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Correlation of intraoperative middle ear status and hearing results in single-stage canal wall down tympanomastoidectomy with PORP—a prospective study

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Abstract

Background: Mastoidectomy is one of the common surgical procedures performed by the otologist. It is commonly done for cholesteatomatous chronic otitis media (CCOM) and can be performed as either canal wall up or down techniques. Most of the CCOM is associated with ossicular erosions which require ossicular chain reconstruction (OCR) which can be done either in one stage or multiple stages.

A multitude of factors affects postoperative OCR results with tympanomastoidectomy. Among various factors, the status of the tympanic membrane and middle ear mucosa is quite essential. To date, there are no randomized or prospective studies assessing the integrity of pars tensa and status of the middle ear mucosa in hearing outcomes in single-stage tympanomastoidectomy using partial ossicular replacement prosthesis (PORP) in the literature. Therefore, this study is performed to correlate the integrity of pars tensa and middle ear mucosa condition with postoperative hearing results of single-stage canal wall down (CWD) tympanomastoidectomy with PORP.

Results: Forty-two patients with cholesteatomatous chronic otitis media underwent single-stage canal wall down mastoidectomy (CWD) and partial ossicular replacement prosthesis (PORP) placement. The statistical analysis was done to compare the results of postoperative hearing with the intraoperative integrity of pars tensa and middle ear mucosa status. The mean pre- and postoperative air-bone gaps (ABGs) of all cases were 23.9 dB and 21 dB, respectively, with no statistically significant difference. In the pars tensa intact group, the mean pre- and postoperative ABGs were 21.5 dB and 18.5 dB, respectively, and in the pars tensa not intact group, the mean pre- and postoperative ABGs were 25.7 dB and 22.8 dB, respectively, and both groups had statistically insignificant difference. The pre- and postoperative ABGs in the healthy middle ear mucosa group were 20.7 dB and 19 dB, respectively. Similarly, the pre- and postoperative ABGs in non-healthy middle ear mucosa were 24.4 dB and 21.2 dB, respectively. The differences were not statistically significant in both groups.

Conclusion: There was a statistically significant improvement in postoperative air conduction threshold (ACT) in all cases. The integrity of pars tensa and middle ear mucosa status did not affect the postoperative hearing outcome in single-stage CWD tympanomastoidectomy using PORP.

Keywords: Chronic otitis media, Cholesteatoma, Canal wall down mastoidectomy, Partial ossicular replacement prosthesis, Tympanoplasty

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Background

Chronic otitis media (COM) is one of the most common ear diseases encountered by an otologist [1]. It can be divided as cholesteatomatous or non-cholesteatomatous [2]. Cholesteatomatous COM is often associated with erosion of the adjacent bone and ossicles, mainly long and lenticular process of the incus [3]. The management of the cholesteatoma is still surgery to date [4]. The primary aim of the surgery is to eradicate infection and disease. The secondary aim is to restore or preserve hearing [5].

Mastoidectomy can be performed as either canal wall up (CWU) or down (CWD) techniques, distinguished by preserving the external canal wall [6]. Both techniques have their merits and demerits, and the choice depends on different factors such as the surgeon's experience, belief, and confidence. However, CWD has been considered a gold standard technique in terms of disease eradication [7, 8]. Similarly, there exists a difference in opinion regarding the staging of the surgical procedure for COM. Some studies support single-stage surgery for both elimination of disease and tympanoplasty [9]. In low- and middle-income countries, the major restraints for two-stage surgery include the cost and absence from the work [10]. The prediction of the surgical outcome depending on the middle ear pathological condition could be cost-effective and improve the patient's compliance.

Ossicular chain reconstruction (OCR) can be done either in one stage or multiple stages. The purpose of OCR is to improve the postoperative hearing level [11]. Numerous materials have been used for OCR, ranging from autologous tissue, such as the cartilage, cortical bone, or incus interposition grafts, to synthetic prostheses, such as hydroxyapatite and plastipore [12]. An ideal prosthesis should be biocompatible, suitably rigid, be of long-term durability, and should have ease of workability [13].

