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Early Results of Type I Tympanoplasty in Underprivileged Nepalese Children and Factors Influencing the Surgical Outcomes

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Abstract

Introduction Type I Tympanoplasty is a common ear surgery performed in Nepalese children, but no studies have been published about the success rate of the procedure and the factors affecting surgical outcomes.

Objectives To find out the surgical outcome of type I tympanoplasty and to evaluate the factors affecting the success of the surgery in Nepalese children.

Methods This is a retrospective study conducted by analyzing the medical records of a five-year period. Children aged 8–16 years who underwent type I tympanoplasty were included in the study. Surgical pro-forma and records of pre and post-operative pure tone audiometry were documented. Outcome of the surgery was considered a success in terms of graft uptake and hearing improvement six months after surgery.

Results Out of 629 children who underwent type I tympanoplasty, anatomical success was observed in 93.32% ($n = 587$) and functional success in 76% ($n = 478$). Factors such as age, site and size of the perforation, status of the middle ear and contralateral ear, surgical approach, and the graft used were not the predictors of the surgical outcome.

Conclusions The surgical outcome of type I tympanoplasty in Nepalese children was good. Although surgical outcome was better with older children, post-aural approach, temporalis fascia, inferiorly positioned perforations, and in children with dry middle ear mucosa, none of the parameters considered in this study were found to be a significant predictive factor of the surgical outcome.

Keywords
- Pediatric tympanoplasty
- Myringoplasty
- Predictive factors
- Tympanic membrane perforation

Introduction

There is a huge burden of hearing loss in Nepal, the main cause of which is chronic otitis media (COM).[1] A study done by Little et al found that 7.4% of the Nepalese population had perforated ear drum.[1] COM is one of the commonest causes of avoidable hearing loss in developing countries.[2] COM is infection of the middle ear cavity with permanent abnormality of the pars tensa or pars flaccid.[3] Chronic otitis media without cholesteatoma with perforated tympanic membrane is one of the commonest COM observed, and type I tympanoplasty is the treatment of choice. Type I tympanoplasty is a surgical procedure aimed at restoration of the hearing mechanism with intact and mobile ossicular chain in which the reconstructive procedure is limited to the repair of the perforation of the tympanic membrane.[4] The history of

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closure of the tympanic membrane perforation dates back to 1887 when Blake introduced paper patch technique, and to Hermann who in 1958 established temporalis fascia.[5] Since then temporalis fascia has been the most commonly used graft material. Other graft material like perichondrium, fat, vein and cartilage are less commonly used. The objectives of tympanoplasty are restoration of hearing, provision of a dry ear, prevention of migration of squamous epithelium in the middle ear, and prevention of cholesteatoma formation.

The success rate of tympanoplasty has been reported between 56–94%,[6] and this wide difference is due to various criteria used to define the term success. The standard definition of successful tympanoplasty is when at one year post surgery there is complete graft uptake, post operative hearing gain, and when the graft is in the correct anatomical position.[7] Parameters like age at the time of surgery, site and size of perforation, state of the middle ear mucosa and contralateral ear, surgical approach, and technique and graft material used have been considered as predictors of the success of the tympanoplasty,[8–11] especially in children due to the eustachian tube anatomy and recurrent upper airway infections.

High prevalence of COM and surgical intervention being the treatment of choice for the closure of perforated tympanic membrane, tympanoplasty is one of the commonest middle ear surgeries performed in Nepal. Despite tympanoplasty being commonly performed, very few studies on its success rate have been published, especially in the pediatric population. Therefore, the main objectives of this study are to find out the surgical outcome of type I tympanoplasty in Nepalese children and to further analyze the various factors that influence the success rate of the procedure.

Methods

This is a retrospective study. Analysis of the medical records and surgical pro-forma of ear surgeries conducted at our institute over the five year period from 2015 to 2019 was done. Children aged between 8–16 years who were diagnosed with tympanic membrane perforation without cholesteatoma and were referred to our institute from different parts of rural Nepal were included in the study. Only the children who underwent type I tympanoplasty were included in the study. Cases with chronic otitis media with cholesteatoma, suspected ossicular chain pathology, and children with sensorineural hearing loss were excluded from the study. Children who underwent middle ear surgeries other than type I tympanoplasty were also excluded from the study. Signed written consent was obtained from the parents at the time of the surgery. This study was approved by the ethical board of Nepal Health Research Council.

