The OtoData Project

Quality of ear surgery
Otorhinolaryngology department
Erasmus MC Rotterdam

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Kaliteit van oorchirurgie
Afdeling Keel-, Neus- en Oorheelkunde
Erasmus MC Rotterdam

Proefschrift

ter verkrijging van de graad van doctor
aan de Erasmus Universiteit Rotterdam
op gezag van de Rector Magnificus

Prof.dr.ir. J.H. van Bemmel

en volgens besluit van het College voor Promoties.
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Contents

Chapter 1 General introduction

Introduction

Reliable information concerning daily clinical practice is a prerequisite to gain insight in the quality of (ear) surgery from the ENT-department as a whole. Insight in daily clinical practice makes medical care more transparent and thus better manageable.

Background

There is a general agreement that medical care should be *evidence based*. Until now medical research is the only way to provide *evidence* on the effectivity of medical treatment. Clinical trials that have to meet high criteria provide the evidence. We assume that this evidence can be extrapolated to the patient consulting us. But even when all medical care is *evidence based,* daily clinical practice still can differ from the results booked in clinical trials. This because the circumstances in daily clinical practice can very well differ from those during the trail, such as the performing surgeon. To have reliable information about daily clinical practice *clinical feedback information* is needed.

All parties involved might benefit from this *clinical feedback information*; Patients can decide whether to have the operation or not and to give informed consent, the involved surgeons are able to compare results with peers and be able to improve the quality of care, and hospital management can ground budgets.
This study concerns the performance on ear surgery in a university hospital. To gain insights in quality of medical care clinical feedback information about daily clinical practice is necessary. To make this information available physicians, computer scientists and hospital management must co-operate.

Digitalisation in medicine

It is a misconception that reliable medical documentation evolves from 'putting everything in the computer'. A badly designed database can turn into a 'data graveyard' from which information can't be easily retrieved. When in normal daily clinical practice documentation is insufficient, i.e. by writing too little down or by an unreadable handwriting, the same will apply for digital documentation. Items will be forgotten, filled out wrongly or ambiguous in the same way as with paper and pen.

Although documentation is essential in medicine it is still viewed upon as a burden. Patient contact and interventions are mainly seen as 'the real work'. The daily work schedule often leaves no time for administration. Also there is little consensus about how to register, i.e. how good operation notes are made.
Nowadays most administrative tasks in hospitals are done by aid of the computer. However, as most information is stored in free-text formats, data suffer from the same limitations as the data in medical records. In order to have data that can be used for purposes such as *clinical feedback information*, they need to be in 'computer-understandable chunks' [1]. In other words the data need to be structured. Structured data entry facilitates entering data in a structured format, and at the same time promotes completeness, and less ambiguous data. [2].
The implementation of such systems in daily practice, however, is slow; most of such systems increase clinical time pressures and drastically change the way of working [3-6]. For this research we asked ourselves whether obtaining clinical feedback information is also feasible, without too much impact on daily practice, and current way of working [7].

Structured data entry

A single-sheet and easy to understand data-collection form that contains only key items [9], e.g. patient identification, procedure, middle ear structures, mastoid contents and used materials was used. The data-collection form does not replace the operation notes. Moreover, it is not filled, but rather dictated together with the operation notes. When typing the notes, the secretary also enters the data in a database in the hospital network. This continuously ongoing data collection from all earsurgery (OtoData) started the 1st of July 1992, and includes data from the Erasmus MC Rotterdam: the Sophia children's hospital and the Dijkzigt hospital.

Clinical feedback information

All parties involved might benefit from clinical feedback information. The first two articles in this dissertation have its own scope specifically aimed at one general question concerning the efficiency of the ENT department as a whole concerning ear surgery.

Chances on cure.

One way a patient might benefit from an ear operation is improvement in hearing. The object of this study was to measure our performance for all ossicular chain reconstructions, performed as a single procedure, or in combination with disease eliminating surgery.

Quality control.

A reliable registration of all adverse events and complications shows to what cost ear surgery is performed. A standard classification allows for patient information based on data from the clinic where the surgery will be performed, the comparison of results from different centres and the possibility of adapting the process of care based on facts. Stapedotomies were not as beneficial as presumed from the literature. This study investigates if results improved after changes in the assignation of surgeons that perform otosclerosis surgery.

Sinus surgery

Our classification of adverse events and complications is extrapolated to other regions of ENT-surgery. In this gradation consequences for the patient are taken much more in account. When compared to earlier classifications some complications change from major (residual damage) to minor (resolving), which is partly due to better techniques. But when the complaints of the patient are weighted heavier some complications change from adverse event to major complication.

Evaluation of the feedback system itself.

What insights can evolve from a simple data collection, requiring only minimal effort, was researched. The first experiences with a continuous data collection system for ear surgery at the Erasmus MC are described. When designing a data collection system only a few major key items should be recorded. A minimal data set for basic feedback on clinical procedures is proposed. When integrated in daily practice this allows for feedback.

By selecting one ailment (chronic suppurative otitis media) the contribution to general health becomes clear. From the overviews of different surgical treatment modalities the benefits to the patient population can be deduced.

Reasons for complication registration

Transparency allows for improvement of quality of care. Pros and contras of adverse event and complication registration are discussed.

How to register outcome

Outcome is not linked to complications and has therefore to be registered separately. To be able to improve quality of care these data need to be collected routinely in daily clinical practice, preferably in a simple effective way.

Goal

The goal of this research project has two aspects. The first was to evaluate the performance of the Erasmus MC ENT department concerning a complete cohort of 3-year ear surgery and additional 4-year otosclerosis surgery cohort with key items collected in a database. The second aspect was that we wanted to investigate if there is something as a 'minimal required dataset', which can give feedback information concerning daily clinical practice.
The effectivity of surgical procedures is proved in the literature. The efficiency of earsurgery in the own department remains to be proven.

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Chapter 2 Performance assessment of ossicular chain reconstructions in a university hospital.

J. Rombout, A.F. Holm & K.H. Pauw
Clinical Otolaryngology. (2000) 25: 280-286

Summary

It remains to be demonstrated that normal, day-to-day routine surgery is as effective as would appear from the literature, where the results of very experienced surgeons are presented. The object of this study was to measure our performance for ossicular chain reconstructions. One hundred and thirty-eight total and partial reconstructions performed by 13 different surgeons were evaluated. The population was divided into four different groups based on the presence or absence of the canal wall and stapes suprastructure. The results varied widely. A number of patients benefited greatly, whereas others experienced deterioration in their hearing. The best improvement (median 13 dB) was achieved in the group with an intact canal wall and absent stapes suprastructure. The postoperative air bone gap was better for autologous incus rather than prosthesis in the group where the canal wall and stapes were intact. There were 3 minor complications. This continuous feedback reports exceptional results (good and bad). The strengths and weaknesses of the department can be determined. This feedback on indicates that this procedure is safe and beneficial for the patients in our institution.

Keywords: Earsurgery, Performance, Ossicular chain reconstruction, Ear Diseases

Introduction

Patients are entitled to know what their chances are of recovering their hearing after an ear operation. It remains to be proven that normal, day-to-day routine surgery is as effective as would appear from the literature, where the results of very experienced surgeons are presented. Ossicular chain reconstruction has been attempted since the end of the 1950s and early 1960s. Hall and Rytzner performed the first ossicular chain reconstruction using autologous ossicular bone in 1957.[1] Farrior was one of the surgeons to describe how to reshape the incus before interposition.[2] In 1966, House introduced the incus allograft.[3] The drawback of using bone is the risk of the presence of residual infection or transmission of diseases.[4,5] Wullstein was the first to use artificial, polyethylene implants in 1952, but abandoned these due to extrusion, infection and erosion of adjacent ossicles.[6] Shea designed a plastipore implant, but these still were prone to extrusion.[5] Brackman covered the prosthesis with cartilage to prevent extrusion.[7,8] Grote introduced hydroxyapatite as a material for ossicular chain reconstruction.[9] In our department, autologous incus is preferred. When this is not available, the Wehrs prosthesis and sometimes a Gausse prosthesis are used.[10]

To be able to make a performance analysis of the ENT department of the university hospital as a whole, data for all ear operations is stored in a database. This OtoData system is a continuous follow-up which makes it possible to acquire data for performance analysis at any moment. The OtoData system allows selection of patient data by ossiculoplasty.

The aim of this study was to document the numbers and to measure our performance for ossicular chain reconstruction. The postoperative hearing levels and the complication rates provide an indication of performance for 138 consecutive ossicular chain reconstructions. Patients can make a well-informed choice about the suggested ear operation based on this evaluation.

Patients and methods

Patients

Of 1009 consecutive ear operations performed from July 1992 until June 1995, 138 involved an ossicular chain reconstruction. These were total and partial reconstructions with autologous incus, bone or prosthesis (PORP/TORP). The cases were selected from the OtoData continuous follow-up system. In 52 cases (38%), the

reconstruction was only part of the operation (table 1). At the ENT department of the University Hospital Rotterdam, five members of staff perform ear operations on a regular basis. During this period, eight residents performed ear operations. Audiometry was added from the databases of the Audiometry Department. In 126 (91%) cases, both pre- and postoperative audiometry was made available, in order to enable a comparison.

Methods

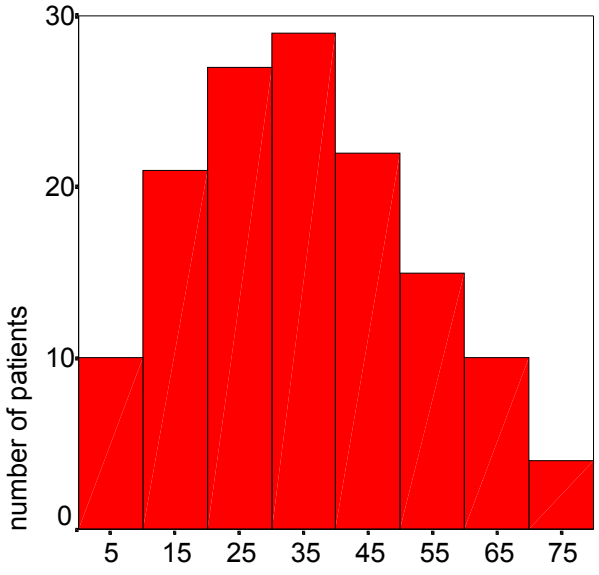
All ear surgeons dictated a form postoperatively, which contained key items about the identification of the patient and procedure, middle ear structures, mastoid contents and materials used. The secretary entered these data in a database in the hospital network when the dictated operation notes are typed out. This continuously ongoing data collection of all ear surgery (OtoData) was started on 1st July 1992.
Each record in the OtoData contains one surgical procedure. The follow-up ends on the date of the last outpatient-clinic visit, or the date of reoperation on the same ear. The coupling with the database in which all audiometry is stored at the University Hospital Rotterdam (AZR) turned out to be impossible. The data had to be selected by hand and then added. Postoperative audiograms were not always performed. Also not every operation was added to the database and some forms were incomplete or

Table 1. Combination surgery with Ossicular chain reconstruction

Operation:	*n*
CWU mastoidectomy	12
CWD mastoidectomy	11
Myringoplasty	9
Revised CWU mastoidectomy	8
Middle ear inspection	7
Revised CWD mastoidectomy	5
TOTAL	52

CWU=canal wall up; CWD = canal wall down

Figure 1. Number of patients per age group



wrongly dictated. To compensate for these omissions it was decided to check and complete the records of the first 3 years.

The population that underwent an ossicular chain reconstruction was divided into four different groups; canal wall down/ stapes suprastructure-missing (CWD/stap–); canal wall down/ stapes intact (CWD/stap+); canal wall up/ stapes suprastructure-missing (CWU/stap–); canal wall up/ stapes intact (CWU/stap+). The median Fletcher index (mean 500-1000-2000 Hz) air-conduction thresholds and changes therein - rather than changes in air-bone gaps are given for each group, showing the levels of the hearing losses that were treated. Air conduction was chosen because this is what the patient hears. ENT surgeons are used to audiograms; median pre- and postoperative audiograms are therefore also presented. Postoperative audiograms were planned 1 year after surgery. The 10th and 90th percentiles are plotted, in order to eliminate the influence of the range of the audiometer. When an ossicular chain reconstruction is performed in combination with a mastoidectomy, preservation of hearing was the aim. For comparison purposes, pre-operative ABG rates are not presented. In the literature generally, the postoperative ABG is presented. In this paper, the postoperative ABG is presented in 4 categories: 0-10, 10-20, 20-30 and >30 dB hearing loss.

Results

In the series there were 74 male patients and 64 female. The average age was 35 years and the age distribution is shown in figure 1.

The median air-conduction thresholds, from the Fletcher index (mean 0,5-1-2 kHz) pre- and postoperatively, are given in figures 2 and 3. The median improvement for

Figure 2. Pre-operative median air conduction levels Fletcher index (mean 500-1000-2000 Hz) in dB per group

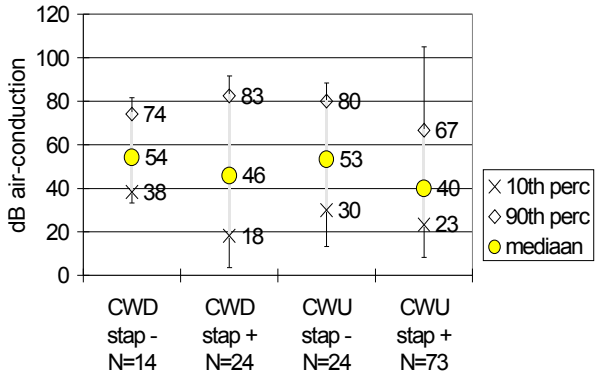
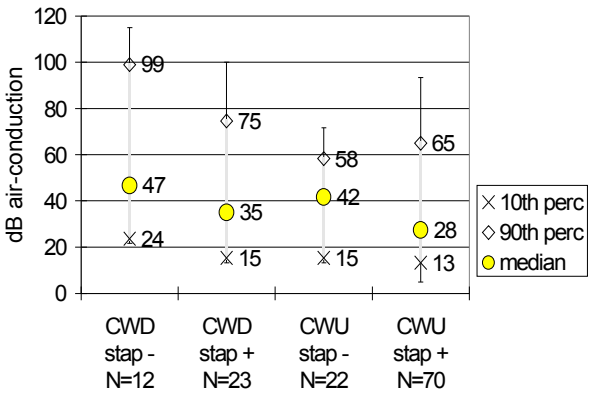


Figure 3. Postoperative median air conduction levels Fletcher index (mean 500-1000-2000 Hz) in dB per group



each group is given in figure 4. Postoperative audiograms were performed, on average, 1.1 years (SD 0.93) after surgery. In the canal wall down/ stapes suprastructure-missing group, the results were different for ossicular chain reconstructions performed in combination with other operations. If the reconstruction was the main objective, the median improvement was 10 dB. If the reconstruction was part of the operation, the median improvement was 0 dB. In the other groups, there were no dissimilarities in the results of reconstructions performed alone and those performed in combination with other operations. The results varied widely. A number of patients benefit greatly from the reconstruction, whereas others experienced deterioration in their hearing. The best results (median 13 dB) were achieved in the canal wall present/ stapes suprastructure-missing group.

Table 2. Complications in 138 ear operations with Ossicular chain reconstruction

Name complication	operation
Otological:	
Loss of taste	CWU mastoidectomy
Perforation of the tympanic membrane	Ossicular chain - reconstruction
general:	
Urine retention	CWD mastoidectomy
Locked knee on dangling	Ossicular chain - reconstruction

For autologous incus and prosthesis in the canal wall present/ stapes intact group the postoperative ABG is shown in figure. Seventy-eight of the own incus and 58% of the prosthesis have a postoperative ABG < 20 dB. In the canal wall present/ stapes suprastructure-missing group the autologous incus results in a postoperative ABG <30 dB in 85% and <20 dB in 50%. The other groups are too small for reliable conclusions.

The median pre-operative and postoperative audiograms are presented in figures 6-9, with the 10th and 90th percentile. These show that the main improvement in hearing occurs in the lower frequencies. The hearing loss was worse when the canal wall and/ or stapes suprastructure was missing.

There were three minor complications. There was one complication with prolonged morbidity (temporary loss of taste). There were no major complications with permanent damage.

Discussion

The OtoData continuous follow-up system allows us to monitor our audiological results in ossicular chain reconstructions. Results analysed with the OtoData are comparable to the literature. Moreover, the results of ossicular chain reconstruction in our hospital are not different from those reported elsewhere. Thirteen dB was the median hearing improvement in the canal wall present/ stapes suprastructure-missing group. Ten dB was the median hearing improvement in the canal wall down/ stapes intact and canal wall present/ stapes intact groups. In the canal wall down/ stapes suprastructure-missing group, the median hearing improvement was 3 dB. In this group, the results are different for ossicular chain reconstructions performed in combination with other operations. If the reconstruction was performed as a single procedure, the median improvement was 10 dB. If the reconstruction was only part of the operation, the median improvement was 0 dB.

Mills reported an average hearing improvement of 11 dB when using cortical bone and 14 dB when using an ossicular graft.[11] Nikolaou found a mean hearing improvement of 11 dB when using autologous incus. He reported 16-17 dB improvement when using a TORP (Polyethylene/Wehrs), 6 dB when using a Polyethylene PORP and 22 dB when using a Wehrs PORP.[12] Vartiainen reported a hearing gain of 11 dB for all cases.[13]

The improvement in median air-conduction thresholds mainly occurs in the lower frequencies. Mills describes the same phenomena in his study of incus transposition and the use of cortical bone.[14]

A possible explanation for this modest median improvement might be the spread in improvement (figure 4). There are patients who benefit greatly from the ossicular

Figure 4. Change in median air conduction levels Fletcher index (mean 500-1000-2000 Hz) in dB per group

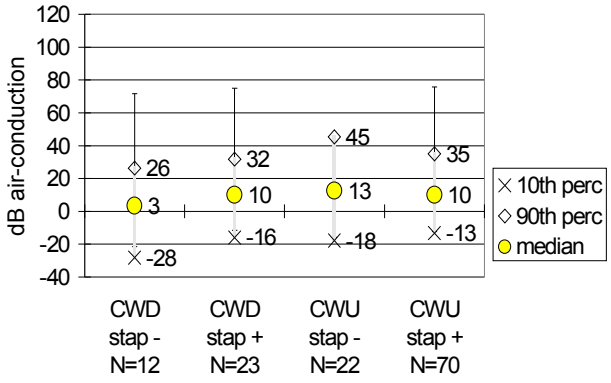
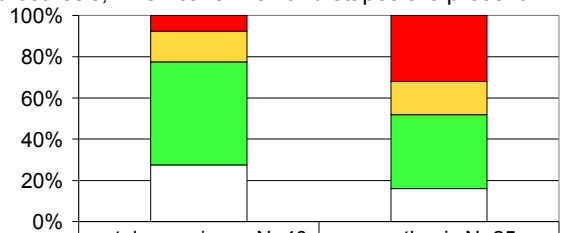
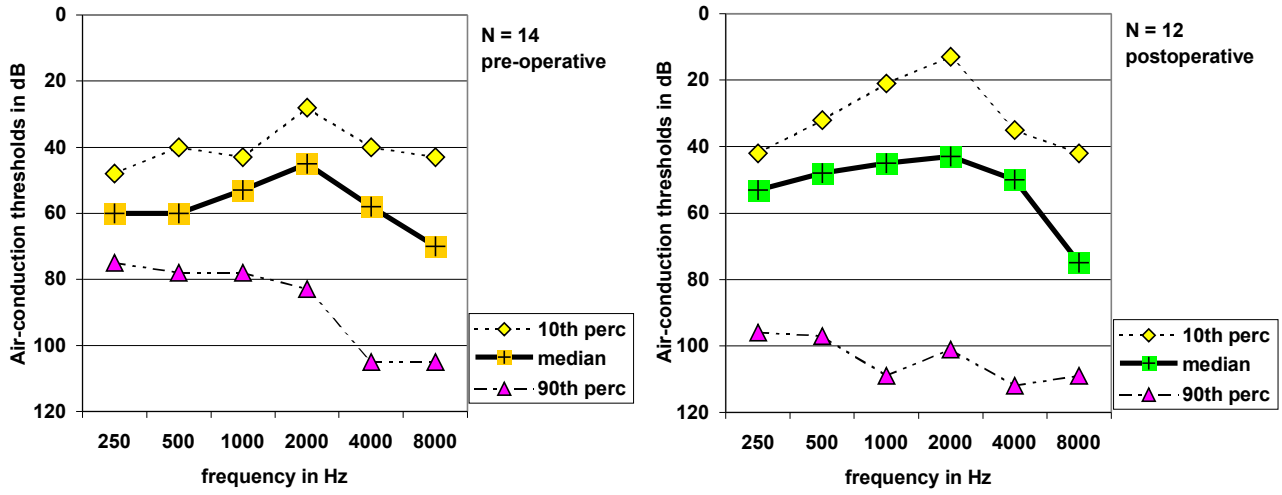


Figure 5. Postoperative air-bone gap Fletcher index (mean 500-1000-2000 Hz) for autologous incus and prosthesis, when canal wall and stapes are present



	autologous incus N=40	prosthesis N=25
>30 dB	3	8
20-30 dB	6	4
10-20 dB	20	9
0-10 dB	11	4

Figure 6. Pre and postoperative median air conduction audiograms with 10th and 90th percentile CWD / stap -



chain reconstruction and there is a group that experiences deterioration of hearing. Rhageb reports a similar spread in air-conduction threshold changes.[15] Whether the amount of improvement can be predicted remains to be determined.