There are two main categories of OCR implants. Partial ossicular replacement prosthesis (PORP) is used when a mobile stape suprastructure is present, and the incus, malleus, or both are absent. Total ossicular replacement prosthesis is used when stape suprastructure is either absent or damaged [11, 14]. Hearing improvement after surgery depends upon several factors such as the disease extent, middle ear biological environment, structure, design, and material of prosthesis used, Eustachian tube function, degree of preoperative hearing loss, expertise, and experience of the surgeon with techniques used, and the presence or absence of infection and inflammation of the middle ear [15].

Many factors affect tympanoplasty outcomes; therefore, different authors developed various indices to predict the results. However, none of these indices could achieve universal acceptance [16]. A multitude of factors affects postoperative OCR results with tympanomastoidectomy. Among various factors, the status of the tympanic

membrane and middle ear mucosa is quite essential. To date, there are no randomized or prospective studies assessing the integrity of pars tensa and status of the middle ear mucosa in hearing outcomes in single-stage tympanomastoidectomy using PORP in the literature. Therefore, this study is performed to correlate the integrity of the pars tensa and middle ear mucosa condition with postoperative hearing results of single-stage CWD tympanomastoidectomy with PORP.

Methods

We conducted a descriptive study of 42 cases that were followed prospectively and that underwent surgery from June 2015 to August 2016 in our hospital. Patients with a cholesteatomatous COM who underwent single-stage CWD mastoidectomy with PORP placement were included in the study. Patients who developed postoperative sensorineural hearing loss, postoperative extrusion of PORP within 3 months, and postoperative pars tensa perforation were excluded from the study.

A nonprobability convenient sampling method was applied. Epi info 2000 software for population survey was used to calculate the sample size. The study population was taken as the number of operations of tympanomastoidectomy with PORP that were performed during the period of the past 18 months. The study population was 47, confidence level 95%, and confidence interval (CI) 5%. The data were entered in the above software calculator, and the sample size was calculated as 42.

Before the procedure, the patient underwent detailed history taking, physical examination, and ear examination with an otoscope. A temporal bone CT scan was acquired before the surgery. Intraoperative observation of the middle ear was done and divided into different groups: Pars-tensa intact group and not intact TM group, mucosa healthy group, and mucosa non-healthy group. The study underwent ethical clearance by the institutional review board. The informed written consent to participate in the study was provided by all the participants and their parent or legal guardian in the case of children under 16.

The audiological evaluation was performed 7 days before the procedure and at 3 months post-surgery, with a second postoperative test yearly or as needed. Follow-up was done on the 10th postoperative day, 6 weeks, 3 months, and yearly/or as required. At the end of 3 months, otological examination and hearing evaluation were done. The graft status was evaluated. The postoperative bone conduction and air conduction threshold were noted. Air conduction threshold and air-bone gaps were calculated by using an average of four frequencies of 500, 1000, 2000, and 3000 Hz.

Patients underwent examination under the microscope before the operation, and the findings were noted. All surgeries were performed under hypotensive general

anesthesia via a postauricular approach. Temporalis fascia graft was harvested. Tympanomastoidectomy was done by either out-to-in or in-to-out technique. Complete removal of disease from the mastoid air cell system was ensured. The total clearance of disease from the anterior epitympanum and middle ear was done. The ossicular chain was evaluated, and the head of the malleus and incus, if diseased, were removed. Temporalis fascia was placed by the underlay technique. PORP was cut to the desired length. PORP was fitted after raising and reflecting the graft and flap complex anteriorly. A cartilage disc graft was then interposed between the head-plate of the prosthesis and the tympanic membrane. Antibiotic ciprofloxacin-soaked gel-foam pieces were placed in the middle ear to help stabilize the prosthesis and to avoid contact of the prosthesis with the fallopian canal posterosuperiorly. The flap was repositioned, and the ear pack was kept.

