; $P<.001$), and similarly for the removal of the first accessory trocar (without audio, 27 of 79 [34.2%] vs with audio, 16 of 79 [20.3%]; $P=.02$), the second accessory trocar (without audio, 24 of 79 [30.4%] vs with audio, 11 of 79 [13.9%]; $P<.001$), and the third accessory trocar (without audio, 27 of 79 [34.2%] vs with audio, 14 of 79 [17.7%]; $P<.001$). The total discrepancy was lower with audio adjustment (without audio, 254 of 1089 observations [23.3%] vs with audio, 128 of 1089 observations [11.8%]; $P<.001$).

Conclusions and Relevance

Audio recording during LC significantly improves the adequacy of depicting essential surgical steps and exhibits lower discrepancies between video and operative note.

INTRODUCTION

Cholecystectomy is currently the most common abdominal surgical procedure, including more than 25 000 procedures each year in the Netherlands (a nation of 17 million inhabitants), with most performed laparoscopically.[1] Since the introduction of laparoscopic cholecystectomy (LC), considerable effort has been made to improve its safety. Because LC was rapidly embraced as the gold standard for cholecystectomies, it paved the way for many surgical specialties to improve the laparoscopic approach.[2,3] Nonetheless, this rapid introduction and its accompanying learning curve have led to increased biliary injury rates with rates up to 1.5%, compared with 0.2% in the open approach.[4-11] The reported intraoperative detection rate of these complications differs widely, ranging from 25% up to 89%.[12,13] The higher patient numbers and the increased operator experience in the last few decades have lowered the incidence of biliary injuries to rates around 0.08% to 0.30%, matching the biliary complication rates of the open approach.[10,13-15] At first sight, these rates seem low, but because LC is a high-volume procedure, the incidence of bile duct injuries is substantial and cannot be ignored. Current understanding of these injuries attributes them mainly to misidentification of anatomical structures, which could lead to life-threatening complications, poorer surgical outcomes, prolonged hospitalization, high financial expenditures, and litigations.[16,17] The most widely accepted method for identification of cystic structures is the Critical View of Safety (CVS) technique introduced by Strasberg et al,[16,18-20] in which the cystic duct and cystic artery are circumferentially identified within the limits of the Calot hepatobiliary triangle prior to transection. For quality-control purposes, the operative note alone is not sufficient to adequately record CVS.[21] Therefore, it is standard practice in the Netherlands to capture CVS either with video or image capture[22-24] This method, however, is not widely implemented in the rest of the world.

Another difficulty is that all events that transpire during surgery cannot be adequately reproduced in a postoperative setting. The only tangible source of information about the surgical procedure is the operative note, which is subjective by nature and frequently omits essential information.[25] To fill this gap in procedural information, systematic video recording during surgery has proven to be feasible and useful, as has recently also been demonstrated in colorectal cancer surgery.[26,27] These studies have determined that systematic video recording as a supplement to the operative note improves the availability of necessary intraoperative information and thus contributes to quality control and objectivity in reporting.

We hypothesize that by adding synchronous voice recording alongside intraoperative video recording, a new dimension could be added by capturing the surgeons' considerations during surgery, which might provide a better understanding of the procedure on review. To our knowledge, no study has been conducted yet in which the availability of essential information during surgery has been compared without vs with the implementation of real-time voice dictation. Our aim is to investigate whether voice dictation can resolve discrepancies between videos and operative notes.

METHODS

The Simultaneous Video and Audio Recording of Laparoscopic Cholecystectomy Procedures (SONAR) trial is a multicenter prospective observational trial (Netherlands Trial Registry identifier NL6822 [NTR7008]) conducted at 4 surgical centers in the Netherlands (Isala Hospital, Zuyderland Medical Center, IJsselland Hospital, and Park Medical Center). The medical research and ethics committee of the Erasmus University Medical Center exempted this study from the Research Involving Human Subjects Act. Institutional review boards of the participating centers provided separate approval of this study prior to local initiation. Informed consent was obtained from the operators for the use of their voice recordings.

Study Participants

Operators (surgeons, fellows, and resident physicians) were eligible as study participants. Endoscopic video recordings were made using a MediCap USB300 Medical Video Recorder or Epiphan Pearl (MediCapture Inc) or a Stryker Digital Capture System (SDC ULTRA HD, Stryker Corp). The operator was requested to dictate the essential steps of the procedure in real time during the procedure with a wireless and wearable microphone (Revolabs Xtag Wireless Microphone [Yamaha Unified Communications Inc]), which was attached to the operator's scrub top. Video recordings were saved as videoLAN client (VLC) files and audio recordings as music player 3 (MP3) files using Audacity recording and editing software version version 2.3.3 (the Audacity Team) on a password-protected external hard drive. Video and audio files were synchronized using Adobe Premiere Pro CC 2018 (Adobe Systems). Elective LCs of patients 18 years or older were eligible for inclusion. Cases with incomplete video recordings, audio recordings, or unavailable operative notes were excluded.

Data Collection

The recordings were started at the moment of endoscope introduction in the abdomen and discontinued after endoscope disconnection. These recordings and notes were retrieved and anonymized for further analysis. Data regarding baseline characteristics were gathered from the patients' medical records and anonymously entered in a database (Excel 2016 [Microsoft]).

Study Outcomes

Video recordings and corresponding operative notes were reviewed for adequacy according to predefined key steps for LC (see *Appendices*). The term *adequacy* was defined as the *competent* depiction of a surgical step. Adequacy should not be confused with surgical competence, because it only depicts whether the step could be observed in the video, was mentioned by the operator in the audio recording, or was described in the operative note.

Two researchers (Ö.E. and F.v.d.G.) analyzed the recordings based on the stepwise LC guideline of the Dutch Society for Surgery.[22] The independent reviewer form can be found in the *Appendices* in the Supplement. Steps concerning the adequate depiction of the circumferential dissection of the cystic duct and cystic artery were analyzed by an expert panel of 2 surgeons (L. and A.M.). The cumulative adequacy ratings for the video recordings were compared with those for the operative notes. In case of discrepancies between a video and an operative note in which a step was adequately observed in the video but inadequately reported in the operative note, the expert panel of surgeons would analyze the added value of audio on the discrepant steps by assessing if the aforementioned surgical steps were adequately mentioned by the operator during the procedure. The discrepancy without vs with the implementation of audio was compared. A flow diagram summarizing the steps taken to conduct this study can be found in the Figure 1.

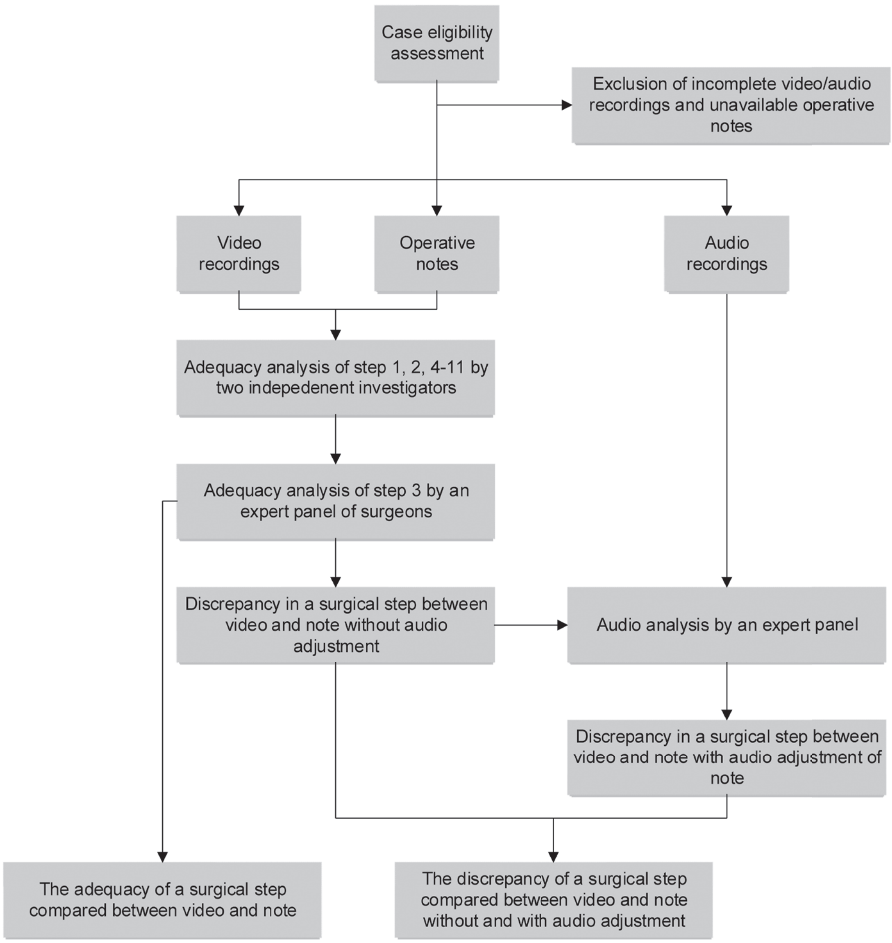

Figure 1. Flow diagram summarizing the steps taken to conduct this study.

Statistical Analysis

Categorical data were presented as numbers and percentages. Data were expressed as medians (interquartile ranges) or means (SDs) for normally distributed data. Individual video recordings and operative notes were compared, assuming the probability that a specific procedural aspect was the same for both the video and the operative note. Adequacy and discrepancy between individual steps were compared with the exact McNemar test, excluding missing values.[28] The total adequacy and discrepancy was compared with the paired-samples t test or Wilcoxon signed rank test, depending on normality. To reduce the probability of a type I error occurring, the Bonferroni correction was applied for multiple comparisons by multiplying the obtained P values with the number of completed tests, using $P<.05$ as our cutoff value for statistical significance. Data were analyzed with statistical software R, version 3.4.1, for Windows (R Foundation for Statistical Computing). Figures were created with Prism version 8.1.1 for Windows (GraphPad Software).

Sample Size

The sample size was calculated based on prior data by Wauben et al[25] evaluating the quality of the narrative operative note. The step regarding CVS was selected for this calculation because this is unequivocally the most critical part of the procedure and thus most important to report adequately. The CVS technique was seen on video recordings in 99 of 125 cases (79.2%). The amount of CVS reported in the narrative operative note and seen on the video recordings was in 63 of the 125 reviewed cases (50.4%). With $\alpha = .05$, power of 0.80, and α equal to 0.10, a minimal sample size of 73 procedures was calculated. After accounting for loss of data, 90 patients were intended to be included in this trial.

RESULTS

Study Population

Between September 18, 2018, and November 13, 2018, 90 patients who met the inclusion criteria underwent LC in the participating centers. Subsequently, 11 cases were excluded from analysis, 10 because of technical malfunctioning of the recording equipment or problems in data storage and 1 because of early termination of the procedure because of suspected liver metastases. Hence, 79 patients (49 women [62.0%]) were included for further analysis. The mean (SD) age was 54.3 (15.9) years. Study characteristics are presented in Table 1 and Table 2. Twenty-four different primary operators conducted the procedures, with a mean

Table 1. Patient characteristics

Characteristic	Mean (SD)
Total, No.	79
Age, y	54.3 (15.9)
Women, No. (%)	49 (62.0)
Height, cm	171.3 (9.9)
Weight, kg	84.7 (16.8)
BMI	28.9 (5.2)

BMI body mass index (calculated as weight in kilograms divided by height in meters squared).

number of 3 cases per operator (range, 1-18 cases). Two procedures were converted to open LCs because of difficulties with identifying the anatomical structures.

Table 2. Surgery characteristics

Characteristic	No. (%)
Primary operator position	
Surgeon	9 (11.4)
Fellow	59 (74.7)
Resident	11 (13.9)
Secondary operator position	
Surgeon	20 (25.3)
Fellow	11 (13.9)
Resident	2 (2.5)
Operation assistant	37 (46.8)
Medical student	9 (11.4)
Surgery duration, mean (SD), min:s	43:21 (24:52)
Indication for surgery	
Symptomatic cholelithiasis	66 (83.5)
Other	8 (10.1)
Acute cholecystitis	5 (6.3)
Time >7 d between onset acute cholecystitis and surgery	5 (100.0)
Conversion to open surgery	2 (2.5)

Quantitative Technical Data

A total of 57 hours and 23 minutes of footage was recorded. The mean (SD) duration per recording was 43 (25) minutes. The total required digital storage space was 590 348 megabytes, with a mean (SD) size of 7473 (4634) megabytes per case.

Adequacy

Adequacy rates are summarized in Table 3. The lowest adequacy rates in notes were with respect to the inspection of the liver condition (17 of 79 cases [21.5%]), the circumferential dissection of the cystic duct and cystic artery (25 of 77 cases [32.5%]), and the inspection of the gallbladder condition (39 of 79 cases [49.4%]). The lowest adequacy rates for the video recordings were the removal of the first accessory

trocar (59 of 79 cases [74.7%]) and the circumferential dissection phase (62 of 77 cases [80.5%]). After Bonferroni correction, the video recordings resulted in significantly higher adequacy compared with the operative note for the inspection of the gallbladder (note, 39 of 79 cases [49.4%] vs video, 79 of 79 cases [100%]; $P<.001$), the inspection of the liver condition (note, 17 of 79 [21.5%] vs video, 78 of 79 [98.7%]; $P<.001$), and the circum-

Table 3. Adequacy rates in the operative note and the video recordings

Procedure steps (n = 79 operations)	No./total No. of steps (%) Note	Video	*P-value* exact McNemar's test[a]
1a. Introduction of the first accessory trocar	79/79 (100.0)	79/79 (100.0)	>.99
1b. Introduction of the second accessory trocar	79/79 (100.0)	79/79 (100.0)	>.99
1c. Introduction of the third accessory trocar	79/79 (100.0)	79/79 (100.0)	>.99
2a. Inspection of the gallbladder	39/79 (49.4)	79/79 (100.0)	<.001
2b. Inspection of the liver condition	17/79 (21.5)	78/79 (98.7)	<.001
3. Circumferential dissection of the cystic duct and the cystic artery	25/77 (32.5)	62/77 (80.5)	<.001
4. Transection of the cystic artery	71/77 (92.2)	67/77 (87.0)	>.99
5. Transection of the cystic duct	77/77 (100.0)	76/77 (98.7)	>.99
6. Removal of the gallbladder from the liver bed	76/77 (98.7)	77/77 (100.0)	>.99
7. Inspection of liver hemostasis	65/77 (84.4)	65/77 (84.4)	>.99
8. Presence of spill	32/35 (91.4)	35/35 (100.0)	>.99
9. Saline irrigation	27/34 (79.4)	34/34 (100.0)	.27
10. Drain placement	3/3 (100.0)	3/3 (100.0)	>.99
11a. Removal of the first accessory trocar	60/79 (75.9)	59/79 (74.7)	>.99
11b. Removal of the second accessory trocar	60/79 (75.9)	68/79 (86.1)	>.99
11c. Removal of the third accessory trocar	60/79 (75.9)	65/79 (82.3)	>.99
Total	849/1089 (78.0)	1005/1089 (92.3)	<.001[b]

[a] Bonferroni corrected
[b] Wilcoxon signed-rank test (Bonferroni corrected)

ferential dissection of the cystic duct and cystic artery (note, 25 of 77 [32.5%] vs video, 62 of 77 [80.5%]; P<.001). The total adequacy was also significantly higher in the video recordings (note, 849 of 1089 observations [78.0%] vs video, 1005 of 1089 observations [92.3%]; P<.001).

Discrepancy

Discrepancy rates are summarized in Table 4 and shown in Figure 2. A discrepant step was classified as an essential surgical step that was adequately observed in the video but inadequately reported in the operative note. Discrepancies were resolved if the operator adequately mentioned the step out loud intraoperatively. After Bonferroni correction, audio adjustment of the operative note resulted in significantly lower discrepancy for the inspection of the gallbladder (without audio, 40 of 79 [50.6%] vs with audio, 17 of 79 [21.5%]; P<.001), the inspection of the liver condition (without audio, 61 of 79 [77.2%] vs with audio, 37 of 79 [46.8%]; P<.001), the circumferential dissection of the cystic duct and cystic artery (without audio, 43 of 77 cases [55.8%] vs with audio, 17 of 77 cases [22.1%]; P<.001), the removal of the first accessory trocar (without audio, 27 of 79 [34.2%]

Table 4. Discrepancy rates between video and note without and with adjusting of the note with audio

Procedure steps (n = 79)	No./total No. of steps (%)				P value for exact McNemar test[d]
	Without audio adjustment		With audio adjustment		
	Seen but not described[a]	Described but not seen[b]	Seen but not described	Described but not seen[c]	
1a. Introduction of the first accessory trocar	0/79 (0.0)	0/79 (0.0)	0/79 (0.0)	0/79 (0.0)	>.99
1b. Introduction of the second accessory trocar	0/79 (0.0)	0/79 (0.0)	0/79 (0.0)	0/79 (0.0)	>.99
1c. Introduction of the third accessory trocar	0/79 (0.0)	0/79 (0.0)	0/79 (0.0)	0/79 (0.0)	>.99
2a. Inspection of the gallbladder	40/79 (50.6)	0/79 (0.0)	17/79 (21.5)	0/79 (0.0)	<.001
2b. Inspection of the liver condition	61/79 (77.2)	0/79 (0.0)	37/79 (46.8)	0/79 (0.0)	<.001
3. Circumferential dissection of the cystic duct and the cystic artery	40/77 (51.9)	3/77 (3.9)	14/77 (18.2)	3/77 (3.9)	<.001
4. Transection of the cystic artery	1/77 (1.3)	5/77 (6.5)	0/77 (0.0)	5/77 (6.5)	>.99
5. Transection of the cystic duct	0/77 (0.0)	1/77 (1.3)	0/77 (0.0)	1/77 (1.3)	>.99
6. Removal of the gallbladder from the liver bed	1/77 (1.3)	0/77 (0.0)	0/77 (0.0)	0/77 (0.0)	>.99
7. Inspection of liver hemostasis	7/77 (9.1)	7/77 (9.1)	1/77 (1.3)	7/77 (9.1)	.53
8. Presence of spill	3/35 (8.6)	0/35 (0.0)	0/35 (0.0)	0/35 (0.0)	>.99
9. Saline irrigation	7/34 (20.6)	0/34 (0.0)	2/35 (5.9)	0/34 (0.0)	>.99
10. Drain placement	0/3 (0.0)	0/3 (0.0)	0/3 (0.0)	0/3 (0.0)	>.99
11a. Removal of the first accessory trocar	13/79 (16.5)	14/79 (17.7)	2/79 (2.5)	14/79 (17.7)	.02
11b. Removal of the second accessory trocar	16/79 (20.3)	8/79 (10.1)	3/79 (3.8)	8/79 (10.1)	<.001
11c. Removal of the third accessory trocar	16/79 (20.3)	11/79 (13.9)	3/79 (3.8)	11/79 (13.9)	<.001
Total	205/1089(18.8)	49/1089 (4.5)	69/1089 (7.3)	49/1089 (4.5)	<001[e]

[a] Steps adequately seen upon video review, but not adequately described in the narrative operative note.
[b] Steps adequately described in the operative note, but not adequately seen upon video review.
[c] The "described but not seen" column was not adjusted with audio; the two columns will thus stay similar.
[d] Comparison of the combined discrepancies per step without audio adjustment vs with audio adjustment. Values are Bonferroni corrected.
[e] Comparison of the combined discrepancies in total without audio adjustment vs with audio adjustment. Value is per the Wilcoxon signed rank test and is Bonferroni corrected.

