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Audiological Outcome in Myringoplasties with an Intact Ossicular Chain: Is there a Difference between Chronic Otitis with or without Cholesteatoma?

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Abstract **Introduction** Chronic otitis media (COM) with a central perforation or a concomitant cholesteatoma are both inflammatory lesions, however, with different etiologies. Both entities may present with an intact chain, and the final reconstruction is quite similar. Does it also apply for the hearing outcome? **Objectives** In a retrospective analysis, we investigated the preoperative hearing and the final hearing outcome of two groups of patients: those with COM and those with cholesteatoma, and compared various factors. Methods Patients operated between 2010 and 2019 were entered prospectively into a research database, and the integrity of the ossicular chain, the extent of the cholesteatoma, and the findings on computed tomography (CT) scans were retrospectively analyzed and correlated to the final hearing outcome. **Results** Out of 210 tympanoplasties for COM, 162 (80%) presented with an intact chain, and 85 (40%) ears could be analyzed. Out of 283 cholesteatoma surgeries, 53 (19%) ears presented with an intact chain. The preoperative air-bone gap (ABG) was worse in the COM group, but the postoperative ABG over the frequencies of 0.5 kHz and 4 kHz was the same (10 dB to 12 dB) in both groups, and remained within 20 dB in 90% (40 and 78 patients, respectively). The extension of the disease was rather limited in the cholesteatoma group (stages Ch1a and 1b), and better pneumatization and ventilation were beneficial for a good **Keywords** ► chronic otitis media result. Postoperatively, the frequency of 4 kHz had the largest ABG (14 dB and 18 dB). ► cholesteatoma **Conclusion** Overall, 80% of the patients with COM and less than 20% of those with hearing outcome cholesteatoma had an intact and mobile chain at surgery. Using equivalent surgical techniques for the tympanoplasty, the final outcome was almost the same for both air-bone gap tympanoplasty groups, with a mean ABG of 10 dB to 12 dB.

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Introduction

Chronic otitis media (COM) is defined as an inflammation of the middle ear and mastoid mucosa with more than 3 months of duration. In case of an intact eardrum, the most frequent entity is otitis media with effusion (OME), whereas a chronic inflammation with a central perforation is termed as chronic suppurative otitis media (CSOM) or otitis media chronica simplex (OMCS). Intermittent or persistent otorrhea may be a leading symptom besides a moderate hearing loss. The prevalence of an intact ossicular chain in cases of COM has been reported in the literature to range from 72% to 90%.^{1,2} Size matters regarding the perforation and its impact on the preoperative air-bone gap (ABG). An almost linear correlation between the size of the perforation and the ABG in cases of an intact and mobile chain was documented in a recent publication.³ Chronic otitis media with cholesteatoma (Chole) is defined as skin and retention of keratin in the middle ear and/or temporal bone with surrounding inflammatory reaction and progressive bone resorption. Intermittent or persistent foul smelling otorrhea combined with progressive hearing impairment are the leading symptoms. Due to the aggressiveness of the disease, the prevalence of an intact ossicular chain is markedly reduced, and it has been reported to range between 5.5% and 30%.^{4–9} Most often, the preoperative ABG is quite variable and cannot be predicted, since the Chole mass itself may transmit sound to the stapes footplate even in severely impaired ossicles. We have recently presented our Chole staging system, coding the extent of the disease, the integrity of the ossicular chain, the type of complications (by the Chole) and a rating of mastoid pneumatization and ventilation.¹⁰

In both disease entities (COM and Chole) with an intact ossicular chain, the final steps of surgery are equal and consist in the preservation of the ossicles and reconstruction of the tympanic membrane. Our study addressed three research questions: 1) Is the final outcome "normal" hearing with closure of the ABG? 2) Do patients with Chole present a worse result than patients with "simple" perforations? 3) What is the impact of the mastoid pneumatization/ventilation on the hearing outcome in cholesteatomatous patients?