After surgery, an antibiotic (Amoxicillin) was given for 7 days. Suture removal was done on the 6th postoperative day and pack removal on the 10th postoperative day. Follow-up was scheduled as on the 10th postoperative day, 6 weeks, 3 months, 6 months, and yearly. At the latest follow-up, ear examination and hearing evaluation were done. The graft status was evaluated. The postoperative bone conduction and air conduction threshold were noted. Air conduction threshold and air-bone gaps were calculated using an average of 4 frequencies of 500, 1000, 2000, and 3000 Hz. Chi-square test and Pearsons' correlation test were applied for categorical variables, and paired *t* test was used for the analysis of hearing results on SPSS statistical package version 20. The level of statistical significance was set at *p* < 0.05.

Results

There were 42 patients enrolled for the study, and all of them completed the follow-up. Demographic profiles of the patients are shown in Table 1. The patients' mean age was 21.9 ± 5.06, which ranged from 7 to 49 years old. There was 26 (62%) male, and 16 (38%) were female. Regarding the laterality of the disease, 19 (45.2%) of the patients had disease on the left side, and 23 (54.8%) had on the right side. The most common disease distribution was the only cholesteatoma in 30 (71.4%) patients, followed by cholesteatoma with granulations in 12 (28.6%).

Hearing results are shown in Table 2. All patients had four frequency average pre- and postoperative air conduction threshold (ACT) of 40.05±14.2 dB and 36.3±13.6 dB, respectively, with a net gain of 3.75dB. The difference was statistically significant with a *p* value of 0.049. Regarding the air-bone gap (ABG), the average pre- and postoperative ABG was 23.9±11.6dB and 21±11.6dB, respectively, with the air-bone gap closure of 2.9dB statistically non-significant (*p*=0.08). Two groups were created depending on the status of the tympanic membrane as intact and non-intact. Similarly, another group was created depending on healthy or non-healthy mucosa, as shown in Table 1. In the intact pars tensa group, 14 (77.7%) patients had improvement in postoperative ABG, whereas 3 (16.6%) patients had no improvement and 1 (5.5%) had no change in postoperative ABG. The maximum air-bone gain was 21.25 dB, and the worst was -26.25 dB. The average preoperative and postoperative ABG was 21.5±10.3 dB and 18.5±9 dB, respectively, with a net gain of 2.91dB. However, this gain was not statistically significant (*p*=0.221). In pars tensa

Table 1 Distribution of enrolled patients

	Enrolled	Lost to follow-up	Included
	42	0	42
Age (years)	Range	Mean	
	7–49	21.9 ± 5.06	
Age group (years)	<15	15–29	30–49
	12 (28.6%)	19 (45.2%)	11 (26.2%)
Sex	Male	Female	
	26 (62%)	16 (38%)	
Site	Left	Right	
	19 (45.2%)	23 (54.8%)	
Disease distribution	Cholesteatoma only	Cholesteatoma and granulation	
	30 (71.4%)	12 (28.6 %)	
Tympanic membrane (Pars tensa)	Intact	Not intact	
	18 (42.9%)	24 (57.1%)	
Middle ear mucosa	Normal	Abnormal	
	18 (75%)	6 (25%)	

Table 2 Hearing results

Total patients (n=42)	Preoperative ABG (dB)	Postoperative ABG (dB)	P value
Air conduction threshold (ACT)	40.05±14.2	36.3±13.6	0.049
Air bone gap (ABG)	23.9±11.6	21±11.6	0.08
Tympanic membrane (Pars tensa)	Intact	Not Intact	
Included	18	24	
Preoperative ABG (dB)	21.5±10.3	25.7±12.3	
Postoperative ABG (dB)	18.5±9 dB	22.8±13.2	
P value within the group	0.221	0.239	
Middle ear mucosa	Non-healthy	Healthy	
Included	37	5	
Preoperative ABG (dB)	24.4±11.5	20.7±12.3	
Postoperative ABG (dB)	21.2±12.2	19±7	
P value within the group	0.105	0.633	

not intact group, 14 (58.3%) patients had improvement in postoperative ABG, whereas 9 (37.5%) patients had no improvement, and 1 (4.1%) patient had no change in postoperative ABG. The maximum air-bone gain was 18.75 dB, and the worst was -27.5 dB. The average pre-operative and postoperative ABG was 25.7±12.3 dB and 22.8±13.2 dB, respectively, with a net gain of 2.9 dB but statistically insignificant (*p*-0.239).