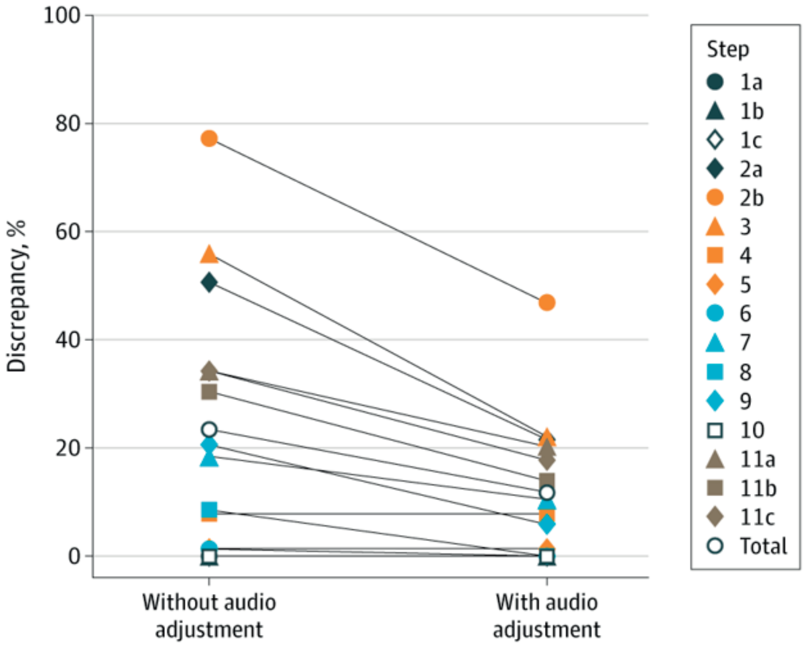

Figure 2. Discrepancy Rates per Step and in Total Between Videos and Operative Notes, Without and With Audio Adjustment of the Operative Notes

vs with audio, 16 of 79 [20.3%]; P=.02), the second accessory trocar (without audio, 24 of 79 [30.4%] vs with audio, 11 of 79 [13.9%]; P<.001), and the third accessory trocar (without audio, 27 of 79 [34.2%] vs with audio, 14 of 79 [17.7%]; P<.001). The total discrepancy was also significantly lower after audio adjustment (without audio, 254 of 1089 [23.3%] vs with audio, 118 of 1089 [11.8%]; P<.001).

DISCUSSION

Because quality control has long been an afterthought in surgery, its importance has rapidly gained recognition. However, capturing operations with multimedia to improve surgical safety and knowledge is not a new idea. In 1899, just 4 years after the introduction of the cinematograph, Argentinian surgeon Alejandro Posadas and French surgeon Eugène-Louis Doyen were the first to produce films of their operations.[29,30] Doyen wrote in "*The Cinematograph and the Teaching of Surgery*" that cinema allowed him to improve his surgical technique and he was happy to be able to criticize himself and his operations of the previous days.[29]With the introduction of the cinematograph, we could make hundreds of people follow in 1 minute what a whole lecture could not make clear to a limited number of students.

As health care professionals must now meet stricter criteria for maintaining high surgical–quality standards, the availability of quality-control tools, such as real-time video recording and electronic synoptic reports, are improving. This study demonstrates that video and audio recordings during LC significantly improve the adequacy of reporting essential surgical steps, with lower discrepancies between what was captured on video and what was written in the operative note.

Of the steps in the note, 78.0% were adequately described. However, for quality-control purposes, the adequacy of the note in its current form is still insufficient. The lowest adequacy rates for the note were the inspection of the liver condition, the circumferential dissection of the cystic duct and cystic artery, and the inspection of the gallbladder condition. The inadequate description of the inspection of the gallbladder and the liver might be because operators are less likely to report normal gallbladder and liver conditions. However, by not reporting these essential steps, future readers of the operative note cannot ascertain the absence of any abnormal findings. The circumferential dissection phase is reported inadequately mainly because most operators only mention the Calot triangle, dissection of the cystic duct and cystic artery, or just CVS. Earlier findings by van de Graaf et al[31] suggest that many operators are not able to adequately reproduce the definition of CVS. It simply cannot be known if the operator truly performed this technique according to the guidelines. In this respect, the description of this step should at least contain keywords describing the circumferential dissection of the cystic duct and cystic artery. Possible reasons for inaccuracy in operative notes are associated partly with practical problems. It was common that multiple elective LCs were performed clustered and subsequently after another in the centers. As a result, reporting several, nearly identical procedures at the end of the day may lead to inaccuracies. Moreover, adequacy could also be variable dependent on work experience. Some operators used self-made formats to quickly fill in operative notes. These notes were nonstandardized and often insufficient to meet current reporting standards. A standardized, preferably electronic operative note could considerably improve the adequacy of reporting.[32]

Of all the steps, 92.3% were adequately observed in the video recordings. The lowest adequacy rates were the removal of the first accessory trocar and the circumferential dissection phase. One important reason for the somewhat lower adequacy rate for the removal of the first accessory trocar is that the optic port is frequently used for extrication of the gallbladder; the camera would then be inserted into the first accessory trocar, after which removal of this particular trocar would frequently not be performed under vision. The circumferential dissection phase could not be adequately seen in 19.5% of the cases. This rate is substantial and should not be overlooked.

We also analyzed whether audio recordings—in which the essential steps of LC were actively dictated during the operation—could reduce discrepancies between videos and operative notes. Because video was used as the golden standard, we only adjusted the operative note with audio recordings. Discrepancies in which steps were adequately described in the note but not adequately seen in the video were thus not resolved by audio. After adjusting the notes with the audio recordings, the total discrepancy significantly declined from 23.3% to 11.8% for steps that were adequately depicted in the videos but not in the notes. The significant decline in discrepancies was again seen in the inspection of gallbladder and liver condition and the circumferential dissection phase. Additionally, discrepancies regarding the removal of the first, second, and third accessory trocars were diminished after adjustment with audio. Overall and specifically for these aforementioned steps, it can be stated that audio recordings are of additional value for the adequate description of the actions performed during surgery (Figure 1). These discrepancies are mainly the result of operative notes that are not written according to the guidelines. It could also be the case that steps have not been seen in the video. To reach a consensus on whether a step has been performed according to the guidelines, audio recording could be effective.

The clinical implementation of audio recordings during surgery could enable us to analyze whether this addition could lead to higher awareness among surgeons and assistants in the long term and perhaps lower complication rates. Furthermore, video with synchronous audio could be beneficial for the education of future surgeons and could also act as a tool for operators to reflect on their operations.

Limitations

A limitation of this study was that operators were not blinded for the intervention. This might have led to the Hawthorne effect, in which individuals positively modify an aspect of their behavior in response to their awareness of being observed. Because of this phenomenon, an immediate increase was expected in the operator's awareness and prudence and thus possibly the quality of the operation. This type of autoregulation could also result in fellows and residents seeking help earlier in case of difficult situations during surgery. It is therefore expected that this phenomenon might have influenced outcomes in a positive manner, and this occurrence would also transpire in clinical practice. However, prior research introducing systematic recording using a checklist in laparoscopic colorectal cancer surgery, which was comparable with our approach, did not seem to have a significant association with operative note adequacy, and therefore the amount of bias caused by this knowledge appears to be negligible.[26]

Data storage requirements were higher for full-length operation recordings compared with short clips of key moments or pictures of CVS. However, with modern-day technology, the storage of these full-length video and audio recordings should be simple and inexpensive. The ultimate advantage of full-length recordings is that they will encompass possible adverse events that would have been disregarded otherwise and data regarding the technical performance of operators can be analyzed thoroughly so that they can reflect on their actions. An important disadvantage of the full-length recordings is that the density of convenient information is low, which will lead to laborious review processes, mainly in case of lengthier operations. To make information retrieval of surgical proceedings more convenient for clinical use, real-time annotation of key moments might be a solution.

A pitfall in the logistics of audio recording was the absence of routine use of audio-recording devices in the participating centers. Multiple devices (a microphone with charging base, laptop, and external hard drive [all in a nonsterile zone]) were required to record the operator's voice. One researcher (Ö.E.) was responsible for the storage of the recordings to minimize technical failures. Loss of data mainly occurred in the starting phase of the study, when video recording devices would be inadvertently switched off before storage was completed. Today, as multimedia equipment is being integrated into smart operating rooms, operations can be recorded with the touch of a button.

Conclusions

Video and audio recordings during LC significantly improve the adequacy of the depiction of essential surgical steps compared with the narrative operative note. The addition of audio leads to lower discrepancies between the video recording and the narrative operative note, which could lead to a better understanding of the operative procedure on review.

Acknowledgment

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Additional information

The SONAR-trial was registered in the Netherlands Trial Registry as Trial NL6822 (NTR7008).

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Chapter 11

A comparison between intraoperative voice dictation and the operative report in laparoscopic cholecystectomy: a multicentre prospective observational study

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ABSTRACT

Background

The operative report inadequately reflects events occurring during laparoscopic cholecystectomy (LC). Intraoperative video recording has already proven to add important information. It was hypothesised that real-time intraoperative voice dictation (RIVD) can provide an equal or more complete overview of the operative procedure compared to the narrative operative report (NR) produced postoperatively.

Methods

SONAR is a multicentre prospective observational trial, conducted at four surgical centres in the Netherlands. Elective LCs of patients aged 18 years and older were included. Participating surgeons were requested to dictate the essential steps of LC during surgery. RIVDs and NRs were reviewed according to the stepwise LC guideline of the Dutch Society for Surgery. The cumulative adequacy rates for RIVDs were compared with those of the postoperatively written NR.

Results

RIVD resulted in a significantly higher adequacy rate compared to NR for the circumferential dissection of the cystic duct and artery (NR 32.5% vs. RIVD 61.0%, P = 0.016). NR had higher adequacy rates in reporting the transection of the cystic duct (NR 100% vs. RIVD 77.9%, P = <0.001) and the removal of the gallbladder from the liver bed (NR 98.7% vs. RIVD 68.8%, P<0.001). The total adequacy was not significantly different between the two reporting methods (NR 78.0% vs. RIVD 76.4%, P = 1.00).

Conclusions

Overall, RIVD is not superior in reporting surgical steps in LC compared to the postoperatively written NR. However, the most essential surgical step, the circumferential dissection of the cystic duct and artery, was reported more adequately in RIVD.

INTRODUCTION

In the past century, the narrative operative report (NR) has been the mainstay of surgical procedure documentation.

Either written, dictated, and then described or typed directly in the electronic patient file, it provides a narrative in which the course of the surgical procedure is described. Despite its long use, the traditional NR is known to be lacking in objectivity. It portrays a subjective view of the surgeon by definition, and therefore often omits or even inaccurately reflects essential procedural information.[1] In the case of laparoscopic cholecystectomy (LC), prior research has demonstrated that the current form of NR is not sufficient to adequately record the critical view of safety (CVS), in which the cystic duct and artery are circumferentially identified in the limitations of Calot's hepatobiliary triangle, prior to transection.[2] This step is of great importance to perform correctly, but also to document in an adequate fashion, because 70-80% of iatrogenic bile duct injuries (BDI) originate during this step due to misidentification of biliary structures.[3,4] Also, with BDI potentially leading to life threatening complications, prolonged hospitalisation, high financial expenditures, and risk of litigation,[5] it is warranted that proper documentation exists.

Several methods to improve the documentation of CVS, such as photography and video recording, have been investigated and proven feasible as an adjunct to NR.[2,6-9] In a recently published practice guideline on prevention of bile duct injury during LC, CVS was recommended by an expert panel as anatomical recognition method. This panel also agreed on the superiority of video documentation to operative reports for the accurate documentation of CVS.[10] In the Netherlands, it is standard practice to capture CVS either with video or image capture.[11-13] This method, however, is not widely implemented in the rest of the world.

Despite the benefits and increasing availability of audio recording modalities in the operating room, current videos of LCs are recorded without sound, potentially withholding a better understanding of the intraoperative proceedings. To further broaden the range of alternatives to NR and to investigate the feasibility of a real-time dictated operative report compared to NR, produced with delay, we intended to introduce real-time intraoperative voice dictation (RIVD) during LC. In a previous study we have demonstrated that video recordings with simultaneous audio recordings of the operator significantly improved the adequacy of the depiction of essential surgical steps compared to NR by lowering discrepancies between the video and the report.[7] In this study, our aim is to focus on RIVD, to investigate whether this reporting modality can provide an equal or better understanding of LC compared to the traditional NR. To our knowledge, no study has been conducted yet in which the availability of information essential to the surgical procedure has been compared between an intraoperatively voice dictated report and a postoperatively written report.

Methods

This study is part of The Simultaneous Video and Audio Recording of Laparoscopic Cholecystectomy Procedures (SONAR) trial, which is a multicentre prospective observational study conducted at four surgical centres (Isala, Zuyderland Medical Centre, IJsselland Hospital, and Park Medical Centre) in the Netherlands between 18 September 2018 and 13 November 2018. The medical research and ethics committee of the Erasmus University Medical Centre exempted this study from the Research Involving Human Subjects Act and Institutional review boards of the participating centres provided separate approval of this trial prior to local initiation. Written informed consent was obtained from the operators for the use of their voice recordings.

Study subjects

Operators (surgeons, fellows, and surgical residents) from the respective institutions were approached for participation. During the surgical procedure, the operator was requested to dictate the essential steps of the procedure in real-time over the course of the surgical procedure with a wireless and wearable microphone (Revolabs Xtag™ Wireless Microphone, Yamaha Unified Communications Inc, Sudbury, MA, U.S.A.). The microphone was attached to the operator's scrub top. RIVDs were saved as music player 3 (MP3) files using Audacity® recording and editing software version 2.3.3. (The Audacity Team) on a password-protected external hard drive. Elective LCs of patients aged 18 years or older were eligible for inclusion. Study cases with incomplete RIVDs or unavailable NRs were excluded.

Data collection

The audio recordings were initiated at the moment of endoscope introduction in the abdomen and terminated upon disconnection of the endoscope. RIVDs and NRs were retrieved and subsequently anonymised for further analysis. Patient data regarding baseline characteristics were retrieved from the patients' electronic health records and anonymously entered into a database.

Study outcome

The recorded audio, as well as the corresponding NRs, were reviewed for adequacy according to predefined key steps for LC, as mentioned in the *Appendices*. Adequacy was defined as the competent depiction of a surgical step. Recordings were analysed by two researchers (ÖE, FvdG) based on the stepwise LC guideline of the Dutch Society for Surgery.[14] The independent reviewer form is shown in the *Appendices*. Subsequently, steps regarding the circumferential dissection of the cystic duct and artery were analysed by an expert panel of two surgeons qualified in laparoscopic surgery (JL, AM) for an adequate depiction in both RIVDS and NRs. The cumulative adequacy ratings for RIVD were compared with those for NR. A flow diagram summarising the execution of this study is shown in Figure 1.

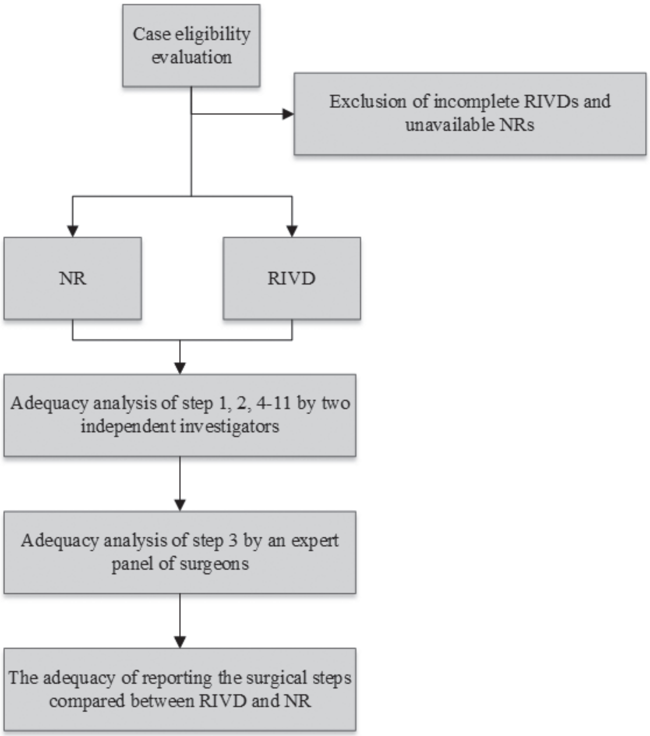

Figure 1. Flow diagram summarising the execution of this study

Statistical analysis

Categorical data are presented as numbers and percentages, normally distributed data are expressed as median (interquartile range), or mean (standard deviation). RIVDs and NRs were individually compared with the assumption that a specific aspect of the procedure was identical for both RIVD and NR. Adequacy between individual steps were compared with the exact McNemar's test, excluding missing values.[15] The total adequacy was compared with the paired samples t-test or Wilcoxon signed-rank test, depending on normality. In case of multiple comparisons, Bonferroni correction was applied by multiplying the obtained *P* values with the number of completed tests. A *P* value of <.05 was considered statistically significant. Data were analysed with statistical software R, version 3.4.1, for Windows (http://www.rα project.org). Flow diagrams were created with Microsoft Visio version 8.1.1 for Windows (GraphPad Software, La Jolla, CA, U.S.A.).

Sample size

The sample size calculation was based on prior data by Wauben et al., evaluating the quality of NR.[1] For this calculation, CVS was selected as most essential step, for this is unequivocally the most critical part of the surgical procedure, thus most important to report adequately. In

79.2% of the video recordings, CVS was observed. In 50.4% of the reviewed cases CVS was adequately reported in NR and observed in the video recordings. A minimal sample size of 73 procedures was calculated with $\alpha = .05$, power = 0.80, and δ equal to 0.10. In this trial, 90 patients were intended to be included after accounting for loss of data. No prior trials were found in which audio recordings were used during surgery for operative reporting.

RESULTS

Study population

Between 18 September 2018 and 13 November 2018, 90 patients who met the inclusion criteria underwent LC in the participating centres. Subsequently, 11 cases were excluded from the analysis, ten due to technical malfunctioning of the recording equipment or problems in data storage and one because of early termination of the surgical procedure due to suspected liver metastases.79 RIVDs and NRs of the SONAR-trial were eligible for inclusion and available for further analysis. 49 of 79 patients were women (62.0%) and the mean (SD) age was 54.3 (15.9) years. Patient and surgery characteristics are presented in Tables 1 and 2. Twenty-four different primary operators conducted the procedures, with a mean number of 3 cases per operator (range, 1-18). Two procedures were converted to open LC due to difficulties with identifying the anatomical structures.

Table 1. Patient Characteristics

Characteristic	Study patients, mean (SD)
Total, No.	79
Age, y	54.3 (15.9)
Women, No. (%)	49 (62.0)
Height, cm	171.3 (9.9)
Weight, kg	84.7 (16.8)
BMI	28.9 (5.2)

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).

Quantitative technical data

A total of 65 hours 7 minutes of audio footage was recorded. The mean (SD) duration per recording was 49 minutes (25). The total required digital storage space was 2 851 megabytes, with a mean (SD) size of 36 (24) megabytes per case.

Table 2. Surgery Characteristics

Characteristic	Operations (n = 79)
Primary operator function, No. (%)	
Surgeon	9 (11.4)
Fellow	59 (74.7)
Surgical resident	11 (13.9)
Secondary operator function, No. (%)	
Surgeon	20 (25.3)
Fellow	11 (13.9)
Surgical resident	2 (2.5)
Operation assistant	37 (46.8)
Medical student	9 (11.4)
Surgery duration, mean (SD), min:s	43:21 (24:52)
Indication for surgery, No. (%)	
Symptomatic cholelithiasis	66 (83.5)
Other	8 (10.1)
Acute cholecystitis	5 (6.3)
Time >7 d between onset acute cholecystitis and surgery, No./total No. (%)	5 (100.0)
Conversion to open surgery, No. (%)	2 (2.5)

Adequacy

Adequacy rates are summarised in Table 3. After Bonferroni correction, RIVD resulted in a significantly higher adequacy rate compared to NR for the circumferential dissection of the cystic duct and artery (NR 32.5% vs. RIVD 61.0%, $P = 0.016$). NR had a higher adequacy rate in reporting the transection of the cystic duct (NR 100% vs. RIVD 77.9%, $P = 0.00026$) and the removal of the gallbladder from the liver bed (NR 98.7% vs. RIVD 68.8%, $P<0.0001$). The total adequacy was not significantly different between the two reporting methods (NR 78.0% vs. RIVD 76.4%, $P = 1.00$).