Detail socio-demographic history collected at the time of admission was recorded. The findings of the otoscopic examination documented at the time of admission by the operating surgeon and the pure tone audiogram findings conducted by an audiologist in a sound treated room using Arphi Proton SX5 audiometer were documented. Average hearing threshold at 500, 1000, 2000 and 4000 Hz frequencies was measured and recorded. Audiogram was done twice; the first audiogram was done one day before surgery and the second audiogram six months after surgery.

All the surgeries were conducted under general anesthesia by three senior Ear Nose Throat consultants who had more than 5 years of experience in ear surgery. For the purpose of the study, tympanic membrane was divided into four quadrants; anterosuperior (AS), posterosuperior (PS), anteroinferior (AI) and posteroinferior (PI). The perforation was called posterior if the perforation involved posterosuperior and posteroinferior quadrants, anterior if it involved anterosuperior and anteroinferior quadrants, inferior if it involved anteroinferior and posteroinferior quadrants, and total if it involved all four quadrants of the tympanic membrane. Size of the perforation was classified as small if perforation involved $<25\%$ of the tympanic membrane, medium if it involved between 25–50%, and large if the perforation involved $>50\%$ of the tympanic membrane. COM was considered active if there was active discharge with inflamed middle ear mucosa at the time of the surgery and inactive if the ear was dry with healthy middle ear mucosa. Other parameters like graft material used, surgical approach and technique used during surgery were documented.

All children were admitted for 3 days and they were followed up for up to 6 months after surgery. During final follow up, otoscopic examination and pure tone audiometry were re-evaluated and findings documented. The surgery was considered an anatomical success if there was complete graft uptake and a functional success if six months after surgery there was an average hearing gain of at least 10dB HL. Only children who fulfilled all of these criteria were included in the study. The data entry and analysis was done by using Excel 2007 and SPSS statistical program version 25.0.

Results

A total of 629 children aged 8–16 years underwent type I tympanoplasty from 2015 through 2019. Out of the 629 children, 53.73% ($n = 338$) were male and 46.26% ($n = 291$) female. While 48.97% ($n = 308$) had surgery to the right ear, 51.03% ($n = 321$) had it to the left ear. Anatomical success with complete graft uptake was observed in 93.32% ($n = 587$) and functional success with improvement of hearing was seen in 76% ($n = 478$) of the children. Distribution of the surgical outcome is described in ►**Table 1**.

Although surgical outcome was slightly better in older children aged 12–16 years than in the younger age group of 8–11, it was not statistically significant. Parameters like surgical approach, surgical technique, graft material, location of the perforation, status of the middle ear and contralateral ear were not found to be of significant predictive value for surgical outcome of type I tympanoplasty. A 100% success rate was observed in children with small size perforations, and in cases where the surgical route was endaural, but none of these parameters were found to be statistically significant. Out of 629 children who underwent surgery, 204 children had bilateral chronic otitis media but the status of the

Table 1 Distribution of the surgical outcome of type I tympanoplasty

Variable		Number of children (n)	Percentage (%)
Intact tympanic membrane	Yes	587	93.32
	No	42	6.68
Hearing improvement	Yes	478	76
	No	151	24

contralateral ear was not found to be predictive of surgical outcome. The surgical outcomes in relation to various parameters predictive of the success rate are shown in ►**Table 2**.

Post-surgical hearing improvement was observed in 76% ($n = 478$) children. Pre-operative average hearing threshold was 36.01dB HL and post-surgical average hearing threshold was 20.39dB HL. Similarly, pre-surgical average air bone gap was 24.47dB HL and post-surgery it reduced to average air bone gap of 8.85dB HL.

Discussion

A total of 629 children aged between 8 to 16 years who were referred from different rural parts of Nepal and who underwent type I tympanoplasty at our institute were studied. This study was conducted among children who attend government schools. In Nepal, only the children who cannot afford privately run schools attend the government schools, as the quality of education in these state run schools are markedly inferior to that available in private schools. Therefore, the children who attend the government schools are from the most underprivileged family backgrounds. The anatomical success with intact tympanic membrane was observed in 93.32% ($n = 587$) children and functional success with improvement of hearing was seen in 76% ($n = 478$) children.