Materials and Methods

All patients operated at our tertiary referral center are entered prospectively into an otology database (InnoForce, Ruggell, Liechtenstein). We retrospectively analyzed the data of patients operated by two senior surgeons using the same surgical technique in the period from 2010 to 2019. We only selected patients with the diagnosis of COM or Chole and an intraoperatively intact and mobile ossicular chain. Patients with insufficient follow-up (shorter than 3 months) or residual/recurrent disease were excluded. The pre- and latest postoperative pure tone audiograms were analyzed for the individual frequencies as well as the average between 0.5 kHz and 4 kHz. The degree of pneumatization and ventilation and the location of the disease in Chole patients was coded by the surgeon by applying the criteria of the ChOLE classification (https://chole.surgery) and evaluating the preoperative computed tomography (CT) scans. Most patients with COM did not have a preoperative CT scan or tympanometric volume measurement, and therefore could not be analyzed regarding their "Eustachian tube" function. The ENT Statistics software Innoforce-cerative solutions (Industriestrasse 56, 9491 Ruggeli, Liechtenstein) was used for the statistical analysis. The Mann-Whitney U test was used to compare the preoperative, postoperative and the improvement of the mean ABG and isolated frequencies among the different groups. The ranges of the mean ABGs and frequencies between 0.5 kHz and 4 kHz (0.5 kHz, 1 kHz, 2 kHz, 3 kHz, and 4 kHz) were all considered for comparison.

The present study was approved by the local Ethics Committee under protocol number 2019–00914.

Results

The initial COM group consisted of 210 surgeries in 182 patients who underwent primary tympanoplasty with temporalis fascia or tragal cartilage. Out of this group, 162 ears had an intact ossicular chain (80%) and 77 were excluded because they did not meet the inclusion criteria or due to insufficient follow-up. Finally, the group with COM with intact ossicular chain involved 85 ears (43 left and 42 right ears, 50% each). Overall, 38 (45%) patients were male, and 47 (55%) were female. The average age was 34.3 years at the time of the surgery (range 6.4 to 84.3 years).

In the second group with Chole, 279 patients (283 operated ears) with primary closed cavity tympanomastoid surgery and tympanoplasty using temporalis fascia or cartilage were initially enrolled. All of them had been classified using the ChOLE staging system. A subgroup analysis (**-Table 1**) of these patients examined the impact of the location (Ch1a to Ch4b), the status of the ossicular chain (O0 to O4b) and the impairment of pneumatization and ventilation (E0 to Ex).

Only 53 operated ears presented with an intact ossicular chain, classified as O0, and 9 patients were excluded due to insufficient follow-up. The final Chole group consisted of 44 ears (21 left and 23 right ears) of 22 male (50%) and 22 (50%) female patients. The average age at the time of surgery was 38.3 years (range 4.1 to 81.7 years) **►Tables 1 & 2.** For consistency a minor change could be made: The extension of

Table 1 Overall classification of all cholesteatomas

Ch stage	N	%	E stage	n	%
Ch1a	112	39%	EO	75	26%
Ch1b	48	17%	E1	72	26%
Ch2a	28	10%	E2	126	44%
Ch2b	17	6%	Ex	10	4%
Ch3	34	12%			
Ch4a	42	15%			
Ch4b	2	1%			
Total	283	100%	Total	283	100%

 Table 2 Classification of operated ears with cholesteatoma and an intact ossicular chain

Ch stage	Ν	%	E stage	n	%
Ch1a	30	68%	EO	24	55%
Ch1b	10	23%	E1	7	16%
Ch2a	1	2%	E2	9	20%
Ch2b	2	5%	Ex	4	9%
Ch3	1	2%			
Total	44	100%	Total	44	100%