DISCUSSION

As the availability of modalities to capture events that transpire during surgery is increasing, the call for improvement in surgical reporting will become increasingly evident. However, in surgical specialties, the operative report has remained unaltered in the last decades.

RIVD as one of these modalities might be of benefit, as it could provide a real-time narrative of the course of surgery, including comments on certain important findings that may not be included in the traditional NR.

Table 3. Adequacy rates for the narrative operative report and real-time intraoperative voice dictation

No./total No. of steps (%)			
Procedure steps (N = 79 operations)	NR	RIVD	*P* value for exact McNemar's test[a]
1a. Introduction of the first accessory trocar	79/79 (100.0)	72/79 (91.1)	0.266
1b. Introduction of the second accessory trocar	79/79 (100.0)	72/79 (91.1)	0.266
1c. Introduction of the third accessory trocar	79/79 (100.0)	72/79 (91.1)	0.266
2a. Inspection of the gallbladder	39/79 (49.4)	46/79 (58.2)	1.00
2b. Inspection of the liver condition	17/79 (21.5)	33/79 (41.8)	0.12
3. Circumferential dissection of the cystic duct and artery	25/77 (32.5)	47/77 (61.0)	0.016
4. Transection of the cystic artery	71/77 (92.2)	64/77 (83.1)	1.00
5. Transection of the cystic duct	77/77 (100.0)	60/77 (77.9)	0.00026
6. Removal of the gallbladder from the liver bed	76/77 (98.7)	53/77 (68.8)	<0.0001
7. Inspection of liver hemostasis	65/77 (84.4)	56/77 (72.7)	1.00
8. Presence of spill	32/35 (91.4)	33/35 (94.3)	1.00
9. Saline irrigation	27/34 (79.4)	32/34 (94.1)	1.00
10. Drain placement	3/3 (100.0)	3/3 (100.0)	1.00
11a. Removal of the first accessory trocar	60/79 (75.9)	63/79 (79.7)	1.00
11b. Removal of the second accessory trocar	60/79 (75.9)	64/79 (81.0)	1.00
11c. Removal of the third accessory trocar	60/79 (75.9)	62/79 (78.5)	1.00
Total	849/1089 (78.0)	832/1089 (76.4)	1.00[b]

[a] Bonferroni corrected.

[b] Wilcoxon signed rank test (Bonferroni corrected).

NR narrative operative report *RIVD* real-time intraoperative voice dictation

This study demonstrates that, overall, RIVD during LC is not superior in the adequate depiction of essential surgical steps compared to NR. However, the circumferential dissection of the cystic duct and artery, the most essential step in LC, was reported significantly more accurately in RIVD compared to NR.

In NR, 78.0% of the essential steps were reported according to the guidelines. However, for quality control purposes, the adequacy of NR in its current form is still insufficient: the lowest adequacy rate for NR was the inspection of the liver condition (21.5%), the circumferential dissection of the cystic duct and artery (32.5%), and the inspection of the gallbladder condition (49.4%). The inadequate description of the inspection of the gallbladder and the liver conditions might be caused by the fact that operators are less likely to report normal organ conditions. Though, underreporting will impede future readers of NR in ascertaining the absence of any atypical findings. The circumferential dissection phase is reported inadequately in NR mainly due to the fact that most operators only mention *'Calot's triangle'*, *'dissection of the cystic duct and artery'*, or just simply *'CVS'*. Earlier findings by van de Graaf et al. demonstrated that many operators are unacquainted with the correct definition of CVS.[16] In this respect, we believe that the description of this step should at least contain keywords describing the circumferential dissection of the cystic duct and artery. Possible reasons for inaccuracy in NR relate partly to practical problems. It was common in the participating centres that multiple LCs were performed in close succession. Subsequently, reporting several, nearly identical, procedures at the end of the day may lead to inaccuracies due to physical and mental fatigue and tiredness. Moreover, the adequacy could also be variable dependent on years of work experience. Some operators used self-made formats to quickly fill in NRs. The use of these non-standardised NRs could be a pitfall in surgical reporting, leading to mix-ups of events or even underreporting of anomalous details. A standardised – preferably electronic – operative report, such as synoptic reporting, could considerably impact the adequacy of reporting.[17]

In RIVD, 76.4% of the essential steps were adequately documented. Similar to NR, the lowest adequacy rate in RIVD was the inspection of the liver condition (41.8%), the inspection of the gallbladder condition (58.2%), and the circumferential dissection of the cystic duct and artery (61.0%). Although the latter step was adequately dictated in 61.0%, this adequacy rate is significantly different and almost twice as high compared to the same step in NR. Given the fact that misidentification of anatomical structures is the foremost reason for biliary complications, this improvement in adequacy is an important finding. It is a clear indication that audio in this case would be of greater value than NR for the adequate depiction of this step. Audio can easily be synchronised with intraoperative video recordings, which were also proven to be effective in the adequate description of the operative procedure.[1,7-9] Two other significant differences were found in the transection of the cystic duct and the removal of the gallbladder from the liver bed. One explanation for this finding is that these steps are so apparent in the course of the operation that they are frequently skipped in RIVD. Both steps were almost 100% reported in NR. As might be expected, copy-pasting prewritten formats to all reports have contributed to the fact that these steps were almost never skipped in NR.

According to the Joint Commission guidelines concerning the record of care, treatment, and services, the operative report should be *"written or dictated upon completion of the operative or other high-risk procedure and before the patient is transferred to the next level of care"*.[18] However, this is often not possible due to other responsibilities of the surgeon or time constraints in the operating room. This method of delayed composition is prone to omission or even incorrect representation of essential information. Despite time until completion was not taken into consideration in this study, it is imaginable that certain aspects of the surgical procedure are not adequately represented in the current NR, yet are adequately addressed in RIVD, such as the circumferential dissection of the cystic duct and artery. These two events might be considered as straightforward in LC and only a means to the goal: the clipping of the cystic duct and artery. However, the dissection phase is often the most dangerous part of LC and many iatrogenic complications occur at this moment.

Our experience is that operators who actively reported the essential steps of the operation during surgery were constantly being triggered with memory items. This resembles the crew resource management checklists that are in use in aviation as reminders to ensure that all necessary checks have been completed by the entire crew.[19] As pre- and post-operative checklists have proven to be effective for safe surgery [20], this additional auditory reporting method, in which the operators provide continuous feedback to themselves and the OR personnel, could serve as an intraoperative checklist. The question still remains if this new reporting method could also improve the early detection of operative progress and surgical complications and may even further elucidate unintended deviations from best practice guidelines during surgery. The additional value of RIVD would then not only be limited to operative reporting, but could also enhance the situational awareness of the operating team.

Limitations

In this study, operators were not blinded for the intervention. This could have led to the Hawthorne effect in which individuals knowingly or unknowingly modify an aspect of their behaviour in response to an observation.[21] Due to this effect, an increase in operator's quality of reporting both for RIVD as NR. However, in other studies, the introduction of systematic recordings in laparoscopic colorectal cancer surgery did not seem to have a significant association with operative report adequacy and therefore the amount of bias caused by this knowledge appears to be negligible.[9]

As modern technology is constantly evolving, storing full-length audio recordings can be simple and inexpensive. The added value of recording the entire operative procedure is that these recordings may incorporate possible adverse events that would have been disregarded otherwise. Technical performance data of the operator can be analysed with these full-length recordings, so that operators can reflect on their own actions. An important disadvantage of the full-length audio recordings is that the density of convenient information is low, which will lead to laborious review processes for lengthier operative procedures. As audio requires small data storage space, these recordings can be easily synchronised with endoscopic video, making it an inexpensive and useful surgical quality tool. For clinical use, RIVD of key moments might be a solution for more convenient information retrieval of surgical proceedings.

The absence of routine use of audio recording devices in the participating centres was an important pitfall in the logistics of RIVD. Different devices (microphone with charging base, laptop, external hard drive (all in a non-sterile zone)) were required to record the operator's voice. One researcher (Ö.E.) was responsible for the storage of the recordings to curtail technical failures. For the clinical implementation of RIVD in the operating theatre, one automated system would be suitable for flawless and user-friendly recordings. Fortunately, as multimedia devices are increasingly being integrated into hybrid operating theatres, the recordings of operative procedures can progress with the "touch of a button".

Conclusions

Real-time intraoperative audio recording is not superior in reporting essential surgical steps in LC but demonstrates higher adequacy in reporting essential aspects of the procedure compared to the postoperatively written operative report. Audio recording can thus be an important tool for the adequate description of the actions performed during surgery.

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Chapter 12

General discussion and future perspectives

We live in a time where great feats in surgical quality have been accomplished. In the treatment of colorectal cancer for instance, a disease of which surgical treatment remains the hallmark of its cure, 5-year survival rates of colorectal cancer has risen by tens of percentage, and the incidence has decreased due to preventive measures.[1,2]. Furthermore, since the introduction of the minimally invasive approach for several types of surgery, a drastic improvement of short- and long-term postoperative morbidity has been noted, without making concessions to surgical results or oncological outcomes.[3-5]

Despite these positive developments, a variability remains concerning the quality of surgical treatment, perhaps the most considerable factor in short- and long-term outcomes. This variability is evident in several types of surgery. For instance in colorectal cancer surgery, postoperative mortality and morbidity ranges from 0.5% to 6% and 15% to 25%, respectively.[3,6-8] In terms of oncological outcomes, disease recurrence ranges from 5% to 50% of patients and 5-year survival rates differing from 32% to 64%.[9-12]. Also a most evident variability is found among the incidence of bile duct injury in laparoscopic cholecystectomy, ranging from as low as 0.08% up to 0.40%.[13-17] The importance of quality assurance to reduce surgical variability is recognized and several quality improvement programs have already been established, such as the implementation of the surgical safety checklist used in the time-out procedure, effectively reducing perioperative mortality,[18,19] and the establishment of national registries and audits (e.g. National Program of Cancer Registries (NPCR) in the United States of America, the National Cancer Registration and Analysis Service (NCRAS) in the United Kingdom and the Dutch Institute for Clinical Auditing (DICA) in the Netherlands).

These registries and audits however merely focus on outcomes of surgery, not on the source of surgical shortcomings leading to decline in quality or potentially substandard care. Outside the often secluded faction of medical practitioners an increasing number of sectors are utilizing multimedia recording for their benefit in quality improvement and assurance. For instance in aviation, the black box records all flight data and communication in real-time during flight for use of accident and incident investigation. However, explicit directions and a chain of command are provided to comply with privacy law and prohibit misuse.[20] Recently in the Netherlands, after an initial small-scale trial period, formal recommendation have been made to the Dutch justice department and Dutch police force to expand roll-out of officer-worn body cams. [21] If other non-medical branches are embracing this novel technology, why not a cutting edge sector as medicine, surgery in particular? The main reason are the barriers that exist before a such a technology with a profound impact could be implemented. These barriers not only contain privacy issues for both medical professionals and patients, but also the technological (i.e. acquisition of hardware and storage) and legal restraints that come with this technology.

The fact remains that the current method of operative reporting is most often not adequate: essential information is frequently omitted or wrongly reported.[22] A possible aid to improve this might be the use of synoptic operative reporting. In **Chapter 3** we reported that synoptic reporting does indeed add in the overall completeness of operative reports, however its use is far from general and a typical synoptic operative report heavily relies on a routine procedure and deviations during surgery are difficult to report in an easy manner and often time consuming. Furthermore, most synoptic reporting methods currently available compile a form upon completion which is, as the name describes, a condensed rundown of the procedure, with all essential information neatly listed in order, yet difficult to interpret in context due to the lack of narrative. A great asset of the synoptic operative report however is the fact that certain mandatory parameters necessary to complete the plethora of clinical audits and national registries could be entered just once, averting the necessity of duplicate registering and in the end saving time. For best effect, combining the readability of the narrative operative report and the accuracy of the synoptic report, a narrative form of synoptic reporting should be developed.

So what are barriers for use of multimedia recording in the operating as considered by end users, being the medical professionals? Our cross-sectional survey among medical professionals from several surgical specialties reported in **Chapter 4** reflects that the current surgical landscape is still divided regarding their readiness for intraoperative video recording. Numerous surgeons are accustomed to intraoperative video recording, as it is readily available in general and most agree it caters to an important element of being a medical professional: accountability. Many surgeons indeed do not oppose transparency. However, for a lot of surgeons the use of intraoperative audio recording feels excessive. Many fear the privacy infringement of the surgical team that follows and in particular the negative impact it might incur on operating room atmosphere. Moreover, nowadays only endoscopic surgeries are suitable for easy recording; everything is set up and implementation could roll out promptly with respect to the technical aspects. A great challenge remains in recording predominantly open surgeries and dynamic procedures covering large parts of the body and different angles, such as vascular surgery and orthopedic surgery. Unless thoroughly prepped, surgeons are not able to document these kind of procedures on video in an effortless manner whilst adequately covering the majority of the surgery.

Aside from the importance of support among those who are using, or are subject to intraoperative multimedia recording, technological feasibility is just as crucial. The studies reported in **Chapter 6, 7, 10 and 11** have proven that both intraoperative video and audio recording are indeed feasible. Moreover, video recordings provide a significant enhancement to the traditional narrative operative report in terms of depiction of surgical events, an improvement of 25.8 to 32.9 percentage points compared to the traditional operative report alone. Also the use of intraoperative audio recording is able to reduce the number of discrepancies (essential surgical steps that were adequately observed on video but inadequately reported in the operative note), providing a reduction from 23.3% discrepancies to 11.8% with use of audio. In its current form however, being either a full-length recording of the entire procedure, or multiple recorded fragments of key steps, intraoperative video and audio documentation presents difficulties in both recording and reviewing, as the former is error prone and the latter is notably time consuming.

In the topic of cholecystectomy it is general knowledge that results have improved over time. Due to the beneficial effects of the minimally invasive approach, most surgeons jumped to the opportunity to exchange the traditional 'open' approach for a laparoscopic one. This resulted in a tremendous increase of laparoscopic cholecystectomies in only a few years time.[23-25] This however was accompanied with an upsurge of bile duct injury, with rates up to 1.5% compared to an average of 0.2% in open cholecystectomy.[26-34] Only in recent years were surgeons able to reduce this incidence to one comparable to the period before introduction of laparoscopic cholecystectomy, however as mentioned before very variable. With these low incidence rates bile duct injury could be interpreted as a "rare occurrence". However, note has to be taken that cholecystectomy, with a number of up to 200 procedures performed per 100,000 inhabitants annually in Europe and the United States, is the most frequently performed type of abdominal surgery today.[35,36] This high volume, associated with the impact that bile duct injury inflicts on patient morbidity and mortality, accumulates to a very common yet severe complication.

Articles covering cholecystectomy and bile duct injury have been published in abundance. Despite this, as the systematic review in **Chapter 8** also demonstrates, the level of evidence provided by this body of research is regrettably very modest. A mere 4.4% (4 out of 90) of included articles in this review has a level of evidence of 2 (according to the Oxford Centre of Evidence-Based Medicine[37]) The majority of articles included, 72.2% (65 out of 90) has a level of evidence of 4, i.e. just above expert opinion. This distribution is mainly attributed to the statistical fact that proper research on bile duct injury prevention is quite impractical. In the case of a randomized controlled trial, over 4,500 cases of laparoscopic cholecystectomy should be included *per arm* to adequately address the issue.[38]

Despite the problem of evidence quality in current literature, the lowest incidence of bile duct injury was reported whilst using the Critical View of Safety technique, first offered by Strasberg et al.[39] Having endured much scepsis, many currently recognize the value of this technique. Among others, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Association of Surgeons of the Netherlands have recommended its use for laparoscopic cholecystectomy.[40,41] Furthermore, in 2018 the Tokyo guidelines committee reached consensus to use the Critical View of Safety whenever possible.[42] Despite this, the correct understanding of critical view of safety technique is presumably considerably less in practice, as we have observed in **Chapter 9**. Most often the Critical View of Safety technique is confused with the infundibular technique, a technique which was standard practice and commendable in open cholecystectomy, and today in the era of laparoscopic cholecystectomy potentially calamitous. An explanation might be the fact that surgeons trained *before* 1995, when the article by Strasberg et al. was published, do not know better or, more regrettably, are reluctant to alter their technique. This hypothesis is supported by the fact that, in our survey, surgeons with more than 15 years of working experience performed and selected steps appertaining to the Critical View of Safety technique less often than other surgeons. Reasons for not properly understanding the Critical View of Safety technique or using a different approach by some surgeons might the paucity of evidence to validate its use with evidence based medicine. Another reason might be the fact that with a relatively low incidence rate, one surgeon might perform over a hundred cholecystectomies without a single bile duct injury and might therefore consider his technique safe.

It is important to note that obtaining the Critical View of Safety should not be an objective on itself. Sometimes patient factors such as anatomy, inflammation, fibrosis or the presence of adhesions could and should prohibit the use of the Critical View of Safety technique and a different approach should be selected, for instance fundus first dissection, subtotal cholecystectomy or conversion to open cholecystectomy.

Intraoperative cholangiography has also been mentioned as a tool in bile duct injury prevention. This technique however is mostly frequented by US and UK surgeons, and rarely used by European and Asian surgeons[43-46]. Most importantly, in regions where this technique is utilized, its use was most likely dependent on surgeon's or institution's preference, rather than patient characteristics and scientific evidence, as should be desired. Also, due to an ongoing decrease in use, many surgeons in training lose the opportunity to familiarize themselves with this technique.[47] If this trend continues, it is imaginable that in the near future, intraoperative cholangiography becomes obsolete for 'straightforward' laparoscopic cholecystectomy and only practiced in specialized centers for hepatobiliary surgery.

FUTURE PERSPECTIVES

Legislation and ethics

Before intraoperative video and/or sound recording could be implemented in any capacity, fundamental ethical and legal concerns should be addressed. Legislation specifically tailored to these methods are to be formulated, considering that next to no other situation exist in which privacy of both patients and medical practitioners are exposed in such a manner and therefore in need of protection. Also, instead of measuring everything with the same standards, the medical community in cooperation with government authorities should clearly and decisively state criteria for different types of documentation what makes it identifiable. For instance in radiology, the majority of plain film radiographs without patient identifiers are near impossible to trace back to the patient. For head and facial CT-scans however, it is possible to reconstruct the skin surface to a 3D model of the face, as the data to achieve this is essentially included in the image processor.[48] In this case, accuracy for recognition compared to facial color photographs is reported to be 61%.[49] The situation with intraoperative recording of information, albeit the form of text, image, audio or video, is quite similar, as various methods of documentation pose different risks of privacy exposure. To state that all or none of these are a privacy infringement is detrimental and short-sighted. Furthermore, the multiple streams of information that are in play serve multiple purposes; among others information regarding the surgical procedure that could be implemented in the patient record and information that could be used for quality assurance. Data gathered for each of these purposes have different requirements in terms of accessibility, storage and ownership. To simply amass all information under one label would be a serious disservice for the other.

Technological aspects

Currently, most operating rooms are equipped with some sort of recording technology. The quality and ease of use are however highly variable across the board. Newly built or renovated operating rooms often incorporate modern technology, including recording facilities and logistics for live surgery broadcasting. These facilities are essential for implementation of systematic video recording to reach its potential.

In the future we might also see an increased use of artificial intelligence to aid us in these matters. For example, using synoptic operative reports and relating these with intraoperatively recorded video using artificial intelligence might facilitate easy lookup of video segments linked to parts of the report. Also, including data entered in the nursing station, like data regarding opened surgical equipment or registered devices or prostheses used for implant, could provide us with useful information to aid in effortless review of a surgical procedure.

