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# 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.

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#### 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3,4</sup> Also, with BDI potentially leading to life threatening complications, prolonged hospitalisation, high financial expenditures, and risk of litigation, <sup>5</sup> 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.<sup>2,6-9</sup> 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.<sup>10</sup> In the Netherlands, it is standard practice to capture CVS either with video or image capture.<sup>11-13</sup> 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.<sup>7</sup> 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.

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#### 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<sup>™</sup> 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.<sup>14</sup> 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.

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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.<sup>15</sup> 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.r 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.<sup>1</sup> 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

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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  $\delta$  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.

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)

Table 1. Patient Characteristics

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.

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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)

Table 2. Surgery Characteristics

#### 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.

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No./total No. of steps (%)			
Procedure steps (N = 79 operations)	NR	RIVD	P value for exact McNemar's test <sup>a</sup>
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 <sup>b</sup>

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

<sup>a</sup> Bonferroni corrected.

<sup>b</sup> 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

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van de Graaf et al. demonstrated that many operators are unacquainted with the correct definition of CVS.<sup>16</sup> 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.<sup>17</sup>

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.<sup>1,7-9</sup> 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"*.<sup>18</sup> 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.

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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.<sup>19</sup> As pre- and post-operative checklists have proven to be effective for safe surgery <sup>20</sup>, 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.<sup>21</sup> 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.<sup>9</sup>

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".

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## 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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