Although type I tympanoplasty is one of the commonest ear surgeries performed in Nepal because of the prevalence

Table 2 Parameters predictive of the surgical outcome of the type I tympanoplasty

Predictive Factors	Surgical outcome		p-value	Odds ratio (OR)	95%CI (Lower-Upper value)
	Failure N (%)	Success N (%)			
Age					
8–11 years	10 (7.2)	129 (92.8)		Ref.	
12–16 years	32 (6.5)	458 (93.5)	0.782	1.109	0.531- 2.317
Approach					
Permeatal	17 (9.9)	154 (90.1)		Ref.	
Postaural	25 (6.2)	380 (93.8)	0.115	1.678	0.881- 3.195
Endaural	0 (0.0)	53 (100.0)	–	–	–
Graft material					
Temporalis Fascia	37 (6.6)	526 (93.4)	0.761	1.165	0.441- 3.076
Tragal Cartilage	5 (7.6)	61 (92.4)		Ref.	
Site of perforation					
All four quadrants	32 (6.7)	448 (93.3)		Ref.	
Anterior	2 (11.1)	16 (88.9)	0.469	0.571	0.126- 2.595
Posterior	7 (10.0)	63 (90.0)	0.314	0.643	0.272- 1.518
Inferior	1 (1.6)	60 (98.4)	0.156	4.286	0.575- 31.938
Size of perforation					
Small	0 (0.0)	14 (100.0)	–	–	–
Medium	11 (7.9)	128 (92.1)	0.565	0.811	0.396- 1.658
Large	31 (6.5)	445 (93.5)		Ref.	
Middle ear status					
Active disease	7 (10.8)	58 (89.2)		Ref.	
Inactive disease	35 (6.2)	529 (93.8)	0.193	1.824	0.775- 4.292
Contralateral ear					
Chronic otitis media	14 (6.9)	190 (93.1)		Ref.	
Normal	28 (6.6)	397 (93.4)	0.897	1.045	0.538- 2.030

of a large number of chronic otitis media with perforated tympanic membrane, this is the first study conducted in school aged Nepalese children. Some studies done in small adult population in Nepal have reported success rate of up to 83.1%.[12–14] Success rate of tympanoplasty across the globe has been reported to be between 56–94%.[6] There are various factors behind the wide range in the reported success rate, such as, small cohort, age at the time of the surgery, follow up period, and the absence of a standardized definition of the term success. In our study, success was defined as complete graft uptake without residual perforation and average hearing gain of at least 10dBHL across 500–4kHz frequencies six months after surgery.

In this study although the surgical outcome was relatively better in older children aged 12–18 years, end-aural route, temporalis fascia graft, inferiorly located and small size perforations and dry middle ear mucosa, it was not statistically significant. Other parameters like age of the patient, size and site of the perforation, status of the middle ear, surgical approach, graft material used and the state of the contralateral ear weren't considered predictive of the success of type I tympanoplasty in our study.

Patient's age at the time of the surgery has always been a subject of discussion as age is often said to be one of the key prognostic factors that could influence the surgical outcome, especially in children younger than the age of 8. The debate is because of the anatomy of the eustachian tube, the chances of recurrent upper airway infection, increased possibility of self-healing of the perforation and re-perforation of the tympanic membrane in the pediatric population. In our study, surgical outcome was better in older children than younger children aged 8–11 years. Age less than 10 years was found to be a poor prognostic factor by Black et al[15] and MacDonald et al.[16] Contrary to this, Sckolnick et al reported that increasing age led to a lower success rate.[17] While a few studies reported better outcomes in older children than their younger peers,[6,10,18,19] others didn't find significant correlation between age and surgical outcome.[9,20–28]

Studies have emphasized that follow up period after surgery is also a key factor to correctly define the term success. Longer follow up is often suggested in children to observe the integrity of the graft because of the increased chances of re-perforation of the grafted tympanic membrane and middle ear effusion. Knapik et al observed some deterioration in success rates in long term follow up.[29] In our study the follow up was done for up to 6 months post-surgery. It was difficult to follow up for a longer period because the majority of the children in our study were from rural parts of Nepal or were children of migrant workers who constantly migrated. Follow up periods have ranged from as short as the 9 weeks[12,13] to a few years.[11,21,22,26,28,29] However, most of the reported follow ups ranged between 6 months to 1 year.[7–10,14,15,19,23]

