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A comparison of two myringoplasty techniques in Nepalese children: A prospective randomized trial☆

Prashant Tripathi [a,*], Rajendra Prasad Guragain [b], Chop Lal Bhusal [b], Sureshwar Lal Karna [b], Johannes Borgstein [c]

[a] Children's Hospital for Eye, ENT and Rehabilitation Services (CHEERS), BP Eye Foundation, Manohara, Bhaktapur, Nepal
[b] Ganesh Man Singh Memorial Academy of ENT-Head and Neck Studies, TUTH, Kathmandu, Nepal
[c] Department of Otolaryngology, Tergooi Hospital, Rijksstraatweg 1, 1261AN, Blaricum, Netherlands

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ABSTRACT

Background: In children, the success of myringoplastywith temporalis fascia is lower compared to adults and cartilage as an alternative graft material has shown higher success rate.
Objective: To compare results of myringoplasty using tragal cartilage palisades with the use of temporalis fascia in children with large tympanic membrane perforations.
Materials and methods: This is a prospective and randomized study conducted in children of age 6–14 years with large tympanic membrane perforation of more than two quadrants. Status of graft at or around 6 weeks after surgery was used as morphological outcome measure. Pre- and postoperative audiograms were compared to evaluate audiological outcome in two groups.
Results: Forty seven out of 55 patients completed follow-up. The graft uptake rate in the cartilage palisades and temporalis fascia myringoplasty group was 91.3% (21/23) and 83.33% (20/24), respectively; the difference was not statistically significant ($P = 0.666$). The mean preoperative air-bone gaps (ABG) in cartilage palisades and temporalis fascia group were 36.2 ± 8.9 dB and 33.8 ± 7.5 dB, the difference was not statistically significant ($P = 0.412$). Similarly, the postoperative ABG in cartilage palisades and temporalis fascia group were 25.1 ± 12.2 dB and 17.2 ± 9.2 dB, respectively, the difference was statistically significant ($P = 0.040$). The gap closure was 11.0 dB in palisades group and 16.8 dB in fascia group, but it was not significant ($P = 0.133$).
Conclusion: In our study of pediatric myringoplasty, the morphological and functional outcomes in both cartilage palisades and temporalis fascia groups were comparable.

1. Introduction

Chronic otitis media (COM) is any structural change in middle ear system associated with a permanent defect in tympanic membrane (TM) [1]. TM perforation with no associated middle ear inflammation and discharge is classified as COM mucosal inactive [2]. The usual causes are infection, atelectasis, ventilation tube insertion, and trauma [3]. COM is more prevalent in low socioeconomic groups and overcrowded homes with significant smoke exposure and substandard sanitation [1]. The overall prevalence of COM in Nepal is estimated to be 7.4% and is more prevalent in children of age between 0 and 15 years where it is estimated to be 9.28% [4].

COM mucosal disease usually presents with intermittent ear discharge of variable duration and hearing loss dependent on the size of the perforation [5]. The treatment is aimed at controlling active infection with the use of systemic and/or topical antibiotics, followed by surgical repair of the TM defect. A wide variety of grafting materials, such as fascia, perichondrium, periostium, vein, (allograft) dura mater, and cartilage have been used for the closure of TM perforations [6].

The success of myringoplasty in children increases with age [7] but there is no consensus on the age limit below which results are generally poor [8–10]. Reasons for early closure of TM defect in children are to prevent frequent infections to avoid effect of hearing loss on speech and language development [11] and to allow unrestricted water-related activities [12]. Various factors

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* Corresponding author at: Children's Hospital for Eye, ENT and Rehabilitation Services (CHEERS), BP Eye Foundation, Manohara, Madhyapur thimi 16, Bhaktapur, Nepal. Tel.: +977 9841372760.
E-mail address: prashantiom@gmail.com (P. Tripathi).

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contributing to low success rate of myringoplasty in children are high frequency of otitis media and URTIs, immature immune system, and unpredictable eustachian tube function [13–15].

Presently, temporalis muscle fascia is the most frequently used grafting material for the repair of tympanic membrane perforation in children and recent studies have reported graft success rate of 70–91% [8,9,11,12,16,30], which is comparable to success rate of 60–99% [17,18] in adults. The problems with the use of fascia as a graft material are due to atrophy or shrinkage of graft or its nonvascularization leading to failure [19]. TF can undergo atrophy in atelectatic ear, cholesteatoma, and revision tympanoplasty [20]. Due to these reasons, surgeons have advocated the use of more stable, less compliant materials like cartilage for the reconstruction of the TM perforation. Currently, cartilage tympanoplasty is variously recommended in high-risk perforations like subtotal or bilateral perforations, revision tympanoplasty, anterior perforation, coexisting craniofacial abnormalities, atelectatic ears, and cholesteatoma [21]. Cartilage palisades technique was first described by Heermann in 1962 [22]. Currently, it is the commonest technique used in cartilage tympanoplasty [23]. The reported graft uptake rate with cartilage palisades myringoplasty is higher than fascia and reported to have successful outcome in 82–100% of cases [22,24–26]. Results have also shown that there is no significant interference with hearing by use of cartilage for myringoplasty [26–28]. However, there is no previous prospective study comparing the results of fascia myringoplasty with the cartilage palisades myringoplasty in children. The aim of the study is to compare the results of myringoplasty with cartilage palisades and temporalis muscle fascia in large TM perforations in children.

