

Patient Satisfaction after Middle Ear Surgery: Data from a National Quality Registry.

Patientnöjdhet efter myringo- ossikuloplastik: Analys av PROMs (patient related outcome measures) i nationellt kvalitetsregister ÖNH

Louise Bogered

Supervisor: Department: Eva Westman Dep. of Clinical Sciences, Otorhinolaryngology

Abstract

Objective/Hypothesis: The majority of patients are satisfied with the result of their middle ear surgery. A small group pf patients are not satisfied, who are these patients? Is it possible to in advance identify patients who will be dissatisfied?

Study Design: This study was a retrospective analysis of prospectively collected data from the Swedish National Quality Registry for Myringo- and Ossiculoplasty (QRMO).

Methods: A total of 2080 surgeries performed between 2013 and 3/9 2019 were included in the analysis. Data from a perioperative report, a follow-up report and a patient questionnaire were analyzed in regards to patient satisfaction with the result of the surgery. The factors which increase the risk of being dissatisfied with the result of the surgery were determined.

Results: A majority, 82% (n=1699), of the patients were satisfied with the result of the surgery while 18% (n= 381) were dissatisfied. Patients who are 15 or older, who don't undergo surgery at a university hospital, who have had prior ear surgery, who don't have an intact eardrum at the follow-up visit, who have a postoperative infection within six weeks after surgery, who have a hearing impairment postoperatively and who have deteriorated hearing (< -5 dB PTA4 gain) have an increased risk of being dissatisfied with the result of the surgery. Furthermore, patients who report experiencing worse hearing, inconvenience from the operated ear, who report being dissatisfied with the care given in connection to the surgery and who report being dissatisfied with the follow-up care after the surgery in the PROMq also have an increased risk of being dissatisfied with the result of the surgery.

Conclusion: The majority of patients who undergo middle ear surgery are satisfied with the result of the surgery, however there are certain factors which increase the risk of a patient being dissatisfied.

Key Words: Myringoplasty, ossiculoplasty, patient satisfaction, quality registry, patientreported outcome measures

Abbreviations	3
QRMO TM dB	The Swedish National Quality Registry for Myringoplasty and Ossiculoplasty Tympanic Membrane Decibel
AC PTA4	Air Conduction Pure Tone Average for the four frequencies 0.5, 1, 2, 4 kHz
PROM	Patient Reported Outcome Measures
PROMq PREM	Patient Reported Outcome Measures questionnaire Patient Reported Experience Measures

Introduction

In Sweden there are numerous publicly funded national quality registries (1). These registries allow for continuous learning and constant improvements of Swedish health care, both on a local and national level. The national quality registry for myringoplasty and ossiculoplasty (QRMO) is currently one of nine Swedish ear, nose and throat (ENT) registries (2). The registry was originally established in 1997, however it has been revised since then, the latest time being in 2013. The registry collects data from myringoplasties and ossiculoplasties performed in Sweden. Participation in the registry is voluntary for clinics, however all otorhinolaryngology departments performing ear surgery in Sweden are currently participating. Nowadays about 80% of patients in Sweden who go through a surgical procedure to repair a perforation in the tympanic membrane (TM) and/or ossicular reconstruction are registered in the registry.

Delivering patient-centered care is an important component of a high-quality health care system (3). Over the last couple of years there has been a growing interest and discussion surrounding quality of health care and how it is to be measured. One health care quality measure is patient satisfaction. Previous studies have shown that patient satisfaction is not easily defined. Satisfaction is a broad term and in relation to assessing outcome, it has been described as a multi-dimensional measure that encompasses a range of issues including the patient's belief in what the treatment can provide, expectations of what they want the treatment to achieve, the level of pre-treatment symptoms and the relative change in these symptoms, as well as the process and delivery of the treatment (4). In a previous study, it has been stated that despite the difficulty in pinpointing what satisfaction entails, if patients are dissatisfied, health care hasn't achieved its goal (5). Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) are measures that provide a patient-centric view of healthcare. PROMs are self-reported questionnaires that patients complete to provide information on aspects of their health that are relevant to their quality of life and that provide insight on the effectiveness of care from the patient's perspective. PREMs are self-reported questionnaires that patients complete to provide information about their satisfaction with and experience of receiving



health care (6). Currently there are only a few published studies about patient satisfaction specifically after ear surgery.

Perforation of the TM primarily results from middle ear infections, trauma or iatrogenic causes. Up to 80% of these perforations heal spontaneously; for the remaining, surgical repair, known as myringoplasty, is usually recommended. Myringoplasty is a surgical procedure which aims at repairing a perforated TM in order to regain a functional ear (7). The purpose of the procedure is to close the TM, improve hearing and limit patient susceptibility to middle ear infections (8). There are currently two established surgical techniques used in Sweden, conventional myringoplasty and fat grafting. Conventional myringoplasty can be performed with an underlay or an overlay surgical technique, with the underlay method almost exclusively used nationwide. In the underlay technique the graft is placed medial to the perforation, preferably with autologous grafting material, generally fascia or cartilage (7). Fat grafting is a technique in which fat, usually from the ear lobule, is used as graft material for the closure of small perforations of the TM (9). The success rate (healed TM) in Sweden for conventional myringoplasty is 87% and 78% for fat grafting (10).

