Abstract:
**Objective:** To determine subjective outcomes after cholesteatoma surgery.
**Design:** Cross sectional observational study
**Methods:** Study place: Shaheed Ziaur Rahman Medical College Hospital (SZMCH), Bogura, Bangladesh
**Study population:** Chronic otitis media (COM) with extensive cholesteatoma.
**Interventions:** Canal wall down mastoidectomy for cholesteatoma.
**Main Outcome Measures:** In this study, the Chronic Ear Survey (CES) was provided to all patients preoperatively and one year after surgery. The preoperative and postoperative score differences were analyzed. We also assessed correlations between chronic ear survey scores and air conduction threshold.
**Results:** Seventy six patients were enrolled in our study & marked improvements were found in total CES score & all subscale scores postoperatively (P value: 0.00). The total CES score and symptom subscale scores were observed greater improvement (P value: 0.00). Significant negative linear correlations were observed among total CES scores, symptom subscale scores and air conduction thresholds (P<.05).
**Conclusion:** The present study suggests that canal wall down mastoidectomy (CWDM) provides a significant improvement in the post-operative Quality of life (QoL) & there is a significant association between subjective outcomes & the objective audiometric results.
**Keywords:** Cholesteatoma, Chronic ear survey, Quality of life, Canal wall down mastoidectomy, Chronic otitis media.
Introduction:
Cholesteatoma surgery is one of the most controversial topics in otology. The aims for surgery are to eradicate the infection, to make well epithelialized, self-cleaning ear, to reconstruct hearing mechanism and to improve quality of life (QoL). The aim of cholesteatoma surgery is not simply to remove disease in order to create a safe ear. Most of the patients present with hearing loss & may not be satisfied with treatment that gives no apparent benefit. CWDM is an established surgical technique in the management of cholesteatoma. Number of modifications has been introduced in CWDM in order to overcome some of its drawbacks while maintaining its best outcome. Advantages of CWDM are complete removal of the disease, easy inspection of the hidden area of cholesteatoma, less formation of the new retraction pockets, early detection of recurrence of disease and improved post-surgical outcome\(^1\). Although the expectations of hearing gain after surgery is minimal but a successful tympanoplasty or ossiculoplasty can reconstruct the mechanism hearing and improve hearing status.

Presently, the results of cholesteatoma surgery have focused on hearing gain and eradication of the disease, which are measured by objective pure tone audiometry. But there is some discrepancy between hearing results after surgery or anatomical changes of the ear canal and satisfaction of the patients with ear symptoms in daily life. Thus, patient-based subjective outcomes after micro ear surgery have evaluated in some trials\(^2,3\).

Some studies have been structured to assess QoL after cholesteatoma surgery and some specific tools are also available. Recently to evaluate the specific aspects of COM and its impact on daily life, several specific surveys have been developed\(^4\). Nadol et al first introduced the chronic ear Survey (CES) which is a statistically validated questionnaire, specific for patients affected by COM & it has a significant correlation with the pure tone audiometry, with other QoL surveys, and undergoing to a marked post-surgical improvement\(^5,6\). The CES is composed of 13-item survey that measures the frequency, duration and severity of problems associated with COM. It is divided into three subscales that include activity restrictions, symptoms and medical resource utilization. According to the patient’s answers to the questionnaire, a score resulting in a scale ranging from 0 to 100 is obtained with 0 indicating the maximum restriction of quality of life.

Objectives of this study were to (1) measure subjective outcomes using the CES before & after cholesteatoma surgery, (2) compare preoperative & postoperative CES score, (3) correlated CES scores with objective pure tone audiometry

Methods:
This cross sectional study was carried out in the Department of ENT & Head-Neck surgery, Shaheed Ziaur Rahman Medical College Hospital, Bogura, Bangladesh during the period of July 2017 to January 2020. We enrolled 76 patients admitted for Chronic otitis media with cholesteatoma. Micro-otoscopy and pure tone audiometry were performed in all patients. The diagnosis was confirmed by microscopic examination & CT scan of the temporal bone. All patients were candidates for surgery & a CWD technique was performed, due to the large extent of the pathology, anatomical conformation and/or erosion of the external ear canal. CWDM with tympanoplasty was carried out in a single stage. Partial obliteration of the neo-mastoid cavity with bone dust & cartilage was performed. All patients underwent standard pure-tone audiometry for testing conventional...
frequency range (0.25 to 8 kHz). Pure-tone average (PTA) values were calculated as the mean of 0.5, 1, 2, and 4 kHz thresholds. Audiological assessment performed 24 hours preoperatively and 12 months post-operatively. The CES questionnaire was translated from English into Bengali & was administered preoperatively and at 1 year postoperatively, and differences in scores within the groups were analyzed. Scoring for each CES question was normalized to a scale of 0 to 100, with 100 being the highest score. The total scores and sums of subscale scores were averaged on the basis of the number of questions included in each category.