In the healthy middle ear mucosa group, two patients had improved postoperative ABG, two patients had deterioration, and one had no change. The maximum air-bone gain was 11.25 dB, and the worst was -7.5 dB. The average preoperative ABG was 20.7±12.3 dB, reduced to 19±7 dB postoperatively, with a net gain of 1.7dB. But the difference was not statistically significant (*p*-0.633). In the non-healthy middle ear mucosa group, 27 (72.97%) patients had improved postoperative ABG, whereas 10 (27.02%) patients had no improvement. The maximum air-bone gain was 21.25 dB, and the worst was -26.25 dB. The average ABG preoperatively was 24.4±11.5 dB and postoperatively was reduced to 21.2±12.2 dB, a net gain of 3.2dB. The observed difference, however, was not statistically significant (*p*-0.105).

We also compared pre- and postoperative hearing results in terms of the percentage of the patient with ABG in strata of 10dB, as shown in Table 3. The ABG was divided into different bins of ≤10dB, 11–20dB, 21–30dB, and >30dB. Preoperatively, 35.7% of the patients fell

Table 3 ABG range in strata of 10dB (n=42)

ABG range	Pre-operative (%)	Post-operative (%)	P value
≤10dB	5 (11.9)	9 (21.4)	0.569
11–20 dB	10 (23.8)	13 (30.95)	0.575
21–30 dB	15 (35.7)	11 (26.19)	0.99
>30 dB	12 (28.57)	9 (21.42)	0.56

within the 21–30dB ABG, and postoperatively 30.95% were within the 11–20dB ABG. The percentage change in ABG was not found to be statistically significant in any strata. Postoperatively, 52.35% of patients were within ≤ 20 dB ABG.

Frequency-wise comparison of pre and postoperative ACT was also done, as shown in Table 4 and Fig. 1. Postoperatively average ACT improvement was seen in 500 Hz, 1000 Hz, and 3000 Hz, but in 2000 Hz, there was no improvement.

Discussion

In this study, we correlated the intra-operative integrity of pars tensa and middle ear mucosa status with postoperative hearing results of single-stage CWD tympanomastoidectomy with PORP. All the patients with completed follow-up had graft uptake. There were no extrusions of the prosthesis or postoperative sensorineural hearing loss.

In this study, 18 (42.85%) patients had intact pars tensa, and 24 (57.14) patients had no intact pars tensa intraoperatively. When correlating pars tensa integrity with the postoperative hearing result, 14/18 (77.77%) of the pars tensa intact group and 14/24 (58.33%) of pars tensa not intact group had improved hearing, with both groups having ABG gain of 2.91 dB. However, these observed differences were not statistically significant.

No literature studied the status of preoperative pars tensa and compared pre- and postoperative hearing using PORP in a single-stage CWD tympanomastoidectomy. Though there is abundant literature about the techniques of tympanomastoidectomy, the data about factors affecting the outcome is lacking. The middle ear's abnormal status as a predictor of outcome has still been a confusing issue in the literature [10]. For this purpose, a grading system has been devised, known as the middle

Table 4 Frequency wise average pre-op and post-operative ACT in dB (n=42)

Frequency (Hz)	Pre-operative (dB)	Post-operative (dB)
500	45	39.2
1000	41.5	36.30
2000	33.1	35.35
3000	37.7	36.54

ear risk index (MERI) [17]. However, in MERI, an ossiculoplasty outcome measurement system, high importance is given to a tympanic membrane’s status that can affect postoperative hearing after OCR [18]. In MERI, intact tympanic membrane scores zero while perforated TM scores one point where the higher the score, the worse is the possible prognosis. However, predicting the prognosis of postoperative hearing based on MERI is not free from controversies. Lailach et al. [19] divided patients into three groups based on MERI scores to compare the risk categories with the hearing results in cholesteatoma surgery. The patients with MERIs 1 to 3 were included in the mild group, 4 to 6 as moderate, and 7 to 12 as severe groups. When the MERI groups were compared to their postoperative PTA-ABGs, the differences between the three groups were statistically significant. But Emir et al. [20] while evaluating postoperative hearing according to MERI grades did not find a statistically significant correlation between hearing results for the prostheses and preoperative MERI grades.