Hearing deficiency is one of the indications for middle ear surgery and it can be categorized either into sensorineural or conductive hearing loss. Sensorineural hearing loss is mainly caused by disease in the inner ear. Conductive hearing loss is caused by impairment in air transmission of sound waves to the inner ear. The impairment may be caused by pathology at the level of the external auditory canal, at the TM or at the ossicular chain. In the case of ossicular chain, reconstructive surgery known as ossiculoplasty is performed. Depending on the damage of the ossicles, either a partial prosthesis or a total prosthesis is needed. A variety of prosthesis material are available, the most commonly used today are titanium and autologous homograft from the incus body. By regaining the original mechanics of the ossicular chain to transfer sound energy to the inner ear, patients' overall hearing can be improved (11).

Complications after middle ear surgery, such as tinnitus and taste disturbances, are reported in the QRMO. Tinnitus, the perception of sound without external stimuli, is a distressing symptom that leads to a decrease in the quality of life. Taste disturbance is a complication associated with surgical procedures in the middle ear due to manipulation of the chorda tympani nerve which controls taste in the anterior two-thirds of the tongue on each side (12). Complications reported after middle ear surgery has previously been analyzed using data from the QRMO from 2002-2012 and 2013-2017. The study showed that tinnitus and taste disturbances were more common after middle ear surgery when patients reported their symptoms than when physicians reported the symptoms (13). In a previous master thesis, patient satisfaction after myringoplasties performed between 2002-2012 was analyzed. The vast majority (80%) of patients were satisfied, patient satisfaction was however negatively affected if the patient had postoperative complications and/or a remaining TM perforation. These patients were also less satisfied with the information that they had received before surgery (14).

The aim of this project is to present patients' experiences approximately one year after middle ear surgery (myringoplasty and/or ossiculoplasty performed between 2013-2019), by analyzing data included in the QRMO. In particular, the patient related outcome (PROM) of patient satisfaction and the factors which affect it will be analyzed. Is it possible to identify patients who will be dissatisfied before surgery?

Materials and Methods

Study design

A retrospective analysis of prospectively collected data from the QRMO was performed. Raw database extraction was made on September 3rd 2019.

QRMO and Patient-Reported Outcome Measures questionnaire (PROMq)

The data in the registry consists of a perioperative report, a follow-up visit report (approximately 12 months after surgery) and a patient-reported outcome measures questionnaire (PROMq). The perioperative report and follow-up report were filled out by a physician either in paper form or online. The PROMq was filled out by the patients themselves or with the help of parents/guardians if the patient was not old enough to answer or comprehend the questions. The patients received the PROMq approximately 12 months after surgery either by mail, e-mail or at the follow-up visit. The PROMq includes 13 questions. The majority of these questions have multiple choice answers in the form of a Likert scale with four or five alternatives. The are two exceptions to this, these questions only have two response alternatives, "yes"/"no" and "the person who has been operated"/"relative or other". See table 2 for more details.

Study population

The database contained information from 5273 surgeries performed between 2013 and 3/9 2019. After duplicates (n = 14), defined as surgeries with an identical surgery date and operated ear, were excluded a total of 5259 surgeries remained. Out of these, 3062 (58%) had follow-up data registered and 2066 (39% response rate) had a PROMq registered. To acquire additional PROMqs to be included in the analyses, a total of 168 questionnaires were sent out to patients who had not yet answered it, who had follow-up data registered and who had undergone surgery during 2017-2018 in Sundsvall, Örnsköldsvik, Stockholm, Gothenburg, Uppsala or Örebro. The criterion of having revisit data registered was excluded for patients who had undergone surgery in Sundsvall and Örnsköldsvik. Of the 168 questionnaires that were sent out, 54 (32% response rate) were completed and returned within the one-month time limit. Of these 54 questionnaires, 34 were correctly filled out and were therefore included in the database. After increasing the response rate of the PROMq, the major exclusion criterion, patients who had not answered the question "Are you satisfied with the result of the surgery", was applied. A total of 2080 patients remained for evaluations, out of these, n = 1736 (83%), had follow-up data registered.

Audiogram analyses



Audiometric data both pre- and postoperatively (air and bone conduction) for frequencies 0.25, 0.5, 1, 2, 3, 4, 6 and 8 kHz were registered for both ears in the database. Only the audiograms testing air conduction of the operated ears were analyzed. A four-frequency (0.5, 1, 2, 4 kHz) pure-tone average for air conduction (PTA4) for the operated ear was calculated pre- and postoperatively. Using the PTA4, patients were categorized into groups with normal hearing or hearing impairment. The World Health Organization (WHO) classification was used which defines normal hearing as ≤ 25 dB hearing threshold and hearing impairment as > 25 dB hearing threshold. Postoperatively, was also calculated. According to the postoperative hearing gain patients were divided into three groups, hearing improvement (> 5 dB), unchanged hearing (-5 dB-5 dB) or deteriorated hearing (< -5 dB).

Outcomes

Primary outcome for the study was dissatisfaction among patients who had undergone middle ear surgery, measured using the PROMq. Secondary outcomes were the occurrence of complications (tinnitus, taste disturbance), how care given in connection to and following the surgery was perceived by the patient, physical examination findings at the follow-up visit (intact eardrum, infection) and hearing according to pre- and postoperative audiograms. These parameters were obtained from the PROMq and the pre- and postoperative reports from physicians.