Support by key players

In concordance with the Technology acceptance model (figure 1), two main factors apply for users to accept a new technology.[50] The first is the Perceived usefulness, which is "the degree to which a person believes that using a particular system would enhance his or her job performance".[51] According to the results of our survey in **Chapter 4** this is dichotomous among responding surgical professionals. We have demonstrated in this thesis that intraoperative video and audio recording are in fact useful. However, the fact remains that for an increase in perceived usefulness among key players more research is necessary to ascertain the benefit of intraoperative recording for multiple uses. Additionally, the beneficial results that are expected to arise from this research should then be gathered and consolidated in a concrete recommendation for potential users, for instance in the creation of a professional guideline.

The second factor is the perceived ease-of-use, which is "the degree to which a person believes that using a particular system would be free from effort". For now, only feasibility and potential benefit has been demonstrated. Currently, and due to the differences in infrastructure in different hospitals, easy-of-use is varying widely. If usefulness is present without doubt, ease-of-use should be next in line. Because when recording certain aspects of surgery are complicated to perform, positive attitude towards the technology is hard to find.

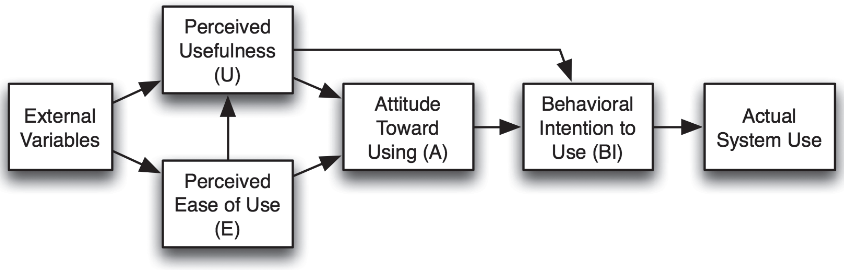

Figure 1. Technology acceptance model (Davis, Bagozzi & Warshaw 1989)

Furthermore, mere intraoperative recording to eventually be used as an afterthought is obviously insufficient. To err is human and therefore iatrogenic complications will happen in surgery. The main benefit in the situation of intraoperative recording is that, unlike now, most complications can be condensed to the its exact origin. However, this necessitates routine and systematic review by the involved parties at the least.

But why stop there? A successful surgery is not a result of the surgical aspect alone. Conversely, the surgical facets are not solely to blame when surgery has gone awry. Surgery is a team effort, only successful when all team players are working in coalition. Today, each of these team members have their own, unique stream of information, often segregated from one another. If one is to adequately review a complicated procedure, one should not only focus on just one of these information streams. 'The surgical black box', which is currently receiving critical acclaim, is the first project to make an attempt at combining these information streams between team members. It should be a priority in any case to approach each procedure in the operating room as a proper team endeavour and consequently team training must be focused on this.

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Chapter 13

Summary

There are several methods to reproduce the course of a surgical procedure. The most obvious is by eye witness account, i.e. the primary surgeon or those first hand involved in surgery. For purposes of accessibility and continuity of care, an operative report is composed, describing the most important events that transpire during surgery and providing the reader with extra information regarding the surgeon's considerations for certain actions. All content however is determined by the extensiveness and whim of the person transcribing and therefore subject to omission and error. Addition of video and/or audio recording to this narrative operative report would supply other parties with objective information of the aforementioned events almost in full.

In this thesis, we aimed to identify the quality factors in abdominal surgery, with laparoscopic colorectal surgery and laparoscopic cholecystectomy as focal point, that might benefit from use of intraoperative video and audio recording.

PART 1 – Multimedia as a quality improvement tool in surgery

In **Chapter 2,** we outlined benefits of intraoperative video recording during surgery and put them in context with important legal, ethical and technical issues currently forming a barrier for implementation. First is the argument of consent, mainly regulated by the Medical Treatment Agreement Act and the former Personal Data Protection Act (now covered by the European General Data Protection Regulation – GDPR). Three situations exist in the process of intraoperative video recording: Situation 1: Video is integral to the treatment provided, i.e. endoscopic surgery. Situation 2: Recorded images are not indispensable in terms of treatment, however might be of added value. Situation 3: Use of images for different purposed than initially intended. For situation 1, consent for intraoperative video is interwoven with consent for the surgical procedure in the Medical Treatment Agreement Act. For situation 2 and 3, additional consent is necessary. The second issue is retention period. For images included in the patient file a retention period of 15 years is uphold. For images not included in the patient file, no consensus have been met yet and the period has to be well defined before collection.

As an improvement to the error prone narrative operative report, some practitioners in the surgical field have been experimenting or even implementing the synoptic operative report. A synoptic operative report is a summarized documentation containing essential criteria of a surgical procedure, often formalized in computerized templates. To compare the completeness and the user-friendliness of the synoptic operative report compared to the currently used narrative operative report, we conducted a systematic review, of which the results are reported in **chapter 3.** For the synoptic operative report, overall completion and completion of subsections were higher than the narrative operative report. Furthermore, the time until completion of the report was shorter when the synoptic format is used.

Despite the increasing availability and use of multimedia capturing devices and recording tools inside the operating room, the perspectives of medical professionals are poorly known.

Consideration of these are imperative before implementation could be considered. We present the results of a cross-sectional survey in **chapter 4** regarding the use of intraoperative multimedia recording. Of the respondents, half feel that the operative report currently used is insufficient for future quality requirements. Most of the respondents recognize the added value of intraoperative video recording, and, to a lesser extent, for intraoperative audio recording. Furthermore, over half would think it's unlikely they would alter their behavior during surgery whilst recorded on video and the vast majority, 82.8%, would think it is unlikely that their surgical methods would be altered. Many, however, fear for privacy infringement.

In **chapter 5** the effects of segmentation in video-based learning of a surgical procedure (i.e. open inguinal hernia repair) are assessed. We used point-of-view recordings of medical students performing open inguinal hernia repair (Lichtenstein's procedure) after being exposed to either a step-by-step or continuous video-demonstration of the procedure, after which the steps of the procedure were reviewed on the video recordings for procedural and executional errors using the principles of the Observational Clinical Human Reliability Assessment. We found out that subjects in the step-by-step group made fewer procedural errors than the continuous group and also experienced a lower extraneous cognitive load compared to the continuous group

PART 2 – Quality assurance in colorectal cancer surgery

To investigate the added value of intraoperative systematic video recording we performed the Imaging for Quality control trial (IQ-Trial). In this trial we aimed to investigate the added value of intraoperative systematic video recording during laparoscopic colorectal cancer surgery in terms of quality and safety and information collection. This trial consists of a pilot study (**chapter 6**) in which we aimed to explore the feasibility of systematic intraoperative video recording and the main study (**chapter 7**). For the pilot study, 15 elective cases of laparoscopic colorectal cancer surgery were intraoperatively recorded using standard endoscopic recording modalities available. We then compared them to a retrospective group of 32 cases from the historic control group and in terms of the availability of information (i.e. predetermined essential steps of laparoscopic colorectal procedures) between video and operative report. Significant differences in availability of information were found in favor of video, as well as a combination of video and the operative note, compared to the written operative note alone

After feasibility was established, the main study, a multicenter, prospective, observational cohort study, was performed (**chapter 7**). In this study, procedures of 113 study patients were recorded and analyzed for availability of information and then compared to an identical number of case-matched individuals. This resulted in a significant increase in reporting quality by using intraoperative systematic video recording (78.5% adequacy for systematic video recording and 85.1% for the combination of the systematic video recording with the narrative operative report). Only half of the steps reported in narrative report were adequately described.

PART 3 – Quality and safety in laparoscopic cholecystectomy

Cholecystectomy is one of the most common surgical procedures performed today, of which more than 80% is performed laparoscopically. Despite the benefits of the laparoscopic approach over the classic 'open' approach, the incidence of one major complication, bile duct injury, increased drastically. To counter this upsurge, several safety measures have been developed. We performed a comprehensive systematic review on several of these modalities in **chapter 8**, categorizing for dedicated surgical approaches, (including the Critical View of Safety technique, fundus first laparoscopic cholecystectomy and laparoscopic subtotal cholecystectomy), supportive imaging techniques (including intraoperative radiologic cholangiography, intraoperative ultrasonography and fluorescence cholangiography) and other techniques. Dedicated surgical approaches demonstrate promising results. Also intraoperative radiologic cholangiography and ultrasonography show beneficial effects in BDI prevention, however are hampered by their learning curve. For all studies the level of evidence is low.

The Critical View of Safety technique is one of the most important surgical techniques to reduce the odds of bile duct injury in laparoscopic cholecystectomy. The crux of this technique is the decisive identification of the structures to be transected (i.e. cystic duct and cystic artery), without inflicting accidental damage to the central ducts of the biliary system. Many surgeons in the world utilize this technique in their procedures. However, to what extent surgeons and residents properly utilize the Critical View of Safety is unknown. To explore this, we conducted a nationwide survey among surgeons and residents in training. The results are reported in **chapter 9**. We inquired surgeons and surgical residents for their current methods of performing laparoscopic cholecystectomy and their knowledge on the topic of the Critical View of Safety technique.

Almost all respondents stated to use the Critical View of Safety technique in their current practice. Only 72% performed the essential steps of the technique frequently however. Furthermore, only half of the respondents were able to identify the corresponding steps of the Critical View of Safety technique, and just 16.9% were able to distinguish these adequately from possible harmful steps. Noteworthy was the fact that residents performed and selected the steps of the Critical View of Safety technique significantly more often than surgeons.

In **chapter 10 and 11** we investigated the value of both intraoperative video and audio recording in operative reporting. The addition of synchronous voice recording next to intraoperative video recording might add a new dimension to operative reporting by capturing the surgeons' considerations as well. To explore this, we investigated in a multicenter prospective observational trial whether intraoperative voice dictation could resolve discrepancies between videos and operative notes in laparoscopic cholecystectomy. For this, a total of 79 procedures were recorded on video whilst simultaneously recording audio (i.e. speech). Video recordings resulted in higher adequacy for the inspection of the gallbladder, inspection of the liver condition and the circumferential dissection of the cystic duct and the cystic artery. The total adequacy was also higher for the video recordings compared to the narrative operative report. The additional audio recordings significantly lowered the discrepancy rate between video and operative report note.

Chapter 14

Nederlandse samenvatting

Er zijn verschillende methoden om het verloop van een chirurgische ingreep te reproduceren. De meest voor de hand liggende manier is uit de eerste hand van de chirurg die bij de ingreep betrokken was. Om het beloop en resultaat van een operatie voor eenieder toegankelijk te maken, en om tevens de continuïteit van zorg te waarborgen, wordt een operatieverslag opgesteld met daarin de belangrijkste gebeurtenissen van de operatie. De inhoud van dit operatieverslag wordt echter bepaald door de uitvoerigheid waarmee de chirurg een en ander noteert, maar ook door de bereidheid van de chirurg om dit te bewerkstelligen. Het operatieverslag is derhalve kwetsbaar voor onvolkomenheden. Door video- en/of geluidsopnamen toe te voegen aan dit narratieve (verhalende) operatieverslag zouden andere partijen met objectieve informatie worden voorzien van hetgeen tijdens de operatie plaatsvindt.

In dit proefschrift trachtten wij de kwaliteitsfactoren te identificeren in abdominale chirurgie welke baat zouden kunnen hebben bij intra-operatieve video- en geluidsopnamen, waarbij wij ons voornamelijk richtten op laparoscopische colorectale chirurgie en laparoscopische cholecystectomie.

DEEL 1 – Multimedia als kwaliteitsverbeteraar in de chirurgie

In **hoofdstuk 2** kenschetsen wij de voordelen van het intra-operatief opnemen van videobeelden in de operatiekamer, waarbij wij deze in context plaatsen met de juridische, ethische en technische kwesties die heden een obstakel vormen voor implementatie van deze techniek in de huidige praktijk. De eerste kwestie gaat over toestemming geven voor opname. De rechten met betrekking tot dit onderwerp worden vertegenwoordigen door Wet op de Geneeskundige Behandelingsovereenkomst (WGBO) en Algemene verordening gegevensbescherming (AVG) – voorheen de Wet Bescherming Persoonsgegevens (WBP). Er wordt onderscheid gemaakt tussen drie verschillende situaties. Situatie 1: Video is een integraal onderdeel van de verschafte zorg, zoals in het geval van endoscopische chirurgie. Situatie 2: Opgenomen beelden zijn niet noodzakelijk om de behandeling uit te voeren, echter zijn wel van toegevoegde waarde. Situatie 3: Videobeelden worden voor andere doelen gebruikt dan het oorspronkelijk doeleinde. Voor de eerste situatie is toestemming voor het opnemen van videobeelden verweven met de toestemming voor het uitvoeren van de operatie conform de WGBO. Voor situatie 2 en 3 is aanvullende toestemming vereist voor het opnemen of gebruiken van videobeelden. De tweede kwestie is het bewaartermijn. Voor beelden die zijn toegevoegd aan het patiëntendossier wordt een bewaartermijn aangehouden van 15 jaar. Voor beelden welke niet in het patiëntendossier worden opgeslagen bestaat momenteel geen consensus ten aanzien van de bewaartermijn. Deze dient derhalve ook goed te worden gedefinieerd voorafgaand aan het vergaren van videobeelden.

Om het foutgevoelige narratieve operatieverslag te verbeteren experimenteren sommige zorgverleners met het synoptische operatieverslag. Een synoptisch operatieverslag is een methode van documenteren waarbij de essentiële onderdelen van een chirurgische ingreep in een samengevatte vorm wordt vastgelegd, vaak door gebruik te maken van sjabloon. Om de volledigheid en gebruiksgemak van het synoptische operatieverslag in vergelijking met het narratieve operatieverslag welke momenteel in gebruik is te onderzoeken hebben wij een systematic review uitgevoerd, waarvan de resultaten staan beschreven in **hoofdstuk 3**. Wij ondervonden dat de volledigheid over het algemeen, net als de volledigheid van subsecties bij het synoptische operatieverslag beter is dan dat van het narratieve operatieverslag. Bovendien kostte het minder tijd om een operatieverslag op te stellen als de synoptische methode wordt gebruikt.

Ondanks dat de beschikbaarheid van opnameapparatuur in de operatiekamer almaar toeneemt zijn de standpunten van hulpverleners dit aangaande nog onvoldoende bekend. Ten aanzien van mogelijke implementatie van intra-operatieve video- en geluidopname is de opinie van deze doelgroep van groot belang. In **hoofdstuk 4** zetten wij de resultaten van een enquête over dit onderwerp uiteen. Onder de respondenten is de helft van mening dat het operatieverslag in de huidige hoedanigheid onvoldoende is om aan toekomstige kwaliteitseisen te voldoen. Het merendeel erkent de toegevoegde waarde van intra-operatieve video-opnamen en, in mindere mate, geluidsopnamen. Daarnaast is meer dan de helft van de respondenten van mening dat het onwaarschijnlijk is dat hun gedrag wordt beïnvloed doordat zij op video worden opgenomen. Tevens meent de overgrote meerderheid, 82,8%, dat het onaannemelijk is dat zij hun chirurgische methoden zullen aanpassen door het feit dat er video-opnames plaatsvinden. Een aanzienlijk deel uitte wel hun zorgen voor schending van privacy in deze situaties.

In **Hoofdstuk 5** worden de effecten segmentatie op het leren van chirurgische ingreep – open correctie van hernia inguinalis (‘liesbreuk’) – aan de hand van een video module onderzocht. We maakten gebruik van ‘point-of-view’ video-opnames van geneeskundestudenten die een liesbreukcorrectie (Lichtenstein procedure) op een trainingsmodel uitvoerden nadat zij hadden deelgenomen aan ofwel een stapsgewijze ofwel een continue videodemonstratie van de ingreep. Vervolgens werden de videobeelden van deze ingrepen geanalyseerd waarbij het aantal procedurele en executionele fouten werden gescoord door gebruik te maken van een checklist (Observational Clinical Human Reliability Assessment – OCHRA). We leerden dat geneeskundestudenten in de stapsgewijze groep minder procedurele fouten maakten dan hun soortgenoten in de continue groep en tevens een lagere extraneous (irrelevante) cognitieve belasting ervoeren.

DEEL 2 – Zekeren van kwaliteit in colorectale oncologische chirurgie

Om de toegevoegde waarde van intra-operatieve videoregistratie te onderzoek hebben wij de ‘Imaging for Quality control trial’ (IQ-Trial) uitgevoerd. In deze studie onderzochten we de toegevoegde waarde van systematische intra-operatieve video-opnames van laparoscopische operaties voor dikkedarmkanker in het kader van kwaliteit en veiligheid en het vergaren van informatie. Deze studie bestond uit een pilot (**hoofdstuk 6**) waarmee we de haalbaarheid van systematische intra-operatieve video-opname onderzochten, en de hoofdstudie (**hoofdstuk 7**). Voor de pilot werden 15 laparoscopische operaties voor dikke darmkanker op video opgenomen door gebruik te maken van de standaard aanwezige endoscopische opnameapparatuur. De videobeelden van deze 15 operaties werden vervolgens vergeleken met 32 operaties uit het verleden met betrekking tot de beschikbaarheid van informatie (te weten vooraf bepaalde essentiële momenten van laparoscopische dikkedarmoperaties) tussen video's en het operatieverslag. We vonden een significant verschil in de beschikbaarheid van essentiële informatie ten faveure van video's, evenals een combinatie van video's en het operatieverslag.

Zodra de haalbaarheid van systematische video-opnamen was vastgesteld werd de hoofdstudie, een multicenter, prospectieve, observationele cohortstudie, uitgevoerd (**hoofdstuk 7**). In deze studie werden de operaties van 113 deelnemers opgenomen op video en geanalyseerd ten aanzien van de beschikbaarheid van informatie en vervolgens vergeleken met een identiek aantal case-matched operaties uit het verleden. Door gebruik te maken van intra-operatieve systematische video-opnames ontstond een significant betere verslaglegging (78,5% van de essentiële momenten adequaat weergeven door systematische video-opnamen en 85,1% adequaat weergeven door een combinatie van systematische video-opnamen in combinatie met het narratieve operatieverslag). Dit in tegenstelling tot slechts de helft van de essentiële momenten welke adequaat werd weergeven door het narratieve operatieverslag.

DEEL 3 – Kwaliteit en veiligheid bij laparoscopische cholecystectomie

Cholecystectomie is een van de meest uitgevoerde operaties van het moment, waarvan meer dan 80% laparoscopisch wordt verricht. Ondanks de voordelen van laparoscopisch opereren vergeleken met de traditionele 'open' benadering, is de het aantal galwegletsels, een ernstige complicatie van operaties aan de galwegen, drastisch toegenomen. Allerhande veiligheidsmaatregelen zijn ontwikkeld en onderzocht om deze stijging terug te brengen naar het oude niveau. In **hoofdstuk 8** beschrijven we een uitgebreide systematic review naar enkele van deze modaliteiten, waarin we onderscheid maken tussen chirurgische technieken specifiek gewijd aan dit probleem, (waaronder de 'Critical View of Safety' techniek, 'fundus first' laparoscopisch cholecystectomie en laparoscopische subtotale cholecystectomie), ondersteunende beeldvorming (waaronder intra-operatieve radiologische cholangiografie, intra-operatieve echografie en fluorescentie cholangiografie) en overige technieken. De toegewijde technieken zijn veelbelovend. Studies naar intra-operatieve radiologische cholangiografie en intra-operatieve echografie rapporteren eveneens gunstige resultaten ten aanzien van galwegwetselpreventie, echter deze technieken worden bemoeilijkt door een steile leercurve. Voor alle studies in dit review was de bewijskracht laag.