Figure 7. Pre- and postoperative median air conduction audiograms with 10th and 90th percentile CWD / stap +

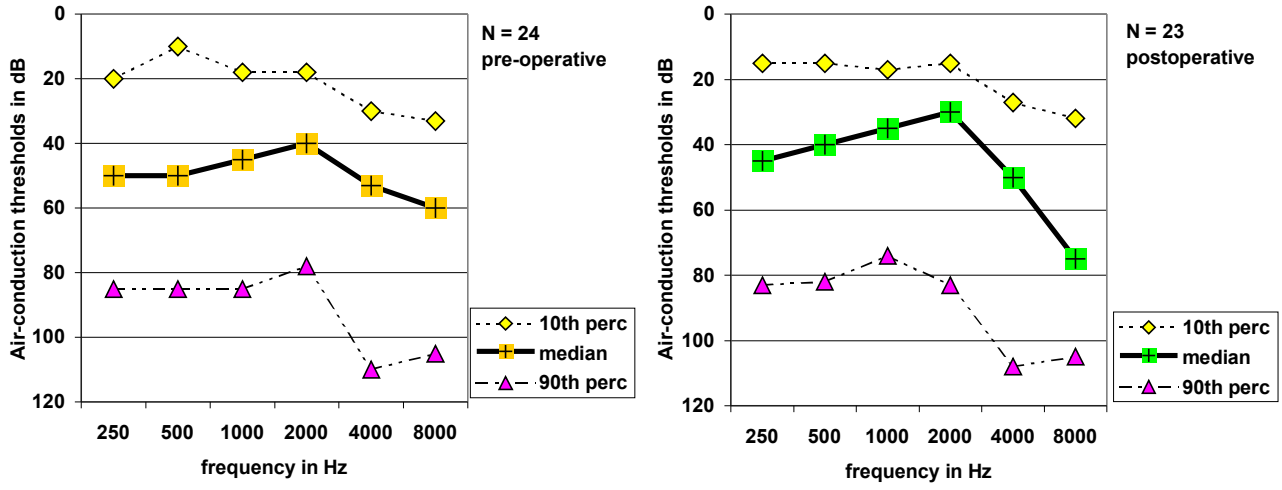
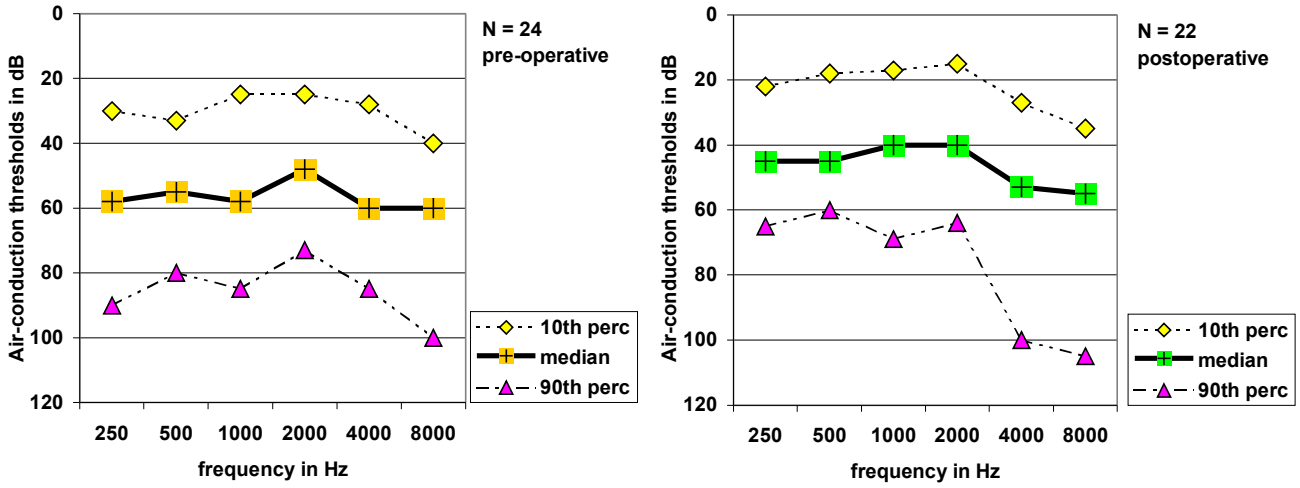
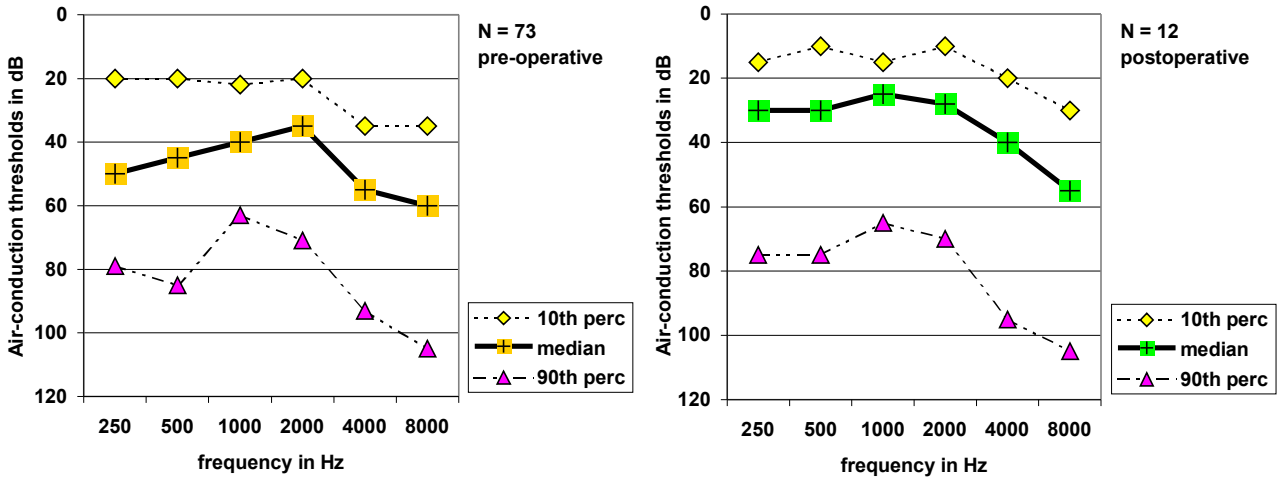


Figure 8. Pre- and postoperative median air conduction audiograms with 10th and 90th percentile CWU / stap -



When the stapes suprastructure is missing, the aim is to achieve a postoperative ABG < 30 dB. When the stapes is intact, an ABG < 20 dB is acceptable.[16] When using these criteria, the incus interposition appears to be more successful than the use of a prosthesis when the stapes suprastructure and canal wall are present (fig 8).

Figure 9. Pre- and postoperative median air conduction audiograms with 10th and 90th percentile CWU / stap +



McElveen achieved an postoperative ABG of < 20 dB in 59% by using an IONOS PORP.[17] Wehrs reports a postoperative ABG of less than 20 dB in 85%.[10] Slater describes a postoperative ABG of < 20 dB in 75% when using a PORP made of polyethylene (N=250).[8] Brackman reports, when using a PORP, a postoperative ABG<20 dB in 73% (N=1042).[7] Our rates are slightly lower than those mentioned in the literature, possibly as a result of the larger number of surgeons and the fact that ossicular chain reconstructions were performed in combination with other operations.
Ragheb states that the stapes suprastructure does not add much to hearing preservation.[15] In this study, when the canal wall is intact, an absent stapes leads to better hearing results postoperatively (figure 4). However, the small numbers preclude a statistical analysis.

According to our study, postoperative hearing levels are worse when the canal wall is absent. In the case of his population (91% otitis media), Brackmann found that the presence of the canal wall has little influence on postoperative hearing.[7] Albu reports, however, that an intact posterosuperior bony wall is the most important predictive factor in the achievement of near-normal hearing.[18]

Complications mentioned in the literature are: damage to the chorda tympani, damage to the cochlea or labyrinth and facial nerve.[19-21] In this population, there were only 3 minor and 1 severe complications (postoperative loss of taste). The risk of complications is low.

Patients must be informed about the chances of recovering their hearing after an ear operation. In the Netherlands, a new law (WGBO) requires informed consent of the patient based on the results of the department where the treatment will be performed. The OtoData system makes this possible. On the basis of these results and a low complication rate, it may be said that generally speaking ossicular chain reconstruction is a beneficial and safe operation in our department. The benefits must, however, not be overestimated because there is a group that experiences deterioration in hearing.
Presenting a cumulative overview of 3 consecutive years of ossicular chain reconstructions by many ear surgeons in a training hospital in a very diverse patient population is not standard. It is therefore difficult to compare these results to the world literature. An evaluation of every separate kind of reconstruction or the statistical analysis of these small numbers would not seem appropriate. Long waiting

lists mean that it is not known beforehand which surgeon is going to perform the ear operation. From a patient point of view, then, the performance of the department as a whole on hearing improvement is important. To give adequate, clear information to this very diverse patient population, one needs to know the results for this whole group. Despite this unconventional approach, it seems that our day-to-day surgical efforts can stand up to the standard in the world literature.

The advantage of registering all ear operations in a continuous follow-up is that there is access to performance information. An overview of ear surgery can be generated at any moment. This follow-up system is also an easy search medium for finding appropriate patients for inclusion in retrospective studies. The drawback is that this data is very crude and only suitable for internal use. Our continuous follow-up reports exceptional results (good and bad). This allows us to determine the strengths and weaknesses of the department. Hereby the loop from registering additional data and giving feedback to the surgeons is closed. Mostly the crude overviews were a confirmation of our general feeling about the results of ear surgery. However when these data are presented to outsiders, a literature study and medical record research must be performed.
This paper is a trial for the presentation of performance data. It is hoped that more performance analysis will be presented in the future.

Conclusions

- This performance analysis shows that ossicular chain reconstructions are safe and beneficial for the patients at the University Hospital Rotterdam.
- When giving patient information, we can refer to our own performance analysis.
- Continuous follow-up gives access to performance data and makes inclusion of patients in a retrospective study easy.

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Chapter 3 Clinical consequences of feedback on ear surgery by continuously recording adverse-events and complications, with regard to reduction in number of surgeons who perform otosclerosis surgery.

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Summary

Electronically stored data may be used to generate feedback overviews. This paper describes a method for establishing a picture of ear surgery complications. In this prospective study, the working definition of adverse events and complications is 'incidents that are not intrinsic to the surgical procedure and that have a potential or actual negative effect on surgical outcome or postoperative morbidity'. A simple method is used to categorise otologic adverse events and complications. This scale varies from adverse events (grade A) to death (grade D).

All adverse events and complications in ear surgery that met this definition were documented electronically as part of continuous follow-up between 1 July 1992 and 30 June 1999.

In the first 3 years, 1,009 ear operations were performed and in 51 (5%) of them adverse events or complications were noted during or after surgery. There were 30 (3%) grade A (adverse events), 18 (2%) grade B (minor complications), 3 (0.3%) grade C (major complications) and no grade D complications. Otosclerosis surgery was evaluated additionally because halfway through a seven-year period the number of surgeons was changed. Only three experienced, senior members of staff were involved, and inexperienced residents were no longer allowed to perform this kind of surgery. The reduction of surgeon numbers did indeed improve the outcome of the stapes surgery. Our results were comparable to the literature. This monitoring of outcome-results in relation to changes in care can be seen as a study of care quality. A review of this kind links daily clinical practice to the literature and induces an improvement in quality.

Keywords:
Ear, Ear surgery, Otosclerosis, Stapes surgery, Complications, Quality of care, Audit.

Introduction

Feedback about the delivery of medical care may lead to improvement of the quality of care. With the advent of electronically stored medical data, events can be registered better than before. This paper describes a simple, challenging, method for recording otologic adverse events and complications.

We could not find a clear definition of complications in otologic literature. The Concise Oxford Dictionary defines a complication as a secondary disease or condition aggravating a previous one [2] and Webster's dictionary states: a secondary disease or condition developing in the course of a primary disease or arising from independent causes [1].

In this prospective study of ear surgery, the working definition of adverse events and complications is: incidents that are not intrinsic to the surgical procedure and that have a potential or actual negative effect on surgical outcome or postoperative morbidity [14,23]. This broad definition meant that even minor adverse events that did not result (but could have resulted) in some minor complications were also documented.
In addition to complications, two other outcomes of treatment should be mentioned that may result in inconvenience, i.e. sequelae and failures (see table 1). Occasionally, both sequelae and complications may be present in one case, an

Table 1. Definition of complications, sequelae and failures used in this paper.

	Description	Occurrence
Adverse events & complications	Incidents that are not intrinsic to the surgical procedure and that have a potential or actual negative effect on surgical outcome or postoperative morbidity	Unexpected and not intrinsic to the procedure
Sequelae	Outcomes other than complications resulting from the surgical procedure.	Inherent to the procedure
Failures	The purpose of the procedure is not fulfilled.	Part of the original problem

example being severe postoperative dizziness after stapedotomy. The difference between a failure and a complication is that, in the former, the original problem is not eradicated completely whereas in the latter a new element has been added to the problem [14].

Two complication classifications were found in literature about general surgical procedures [14,36]. Clavien's classification was readily adaptable to ear surgery. This scale contains four grades of severity, varying from resolution with simple procedures (grade I) to death (grade IV). We adapted this classification to otology for our study (table 2).
Grade A; an adverse event that resolves if left untreated or requires a simple bedside procedure. These events are more a nuisance to the patient and/or the surgeon than a genuine complication.
Grade B; a minor complication that usually requires an additional intervention that involves a risk of its own, but eventually resolves.
Grade C; a major complication that is associated with a residual or a lasting disability.
Grade D; a complication that results in death. This does not happen often in ear surgery but it has been added for the sake of completeness.

To illustrate the possibilities of this gradation we studied 7 years of otosclerosis surgery to evaluate our outcomes and to monitor changes in the process of care. Halfway through this evaluation period, the number of surgeons was almost entirely restricted to three senior members of staff. Up to that time, stapes surgery had been performed by six surgeons, some of whom were relatively inexperienced. We wanted to know if our results were comparable to literature and if the change in assignment of surgeons improved our results.

Material & methods

All adverse events and complications in ear surgery that met our definition were documented electronically. This was part of a continuous follow-up of all ear surgery between 1 July 1992 and 30 June 1999. Of the first three years (until June 1995) all ear surgery complications are presented. Additionally all stapes surgery in our ear surgery database, i.e. small hole stapedectomy (further called stapedotomy), stapedectomies and revision stapes surgery conducted between July 1992 and June

1999 was reviewed. The procedures were broken down into two periods: July 1992 to December 1995 and January 1996 to June 1999.

Immediately after the operation, the surgeon dictated methodically all those items considered being important. These items were then fed into a database in the hospital network.
Eighteen months after the operation, the file was reviewed and the outcome of the

Table 2. Classification of adverse events and complications by severity.

Grade A: Adverse events
- Resolution spontaneous or with simple bedside procedure
- This is a truly low-morbidity group and these events are only a nuisance to the patient and/or doctor
- Small iatrogenic injuries with no consequences for the patient
- Therapy included in this category:
  - Analgesic, antipyretic, anti-emetic medication and drugs required for a low grade wound infection

Grade B: Minor complications
- Usually requiring some form of intervention which involves risk itself.
- This is a prolonged morbidity group
- Undesirable iatrogenic injuries are included
- Therapy examples included in this category:
  - Drug therapy other than that allowed for grade A, including total parental feeding and blood transfusion.
  - Invasive procedures, including reoperation or invasive therapeutic imaging.
  - Unwanted iatrogenic injuries requiring additive operative procedures, even when performed during the same surgery.
  - Significant prolonged hospital stay or more than doubling time needed until returning to normal life and work.

Grade C: major complications
- Residual or lasting disability which interferes with normal life.
- Gross surgical error is always included in Grade C.

Grade D:
- Death as a result of any complication (added here for the sake of completeness only)

surgery recorded. A history was established which included all complications at surgery and all postoperative adverse events.

The conventional Fletcher Index (mean 0.5-1-2 kHz) for the postoperative Air Bone Gap (ABG) is presented in 4 categories: 0-10 dB, 10-20 dB, 20-30 dB and >30 dB hearing loss. The Fletcher Index of the air conduction thresholds (AC) is used as the pre- and post-operative determinant of hearing (figures 1a and 1b).

Results

Complications

In the first three years of data collecting, 1009 ear operations were performed and in 51 (5%) of them complications were recorded during or after surgery (table 3). The male / female ratio was 54.6% / 46.4%. The mean age at surgery was 33.3 years (SD 20.0). The mean follow-up period was 1.57 years.

Grade A (adverse events)

There were 30 (3%) grade A events (tables 3 an 4). In eight cases, damage to middle ear structures was recorded without any postoperative consequences. These included

Table 3: complication rates per operation in descending order.

	Freq.	classification						Total	
		Grade A		Grade B		Grade C			
	N	N	%	N	%	N	%	N	%
Name ear operation									
Stapedotomy	85	7	8%	4	5%	2	2%	13	15%
CWD mastoidectomy	128	4	3%	2	2%	1	1%	7	5%
Meatoplasty	48	2	4%	2	4%			4	8%
Middle ear inspection	75			4	5%			4	5%
CWU mastoidectomy	175	3	2%	3	2%			6	3%
Revision CWD mastoidect.	83	2	2%	1	1%			3	4%
Bone achored hearing aid	28			1	4%			1	4%
Ossicular chain reconstr.	88	2	2%	1	1%			3	3%
Revision CWU mastoidect.	73	2	3%					2	3%
Subtotal petrosectomy	45	1	2%					1	2%
Myringoplasty	148	3	2%					3	2%
Miscellaneous	33	4	12%					4	12%
Table total	1009	30	3%	18	2%	3	0,3%	51	5%

CWD = Canal Wall Down, CWU = Canal Wall Up

severing of the chorda tympani without taste disturbances, etc.

Grade B (minor complications)

The 18 (2%) grade B complications are presented in table 5. One case of endolymph

Table 4: Grade A (adverse events) in alphabetical order of kind of surgery.

CWD mastoidectomy	Bony defect anterior meatus
	Dizziness postoperative during 4 days
	Transient, partial facial palsy = 3 days corticosteroids
	Opening sheath facial nerve: corticosteroids
CWU mastoidectomy	Transient loss of taste
	Profuse bleeding during operation = more time
	Suspected postoperative wound infection = antibiotics
Meatoplasty	Bleeding peroperative, termination of operation
	Wound abscess postoperative = bedside drainage
Myringoplasty	Cutting of chorda tympani without complaints of loss of taste: 2 cases
	Transient postoperative loss of taste
Ossicular chain reconstr.	Tympanic membrane perforation
	Wound infection = antibiotics
Revision CWD mastoidec.	Perilymph leakage during operation
	CSF leakage during operation
Revision CWU mastoidec.	Bleeding from jugular bulb during operation
	Minimal liquor leakage postoperatively for 2 days
Stapedotomy	Cutting of chorda tympani without complaints of loss of taste
	Fracture of footplate
	Transient loss of taste
	Mobilisation of anterior part of the footplate
	Perilymph leakage, no hearing gain
	Tympanic membrane perforation: 2 cases
Subtotal petrosectomy	Profuse bleeding from jugular bulb without need for transfusion
Miscellaneous:	
Exploration after obliterat.	Perforation of the drum
Facial nerve graft	Opening of anterior semi-circular canal
Infratemp. glomus tumor	Temporary liquor cyst = 7 days extra hospital admittance
Labyrinthectomy	2 days postoperative 1st degree nystagmus and dizziness

leakage from semi-circular canal was included because this undesirable iatrogenic damage could have led to serious consequences for the patient. Two cases of severe dizziness were put into category B as they significantly extended the time before the patient was able to return to normal life.