Statistics

The collected data was transferred to an Excel 2016 spreadsheet. IBM SPSS statistics version 26 was used for statistical analyses. Chi-square tests were used to analyze categorical variables. Binomial logistic regression was used to estimate the factors associated with being dissatisfied after surgery. Crude and adjusted odds ratios were calculated. A p-value of < 0.05 was considered statistically significant.

Ethical Considerations

The declaration of Helsinki was followed. An ethical approval had already been obtained (D-nr 2014/2203-31/4).

Results

Descriptive data (table 1)

Out of a total of 5273 surgeries, 2080 were included in the study after exclusion. Of the 2080 patients, 1087 (52%) were female and 993 (48%) were male. Patients were between 5 and 93 years old, with a mean age of 34 years old. A total of 490 (24%) patients were under 15 years old and 1590 (76%) were 15 years or older. About half of the patients, 1038 (50%) had undergone surgery at a university hospital. Further subgrouping into three different regions (north, middle, south) showed that out of the 2080 surgeries, 340 (16%) were performed in the north, 808 (39%) in the middle and 932 (45%) in the south. Indication for surgery was hearing improvement and/or infection prevention, the most



common being a combination of the two (45%). Out of the different types of surgeries the majority of patients, 1473 (71%), had undergone conventional myringoplasty, 175 (8%) fat grafting, 123 (6%) ossiculoplasty and 309 (15%) myringo- and ossiculoplasty. According to the WHO classification, 661 (32%) patients had normal hearing and 1396 (67%) patients had a hearing impairment preoperatively. Postoperatively, 996 (48%) patients had normal hearing and 708 (34%) patients had a hearing impairment. Approximately half of the patients, 1101 (53%), had improved hearing (>5 dB PTA4 gain) while 416 (20%) had unchanged hearing (-5 dB – 5dB PTA4 gain) and 171 (8%) experienced deteriorated hearing (< -5 dB PTA4 gain) following surgery. A healed TM is a measure of the success rate of a conventional myringoplasty and fat grafting. After having undergone a conventional myringoplasty, 87% of patients had a healed TM and after fat grafting 80% of patients had a healed TM. After ossiculoplasties the hearing result is the primary outcome, improved hearing was achieved in 80% of the cases.

Patient Survey

For extensive descriptive data see table 2. Most patients, 1664 (80%), filled out the survey themselves. A majority, 82% (n=1699), of the patients were satisfied with the result of the surgery while 18% (n= 381) were dissatisfied. Complications such as taste disturbance and tinnitus were reported by 262 (13%) patients. Other negative outcomes after surgery were also reported, these showed that 124 (6%) patients had experienced pain at the operated ear, 167 (8%) patients had experienced a reduced sense of touch/sensation on the outer ear, 688 (33%) patients had had recurrent infections or ear discharge coming from the operated ear and 247 (12%) patients had experienced inconvenience from the operated ear. A majority of patients, 1806 (87%), perceived their hearing as unchanged or better at the time of filling out the survey compared to before the surgery. Most patients were satisfied with the care they received, 1910 (92%) patients felt that the information that they had received before the surgery was in line with how they experienced the surgery and the time after, 1993 (96%) were satisfied with the care given in connection to the surgery and 1889 (91%) were satisfied with the follow-up care given after surgery. The question regarding inconvenience from the operated ear when not protecting it from water when showering/bathing, was difficult to interpret since patients in many cases avoided answering the question or ticked more than one of the answer alternatives. It was therefore not further analyzed.

Dissatisfaction in regards to age and gender

Figure 1 shows the number and percentage of patients dissatisfied with the result of their middle ear surgery according to age and gender. The age category 10-19 years was the category which included the most patients (n = 548). There was an even distribution of men and women in every age category except for in the 40-49 and 70-79 age category where there was a clear over-representation of women. The percentage of dissatisfied patients steadily increased for every age category up until 50-59 years where it peaked at 26,2% before decreasing.

Descriptive data - Very dissatisfied patients

In the group of patients who were very dissatisfied (answer alternative "1" on the PROMq) with the result of their surgery (n = 121) there was an even distribution of men



and women. The mean age was 37 years old. Out of the different types of surgeries the majority of patients, 64% (n = 78), had undergone conventional myringoplasty, 7% (n = 9) fat grafting, 7% (n = 9) ossiculoplasty and 21% (n = 25) myringo- and ossiculoplasty. Roughly 42% (n = 51) of the patients had undergone surgery at a university hospital. Surgeries were performed in all three regions, 13 (11%) were performed in the north, 41 (34%) in the middle and 67 (55%) in the south. According to the WHO classification, 29% (n = 34) of the patients had normal hearing and 71% (n = 85) had a hearing impairment preoperatively. Postoperatively, 15% (n = 13) of patients had normal hearing and 85% (n = 72) had a hearing impairment. Approximately 30% had improved hearing (>5 dB PTA4 gain) while 25% had unchanged hearing (-5 dB – 5dB PTA4 gain) and 45% experienced deteriorated hearing (<-5 dB PTA4 gain) following surgery. About 57% (n = 51) had a healed TM at the follow-up visit. Complications were more frequently reported, approximately 23% (n = 28) of patients reported experiencing a taste disturbance postoperatively and 39% (n =47) reported experiencing bothersome tinnitus postoperatively.