De Critical View of Safety techniek is een van de belangrijkste technieken om de kans op galwegletsel bij laparoscopische cholecystectomie te verkleinen. De kern van deze techniek is dat structuren welke doorgenomen gaan worden (dat wil zeggen de ductus cysticus en de arteria cystica) zonder twijfel geïdentificeerd dienen te worden en zonder accidentele schade toe te brengen aan de rest van de galwegen. Veel chirurgen gebruiken deze techniek, echter in welke hoedanigheid chirurgen en chirurgen in opleiding de Critical View of Safety techniek op een correcte manier uitvoeren is niet duidelijk. Om dit te onderzoeken hebben wij een landelijke enquête uitgevoerd onder chirurgen en chirurgen in opleiding naar de technieken die zij momenteel hanteren om laparoscopische cholecystectomie uit te voeren en hun kennis op het gebied van de Critical View of Safety techniek. De resultaten van deze enquête zijn gerapporteerd in **hoofdstuk 9**.

Nagenoeg alle respondenten gaven aan dat ze de Critical View of Safety techniek gebruiken in de dagelijkse praktijk. Echter, 72% voert daadwerkelijk de essentiële onderdelen van deze techniek in het merendeel van hun operaties uit. Verder was maar de helft van de respondenten in staat om adequaat de stappen van de Critical View of Safety techniek te identificeren. Slechts 16.9% kon deze stappen naar behoren onderscheiden van potentieel schadelijke handelingen. Het is noemenswaardig dat chirurgen in opleiding significant vaker dan chirurgen aangaven de stappen van de Critical View of Safety techniek uit te voeren.

In **hoofdstuk 10 en 11** onderzochten we de waarde van zowel intra-operatieve video- als geluidsopname in het kader van het documenteren van de operatie. Door de toevoeging van synchrone stemopnames van de operateur, naast intra-operatieve video-opnames, zou het mogelijk zijn een nieuwe dimensie toe te voegen aan een operatieverslag, doordat de overwegingen van de chirurg eveneens worden vastgelegd. Om de waarde hiervan te achterhalen voerden we een multicenter prospectieve observationele studie, waarin we onderzochten of met behulp van intra-operatieve stemopnamen gedurende laparoscopische cholecystectomie de discrepanties tussen video-opnamen en het operatieverslag verhelderd konden worden. Hiervoor werden 79 procedures opgenomen op video terwijl er simultaan geluidsopnames (spraak) werden gemaakt. De video-opnames leidde tot een betere weergaven van de inspectie van de galblaas, inspectie van de lever en de circumferentiële dissectie van de ductus cysticus en arteria cystica. Over het algemeen was de weergave van deze essentiële stappen door de videobeelden beter dan het narratieve operatieverslag. De simultaan opgenomen geluidsopnames leidde tot een significante afname van het aantal discrepanties tussen video-opnames en operatieverslagen.

Chapter 15

Appendices

APPENDIX A. SEARCH STRATEGY *(CHAPTER 3)*

Appendix A

Embase (1950–April 6, 2018)	((((synop* OR template* OR structured* OR structural* OR structuriz* OR structuris* OR standardi* OR checklist) NEAR/3 (report* OR operati*-note* OR operati*-documentation* OR surg*-note* OR surg*-documentation*)) OR (quality NEAR/3 (operati* OR surg*) NEAR/3 reporting)):ab,ti) AND ('surgery'/exp OR 'surgeon'/exp OR 'operating room'/de OR (surger* OR surgical* OR surgeon* OR ((operati*) NEAR/3 (room* OR theat* OR note* OR documentation* OR report*))):ab,ti) NOT ([Conference Abstract]/lim OR [Letter]/lim OR [Note]/lim OR [Editorial]/lim) AND [english]/lim
Ovid MEDLINE (1950–April 6, 2018)	((((synop* OR template* OR structured* OR structural* OR structuriz* OR structuris* OR standardi* OR checklist) ADJ3 (report* OR operati*-note* OR operati*-documentation* OR surg*-note* OR surg*-documentation*)) OR (quality ADJ3 (operati* OR surg*) ADJ3 reporting)).ab, ti.) AND (exp Surgical Procedures, Operative/ OR exp surgeons/ OR exp Operating Rooms/ OR (surger* OR surgical* OR surgeon* OR ((operati*) ADJ3 (room* OR theat* OR note* OR documentation* OR report*))).ab, ti.) NOT (letter* OR news OR comment* OR editorial* OR congres* OR abstract* OR book* OR chapter* OR dissertation abstract*).pt. AND english.la.
Web of Science (1988–April 6, 2018)	TS=(((((synop* OR template* OR structured* OR structural* OR structuriz* OR structuris* OR standardi* OR checklist) NEAR/2 (report* OR operati*-note* OR operati*-documentation* OR surg*-note* OR surg*-documentation*)) OR (quality NEAR/2 (operati* OR surg*) NEAR/2 reporting))) AND ((surger* OR surgical* OR surgeon* OR ((operati*) NEAR/2 (room* OR theat* OR note* OR documentation* OR report*))))) AND DT=(article) AND LA=(english)
Cochrane Central (1998–April 6, 2018)	((((synop* OR template* OR structured* OR structural* OR structuriz* OR structuris* OR standardi* OR checklist) NEAR/3 (report* OR operati*-note* OR operati*-documentation* OR surg*-note* OR surg*-documentation*)) OR (quality NEAR/3 (operati* OR surg*) NEAR/3 reporting)):ab,ti) AND ((surger* OR surgical* OR surgeon* OR ((operati*) NEAR/3 (room* OR theat* OR note* OR documentation* OR report*))):ab,ti)
Google Scholar (1991–April 6, 2018)	"synoptic|structured|structural|structurized|structurised report|reporting"|"synoptic|structured|structural|structurised|standardized operative|operation|surgical note|documentation" surgery|surgical|surgeon|"operative|operating room|theater"

APPENDIX B. SURVEY (TRANSLATED FROM DUTCH) *(CHAPTER 4)*

Demographic data

Question 1. *What is your current function?*

- o Surgeon
- o Gynecologist
- o Urologist
- o Resident in training
- o Retired specialist
- o Other (specify)

Question 2A. *(if surgeon) What is your subspecialization? (Multiple answers possible)*

- o Surgical Oncology
- o Gastrointestinal Surgery
- o Hepatopancreaticobiliary Surgery
- o Pediatric Surgery
- o Pulmonary Surgery
- o Trauma Surgery
- o Vascular Surgery
- o Not applicable

Question 2B. *(if gynecologist) What is your subspecialization? (Multiple answers possible)*

- o General Gynecology
- o Maternal-Fetal Medicine
- o Reproductive Endocrinology and Infertility
- o Urogynecology
- o Gynecological Oncology
- o Not applicable

Question 2C. *(if urologist) What is your subspecialization? (Multiple answers possible)*

- o General Urology
- o Andrological Urology
- o Endourology and Stone Disease
- o Functional and Reconstructive Urology
- o Pediatric Urology
- o Not applicable

Question 2D. *(if resident in training) For what specialty are you in training?*

- o Surgery

- o Gynecology
- o Urology

Question 3A. *(If surgeon, gynecologist or urologist) How many years are you practicing surgery?*

- o <5 years
- o 5 to 10 years
- o 10 to 15 years
- o 15 to 20 years
- o >20 years

Question 3B. *(If resident) What year of the training are you currently in?*

- o Year 1
- o Year 2
- o Year 3
- o Year 4
- o Year 5
- o Year 6

Question 4. *What is your workplace?*

- o University hospital
- o General teaching hospital
- o General non-teaching hospital
- o Other (specify)

Current use of operative reporting

Question 5. *Do you think that the currently used narrative operative report – without video and/or sound – is sufficient for future quality requirements?*

- o Yes
- o No

Question 6. *As far as you are aware, which techniques are currently used to document surgical procedures in your department? (Multiple answers possible)*

- o Endoscopic camera
- o External camera recording the surroundings of the operating room
- o External camera recording the surgical field (e.g. camera in the OR light)
- o Surgical Black Box
- o Mobile phone (picture/video/sound)
- o Audio recording (microphone)

- o Other (specify)
- o None of the above

Question 7. *Is routine video recording during conventional ('open') surgical procedures currently taking place in your department?*

- o Yes
- o No
- o Don't know

Question 8. *Is routine video recording during endoscopic surgical procedures currently taking place in your department?*

- o Yes
- o No
- o Don't know

Question 9. *If surgical procedures are recorded on video in your institution, what is the retention period of these recordings?*

- o <30 days
- o 30 to 90 days
- o 90 days to 1 year
- o >1 year
- o Don't know

Current use of multimedia in the operating room

Question 10. *Please indicate of the following actions in what frequency you apply them.*

	Never	Rarely	Sometimes	Regularly	Always
In current practice, do you make video recordings of endoscopic surgical procedures	○	○	○	○	○
In current practice, do you make video recordings of conventional ('open') surgical procedures	○	○	○	○	○

Question 11. *If you record your surgical procedures on video, for what purposes? (Multiple answers are possible)*

- o Addition to patient file
- o For quality control purposes
- o For educational purposes

- o In the context of proctoring
- o To provide information for patients, patients' family and/or colleagues
- o Other

Question 12. *Please indicate for the following statements to what extent you agree.*

	Very unlikely	Unlikely	Neutral	Likely	Very likely
I would ***behave*** differently in the operating room when video recording is taking place	○	○	○	○	○
I would ***perform surgery*** differently in the operating room when video recording is taking place	○	○	○	○	○
I would ***behave*** differently in the operating room when video ***and*** audio recording is taking place	○	○	○	○	○
I would ***perform surgery*** differently in the operating room when video ***and*** audio recording is taking place	○	○	○	○	○

Question 13. *Please indicate for the following situations, in the context of intraoperative video recording, to what extent you find it objectionable.*

	Not at all objectionable	Not objectionable	Neutral	Objectionable	Very objectionable
Recognizability of my or my colleague's identity on the video recordings	○	○	○	○	○
Potential for medical liability	○	○	○	○	○
Harmful for the quality of surgical care	○	○	○	○	○

Question 14. *Please indicate for the following situations to what extent intraoperative* ***video recording*** *might be of added value.*

	Very unlikely	Unlikely	Neutral	Likely	Very likely
Documenting the operative phase as an addition to the patient file	○	○	○	○	○
For educational purposes	○	○	○	○	○
To provide information for patients, family and/or colleagues	○	○	○	○	○
For quality control purposes	○	○	○	○	○
In the context of proctoring	○	○	○	○	○
Supportive evidence in medicolegal proceedings	○	○	○	○	○

Question 15. *Please indicate for the following situations to what extent intraoperative **video and audio recording** might be of added value.*

	Very unlikely	Unlikely	Neutral	Likely	Very likely
Documenting the operative phase as an addition to the patient file	○	○	○	○	○
For educational purposes	○	○	○	○	○
To provide information for patients, family and/or colleagues	○	○	○	○	○
For quality control purposes	○	○	○	○	○
In the context of proctoring	○	○	○	○	○
Supportive evidence in medicolegal proceedings	○	○	○	○	○

Question 16. *Regarding documentation of surgical procedures, which of the following scenarios would you prefer?*

o Video recordings of the entire surgical procedure
o Video recordings of only the essential steps of the surgical procedure
o Video and audio recordings of the entire surgical procedure
o Video and audio recordings of only the essential steps of the surgical procedure
o No video and audio recordings

APPENDIX C. CASE REPORT FORMS *(CHAPTER 6 AND 7)*

LAPAROSCOPIC RIGHT HEMICOLECTOMY

PATIENT IDENTIFICATION NUMBER ……………………………… DATE . . / . . / . . . .

INDICATION ………………………………………………………………………

SURGICAL PROCEDURE(S) PERFORMED ………………………………………………………………………

SURGEON (INITIALS, LAST NAME) ………………………………………………………………………

VIDEO DOCUMENTATION TECHNIQUE ☐ GOPRO CAMERA
☐ OTHER CAMERA: ……………………………………..

VIDEO DOCUMENTATION (PLEASE CHECK BOX OF EVERY RECORDED STEP OR WRITE N/A IF THIS STEP IS NOT APPLICABLE FOR YOUR PROCEDURE)			
STEP 1			
1	Introduction of trocars under vision	10sec	☐
STEP 2: EXPLORATION			
2A	Liver: right and left lobe	10sec	☐
2B	Parietal peritoneum: including falciform and teres ligament	10sec	☐
2C	Tumor: including ink	10sec	☐
STEP 3: VASCULAR CONTROL			
3A	Ligation level of ileocolic artery and vein	10sec	☐
3B	Ligation of right colic artery and vein (if present) and/or right branches of middle colic artery and vein	10sec	☐
3C	In case of extended right hemicolectomy: ligation of middle colic artery and vein	10sec	☐
STEP 4: MOBILIZATION AND RESECTION			
4A	Transection of distal ileum (within 10cm from ileocecal valve; intracorporeal or extracorporeal)	10sec	☐
4B	Specimen (with unfolded mesentery)	10sec	☐
STEP 5: ANASTOMOSIS			
5A	Anastomosis	10sec	☐
5B	Laparoscopic check of rotation of ascending (ileal) loop	10sec	☐
STEP 6: CLOSURE			
6	Intraperitoneal trocar sites after removal of trocars	10sec	☐
UNEXPECTED FINDINGS			
………			☐

LAPAROSCOPIC TRANSVERSE COLECTOMY

PATIENT IDENTIFICATION NUMBER ……………………………… DATE . . / . . / . . . .

INDICATION ……………………………………………………………………………

SURGICAL PROCEDURE(S) PERFORMED ……………………………………………………………………………

SURGEON (INITIALS, LAST NAME) ……………………………………………………………………………

VIDEO DOCUMENTATION TECHNIQUE ☐ GOPRO CAMERA
☐ OTHER CAMERA: ……………………………………..

VIDEO DOCUMENTATION (PLEASE CHECK BOX OF EVERY RECORDED STEP OR WRITE N/A IF THIS STEP IS NOT APPLICABLE FOR YOUR PROCEDURE)			
STEP 1			
1	Introduction of trocars under vision	10sec	☐
STEP 2: EXPLORATION			
2A	Liver: right and left lobe	10sec	☐
2B	Parietal peritoneum: including falciform and teres ligament	10sec	☐
2C	Tumor: including ink	10sec	☐
STEP 3: VASCULAR CONTROL			
3	Proximal ligation of middle colic artery and vein	10sec	☐
STEP 4: MOBILIZATION AND RESECTION			
4A	Mobilization of splenic flexure (imaging of spleen)	10sec	☐
4B	Specimen (with unfolded mesentery)	10sec	☐
STEP 5			
5	Anastomosis	10sec	☐
STEP 6: CLOSURE			
6	Intraperitoneal trocar sites after removal of trocars	10sec	☐
UNEXPECTED FINDINGS			
………			☐

LAPAROSCOPIC LEFT HEMICOLECTOMY

PATIENT IDENTIFICATION NUMBER ……………………………… DATE . . / . . / . . . .

INDICATION …………………………………………………………………………

SURGICAL PROCEDURE(S) PERFORMED …………………………………………………………………………

SURGEON (INITIALS, LAST NAME) …………………………………………………………………………

VIDEO DOCUMENTATION TECHNIQUE ☐ GOPRO CAMERA
☐ OTHER CAMERA: ……………………………………..

VIDEO DOCUMENTATION (PLEASE CHECK BOX OF EVERY RECORDED STEP OR WRITE N/A IF THIS STEP IS NOT APPLICABLE FOR YOUR PROCEDURE)			
STEP 1			
1	Introduction of trocars under vision	10sec	☐
STEP 2: EXPLORATION			
2A	Liver: right and left lobe	10sec	☐
2B	Parietal peritoneum: including falciform and teres ligament	10sec	☐
2C	Tumor: including ink	10sec	☐
STEP 3: VASCULAR CONTROL			
3A	Ligation level of left colic artery and vein at level of origin from inferior mesenteric artery, sigmoid arteries and vein	10sec	☐
3B	Ligation of left branches of middle colic artery and vein	10sec	☐
3C	In case of extended left hemicolectomy: ligation of middle colic artery and vein	10sec	☐
STEP 4: MOBILIZATION AND RESECTION			
4A	Mobilization of splenic flexure (imaging of spleen)	10sec	☐
4B	Identification of left ureter (manipulation)	10sec	☐
4C	Specimen (with unfolded mesentery)	10sec	☐
STEP 5			
5	Anastomosis	10sec	☐
STEP 6: CLOSURE			
6	Intraperitoneal trocar sites after removal of trocars	10sec	☐
UNEXPECTED FINDINGS			
……			☐

LAPAROSCOPIC SIGMOIDECTOMY

PATIENT IDENTIFICATION NUMBER ……………………………… DATE . . / . . / . . . .

INDICATION ……………………………………………………………………………

SURGICAL PROCEDURE(S) PERFORMED ……………………………………………………………………………

SURGEON (INITIALS, LAST NAME) ……………………………………………………………………………

VIDEO DOCUMENTATION TECHNIQUE ☐ GOPRO CAMERA
☐ OTHER CAMERA: ……………………………………..

VIDEO DOCUMENTATION (PLEASE CHECK BOX OF EVERY RECORDED STEP OR WRITE N/A IF THIS STEP IS NOT APPLICABLE FOR YOUR PROCEDURE)			
STEP 1			
1	Introduction of trocars under vision	10sec	☐
STEP 2: EXPLORATION			
2A	Liver: right and left lobe	10sec	☐
2B	Parietal peritoneum: including falciform and teres ligament	10sec	☐
2C	Tumor: including ink	10sec	☐
STEP 3: VASCULAR CONTROL			
3	Ligation of arteries and veins	10sec	☐
STEP 4: MOBILIZATION AND RESECTION			
4A	Identification of left ureter (manipulation)	10sec	☐
4B	Specimen (with unfolded mesentery)	10sec	☐
STEP 5: ANASTOMOSIS			
5A	Perforation of stapler pin through or near (<1cm) stapler line	10sec	☐
5B	Donuts	10sec	☐
5C	Anastomosis	10sec	☐
5D	Anastomotic (air) leak test	10sec	☐
STEP 6: CLOSURE			
6	Intraperitoneal trocar sites after removal of trocars	10sec	☐
UNEXPECTED FINDINGS			
……			☐

LAPAROSCOPIC (LOW) ANTERIOR AND ABDOMINOPERINEAL RESECTION

PATIENT IDENTIFICATION NUMBER ……………………………… DATE . . / . . / . . . .

INDICATION …………………………………………………………………………

SURGICAL PROCEDURE(S) PERFORMED …………………………………………………………………………

SURGEON (INITIALS, LAST NAME) …………………………………………………………………………

VIDEO DOCUMENTATION TECHNIQUE ☐ GOPRO CAMERA
☐ OTHER CAMERA: ……………………………………..

VIDEO DOCUMENTATION (PLEASE CHECK BOX OF EVERY RECORDED STEP OR WRITE N/A IF THIS STEP IS NOT APPLICABLE FOR YOUR PROCEDURE)			
STEP 1			
1	Introduction of trocars under vision	10sec	☐
STEP 2: EXPLORATION			
2A	Liver: right and left lobe	10sec	☐
2B	Parietal peritoneum: including falciform and teres ligament	10sec	☐
2C	Tumor: including ink	10sec	☐
STEP 3: VASCULAR CONTROL			
3A	Low tie (ligation of upper rectal artery at bifurcation of inferior mesenteric and left colic arteries) or high tie	10sec	☐
STEP 4: MOBILIZATION AND RESECTION			
4A	Identification of left ureter (manipulation)	10sec	☐
4B	Specimen (with unfolded mesentery)	10sec	☐
4C	Identification of hypogastric nerves ("wishbone")	10sec	☐
STEP 5: ANASTOMOSIS			
5A	Perforation of stapler pin through or near (<1cm) stapler line	10sec	☐
5B	Donuts	10sec	☐
5C	Anastomosis	10sec	☐
5D	Air leak test of anastomosis	10sec	☐
STEP 6: CLOSURE			
6	Intraperitoneal trocar sites after removal of trocars	10sec	☐
UNEXPECTED FINDINGS			
……			☐

APPENDIX D. REQUIREMENTS FOR ADEQUATE RECORDING AND REPORTING *(CHAPTER 6 AND 7)*

Requirements for an adequate recording

Step 1: Introduction of trocars under vision:

- Complete visualization of the introduction of all trocars.