Although higher failure rates in cases with large perforation has been reported, our study found very good result even in cases with large perforations. Out of 476 cases with large perforations, 93.5% ($n = 445$) of the children had intact tympanic membrane at 6 months post-surgery. Similar good results were also observed by Gersdorff et al.[22] Some authors found smaller perforations to have better success rates,[10,31,32] while other studies didn't find any significant relation between size of the perforation and the surgical outcome.[9,14,21,25,28,29,33]

Similarly location of the tympanic membrane perforation has been suggested as a predictive factor in determining the surgical outcome. In our study, surgical outcome was better in inferiorly placed perforations 98.4% ($n = 60$) but didn't find significant correlation between site of the perforation and surgical outcome. Although few studies found that anterior perforation have poorer results,[7,22,25] others didn't find a significant correlation between location of the perforation and surgical outcome.[9,14,21,29]

Status of the opposite ear has been considered as predictive of surgical outcome because of the role of the eustachian tube pathology involved as a main cause of chronic otitis media. In our study, we didn't find the status of the contralateral ear as a predictive of the surgical outcome, and this was also observed by others.[21,25,27,29] On the other hand, bilateral chronic otitis media was found to be a strong predictive factor for a poorer surgical outcome by other studies.[8,9,14,18,20,23,28,32,34]

The surgical approach depends not just on the operating surgeon's preference, but also on the size and site of the perforations. The post-auricular route is most commonly used for anteriorly placed perforations and large perforations with narrow external auditory canal, while end-aural route is mainly used for posterior perforations. The transcanal approach is opted for smaller perforations or in cases with wide external auditory canal. In our study, post-auricular route was the most commonly performed 64.38% ($n = 405$) approach. This could be because most of the children 76.31% ($n = 480$) had large central perforations with minimum remaining tympanic membrane. This was also seen in a study by Baklaci et al.[28] Even though 100% success was observed in children where end-auricular approach was chosen, we didn't find the surgical approach to have significant influence on the surgical outcome. Similarly, Black et al didn't find the surgical approach to be a factor that could influence the success rate.[15]

A variety of graft material is used to repair the perforated tympanic membrane, but temporalis fascia is the graft material that is most commonly used. In our study too, temporalis fascia was the most favored graft material and was used in 89.50% ($n = 563$) cases, and the surgical success rate was similar to cases where cartilage was used to repair the tympanic membrane. Other studies, however, suggest better result when cartilage was used as a graft material.[28,35]

We observed better surgical outcome in children when surgery was conducted in dry middle ear cavity, but could not categorize this findings as being predictive of the surgical outcome. In our study it was difficult to wait for the middle ear cavity to be dry and healthy before conducting tympanoplasty because children who were operated upon at our institute were referred from remote parts of Nepal, and had to travel long distances to reach our institute. Some have suggested that better result can be achieved in dry and

healthy middle ear mucosa,[9,18,19,21,22,32] while Calyan et al have contradicted this finding and postulated that a discharging ear is more favorable in children because of increased vascularity.[8]

This is the first study to analyze the success rate of type I tympanoplasty and to validate the predictive factors of the surgical outcome that has been conducted in Nepalese school aged children. Although a few studies covering small cohort have been reported before, no study has been published covering larger pediatric populations in Nepal. The large number of cases included in our study could deliver the message that type I tympanoplasty in Nepalese children has a good success rate. We suggest that surgery should be considered as early as possible in children with chronic otitis media with tympanic membrane perforation to prevent complications and for better cochlear reserve. Since surgery is the treatment of choice, it should be performed in a timely manner to reduce the burden of avoidable hearing loss caused by chronic otitis media. None of the parameters were found to be a significant predictors of the surgical outcome, even though a higher success rate was observed both in children with smaller perforations and in older children.

One of the main limitations of this study is that it is a retrospective study. The authors had to depend on the medical records and surgical pro-forma collected at the time of the surgery. Also a longer follow up of at least one year would have given us an opportunity to better observe the integrity of the grafted tympanic membrane. This was, however, not possible in our study as the majority of the children were from remote parts of Nepal in whom longer follow-ups was not possible.

Conclusion

The success rate of type I tympanoplasty in Nepalese school aged children is good. Since it is the treatment of choice for children with chronic otitis media with tympanic membrane perforation, it should be considered in a timely manner to preserve cochlear reserve. None of the parameters that were considered predictive of surgical outcome in other studies were found to be statistically significant in our study, even if a higher success rate was observed in children with smaller perforations and in older children.

Conflict of Interest
None declared.

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