Grade C and grade D complications

There were three (0.3%) grade C complications (table 6). One patient suffered perceptive hearing loss and had disturbance of equilibrium for 3 weeks after a Canal-Wall-Down (CWD) mastoidectomy. One patient had a gusher at stapedotomy with a permanent loss of perception and severe dizziness. One other patient remained severely dizzy for more than 1 year after stapedotomy.
No deaths (grade D complications) occurred.

Table 5: Grade B complications.

Bone anchored hearing aid	Postoperative hematoma subcutaneously = reopening wound [1]
CWD mastoidectomy	Wound abscess = incision and drainage [1]
	Some endolymph leakage from semi-circular canal
CWU mastoidectomy:	Severe postoperative dizziness during 3 months
	Severe postoperative dizziness during 1 month
	Haematoma with pain postoperative = drainage [1]
Meatoplasty	Tympanic membrane perforation: additive myringoplasty
	Tympanic membrane perforation, leading to second operation
Middle ear inspection	Agitation in local anaesthesia, leading to second operation
	Pain despite local anaesthesia, leading to second operation
	Tympanic membrane perforation, leading to reoperation
	Tympanic membrane perforation: additive myringoplasty
Ossicular Chain Reconstr.	Otosclerosis found, stapedotomy after informed consent [1]
Revision CWD mastoidec.	Spontaneous bleeding 10 days postoperatively = 18 days extra [2]
Stapedotomy	Perceptive high tone loss due to accidental removal footplate 2 cases
	Perceptive high tone loss due to perilymph leakage
	Severe dizziness for 1 year due to accidental removal footplate

1 = separate procedure under general anaesthesia

2 = significant longer hospital stay

Table 6: Grade C complications.

CWD mastoidect.	Perception loss, postoperative dizziness for 3 weeks
Stapedotomy	Perilymph gusher = perception loss, postoperative dizziness
	Postoperative dizziness disabling for > 12 months

In the 'mastoidectomy' subgroup consisting of primary cases and revision cases of Canal Wall Up (CWU) and Canal Wall Down (CWD) mastoidectomies and subtotal petrosectomies, there was one deaf ear (0.2%).

Myringoplasty had the lowest complication rate (1%) and only grade A events.
Stapedotomy had most complications, of which 5% were grade B complications and 2% grade C complications.

Stapedotomies

When we look at stapedotomies on the basis of 'intention to treat', there were four other cases with otosclerosis in addition to the 'gusher' that did not receive a stapedotomy in the first operation. On two occasions, the patients were unable to tolerate local anaesthesia and the operation had to be terminated shortly after the start. In one patient, a myringoplasty had to be performed and ossicular work was precluded due to damage to the eardrum. These three cases underwent a stapedotomy in a second operation (and have been categorised as grade B (minor complication) under middle ear inspection in table 5). In one case, an aberrant facial nerve meant that there was not enough space for a prosthesis. This case has been classified as a failure of therapy.
There were two operations that were set up as revision stapedotomies but no new prosthesis was placed. In one case the prosthesis seemed to function normally and no reason for the persistent conductive hearing loss was found at operation. In the other case the malleus-to-footplate prosthesis had to be removed because of severe postoperative dizziness.
In all, there were fourteen (eleven + three) adverse events and complications (fifteen per cent) in 91 (85 + 6) ear operations scheduled as stapedotomies or revision stapedotomies.

Comparison of two periods stapedotomies

In 7 years of otosclerosis surgery, 226 consecutive stapes operations were performed: 96 in the first and 130 in the second period. Nearly all operations involved primary stapedotomies. In the first period, there were 12 revision stapedotomies and in the second period there were 13. Four were stapedectomies (2 in each period) since the whole footplate was removed instead of only drilling a small hole. In 6 cases a malleus-to-footplate piston was used.

Table 7 shows the general parameters for each cohort. The two cohorts were similar in terms of age at operation and AC Fletcher Index. There were significant differences in pre-operative ABG Fletcher Index (2 tailed *t*-test = 0.01), in postoperative ABG Fletcher Index (2 tailed *t*-test = 0.02) and the postoperative time to audiometry was shorter (2 tailed *t*-test = 0.00). There was no difference in mean improvement in ABG between the first period and the second period (27-9 = 18 dB in the first period and 23-6 = 17 dB in the second period).

Table 8 shows the participating surgeons. In the second period, the mean number of stapes operations performed annually per surgeon more than doubles for senior members of staff relative to the first period (from 5.7 to 12.0 annually). Junior

Table 7. Age, hearing loss in period 1 from 1 July 1992 – 31 December 1995 and period 2 from 1 January 1996 – 30 June 1999.

Variable	Period 1 (N=96) Mean (min-max) Standard deviation	Period 2 (N=130) Mean (min-max) Standard deviation	Significance difference 2-tailed T-test
Age at operation (years)	41 (12-89) 13,0	43 (16-83) 12,4	0,251
Fletcher Index air conduction thresholds (dB)	56 (13-108) 15,9	55 (5-96) 16,8	0,572
Pre-operative Fletcher Index air-bone gap (dB)	27 (5-55) 10,5	23 (0-50) 11,0	0,009
Postoperative Fletcher Index air-bone gap (dB)	9 (–3-+48) 10,5	6 (–10-+45) 10,9	0,023
Postoperative time to audiometry (years)	1,4 (0,7-6,5) 1,4	0,8 (0-3,2) 0,7	0,000

members of staff no longer performed stapes surgery (from 7.2 to 0.6 annually). In the first cohort, 2 senior members of staff performed 40 operations (43%), two junior members of staff performed 51 operations (52%) and two residents performed 5 (5%) operations. One junior member of staff in the first cohort became a senior member of staff in the second cohort. In the second cohort, 3 senior members of staff performed 126 operations (97%) and closely-supervised residents or a junior member of staff with special interest performed stapedotomies in four cases (3%).

Pre-operative audiometry was available in 226 (100%) cases and postoperative audiometry in 218 cases (96%). The median change from post- to pre-operative value of the AC Fletcher was -22 dB (-28 - 50, N=91) in the first period and -25 dB (-23 - 48, N=127) in the second period. There was no significant difference in the changes in AC Fletcher Index between the two cohorts (2 tailed t-test = 0.556).

Table 9 shows the distribution in pre- and post-operative ABG Fletcher Index in 4 groups (<10dB, 10-20dB, 20-30dB, >30dB). Prior to the operation, there was no significant difference in distribution between the two cohorts (Pearson chi-square test = 0.19) (table 9). After the operation, there is a significant difference between the two cohorts (Pearson chi-square test = 0.042) (table 10).
Figures 1a, b show the individual audiologic results. The change in AC Fletcher Index (y-axis) is plotted against the pre-operative AC Fletcher Index (x-axis). A distinction is made between primary and revision stapedotomies. Theoretically,

Table 8. Surgeons involved in otosclerosis surgery in period 1 from 1 July 1992 – 31 December 1995 and period 2 from 1 January 1996 – 30 June 1999.

	Period 1			Period 2		
	N surgeons	N cases	Mean	N surgeons	N cases	Mean
Senior members of staff	2	40	5,7	3	126	12,0
Junior members of staff	2	51	7,3	1	2	0,6
Residents supervised	2	5	0,7	2	2	0,3
Total	6	96	4,6	6	130	6,2

Mean = Number of operations per surgeon annually. Each cohort covers 3.5 years.

maximum improvement is represented by the line: pre-operative AC Fletcher Index – change in AC Fletcher Index = 0. The cases that are plotted closest to the maximum possible improvement line can be considered to be the best results.
The cases that show deterioration in hearing are plotted under the 0 line in the shaded area.

Table 11 shows examples of best results with a postoperative AC Fletcher Index of < 15 dB. There is over-closure on the ABG Fletcher Index in these cases.

Table 12 shows an example of worst results with a deterioration in the AC Fletcher Index of more than 15 dB (<-15 dB in the figure)

Table 13 shows that adverse events (Grade A) were noted in 9 (9%) of 96 cases in the first period and 13 (10%) of 130 cases in the second period. In both periods there were 2 cases in which some damage to the tympanomeatal flap occurred without consequences to the patient. The scutum was reconstructed in 3 cases in the first period and in 5 cases in the second period because the curettage of the posterior canal wall was felt to be too large. This was considered part of the normal procedure.
Minor complications (Grade B) occurred in 4 cases (4%) in the first period and in 0 cases (0%) in the second period. In 3 cases there was a postoperative increase in high tone sensorineural hearing loss. These patients had an improved air-bone gap in the lower tones. One patient was severely dizzy after the operation for about 1 year.

Table 9. Pre-operative Air-Bone Gap Fletcher Index (mean 0.5-1-2 kHz) in 4 groups for in period 1 from 1 July 1992 – 31 December 1995 and period 2 from 1 January 1996 – 30 June 1999.

Pre-opera-tive ABG	Period 1	Period 2	Total
< 10 dB	4 (4%)	15 (12%)	19 (8%)
10 – 20 dB	27 (28%)	40 (31%)	67 (30%)
20 – 30 dB	35 (36%)	43 (33%)	78 (34%)
> 30 dB	30 (31%)	32 (24%)	62 (27%)
Total	96	130	226

Figures are rounded off so total percentages do not add up to 100%. There were no statistically significant differences between periods 1 and 2 for the categorised pre-operative ABG Fletcher Index (Pearson chi-square = 0.190)

There were major complications (Grade C) in 2 patients (2%) in the first period and 1 patient (1%) in the second period. These three patients had perceptive hearing loss and postoperative dizziness. In the first period, one gusher was encountered. In this case a severe worsening of the perceptive component led to hearing loss, although the ABG was closed postoperatively. This was registered as a major complication. Another
patient in the first period had severe perceptive hearing loss after placement of a malleus-to-stapes prosthesis. In the second period, in the one case of severe dizziness, a malleus-to-stapes piston was removed in a separate operation the next day. There were no Grade D (death) complications. There was a statistically significant difference in categorised complications (Pearson chi-square 2-sided 0.047).

Discussion

Electronically stored data may be used to generate feedback overviews. These may result in measures for improving quality and in improvements in the information given to patients about what to expect from surgery. This paper represents an effort to establish a picture of our own ear surgery complications.

It was felt that there was a need for a combined adverse event and complication scale because, during the compilation of prospective complication data, it emerged that many smaller recorded events did not always lead to serious damage. This kind of event is more of a deviation from the textbook descriptions than a complication.

Table 10. Postoperative Air Bone Gap Fletcher Index (mean 0.5-1-2 kHz) in 4 groups for each period.

Postopera-tive ABG	Period 1	Period 2	Total
< 10 dB	67 (74%)	99 (78%)	166 (76%)
10 – 20 dB	10 (11%)	22 (17%)	32 (15%)
20 – 30 dB	10 (11%)	4 (3%)	14 (6%)
> 30 dB	4 (4%)	2 (2%)	6 (3%)
Total	91	127	218

Period 2 had significantly more patients in groups considered to be better in terms of the postoperative ABG Fletcher Index (Pearson chi-square = 0.042)

However, ignoring these adverse events fails to do justice to the real-life situation. The scale of Clavien et al. was therefore adapted for use with ear surgery. A good register and a complete overview prevents the under-reporting of complications [23].

The main advantage of a simple, easy-to-use scale is that it enhances surgeon compliance and this in turn results in comprehensive feedback overviews. A complete adverse events and complication overview diverts the focus from blame and fault-finding ('witch hunting') [24] to quality improvement.
As in any scale, the exact limits of each category are a subject for discussion. For instance, the time period after which a disability is considered residual (difference between grade B and grade C) is usually not stated clearly but could be set arbitrarily at 3 months. However, we feel that the scale presented in this paper can be used intuitively and is clear enough so there is no need for extensive inclusion or exclusion criteria.
We noted an overall rate of 5% for the adverse events and complications (table 3).
Grade A (adverse event) accounted for 30 of 1,009 (3%) ear operations (table 4). Most authors would not even mention grade A cases as they are not likely to lead to serious problems, although they might, as with some cases of trauma to the chorda tympani (minor iatrogenic damage).
Grade B (minor complications) were registered in 18 of 1,009 (2%) cases (table 5). Grade B complications usually require some repair that may possibly involve risk. An example is a tear in the eardrum during stapedotomy requiring intervention. Undesirable iatrogenic damage is included in this category. Hearing and balance disturbances are more problematic. These kinds of problems may be accompanied by prolonged postoperative morbidity. Such a disruption of normal life qualifies as a grade B event (minor complication).
There were three (0.3%) grade C complications (table 6). One patient suffered from perceptive hearing loss and dizziness after a Canal-Wall-Down (CWD) mastoidectomy. Two other patients suffered from severe dizziness and perceptive hearing loss after stapedotomy, one of them being a gusher.

It is not customary to group all ear surgery together when studying results of treatment. Usually, the focus will be on one specific kind of ear surgery [3-5,7,12,13,15,18,20,21,26,27,29,30,33,34,37,44,46,48-50,52-54,56,58-61,66,68].
These studies usually present major complications varying from 0 % for

myringoplasty [61] and stapes surgery [52] to 3.6% for surgery for chronic adhesive otitis media[60]. Moreover, the literature does not usually differentiate between less and more problematic adverse events. Specific reports about complications generally deal only with specific complications [9,17,51,62,65,67,69] such as facial paralysis [19,28,35] and how to prevent it [39].

In order to compare our results with the literature, a breakdown into specific operations is therefore required.
In our sample, myringoplasty caused no grade B or grade C (minor/ major) complications. This is usually the case [61].
For the convenience of comparison to literature, the patients who underwent a mastoidectomy were evaluated separately for severe sensorineural hearing loss. In the mastoidectomy subgroup (N=504), there was one case of hearing loss, a normal percentage [54,59,63]. In otosclerosis surgery also, our results are similar to results claimed in the literature [30,44,52].

The feedback from our study led to a change in the policy for stapes surgery. A 7-year period in which halfway the number of surgeons was reduced to three senior members of staff (table 8) was studied.

In the literature, the criterion for success of stapedectomy is a postoperative air-bone gap < 10 dB. In single surgeon series[22,41-43], success rates vary between 87%[42] and 96 %[22]. When looking at multiple surgeon series[16,18,31,38,53,55-57], the results in this respect vary from 68%[4] to 89%[38]. Application of the laser[6,32,40,45,47,55,64] results in success rates varying from 87%[32] to 93%[64]. In our series, a postoperative air-bone gap of < 10 dB was achieved in 76% (Table 10).
There were 10 (4%) minor complications (Grade B) and 3 (1.3%) major complications (grade C) in 226 operations (table 12), of which 2 (0.9%) involved severe perceptive hearing loss. As expected, there were no deaths and grade D is only mentioned for the sake of completeness. Harkness analyzed 185 stapedectomies by 28 consultants for the Royal College of Surgeons of England. He reported a complication rate of 30%. 26 (14%) were temporary taste disturbance or vertigo. 7 (4%) had persistent vertigo or taste disturbance. 4 (2%) were deaf ears. There were 19 (10%) other complications[30]. Other authors report major complication rates of

approximately 1%[10]. When looking at severe worsening in hearing, Mann reported 20 severe perceptive hearing losses in 1,229 stapes operations (1.6%). This was a multi-centre study including revision and other stapes surgery[44]. In a series operated by Marqet (N=2521), which also included revision stapes surgery, 0.36% early onset sensorineural hearing loss occurred[56]. Causse reported, in 6,724 of his

Table 11. Summarised individual patients with very good hearing results (limits arbitrarily set at postoperative AC Fletcher Index < 15 dB, pre operative AC Fletcher Index > 20 dB) in period 1 from 1 July 1992 – 31 December 1995 and period 2 from 1 January 1996 – 30 June 1999.

Patient number	Fletcher pre	Fletcher post	Improvement air conduction	Improvement air-bone gap	Postoperative air-bone gap	Remarks
Period 1						
1	28 dB	12 dB	17 dB	10 dB	0 dB	-
2	63 dB	13 dB	50 dB	30 dB	0 dB	-
3	42 dB	10 dB	32 dB	13 dB	3 dB	Stapedectomy
Period 2						
4	45 dB	13 dB	32 dB	15 dB	5 dB	Stapedectomy
5	58 dB	10 dB	48 dB	25 dB	8 dB	Stapedectomy
6	45 dB	13 dB	32 dB	15 dB	0 dB	-

Table 12. Summarised individual patients with very bad hearing results (limits arbitrarily set at deterioration AC Fletcher Index > 15 dB = <-15 dB in figure 1a and 1b) in period 1 from 1 July 1992 – 31 December 1995 and period 2 from 1 January 1996 – 30 June 1999.

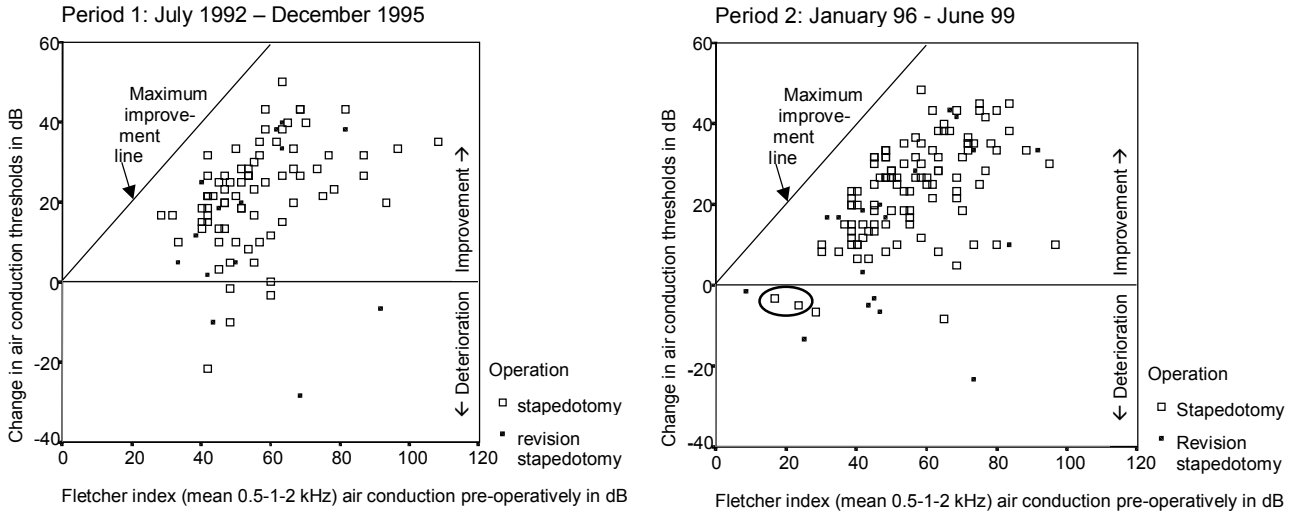
Patient number	Fletcher pre	Fletcher post	Change air conduction	Change air-bone gap	Postoperative air-bone gap	Remarks
Period 1						
1	42 dB	63 dB	-22 dB	-20 dB	38 dB	-
2	68 dB	97 dB	-28 dB	-8 dB	23 dB	Malleus-to-stapes piston
Period 2						
3	74 dB	97 dB	-23 dB	13 dB	28 dB	Severe dizziness = Malleus-to-stapes piston removed

own primary stapedotomies, 2 deaf ears and 14 sensorineural hearing loss (0.2 %)[11]. In 270 stapedotomies by Ramsay, there was 0.4% persisting vertigo and no deaf ears[52]. Fisch reported no deaf ears after stapedotomy and 0.6% after stapedectomy (N=170)[25].

Exceptional results (best and worst) were selected to determine predisposing factors (table 11 and 12). The conventional Fletcher Index (mean 0.5-1-2 kHz) of the air conduction thresholds (AC) was taken as the main measure for hearing acuity. This was chosen because a patient experiences the changes in air-conduction thresholds and does not experience the air-bone gap

On the one hand we selected the best cases by arbitrarily selecting the cases with a postoperative AC Fletcher Index under 15 dB but this could have been any other limit as the hearing levels are stored as continuous data. The best cases (table 11) show that the improvement in AC Fletcher Index is much larger than the improvement in the ABG Fletcher Index. There is over-closure of the air-bone gap in the best results group. Three out of four operations converted to stapedectomy showed up in the best results. A drawback of stapedectomy in this study is that there were two cases of high tone sensorineural hearing loss in the first period after stapedectomy that were grade B complications in the first period. Since the conventional Fletcher Index leaves out

Figure 1. The change between the pre- and post-operative AC Fletcher Index is plotted against the pre-operative AC Fletcher Index. Different symbols are assigned to primary and revision surgery. The maximum improvement line represents a postoperative AC Fletcher index of 0 dB.



the high tones, these did not influence the final result.
On the other hand, the cases that show deterioration in hearing of more than 15 dB (<-15 dB AC Fletcher Index in figure 1) were selected but this could also have been any other criterion (table 12). In the first period, one of two cases was categorised as a major complication (Grade C). The other patient, however, had no complications and suffered mainly an increase in the air-bone gap after placement of a malleus-to-stapes piston. This was categorised as a failure of therapy. In the second period, there was one case in which a malleus-to-stapes piston had to be removed because of severe dizziness. No audiometric data was available after the first operation so the final audiometry (after the second operation) is presented in this case. This hearing deterioration was categorised as a major complication (Grade C). Two of six malleus-to-stapes prostheses gave rise to an increase in hearing loss of >15 dB, one conductive and one perceptive.