Step 2: Exploration

- Complete visualization of right and left liver lobe, both anterior and posterior planes.
- Complete visualization of the tumor and its surrounding tissue before dissection, including ink marker if present.
- Complete visualization of the parietal peritoneum of the abdomen.

Step 3: Vascular control

- Ligation of identified artery and vein.
- If vascular structures are spared, these should be identifiable on the recording.

Step 4: Mobilization and Resection

- In **right hemicolectomy**: The terminal ileum should be transected within 10cm of the ileocecal valve. The amount of terminal ileum resected must be visualized during resection or identified in the specimen
- In **transverse colectomy** or **left hemicolectomy**: after mobilization of the splenic flexure of the colon, an intact spleen should be visible or, if damaged, after hemostasis.
- In **left hemicolectomy**, **sigmoidectomy** or **low anterior resection/abdominoperineal resection**: The left ureter should be identified.
- The resected specimen should be recorded extracorporeal, identifying all of the following elements: tumor (including ink, if present), vessels and unfolded mesentery.

Step 5: Anastomosis

- The anastomosis should be recorded laparoscopic or extra-corporeal, containing the following aspects: tension, interposition and vascularization.
- In sigmoidectomy or low anterior resection/abdominoperineal resection: If the anastomosis is created using the transanal circular stapler:

o Perforation of the distal part of the anastomosis by the transanal stapler pin.
o After removal, donuts should be recorded demonstrating structural integrity.

Step 6: Closure

- The removal of all trocars should be recorded, showing the intraperitoneal trocar sites after removal.

Requirements for an adequate reporting

Step 1: Introduction of trocars under vision:
- Mentioning of trocars introduced under vision

Step 2: Exploration
- Mentioning of visualization of liver with observation.
- Mentioning of tumor visualization and its surrounding tissue, including ink marker (if present).
- Mentioning of visualization of the parietal peritoneum of the abdomen.

Step 3: Vascular control
- Mentioning of identification and ligation of artery and vein.

Step 4: Mobilization and Resection
- In **right hemicolectomy**: The terminal ileum should be transected within 10cm of the ileocecal valve, approximate length should be mentioned.
- In **transverse colectomy** or **left hemicolectomy**: Mobilization of the splenic flexure of the colon should be mentioned, including observation of intact spleen or possible damage followed by intervention
- In **left hemicolectomy**, **sigmoidectomy** or **low anterior resection/abdominoperineal resection**: mentioning of identification of the left ureter.
- Mentioning of investigation of the resected specimen post resection.

Step 5: Anastomosis
- Mentioning of the quality of the anastomosis, including the following aspects: tension, interposition and vascularization (color).
- In sigmoidectomy or low anterior resection/abdominoperineal resection: If the anastomosis is created using the transanal circular stapler:

o Description of the process of creating the anastomosis, including: perforation of the distal part of the anastomosis by the transanal stapler pin and the quality of the donuts

Step 6: Closure
- Mentioning of the removal of trocars under vision.

APPENDIX E. SEARCH STRATEGY *(CHAPTER 8)*

Appendix E

Embase	('cholecystectomy'/exp OR 'cholecystitis'/de OR (cholecystectom* OR cholecystit* OR (gallbladder NEAR/3 (resect*))):ab,ti) AND ('laparoscopy'/exp OR 'laparoscope'/de OR 'endoscope'/de OR endoscopy/de OR 'endoscopic surgery'/de OR 'minimally invasive procedure'/exp OR (laparoscop* OR celioscop* OR endoscop* OR Laparoendoscop* OR (minmal* NEAR/3 invasiv*)):ab,ti) AND ('peroperative cholangiography'/de OR 'fluorescence imaging'/de OR 'fluorescence imaging system'/de OR 'near infrared imaging system'/de OR (('bile duct injury'/de OR 'bile leakage'/de) AND (prevention/de OR prevention:lnk OR 'protection'/de OR 'risk reduction'/de OR 'education'/de)) OR ((Peroperati* NEAR/3 (echogra* OR ultraso*)) OR ((prevent* OR protect* OR reduc* OR avoid* OR technique* OR training OR teaching OR educat*) NEAR/6 (bile-duct*)) OR (safet* NEAR/3 critical-view) OR (gallbladder* NEAR/3 antegrade NEAR/3 dissect*) OR (fundus NEAR/3 first NEAR/3 dissect*) OR infundibul*):ab,ti) NOT ([Conference Abstract]/lim OR [Letter]/lim OR [Note]/lim OR [Editorial]/lim) AND [english]/lim
Ovid MEDLINE	(exp "cholecystectomy"/ OR "cholecystitis"/ OR (cholecystectom* OR cholecystit* OR (gallbladder ADJ3 (resect*))).ab,ti,kf.) AND (exp "Laparoscopy"/ OR "Laparoscopes"/ OR "endoscopes"/ OR endoscopy/ OR "Natural Orifice Endoscopic Surgery"/ OR "Minimally Invasive Surgical Procedures"/ OR (laparoscop* OR celioscop* OR endoscop* OR Laparoendoscop* OR (minmal* ADJ3 invasiv*)).ab,ti,kf.) AND (("Cholangiography"/ AND "Intraoperative Care"/) OR (("Bile Ducts"/in) AND ("prevention and control".xs. OR "education"/)) OR ((Peroperati* ADJ3 (echogra* OR ultraso*)) OR ((prevent* OR protect* OR reduc* OR avoid* OR technique* OR training OR teaching OR educat*) ADJ6 (bile-duct*)) OR (safet* ADJ3 critical-view) OR (gallbladder* ADJ3 antegrade ADJ3 dissect*) OR (fundus ADJ3 first ADJ3 dissect*) OR infundibul*).ab,ti,kf.) NOT ((letter OR news OR comment OR editorial OR congresses OR abstracts).pt.) AND english.la.
Cochrane Central	((cholecystectom* OR cholecystit* OR (gallbladder NEAR/3 (resect*))):ab,ti) AND ((laparoscop* OR celioscop* OR endoscop* OR Laparoendoscop* OR (minmal* NEAR/3 invasiv*)):ab,ti) AND (((Peroperati* NEAR/3 (echogra* OR ultraso*)) OR ((prevent* OR protect* OR reduc* OR avoid* OR technique* OR training OR teaching OR educat*) NEAR/6 (bile-duct*)) OR (safet* NEAR/3 critical-view) OR (gallbladder* NEAR/3 antegrade NEAR/3 dissect*) OR (fundus NEAR/3 first NEAR/3 dissect*) OR infundibul*):ab,ti)
Web of Science	TS=(((cholecystectom* OR cholecystit* OR (gallbladder NEAR/2 (resect*)))) AND ((laparoscop* OR celioscop* OR endoscop* OR Laparoendoscop* OR (minmal* NEAR/2 invasiv*))) AND (((Peroperati* NEAR/2 (echogra* OR ultraso*)) OR ((prevent* OR protect* OR reduc* OR avoid* OR technique* OR training OR teaching OR educat*) NEAR/5 (bile-duct*)) OR (safet* NEAR/2 critical-view) OR (gallbladder* NEAR/2 antegrade NEAR/2 dissect*) OR (fundus NEAR/2 first NEAR/2 dissect*) OR infundibul*))) AND DT=(article) AND LA=(english)
Google Scholar	cholecystectomy|"gallbladder resection" laparoscopy|laparoscopic|endoscopic|Laparoendoscopic|"minmally invasivive" prevention|protection|reduction "bile duct"

APPENDIX F. SUPPLEMENTAL TABLES *(CHAPTER 8)*

Table 1. Dedicated surgical approaches.

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N (%)	Additional outcomes	Author's conclusion	In favour of technique
Critical view of safety									
Avgerinos et al. (2009)	2002-2007	Retrospective study	3	CVS	1046	0	CVS was achieved in 998 (95.4%), 5 bile leaks (0.48%), conversion in 27 (2.6%)	CVS clarifies the relations of the anatomic structures that should be divided and should be routinely applied because of its highly protective role against BDI	+
Kaya et al. (2017)	2015-2016	Prospective study	4	CVS combined with hydrodissection	120	0	CVS was achieved in all cases (100%), no bile leaks, no conversion occurred in this series.	CVS and hydrodissection techniques minimize BDI during LC	+
Rawlings et al. (2010)	2008-2009	Technique	4	CVS in SILC	54	0	CVS was achieved in all cases (100%), IOC was attempted in all cases and successful in 50 (93%), no bile leaks, no conversion occurred in this series.	CVS can be routinely accomplished with SILC	+/-
Sanjay et al. (2010)	2004-2007	Retrospective study	4	CVS with selective IOC	447	0	CVS was achieved in 388 (87%), IOC performed in 57 (12.8%), no bile leaks, conversion in 47 (10.5%)	CVS is a feasible and safe alternative to routine IOC in patients presenting with acute biliary pathology	+
Tsalis et al. (2015)	2000-2012	Retrospective study	3	CVS	929	0	CVS was achieved in 873 of 911 (95.82%), Conversion in 38 (4.1%), no bile leaks	Using the CVS technique for the identification of the CD is the safest way to perform and teach LC.	+
Vettoretto et al. (2011)	2009-2010	Retrospective study	4	CVS vs. IT	90 CVS 84 IT	0	1 bile leak, conversions were excluded from analysis, no difference in terms of morbidity and outcome	The CVS technique is suggested as the gold standard for resident teaching, because it has a similar rate of biliary and haemorrhagic complications but has a shorter operative time	+
Yegiyants et al. (2008)	2002-2006	Retrospective study	3	CVS as dominant technique in institution	3042	1 (0.03)	BDI occurred in difficult procedure before CVS was established	CVS can reduce BDI and should be incorporated in the surgical curriculum	+

Table 1. Dedicated surgical approaches. (continued)

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N (%)	Additional outcomes	Author's conclusion	In favour of technique
Fundus first laparoscopic cholecystectomy									
Cui et al. (2012)	2009	Technique	4	FFLC in SILC	16	0	No complications were observed	SILC using a modified dome-down approach is technically feasible and safe	+
Mahmud et al. (2002)	1993-2000	Retrospective study	3	FFLC	710	0	FFLC was performed in 35 (5%) and successful in 31 (89%), 1 bile leak in the FFLC group (2.9%), conversion in 9 (1.2%).	FFLC is a feasible and safe option when dealing with a difficult LC. The conversion rate is significantly reduced	+
Martin et al. (1995)	1990-1993	Retrospective study	4	FFLC	333	0	FFLC was performed in 53 (16%) and successful in 52 (98%). In the FFLC group: No BDI, 1 bile leak (2%), conversion in 1 (2%).	Data too preliminary to conclude that FFLC will significantly improve the outcome of LC. Potential benefits are present.	+/-
Raj et al. (2001)	2001	Technique	4	FFLC	50	0	No complications, no unusual technical difficulties	The fundus-down technique of LC may lower the incidence of common bile duct injury	+/-
Rosenberg et al. (2004)	2004	Prospective study	4	FFLC	20	0	No complications	The laparoscopic dome down technique for laparoscopic cholecystectomy seems promising especially in cases of acute inflammation and in fibrosis or contraction of triangle of Calot.	+
Tuveri et al. (2008)	1994-2005	Retrospective study	3	FFLC	1965	2 (0.1)	FFLC was performed in 29 (1.5%), and successful in 23 (80%), 2 bile leaks (0.1%), conversion in 6 (0.3%)	FFLC remains a safe option when dealing with patients with difficult anatomy at the Calot's triangle	+

Table 1. Dedicated surgical approaches. (continued)

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N (%)		Additional outcomes	Author's conclusion	In favour of technique
Laparoscopic subtotal cholecystectomy										
Beldi et al. (2003)	1995-2000	Retrospective study	3	LSC	345	1	(0.29)	LSC was performed in 46 (13.3%) and successful in 37 (80.4%), 33 bile leaks (9.6%), conversion occurred in 13 (3.8%) of which 9 in the LSC group (19.6%)	LSC offers a feasible and safe way to prevent BDI and lower the conversion rate in technically difficult, severely acute, and chronic cholecystitis	+
Hubert et al. (2010)	2004-2007	Retrospective study	4	Endovesicular LSC with IOC	500	0		Endovesicular LSC was performed in 39 (7.8%) and successful in all (100%), IOC was attempted in all 39 cases and successful in 31 (79.5%), no bile leaks, conversion in 10 (2%)	the endovesicular approach to the gallbladder followed by LSC is an effective and safe technical alternative to the classic external Calot's triangle dissection during LC when there is severe inflammation or difficult local conditions.	+
Kuwabara et al. (2014)	2005-2008	Retrospective study	4	LSC vs. Conventional LC	246	0		LSC was performed in 26 (10.6%), no bile leaks, no conversion occurred	Performing LSC for acute cholecystitis is safe and particularly effective in patients unable to undergo early surgery.	+
Nakajima et al. (2009)	1992-2008	Retrospective study	3	LSC	1226	12	(1.0)	Before introduction of LSC (n=643): BDI occurred in 10 (1.6%), conversion in 16 (2.5%); After introduction of LSC (n=583): LSC was performed in 60 (10.3%), BDI occurred in 2 (0.3%), no bile leaks, Conversion in 2 (0.3%)	LSC is safe and effective for preventing BDI and lowering the conversion rate in patients with technically difficult severe cholecystitis.	+
Philips et al. (2008)	2001-2004	Retrospective study	4	LSC	1917	NR		LSC was performed in 26 (1.4%), 4 bile leaks in the LSC group (15.4%)	When conventional LC is not possible, LSC is a viable and acceptable alternative to conversion to OC. It avoids the risk of major BDI.	+
Tian et al. (2009)	2004-2007	Retrospective study	4	LSC	1558	NR		LSC was performed in 48 (3.1%) in which 4 bile leaks (6.3%) occurred. No conversion or BDI occurred in the LSC group	LSC is a safe and feasible alternative to conversion to open surgery during difficult LC for patients with complicated cholecystitis.	+

Table 1. Dedicated surgical approaches. (continued)

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N (%)		Additional outcomes	Author's conclusion	In favour of technique
Yoon et al. (2016)	2012-2014	Retrospective Study	4	LSC with routine IOC	404	1	(0.25)	LSC was performed in 23 (5.7%), 7 bile leaks (1.7) of which 5 in the LSC group (22%), conversion in 8 (2%). No BDI occurred in the LSC group	LSC is a viable alternative to conversion in cases of difficult laparoscopic cholecystectomy	+

*BDI b*ile duct injury, *CBD* common bile duct, *CD* cystic duct, *CHD* common hepatic duct, *CVS* Critical view of safety, *FFLC* Fundus first laparoscopic cholecystectomy, *IOC* intraoperative cholangiography, *IOUS* intraoperative ultrasonography, *IT* Infundibular technique *LC* laparoscopic cholecystectomy, *LSC* laparoscopic subtotal cholecystectomy, *NR* Not reported, *OC* Open cholecystectomy, *SILC* Single incision laparoscopic cholecystectomy.

Table 2. IOC

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N (%)		Additional outcomes	Author's conclusion	In favor of IOC
Intraoperative radiologic cholangiography in general										
Akolekar et al. (2009)	2000-2003	Retrospective study	3	IOC	1651	2	(0.12)	IOC attempted in 745 (45.1%) and successful in (88.6%).	Possible role of IOC in BDI prevention, interpretation can be difficult	+/-
Caratozzolo et al. (2004)	1993-2001	Retrospective study	3	IOC	1074	1	(0.08)	IOC attempted in 993 (83%) and successful in 802 (80.7%). 6 Bile leaks (0.56%)	IOC and timely conversion may help to significantly reduce major BDI	+
Ding et al. (2015)	2012-2014	Randomized Controlled Trial	2	Routine LC vs. LC + IOC	404	2	(0.54)	BDI rate and conversion rate similar between the two groups; BDI: 1 in 185 (0.54%) vs. 1 in 186 (0.54%), Conversion in 3 of 185 (1.6%) vs 4 in 186 (2.1%). Bile leak 1 in 185 (0.54%) vs 0 in 186	No statistically significant advantage for the use of IOC during LC for the improvement of BDI rates	-
Fletcher et al. (1999)	1988-1994	Retrospective study	3	Incidence of BDI in a population based study with relation to IOC	7675	25	(0.32)	Per period; 1988-1990 (n=15): 1 BDI (6.66%), 0 bile leaks. 1991-1992 (n=2593): 9 BDI (0.35%), 7 Bile leaks (0.27%). 1993-1994 (n=5067): 15 BDI (0.30%), 26 bile leaks (0.51%). OR for all injuries and leaks using IOC = 0.5	One third of all cases of BDI might be prevented by the routine use of IOC	+
Flum et al. (2001)	1991-1998	Retrospective study	2	IOC and surgeon's experience in relation to CBD injury	30630	76	(0.25)	Incidence BDI significantly lower with IOC use: 2.0 vs. 3.3 per 1000)	Increased use of IOC should be considered	+
Routine intraoperative radiologic cholangiography										
Alvarez et al. (2014)	1991-2012	Retrospective study	3	IOC; routine	11423	20	(0.17)	IOC successful in 10932 (95.7%). 5 bile leaks (0.04%). Sensitivity and specificity for detection of BDI using IOC (respectively): 79% and 100%	IOC is suitable for BDI prevention	+
Carroll et al. (1996)	1989-1995	Retrospective study	4	IOC; routine	3242	12	(0.37)	11 of 12 (92%) BDIs were detected peroperatively and successfuly repaired	Routine IOC increases the early identification of BDI. Early recognition reduces the severity, cost, and consequences of BDI	+
Cox et al. (1994)	1991-1992	Retrospective study	4	IOC; routine + gallbladder-down dissection technique	410	1	(0.24)	IOC successful in 356 (87%). Conversion in 54 (13%). 7 bile leaks (1.7%)	The gallbladder-down dissection technique for LC is a safe method that avoids injury to the CBD. The routine use of IOC prevents clip application across a tented bile duct and may detect any BDI	+

Table 2. IOC (continued)

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N (%)	Additional outcomes	Author's conclusion	In favor of IOC
Ido et al. (1996)	1990-1993	Retrospective study	4	Combination of technique combined with routine IOC	802	0	Conversion in 3 (0.4%)	IOC can facilitate in the confirmation of a safety zone for BDI prevention in LC	+
Jones et al. (1995)	1992-1994	Prospective study	4	IOC; routine	356	0	IOC successful in 328 (95%). Conversion in 11 (3%). 1 bile leak (0.3%)	IOC is accurate, safe, permits rapid evaluation of the biliary tree, and facilitates management of CBD stones	+
Kullman et al. (1996)	1991-1994	Prospective study	4	IOC; routine	630	3 (0.5)	IOC successful in 591 (98%). 4 bile leaks (0.6%)	These results show that routine IOC is feasible and provides valuable information about the anatomy of the biliary tract, thereby improving the safety of laparoscopic cholecystectomy	+
Kumar et al. (2015)	2013-2014	Prospective study	4	IOC; routine	100	0	IOC successful in 92 (92%)	IOC was successful and safe. Operating time was significantly longer. Very little useful clinical information compared to the selective use of IOC	+/-
Nassar et al. (2016)	1992-2014	Retrospective study	4	IOC; routine	4088	2 (0.05)	IOC attempted in 3691 (90.2%) and successful in 3635 (98.4%). Conversion 26 (0.7%). 14 bile leaks (0.34%). Both BDI occurred before IOC was performed	IOC can be routinely and safely performed in LC and should be considered for routine use	+
Noji et al. (2011)	2000-2010	Retrospective study	4	IOC; routine	1835	NR	ENBD was used in 38 (2.1%). 1 BDI occurred in the ENBD group (2.6%). Conversion in 1 (2.6%) of the ENBD group vs 106 (5.9%) in the standard LC group	ENBD tube placement prior to LC may have successfuly decreased the incidence of complications	+
Panton et al. (1995)	1991-1993	Retrospective study	4	IOC; routine	236	0	IOC attempted in 224 (94%) and successful in 198 (89%). Conversion in 10 (4%). bile leaks in 4 (2%)	Data supports that LC is safe and that IOC has a rol in identifying anomalies and the prevention of BDI	+
Photi et al. (2017)	2013-2015	Retrospective study	4	IOC; routine	1005	0	IOC successful in 997 (99.2%). Conversion in 6 (0.4%). 3 bile leaks (0.3%)	high-volume routine IOC is associated with a low risk of BDI and can be performed safely in emergency and elective cases	+
Stuart et al. (1998)	1995-1996	Retrospective study	4	IOC; routine	669	0	IOC attempted in 606 (90.5%) and successful in 566 (93%). Conversion in 63 (9%)	IOC is safe, quick, detects unsuspected choledocholithiasis, and can prevent common bile duct transection. It should be routine.	+