Patients undergoing revision surgery, patients with bilateral disease who underwent a different surgical technique in the two ears, patients affected by petrous apex cholesteatoma and Patients with other medical conditions that could affect QoL were excluded from this study.

Statistical analysis was performed using SPSS statistical software. We adopted the Mann-Whitney test to compare parametric mean values and used the paired t test to compare changes within groups. We evaluated correlations between CES scores and objective AC thresholds using Spearman rank correlation analysis. P<.05 was considered statistically significant.

Results:
The results are shown in tables and figures.

### Table - I:
Gender distribution (n=76)

<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency (n)</th>
<th>Percent(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>44</td>
<td>57.9</td>
</tr>
<tr>
<td>Female</td>
<td>32</td>
<td>42.1</td>
</tr>
<tr>
<td>Total</td>
<td>76</td>
<td>100</td>
</tr>
</tbody>
</table>

### Table - II:
Distribution of Age (n=76)

<table>
<thead>
<tr>
<th>Age</th>
<th>Frequency (n)</th>
<th>Percent (%)</th>
<th>Mean age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 12 years</td>
<td>19</td>
<td>25</td>
<td>10.11</td>
</tr>
<tr>
<td>13-35 years</td>
<td>38</td>
<td>50</td>
<td>23.68</td>
</tr>
<tr>
<td>Above 35 years</td>
<td>19</td>
<td>25</td>
<td>46.37</td>
</tr>
<tr>
<td>Total</td>
<td>76</td>
<td>100</td>
<td>25.96</td>
</tr>
</tbody>
</table>

### Audiological outcome:
Pre-operatively, the mean PTA(AC threshold) was 46.57 dB (SD = ±15.61). Whereas at the 12-month post-operative assessment, the overall mean PTA (AC threshold) was 43.88 dB (SD = ±17.10). The mean preoperative PTA & mean postoperative PTA differences were statistically significant (p=0.000). The mean preoperative ABGs were 26.51±8.38 dB and the mean postoperative ABG had improved to 24.17±10.16 dB.

The pre- and post-operative audiological results are reported in Table III.

### Table - III:
Pre- and Post-operative Audiological Data

<table>
<thead>
<tr>
<th></th>
<th>PTA AC threshold(Mean)</th>
<th>BC Threshold(Mean)</th>
<th>AB gap(Mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop PTA(dB)± SD</td>
<td>46.57±15.61</td>
<td>20.11±9.64</td>
<td>26.51±8.38</td>
</tr>
<tr>
<td>postop PTA(dB)± SD</td>
<td>43.88±17.10</td>
<td>19.75±9.52</td>
<td>24.17±10.16</td>
</tr>
<tr>
<td>MD(95% CI)</td>
<td>2.69(1.75,3.64)</td>
<td>0.36(0.23,0.49)</td>
<td>2.33(1.38,3.28)</td>
</tr>
<tr>
<td>P value</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
</tr>
</tbody>
</table>

MD: Mean difference
Table - IV:
Postoperative Complications

<table>
<thead>
<tr>
<th>Complications</th>
<th>Cases(n=76)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrence</td>
<td>0</td>
</tr>
<tr>
<td>Ear drum retraction</td>
<td>4</td>
</tr>
<tr>
<td>Residual TM perforation</td>
<td>4</td>
</tr>
<tr>
<td>Myringitis</td>
<td>2</td>
</tr>
<tr>
<td>Facial nerve palsy</td>
<td>1</td>
</tr>
<tr>
<td>Residual cholesteatoma</td>
<td>0</td>
</tr>
<tr>
<td>Discharging mastoid cavity</td>
<td>4</td>
</tr>
</tbody>
</table>

Chronic Ear Survey
The preoperative and 12 month’s postoperative administration of the CES results were compared in this study. The mean preoperative total score was 38.17. This score was improved to 74.87 at 1 year postoperatively (P=0.000; Figure I), and the MR. The total score and each subscale score improvements were significant (P value: 0.000 Table:V).

Analysis of correlation & comparison of subjective Vs objective audiometric outcomes
The Symptom subscale(S) score & total CES score had significant negative correlation with the air conduction threshold preoperatively & postoperatively (Fig.3). Other subscale scores also showed negative correlations with the hearing thresholds, but not to a statistically significant degree(P>.05).