Risk of being dissatisfied

Binary logistic regression was performed for the risk of being dissatisfied with the result of a surgery. The analyses were performed on three different datasets, one with all the variables known at the time of surgery, the second for objective variables registered postoperatively and the third performed with subjective variables from the PROMq. All of the analyses included age and gender. The objective variables (at the time of surgery and postoperatively) showing statistical significance were age ≥ 15 (aOR 1.81, p < 0.001), not undergoing surgery at a university hospital (aOR 1.41, p = 0.006) or in the middle/south regions (aOR 0.63, p = 0.026), having had prior ear surgery (aOR 1.84, p < 0.001), not having an intact TM at the follow-up visit (aOR 5.16, p < 0.001), having a postoperative infection within six weeks (aOR 2.06, p = 0.002), having a hearing impairment postoperatively (aOR 2.99, p < 0.001) and deteriorated hearing postoperatively (PTA4 gain < -5 dB) (aOR 3.03, p < 0.001). No significance was seen for gender, hearing impairment preoperatively, operated side, if ossiculoplasty was performed, being given perioperative systemic antibiotics, time (≤ 12 months) until follow-up visit, not being infection free on the day of the surgery or at the follow-up visit. Tables 3 and 4 summarize these findings.

The subjective variables showing statistical significance were experiencing pain at the operated ear (aOR 0.40, p = 0.006), experiencing worse hearing postoperatively (aOR 5.10, p < 0.001), experiencing inconvenience from the operated ear (aOR 11.48, p < 0.001), not being satisfied with the care given in connection to the surgery (aOR 8.22, p < 0.001) and not being satisfied with the follow-up care given postoperatively (aOR 3.00, p < 0.001). No significance was seen for taste disturbance, reduced sense of touch/sensation on the outer ear, tinnitus, reoccurring infections/ear discharge or the information given preoperatively. Table 5 summarizes these findings.

A second binary logistic regression was performed for the subjective variables. This time the answer alternatives were categorized differently for five variables. Previously, for the



questions about pain, reduced sense of touch/sensation, tinnitus and postoperative inconvenience from the operated ear, the answer alternatives "not at all" and "a little" were combined and "somewhat" and "very much" were combined. If the patient had answered "somewhat" or "very much" the complication was considered to be bothersome. In this second analysis, the answer alternatives "a little", "somewhat" and "very much" were combined into one category and "not at all" was one category. Unlike the first analysis, additional variables showing statistical significance were having tinnitus (aOR 1.36, p = 0.04) and not being satisfied with the information given preoperatively (aOR 1.72, p = 0.031). The variable, experiencing pain at the operated ear, was no longer showing statistical significance.

Discussion

In this study patients' experiences after middle ear surgery was analyzed with emphasis on finding the factors which increase the risk of being dissatisfied with the result of the surgery. In general, the study showed that the average patient was satisfied with their middle ear surgery, few experienced postoperative complications and the majority were satisfied with the information given prior to the surgery, the care given in connection to the surgery, the follow-up care as well as the result of the surgery.

One of the factors associated with dissatisfaction was not having a healed TM. The overall healing rate of the TM after surgery was 88%, which is in accordance with previous studies (15). In the group of patients who were very dissatisfied with the result of the surgery, the overall healing rate of the TM was only 57% (p < 0.001). The frequency of taste disturbance and bothersome tinnitus in this group was significantly higher compared to the entire study population. The increase in tinnitus could be due to impaired hearing, inflammation or even an increased awareness or stress. The surgical trauma and manipulation of the chorda tympani nerve could cause an inflammation with an increase in taste disturbance. As stated in a previous study, there seems to be a higher frequency of tinnitus and taste disturbance when the TM is not healed (13).

It could easily be taken for granted that not having a healed TM postoperatively would always be negatively associated with the PROMqs. It is therefore interesting when comparing healed TM and inconvenience from the operated ear, shown in figure 2. The middle aged patients have a higher frequency of healed TM but at the same time experience more inconvenience from the operated ear whereas younger patients have a lower frequency of healed TM but experience less inconvenience from the operated ear. This is surprising as one would think that the higher the frequency of healed TM, the lower the frequency of inconvenience from the operated ear would be. There must be other factors affecting contentment, for example adults are maybe more observant and react to the smallest of inconveniences whereas children aren't as sensitive or meticulous even though they may be experiencing some inconvenience.



Having had prior ear surgery also significantly increased the risk of being dissatisfied with the result of the surgery. In the group of patients who were very dissatisfied with the result of the surgery, about 42% had had prior ear surgery compared to 25% in the entire study population, which also indicates that it's an important factor. Having revision surgery has an effect on the rates of postoperative complications and the chance of having a successful surgery. It has for example been shown in a previous study that the frequency of tinnitus following conventional revision surgery was almost twice as high as that after primary surgery (13). Another study reported an overall success rate of 54.7% in 70 revision myringoplasty operations (16). It seems as if the repeated surgical trauma affecting the ear could be the reason for this.

