i. **Outcomes of tympanoplasty in a low resource setting: Our experience in 429 ears in Cambodia**

ii. Tympanoplasty outcomes in Cambodia

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v. We would like to thank the Children's Surgical Centre for their help in this research, especially the ENT surgeons and Audiology technicians for their tireless contributions to their patients.

Ethical considerations

This study was approved by the Ethics committee of the Royal Victorian Eye and Ear Hospital, Melbourne (18/1371HS).

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Funding information:

There was no specific funding associated with this project.

Author contribution statement:

Patrick Bowers and Carolina Watters analysed the data and wrote the paper; Touch Sokdavy and Mahmood Bhutta performed the surgeries and assisted with critical revision; Kelley Graydon and Chris Waterworth aided with statistical analysis and critical revision. All authors have approved submission of this manuscript.

Outcomes of tympanoplasty in a low resource setting: Our experience in 429 ears in Cambodia

KEY POINTS

- Tympanoplasty outcomes are well established in high income nations, but less reported in low-middle income countries (LMICs).
- LMICs see a higher prevalence of chronic suppurative otitis media, with anecdotal evidence of greater disease severity at presentation.
- Here we find that tympanoplasty performed by local surgeons in the LMIC of Cambodia has 85.8% successful closure, which is comparable to other settings.
- For audiological outcomes, there was a mean reduction in the air-bone gap of 15.8dB, and improvement in the air-conduction average in 85.5% of participants.
- We find no evidence that tympanoplasty outcomes in LMICs should differ from those in other settings.

KEYWORDS

LMIC; CSOM; Tympanoplasty; Myringoplasty; Conductive hearing loss; Audiology; Cambodia

INTRODUCTION

Chronic Suppurative Otitis Media (CSOM) is a disorder that disproportionately affects disadvantaged populations, with 90% of cases in Low and Middle-Income Countries (LMICs).[1] Otorrhoea and hearing loss (HL) associated with CSOM can contribute to poverty through reduced earning potential, social isolation due to stigma, and reduction in overall quality of life.[2] Disease that fails to heal can be treated with tympanoplasty, with the aim of closing the tympanic membrane (TM) to prevent otorrhoea, and improve hearing. Meta-analyses show an intact tympanic membrane (closure rate) is achieved in 83.4-86.6% of cases, and closure of the air-bone gap (ABG) within 20dB in 68.6-76.7% of cases. [3, 4]

In the largest meta-analysis, which included over 26,000 patients, an intact tympanic membrane was achieved in 86.6%, of cases. In that study, variables found to reduce success were an age of 17 or less, use of fascia as opposed to cartilage for the graft material, and a perforation size larger than 50%.[4] That study did not compare outcomes in LMICs to those from high income countries (HICs), perhaps because there are fewer reported studies from LMICs, despite this being where CSOM is most prevalent.

Clinical experience and published reports suggest that in LMICs suppurative ear disease is more severe and presents later, which could reduce the success of tympanoplasty.[5] We recently searched the literature (PubMed and Scopus using keywords ‘tympanoplasty’ OR ‘myringoplasty’ AND names of

individual countries) and found that only a third of relevant studies were from LMICs (279/804 = 34.7%). Very few of these studies were adequately powered to detect a difference in outcome compared to the mean closure rate of 86.6%. For example, to detect a 10% relative reduction in achieving an intact tympanic membrane would require a sample size of 302 (rate difference 77.9%, vs 86.6%, alpha 0.05, power 80%, 2-tailed; calculated at https://clincalc.com/stats/samplesize.aspx). Only nine of the studies we found (from Ethiopia, India, Iran, Lebanon, Pakistan and Turkey) included a sample of this size or greater. They reported closure rates of 76-99% and improvements in ABG of 3.2-18.5dB. [6-14]

Here we add to knowledge on outcomes of tympanoplasty in low resource settings, using data from 429 ears of patients at a charity hospital in Phnom Penh, Cambodia (a lower-middle income country).

MATERIALS AND METHODS

Ethical considerations

This study was approved by the Ethics committee of the Royal Victorian Eye and Ear Hospital, Melbourne (18/1371HS).

Data extraction and analysis

This was a retrospective study of consecutive patients who underwent tympanoplasty for CSOM between January 2014 and January 2019 at the Children's Surgical Centre in Phnom Penh, Cambodia. The majority of such procedures were performed by the local surgeons, who were trained by temporarily resident foreign surgeons from the UK.[15] We included patients of all ages, and excluded those with cholesteatoma. The majority of surgeries were performed under general anaesthesia, using a postaural approach and an underlay composite graft of tragal cartilage and perichondrium (table 1). Partial data on some of this cohort has previously been reported in a different study.[15]

We extracted data on patient demographics and comorbidities, perforation size and location, operative technique, and presence of ossicular erosion at operation. We recorded tympanic membrane closure rate at 6 weeks post-op (due to significant attrition due to non-attendance, we had few data available at later time points). We compared closure rate to size of perforation, age (<18 or ≥18), and sex using the Chi-squared test (significance set at $p < 0.05$).