In comparing two periods, a slightly significant difference between the first period and the second period was found in the postoperative ABG Fletcher Index in 4 groups (table 10). There was no difference in the categorised pre-operative ABG Fletcher Index between the first period and the second period (table 9). Compared to the first period, the second period saw significantly more operations which resulted in a postoperative ABG Fletcher Index between 10 and 20 dB. There were fewer patients in worse categories (=postoperative ABG Fletcher Index > 20 dB) (Pearson chi-square test: 0.042). A categorised postoperative ABG Fletcher Index seems to be a valid method for visualising results in this study. Since the categorised pre-operative ABG Fletcher Index did not change and the postoperative ABG Fletcher Index was significantly better in the second period, we tend to conclude that postoperative hearing results were better in the second period than in the first period.

Minor complications (Grade B) were reduced from 4 (4% of 96) in the first period to 0 in the second period (table 13) . There were two (2%) major complications (Grade C) in the first period and there was one major complication (1%) in the second period. In the first period, a gusher was encountered. This could also have occurred in the second period or not at all because it is such a rare complication[11,44,56]. The adverse events (Grade A) increased from 7% (7 of 96) to 10% (13 of 130). More damage to the chorda tympani was recorded in the second period. This did not usually lead to a loss of taste. There is a tendency towards fewer minor and major

complications in the second period (Pearson chi-square test, 2-sided 0.05). Given the low number of complications, a definite conclusion cannot be stated.

In addition to significant differences in hearing results and complications, there were other significant differences. Both the mean pre-operative and post-operative ABG Fletcher Indices were significantly lower in the second period (table 7). We conclude

Table 13. Adverse events and complications per cohort grouped by severity.

		Period 1 (N=96)	Period 2 (N=130)
Uneventful operations		82	115
Events	Consequences to the patient		
Grade A (adverse events)			
Damage to the chorda tympani	Without complaints of taste loss	1	4
	With temporary taste loss		1
Temporary loss of taste		1	
Luxation of ossicular chain			1
Perforation tympanic membrane		2	2
Fracture of footplate		3	3
Accidental removal footplate			2
	Total grade A	7	13
Grade B (minor complications)			
Severe dizziness	Not working for 1 year	1	
Accidental removal footplate	Sensorineural high tone loss	2	
Perilymph leakage	Sensorineural high tone loss	1	
	Total grade B	4	0
Grade C (major complications)			
Gusher	10 dB hearing loss + dizziness	1	
Sensorineural hearing loss		1	
Severe dizziness = removal of piston resulting in hearing loss			1
	Total grade C	2	1
	TOTAL Grade A - C events	14	15

that, generally speaking, cases with smaller air-bone gaps tend to be operated in the second period. For instance, the scatter plot shows that in the second period there were 2 primary stapedotomies with a pre-operative AC Fletcher Index of around 20 dB (circled in figure 1b). The mean reduction in ABG Fletcher Index is however nearly the same in both cohorts (27-9 = 18 dB in the first period and 23-6 = 17 dB in the second period). Time to postoperative audiometry was significantly longer in the first period because, in this system, the last audiometry in the follow-up is selected (table 7). When trying to monitor a change in surgical procedures, it is preferable for other parameters to stay the same. However, as this study concerns daily clinical practice, it is unavoidable that, over time, other parameters will also differ.

There was a tendency in this study towards better results in the second period. We ascribe this to the selection of more experienced surgeons. In the literature, the general feeling is that experience is very important to achieve good results in otosclerosis surgery. This is mainly known from experience with stapedectomy[4,12,33]. Belluci warned already in 1979 that it might become impossible to provide sufficient experience in otosclerosis surgery for all trainees in Otolaryngology[8]. By restricting the number of surgeons involved, better use of experience was made and junior members of staff built up experience quicker. Senior members of staff operated on 40 out of 96 (43%) cases in the first period and on 126 of 130 (97%) cases in the second period. It must be noted that 1 junior member of staff in the first period became a senior member of staff in the second period. However, the mean number of stapes operations performed annually by senior members of staff also more than doubled (in the first period 5.7 and in the second period 12.0). It turned out to be possible to change how surgeons were assigned. Obviously this involves a risk of losing expertise immediately when one of those surgeons leaves. So it is essential to keep training junior members of staff and residents with special interest in order to guarantee sufficient numbers of surgeons who are able to perform stapes surgery in the future.

Conclusion

When routinely gathering information about ear operations and postoperative course, all events and complications are included in the charts and no detail should escape. A prerequisite for concise overviews is a good definition of adverse events and complications and a convenient gradation. This gives a nearly complete picture of all

adverse events and complications in patient care that leads to the potential for comparing daily clinical practice to the literature by means of specific studies of aberrant results. The achievements in air-bone gap closure and the complication rate for 226 successive cases of stapes surgery can stand up to comparison with the literature but were in the lower range of reports from elsewhere.

Increased awareness among surgeons of what exactly is going on in their department can induce changes in procedures. By assigning more experienced surgeons for otosclerosis surgery an improvement in hearing results and a tendency towards fewer minor complications occurred.

The outcomes of daily clinical practice can be monitored and this information can be used to direct changes in the process of medical care.

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Chapter 4 Complications in sinus surgery and new classification proposal.

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Summary

Complication overviews may lead to measures directed towards quality improvement and to better information for patients. When evaluating the rhinological literature from 1979 until 1999 a detailed comparison could not be made due to differences in reporting. With the advent of electronically stored medical data, events can be registered better than before. To be able to compile very diverse data from electronic dossiers into concise overviews for feedback a simple general scale with broad categories is needed. These feedback overviews enable insight in the complication rates of different kinds of sinus surgery and monitoring of changing trends in sinus surgery. An example of a general classification based on severity is presented for use when electronically storing medical data. This scale varies from adverse events (grade A) to death (grade D). A consensus on categorization of complications is a prerequisite for a valid comparison with other clinics. In order to instigate a discussion about consensus, this classification is presented as an example. Our proposal is presented together with an overview of sinus surgery complications in recent literature for reference.

Introduction

Feedback about the delivery of medical care may lead to improvement of the quality of care. With the advent of electronically stored medical data, events can be registered better than before. To be able to compile very diverse data from electronic dossiers into concise overviews for feedback a simple general scale with broad categories is needed. A general classification based on severity is presented with the aim of instigating a discussion about a consensus on complication definition that is applicable in electronic medical dossiers. Our proposal for a complication classification is presented against the background of an overview and analysis of complication rates in recent literature about sinus surgery.

Complications can occur during any medical treatment. Despite great care taken to prevent complications, some are unavoidable. The maximum level of complications that is acceptable must be in proportion to the expected benefits to the patient and depends on the indication. Some indications (i.e. massive polyposis which does not respond to medical treatment) outweigh others (i.e. rhinogenic headache). These considerations must be made clear to patients.

Alongside complications, two other outcomes of treatment should be mentioned that might lead to inconvenience, i.e. sequelae and failures. A sequela is inherent to the procedure. Occasionally both sequelae and complications may occur in one case, an example being prolonged transient postoperative bleeding after sinus surgery. The difference between a failure and a complication is that with a failure the original problem is not eradicated completely, whereas with a complication a new element has been added to the problem [1,2] .

To report complication rates, a generally accepted classification is needed. Although several authors have suggested classification systems, we feel that none have been generally accepted [3-5] . Complications can be graded in different ways: gravity (major versus minor), timing (during surgery or post-operative), anatomical (locally, orbit, intracranial, vascular, general) or temporary versus permanent. Some authors report per operated side, some per operation and some per patient. Ideally, what is needed is a simple and clear classification that is suitable for intuitive use.

Table 1. Classification of complications as major and minor as found in rhinological literature.

Major complications

Orbit	Hematoma Loss of vision Diplopia Trauma tear canal necessitating surgical repair
Intracranial	CSF rhinorrhea Pneumocephalus and tension pneumocephalus Encephalocele Brain abscess Meningitis Intracranial (subarachnoidal) bleeding Brain damage
Bleeding	Major, necessitating extensive tampons and blood transfusion
Other and systemic	Exacerbation (pre-existent) asthma and bronchospasm Toxic shock syndrome Anosmia Lesion N V2, (transantral route), permanently Death

Minor complications

Orbit	Orbital emphysema Ecchymosis eyelids
Intracranial	CSF rhinorrhea, uncomplicated
Bleeding	Small, only needing extra tampon, no transfusion
Other and systemic	Anisocoria Synechia Moderate exacerbation of pre-existent asthma Hyposmia Local infection (osteitis) Post-FESS MRSA Sinusitis Myospherulosis Lesion N V2, (transantral route) transient Hypesthesia lip and teeth

Material and methods

We reviewed the rhinological literature from 1979 until 1999.
We could not present all published articles in this paper; therefore we chose to limit the number of articles to the most relevant ones. The selection criteria were set rather arbitrarily to those that reported on at least 85 cases of macroscopic sinus surgery (use of headlamp) and at least 100 cases of endoscopic or microscopic sinus surgery.

The categorization used in the articles was respected. Mostly, there was a division in major and minor complications. What the authors generally thought to be major and minor complications is listed in table 1.

The major complications were divided into four categories: orbital lesions, intracranial damage, bleeding and other. The different articles and the reported numbers of complications are listed in table 2.

Results

Thirty-four articles about sinus surgery were found in MedLine, which covered a consistently adequate number of cases. There were eight articles that reported on macroscopic sinus surgery (use of headlamp), which varied from 87-3000 cases [6-13] . Analysis of these eight series shows an overall incidence of major complications of 1%. Minor complications were reported in <3%.

Twenty-six articles were found that reported on Functional Endoscopic Sinus Surgery (FESS). Numbers varied from 100-1500 cases [14-22,3,23-36] . Two articles concerned microscopic sinus surgery [37,38] . Analysis of these series shows an overall incidence of major complications of ~ 1%. Minor complication rates of 5% - 6% were reported. We were unable to make a detailed comparison.

Discussion

Complication overviews may lead to measures directed towards quality improvement and to better information for patients. A general classification based on severity is presented for use when electronically storing medical data. This scale varies from adverse events (grade A) to death (grade D). Our proposal is presented together with an overview of sinus surgery complications in recent literature for reference.

We were unable to find a generally accepted complication classification in rhinology [3-5] . In literature on general surgical procedures, two classifications of complications were found [39,1] . The classification system used by Clavien was readily adaptable to sinus surgery. This scale contains four grades of severity, varying from resolution with simple procedures (grade I) to death (grade IV). We adapted this classification to sinus surgery for this overview as an example of a classification based on severity, in which the effects on the well-being of the patient occupy a more prominent place than in other classifications. The adverse event and complication definition used was: incidents not intrinsic to the surgical procedure that (may) have a negative effect on the surgical outcome or postoperative morbidity. Each operation is counted as one surgical intervention and it may be unilateral or bilateral.

Grade A– an adverse event that resolves if left untreated or requires a simple bedside procedure. These events are more a nuisance to the patient and/or the doctor than a real complication. Grade B– a minor complication that usually requires an additional intervention that involves a risk of its own, but is eventually resolved. Grade C– a major complication that is associated with a residual or a lasting disability. Grade D– any complication that results in death.

Table 2. Frequencies of complications as reported by different authors devided in macroscopic and endoscopic treatment modalities.

2A. With use of headlamp.

Author	**N**	**Major**				**Minor**
		Orbit	**Intracranial**	**Bleeding**	**Other**	
Freedman and Kerr 1979	565	4	2	2	1	16
Taylor *et al.* 1982	284	1	3	-	-	8
Eichel 1982	123	1	2	1	-	NM
Stevens and Blair 1988	87	3	-	3	-	8
Sogg 1989	146	-	-	-	-	4
Friedman and Katsantonis 1990	1163	-	4	3	-	25
Lawson 1991	600	2	3	-	2	5
Sogg and Eichel 1991	3000	-	5	2	-	288

(NM = Not mentioned)

2B. Endoscopic and microscopic.

Author	N	Major				Minor
		Orbit	Intracranial	Bleeding	Other	
Schaefer *et al.* 1989	100	-	-	-	-	14
Toffel *et al.* 1989	170	-	-	1	-	6
Rice 1989	100	-	-	-	-	10
Stammberger and Posawetz 1990	500	-	-	1	-	22
Matthews 1991	155	-	-	-	-	3
Salman 1991	118	-	-	-	-	28
Wigand and Hosemann 1991	500	-	10	-	-	NM
Lazar *et al.* 1992	210	-	-	-	3	16
Vleming *et al.* 1992	593	2	2	2	1	38
Weber and Draf 1992*	589	20	15	1	-	NM
Kennedy 1992	120	-	-	-	-	1
Levine and May 1993	1165	-	4	3	-	94
Smith and Brindley 1993	200	1	-	-	-	16
Dessi *et al.* 1994	386	3	2	-	-	NM
Cumberworth *et al.* 1994	551	1	2	-	-	NM
Lund and Mackay 1994	650	1	1	-	-	NM
Ramadan and Allen 1995	337	1	3	-	-	34
Stamm 1995	632	-	8	6	9	NM
Danielson and Olofsson 1996	230	-	-	-	10	6
Castillo *et al.* 1996	553	2	2	8	-	36
Weber *et al.* 1997*	325	4	3	30		NM
Lee *et al.* 1997	554	1	1	1	-	NM
Rudert *et al.* 1997	1172	3	10	10	-	NM
Dursun *et al.* 1998	415	12	1	12	-	56
Keerl *et al.* 1999	1500	2	5	9	-	NM
Marks 1999	393	1	3	5	-	22

* = microscopic, NM = Not mentioned

Table 3. Classification based on severity, in which the effects on the well-being of the patient are taken into account, varying from adverse events (grade A) to death (grade D).

Grade A (adverse event = spontaneous resolution or with simple bedside procedure)

Orbit	Orbital emphysema Ecchymosis eyelids
Bleeding	Small, only needing extra tampon, no transfusion
Other and systemic	Synechia, asymptomatic Lesion N V2, (transantral route) transient Light exacerbation of pre-existent asthma Local infection requiring normal antibiotics Significantly more postoperative pain, requiring NSAID

Grade B (minor complication = extra intervention, no residual disability)

Orbit	Hematoma necessitating decompression. Trauma tear canal necessitating surgical repair
Intracranial	CSF rhinorrhea requiring closure
Bleeding	Major, necessitating extensive tampons and blood transfusion
Other and systemic	Toxic shock syndrome Synechia, symptomatic requiring additional procedures Anisocoria Hyposmia with adaptation Osteitis requiring major, long-term, high dosed antibiotics Post-FESS MRSA Sinusitis Myospherulosis Exacerbation (pre-existent) asthma and bronchospasm, potentially life-threatening

Grade C (major complication = residual or a lasting disability)

Orbit	Loss of vision Diplopia occurring after orbital lesion
Intracranial	Brain damage due to i.e.: (tension) pneumocephalus, encephalocele, brain abscess, meningitis or intracranial (subarachnoid) bleeding.
Other and systemic	Anosmia Hyperesthesia lip and teeth, disabling Lesion N V2, (transantral route), permanently Subarachnoidal bleeding with permanent neurologic problems.

Grade D (death)

When our complication classification is applied, some complications that have been historically categorized as major complications are found, in our view, to be minor complications and vice-versa. Historically cerebrospinal fluid (CSF) rhinorrhea is categorized as a major complication because this had to be repaired endocranially [40] and led to anosmia (grade C). But nowadays a CSF leak that is immediately endonasally repaired during the same surgical procedure can heal without a trace [41-43] and could be considered a minor complication (grade B). Disabling hyperesthesia leading to lasting disability for the patient could be categorized as a major complication because (grade C). An example is given in table 3 in which the items of the traditional classification as mentioned in table 1 are re-arranged.
As in any scale, the exact limits of each grade can lead to discussion. For instance, the time period after which a disability is considered residual (difference between grade B and grade C) is not stated but could be set at 3 months. However, we feel that the scale presented in this paper can be used intuitively and is clear enough so there is no need for extensive inclusion or exclusion criteria. When there is a delay in occurring of the complication, such as meningitis months or years after surgery, it is important to link this to the original surgery to be able to make long-term follow-up overviews.

The main advantage of a simple, easy-to-use scale is that it allows for concise feedback overviews. A complete adverse event and complication overview diverts the focus from blame and faultfinding (witch hunting) to quality improvement [44] .

Patient and surgeon factors have an effect on the risk of complications in sinus surgery. Patient factors that increase the risk of complications include extensive pathology and revision surgery. This fact is explained by the absence of landmarks, possible absence of the lamina papyracea and fibrosis that can lead to loss of orientation [3,45,26] .
Major surgeon factors are experience, operating under local anesthesia and possibly whether the surgeon is left- or right-handed [6,12,46,3,30] .
Increasing experience seems to be correlated with fewer complications in sinus surgery in multiple studies [47-49,25,4,35] . However these reports relate to the early days of FESS. Today the relation between complication rate and surgeon experience may not be as clear [50,28,51,36] . Surgeons still had complications even after more than 300 endoscopic procedures. More experienced surgeons may have complications due to

increased time pressure, with greater self-confidence resulting in lower concentration levels and the acceptance of more complicated cases

Some authors feel that complications in functional endonasal sinus surgery (FESS) have increased. This may be true for the total number of complications, but not for the risk of complications per patient. The introduction of the endoscope has extended indications for sinus surgery and the absolute number of sinus operations has therefore increased since the 1980s [4] . Many Ear, Nose and Throat (ENT) surgeons and residents had to master this difficult technique in a relatively short time. These factors led to an increase in total numbers of complications in sinus surgery. In America, sinus surgery and endoscopic sinus surgery top the charts for legal suits in ENT surgery in 1993 [52] . However, our statistical analyses do not indicate any major differences between macroscopic, microscopic and endoscopic sinus surgery per patient.

Electronic collection of all complications in the own clinic makes comparison of various time periods and different treatment modalities possible and may give more insight in the above mentioned questions about changing trends in FESS.

The complications are placed in the context of our proposed gradation with recommendations for dealing with them (table 3).

Damage to the lamina papyracea is probably the most common complication in FESS. A lesion of the periorbital fascia is always accompanied by a (small) venous intraorbital hematoma. Treatment is not always necessary, but postoperative checks of the eye are mandatory. When this heals spontaneously we would account this as grade A.

Emphysema of the eyelids can occur after damage to the lamina papyracea. If the periorbital fascia has also been opened, intraorbital emphysema is possible. The emphysema mostly resolves within a few days and is then accounted as grade A.

Orbital hematoma can lead to blindness in the affected eye as a result of the compression of the optic nerve and the central retinal artery caused by increased intraorbital pressure. External signs of increased intraorbital pressure are pain, swollen eyelids, ecchymosis, increased pressure of the eyeball on palpation, subconjunctival bleeding, chemosis, proptosis, reduced pupil reactions (afferent pupil deficit) and finally loss of vision. During general anesthesia funduscopy is indicated to assess vision. If there are signs of pulsation or occlusion of the central retinal artery, retinal edema or swelling of the optic disc vision is endangered. Treatment consists firstly of massaging the eye and removal of tampons if present to

evacuate the blood if there is any sign of an arterial intraorbital hematoma. When this is enough to evacuate the hematoma, we would categorize this as a grade A. When endangered vision is suspected, exploration of the orbit must be undertaken within 5 - 90 minutes [53,54] . Lateral cantholysis is the easiest and most widely-used decompression method. The second step is removal of the lamina papyracea by external approach [45] or endonasally [55] . This may not be sufficient [56] and, in that case, infraction of the orbital floor or exploration of the lateral orbit may be necessary. When an extra intervention is necessary to evacuate the hematoma we would categorize this as a grade B. When this complication results in loss of vision or permanent diplopia we would categorize this as a grade C.

Anosmia can occur or persist after sinus surgery. The effect of sinus surgery on the sense of smell is in our opinion an important outcome parameter and has to be assessed postoperatively. Usually, endonasal sinus surgery improves smell [57-59] . When patients are not informed beforehand that anosmia can occur after septal or sinus surgery, legal action may result [60] . As anosmia reduces quality of life by impairing taste, which we see as permanent damage and would categorize as grade C.