Table 3 Mean pre- and postoperative hearing outcome

	Chole group (n = 44)	COM group (n = 85)	p Value
Preoperative ABG (dB)	11.8	20	p = 0.0000
Postoperative ABG (dB)	11.2	10.8	p = 0.8935
Improvement of ABG (dB)	0.7	9.2	<i>p</i> = 0.0001
Preoperative AC (dB)	24.8	33.1	p = 0,0007
Postoperative AC (dB)	25.4	25.7	p = 0.8597
Improvement of AC (dB)	-0.5	7.4	<i>p</i> = 0.0004

Abbreviations: ABG, air-bone gap; AC, air conduction; dB, decibels.

the disease among the cholesteatomatous patients in this group was limited (Ch1 in 90%, versus 57% out of the overall group), and they had better pneumatization and ventilation (E0 in 55% versus 26%) than the patients with ossicular destruction (**-Tables 1** and **2**).

- Table 3 summarizes the differences between the two groups for the pre- and postoperative audiograms. The mean preoperative ABG of 12 dB in the Chole group was significantly better than the almost 20 dB of the COM group. The final ABG of the two groups was 11.2 dB and 10.8 dB respectively, and did not differ significantly anymore. The final air

Table 5 Postoperative air-bone gap for both groups

Postoperative ABG (dB)	Chole group (n = 44)	COM group (n = 85)
0–10 dB	19 (43%; < 20dB)	45 (53%; < 20dB)
< 20 dB	40 (93%)	78 (92%)
20-30 dB	2 (5%)	7 (8%)
>30 dB	1 (2%)	0 (0%)

Abbreviations: ABG, air-bone gap; Chole, cholesteatoma; COM, chronic otitis media; dB, decibel.

Table 6 Degree of	pneumatization	and	hearing	outcome	in
cholesteatoma pati	ents				

	E0 (n = 24)	E1 (n = 7)	E2 (n = 9)	Ex (n = 4)
Preoperative ABG (dB)	10.7	12.5	11.1	15.4
Postoperative ABG (dB)	9.4	14.7	9.4	16.9
Improvement (dB)	1.3	-2.2	1.7	-1.5

Abbreviations: ABG, air-bone gap; dB, decibel.

conduction for the mean frequencies between 0.5 kHz and 4kHz was 25 dB for both entities. Therefore, the overall hearing improvement was higher in COM patients. Analyzing individual frequencies (>Table 4), the Chole group had a better preoperative ABG in each one in comparison with the COM group (p < 0.05). Postoperatively, they no longer differed from each other. The lowest ABG was consistently found at 2 kHz, whereas the predominant ABG was at 0.5 kHz and 4 kHz. A postoperative ABG < 20 dB is considered a successful outcome in most studies. In the Chole group, 40 ears (93%) reached this goal, and 19 (43%) of those had an $ABG < 10 \, dB$. In total, 2 (5%) patients remained with a postoperative ABG between 20 dB and 30 dB, and 1 patient presented with a poor result (ABG > 30 dB). In the COM group 78 ears (92%) remained within < 20 dB, and 45 (53%) had results < 10 dB. A total of 7 (8%) patients had ABGs between 20 dB and 30 dB, and none of the patients in this group had an $ABG > 30 \, dB$. The results are presented in the ► Table 5.

As part of the study, we evaluated the hearing outcome in the Chole group considering the ChOLE classification. The

 Table 4
 Pre- and postoperative air-bone gap single frequencies for both groups

Frequencies (kHz)	Chole group (dB)	COM group (dB)	p Value	Chole group (dB)	COM group (dB)	p Value
0.5	13.1	21.1	<i>p</i> = 0.0015	12.6	10.6	NS
1	13.5	20.4	<i>p</i> = 0.0016	11.9	10.3	NS
2	7.1	16.6	<i>p</i> = 0.0000	4.4	5.0	NS
3	9.6	19.7	<i>p</i> = 0.0000	9.8	9.4	NS
4	13.9	22.3	<i>p</i> = 0.0021	13.9	17.6	NS
	Preoperative air-bo	ne gap		Postoperative air-bone gap		