Not undergoing surgery at a university hospital increased the risk of being dissatisfied with the result of the surgery. One possible explanation to this could be that in this particular study more surgeries were performed at university hospitals (1038 surgeries were performed at seven university hospitals compared to 1042 surgeries performed at 25 smaller hospitals) and therefore the surgeons are most likely more experienced. In a previous study the success rate of the myringoplasties performed by two senior surgeons was 87.2% while it was 56.1% in myringoplasties performed by six junior surgeons. The study came to the conclusion that significantly better results were obtained by experienced staff members or senior surgeons, however technical skill and attention to details varies among clinicians in a manner that is not strictly related to the level of training and experience (17).

Not surprisingly, other factors which increased the risk of being dissatisfied were deteriorated hearing or having a hearing impairment postoperatively. This seems reasonable since the indication for surgery was in many cases hearing improvement. Approximately 45% of patients had both infection prevention and hearing improvement as indications for surgery. Having deteriorated hearing will most likely have an effect on a person's quality of life and therefore it is not foreign to think that anyone who experiences a hearing loss will be dissatisfied.

Postoperative complications and care-related factors can be associated with dissatisfaction. Approximately 19% of patients in the very dissatisfied group experienced a postoperative infection within six weeks after surgery compared to 8% in the entire study population (p < 0.001). About 39% of patients reported experiencing tinnitus while 23% reported experiencing a taste disturbance in the very dissatisfied group, this compared to 13% in the entire study population (p < 0.001). Also, in the very dissatisfied group about 27% were dissatisfied with the information given prior to surgery as well as the care given in connection to the surgery and 36% were dissatisfied with the follow-up care given, compared with 7%, 4% and 8% respectively in the entire study population (p < 0.001). It seems that patients who are dissatisfied with the result of the surgery have a higher frequency of postoperative complications and are more dissatisfied with the information given prior to surgery and the follow-up care. In a previous master thesis, it was also seen that patients who experienced postoperative complications such as tinnitus, taste disturbance and infection were more



dissatisfied with the result of the surgery as well as the information given prior to surgery (14). This could imply that the preoperative information is not comprehensive enough in describing the risks associated with the surgery. It is possible that because complications are not so common (when physicians report them), that physicians chose not to inform patients about them and that patients are dissatisfied afterwards because they felt they were not informed about the complication they experienced. Maybe the time given at the outpatient clinical visit before surgery is not enough for a thorough discussion about all the possible scenarios that could happen? Or perhaps the patients do not listen to the information given?

There are a few limitations to this study that need to be taken into consideration. Missing data and low coverage are reported to be a common problem with registries, this is also the case with the QRMO. Quite a lot of patients are missing data such as postoperative audiograms and follow-up data. In these cases, it is not possible to make comparisons or evaluate the outcomes of the surgery. One of the reasons for loss of follow-up could be that patients who do not have any complaints might not turn up for a control. The PROMq has a low response rate, in this particular study it was calculated to be about 40%. In order to draw more accurate conclusions the response rate needs to be higher. The low coverage could be due to patients not receiving the questionnaire or less susceptibility to answering the questionnaire if the patients are satisfied with the result of the surgery. Another limitation to this study is that since everything that is reported in the QRMO is typed in manually, there are an unknown number of typing errors. Also, there is a limit as to how much information is collected in the registry database. Two parameters that are not included for example are the size and location of the TM perforation. A previous study has shown that larger and more anteriorly placed perforations were associated with lower rates of successful closure (healed TM) (18). Since this study showed that not having a healed TM at the follow-up visit increases the risk of being dissatisfied with the result of the surgery it would have been interesting to have known how many of the dissatisfied patients had large and anteriorly placed perforations.

Conclusion

The majority of patients who undergo middle ear surgery are satisfied with the result of the surgery. Patients who are 15 or older, who don't undergo surgery at a university hospital, who have had prior ear surgery, who don't have an intact eardrum at the follow-up visit, who have a postoperative infection within six weeks after surgery, who have a hearing impairment postoperatively and who have deteriorated hearing (< -5 dB PTA4 gain) have an increased risk of being dissatisfied with the result of the surgery. Furthermore, patients who report experiencing worse hearing, inconvenience from the operated ear, who report being dissatisfied with the care given in connection to the surgery and who report being dissatisfied with the follow-up care after the surgery in the PROMq also have an increased risk of being dissatisfied with the result of the surgery.



References

1. Regioner. SKo. Om Nationella Kvalitetsregister [Available from: <u>http://www.kvalitetsregister.se/tjanster/omnationellakvalitetsregister.1990.html</u>.

2. Nationellt kvalitetsregister för öron- n-oh. Registret för myringo- och ossikuloplastik [Available from: https://myr.registercentrum.se/.

3. Tsai TC, Orav EJ, Jha AK. Patient satisfaction and quality of surgical care in US hospitals. Ann Surg. 2015;261(1):2-8.

4. McGregor AH, Dore CJ, Morris TP. An exploration of patients' expectation of and satisfaction with surgical outcome. Eur Spine J. 2013;22(12):2836-44.

5. Arnetz JE, Arnetz BB. The development and application of a patient satisfaction measurement system for hospital-wide quality improvement. Int J Qual Health Care. 1996;8(6):555-66.