We also extracted data on pre- and post-operative pure tone air conduction (AC) and bone conduction (BC) audiological thresholds across four frequencies (500, 1000, 2000 and 4000 Hz). For audiology data we only included patients between October 2016 and January 2019, because prior to this date audiology services were provided by an organisation external to our hospital and we were uncertain of the validity of those assessments. We calculated the four-frequency air conduction average (4FAHL), and air-bone gap (ABG), and compared pre and post-operative data using a paired sample t test, (significance set at $p < 0.05$). We analysed size of perforation, age (<18 or ≥18), and sex on ABG improvement using one-way analysis of variance (significance set at $p < 0.05$). We also tallied the

number of pre and post-operative patients with mild, moderate, severe or profound grades of hearing loss (defined by World Health Organisation criteria[16]) based upon 4FAHL air conduction thresholds.

We compared outcomes to the mean using the Chi-squared test, with significance set at $p<0.05$. The Statistical Analyses and Methods in the Published Literature (SAMPL) Guidelines were consulted in the preparation of this study.

RESULTS

There were 477 ears in 397 patients in the dataset from January 2014 to January 2019, and 267 ears in 228 patients in the dataset from October 2016 to January 2019 (total 664). Attrition and incomplete data meant that outcomes for closure were only available on 429 (89.94%) ears and for audiological outcomes in 110 (23.06%) ears. Details of surgical technique are summarised in table 1, and patient demographics and preoperative clinical findings in table 2.

The closure rate at 6 weeks was 368/429 ears (85.8%). Closure rate did not differ significantly to the mean of 86.6% in the previous meta-analysis ($X^2 = 0.244$, $p = 0.621$). Size of perforation was not significantly related to closure rate ($X^2 = 4.076$, $p = 0.130$), nor was sex ($X^2 = 0.233$ $p = 0.629$) or age ($X^2 = 0.714$ $p = 0.398$).

The 4FAHL improved from 48.4dBHL (SD=17.00) preoperatively to 33.9dBHL (SD=18.45) postoperatively ($p < 0.001$), with an improved air conduction 4FAHL in 94/110 (85.5%) ears. Outcomes by grade of hearing loss are presented in figure 1. 53.6% of patients (59/110) had moderate to severe hearing loss pre-operatively, but postoperatively this was only 18.2% of patients (20/110).

The ABG improved across all frequencies (figure 2), with a mean four frequency ABG reduction of 15.8dB (31.3dB, SD=12.7 pre-operatively vs 15.5dB, SD=10.7 postoperatively: $p < 0.001$). Post-operatively 43/110 ears (39.1%) had a mean ABG of ≤ 10dB, 41 (37.3%) ears of 11-20dB, 15 (13.6%) of 21-30dB, and 11 (10%) >30dB. The functional hearing success rate (surgeries achieving an ABG ≤ 20dB) did not differ significantly from meta-analysis results ($X^2 = 2.994$, $p = 0.0836$). Mean preoperative ABG for each size category (0-30%, 31-60%, 61-100%) were 19.1dB (SD=10.6), 31.7 (SD=11.6), and 35.2dB (SD=11.9) respectively. Postoperatively, these improved to 12.5dB (SD=11.2), 15.2dB (SD=10.6), and 17.0dB (SD=10.6) respectively. Perforations greater than 30% in size showed a greater improvement in ABG compared to those smaller than this size ($p = 0.029$ and 0.011). ABG improvement did not differ significantly by sex ($p = 0.440$), or age ($p = 0.909$).

DISCUSSION

This report demonstrates that in Cambodia outcomes of tympanoplasty for tympanic membrane closure and improvement in ABG mirror the mean reported globally. We find no evidence that we should expect outcomes in this setting to be different to those from elsewhere.

Our findings also replicate audiological findings in other reports of patients undergoing tympanoplasty.[17] The lower frequencies (500 and 1000Hz) had worse preoperative hearing thresholds but also the highest gain compared to higher frequencies. Unsurprisingly, smaller perforations lead to less improvement in the ABG, again replicating previous findings.

Pre-operatively fewer than half of our patients had functioning hearing in the affected ear (mild or no hearing loss) but after surgery this was more than 90%. This would predict significant improvements in the quality of life of such patients, and improved opportunity for employment and participation in society.[2] Where hearing loss persists, assistance through a hearing device (where available) can aid rehabilitation, particularly if the tympanic membrane is intact and otorrhea no longer a contraindication for fitting. Adequate aural rehabilitation programs in low resource settings are scarce,[18, 19] but hearing aid fitting is a possibility in Cambodia, with a growing number of providers in the government, non-government and private sector.