Table 2. IOC (continued)

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N	(%)	Additional outcomes	Author's conclusion	In favor of IOC
Tornqvist et al. (2015)	2005-2010	Retrospective study	2	IOC; routine	51041	747	(1.4)	LC performed in 44241 (89.8%). IOC attempted in 44401 (87.7%) and successful in 42346 (95.4%). Conversion in 3965 (9.0%)	Any proposed protective effect of IOC was restricted to patients with (or a history of) acute cholecystitis.	+/-
Van Campenhout et al. (1993)	1990-1991	Retrospective study	4	IOC; routine	107	0		IOC attempted in 105 (98%) and successful in 75 (71%)	Our results show that IOC is feasible and useful in patients undergoing LC	+
Vezakis et al. (2000)	1990-1998	Retrospective study	4	IOC; routine	950	3	(0.3)	IOC attempted in 896 (94.3%) and successful in 734 (82%). 13 bile leaks (1.4%). In 2 cases, the CBD was cannulated instead of the CD	Findings show that IOC is a safe technique. Its routine use during LC may not prevent BDI, but it minimizes the extent of the injury so that it can be repaired easily without any consequences for the patient. The prevention of a major BDI makes IOC cost effective.	+
Selective intraoperative radiologic cholangiography										
Giger et al. (2011)	1995-2005	Retrospective study	2	IOC; selective	31838	101	(0.3)	IOC performed in 11642 (36.6%). No difference in BDI rate between IOC and no-IOC groups.	the incidence of BDI missed during surgery was similar with or without the use of IOC. Selective use of IOC may be worthwhile.	+/-
Hawasli (1993)[55]	1989-1992	Retrospective study	4	IOC; selective	1000	3	(0.3)	IOC attempted in 102 (10%) and successful in 96 (94%)	Routine use of IOC through the CD does not decrease the number of injuries to the CBD but actually may increase this number. IOC should be used for diagnosis or management of CBD stones. To avoid mishaps, a cholecystocholangiogram should be done first in every case where the anatomy is obscure.	+/-
Robinson et al. (1995)	1990-1991	Retrospective study	4	IOC; selective	542	0		IOC was performed in 161 (32.5%) and adequate in 121 (75%) IOC imaging was adequate. Conversion in 28 (5.2%) 1 bile leak (0.18%)	Selective IOC during LC is a safe practice when the ductal anatomy is clearly defined and there is no laboratory or clinical evidence of CBD abnormalities.	+
Verma et al. (2016)	2013-2014	Retrospective study	4	IOC; selective	75	0		IOC attempted in 38 (50.7%) and successful in 29 (76.3%)	Routine IOC can be considered in patients undergoing LC to detect and remove CBD stones, confirm biliary tree anatomy and prevent BDI. .	+

Table 2. IOC (continued)

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N	BDI (%)	Additional outcomes	Author's conclusion	In favor of IOC
Buddingh et al. (2011)	2004-2009	Retrospective study	3	IOC; routine vs selective	835	26	(3.1)	IOC was attempted in 260 of 435 (59.8%) routine IOC cases and successful in 226 (86.8%). IOC was attempted in 25 of 421 (5.9%) selective IOC cases and successful in 23 (91.7%). 11 BDI in routine IOC group (2.5%) and 15 BDI in selective IOC group (3.6%). Rate of major BDI significantly lower in routine IOC group (1.9% vs. 0%)	Marked reduction in major BDI after implementation of routine IOC	routine IOC
Carlson et al. (1993)	1993	Retrospective study	4	IOC; routine vs selective	319	1		IOC performed in 127 of 164 (77.4%) routine IOC cases and successful in 90 (70.9%). IOC was performed in 21 of 155 (13.5%) selective IOC cases. 1 BDI in routine IOC group (0.61%), 0 BDI in selective IOC group	Selective IOC does not result in a high incidence of common bile duct injury	Neutral
No use of intraoperative radiologic cholangiography										
Barkun et al. (1993)	1990-1992	Retrospective study	3	No IOC	1300	5	(0.38)	12 bile leaks (0.9%)	LC can be performed safely without routine IOC.	-
Lepner et al. (2005)	2000-2001	Prospective study	4	No IOC	413	0		Conversion in 8 (1.9%)	IOC can be safely omitted in LC without BDI	-
Lorimer et al. (1995)	1991-1993	Retrospective study	4	No IOC	525	0		Conversion in 25 (4.8%). No bile leaks	IOC is not essential to prevent BDI during LC. In case of uncertain anatomy, further careful dissection should be carried out until any uncertainty has been resolved	-
McFarlane et al. (2005)	1997-2003	Prospective study	4	No IOC in selected patients	159	1	(0.62)	Conversion in 12 (6.1%)	IOC is not necessary for patients undergoing LC who have no history of gallstone pancreatitis or jaundice, normal liver functions tests and a CBD diameter less than 10 mm.	+/-
Mir et al. (2007)	2001-2007	Prospective study	3	No IOC	1267	1	(0.08)	Conversion in 23 (1.8%). 4 bile leaks (0.32%)	IOC is not essential to prevent biliary tract injuries or missed CBD stones	-
Morris et al. (1993)	1990-1991	Retrospective study	4	No IOC	82	0	(0)	1 bile leak (1.2%)	LC can be performed safely without IOC.	-

Table 2. IOC (continued)

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N (%)		Additional outcomes	Author's conclusion	In favor of IOC
Pesce et al. (2012)	2003-2011	Retrospective study	4	No IOC	1100	2	(0.18)	Conversion in 33 (3%). 3 bile leaks (0.27%)	LC can be performed safely without the use of IOC and with acceptable low rates of biliary complications.	-
Taylor et al. (1997)	1990-1995	Retrospective study	3	No IOC	2038	NR		Conversion 64 (3.1%). minor duct injury and bile leaks in 22 (1.1%)	Omission of IOC is equally safe as published results using routine IOC	-
Wright et al. (1998)	1990-1996	Retrospective study	4	No IOC	1200	7	(0.58)		IOC is not a prerequisite for the safe performance of LC and cannot be relied upon to prevent all BDI	-
Zacharakis et al. (2007)	1992-2005	Retrospective study	3	No IOC	1851	7	(0.37)	Conversion in 99 (5.3%)	Performing an LC procedure without IOC is recommended	-
Other uses of intraoperative cholangiography										
Duff (2006)	2003-2005	Prospective study	4	Use of cystic duct marking technique in conjunction with percutaneous cholecystocholangiography	204	0		CD was successfully identified in 191 (94%). In 3 patients (1.5%) the CBD was marked and correctly identified, avoiding injury. 2 bile leaks (1.0%)	IOC through the gallbladder combined with the CD marking technique proves to be useful in avoiding BDI	+
Fox et al. (1996)	1996	Retrospective study	4	IOC; trough gallbladder (cholecysto-cholangiography)	113	NR		IOC successful in 92 (81.4%). Conversion in 12 (10.6%)	IOC trough the gallbladder is a safe, simple, and an effective procedure that can be used as an alternative to IOC trough the CD to identify biliary anatomy and diagnose CBD calculi prior to laparoscopic dissection.	+
Kuster et al. (1995)	1989-1994	Retrospective study	4	IOC; routine trans gallbladder vs routine trough CD vs no IOC	677	2	(0.3)	IOC successful in 271 (94%) cholecystocholangiograms and in 133 (82%) CD cholangiograms. 6 bile leaks (0.89%)	IOC performed through the gallbladder before any dissection was initiated significantly facilitated the operation and helped decrease the incidence of technical complications	+
Liyanage et al. (2009)	1996-2007	Retrospective study	4	IOC; ENBD	508	2	(0.39)	Conversion in 9 (1.8%). 4 bile leaks (0.8%) IOC trough ENBD was used in 26 (5.2%)	IOC trough ENBD is a safe and effective technique and should be done without hesitation, especially if the patient is to undergo ERCP	+

BDI bile duct injury, CBD common bile duct, CD cystic duct, CHD common hepatic duct, ENBD endonasobiliary drainage tube ICG-NIR indocyanine green near infrared imaging, IOC intraoperative cholangiography, IOUS intraoperative ultrasonography, LC laparoscopic cholecystectomy, LHD Left hepatic duct, NR not reported, RHD right hepatic duct.

Table 3. IOUS

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N (%)	Additional outcomes	Author's conclusion	In favor of IOUS
Intraoperative ultrasonography									
Biffl et al. (2001)	1995-2000	Retrospective study	4	IOUS (with selective IOC)	842	5 (0.6)	6 bile leaks (1%). Conversion in 84 (14%) of Non-US group and 30 (12%) in US group (not significant). All BDI occurred in the non-US group (incidence 0.8%)	LC with IOUS is associated with fewer bile duct complications	+
Hakamada et al. (2008)	1991-2006	Retrospective study	4	IOUS; selective vs routine	644	4 (1.1)	BDI occurred in 4 of 368 (1.1%), all before introduction of routine IOUS use. Identification rates: CD 96.8%, confluence CD-CHD 93.7%, CHD 95.4%,	IOUS during LC is feasible, which provided accurate, real-time information about the biliary structures.	+
Machi et al. (2007)	2004-2005	Retrospective study	4	IOUS; routine	200	0	IOUS was successful in 193 of 200 (96.5%) patients. IOC was not needed in these 193 patients, and was used in the remaining 7 (3.5%)	Routine IOUS accurately identified biliary anatomy and significantly reduced the need for selective IOC without adversely affecting the outcome of the LC or increasing the overall cost.	+
Machi et al. (2009)	2007-2008	Retrospective study	3	IOUS; routine	1381	0	IOUS was successful in 1352 of 1381 (98.0%)	IOUS can be performed successfully to delineate biliary anatomy and improves the safety of LC by clarifying anatomy and decreasing BDI.	+
Tomonaga et al. (1999)	1995-1997	Retrospective study	4	Routine predissection IOUS	43	NR	Visualization of biliary structures using IOUS (before dissection): CHD 95%, confluence CD-CHD 98%, CBD 98%. Cystic duct length accuracy was 87.1%	CD length and biliary structures were determined by IOUS with a high level of accuracy	+
Intraoperative ultrasonography vs. intraoperative cholangiography									
Ohtani et al. (1997)	1993-1994	Prospective study	4	IOC vs. IOUS	65	0	IOC attempted in 58 (89.2%), successful 54 (93%). Identification rates: CHD + confluence 46 (85%), CHD 48 (89%), CBD 54 (100%) IOUS attempted by 65 (100%). Identification rates: CHD + confluence 63 (97%), CHD 65 (100%), CBD 63 (97%), CD and confluence 61 (94%). Conversion in 2 (2.9%). No bile leaks occurred	IOUS compares favourably with IOC in the exploration for bile duct stones and demonstrating hepatobiliary anatomy	+

Table 3. IOUS (continued)

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N (%)	Additional outcomes	Author's conclusion	In favor of IOUS
Rijna et al. (1999)	1997	Prospective study	3	IOC vs. IOUS	50	NR	IOC successful in 38 (76%). Complete imaging of biliary tract in 34 (89%). IOUS: Complete visualization of CBD 45 (92%)	IOUS has comparable results to IOC in regard of identification of CBD anatomy and the assessment of CBD stones, but with almost no technical failures, no use of contrast and no complications	+/-
Tranter et al. (2003)	2001	Prospective study	3	IOC vs. IOUS	135	NR	IOC successful in 121 (89%), IOUS successful in 131 (97%)	IOUS examination of the bile duct is superior to IOC and could replace it.	+

*BDI b*ile duct injury, *CBD* common bile duct, *CD* cystic duct, *CHD* common hepatic duct, *IOC* intraoperative cholangiography, *IOUS* intraoperative ultrasonography, *LC* laparoscopic cholecystectomy, *LHD* Left hepatic duct, *NR* not reported, *RHD* right hepatic duct.

Table 4. Fluorescence imaging

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	Detection rates (%)			
						CHD	CD-CHD	CD	CBD
ICG-NIR fluorescence imaging									
Ankersmit et al. (2017)	2015	Prospective study	4	ICG-NIR	18	NR	NR	NR	NR
Boni et al. (2015)	2013-2014	Prospective study	4	ICG-NIR	52	NR	100	100	100
Daskalaki et al. (2014)	2011-2013	Retrospective study	4	ICG-NIR	184	94	83.6	97.8	96.1
Dip et al. (2013)	2011	Prospective study	4	ICG-NIR	65	NR	NR	100	100
Dip et al. (2015)	2013	Prospective study	4	ICG-NIR	45	60	NR	97.8	80
Dip et al. (2016)	2014	Prospective study	4	ICG-NIR	71	70.4	NR	100	87.3
Igami et al. (2016)	2013-2014	Prospective study	4	ICG-NIR during SILC	21	81	71.4	47.6*	NR
Ishizawa et al. (2010)	2008-2009	Prospective study	4	ICG-NIR	52	100	100	100	NR
Kono et al. (2015)	2008-2012	Prospective study	4	ICG-NIR	108	93	92	95	NR
Prevot et al. (2014)	2012	Prospective study	4	ICG-NIR	23	48	74	100	87

Additional outcomes	Author's conclusion
In 6 (33,3%) earlier CD visualization using ICG-NIR, additional CBD identification in 7 (38,9%)	Early visualization of the CD or additional identification of the CBD using ICG-NIR imaging can be helpful in preventing CBD injury
Biliary anatomy is identified in all cases, irrespectively of normal or inflamed tissue	ICG-NIR imaging can be applied during LC to clarify anatomy within Calot's triangle
All 4 structures (CD, CHD, CBD, and confluence) were visualized in 153 (83.1%). An anatomical variation of the biliary tree was identified using the ICG in 5 patients (2.7%)	ICG-NIR fluorescent cholangiography during robotic cholecystectomy is a safe and effective procedure that helps real-time visualization of the biliary duct anatomy.
For detection of the CD and CBD smooth resection was necessary in 15 (23.1%) and 15 (23.1%) respectively.	Preliminary data demonstrates that ICG-NIR imaging is a feasible method of identifying biliary structures as an adjunct to conventional LC technique
ICG-NIR was attempted and successful in all cases	ICG-NIR imaging appears to be a feasible, low-cost and effective imaging modality when performing LC. It is safe, easy to perform and interpret, and does not require a learning curve or X-ray
Detection rates in obese cases (BMI ≥30 N=38): CD 38 (100%), HD 23 (60.5%), CBD 31 (81.6%), Accessory duct 2 (5.3%)	ICG-NIR fluorescent cholangiography is safe for utilization in the obese population.
Significant lower detectability in patients with BMI >25	fluorescent cholangiography can prevent biliary injury during SILC and facilitate SILC. Obesity is the major factor that could prevent identification of biliary structures under fluorescent cholangiography.
Accessory hepatic ducts (n=8) were detected in 2 (25%) before dissection and 8 (100%) after dissection. Comparison with IOC (drip infusion, n = 46): CD 17 (37%); CHD 36 (78%); CD-CHD junction 17 (37%); Right and left hepatic duct junction 28 (61%); accessory hepatic duct 6 (75%)	Fluorescent cholangiography enables real-time identification of biliary anatomy during dissection of Calot's triangle. This simple technique may become standard practice for avoiding bile duct injury during laparoscopic cholecystectomy, replacing radiographic cholangiography.
Accessory hepatic ducts detected in 9 of 10 cases (90%)	ICG-NIR is a simple navigation tool that is easy to use during LC. It can provide a road map of the extrahepatic bile ducts to reach the "critical view of safety" without any interventions involving the biliary tracts or exposure to radiation.
Standard vision: sensitivity 33%, specificity 75%, accuracy 48%; ICG-NIR (before dissection): sensitivity 53%, specificity 50%, accuracy 52%; ICG-NIR (after dissection): sensitivity 87%, specificity 50%, accuracy 74%. No BDI occurred, no conversion occurred	ICG-NIR appears to be feasible and safe for assessing the extrahepatic bile duct anatomy before and during dissection.

Table 4. Fluorescence imaging (continued)

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	Detection rates (%)			
						CHD	CD-CHD	CD	CBD
Schols et al. (2013)	2011-2012	Prospective study	4	ICG-NIR	15	NR	NR	100	100
Schols et al. (2013)	2011-2012	Prospective study	4	ICG-NIR + Arterial phase	30	NR	NR	97	83
Spinoglio et al. (2013)	2011-2012	Prospective study	4	ICG-NIR during single site robotic cholecystectomy	45	97	97	97	97
Zroback et al. (2016)	2016	Retrospective study	4	ICG-NIR	12	50	NR	100	83
ICG-NIR fluorescence imaging vs. radiologic IOC									
Osayi et al. (2015)	2013-2014	Prospective study	4	ICG-NIR vs IOC	82	69.4	79	98.4	82.3
Other fluorescence imaging modalities									
Mohsen et al. (2015)	2015	Prospective study	4	UV-A/Fluorescein	40	NR	NR	NR	NR

**Detection of entire running course of CD, not only identification of the CD.*

*BDI b*ile duct injury, *CBD* common bile duct, *CD* cystic duct, *CHD* common hepatic duct, *CD-CHD* confluence of cystic duct and common hepatic duct, *ICG-NIR* indocyanine green near infrared imaging, *IOC* intraoperative cholangiography, *LC* laparoscopic cholecystectomy, *LHD* Left hepatic duct, *NR* not reported, *RHD* right hepatic duct, *UV-A* ultraviolet-A..