6. Information CIfH. Patient-Centred Measurement and Reporting in Canada [Available from: https://www.cihi.ca/sites/default/files/document/visioning-day-paper-en-web.pdf.

7. Sergi B, Galli J, De Corso E, Parrilla C, Paludetti G. Overlay versus underlay myringoplasty: report of outcomes considering closure of perforation and hearing function. Acta Otorhinolaryngol Ital. 2011;31(6):366-71.

8. Levin B, Rajkhowa R, Redmond SL, Atlas MD. Grafts in myringoplasty: utilizing a silk fibroin scaffold as a novel device. Expert Rev Med Devices. 2009;6(6):653-64.

9. Mukherjee M, Paul R. Minimyringoplasty: repair of small central perforation of tympanic membrane by fat graft: a prospective study. Indian J Otolaryngol Head Neck Surg. 2013;65(4):302-4.

10. Nationellt kvalitetsregister för öron- n-oh. Läkta trumhinnor: pluggning respektive konventionell myringoplastik [Available from: <u>https://myr.registercentrum.se/statistik/laekningsresultat-trumhinnor-riksdata/laekta-trumhinnor-pluggning-respektive-konventionell-myringoplastik/p/H1QpU1YxE</u>.

11. Mudhol RS, Naragund AI, Shruthi VS. Ossiculoplasty: revisited. Indian J Otolaryngol Head Neck Surg. 2013;65(Suppl 3):451-4.

Sakagami M. Taste disturbance and its recovery after middle ear surgery. Chem Senses. 2005;30 Suppl 1:i220-1.

13. Berglund M, Suneson P, Florentzson R, Fransson M, Hultcrantz M, Westman E, et al. Tinnitus and taste disturbances reported after myringoplasty: Data from a national quality registry. Laryngoscope. 2019;129(1):209-15.

14. Mohammadi F. Patientrapport efter Myringoplastik. Analys av enkätsvar i Nationellt Kvalitetsregister: Umeå University, Site Sundsvall; 2014.

15. Berglund M, Florentzson R, Fransson M, Hultcrantz M, Eriksson PO, Englund E, et al. Myringoplasty Outcomes From the Swedish National Quality Registry. Laryngoscope. 2017;127(10):2389-95.

16. Berger G, Ophir D, Berco E, Sade J. Revision myringoplasty. J Laryngol Otol. 1997;111(6):517-20.

17. Onal K, Uguz MZ, Kazikdas KC, Gursoy ST, Gokce H. A multivariate analysis of otological, surgical and patient-related factors in determining success in myringoplasty. Clin Otolaryngol. 2005;30(2):115-20.

18. Phillips JS, Yung MW, Nunney I. Myringoplasty outcomes in the UK. J Laryngol Otol. 2015;129(9):860-4.

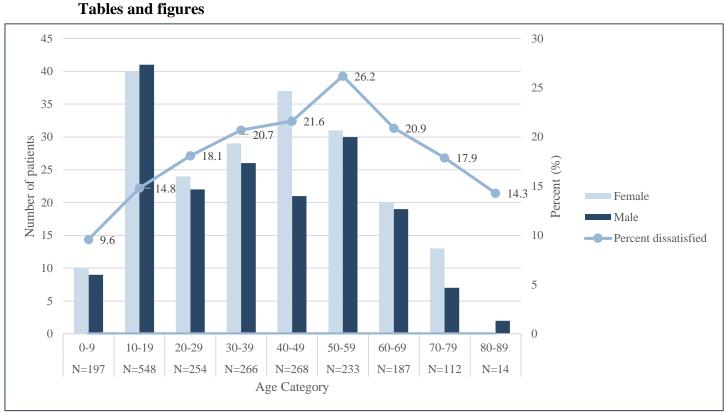


Figure 1. Number of patients dissatisfied with the result of their middle ear surgery according to age categories and gender. The number of dissatisfied patients in regards to the total number of patients in every age category is plotted as percentages on the line graph. The age category, 90-99 years, is not included since it is made up of a single patient.

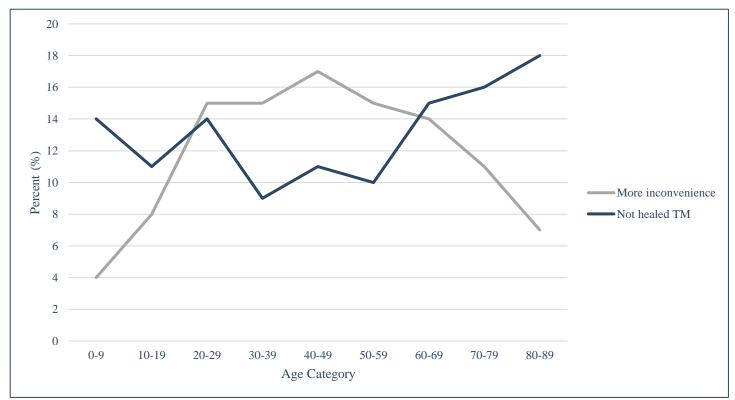


Figure 2. Comparing not healed TM and postoperative inconvenience from the operated ear reported by the patient. The age category, 90-99 years, is not included since it is made up of a single patient.