Limitations of our study mostly relate to short-term follow up, attrition and incomplete audiometry data. It is possible that longer term outcomes may be less successful than the data we have presented here, and the outcomes of those not returning for follow up differ from the cohort we included. Our sample is also too small to detect small differences in subgroup analyses.

CONCLUSION

This study shows outcomes for tympanoplasty in Cambodia, a low resource setting, are comparable to the mean reported globally. This high success rate of surgery, coupled with the huge burden of disease, should further encourage the development of services for tympanoplasty in low resource settings.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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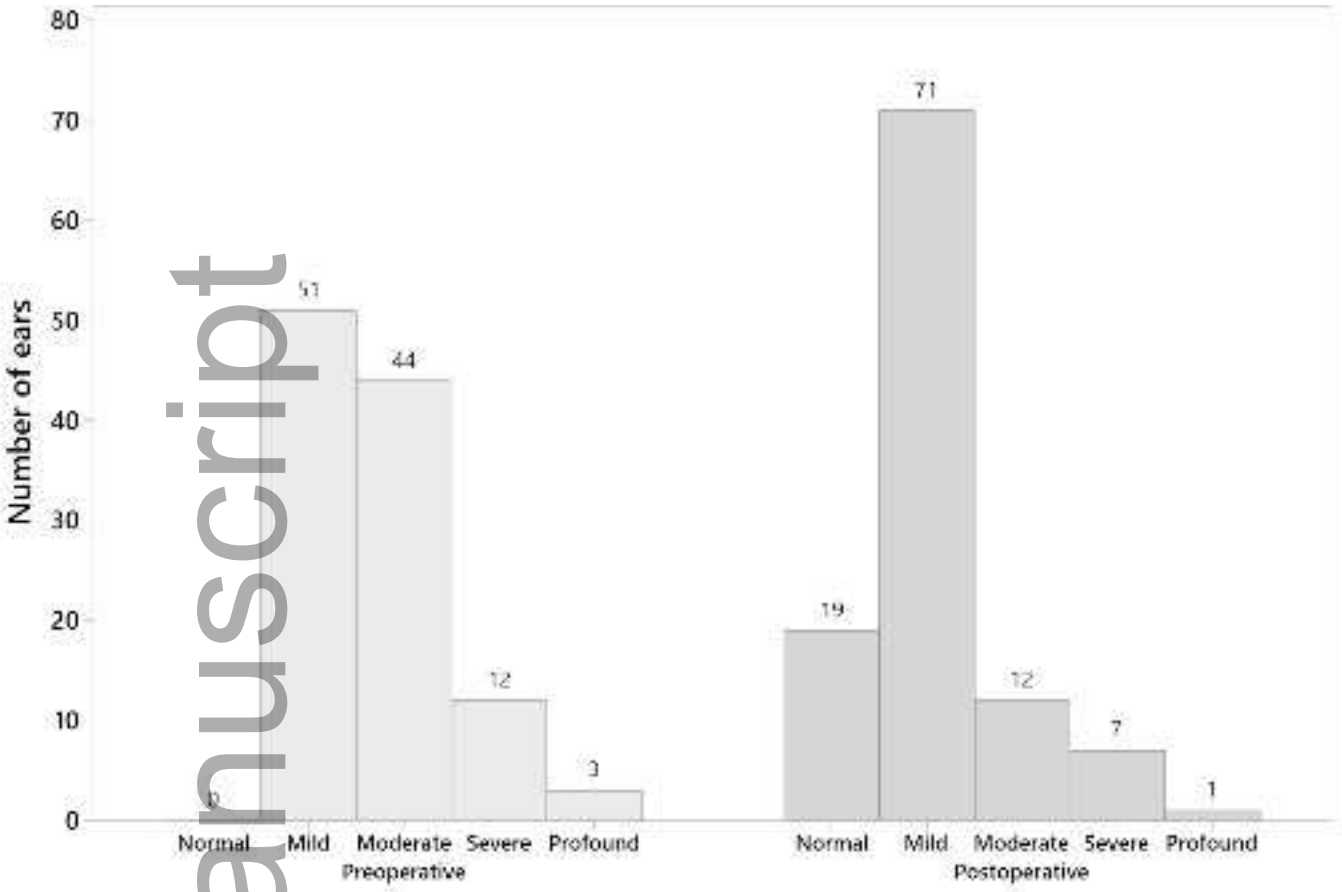
Table 1. Details of surgical procedure	
Variable	**Value** (n (%))

TABLES

Anaesthesia	
General	425 (99.1)
Local	4 (0.9)
Material	
Cartilage	8 (1.9)
Composite	304 (70.9)
Perichondrium	75 (17.5)
Temporalis Fascia	42 (9.8)
Approach	
Endaural	15 (3.5)
Postaural	414 (96.5)
Technique	
Underlay	423 (98.6)
- with anterior tuck	309 (72.0)
Overlay	2 (0.5)
Push-through	4 (0.9)