CSF rhinorrhea is due to damage to the skull base and dura. Most perforations occur in the anterior ethmoidal roof. The skull base can be much lower on the medial side of the attachment of the middle turbinate than laterally in the ethmoid. This is traditionally regarded as a major complication. However, given timely diagnosis and immediate adequate treatment, the course can be asymptomatic as far as the patient is concerned. CSF leakage can be recognized during surgery when clear fluid streams can be seen in the blood on the ethmoidal roof. Closure is indicated, i.e. with a free flap of healthy mucosa and tissue glue [43] . In addition to this carefully applied tampons and postoperative bed rest are necessary. Closure of a CSF leak during the same session or as separate surgery is categorised as grade B.

Meningitis after sinus surgery can evolve from (initially closed) CSF rhinorrhea or from microlesions in the skull base which connect the dura to the nasal cavity. Even years after sinus surgery, recurrent meningitis can develop [61] . Finding small defects can be a diagnostic problem. Meningitis mostly requires hospital admission and strong intravenous antibiotics, which makes this a grade B complication.

Occlusion of the nasolacrimal duct can typically occur when the entrance to the maxillary sinus is opened too much in the anterior direction and the duct is severed with a sharp instrument. However, other parts of the bony canal and the nasolacrimal duct can also be damaged. Epiphora can evolve in the immediate postoperative period

or within the next 2-3 weeks [62] . Dacryorhinocystotomy is then indicated, which makes this a grade B complication.

Asthma and bronchospasm can occur during and after sinus surgery in 1% in of patients who do not have asthma and in up to 40% of pulmonologically non-prepared patients with astma [63] . Sinus surgery with local anesthetic has a higher prevalence than general anesthesia [5] . Patients with pre-existent asthma and especially those with Samter's triad; astma, nasal polyps and aspirin intolerance (APA) should receive adequate pulmonologic preparation. When treatment consists of what could have been normal pulmonologic preparation, this is categorized as grade A.

Trauma to the optic nerve can occur when the lamina papyracea in the posterior ethmoid or lateral wall of the sphenoid is damaged. If the nerve is severed, no therapeutic options are left (grade C). This can be diagnosed using a CT scan. If there is neurapraxia or a hematoma, high doses of intravenous corticosteroids can be given for a period of 24 hours [56] . Because high intravenous corticosteroids carry a risk in itself (i.e. gastric bleeding) this treatment falls under grade B. If no improvement occurs, transethmoidal-transsphenoidal resection and decompression of the optic nerve is indicated [55] (grade B when no residual damage).

Bleeding of the internal carotid artery is rare in FESS and occurs in less than 0.1% of cases. Hemorrhage can occur after penetration of the lateral wall of the sphenoid sinus. The absence of a bony coverage of the internal carotid artery in the sphenoid is reported in 22% of patients [64] and in 12% the artery is found in the extreme medial area of the sphenoid [65,66] . Guidelines were developed for treating this catastrophic complication [67] . When tight tampons in the sphenoid stop the bleeding, hypotension is treated adequately and there is no permanent damage this is accounted as grade B [68,69,38] . When this complication is lethal it is accounted as grade D.

Anisocoria can develop during sinus surgery without damage to the optic nerve or intraorbital hematoma. This unilateral widening of one pupil is then possibly due to perineural edema of the postsynaptic parasympatic part of the oculomotor nerve. If consultation of an ophthalmologist shows no loss of vision, no inhibited eye movements, a normal fundus and a normal parasympathic reaction on pilocarpine, exploration is not necessary [70-73] . If it persists with vision impairment it is grade C, when there is no impairment, we would suggest accounting this as grade B.

In Pneumocephalus headache is prominent. [74-76] . Additive (neuro) surgical interventions [5] make this a grade B complication if healed without permanent damage.

Encephalocele can evolve when a big enough defect with disruption of the dura is present in the ethmoid roof [77,78] . When intracranial correction is necessary, and anosmia evolves this a grade C complication.

Post-FESS methicillin-resistant Staphylococcus aureus (MRSA) sinusitis has been reported in Taiwan [79] . Treatments with quinolone antibiotics fall outside normal antibiotics and are therefore grade B.

Myospherulosis is a chronic inflammatory reaction to the mixture of red blood cells and petroleum-based ointments [80,81] . Removal of all the affected tissue is necessary and makes this a grade B complication.

Diplopia after FESS can occur from damage to medial eye muscles [82-84,46,56] , or when removal of a big part of the lamina papyracea with rupture of the periorbital fascia allows for displacement of periorbital fat and the eye bulb. If this condition persists (despite surgical correction) this is a grade C complication.

Subarachnoidal bleeding can occur as a result of the rupture of subarachnoid branches of the medial cerebral artery or intrameningeal branches of the anterior ethmoidal artery, mostly after damage to the skull base. Neurological evaluation and treatment is indicated [85] . When there is permanent damage, this is a grade C complication.

Toxic shock syndrome is diagnosed on the basis of the following four main symptoms: high fever, a scarlatiniform rash, hypotension or shock and fine desquamation of affected skin and peeling of palms and soles during convalescence. [86,87] . Toxic shock syndrome is usually associated with the use of tampons and splints but it can occur without the use of these [88] . When tampon removal, restoring blood pressure, rehydration and adequate antibiotics is sufficient this is a grade B complication. When there is internal organ damage caused by the shock this is categorized as grade C.

Damage to the infraorbital nerve can occur when the transantral route is used and has been greatly reduced since the introduction of endoscopic sinus surgery [89-91] . The treatment is largely dependent on etiology [92] . When the patient is severely disabled by this condition it could even be accounted as grade C.

Conclusions

- When evaluating the rhinological literature from 1979 until 1999 a detailed comparison could not be made due to differences in reporting.

- In order to instigate a discussion about consensus, a classification based on severity is presented as an example. The main advantage of a simple, easy-to-use scale is that it that it allows for concise feedback overviews. Compilation of electronically stored complication data in four categories (grade A-D) enables insight in the complication rates of different kinds of sinus surgery and enables monitoring of changing trends.
- A consensus on categorization of complications is a prerequisite for a valid comparison with other clinics.

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Chapter 5 The methodical collection of ear surgery data as a basis for quality control.

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Summary

Data relating to daily clinical practice was collected in an otologic database. Over a period of 3 years, information was gathered about 1,000 ear operations.
This led to the following conclusions: the collection of data is difficult; the selection of data and the moment it should be fed into the systems are very important; there is a risk of using too many items and therefore of reducing surgeon compliance. On the other hand, too few items result in irrelevant overviews. The collection of ear surgery data makes it easier to understand positive and negative outcomes.

Introduction

The challenge we face in clinical practice is to apply knowledge about populations – preferably obtained using evidence-based principles – to the individual patient. We assume that this knowledge can be extrapolated to the patient consulting us. However, the population in our own clinic may differ from the clinic or clinics discussed in literature. For instance, if the literature states that surgery is preferable to medication for a particular population, local complication rates will ultimately influence the final decision for an individual patient [24]. An understanding of one's own population and results is mandatory in determining the degree to which evidence from the literature may be extrapolated to one's own practice. This understanding can be established by collecting data about daily clinical practice [28]. Overviews generated from this data provide, for example, improved and up to date local patient information [30], a starting point for clinical audit [15,16,32,35] and a basis for quality improvement activities.
In this paper, the expression 'clinical feedback information' is used for overviews of which clarify the data collected from our own patients. As an example we analysed all cases of chronic suppurative otitis media (CSOM) to compare the results with the literature and to determine the possibilities of our database in this respect.

The methodical collection of the data needed for clinical feedback information has proven difficult for the following reasons:

(1) Data has to be gathered by medical professionals since only physicians can reliably judge data in records.[21]
(2) Retrieving data from medical records is time-consuming because documentation is not standardised and the data is erroneous and incomplete.
(3) Fall-out should not be accepted. Missing data may contain valid information that is required for adequate feedback information. For instance, the number of complications in missing cases may be twice as high as in the selected case corpus.[11]

The switch from paper to computers for recording patient information means that it is, theoretically, easier to generate feedback information [1,6,12]. However, in practice, this proved very difficult as most information is stored incoherently (in free-text formats) so that the data suffers from the same limitations as the data in paper

medical records. For data to be of practical use, it must be structured (in computer-understandable chunks). Structured data entry facilitates the handling of the data and, at the same time, encourages full data collection.[26]

The implementation of such systems in daily practice is slow. Most of them use up scarce clinical time and, moreover, result in changes in working procedures.[18,31,39]

We wished to learn whether it was feasible to obtain clinical feedback information in ear surgery without disrupting daily practice.[27,28] The purpose of this paper is to share our experience in implementing data collection methods and to demonstrate the acquired insights that such data collection may provide.

Figure 1. OtoData form which is dictated with the operation record. The bold capitals are the possible choices when the question is 'multiple choice' variant.

Name patient: .....
PID number & birth date: .....

Identification procedure

Right / **L**eft ear
Surgeon name: .....
Date: .....
Operation code: .....

Present state

- Middle ear inspection: **N**o (go to 'mastoid inspection') / **Y**es
  tympanic membrane: **I**ntact or perforation **S**hrapnel / **E**lsewhere / **A**bsent
  previous myringoplasty: **N**o/ **Y**es
  infection mucosa middle ear: **N**o / **Y**es / **C**holesteatoma
  ossicular chain mobility: **N**ormal/ **I**mpaired
  stapes: **I**ntact or suprastructure **M**issing / **P**artially absent
  incus: **I**ntact or **M**issing or **P**artially absent
  malleus: **I**ntact or **M**issing or **P**artially absent

- Mastoid inspection: **N**o (go to 'treatment') / **Y**es
  mastoid: previous mastoidectomy: **N**o / **Y**es
  previous antrotomy: **N**o / **Y**es
  thickened mucosa: **N**o / **Y**es
  pneumatisation: **N**o / **S**clerotic / **Y**es
  contents mastoid: **C**holesteatoma / **P**us / **A**ir / **E**lse
  canal wall present: **N**o / **Y**es

Treatment

Tympanoplasty: **N**o / **Y**es, with: .....
Ossiculoplasty / stapedotomy: **N**o / **Y**es, with: .....
Canal wall removal: **N**o / **Y**es / was already **M**issing
Obliteration: **N**o / **Y**es, with: .....
Peroperative complication: **N**o / **Y**es, description: .....
Remarks: .....

Material & methods

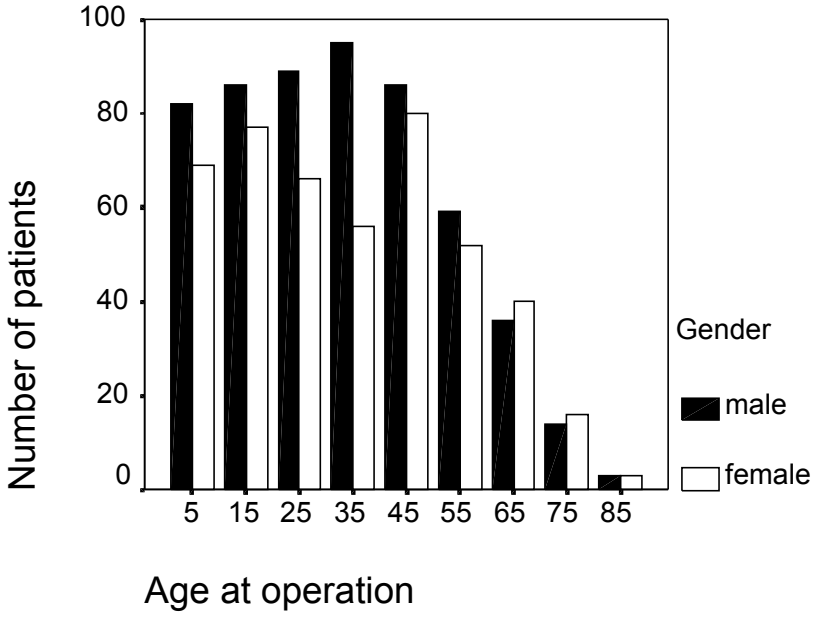
A special form was used to collect data (figure 1). To minimise the required registration time, only key items were registered. The surgeons dictated the extra data when dictating the usual operation notes shortly after the ear operation. On ten occasions, a senior staff member used a stopwatch to record the time needed for this procedure. The secretary entered the data in a database in the hospital network when typing the operation notes. On ten occasions, an experienced secretary used a stopwatch to record the time required.

A second form had to be filled out in the outpatient clinic 6 and 12 months after surgery. This form asked whether there had been a relapse and if the ear was dry. Data collection about a patient ended on the date of the last visit to the outpatient clinic or on the date of reoperation on the same ear.

Checks to ensure completeness were performed by the secretaries and one of the authors (JR).

We went through all medical records and discharge letters in order to check the whole database for omissions and errors prior to writing this paper. Some additional items were completed, such as indications for surgery and post-operative complications. Since full automatic integration of the audiometry was not yet possible, retrieving the data from the audiologic database for the last audiometry conducted (pre- and post-operatively) demanded a thorough check.

Figure 2. Age at operation subdivided by gender.



The data was used to generate general overviews. From the data collected by the surgeons, we made the following overviews:

1. Age and gender distribution of the patient population in groups of 10 years.
2. Frequencies of the types of surgery. Surgeons were classified into three categories: resident, staff or resident supervised by staff.
3. Hearing outcomes per surgery type. The change in the Fletcher Index (mean 0.5-1-2 kHz) was adopted as the measure of hearing acuity. The Fletcher Index was divided into five categories ranging from major loss (<- 30 dB) to major improvement (>+30 dB) in categories of 20 dB.
4. Change in hearing for CSOM surgery. The median conventional Fletcher Index (mean 0,5-1-2 kHz) of the air conduction thresholds (AC) is used as the pre- and the post-operative determinant of hearing.

From additionally collected data, we generated the following overviews:

1. Peroperative findings compared to pre-operative diagnosis: the frequency of variance between pre-operative diagnosis (indication) and findings at operation.
2. The types and frequencies of surgeries performed as 'second look' after CWU mastoidectomy for cholesteatoma.

Table 1. Frequency of the different types of surgery and surgeon performing the surgery.

	Freq.	kind of surgeon					
		resident		staff		resid.+staff	
	N	N	%	N	%	N	%
Name ear operation							
Stapedotomy	85			25	29%	60	71%
CWD mastoidectomy	128			37	29%	91	71%
Subtotal petrosectomy	45			12	27%	33	73%
Meatoplasty	48			12	25%	36	75%
Middle ear inspection	75	1	1%	24	32%	50	67%
Revision CWD mastoidect.	83	1	1%	21	25%	61	73%
Ossicular chain reconstr.	88			18	20%	70	80%
CWU mastoidictomy	175	3	2%	52	30%	120	69%
Revision CWU mastoidect.	73			24	33%	49	67%
Bone achored hearing aid	28			5	18%	23	82%
Myringoplasty	148	9	6%	37	25%	102	69%
Miscellaneous	33			7	21%	26	79%
Table total	1009	14	1%	274	27%	721	71%

3. Adverse events and complications, with the following grade definitions:
   Grade A: an adverse event that resolves if left untreated or requires a simple bedside procedure. These events are more a nuisance to the patient and/or the doctor than real complications. An example of a grade A complication is a low-grade wound infection which is cured by normal antibiotics.
   Grade B: a minor complication that usually requires an additional intervention that involves a risk of its own but eventually resolves. An example of a grade B complication is a tympanic membrane perforation after meatoplasty that requires surgical closure.
   Grade C: a major complication that is associated with a residual or a lasting disability. Severe postoperative perception loss is a grade C complication.
   Grade D: a complication that results in death. This rarely happens in ear surgery but it is mentioned here for the sake of completeness and omitted in the rest of the paper.

- Outcome of CSOM surgery broken down into 3 categories:

Primary result	=	dry ear and no reoperation performed;
Reoperation	=	a second ear operation was performed, usually a planned second look;
Recurrence	=	at the end of the follow-up, the ear was draining and no reoperation was performed.

Results

After 3 years, the OtoData database contained data on 1,009 ear surgery procedures. On average, it took residents and staff surgeons about 2 minutes to dictate the data collection form. The secretary needed about 3 minutes per patient to enter the data in the hospital network.
In 897 of 1,009 cases (89%), the surgeons completed the postoperative form of the procedure. Occasionally, some form of reminder was required later.
Some missing surgical data (11%) had to be retrieved from the medical records and discharge letters. Data about postoperative complications and clinical results was obtained by retrospective research.

The male-to-female ratio was 54.6% / 46.4%. The mean age at surgery was 33 years with a standard deviation (SD) of 20.0 (figure 2). The mean follow-up period was 1.57 years.

Table 2. Change in postoperative Fletcher index (0.5, 1 and 2 KHz) air conduction hearing levels per surgery type divided into 5 categories

	Freq.	Complete		outcome audiometry in dB									
		audiometry		< -30 dB		-30 to-10 dB		-10 to+10dB		+10 to+30dB		> +30 dB	
	N	N	%	N	%	N	%	N	%		%	N	%
Name ear operation													
Stapedotomy	85	75	88%			3	4%	15	20%	40	53%	17	23%
CWD mastoidectomy	128	91	71%	4	4%	26	29%	45	49%	15	16%	1	1%
Subtotal petrosectomy	45	28	62%	3	11%	8	29%	13	46%	4	14%		
Meatoplasty	48	20	42%			1	5%	10	50%	9	45%		
Middle ear inspection	75	59	79%			11	19%	36	61%	11	19%	1	2%
Revision CWD mastoidect.	83	55	66%	3	5%	6	11%	36	65%	7	13%	3	5%
Ossicular chain reconstr.	88	81	92%	2	2%	8	10%	32	40%	26	32%	13	16%
CWU mastoidictomy	175	109	62%	6	6%	29	27%	49	45%	24	22%	1	1%
Revision CWU mastoidect.	73	46	63%			10	22%	25	54%	11	24%		
Bone achored hearing aid	28	10	36%			5	50%	5	50%				
Myringoplasty	148	122	82%			8	7%	66	54%	43	35%	5	4%
Miscellaneous	33	12	36%	1	8%	2	17%	7	58%	2	17%		
Table total	1009	708	70%	19	3%	117	17%	339	48%	192	27%	41	6%

Table 3. The total number, and the frequency of cases in which the peroperative findings matched the indication.

	Freq.	final diagnosis							
		as expected		otitis media		cholesteat.		other	
	N	N	%	N	%	N	%	N	%
Name ear operation									
Stapedotomy	85	83	98%			1	1%	1	1%
CWD mastoidectomy	128	114	89%	5	4%	9	7%	1	1%
Subtotal petrosectomy	45	44	98%			1	2%		
Meatoplasty	48	47	98%					1	2%
Middle ear inspection	75	55	73%	1	1%	6	8%	12	16%
Revision CWD mastoidect.	83	76	92%			4	5%	3	4%
Ossicular chain reconstr.	88	84	95%	1	1%	3	3%		
CWU mastoidictomy	175	164	94%	3	2%	6	3%	2	1%
Revision CWU mastoidect.	73	53	73%	1	1%	18	25%	1	1%
Bone achored hearing aid	28	28	100%						
Myringoplasty	148	147	99%			1	1%		
Miscellaneous	33	31	94%					2	6%
Table total	1009	926	92%	11	1%	49	5%	23	2%

Table 1 shows the frequencies of the different surgical procedures. Canal Wall-Up (CWU) mastoidectomy is the most common procedure (N=175). This table also shows the kind of surgeon that performed the procedure. Most operations were done by a team consisting of a resident and a member of staff (71%). A member of staff performed the operation single-handed in 27% of operations.

The cases in which hearing deteriorated mostly involved cholesteatoma patients (table 2). As expected, most hearing gain was achieved in patients who were operated with that specific goal. It turned out that audiometric data were occasionally missing.

Table 3 shows that pre- and per-operative findings were the same in 926 (92%) of the 1,009 cases. Explorative surgery of the middle ear (20 of 75 cases (27%)) and revision CWU mastoidectomy (20 of 73 cases (27%)) lead to more unexpected findings than other kinds of surgery.
In 18 of 20 revision CWU mastoidectomies, a cholesteatoma was recorded as unexpected finding. 17 of these were set up as a 'second look'. When corrected in revision CWU mastoidectomies the pre- and per-operative findings matched in 96% (70 of 73 cases).

Table 4. Surgical procedures when the indication was a second look, planned as second stage in eradication of cholesteatoma after Canal Wall Up mastoidectomy.