Medical Programme / T10 Autumn term 2019

		Number (n)	Percent (%)
Gender	Female Male	1087 993	52.3 47.7
Age (mean 34, median 32, range 5-93 years)	< 15 ≥ 15	490 1590	23.6 76.4
Number of surgeries performed according to region	North Middle South	340 808 932	16.3 38.8 44.8
Surgery performed at a University Hospital	Yes 1038 No 1042		49.9 50.1
Indication	Hearing improvement	324 (22 missing)	15.7
	Infection prevention	807	39.2
	Hearing improvement and infection prevention	922	44.8
	Other	5	0.2
Type of surgery	Conventional myringoplasty	1473	70.8
	Plug myringoplasty	175	8.4
	Ossiculoplasty	123	5.9
	Myringo- and ossiculoplasty	309	14.9
Preoperative PTA4 Op-Ear	$\leq 25 \text{ dB} \\ > 25 \text{ dB}$	661 1396 (23 missing)	32.1 67.9
Postoperative PTA4 Op-Ear	$\leq 25 \text{ dB} \\ > 25 \text{ dB}$	996 708 (376 missing)	58.5 41.5
Hearing gain PTA4 (PreOp – PostOp)	Improved, > 5 dB	1101	65.2
	Unchanged, -5 – 5 dB	416	24.6
	Hearing Loss, < - 5 dB	171 (392 missing)	10.1
Healed TM	Conventional Myringoplasty	1076 (239 missing)	87.2
	Plug Myringoplasty	106 (42 missing)	79.7
Table 1. Descriptive data of study population	Total	1524 (349 missing)	88.0

Table 1. Descriptive data of study population.



Patient Survey Questions	Answer Alternatives	Answer alternatives categorized into 2 groups	Total Count N (missing)	0 N (%)	1 N (%)
1. The person filling out the survey is:	0 = Person who was operated 1 = Relative/Other	0 = 0 1 = 1	2064 (16 missing)	1664 (80%)	400 (19.2%)
2. Have you experienced a permanent reduction in taste that is new and had an onset after surgery?	0 = No 1 = Yes	0 = 0 1 = 1	2058 (22 missing)	1796 (87.3%)	262 (12.7%)
3. Do you currently experience pain inside/by the operated ear that is new	0 = Not at all 1 = A little	0 = 0 + 1 1 = 2 + 3	2068 (12 missing)	1944 (93.5%)	124 (6%)
or has increased after surgery?	2 = Somewhat 3 = Very much	0 = 0 1 = 1 + 2 + 3		1377 (66.2%)	691 (33.2%)
4. Do you currently experience a reduced sense of touch or sensation	0 = Not at all 1 = A little	0 = 0 + 1 1 = 2 + 3	2064 (16 missing)	1897 (91.2%)	167 (8%)
on the outer ear that is new and had an onset after surgery?	2 = Somewhat 3 = Very much	0 = 0 1 = 1 + 2 + 3		1351 (65%)	713 (34.3%)
5. Do you currently experience tinnitus (buzzing in the ear) that is	0 = Not at all 1 = A little	0 = 0 + 1 1 = 2 + 3	2062 (18 missing)	1800 (86.5%)	262 (12.6%)
newly developed or has increased after surgery?	2 = Somewhat 3 = Very much	0 = 0 1 = 1 + 2 + 3		1276 (61.3%)	786 (37.8%)
6. Do you experience any inconvenience from the operated ear	$0 = \text{Not at all} \\ 1 = \text{A little}$	0 = 0 + 1 1 = 2 + 3	2033 (47 missing)	1747 (85.9%)	286 (14.1%)
if you don't protect it from water when showering/bathing?	2 = Somewhat 3 = Very much	0 = 0 1 = 1 + 2 + 3		1326 (65.2%)	707 (34.8%)
7. Have you had recurrent infections or ear discharge coming from the operated ear?	0 = Never 1 = 1-2 times since Op 2 = 3-6 times since Op 3 = > 6 times or constantly since Op	$ \begin{array}{l} 0 = 0 \\ 1 = 1 + 2 + 3 \end{array} $	2076 (4 missing)	1388 (66.7%)	688 (33.1%)
8. How do you perceive your hearing today compared to before the surgery?	1 = Much worse 2 = Worse 3 = Unchanged 4 = Better 5 = Much better	0 = 1 + 2 1 = 3 + 4 + 5	2074 (6 missing)	268 (12.9%)	1806 (86.8%)
9. How much inconvenience have you experienced from the operated ear since the surgery?	0 = Not at all 1 = A little 2 = Somewhat	0 = 0 + 1 1 = 2 + 3	2068 (12 missing)	1821 (87.5%)	247 (11.9%)
since the surgery:	3 = Very much	0 = 0 1 = 1 + 2 + 3		1064 (51.2%)	1004 (48.3%)
10. Was the information given before surgery in line with how you experienced the surgery and the time after the surgery?	1 = No, not at all 2 = No, not quite 3 = Yes, almost completely 4 = Yes, completely	$ \begin{array}{l} 0 = 1 + 2 \\ 1 = 3 + 4 \end{array} $	2057 (23 missing)	147 (7.1%)	1910 (91.8%)
11. Are you satisfied with the care given in connection to the surgery?	1 = No, not at all 2 = No, not quite 3 = Yes, almost completely 4 = Yes, completely	0 = 1 + 2 1 = 3 + 4	2070 (10 missing)	77 (3.7%)	1993 (95.8%)
12. Are you satisfied with the follow- up care after the surgery?	1 = No, not at all 2 = No, not quite 3 = Yes, almost completely 4 = Yes, completely	0 = 1 + 2 1 = 3 + 4	2062 (18 missing)	173 (8.3%)	1889 (90.8%)
13. Are you satisfied with the result of the surgery?	1 = Very dissatisfied 2 = Dissatisfied 3 = Satisfied 4 = Very satisfied	0 = 1 + 2 1 = 3 + 4	2080	381 (18.3%)	1699 (81.7%)