Table 2. Participant demographics and clinical findings

Variable	**Value**
Age	
Mean (SD)	26.44 (12.8)
Range	6-61
Sex (n (%))	
M	188 (43.8)
F	241 (56.2)
Affected ear (n (%))	
Left	214 (49.9)
Right	215 (50.1)
Perforation size (n (%))	
0-30%	46 (12.1)
31-60%	176 (46.1)
61-100%	160 (41.8)
Perforation location (n (%))	
Central	266 (62.0)
Marginal	163 (38.0)
Ossicular erosion present at operation (n (%))	
Present	20 (4.7)
Absent	409 (95.3)
Known comorbidities (n (%))	
HIV +	15 (3.5)
Tuberculosis	2 (0.5)
Diabetes mellitus	1 (0.2)



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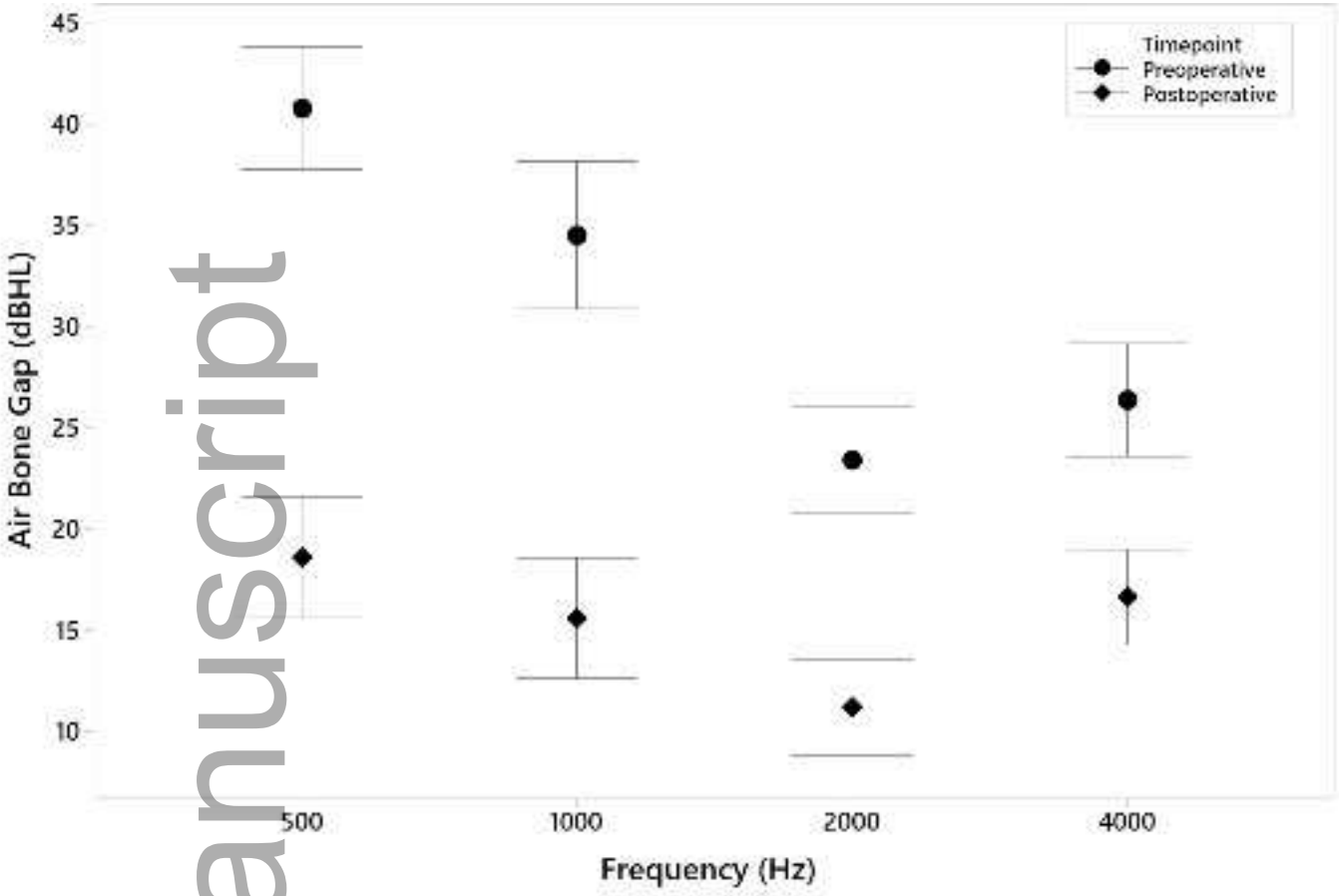

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