	Additional outcomes	Author's conclusion
	Successful identification of the CBD and CD was achieved in 15 of 15 (100%) patients before dissection.	Intermittent ICG-NIR fluorescence imaging seems a useful aid in accelerating visualization of the extrahepatic bile ducts during LC.
	Conventional light identification rates: CBD 22 (73.3%), CD 29 (96.7%) patients. Conversion in 1 (3.3%)	Both biliary and vascular ICG-NIR fluorescence imaging in laparoscopic cholecystectomy are easily applicable, can be helpful for earlier identification of the extrahepatic bile ducts, and are useful for the confirmation of the arterial anatomy.
	Successful identification before dissection: CD 42 of 45 (93%), CHD of 40 of 45 (88%), CD-CHD junction 40 of 45 (88%), CBD 41 of 45 (91%)	Real-time high-resolution ICG-NIR fluorescent imaging to identify the biliary tree anatomy during robot assisted LC was safe and effective
	Positive subjective surgeon's experience	ICG-NIR imaging allows non-invasive real-time visualization of the extrahepatic biliary tree.
	IOC detection rates: CHD 98.4%, CH-CHD confluence 95.2%, CD 95.2%, CBD 100%	ICG-NIR imaging is safe, feasible, and a non-invasive alternative to IOC for imaging extrahepatic biliary structures during LC
	Adequate bile duct visualization in 33 of 40 (82.5%). True negative for other tissues in 40 of 40 (100%)	The developing ultraviolet/fluorescein technique is helpful in early localization of bile ducts at LC

Table 5. Comparison of techniques and other preventive measures

Author (year published)	Study period	Study type	LOE	Focus of study	Cases N	BDI N (%)
Comparison of BDI prevention techniques						
Ohtani et al. (1997)	1993-1994	Prospective study	4	IOC vs. IOUS	65	0
Rijna et al. (1999)	1997	Prospective study	3	IOC vs. IOUS	50	NR
Tranter et al. (2003)	2001	Prospective study	3	IOC vs. IOUS	135	NR
Osayi et al. (2015)	2013-2014	Prospective study	4	ICG-NIR vs. routine IOC	82	NR
Other methods of BDI prevention						
Cai et al. (2015)	2003-2015	Retrospective study	3	Blunt dissection of Calot's triangle by irrigation and aspiration	21497	20 (0.09)
Li et al. (2014)	2009-2010	Retrospective study	4	Use of a rating scale assessing unfavourable factors during surgery.	780	5 (0.64)
Sari et al. (2005)	2003-2004	Prospective study	4	Methylene blue cholangiography	46	0
Wang et al. (2010)	2007-2008	Technique	4	Light cholangiography	16	0
Xu et al. (2004)	2001-2003	Technique	4	Light cholangiography vs. Methylene blue cholangiography	36	

*BDI b*ile duct injury, *CBD* common bile duct, *CD* cystic duct, *CHD* common hepatic duct, *CVS* Critical view of safety, *FFLC* Fundus first laparoscopic cholecystectomy, *GTIUF* graded treatment of Intraoperative unfavourable factors, *LC* laparoscopic cholecystectomy, *NR* Not reported, *SILC* Single incision laparoscopic cholecystectomy.

Additional outcomes	Author's conclusion
IOC attempted in 58 (89.2%), successful 54 (93%). Identification rates: HD + confluence 46 (85%), CHD 48 (89%), CBD 54 (100%) IOUS attempted and tolerated by 65 (100%). Identification rates: HD + confluence 63 (97%), CHD 65 (100%), CBD 63 (97%), CD and confluence 61 (94%). Conversion in 2 (2.9%). No bile leaks occurred	IOUS compares favorably with IOC in the exploration for bile duct stones and demonstrating hepatobiliary anatomy
IOC successful in 38 (76%). Complete imaging of biliary tract in 34 (89%). IOUS: Complete visualization of CBD 45 (92%)	IOUS has comparable results to IOC in regard of identification of CBD anatomy and the assessment of CBD stones, but with almost no technical failures, no use of contrast and no complications
IOC successful in 121 (89%), IOUS succesful in 131 (97%)	IOUS examination of the bile duct is superior to IOC and could replace it.
Identification of biliary anatomy: ICG-NIR: RHD 1.6%, LHD 4.8%, CHD 69.4%, CH-CHD confluence 79.0%, CD 98.4%, CBD 82.3%, IOC: RHD 85.5%, LHD 85.5%, CHD 98.4%, CH-CHD confluence 95.2%, CD 95.2%, CBD 100%	ICG-NIR imaging is safe, feasible, and a noninvasive alternative to IOC for imaging extrahepatic biliary structures during LC
Incidence of BDI is 0.093% Conversion in 239 (1.1%)	Blunt dissection by flushing and aspiration to expose Calot's triangle proved to be a valuable method to avoid BDI.
LC without GTIUF (n=384): conversion in 6 (1.6%), 5 BDI (1.3%) LC with GTIUF (n = 396): conversion in 15 (5.4%), 0 BDI	GTIUF is an effective method of preventing BDI during LC in that it helps identify the course of the extrahepatic bile duct and prevents intraoperative errors, especially for inexperienced operators.
43 of 46 cases had successful painting of gallbladder, CD and CBD (93.5%), no conversion occurred	The incidence of BDI related to anatomic misidentification can be decreased by intraoperative injection of methylene blue and visualization of the gall bladder, CD and CBD
Successful placement of optical fibre in 15 (93.8%) No conversion occurred	this modality can reduce unnecessary biliary duct exploration and reduce retaining of CBD stones, it contributes to the identification of normal and variation of the biliary duct anatomy
Light cholangiography (n=16): successful in 13 (81.3%), CBD and CHD were identified in all cases. CD was identified in 4 (30.8%) Methylene blue (n=20): successful in 18 (90%) with identification of the extra hepatic ducts due to blue coloration	LCP is currently the most effective way to directly observe the extrahepatic ductal system during LC and may play a useful role in clarifying uncertain anatomy in selected cases

APPENDIX G. SURVEY (TRANSLATED FROM DUTCH) *(CHAPTER 9)*

Demographic data

Question 1. *What is your current function?*

- o Surgeon
- o Resident in surgical training
- o Retired surgeon
- o Other (specify)

Question 2. *What is your subspecialization?*

(Multiple answers possible. In case of resident in surgical training en not yet differentiated towards a subspecialization, please select ***not applicable****)*

- o Surgical Oncology
- o Gastrointestinal Surgery
- o Hepatopancreaticobiliary Surgery
- o Pediatric Surgery
- o Pulmonary Surgery
- o Trauma Surgery
- o Vascular Surgery
- o Not applicable

Question 3A. *(If surgeon) How many years are you practicing surgery?*

- o <5 years
- o 5 to 10 years
- o 10 to 15 years
- o >15 years

Question 3B. *(If resident) What year of the education are you currently in?*

- o Year 1
- o Year 2
- o Year 3
- o Year 4
- o Year 5
- o Year 6

Question 4A. *(If surgeon) How many laparoscopic cholecystectomy procedures did you perform or supervise in your carrieer up to now?*

o <100
o 300
o 301 to 500
o >500

Question 4B. *(If resident) How many laparoscopic cholecystectomy procedures did you perform or have you assisted in your carrieer up to now?*

o <50
o 50 to 100
o 101 to 200
o >200

Question 5A. *(If surgeon) How many laparoscopic cholecystectomy procedures did you perform or supervise in the past 12 months?*

o <10
o 10 to 25
o 26 to 50
o >50

Question 5B. *(If resident) How many laparoscopic cholecystectomy procedures did you perform or have you assisted in the past 12 months?*

o <10
o 10 to 25
o 26 to 50
o >50

Question 6. *What is your workplace?*

o University hospital
o General teaching hospital
o General non-teaching hospital
o Other (specify)

Current use of the Critical View of Safety technique

Question 7. *Do you know the critical view of safety technique?*

- o Yes
- o No

Question 8. *Do you use the Critical View of Safety (CVS) technique?*

- o Yes
- o No

Question 9A. *(If answer was 'Yes' at Question 8) Why do you use this technique?*

- o Because i was trained this way
- o this is the most trustworthy method of preventing BDI
- o Other (specify)

Question 9B. *(If answer was 'No' at Question 8) Why do you* ***not*** *use this technique?*

- o This method is cumbersome.
- o I use a different method i deem more trustworthy
- o Other (specify)

Question 10A. *(If answer was 'Yes' at Question 8) Use of the Critical View of Safety technique in de daily practice.*

	Never	Rarely	Sometimes	Regularly	Always
How often do you use the CVS technique	○	○	○	○	○

Question 10B. *(If answer was 'No' at Question 8) What technique do you use to remove a gallbladder?*
Please provide a short description of your method.

Current practice of laparoscopic cholecystectomy

Question 11. *Please indicate of the following actions in what frequency you apply them.*

	Never	Rarely	Sometimes	Regularly	Always
Identification of Rouvière's sulcus	○	○	○	○	○
Opening of the peritoneal envelope as far as possible from the liver hilum	○	○	○	○	○
Full clearance of Calot's hepatobiliary triangle (cystic duct – common hepatic duct – liver) from fat and fibrous tissue	○	○	○	○	○
Circumferential overview of the cystic duct – gallbladder junction after dissection	○	○	○	○	○
Circumferential overview of the cystic artery – gallbladder junction after dissection	○	○	○	○	○
Complete freeing of the gallbladder infundibulum from the liver bed before transection of the cystic duct and the cystic artery	○	○	○	○	○
The cystic artery is transected before the cystic duct	○	○	○	○	○
The cystic duct is transected before the cystic artery	○	○	○	○	○
The gallbladder is dissected fundus first from the liver bed	○	○	○	○	○

Aspects of the Critical View of Safety technique

Question 12. *In case you employ the Critical View of Safety technique, what are, according to you, the essential steps of this technique?*
(Multiple answers are possible)

- o Identification of the cystic duct – common hepatic duct junction
- o The cystic duct is transected after the funnel-shaped junction between the infundibulum and the cystic duct is recognized
- o To identify corresponding structures, Calot's hepatobiliary triangle (cystic duct – common hepatic duct – liver) has to be cleared entirely from fat and fibrous tissue
- o Dissection of the entry point of the *cystic duct* into the gallbladder until circumferential overview is achieved
- o Dissection of the entry point of the *cystic artery* into the gallbladder until circumferential overview is achieved
- o Dissection of the infundibulum free from the liver bed for approximately one third.

Conversion to open cholecystectomy

Question 13. *In which of the following cases would you convert to an open procedure? (Multiple answers are possible)*

- o In case of shrunken gallbladder
- o When the Critical View of Safety is not achieved
- o Extensive adhesions involving the surrounding structures and organs
- o Bile leakage (with an intact gallbladder)
- o Spillage of bile due to gallbladder damage
- o Spillage of gallstones due to gallbladder damage
- o In case of severe bleeding
- o Other (specify)

Other techniques

Question 14. *In what frequency do you employ the following techniques?*

	Never	Rarely	Sometimes	Regularly	Always
Intraoperative radiological cholangiography	○	○	○	○	○
Intraoperative fluorescence (ICG) cholangiography	○	○	○	○	○
Intraoperative ultrasonography	○	○	○	○	○
Partial cholecystectomy	○	○	○	○	○
Leave the gallbladder in situ	○	○	○	○	○

APPENDIX H. REQUIREMENTS FOR AN ADEQUATE VIDEO RECORDING, AUDIO RECORDING, AND OPERATIVE NOTE *(CHAPTER 10 AND 11)*

Requirements for an adequate video recording, audio recording, and operative note

Based on an evidence-based Dutch guideline: Diagnosis and treatment of cholelithiasis. Association of Surgeons of the Netherlands (NVvH); 2016. [Available from: https://heelkunde.nl/sites/heelkunde.nl/files/richtlijnen-definitief/Richtlijn_Galsteenlijden_09032016.pdf].

Step 1: Introduction and positioning of trocars under vision

a) Introduction of the first accessory trocar under vision
b) Introduction of the second accessory trocar under vision
c) Introduction of the third accessory trocar under vision

Step 2: Inspection of surgery site

a) Inspection and description of the gallbladder condition
b) Inspection and description of the liver condition

Step 3: Circumferential dissection of the cystic duct and the cystic artery

Step 4: Transection of the cystic artery (by clipping or sealing)

Step 5: Transection of the cystic duct (by clipping or sealing)

Step 6: Removal of the gallbladder from the liver bed

Step 7: Inspection of liver hemostasis

Step 8: Presence of bile or stone spill

Step 9: Use of saline irrigation (if used)

Step 10: Placement of drain (if present)

Step 11: Removal of trocars under vision and check for port side bleeding (intraperitoneal trocar sites)

a) Removal of the first accessory trocar under vision
b) Removal of the second accessory trocar under vision
c) Removal of the third accessory trocar under vision

APPENDIX I. INDEPENDENT REVIEWER FORM (CHAPTER 10 AND 11)

LAPAROSCOPIC CHOLECYSTECTOMY INDEPENDENT REVIEWER FORM (SONAR-TRIAL)

ANONYMIZED CASE IDENTIFICATION CODE

REVIEW DATE D D M M Y Y Y Y

REVIEWER (INITIALS, LAST NAME)

STEPS RECORDED

		VIDEO		NOTE		AUDIO		COMMENTS
1a	Introduction of the first accessory trocar	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
1b	Introduction of the second accessory trocar	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
1c	Introduction of the third accessory trocar	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
2a	Inspection of the gallbladder	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
2b	Inspection of the liver condition	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
3	Circumferential dissection of the cystic duct and the cystic artery	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
4	Transection of the cystic artery	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
5	Transection of the cystic duct	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
6	Removal of the gallbladder from the liver bed	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
7	Inspection of liver hemostasis	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
8	Presence of spill (clear or purulent bile, stones)	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
9	Saline irrigation (if used)	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
10	Drain placement (if present)	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
11a	Removal of the first accessory trocar	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
11b	Removal of the second accessory trocar	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	
11c	Removal of the third accessory trocar	Ye ☐	No ☐	Ye ☐	No ☐	Ye ☐	No ☐	

Chapter 16

List of publications
PhD Portfolio
Dankwoord
About the author

List of publications

FW van de Graaf, MM Lange, AG Menon, PR O'Mahoney, JW Milsom, JF Lange
Imaging for Quality Control: Comparison of Systematic Video Recording to the Operative Note in Colorectal Cancer Surgery. A Pilot Study
Ann Surg Oncol. 2016;23(Suppl 5):798-803.

FW van de Graaf, AG Menon, MM Lange
Een beeld zegt meer dan 1000 woorden
Ned Tijdschr Geneeskd. 2017;161:D498.

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Lacunar implementation of the critical view of safety technique for laparoscopic cholecystectomy: Results of a nationwide survey
Surgery. 2018;164(1):31-39.

FW van de Graaf, I Zaimi, LPS Stassen, JF Lange
Safe laparoscopic cholecystectomy: A systematic review of bile duct injury prevention
Int J Surg. 2018;60:164-172.

Ö Eryigit, **FW van de Graaf**, JF Lange
A Systematic Review on the Synoptic Operative Report Versus the Narrative Operative Report in Surgery
World J Surg. 2019;43(9):2175-2185.

FW van de Graaf, MM Lange, JI Spakman, WMU van Grevenstein, D Lips, EJR de Graaf, AG Menon, JF Lange
Comparison of Systematic Video Documentation With Narrative Operative Report in Colorectal Cancer Surgery
JAMA Surg. 2019;154(5):381-389.

Ö Eryigit, **FW van de Graaf**, VB Nieuwenhuijs, MN Sosef, EJR de Graaf, AG Menon, MM Lange, JF Lange
Association of Video Completed by Audio in Laparoscopic Cholecystectomy With Improvements in Operative Reporting
JAMA Surg. 2020;155(7):1-7.

T Nazari, **FW van de Graaf**, MEW Dankbaar, JF Lange, JJG van Merrienboer, T Wiggers
One Step at a Time: Step by Step Versus Continuous Video-Based Learning to Prepare Medical Students for Performing Surgical Procedures
J Surg Educ. 2020;77(4):779-787.

FW van de Graaf, Ö Eryigit, JF Lange.
Current perspectives on video and audio recording inside the surgical operating room: results of a cross-disciplinary survey
Updates in Surgery 2020

Ö Eryigit, **FW van de Graaf**, VB Nieuwenhuijs, MN Sosef, EJR de Graaf, AG Menon, MM Lange, JF Lange
A comparison between intraoperative voice dictation and the operative note in laparoscopic cholecystectomy: a multicentre prospective observational study (SONAR-trial)
Submitted for publication.

PhD Portfolio

PhD student:	Floyd Willem van de Graaf	PhD period:	2016-2020
Department:	Surgery	Promotor:	Prof. dr. J.F. Lange
		Co-promotors:	Dr. M.M. Lange
			Dr. A.G. Menon

PhD training	Year	Workload (ECTS)
Courses		
OpenClinica, Erasmus MC	2016	0.1
BROK® (Basiscursus Regelgeving en Organisatie voor Klinisch onderzoekers)	2017	1.5
Biostatistical Methods I: Basic Principles Part A	2017	2.0
Research Integrity course	2017	0.3
Scientific presentations		
NVvH najaarsvergadering	2016	2.0
NVvH Chirurgendagen	2018	4.0
European Association for Endoscopic Surgery (EAES) Congress	2018	2.0
World Congress of the Hepato-pancreatico Biliary Association (IHPBA)	2018	2.0
Wetenschapsdag Heelkunde Erasmus MC	2018	2.0
Conferences		
International Congress of the European Hernia Society (EHS)	2016	1.0
NVvH Chirurgendagen	2017	1.0
Teaching		
Examination Basic Life Support	2016 - 2018	0.9
Basic Laparoscopic Skills (BLS) course	2016 - 2020	2.5
Laparoscopy course colorectal anatomy for surgical residents (CASH 3)	2017 - 2018	1.0
Teaching anatomy to medical students	2017 - 2018	2.0
Other		
Olympus grant proposal	2016	2.0
Grant proposal ZonMW, Quality of Care; Innovation of Care	2017	2.0
Grant proposal Maag Lever Darm Stichting, MDL innovaties	2017	2.0

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Ik wil graag mijn oprechte dank uiten aan alle personen die een bijdrage hebben geleverd aan de totstandkoming van dit proefschrift. Een aantal mensen wil ik in het bijzonder bedanken.

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Mijn co-promotor dr. M.M. Lange, beste Marilyne, aan het begin van mijn wetenschappelijke carrière werd ik door je vader op jouw pad geleid. Het studieconcept wat jij reeds had opgesteld is uiteindelijk de rode lijn van dit proefschrift geworden. Hierdoor heb ik met een duw in de rug mijn eerste stappen in de wetenschap kunnen zetten, en ik vraag me af of ik zonder dit überhaupt aan een promotietraject was toegekomen. Ik wil je enorm bedanken voor je begeleiding en Ik ben blij dat je tijd kon vrijmaken van de drukke quinoa-business.

Mijn co-promotor dr. A.G. Menon, beste Anand, ik kwam je voor het eerst tegen op de operatiekamer van het Havenziekenhuis. Wat daarna volgde: real-time video en later ook audio opnames maken bij een serie van meer dan honderd operaties. Jouw humor, betrokkenheid en passie voor het vak zijn mij het meeste bijgebleven, niet te vergeten een prachtig huwelijk. Ook jij werd uiteindelijk opgetrommeld om samen met prof. Lange en mijzelf vele uren aan operatievideo's te beoordelen, maar ondanks de tijdsbelasting bleef je altijd optimistisch. Hartelijk dank voor jouw input en begeleiding.

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Beste Annelies, wat zou de professor toch zonder jou moeten. Enorm bedankt voor alle ondersteuning en jouw immer sprankelende aanwezigheid.

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Amsterdam, maar na al die jaren zijn we nog steeds clubje Beaufort. Ik vind het mooi om te zien hoe ver iedereen het heeft geschopt.

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About the author

Floyd Willem van de Graaf was born in Rotterdam on December 18th 1990. He graduated from the Erasmiaans Gymnasium in 2009. During his final years there, he participated in the Junior Med School program of the Erasmus Medical Center Rotterdam, which led to his acceptance to medical school at the Erasmus University Rotterdam following his graduation, just across the road from his former high school. During his medical studies, he became captivated by human anatomy and its applications in Surgery. He participated in the Erasmus Anatomy Research Project led by Prof. dr. G.J. Kleinrensink. In the final months of medical school, he joined the REsearch Projects for Abdominal surgery Innovation Rotterdam (*RE-PAIR*) study group under the supervision of prof. dr. J. Jeekel, prof. dr. G.J. Kleinrensink and prof. dr. J.F. Lange) for his master's thesis, which laid the fundaments of his PhD program after obtaining his medical degree in March 2016. In 2018 he started working as a surgical resident in the Reinier de Graaf Gasthuis (Delft), under supervision of dr. M.R. de Vries, and subsequently at Haaglanden Medical Center, under supervision of dr. H.J. Smeets. Despite his interest in surgery and surgical science, his desire for more variety in his profession remained. Therefore, he will start his general practice specialty training in March 2021