Table 2. PROMq in detail. The questionnaire includes 13 questions. Questions 3-13 have multiple choice answers in the form of a Likert scale with four or five alternatives. Questions 1-2 only have two answer alternatives. The answer alternatives were categorized into two groups. For questions 3-6 and 9 the answer alternatives were grouped in two different ways. Frequencies and percentages are presented.

Objective Variables Known at the Time of Surgery	OR (CI 95%)	P-Value	aOR (CI 95%)	P-Value
Age ≥ 15	1.99 (1.47-2.70)	< 0.001	1.81 (1.30-2.52)	< 0.001
Gender	1.07 (0.85-1.33)	0.579	1.00 (0.80-1.27)	N.S
Surgery not performed at university hospital	1.30 (1.04-1.62)	0.023	1.41 (1.10-1.81)	0.006
Hearing impairment preoperatively	1.49 (1.16-1.92)	0.002	1.14 (0.85-1.52)	N.S.
Operated side	1.10 (0.88-1.38)	0.399	1.05 (0.83-1.32)	N.S
Having had prior ear surgery	2.03 (1.60-2.57)	< 0.001	1.84 (1.43-2.37)	< 0.001
Giving perioperative systemic antibiotics	1.13 (0.86-1.48)	0.371	1.17 (0.86-1.59)	N.S
Ear infection free at surgery	1.11 (0.78-1.59)	0.554	1.04 (0.70-1.54)	N.S.
Ossiculoplasty performed	1.42 (1.09-1.83)	0.009	1.05 (0.79-1.41)	N.S.
Region (undergoing surgery in middle/north regions)	0.83 (0.58-1.17)	0.287	0.63 (0.42-0.95)	0.026

Table 3. Objective variables known at the time of surgery. Odds ratios (ORs) with 95% confidence intervals (Cls) for the risk of being dissatisfied with the result of the surgery. Crude and adjusted values are presented. N.S. = not significant.

Objective Variables Registered Postoperatively	OR (CI 95%)	P-Value	aOR (CI 95%)	P-Value
Hearing impairment postoperatively	3.94 (3.00-5.16)	< 0.001	2.99 (2.22-4.03)	< 0.001
Negative gain PTA4 (deteriorated hearing)	5.18 (3.71-7.25)	< 0.001	3.03 (2.07-4.43)	< 0.001
TM not intact at follow-up visit	6.79 (4.97-9.27)	< 0.001	5.16 (3.64-7.33)	< 0.001
Not infection free at follow-up visit	2.41 (1.23-4.73)	0.010	1.17 (0.50-2.75)	N.S.
Postoperative infection within 6 weeks	2.53 (1.73-3.69)	< 0.001	2.06 (1.31-3.25)	0.002
Time to follow-up visit (≤ 12 months)	1.12 (0.88-1.44)	0.362	1.01 (0.76-1.35)	N.S.

Table 4. Objective variables registered postoperatively. Odds ratios (ORs) with 95% confidence intervals (Cls) for the risk of being dissatisfied with the result of the surgery. Crude and adjusted values are presented. N.S. = not significant.

Subjective variables from the PROMq	OR (CI 95%)	P-Value	aOR (Cl 95%)	P-Value
Taste disturbance	2.13 (1.59-2.86)	< 0.001	1.10 (0.72-1.69)	N.S.
Permanent pain	4.44 (3.06-6.45)	< 0.001	0.40 (0.21-0.77)	0.006
Permanent sensation reduction	4.09 (2.94-5.68)	< 0.001	1.08 (0.64-1.82)	N.S.
Tinnitus (new or enhanced)	4.18 (3.17-5.52)	< 0.001	1.14 (0-75-1.76)	N.S.
Reoccurring infections	2.26 (1.80-2.84)	< 0.001	1.21 (0.89-1.64)	N.S.
Postoperative hearing experience (worse hearing)	9.21 (6.97-12.17)	< 0.001	5.10 (3.57-7.28)	< 0.001
Postoperative ear inconvenience	17.45 (12.84-23.70)	< 0.001	11.48 (7.48-17.62)	< 0.001
Information	6.83 (4.82-9.67)	< 0.001	1.58 (0.93-2.68)	N.S.
Satisfied with care during surgery	32.45 (16.94-62.14)	< 0.001	8.22 (3.71-18.19)	< 0.001
Satisfied with follow-up care	10.09 (7.23-14.09)	< 0.001	3.00 (1.90-4.72)	< 0.001

Table 5. Subjective variables from the PROMq. Odds ratios (ORs) with 95% confidence intervals (Cls) for the risk of being dissatisfied with the result of the surgery. Crude and adjusted values are presented. N.S. = not significant.