Abbreviations: Chole, cholesteatoma; COM, chronic otitis media; dB, decibel; kHz, kilohertz; NS, not significant.

individual stages are presented in **-Table 2**. The size and location of the Chole had no impact on the final hearing outcome (p> 0.05), and there was no patient with a large extension of Ch4a or Ch4b. On the other hand, the group with moderate to good pneumatization and ventilation (E0) achieved a significantly better (p = 0.0413) postoperative ABG of 9.4 dB (**-Table 6**) compared with the patients with reduced ventilation (E1) and a mean ABG of 14.7 dB. The hearing outcome of the patients with sclerotic mastoids (E2) was almost to the same as that of the E0 subgroup and did not show a significant difference to the E1 subgroup, due to the limited number of patients in both groups.

Discussion

There are various forms of COM, and all of them - to a different degree - impair sound conduction and, therefore, lead to a conductive hearing loss. Patients with COM with and without suppurative episodes (CSOM) contact their physician to get a dry and stable ear with an intact eardrum, and ask for improvement of their hearing hoping for "normal hearing." In our series, 80% of all COM patients present at surgery with an intact and mobile ossicular chain. In a previous publication,³ we confirmed that the size (and not the location) of the tympanic-membrane perforation had a direct and almost linear impact on the preoperative hearing impairment in these patients. The least severe effect was found at the middle-ear resonance frequency of 2 kHz, and the most pronounced impact, at the low (0.5 kHz) and high (4 kHz) frequencies. Even in cases of subtotal perforations, the preoperative ABG did not exceed 35 dB. On the other hand, patients with middle-ear Choles contact their physician to completely remove the disease, get rid of the foul smelling otorrhea, and hope for some hearing improvement. Choles are much more aggressive. Considering the ChOLE classification,¹⁰ the size and extension of the disease is generally correlated with a higher surrounding bone reabsorption and ossicular erosion. Indeed, in our series, only 20% of all patients presented with an intact ossicular chain. In comparison to the other cholesteatoma patients, their extent of the disease was rather limited (stage-1 Chole in 80% or 35 out of 44 cases), and they had better pneumatization and

ventilation on the preoperative CT scans. Contrary to the COM patients, the extent of the Chole did not have a direct impact on the preoperative ABG. The mean preoperative ABG of 12 dB in the Chole group was significantly better than the almost 20 dB of the COM group, and this was also true for the individual frequencies. In summary, the chance to encounter an intact and mobile chain in cases of COM is of 80%, and it drops to less than 20% in patients with limited cholestea-tomatous ear disease, whereas the preoperative hearing may be better in the Chole patients and is unpredictable.

At the end of the surgery, once the eardrum has been reconstructed, surgeons and patients hope for optimal hearing improvement, and may even expect "normal" hearing in cases of an intact and mobile ossicular chain and closed cavity setting. One might expect that patients with Chole present with a worse outcome due to the severity of the inflammatory disease. However, our results reveal some interesting findings. First, there was no difference between the groups regarding the final postoperative ABG. More than 90% had an ABG (0.5-4 kHz) lower than 20 dB (and 19 (43%) in the Chole and 45 (53%) in the COM group within 10 dB) and only 3 patients in the Chole group had an ABG higher than 20 dB. Reviewing the charts of these 3 patients, they had minor erosion of the incus (but still with an intact incudostapedial joint at the first surgery) and 1 patient underwent an ossiculoplasty 2 years later, with hearing improvement. In the COM group, 7 patients (8%) ended with an ABG >20 dB. Specifically analyzing these cases, we did not find a consistent factor, but the presence of glue, a more severely inflamed middle-ear mucosa or a postoperative eardrum retraction and atelectasis as reasonable explanations. Secondly, the relative hearing improvement was better among the COM patients, but this is due to the fact that the preoperative hearing was worse and the final outcome, the same. Thirdly, we looked at the impact of pneumatization and ventilation, which could be encoded for the Chole group using the ChOLE classification. Unfortunately, we did not perform routine CT scans in the COM patients, and did not record routinely the preoperative volume on tympanometry. Patients with reasonably good ventilation (E0 on the ChOLE score) had a higher chance of having an intact chain and a better hearing outcome, suggesting a positive effect of the function of the Eustachian tube. However, a final statement cannot be made yet.