Table - V:
Comparison of preoperative & postoperative CES scores

<table>
<thead>
<tr>
<th>Mean score ±SD AR</th>
<th>S</th>
<th>MR</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop</td>
<td>42.43±5.00</td>
<td>32.94±8.91</td>
<td>39.14±4.68</td>
</tr>
<tr>
<td>Postop</td>
<td>67.63±11.39</td>
<td>77.27±10.88</td>
<td>79.71±16.35</td>
</tr>
<tr>
<td>Mean difference</td>
<td>25.28(28.17, 22.40)</td>
<td>44.33(47.06, 41.60)</td>
<td>40.46(44.40, 36.51)</td>
</tr>
<tr>
<td>(95% CI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
</tr>
</tbody>
</table>

AR: activity restriction, S: symptoms, MR: medical resources utilization

Figure 3 Scattergrams of total CES scores and pure-tone audiometry (PTA) air conduction (AC) thresholds. Linear analysis of correlation was performed using Spearman rank correlation analysis.
Discussion:
The purpose of the study was to see the patient based subjective outcomes preoperatively & postoperatively for patients with CSOM with cholesteatoma and to see the correlation with objective audio metrical outcomes. Doctor-based objective measurements or patient-based subjective outcome measurements can be used to assess outcomes of surgery in COM. Doctor-based objective measurements like complete disease eradication, formation of a safe and dry ear, and hearing reconstruction, which were used in most reports. On the other hand, patient-based outcome measurements evaluate QoL following surgery using validated tools. As subjective patient based outcome measures do not always correlate with objective doctor based outcome measures, so a combined outcome assessment of both measures is needed. The chronic ear survey has been validated in various reports and is recently the only disease specific outcome survey to assess QOL in COM.

In this study, at 12-months post-operative assessment by CES, CWDM patients showed a significant improvement in all subscale scores and total score. The patients who underwent CWDM patients, aural symptoms, distress related to the frequent medical visits and activity restriction (mainly water restrictions) becomes significantly less over time. It is consistent with another study conducted by Jung KH et al.

However, the Symptom subscale score was markedly lower in the preoperative group, and it was improved more significantly after surgery. These findings suggest that the subjective symptoms of chronic otitis media, such as hearing loss, otalgia and ear discharge influenced the outcome. Postoperative activity restriction subscale improvements scores were relatively lower than other subscales suggesting that patients were more careful about their daily activities even after successful surgery. As Nadol et al. reported that patients having lower total scores had more significant postoperative improvement, and lower individual scores were also predictive of a postoperative increase in the CES score, the greater improvement in the total CES score and symptom subscale scores in our series may be partly a result of lower preoperative Symptom subscale scores.

Regarding objective audiometric outcomes, average hearing did not improve significantly. As most of the patients had extensive cholesteatomas and had undergone CWDM, and only half of them were conducted ossiculoplasty, the hearing results in our series were relatively poor (Table III). It is compared with another study conducted by D. LUCIDI et al.

As the points about hearing impairment are included in the symptom subscale, so hearing thresholds affected the symptom subscale scores. Air conduction thresholds showed linear negative correlations with the overall CES score and the symptom subscale scores. A similar study conducted by Jung KH et al. reported on 21 patients in primary surgery group, the total CES score and some subscale scores showed significant correlations with the objective clinical outcomes.

The association between air conduction threshold and CES scores is a questionable topic: Nadol et al. reported that the CES questionnaire is specifically formed on the basis of level of hearing and they showed strong association between audiometric
threshold and overall score. According to Baumann et al., the correlation is only between audiometric threshold and COMOT-15 hearing function and mental health subsections. Lailach et al. showed a moderate relation between AC threshold and total score of COMOT and strong relation between AC threshold and the HF subsections. Other studies demonstrated only partial or no relation at all between audiometry and the survey' subscales. Our study recommends that a hearing impaired patient does not essentially presents subjective impairment in the overall QOL. Our data also imply that audometric thresholds are not sufficient to evaluate patients satisfaction. Other aural symptoms (such as foul smelling ear discharge, otalgia, frequent need of medical visits, water restriction) and mental health status are also influential in post-operative assessment for comparison of different techniques.

**Limitations:**
CWDM are usually done in extensive chronic ear disease, and therefore patients may presents with severe clinical features. Our post-operative follow up duration was approximately 12 months and more long term follow-up results would be more reliable to assess the quality of life. Impact of recurrence, possible revision surgery, experience of the surgeon, social and cultural factors are also crucial factors affecting outcomes which could not be considered in this study.

**Conclusion:**
This study showed significant quality of life improvement on average 12 months postoperative period of CWDM. The overall CES score and all subscale scores have strong correlations with the objective audiometric thresholds.

**Acknowledgement:**
I wish to express my heartfelt gratitude to all the patients who inspired me with their endless support with regular follow up, valuable consent & patience.

**Funding:** No funding sources

**Conflict of interest:** None declared

**Ethical approval:** The study was approved by the Institutional Ethics Committee.

**References:**