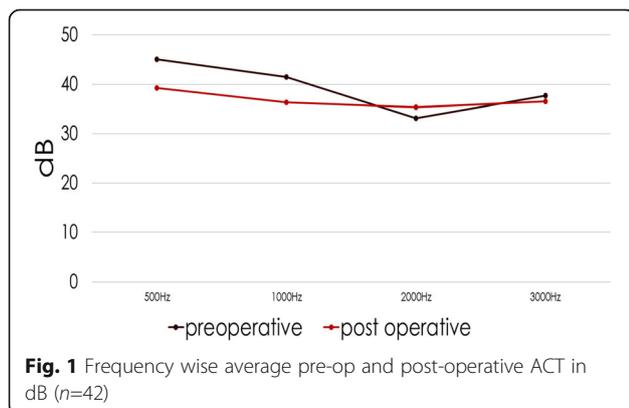
In our study, five (11.9%) patients had intraoperative healthy middle ear mucosa, whereas 37 (88.1%) patients had non-healthy mucosa. While correlating middle ear mucosa status postoperative hearing, in the healthy mucosa group, two patients (40 %) had improved hearing with an average ABG gain of 1.7 dB, whereas in the non-healthy mucosa group, 27/37 (72.97%) of patients had improved hearing postoperatively, an ABG gain of 3.2 dB. Nevertheless, the difference was not statistically significant.

Dornhoffer [21] found that the mucosal status and presence of drainage were more significant than the

pathologic conditions initiating the surgical procedure. Black found the middle ear mucosa to be a predictor of postoperative hearing outcome [22]. De Vos et al. [23] also demonstrated that the inflammatory middle ear mucosa was a significant predicting factor for worse hearing results and reduced the ABG improvement by 7–8 dB. In their study, the mucosa was described as normal in 92 ears, fibrotic with adhesions or scar bands in 30 ears, and as thickened in 18 ears out of 140. The ABG improved by a mean of 20.5 dB for normal mucosa, by 18.4 dB for fibrotic mucosa, and by 12.2 dB when the mucosa was thickened. The postoperative ABG averages were 17.3, 20.6, and 24.7 dB for normal, fibrotic, and thickened mucosa, respectively. These differences were statistically significant. However, some literature has concluded that middle ear mucosa’s status is not related to postoperative hearing outcomes. Brackmann et al. [24] found no significance in this regard.

This study revealed that in all PORP cases, the mean preoperative ACT was 40.05 dB, and postoperative ACT was 36.3dB with ACT gain of 3.75 dB, which was statistically significant. Gupta et al. [25], in their study, had a mean ACT gain of 10.7 dB. Their results were better than that of ours. In our study, the mean pre- and post-operative ABG was 23.9 and 21, respectively, with a mean gain of 2.9dB; this difference was not statistically significant. Whereas in a similar prospective study of Gupta et al. [25] in 30 patients with PORP, pre- and postoperative ABG was 31.2 and 23.1, respectively, with a mean ABG gain of 8.1, achieving good ABG gain. In a study, Alani et al. [26] had higher results in 35 CWD mastoidectomy using PORP with an average postoperative ABG of 14.10 dB.

Postoperatively, the number of our patients with ABGs of 0–10 and 11–20 dB increased from 11.9 percent to 21.4 percent and from 23.8 to 30.95%, respectively. Therefore, almost two thirds (57.1%) of our patients had closure of their ABG PTAs to 20 dB or less. Our findings are similar to those of Kim et al. [27] who in a retrospective review of 11 CWD PORP obtained postoperative ABG within 20 in 6/11(54.5%) cases, and also similar to Corso et al. [28] who had 66.66% success of ABG closure within 20 dB. However, our success results are inferior to those of Chavan et al. [29] 79.16%, Alaani et al. [26] 84.26%, Martins et al. [30] 74.1%, and Yildinm et al. [31] 82%. These discrepancies in results could partly be attributed to the type of prosthesis used. We used a Teflon prosthesis as other prostheses were not available. Some studies favor titanium prosthesis. Open head titanium prosthesis allows accurate placement. Other reasons for discrepancy of the results include factors as variations in the distribution of diseases such as limited vs. extensive disease, surgeon’s expertise, learning curve, and technical issues. Multiple factors, such as the tension of assembly and angle between the



tympanic membrane and prosthesis, impact the successful reconstruction of the middle ear's sound conduction mechanism. The extensive disease leads to gross denudement of the middle ear mucosa; thus, there will be significant scarring in the middle ear that will lead to fixation of stapes, displacement of the prosthesis, and extrusion [25].