	Freq.	findings at operation					
		clean		cholesteat.		otitis media	
	N	N	%	N	%	N	%
Name ear operation							
CWD mastoidectomy	7			5	71%	2	29%
Meatoplasty	1	1	100%				
Middle ear inspection	18	14	78%	3	17%	1	6%
Ossicular chain reconstr.	32	29	91%	3	9%		
Revision CWU mastoidect.	27	10	37%	17	63%		
Myringoplasty	5	5	100%				
Table total	90	59	66%	28	31%	3	3%

In 28 (31%) of 90 ‘second looks’, recurrence of cholesteatoma was found (table 4). A CWD mastoidectomy was performed five times, a revision CWU mastoidectomy 17 times, explorative surgery of the middle ear three times and an ossicular chain reconstruction three times.

Fifty-one of the 1009 cases (5%) showed per- or post-operative surgical adverse events or complications (table 5). Most of them happened in stapes surgery. The three grade C complications were all labyrinthine, i.e. severe hearing loss and dizziness up to three weeks postoperatively after a Canal Wall Down (CWD) mastoidectomy, a stapedotomy, and a 'gusher'.

Results of CSOM surgery

A total of 245 ear operations for CSOM were performed on 228 ears in 208 patients (table 6). The male-to-female ratio was 126 / 119 (51% / 49%).
Median follow-up was 1.8 years (0-4.3). A reoperation was performed after a median of 1.1 years (0.1-3.7). The median age of the patients was 32 years (1.5-86). In 28 operations (11%), the patient was under 5 years of age.

Table 5. Complication rates per operation in descending order

	Freq.	classification						Total	
		Grade A		Grade B		Grade C			
	N	N	%	N	%	N	%	N	%
Name ear operation									
Stapedotomy	85	7	8%	4	5%	2	2%	13	15%
CWD mastoidectomy	128	5	4%	1	1%	1	1%	7	5%
Meatoplasty	48	2	4%	2	4%			4	8%
Middle ear inspection	75			4	5%			4	5%
CWU mastoidictomy	175	3	2%	3	2%			6	3%
Revision CWD mastoidect.	83	2	2%	1	1%			3	4%
Bone achored hearing aid	28			1	4%			1	4%
Ossicular chain reconstr.	88	2	2%	1	1%			3	3%
Revision CWU mastoidect.	73	2	3%					2	3%
Subtotal petrosectomy	45	1	2%					1	2%
Myringoplasty	148	3	2%					3	2%
Miscellaneous	33	4	12%					4	12%
Table total	1009	31	3%	17	2%	3	0,3%	51	5%

CWD = Canal Wall Down, CWU = Canal Wall Up

Grade A: Adverse events, Grade B: minor complications, grade C: major complications (permanent damage)

A dry ear was achieved after one procedure in 212 cases (87%). In twenty of 245 cases (8%) otitis media had recurred at the end of the follow-up period. In 11 cases (4%), a reoperation was performed for recurrent infection, of which three cases proved to be cholesteatoma. In two of 245 cases (1%), the result was not known (table 7A and 7B).

Table 6. Number of ear operations, ears, and patients in CSOM surgery

245		Ear operations for otitis media.
228		Ears
	197	Ears were operated once
	12	Ears twice
	1	Ear three times
	1	Ear four times
208		Patients

In 170 of 245 (69%) cases, the ear was dry and no reoperation was deemed necessary after one procedure. This is the 'primary result'. In 53 of 245 cases (22%), at least one reoperation was undertaken, with 42 cases (17%) involving dry ears.

Audiometry was available from the audiologic database both pre- and post-operatively in 145 of 245 (59%) cases. The median overall improvement on the AC Fletcher Index is 2 dB. The change on the AC Fletcher Index ranges from a decline of 77 dB (-77 dB in the table) to an improvement of 35 dB (table 8).

Pre-operative audiometry was missing from our database in 51 cases. Twenty patients were under five years of age (40% of 51). In the other cases the pre-operative audiometry was performed elsewhere. In the group in which postoperative audiometry was missing, seven patients (8% of 83) were under five years of age, nine (11% of 83) were referred back to the original hospital and 25 (30% of 83) were lost from follow-up.

There was one grade B event (minor complication) (0.4%), a haematoma that had to be drained in a separate procedure. There were 8 (3%) grade A events (adverse events) (table 9).

Discussion

In 'evidence-based medicine', clinical decisions about individual patients are based on extrapolated knowledge (evidence) from literature. An understanding of one's own population and results determines the degree in which extrapolation is justified. Such an understanding can only be derived from clinical data from one's own clinic. In order to determine the feasibility and usefulness of routinely collecting data about daily clinical practice, we introduced a data collection method for all ear surgery. In

this paper we provided examples of insights that evolved from the overviews based on this data, which we call *clinical feedback information*.

The clinical feedback information presented here provided us with valuable new insights.
Some data will allow us to determine how well a study population as described in literature compares to our own. As was shown by Figure 2, we now have a picture of the age and gender distribution of our own population.

Table 7

A: Outcome after surgery for chronic otitis media after 1 operation. Successful = number of dry ears at last follow-up or at reoperation.

Primary result = dry ear and no re-operation.

	Freq.	successful		primary		unknown	
	N	N	%	N	%	N	%
Name ear operation							
Middle ear inspection	6	6	100%	4	67%		
CWU mastoidictomy	95	84	88%	61	64%	1	1%
Revision CWU mastoidect.	31	27	87%	21	68%		
CWD mastoidectomy	34	28	82%	25	74%		
Revision CWD mastoidect.	46	41	89%	37	80%	1	2%
Ext. Rev. CWD + obliteration	28	22	79%	18	64%		
Miscellaneous	5	4	80%	4	80%		
Table total	245	212	87%	170	69%	2	1%

B: Number of recurrences at the end of the follow-up and re-operations in which a recurrent CSOM was found. Total recurrences, together with successful and unknown in table 2A, amount to 100%.

	Freq.	reoperation		recurrence		Total	
	N	N	%	N	%	N	%
Name ear operation							
Middle ear inspection	6					0	0%
CWU mastoidictomy	95			10	11%	10	11%
Revision CWU mastoidect.	31			4	13%	4	13%
CWD mastoidectomy	34	4	12%	2	6%	6	18%
Revision CWD mastoidect.	46	4	9%			4	9%
Revision CWD + obliteration	28	3	11%	3	11%	6	21%
Miscellaneous	5			1	20%	1	20%
Table total	245	11	4%	20	8%	31	13%

Some data merely confirmed our assumptions. For example, the most frequent ear operation is mastoidectomy (table 1) and hearing results for reconstructive surgery are higher than for cholesteatoma surgery (table 2).

In other cases, however, our assumptions proved to be wrong. We believed that all patients underwent postoperative audiometry but this was only true for 70%. We were surprised by the fact that 27% of the operations had been performed without the assistance of a resident. The pre- and per-operative diagnoses of revision canal wall up (CWU) mastoidectomies only matched in 53 of 73 cases. Compared to literature,[22] our otosclerosis surgery results had fewer successful outcomes and more adverse events.

The examples above show the strength of clinical feedback information: it provides a means of identifying weaknesses. Interpretation of the findings, however, should be approached with caution: the data does not imply that we are a 'bad teaching clinic' or that we provide 'poor quality' otosclerosis surgery. Before drawing conclusions, the data should first be understood correctly. Further data exploration with respect to the high diagnostic mismatch in mastoidectomy revealed that 17 of the 20 mismatch cases could be explained by a coding artefact: in these cases the operation had been set up as a second look in which a cholesteatoma was found. Inclusion bias and registration bias may explain the outcomes of otosclerosis surgery: we included all types of otosclerosis surgery (including revision), and explicitly asked surgeons to register adverse events.

So it is only when the data is correctly understood that a debate can be started to determine whether there is a need for improvement, and if so how this can be achieved. Questions that we will need to ask are, for example:

(1) Can we define guidelines describing the cases for which postoperative audiometry is mandatory?
(2) Are there teaching opportunities for residents which are unused and, if so, is adaptation of our training programme feasible?
(3) Do we need, as suggested in the literature [2,5,7,19], to assign only experienced surgeons to otosclerosis surgery to improve the outcome of otosclerosis surgery?

The answers to these questions fall outside the scope of this paper, but the questions themselves illustrate the value of objective data from clinical feedback information.

In the presentation of our clinical feedback information, we categorised data. In the collection of data, however, we make use of continuous scales. This allows us to present data using any categorisation required. The age categories in Figure 2 could just as easily have been 1, 3, or 17 years. In certain cases we broke down data

arbitrarily in order to provide the best overview: the postoperative change on the Air Conduction (AC) Fletcher Index (mean 0.5-1-2 kHz), for example, was presented in Table 2 using five categories ranging from major loss (<- 30 dB) to major improvement (>+30 dB) in categories of 20 dB. These categories were also chosen to enable comparison with literature. At our clinic, 76% of stapes surgeries (including revisions) lead to post-operative improvements of 10 dB or more, which is similar to improvements documented in literature [22]. If desired, analogous comparisons can be made to other measures described in literature, such as improvement on the air bone gap Fletcher Index.
Similarly, the grade C complications presented in Table 5 (0.3% for all surgery) compare to complication rates documented by other institutions [2,14-16,20,23,29,35,37,38]. The way the data is presented in this paper is therefore indicative; other formats could also have been adopted. The essential fact is that clinical feedback information is a means of understanding one's own strengths and weaknesses which also makes comparisons with literature possible.

The challenge in routine data collection for clinical feedback information is to find a method that is acceptable to surgeons. We learned that restricting the time needed to collect the extra data is essential for successful implementation. In addition, surgeon compliance in terms of collecting data depended on when forms had to be filled out: 89% of post-operative forms were completed, as opposed to 2% of outpatient follow-up visit forms. Apparently, post-operative data collection is accepted more readily, but further studies of acceptability will be required. To restrict time requirements,

Table 8. Pre- and post-operative hearing loss and change in hearing in dB Fletcher index of air conduction thresholds. Median values and range are given.

	pre-operative median(range)		postoperative median(range)		improvement median(range)	
Name ear operation	N	dB air cond.	N	dB air cond.	N	dB air cond.
Middle ear inspection	6	28 (13-77)	2	29 (27-32)	2	-2 (-15-12)
CWU mastoidectomy	69	35 (2-78)	63	37 (3-85)	54	+3 (-45-33)
Revision CWU mastoidect.	19	33 (13-90)	18	28 (7-100)	14	+5 (-18-20)
CWD mastoidectomy	28	48 (20-112)	25	53 (5-115)	22	-1 (-77-27)
Revision CWD mastoidect.	45	52 (13-98)	34	50 (12-125)	34	+2 (-61-35)
Revision CWD + obliteration	22	72 (33-123)	16	84 (30-123)	16	-3 (-45-25)
Miscellaneous	5	35 (10-42)	4	23 (12-25)	4	+15 (-13-30)
Table total	194	43 (2-123)	162	45 (3-125)	145	2 (-77-35)

data collection should only include items which are highly relevant in clinical terms[27]. A simple and easy to use data-collection form further enhances compliance and accurateness. For meaningful overviews, reliable data is imperative. There is, however, a thin line between too many items, resulting in a decrease in surgeon compliance, and too few items, leading to non-informative overviews.

Results of CSOM surgery as an example of clinical feedback information

Three years of chronic suppurative otitis media (CSOM) surgery were selected.

Table 9

A. Number of complications of CSOM surgery, graded according to severity.

	Freq.	classification							
		Grade A		Grade B		Grade C/D		Total	
	N	N	%	N	%	N	%	N	%
Name ear operation									
Middle ear inspection	6							0	0%
CWU mastoidectomy	95	2	2%	1	1%			3	3%
Revision CWU mastoidect.	31	2	6%					2	6%
CWD mastoidectomy	34	2	6%					2	6%
Revision CWD mastoidect.	46	2	4%					2	4%
Revision CWD + obliteration	28							0	0%
Miscellaneous	5							0	0%
Table total	245	8	3%	1	0,4%	0	0%	9	4%

B. Description of surgery-related grade A (adverse) events of CSOM surgery

CWU mastoidectomy	Suspected postoperative wound infection = antibiotics
	Transient loss of taste
Revision CWU mastoidect.	Bleeding from jugular bulb during operation
	Minimal liquor leakage postoperatively for 2 days
CWD mastoidectomy	Transient, partial facial palsy = 3 days corticosteroids
	Some endolymph leakage from semi circular canal
Revision CWD mastoidect.	Perilymph leakage during operation
	CSF leakage during operation

C. Description of surgery related grade B (minor) complications of CSOM surgery

CWU mastoidectomy:	Haematoma with pain postoperative = drainage in separate operation

These miscellaneous operations for CSOM resulted in 87% dry ears. To enable comparison to the literature outcome is presented per surgery type (table 7).
After CWU mastoidectomy in draining ears, Balyan reports 86% dry ears[4]. Vartiainen reports 92% dry ears after CWU mastoidectomy, with 15% planned second looks[36]. We found a success percentage of 88% in CWU mastoidectomy, with 5% planned second looks.
After CWD mastoidectomy for CSOM, Van Baerle reports 85% and Harvey 90% dry ears[17,33]. At our institution, CWD mastoidectomy resulted in 82% dry ears.
Extensive revision CWD mastoidectomy with partial obliteration resulted in 79% dry ears. Fisch reported 95%[13] dry ears and East 75% [10].
Our institution serves as a tertiary referral center, as may be concluded from the numbers of revision CWD mastoidectomies in relation to primary mastoidectomies (table 7). Many of our patients may be viewed as 'worst cases' from other hospitals.
From the audiometric data present in our audiologic database it is concluded that the mean change in hearing levels due to the operation is only a few decibels. However, the range varies widely, in line with the literature[8,29]. (table 8).
Unfortunately, much audiometric data was missing from our database. Sometimes pre-operative audiograms were taken by the referring ENT colleague and sometimes the patients were too young or uncooperative for routine audiometry. Postoperatively there were seven children under the age of five and 25 patients were lost from follow-up. Nine patients went back to the referring hospital for follow-up. When correcting for these 41 patients, 79% (162/204) postoperative audiometry was present in the audiometric database. Changes in our procedures for pre-operative examination and control should make more data available in the future.
There were no major complications in CSOM surgery (grade C or D). There was one (0.4%) grade B minor complication and 8 (3%) grade A adverse events (table 4). Shelton described one temporary delayed-onset partial facial paralysis and two patients with severe postoperative sensorineural hearing loss (0.75% major complications) in four hundred cases. Vartiainen describes two deaf ears in 782 patients (0.25% major complications) and three cases of transient facial paralysis (0.4% minor complications)[34]. Harkness reported, in the ‘mastoidectomy audit of the Royal College of Surgeons of England’ 1.6% major complications and 4% other complications[15].
This example shows that it is possible to generate clinical feedback for all CSOM surgery from a database which stores prospectively-collected key data, combined with data from the audiometric database. It confirms the quality of care in our tertiary

referral centre because of the low numbers of complications and results comparable to literature. Our methods allow objective interpretation of surgical results.

If we were to design a new data collection form, we would add the indication and peroperative findings. These items turned out to be important for the interpretation of data. To start collecting data that enables clinical feedback information, we believe that the following items should be present on a collection form [3,9,25] (table 10):

1. **Patient identification**: name, date of birth, male/ female, patient number
2. **Procedure identification**: name surgeon, date, procedure(s) (coded including left or right side), indication(s) (coded).
3. **Procedure description**: Medication administered by surgeon, description of procedure, findings, tissue obtained (biopsies, bacteria), materials used (patient or foreign)
4. **Summary**: final diagnosis (coded), Complications (no / yes + description).

Table 11. On the basis of our experience, we propose the data below as the minimum requirement for all operation notes, regardless of the storage medium.

	Description
Identification patient	Name of the patient Birth date of the patient Male/ female Patient number
Identification procedure	Surgeon Date procedure Procedure(s) (coded) Indication(s) (coded)
Procedure description	Medication administered by surgeon Description of procedure Findings Materials used (patient or foreign) Tissue obtained (biopsies, bacteria)
Summary	Final diagnosis (coded) Complications (no / yes + description)

Conclusion

In this paper, we discussed our initial experiences with clinical feedback information based on routinely collected data. We demonstrated feasibility and provided examples of the usefulness of evaluating one's own 'quality of care' through clinical feedback information. We are convinced that clinical feedback information leads to quality-control activities based on reliable data rather than on incidental findings and quality improvement through the generation of debate about changes to procedures.

- Data collection, however, interferes with daily practice: determining how to collect data, which data to collect, and when to collect data, remain difficult issues which should be further explored.

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Chapter 6 Why register all adverse events and complications?

J. Rombout & L. Feenstra

Summary

Why invest effort in the continuous evaluation of all adverse events and complications?
Prevention: Were there adverse events or complications, and if so can they be prevented in the future, i.e. are changes in procedures required?
Awareness: More successful procedures may be compared with less successful ones.
Feedback information from the work floor is needed to establish an understanding of adverse events and complications. A convenient scale with four categories varying from adverse event (grade A) to death (grade D) leads to concise overviews. Understanding the quality of daily medical care increases safety and convenience and unwanted effects are reduced.

Keywords: Adverse Events, Complications, Quality of care, Audit

Reasons for not collecting data about complications in daily clinical practice might be:

1. Medical professionals practice 'evidence-based medicine', implying that treatment modalities have been tried, tested and proven effective.
2. Attention should be focused on direct patient contact and most problems should be solved in a practical way.
3. When adverse event and complication rates are known, third parties such as patients, hospital management and medical insurance companies may interfere with the way medical care is provided.

Despite these arguments, we feel that a lot can be gained from feedback on adverse events and complications for the following reasons.

1. Evidence on treatment modalities depends on careful feedback. Reports on this feedback lead to imitation. It is usually assumed that same procedures lead to the same outcome. However, circumstances and populations differ. To make an extrapolation from literature to actual practice, we need to prove that treatment (and particularly surgical treatment) is provided under the same circumstances in comparable populations. It would be preferable if medical professionals could compare their own complication rates with those described in the literature [16].
2. Changes in procedures are often based on intuition, subjective recollections from memory and newly designed treatment modalities. For instance, an incident can induce changes in procedures and thus add to workload. When the chance of recurrence is low, extra effort does not always account for the few incidents which may be prevented. The extra work should be in proportion to the numbers and severity of the incidents to be prevented. Furthermore, the evaluation of adverse events can identify a dangerous situation before a real complication occurs. Adequate feedback on adverse events and complications acquired in one's own department is a sound basis for the adjustment of procedures.
3. If feedback on adverse events and complications in daily clinical practice is available, medical professionals themselves should interpret the data and make comparisons with other clinics and the literature. Other parties involved such as patients, hospital management and medical insurance companies are not qualified to interpret feedback since they lack in-depth professional knowledge. Clinical feedback information enables physicians to provide adequate information about the risks of treatment to other parties involved as a part of consent procedures.

We feel that improving the level of day-to-day medical care is important. One of the ways to make improvements is to provide feedback on adverse events and complications in daily clinical practice.

What to collect

We propose a broad definition that includes even minor adverse events that in daily life are generally not seen as such, but might result in minor complications (table 1). Our definition of adverse events or complications is:

- incidents that are not intrinsic to the medical procedure and that have a potential or actual negative effect on outcome or morbidity [4,6].

To prevent extra workload and enhance compliance, registration should only include a few items per adverse event or complication. We propose the following two items per procedure:

1. N = if there is no complication.
   If there is a complication, a simple and convenient classification (table 2) is required:
   Grade A: an adverse event that resolves if left untreated or that requires a simple bedside procedure. These events are generally more a nuisance to the patient and/or the doctor than a genuine complication (i.e. a superficial wound infection treated with conventional medication).
   Grade B: a minor complication that usually requires an additional intervention which, in principle, involves a risk of its own, but eventually resolves (i.e. postoperative haemorrhage that needs reoperation).
   Grade C: a major complication that is associated with a residual or a lasting disability.
   Grade D: a complication that results in death.
2. A brief description in the doctor's own words. Since each adverse event and complication is unique, further differentiation usually leads to more difficulty in choosing the right code and the overviews are then characterised by numerous categories with few complications per category.

A link with the patient ID number makes it possible to track individual cases for evaluation, as well as other parameters such as patient age and sex.

How to collect data on adverse events and complications

Overviews of adverse events and complications should preferably consist of only a few sheets. This can be achieved by reporting only a limited number of items graded in broad categories. We feel that, after presenting the numbers for each event category, the next step in evaluation is listing each adverse event and complication separately. When the need arises for in-depth evaluation of some specific complication, the medical record of that specific patient is reviewed. Gradation in four categories and a brief description in free text are all that is required to register adverse events and complications in daily clinical practice. There is no need for an extensive differentiated overview or tiresome coding procedures.