Thresholds (kHz)	Author	Year	Disease	n	Preop ABG	Postop ABG	Preop AC	Postop AC	Remarks
0.5-4	Our study	2020	COM	85	20	10.8	33.1	25.7	
0.5-4	Our study	2020	Chole	44	11.8	11.2	24.8	25.4	
0.5–3	Horvath et al ¹	2019	COM	147	22.1	17.2			
0.5–3	Ohki et al ¹¹	2019	СОМ	122	19.7 20.3	10.1 13.1	43.4 42.3	32.7 33.9	Endoscopic Microscopic
0.5-4	Pontillo et al ⁴	2018	Chole	65	11,7 17,4	7.7 12.9	27.7 41.2	23.1 35.1	Canal wall up Canal wall down
0.5-3	Hamilton ¹²	2010	Chole	80		11.4			Use of KTP laser

Abbreviations: ABG, air-bone gap; AC, air conduction; Chole, cholesteatoma; COM, chronic otitis media; dB, decibel; kHz, kilohertz; KTP, potassium titanyl phosphate; Postop, postoperative; Preop, preoperative.

Interestingly, not many previous publications have addressed this research question. A comparison is also limited, since some journals require the presentation of the hearing data for the frequencies between 0.5 kHz and 3 kHz, and do not ask for data regarding 4 kHz. It is known that the high frequencies (including 4 kHz) are more important for speech understanding and the overall benefit to the patients. Our data reveal that the closure of the ABG was rather limited at 4 kHz. Therefore, excluding this important frequency would improve the surgeon's success rates, but does not honestly summarize the benefit for the patient. So far we do not routinely ask for postoperative speech audiograms, and, therefore, did not have enough data for comparison. - Table 7 summarizes the results of previous studies in the literature. They are quite similar to our findings, with reported postoperative ABGs of 10 dB to 17 dB for COM and 10 dB to 13 dB in Chole patients. As more and more surgeons switch to an endoscopic approach, it will be very interesting to see the results, since during the endoscopy, most ear surgeons completely detach the remaining eardrum from the malleus handle to access the anterior extensions of the middle-ear disease. The impact of lifting and reinstating the drum from the umbo and malleus handle has not yet been properly addressed. One study by Ohki et al¹¹ ended with a favorable postoperative ABG for the endoscopic as well as microscopic groups (Tabel 7), with comparable hearing outcomes and no inner ear damage. The use of lasers to detach choles from an intact chain has been advocated to preserve the integrity of the chain, and it revealed better and more reliable hearing outcomes in comparison to the more conventional approach of dismantling the chain and reconstructing the gap.¹²

Conclusion

Statistically, 80% of the patients with COM will have an intact and mobile chain at surgery, whereas less than 20% retain their intact chain in cases of Chole. Preoperatively, patients with eardrum perforations (COM) present with worse hearing thresholds than patients with Chole and an intact ossicular chain. Postoperatively, their performance is almost the same, with a mean ABG of 10 dB to 12 dB, which enables a higher hearing gain for COM patients. Roughly, 50% will end up with an ABG lower than 10 dB, and 90%, within 20 dB. In chole patients, the extent of the disease is small, and it seems that better pneumatization and ventilation leads to improved outcomes. It remains difficult to close the ABG at 4 kHz, a frequency that should not be neglected when presenting outcome data.

Conflict of Interests

The authors have no conflict of interests to declare.

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