In our study, for patients aged ≤ 15 years, the mean preoperative and postoperative ACTs were 34.6 dB and 29.75 dB, respectively, with an ACT gain of 3.75 dB, and this difference was statistically significant. But, for patients aged > 15 years, the average preoperative ABG was 42.25 dB which got reduced to 38.9 dB postoperatively with a net gain of 2.21 dB. However, the difference was not statistically significant. Maeng et al. [18] had a better audiological outcome in these two groups of patients than ours. They observed pre- and postoperative ABGs of 28.18 and 20.70 dB, respectively, for 57 patients of age < 15 years and 27.87 and 17.30 dB for those 2022 patients of age ≥ 15 years. These differences were of no statistical significance.

The pediatric population has been considered a high-risk category for tympanomastoidectomy and ossiculoplasty surgery. The increased prevalence of Eustachian tube dysfunction and upper respiratory tract infection led to the procedure's failure. A study found that the age and presence of co-existing cholesteatoma or tympanic membrane perforation do not appear to mitigate against performing ossicular reconstruction in this age group [15].

Our study's frequency-wise comparison of pre- and postoperative ACT revealed improvement in 500, 1000, and 3000 Hz but no improvement in 2000 Hz. However, our findings were in contradiction to the results of other authors. Hales et al. [32] in frequency-specific ABG analysis of OCR with titanium prosthesis, demonstrated best postoperative ABG at 2000 Hz. Babighian et al. [33] in their study of CWD TORP titanium OCR analysis for single frequencies showed the smallest postoperative air-bone gap attainment at 2 kHz among all groups of patients. This could be related to the mass of prosthesis used as mass affects higher frequencies in hearing because of increasing ossicular inertia, which hampers the sound transfer mechanism [31]. The effects of mass are seen above 1 kHz but are most dramatic above 3 kHz, resulting in 10- to 15-dB losses in hearing. With Teflon prosthesis being heavier than titanium, these differences could have occurred.

As with all the studies, this study is not exempted from limitations and weaknesses. Even though this is a prospective study, its limitations include small sample size and heterogeneity of the groups. The inclusion of both pediatric and adult patients in our study was not appropriate as results of tympanoplasty may not be the same in these two categories of groups. The small sample size is due to the narrow inclusion criteria where we

chose selected patients that underwent type III tympanoplasty with PORP. However, a larger sample size would make this study better. Multiple surgeons in the study are another weakness of our study as results may vary greatly with a learning curve, expertise, and experience of surgeons. The study had a limited follow-up period and reported early results only.

Conclusions

There was a statistically significant improvement in postoperative ACTs in all cases. However, pre- and postoperative ABGs were not statistically significant. The integrity of the pars tensa and middle ear mucosa status did not affect the postoperative hearing outcome in single-stage CWD tympanomastoidectomy using PORP.

Abbreviations

COM: Chronic otitis media; CWU: Canal wall up; CWD: Canal wall down; OCR: Ossicular chain reconstruction; PORP: Partial ossicular replacement prosthesis; ABG: Air-bone gap; MERI: Middle ear risk index

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Authors' contributions

NT/DS: Design/concept/prepare manuscript RP/PR/HB: concept/critically reviewed. The authors have read and approved the manuscript.

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Availability of data and materials

The datasets used for the present study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by Institutional Review Board of the Tribhuvan University Teaching Hospital, Institute of Medicine, Kathmandu, Nepal, reference number 231 (6-11-E) 071/072. The informed written consent to participate in the study was provided by all the participants and their parent or legal guardian in the case of children under 16.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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