2. Materials and methods

This is a prospective, randomized, interventional, and comparative study carried out over a period of 18 months from December 2011 to June 2013. The study was carried out at Ganesh Man Singh Memorial Academy (GMSMA) of ENT-Head and Neck Studies, TU Teaching Hospital, Institute of Medicine (IOM), Kathmandu, Nepal.

Inclusion criteria for the surgery were children of 6–14 years with COM mucosal inactive (dry for at least 4 weeks) and large perforation in tympanic membrane (>2 quadrants perforation). The exclusion criteria were congenital craniofacial abnormalities, for example, cleft palate and frank otorrhea and for hearing evaluation residual perforation or total failure, restricted or fixed ossicles, and patients with preoperative sensorineural hearing loss (BC > 25 dB) were excluded. Convenient sampling method was used for sample size calculation after reviewing the number of surgeries carried out in previous years.

Detail history was obtained, ear otoscopy was done, and pure tone audiometry was performed 1 week prior to surgery. Average hearing threshold was calculated from 0.5, 1, 2, 3, and 4 KHz frequencies. Air–bone gap (ABG) was measured by the difference between average of air conduction and bone conduction thresholds done at the same time.

Children meeting the inclusion criteria were randomly divided into two groups by simple random sampling method. The numbers of possible myringoplasty were estimated by reviewing the record of surgeries done in previous years as we have limited availability of operation theater. After exclusion criteria, it was estimated that about 50–55 cases were done in 18-months period in children. For random selection, lottery method was used. Folded paper were marked with group A and B and placed in a container. There were 30 marked as group A and 30 marked as group B, which were prepared by first author (PT). After patient met inclusion criteria and consented for participation, lottery was done by pulling out one of the folded paper from the container just before surgery by the surgeon. The paper was then discarded. Then the surgery was proceeded as cartilage palisade or temporalis fascia myringoplasty.

Group A: tragal cartilage palisades (TCP)

Group B: temporalis fascia (TF)

Ethical committee approval was obtained before starting the study from Ethical Committee of Institutional Review Board (IRB) of Institute of Medicine, Nepal.

Surgical procedure: In both groups, the surgery was carried via either of permeatal, endaural, or postaural approach depending on the necessity to approach tympanic membrane and middle ear.

Freshening of the perforation margin was done to remove the epithelized tissue. A standard tympanomeatal flap was then raised and folded anteriorly along with annulus. Middle ear was assessed for ossicular status and other pathologies. Then the middle ear space was filled with gel foam up to the level of handle of malleus and annulus. After placing the graft material (cartilage palisade or fascia as described later), the tympanomeatal flap was then repositioned over the graft and gelfoam soaked in ciprofloxacin (0.3%), ear drops was placed over the flap and graft. Then ribbon gauze impregnated with bismuth iodoform paraffin paste (BIPP) was packed into the external auditory canal above the gelfoam. Endaural and postaural skin incisions were sutured in layers with 4-0 Vicryl and skin with 4-0 Ethilon, and a mastoid bandage was applied.

For group A (tragal cartilage palisades): An incision was made on medial aspect of tragus and tragal cartilage along with perichondrium was then harvested and the incision site was closed with 4-0 Vicryl if required. Perichondrium from convex surface was removed and cartilage palisades of different sizes were prepared. The first cartilage piece was kept anterior to handle of malleus and parallel to its long axis with the perichondrium side facing laterally toward the external auditory canal and then appropriate-sized pieces of cartilage were placed in posterior quadrant and any gap remaining between palisades was filled with smaller cartilage pieces. In most cases about 3–4 tragal cartilage palisades were used.

For group B (temporalis fascia): Temporalis muscle fascia graft was harvested by a horizontal incision about 2 cm above the upper attachment of pinna for permeatal approach. In postaural and endaural approach, same skin incision was used for harvesting the graft. Standard underlay temporalis fascia grafting was done [29].

Postoperative care: Both groups A and B received similar care with oral amoxicillin 25–50 mg/kg/day for 7 days. Ibuprofen (5–10 mg/kg/dose) + paracetamol (15 mg/kg/dose) as tablet or syrup was given three times daily after surgery for 3 days. The mastoid dressing was changed on the first postoperative day and thereafter on alternate days. Nonabsorbable sutures, if applied, were removed on sixth postoperative day and the BIPP pack was removed on 10th postoperative day. Antibiotic–steroid ear drops Ocupol-D® (chloramphenicol + dexamethasone + polymyxin-B sulfate) were prescribed for 2 weeks after removal of pack.

Follow-up evaluation of the patients was done at or around 6 weeks after surgery. The follow-up evaluation of the patient was done by first author (PT) who was not involved in the surgery of the patient. For morphological outcome, intact graft was taken as success and perforation of any size was taken as failure. For functional outcome evaluation, the postoperative hearing was compared with the preoperative hearing status. Preoperative and postoperative air–bone gap was calculated and compared.

Results analyzed were graft uptake rate and change in postoperative hearing thresholds. SPSS 18 software was used for analysis of results. The statistical tests used for analysis were fisher's exact test, dependent and independent *t*-test. The level of statistical significance was set at the $P < 0.05$.