The spread of computers means that most administrative tasks are now performed electronically [14]. Extra items about complications may be included in each document. A database can therefore be filled with data on adverse events and complications in daily clinical practice [8]. For instance, each discharge letter can have a code showing that there has been an adverse event or complication during admission, and indicating the severity of the complication [3,13].

Evaluation procedure

The first step in adverse event and complication rate evaluation is to establish whether there is anything unusual. The normal range for the adverse event and complication rate remains to be determined. When an unexpectedly high or low number of adverse events and complications are registered, further evaluation is mandatory.
The second step should be to check whether standard procedures have been followed. Reasons for departures from normal routine should be analysed.
The third question is whether procedures should be changed. This should be done in order to prevent repetition. Of course, the additional workload should be kept to a minimum, as the burden of extra work should be in proportion to the expected benefit.

Discussion

Feedback on all adverse events and complications is highly informative. When compared to other data, it can act as a stimulus to improve or change procedures.

Feedback on adverse events and complications is not readily available because retrieving data from medical records is time consuming [15]. Furthermore, non-standardised documentation [2], and erroneous and incomplete data compromise reliability [1]. Elfström et al. demonstrated that, compared to reported cases, the number of complications in missing cases was twice as high [5]. With the advent of computers it became theoretically easier to provide feedback information. However, as most information is stored in free-text formats, the data suffers from the same limitations as the data in medical records [12]. In order to have data that can be used for purposes such as adverse events and complications registration, structuring is required. Structured data entry facilitates completeness and provides less ambiguous data [10,11,14].
In most hospital departments, administrative tasks are generally digitalised. Examples are typing discharge letters and financial administration. It is possible to add electronic fields to a document in order to register complications. Here, an indication will be given of whether the treatment proceeded without adverse events and complications and, if not, there will be a brief record with an indication of severity and a brief description of the complication. Data structured in this way will then be stored in a separate database. This data should preferably be linked to patient parameters already stored for other purposes such as date of birth and financial parameters [9]. When making monthly overviews, it is then possible to see how many patients were admitted, the treatment that was administered and the number of adverse events and complications.

If registering adverse events and complications is this easy, why has it not been generally implemented yet? Some reasons have been explained in the introduction. At present, it has not been demonstrated conclusively that an adverse event and complication register is a sound instrument for evaluating the level of medical care for improvement purposes. Normally, when improvements in medicine are being considered, thoughts turn to new techniques such as lasers or new drugs. These days, third parties ask for audit procedures. Feedback information is needed in addition to the set of instruments the medical professional already has. The introduction of new medical procedures, instruments or pharmaceuticals generally takes many years and, finally, efficacy has to be proved scientifically. The next step in developing an adequate feedback instrument is to standardise of overviews and interpretations for the purposes of comparison. A generally accepted definition of adverse events and complications is a prerequisite. Our definition of an adverse event or complication in

daily medical care is: an incident that is not intrinsic to the medical procedure and that has a potential or actual negative effect on outcome or morbidity (table 1). We feel that the person who writes the discharge letter is responsible for collecting information about adverse events and complications, i.e. his own, those of other consultants and those of the nursing staff. The categories used in overviews should be shared by everybody. We propose a division into four categories varying from adverse event (grade A) to death (grade D) (table 2). If other clinics reported on similar lines, the possible result would be an improved picture of the overall quality of medical care.

The main advantage of a complete overview with all adverse events and complications, including their gradation, is the possibility of evaluation within the peer group in an open discussion and based on facts. The aim of such a discussion is not blame and fault-finding but to arrive at a decision to change procedures if better ones seem possible [7]. In addition, excellent deliverers of care can share their experience with less successful ones. Learning from adverse events and complications and therefore the possibility of improving care are goals which should appeal enough to any care provider as an incentive to register those events and complications.

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Chapter 7 Quality of care.

J. Rombout, L. Feenstra

Introduction

Attention for quality has always been with us and is indeed not entirely new. It became very much in the public eye forty years ago since the early sixties due to the huge economical potential which became apparent by the successes of the Japanese Industry who took to heart the lessons of the American statistician Deming who moved to Japan in the year 1948. According to Deming the management philosophy to listen to the co-workers in the organisation and planned action based on facts rather than on opinion is basic for the quality of an organisation.

This professional interest in quality gradually filtered into other countries and other areas of human endeavour among which medicine.
In medicine reflection on quality also is nothing new. Obductions and pathological analysis, although in principle started to study disease a few centuries ago, have been applied to check the diagnostic accuracy of physicians ever since.
By analysing the results of their interventions doctors and surgeons always have tried to improve on them. Studying the outcomes of the diagnostic process and therapy has been self-evident in medicine since early times. However as a specific endeavour quality control, (total) quality management, quality improvement, continuous quality improvement, continual improvement, organisation-wide improvement and the like only started in medicine in the early seventies in the USA and about ten years later in the Netherlands [1-9]. Gradually as the name total quality management implies not only the medical side of patient care received attention, but also nursing, management, organisation and a lot more. Also apart of the physicians and their professional organisations many more people are busy in the field of health care, like patient organisations, third parties such as health care insurance companies and governments.

Quality of care cycle

E.C. Nelson stated that nowadays quality improvement in health care involves [10]:

1. Understanding and meeting the recognised and unrecognised needs and expectations of patients and other purchasers of health care.
2. Understanding what quality means from the viewpoint of patients, families, and other purchasers of health care.
3. Leading health care organisations seeking to meet needs and expectations through systematic efforts to improve quality and value.

4. Understanding that all health care is provided in systems, medical procedures are interdependent with the delivery system and knowledge of these interdependencies is fundamental to improvement.
5. Understanding the core patient care delivery process and related supporting processes in the settings where care is delivered.
6. Evaluating variation in patient case-mix, delivery processes, and outcomes as a guide to taking economical action on processes and outcomes.
7. Measuring the quality control and value of health care using multiple indicators based on knowledge of the systems, "customers," and underlying social need for health and health care.
8. Taking action for improvement (that is, planned improvement trials) that simultaneously build knowledge on how to take action effectively.
9. Involving the energies of everyone in the health care organisation for the task of never-ending improvement.

The start of any process of quality improvement is usually the feeling of being bothered that something is not really up to the level, that some process is not as good as it was formerly thought and that something should be done about it. Such a feeling is very much like the start of any creative process, i.e. there is some room for improvement and for something new. The logical next step is to start organising some process that might lead to that improvement or that entirely new way of thinking, handling or organising.

A methodical way of to embark on such a quality improving process is known under the name of Deming cycle or quality control circle [11].

This cycle consists of phases similar with those of the 'empirical cycle' a term coined by A.D. de Groot to describe any scientific process [12].

The first phase after the itching feeling that something might be improved is the definition and analysis of this something, preferably in quantifiable (sub)procedures.

The second phase is the construction of a some pragmatic plan to mend the (sub)problems.

The third phase is the execution of that plan.

The fourth phase consists of collecting the outcomes of the different (sub)steps in some systematic way.

The logical next step is to check if the goal(s) has (have) been reached, the so-called check-phase of the Deming cycle.

Only after analysing the results and comparing them with the original goal as defined, the time has come to reach for the whiskey in order to forget the whole business or to congratulate oneself being such an outstanding performer.
Those goals that are not reached might be used to start a next cycle. The successive Deming cycles or quality circles build a spiralling process of continuing improvement.

Gradually this system of reasoning and acting is woven into every branch and activity, indeed every single subsystem and action within the organisation. When this has been implemented and the whole organisation works according Deming cycles the system should strive to foresee the future demands on the organisation. The system then tries to prevent not yet existing problems that in theory might arise. Theoretically the ultimate goal of any quality process is zero-tolerance, i.e. no faults, no mistakes, no unhappy clients or patients.

Obviously such an ideal does not exist, but, on the other hand some sub-systems are surely not very far from reaching such a goal. Within medicine many people trying to work within a framework of quality improvement are pointing to the aviation that has in common with medicine a complex environment where teams interact with technology. [13]. In both domains, risk varies from low to high with threats coming from a variety of sources in the environment. Safety is paramount for both professions, but cost issues can influence the commitment of resources for safety efforts.
Many valuable lessons are to be learned from aviation, among which dealing with latent factors that have been detected and providing feedback on technical performance are some. It is about this subject that the next chapters deal.

Complication registration

One process that should be able to arouse interest in every surgeon is the registration of complications of his or her operations and those of others within the department. Registration of complications is one of the ways to become aware of faults, mistakes, careless behaviour or insufficient technique. It may lead to damage control, or even better to prevention or striving after zero-mistakes. Complication registration and feedback could very well be the first cycle of the quality process.

According to Vincent medical accidents are little researched and consequently little understood, although there are strong suspicions about some of their likely causes. If a greater understanding is to be reached, the systematic analysis of errors and accidents will have to acquire a higher priority in future [14]. Nowadays most hospitals have an accident reporting procedure. However research of these errors and accidents is necessary to consolidate evolved insights in single institutions. This leads to more openness about medical care.

Reason stated that one of the most obvious signs of this new openness has been the recent involvement of human factor specialists in studies of patient safety. This has brought at least two obvious benefits. The first is mainly methodological, permitting techniques like critical incident analysis and event reporting programmes, initially developed in the field of aviation, to be applied to studying the medical accident process. Second, the results of these and other investigations have clearly shown that medical mishaps share many important causal similarities with the breakdown of other complex socio-technical systems [15]. Perhaps knowledge from non-medical systems can be applied to medical care. However, surgery is not an exact science and deviations from the planned course may be perfectly acceptable. Scurr describes that these deviations may encompass standard clinical practice [16]. However, errors in judgement and technique can occur, producing an unsatisfactory result for both the patient and the doctor that may be avoidable. In some situations though, the outcome cannot be planned and the results can not be guaranteed. Some surgical procedures are associated with known risks; these risks, and the chances of a successful outcome, form an important part of the consent. Openness is imperative for all involved parties (surgeons, patients, third parties, etc.) to make well-founded decisions to administer or receive certain medical treatment.

Why do medical accidents occur? Are there patterns and are they preventable?

Before any serious surgical research can be undertaken, a proper database recording surgical procedures and untoward events, complications, poor outcome, and patient satisfaction, is essential. However, until we define what constitutes a medical accident, it will be difficult to record and analyse all these events, and to make specific recommendations.

Before any conclusions can be drawn other factors concerning the medical care have to be known and described. A few important are listed below:

Surgery is an acquired skill. The more often the surgeon performs a particular surgical procedure, the better he or she becomes. All surgical procedures include a

leaning curve and to minimise the risks to patients, these operations should always be performed with a senior, supervising consultant present. However surgical skills do not last forever, and with advancing age, some surgeons lose their acquired skills, or lack the ability to respond rapidly to a surgical situation.
Surgical practice can change overnight. We have, in the last three years, seen endoscopic surgery mushroom. These revolution was brought about by technical advances in instrumentation, allowing these procedures to be performed. Modern techniques have to be compared with earlier.
Limitations of the institution means that certain procedures are not performed. This makes some complications unlikely. Also this could mean that if there is the chance of a too difficult complication the patient is treated in another institute.
Patient population differs per surgeon and per institute. Each individual and each institute tends to develop subspecialties. When a surgeon is experienced in a certain procedure he or she may feel confident to take on more difficult cases, which increases the chance on complications or less favourable outcome.

Large studies are disappointing for those interested in the cause of accidents and errors. [17]. They do not provide detailed information or the causal chains that lead to each injury. Cooper et al in the USA suggested that it might be more profitable to study incidents rather than harmful outcomes. Incidents are commonplace and therefore a better starting point for a study. Incidents can also be discussed more freely because complication discussions can lead to a 'witch hunt'. Incidents are also worth studying even when no harm ensues because sooner or later they may trigger a sequence of events leading to injury. Such incidents are called 'critical incidents' and through a fortuitous double meaning the term is particularly appropriate since it suggests an impeding crisis.

Many studies bear on the problem of medical accidents [14]. At one extreme are broad-brush epidemiological analyses and at the other studies of individual cases that provide a picture of the evolution of an accident and the factors that contributed to the final injury. Much information seems to be collected without any clear idea of how it might be analysed and what implications can be drawn form it. Studies that attempt to understand how medical accidents occur are still rare. Anyone concerned with medical accidents, whether from management, clinical, or research perspective, needs to consider which method of study will provide the best information for their particular purpose. A variety of methods is needed in research into medical accidents,

each having its particular advantages and disadvantages.
Fine-grained analyses of causes and effective well-targeted risk management, or other interventions aimed at reducing accidents, both depend upon first collecting detailed and reliable accounts of accidents.
Understanding accidents requires 'backward reasoning'.

Every error is a treasure. Studying and being aware of errors in clinical practice facilitates learning [18]. Unless one has feedback on one's own performance (in any task) there is little hope of improving performance. A further benefit is that awareness of errors provides a stronger motivation for change than simply a general desire to improve a stronger motivation for change than simply a general desire to improve standards[19].

Outcome registration

Medical care is a complex process and many factors influence the final outcome. The medical professional does his or her utmost best to deliver state-of-the art, evidence based medicine. This does however not mean that there is no need for outcome evaluation. Reflection is needed to identify strong and weak points in the specific circumstances in which the medical care was delivered.
The results of medical treatment do not always correlate with the spent energy. This means that on the one hand an unfavourable outcome not always means that there is anyone to blame. On the other hand is an excellent result not always a sign of excellent care. The medical professional cannot control the whole process. Apart from this is the perception of the final result very subjective.
Of course there is much to learn from errors. Leval stated that ' Knowledge does grow here and there by accumulation. Yet far more often knowledge grows by the recognition of error.' [18]. This is a fundamental principle of the philosophy of knowledge. Besides new facts, known errors could be taught in an equally positive way. Such an education duality should start early on so as to foster a cult of error [13].

Collecting outcomes of medical treatment is a difficult matter. Major reasons for this could be:

- Filling out forms may not add to the administrative workload.
- The end-result is dependent on many factors including patient related topics which makes the end-result unpredictable. This implies that there is a factor 'luck' in the final result and how patients and care providers value the end-result.

- New insights in quality of care have to be translated to adjustment of procedures; the cycle has to be closed.

Outcome reports should be brief and only point out outstanding (good and bad) results. Therefore there is no need for elaborate questionnaires because the aim is to determine a simple fail or pass in each patient. A simple gradation that indicates how successful each treatment was suffices for this goal. It is not necessary to design separate questionnaires for each treatment, the most important question is if the aim of the treatment was achieved. The main advantage of simplicity is that it takes little time to register. If necessary further investigations can be conducted into cause and effect of peculiar results and then other factors can be added retrospectively in the selected cases. The results of these investigations can lead to changes is procedures or scientific reports.

Modern text programs make it possible to ad an electronic field to the clinical release letter that stores the outcome grade. The registration then is included in routine secretarial work. The only backdrop is that the correspondence concerning the release letters has to be complete, but that is a management problem. The usefulness of the gradation of course has to be proven scientifically, the use can be quite easy. Outcome registration should be a small effort.

The medical professional self is the only one apt to interpretation of the results of outcome registration [20]. All others, even professionals from adjoining fields do not have the in-depth knowledge as to why a treatment is considered successful or not. Comparison with other institutions is difficult because of differences in circumstances. Populations and hospital equipment differs. Furthermore professionals with a specific field of interest tend to treat more difficult cases which enhances the chances on complications and therapy resistance.

Outcome data are propriety of the physician. Professional privacy is important to be able to register outcomes uninhibited by worries about third parties influencing decisions in the delivery of medical care. Therefore these audit figures can only be revealed to the national society to which the professional belongs for comparison with accumulated results of others. Judging the outcomes of medical treatment should not be left to management and governmental civil servants. Only medical professionals themselves can take the lead in openness about the results of medical treatment.

Conclusion

Improving quality of daily medical care can consist of closing the quality of care cycle. This means knowing what patients and other purchasers of health care perceive as quality and understanding the underlying processes in health care. Also quality has to be measured and action for improvement has to be undertaken. A fist step conceiving this is reporting on complications. Learning of accidents leads to prevention and identification of critical moments. Outcome registration of daily medical care can be a second step, which points out outstanding (good and bad) results. The two are independent because complicated cases still can have excellent results and vice versa. To be able to improve quality of care these data need to be collected routinely in daily clinical practice, preferably in a simple effective way. Eventually for some highly relevant topics an extensive evaluation can follow. The interpretation must be left to the medical professionals themselves because in-depth knowledge is required. By reducing unwanted effects more attention can be given to successful, safe procedures.

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Chapter 8 General Discussion.

Introduction

Management and financial overviews are inadequate for the purposes of clinical audit, quality-improvement activities, medical research and education[1,2]. They must be supplemented by a clear picture of daily clinical practice.

As shown by the literature, many medical treatment modalities are thought to be evidence-based. Medical research is the principal method for generating feedback on treatment. Extracting data from medical records for this purpose is time-consuming and, since only physicians can reliably judge data in records [3], medical professionals themselves should collect these data. In daily clinical practice, time constraints preclude continuous data collection. It is therefore often assumed that the results from literature can be extrapolated to one's own department.

Successful surgery requires a long period of training and extensive experience. Comparing initial results with later results shows that there is a learning curve. After the completion of residency, all registrars are themselves responsible for maintaining and improving their surgical abilities. In addition to practical courses, congresses and reading literature, a review of one's own results helps to identify strengths and weaknesses, and to continue to learn.
Feedback is required to establish a picture of the results of daily clinical practice in one's own department. We will call data that provides us with a picture of daily practice *clinical feedback information.*

Theoretically, with the advent of computers, it became easier to generate feedback information [4-6]. However, as most information is stored in free-text formats, data suffer from the same limitations as the data from medical records. Data that can be used as clinical feedback information should preferably be in 'computer-understandable chunks'. In other words, the information needs to be structured. This encourages comprehensiveness and more precise registration [7].

Clinical feedback information can demonstrate whether the extrapolation of results reported in literature to one's own practice is appropriate [8-11]. It may serve as a basis for further research. Furthermore, it can be used to answer patients' questions about the benefits and risks of treatment [12].

The aim of the OtoData project was to obtain clinical feedback information while keeping additional demands on clinical time to a minimum and avoiding excessive interference with working methods [1,13-16].

Procedures

Initial experiences (1985-1992):

In our first attempt to achieve structured data entry, a 7-sheet computer form was designed. The idea was that it would replace the operation notes of the ENT department. It took half an hour to complete the form, so otologists deferred the task to residents. Newly-arrived residents, however, had great difficulty in answering questions for which more knowledge and/or experience was needed. Furthermore, the sheets to be completed in the out-patient department were hardly ever filled in, if at all. No usable feedback information was obtained because of non-cooperation resulting from poor design.

Original data collection (1992-1995):

With the benefit of this experience, it was then decided to introduce a single-sheet – and easily comprehensible – data-collection form. This form was limited to key items only, e.g. patient identification, procedure, middle ear structures, mastoid contents and materials used (figure 1). The data-collection form does not replace the operation notes. Moreover, it is not filled in, but dictated together with the operation notes. When typing the notes, the secretary also enters the data in a database in the hospital network.

The OtoData project, which is a continuous data collection process for all ear surgery, started on 1 July 1992, and includes data from the two otology groups from the children's hospital and the general university hospital.

Data collection starts at the time of ear surgery and ends on the date of the last out-patient appointment, or the date of reoperation on the same ear.

Additional data collection

Upon analysis of the data, it turned out that only some overviews could be generated, mainly because many key items were missing. Not every operation was added to the

database, not all forms were complete or correctly dictated and many postoperative audiograms had never been made.

Figure 1. OtoData form which is dictated with the operation record. The bold capitals are the possible choices when the question is 'multiple choice' variant.

Name patient: .....
PID number & birth date: .....

Identification procedure

Right / **L**eft ear
Surgeon name: .....
Date: .....
Operation code: .....

Present state

- Middle ear inspection: **N**o (go to 'mastoid inspection') / **Y**es
  tympanic membrane: **I**ntact or perforation **S**hrapnel / **E**lsewhere / **A**bsent
  previous myringoplasty: **N**o/ **Y**es
  infection mucosa middle ear: **N**o / **Y**es / **C**holesteatoma
  ossicular chain mobility: **N**ormal/ **I**mpaired
  stapes: **I**ntact or suprastructure **M**issing / **P**artially absent
  incus: **I**ntact or **M**issing or **P**artially absent
  malleus: **I**ntact or **M**issing or **P**artially absent

- Mastoid inspection: **N**o (go to 'treatment') / **Y**es
  mastoid: previous mastoidectomy: **N**o / **Y**es
  previous antrotomy: **N**o / **Y**es
  thickened mucosa: **N**o / **Y**es
  pneumatisation: **N**o / **S**clerotic / **Y**es
  contents mastoid: **C**holesteatoma / **P**us / **A**ir / **E**lse
  canal wall present: **N**o / **Y**es

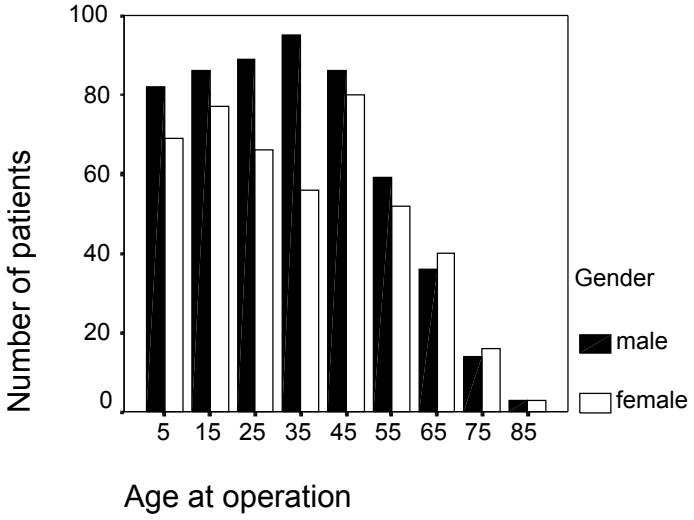
Treatment
Tympanoplasty: **N**o / **Y**es, with: .....
Ossiculoplasty / stapedotomy: **N**o / **Y**es, with: .....
Canal wall removal: **N**o / **Y**es / was already **M**issing
Obliteration: **N**o / **Y**es, with: .....
Peroperative complication: **N**o / **Y**es, description: .....
Remarks: .....

To overcome these shortcomings, we decided to check the whole database for omissions and errors. To this end, we went through the medical records and discharge letters. While doing so, we also collected additional items, such as indications for surgery and post-operative complications.
The audiometry data had to be added by hand to our database as automatic integration of data from the audiometry database was not possible at that time.

Output

The data presented in overviews could be categorised in any subdivision. For example the age distribution is in 10-year categories and subdivided by sex (figure 2). In our case, any other subdivision could have been made because of numeric data registration in continuous scales. This turned out to be important.
Our compiled overviews had to be broken up to enable comparison to literature since the reporting of results of ear surgery usually takes place for each kind of surgery individually. Where necessary, an in-depth evaluation took place.
The output provided insights into statistics that would otherwise be hard to obtain. An example is that the results of ossicular chain reconstruction varied widely. A number of patients benefited greatly, whereas others experienced deterioration in their hearing (Chapter 2). Overviews sometimes confirmed intuitive impressions. For example, mastoidectomy is the most common ear operation (Chapter 5, table 1), and the best results in terms of hearing improvements are achieved by reconstructive surgery

Figure 2. Age at operation subdivided by gender.



(Chapter 5, table 2). However, we also saw unexpected results such as the results of stapedotomies (Chapter 3). Although we were under the impression that post-operative audiometry was routinely performed on all patients, our results showed this was only true in 70% of cases. These insights bring to the surface some strengths – and weaknesses – of the department, allowing us to monitor the 'quality' of care continuously and thereby identify areas for improvement.

Benefits

Clinical feedback information provided us with insights that led to changes in the delivery of medical care by our department (Chapter 3). These changes were based on facts in general overviews and not on intuition or incidents (where the risk of recurrence is unclear). Two examples of changes are given, as well as one example where changes were not thought to be necessary.

In the first example, we had compared our overviews for stapedotomies to the literature [17]. We found that our success rate was at the lower end of the range reported in the literature. The literature shows that experience is very important for the success rate of stapes surgery [18-21]. In the overviews, we found that, at that time, only 30 stapedotomies were performed each year. These operations had been performed by 6 different surgeons (including residents and junior members of staff in the early days of training). This observation led to the conclusion that 5 stapedotomies per surgeon per year is definitely inadequate for acquiring and maintaining experience. Limiting these operations to experienced surgeons, occasionally accompanied by a resident with special interest, improved the performance of the department.

In the second example, we found that many operations are performed by members of our staff without the assistance of a resident (27%). Furthermore, it followed from the overviews that simpler operations could have been performed by senior residents alone. Adaptation of the training programme means that residents can now learn to perform 'simple' ear surgery by themselves earlier in their residency.

Clinical feedback information can also confirm the efficacy of daily medical care and does not always have to lead to change. As an illustration of an insight into the effectiveness of treatment, we discuss the results of ossicular chain reconstruction (Chapter 2). If the reconstruction was performed as a single procedure, the median improvement was 10 dB. If the reconstruction was only part of the operation, the median improvement was 0 dB.

These figures are comparable to the literature [22-25]. A possible explanation for this modest median improvement could be the spread in improvement. There are patients who benefit greatly from the ossicular chain reconstruction and there is a group that experiences deterioration of hearing [26].

Lessons learned

Although, in our clinic, data collection was well accepted, the postoperative form was not completed in 11% of procedures. Reasons given by the surgeons when asked why they had neglected the extra procedure were:

- they did not think it necessary for standard procedures such as placing a bone-anchored hearing aid;
- they had completely forgotten to fill out the forms.

Surgeons also recorded some data in an ambiguous format.

It turned out to be important for one person to be responsible for obtaining the data. In this experimental setting, the aim of comprehensiveness was difficult to achieve, and it proved difficult to combine several databases. When setting up a continuous data-collection system, it is imperative to be sure that output can be generated easily. Otherwise, the data end up in a 'data graveyard'. Although only a single-sheet data-collection form was used, many record fields were still *not* used in the final analysis. For instance, the state of the ossicles did not seem relevant at reporting, because it was not used in any overview. The operation notes are the place for documenting these exact procedures. In the out-patient department, surgeons completed only 20 forms out of 1009 (2%). This was also the case in the initial period (1985-1992). Time pressures may explain this lack of cooperation. It may be difficult for clinicians to take the time to evaluate the result of a surgical procedure objectively if they lack time. A solution to this problem could be to develop simple, generally-applicable scales without extensive inclusion and exclusion criteria.

The limitation of items to the minimum will, in our opinion, improve compliance.

These few items need to be chosen judiciously, because we discovered, during the process of data collection, that indication and peroperative findings were missing in the original data collection. Additional information was therefore needed about the effectiveness of treatment. To determine the impact of missing data, it was decided to check and complete the entire database. The author corrected ambiguous data (no percentage given) and retrieved missing items. In conclusion: there is a thin line between too many items, reducing surgeon compliance, and too few items, leading to incomplete and therefore uninformative overviews.

Publicity

A drawback of all feedback projects is that the overviews presented could also be of interest to other parties and can easily be misinterpreted. For example, hospital management and insurance companies could misuse clinical feedback information by placing it out of context to reduce costs, and patients could compare data from different departments and draw unjustified conclusions. Circumstances differ, and this can account for variability in results. Furthermore, the outcome of the registration is a reflection of the individual attitude towards success; some people are more easily satisfied than others. This has to be taken into account when making comparisons. We feel that the information gathered is the property of the quoted individual physician or department. When professional privacy is assured, uninhibited event registration can take place. On the other hand, we think that patients need information based on results from the clinic where the surgery takes place, for example to give informed consent. We also believe that transparency is essential to make medical care more manageable. At the same time, we are convinced that it is of the utmost importance for medical professionals themselves to retain responsibility for recording this kind of data, and interpreting the data, if they are to remain in charge of the delivery of medical care. More importantly, they should be the ones that start collecting such data before others do so with other motives.

Recommendations

Collecting data to provide feedback is only feasible when it does not interfere with daily chores. The challenge of routine data collection lies in the fact that it should be acceptable.

We found that the time when extra data are registered is of essential importance. There was a sharp contrast between gathering the data straight after surgery (89% compliance) and collection in the postoperative period (2% compliance). From this, we conclude that a slightly more extensive questionnaire is possible straight after surgery but that only a minimal scale is feasible in the outpatient clinic.

Well-designed data collection enhances compliance and accuracy. For meaningful overviews, reliable data are imperative. A pitfall in the design of data collection is the assumption that 'everything should be registered'. We do not think that it is necessary to register everything. A good data-collection form consists of only highly clinically-relevant items that are sure to be used in overviews [14].

When designing data collection systems, it seems advisable to incorporate the operation notes. These should be highly structured. However, this is not always the case [27-29]. On the basis of our experience, we suggest registering at least the following items in every chart, regardless of the type of surgery or storage medium:

Patient identification: name, date of birth, male/female, patient number

Procedure identification: name surgeon, date, procedure(s) (coded including left or right side),

Procedure description: Medication administered by surgeon, description of procedure, findings, tissue obtained (biopsies, bacteria), materials used (patient or foreign)

Summary: indication(s) (coded), final diagnosis (coded), Complications (no / yes + description).

The next step is to store specific fields in some coded form. In the Netherlands, financial codes are already registered for each surgical procedure. If additional codes for indication, diagnosis and complications are chosen with care, they might be used to generate operation notes quicker by incorporating standard sentences. In our opinion, the procedure description itself should be in the surgeon's own words because subtle, but important, variations cannot be captured in standard texts.

Outcome registration may be another step in establishing a clearer picture of the quality of surgery. (see Chapter 6 and Chapter 7). When all these categorised data are presented in comprehensive overviews, the feedback loop is closed.

Pros and cons

When a department has a specific interest in quality of care, the continuous registration of complications is feasible. Gathering clinical feedback information takes effort. It also takes courage to go public with complications and, perhaps, the results of surgery. As of yet, there are no objective standards to measure overall success in medicine. Data collection by the specialists themselves is always subjective. Results can be improved by being aware of quality and of the possible pitfalls beforehand. Simple complication registration indicates which facets of care can be improved. When the loop is closed by adaptation of the treatment on a continuous basis, the result is a quality spiral. Since this is applicable to all patients and treatment modalities and not just to a specific sub-population, this could very well be a step in the right direction.

Conclusion

In this project, our initial experiences with clinical feedback information on ear surgery based on routinely-collected data led to the following conclusions:

- Evaluating one's own 'quality of care' through clinical feedback information is feasible.
- Quality-control activities can be based on reliable data rather than on incidental findings.
- Data collection, however, interferes with daily practice: determining how to collect data, which data to collect, and when to collect data, remain difficult issues that should be further explored.

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Chapter 9 General Conclusion.

The first goal of the OtoData project was to evaluate the ear surgery performed at the Erasmus MC. We demonstrated that developing and implementing data collection for daily clinical care was feasible. The feedback derived from this project provided us with an understanding of ‘quality’ in our department. Comparing these findings with literature allowed us to identify potential improvements.

The second goal was to investigate a 'minimum dataset requirement' that will ensure adequate feedback on daily clinical practice. This led to the conclusion that the operative charts need other information in addition to the collected data, i.e. indication(s), final diagnosis and complications. It is preferable to store these items automatically in a database when generating the text. A convenient complication scale was developed to save time while still producing adequate overviews. It consists of four levels varying from grade A (adverse event) to grade D (death). Grade B includes minor complications that require extra procedures involving risks but no damage. Grade C (major) complications result in residual damage. This clinical feedback information can be used to base quality control activities on reliable data rather than on incidental findings.
Data collection, however, interferes with daily practice: determining how to collect data, which data to collect, and when to collect data, remain difficult issues that need to be further explored.

Chapter 10 Summary.

The first goal of the OtoData project was to evaluate the performance of the Erasmus MC ENT department for a complete cohort of three years of ear surgery and four years of otosclerosis surgery. In this project, our daily clinical care, as recorded in a database consisting of key elements, was compared to the literature. The second goal was the construction of a 'minimum dataset requirement' for adequate feedback information about daily clinical practice.

The first study concentrated on specific hearing improvement following ear surgery. The continuous collection of data leads to satisfactory follow-up. Patient information nowadays is therefore based on information about our own results. Ossicular chain reconstruction is a safe and reliable procedure.

The second study evaluated the routine for collecting information about ear operations and their postoperative course. Much attention was paid to the definition and convenient gradation of ‘complications’. Sound records give a near-complete picture of all possible adverse events and complications in patient care. This makes it possible to compare daily clinical practice to the literature. As an example, the results of stapes surgery and the complications of 226 successive cases were studied. They are comparable to the literature, albeit less than perfect. This increased awareness among surgeons, leading to a reduction in the number of stapes surgeons and an improvement in hearing results and fewer complications.

The third study analysed the results of rhinological surgery. Evaluating the rhinological literature from 1979 until 1999 showed that there were many differences in reporting. A classification based on severity is proposed. The main advantage of a simple, easy-to-use system of registration is that it allows for concise feedback overviews. Our four categories (grade A-D) make it possible to establish a picture of complication rates for different kinds of surgery and to monitor changing trends. Consensus about categories of complications may cross specialisms and sub-specialisms and it is a prerequisite for valid comparisons with other clinics.

In the fourth study, we describe our initial experience with clinical feedback information based on the routine collection of data. Feasibility was demonstrated, and examples were found of the usefulness of clinical feedback information. Clinical

feedback information makes it possible to base quality-control activities on data rather than on incidental findings.
Data collection interferes with other daily routines. Determining how to collect data, which data, and when to collect them, proved stubborn problems.

The sixth chapter discusses the advantages of a complete overview of all adverse events and complications and their evaluation among peers. The aim of this approach is not to apportion blame, find fault or identify scapegoats, but to improve procedures. In addition, excellent results might be used to assist less fortunate colleagues.

Chapter seven focuses on improving the quality of care. Definitions and aspects of quality are discussed. A first step here is reporting on complications. Learning from accidents leads to the identification of critical moments, and to prevention. Outcome registration of daily medical care may be a next step. All this requires routine data collection in daily clinical practice. Analysis and interpretation must be left to the medical professionals as in-depth knowledge is required.

Our initial experiences with clinical feedback information about ear surgery based on routinely-collected data led to the following conclusions:

- Evaluating one's own ‘quality of care’ through clinical feedback information is feasible.
- Results of ear surgery were improved by comparing our own results to those reported in the literature.
- Quality-control activities should be based on reliable data rather than on incidental findings.
- Data collection, however, interferes with daily practice: determining how to collect data, which data to collect, and when to collect data, turned out to be difficult issues.

Samenvatting

Het OtoData project is in eerste instantie opgezet om de kwaliteit van Ooroperaties in het Erasmus MC te evalueren. De gegevens van drie jaar ooroperaties, aangevuld met vier jaar stapes chirurgie werden bewerkt. De gegevens waren samengevat in een database met kernpunten. De resultaten van het dagelijks klinisch handelen werden vergeleken met de literatuur.
In tweede instantie werd er gezocht naar een minimale lijst met kernpunten welke adequate feedback zou kunnen geven over de dagelijkse klinische praktijk.

De eerste studie concentreerde zich op de behaalde gehoorsverbetering na operaties aan de gehoorbeenketen. Hiermee werd aangetoond dat een continue dataverzameling een goede follow-up mogelijk maakt van ooroperaties. Patiënteninformatie wordt nu verstrekt op basis van de eigen resultaten. Ketenreconstructies worden veilig en betrouwbaar uitgevoerd in het Erasmus MC.

In de tweede studie werd gekeken naar het verzamelen van data over ooroperaties en het postoperatieve beloop. In deze studie werd veel aandacht besteed aan de definitie van complicaties en een eenvoudige, maar doeltreffende indeling naar ernst werd gepresenteerd. Een robuuste registratie leidt tot een vrijwel compleet overzicht van alle mogelijke ‘adverse events’ en complicaties in patiëntenzorg. Hierdoor kan de dagelijkse praktijk worden vergeleken met de literatuur.
Als voorbeeld werden de resultaten en complicaties van 226 stijgbeugel operaties nader bekeken. Deze waren weliswaar vergelijkbaar met de literatuur, maar niet perfect. Doordat de oorchirurgen zich beter bewust werden van deze uitkomst werd het aantal chirurgen deze vorm van oorchirurgie deed aangepast. Dit leidde tot beter postoperatief gehoor en minder ernstige complicaties.
De derde studie behelsde de resultaten van neusbijholte chirurgie in de literatuur van 1979 tot en met 1999. Het bleek dat er verschillende manieren van rapporteren bestonden. Daarom werd een classificatie voorgesteld, gebaseerd op ernst van de complicatie. Het voordeel van een eenvoudig te gebruiken systeem is dat er degelijke, duidelijke en niet al te uitgebreide overzichten beschikbaar zijn voor feedback. Ons voorstel is om vier categorieën te gebruiken, variërend van graad A tot graad D. Dit laat de complicatie percentages van verschillende soorten van chirurgie zien en maakt veranderende trends inzichtelijk. Het is van belang dat consensus bereikt wordt over de categorieën om vergelijking met andere klinieken mogelijk te maken.

In de vierde studie worden de eerste ervaringen beschreven met klinische feedback informatie gebaseerd op routine gegevensregistratie. Er werd aangetoond dat dit haalbaar is in de praktijk en bruikbare overzichten oplevert. Deze klinische feedback informatie maakt het mogelijk kwaliteitsverbeteringen door te voeren gebaseerd op data en niet meer op incidenten.
Gegevensregistratie zal echter altijd z'n weerslag hebben op de dagelijkse praktijk. Welke gegevens, wanneer en hoe ze vastgelegd worden blijft een lastig probleem.

Het zesde hoofdstuk toont de voordelen van een compleet overzicht van alle 'adverse events' en complicaties en de evaluatie met vakgenoten. Het doel is niet om een zondebok te vinden voor de complicatie, maar om de procedures te verbeteren.
Uitmuntende procedures kunnen een voorbeeld zijn voor wat minder succesvolle collegae.

In het zevende hoofdstuk wordt besproken hoe de kwaliteit van zorg verbeterd kan worden. Er wordt ingegaan op definities en de verschillende aspecten van kwaliteit.
Een eerste stap om te kunnen verbeteren is een complicatie registratie. Van zaken die fout verliepen kan geleerd worden waar de kritische momenten zitten in de procedures. Uitkomst registratie van de dagelijkse klinische praktijk zou de volgende stap kunnen zijn. Een routine gegevensregistratie is onontbeerlijk om eerder genoemde evaluaties te kunnen doen. Alleen medische professionals kunnen de gegevens interpreteren omdat er uitgebreide vakkennis voor nodig is om de juiste conclusies te kunnen trekken.

Uit onze eerste ervaringen met klinische feedback informatie over oorchirurgie door middel van continue gegevensregistratie kunnen de volgende conclusies getrokken worden:

- De eigen kwaliteit van zorg kan bepaald worden aan de hand van klinische feedback informatie.
- De resultaten van oorchirurgie verbeterden na vergelijk van de eigen resultaten met de literatuur.
- Kwaliteitsverbetering kan op basis van betrouwbare gegevens bereikt worden.

Gegevensverzameling in de dagelijkse praktijk kost extra moeite. Welke gegevens, hoe en wanneer verzameld moeten worden bleek weerbarstige materie.

Curriculum vitae

Jan Rombout was born on 11 September 1964 in Rheden. He completed his secondary education at the Cals College in 1983 before starting his medical studies at the Erasmus University in Rotterdam in the same year. He spent his military service with the Royal Dutch Navy as a ship's doctor. In 1992 and 1993, he was a resident in general surgery at the Merwede Hospital (now Albert Schweitzer) in Dordrecht. From 1994 until 1999 he was an ENT resident at the Dijkzicht University Hospital (now Erasmus MC) in Rotterdam. In 2001 and 2002 he was part-time junior registrar at the Lucas Andreas Hospital in Amsterdam and part-time researcher. In 2002 he was appointed senior registrar at the Oosterschelde Ziekenhuis and now works in Goes.

Jan Rombout werd op 11 september 1964 geboren te Rheden (Gelderland). Het atheneum diploma werd gehaald aan het Cals College te Nieuwegein in 1983, waarna hij hetzelfde jaar geneeskunde ging studeren aan de Erasmus Universiteit te Rotterdam. In 1990 behaalde hij het artsexamen en vervulde daarna zijn dienstplicht bij de Koninklijke Marine o.a. als scheepsarts. In 1992 en 1993 was hij arts-assistent chirurgie (AGNIO) in het Merwede Ziekenhuis (nu Albert Schweitzer) in Dordrecht. Van 1994 t/m 1999 specialiseerde hij zich tot KNO-arts in het Academisch Ziekenhuis Rotterdam (nu Erasmus MC). In 2000 en 2001 was hij parttime werkzaam als chef de clinique in het Lucas Andreas Ziekenhuis te Amsterdam en deed daarnaast onderzoek. Vanaf 2002 is hij lid van de maatschap KNO van het Oosterschelde Ziekenhuis en werkt in Goes.

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