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Original Research Article

Comparison of outcomes of palisade cartilage with temporalis fascia following tympanoplasty at a tertiary care centre in Nepal

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ABSTRACT

Background: Mucosal type of chronic otitis media is a common disease worldwide with 5.2% prevalence in Nepal. Cartilage material is criticized in terms of hearing results due to its thickness. The objective of this study was to compare graft uptake and post-operative hearing of palisade cartilage with temporalis fascia following tympanoplasty.
Methods: A prospective randomized study conducted over 12 months included subjects of chronic otitis media mucosal inactive having dry ear for at least 4 weeks. 76 subjects were enrolled and reviewed on 6th post-operative day, 6th and 12th post-operative week. The graft uptake and post-operative hearing were evaluated. The results were compared within and between the groups.
Results: The graft uptake on 42nd and 90th post-operative days were comparable with no statistical difference. The difference of mean pre-operative, 42nd and 90th post-operative air bone gaps in palisade cartilage and temporalis fascia were also comparable. The results were statistically significant, showing improvement in hearing after surgery. Closure of air-bone gap within 30 dB was achieved in 71.87% in temporalis fascia and 88.89% in palisade cartilage. The intergroup difference was not statistically significant.
Conclusions: The graft uptake rates and hearing results after palisade cartilage are similar to temporalis fascia.

Keywords: Tympanoplasty, Palisade cartilage, Temporalis fascia

INTRODUCTION

Mucosal type of chronic otitis media is a common disease worldwide. Prevalence of mucosal type of disease in Nepal is 5.24%.[1] Tympanoplasty was first described in 1952 by Wullstein and Zollner as the mainstay for tympanic membrane reconstruction.[2,3] The grafts used to reconstruct the tympanic membrane are varied and range from homograft, heterograft, xenograft, autograft and isograft. The varied autografts used are skin, perichondrium, vein, temporalis fascia, dura and cartilage.[4-6]

Temporalis fascia remains the most frequently used graft material. Cartilage was first used in middle ear surgery for ossicular chain reconstruction in 1958 by Jansen[7] and the popular techniques for cartilage tympanoplasty described by MirkoTos include inlay butterfly, perichondrium-cartilage island flap, cartilage shield technique and palisade technique. In our department, temporalis fascia grafts were previously used to reconstruct the tympanic membrane. The thought of a prospective study using cartilage as to reconstruct the tympanic membrane came after going through the limited number of clinical studies exploring the outcomes of cartilage palisade in tympanoplasty procedures.[8-12]

The aim of this article was to compare the graft acceptance rates and auditory outcomes of cartilage tympanoplasty operations using the palisade technique with those of primary tympanoplasty using temporalis fascia in two groups of patients.

METHODS

A prospective randomized study was conducted in the department of otorhinolaryngology and head & neck surgery, B.P. Koirala Institute of Health Sciences, Dharan, Nepal from 25th April 2014 to 24th March 2015. The sample size calculated according to Shishegar et al and taking into consideration the maximum pre and post-operative air bone gap, keeping the power of the study at 80%, significant at 0.05 and loss in follow up of 10%, the corrected sample size was 76, which was divided by lottery method into 38 subjects in two groups.[13]

All cases of chronic otitis media-mucosal inactive, dry ear for at least 4 weeks and patients willing to give informed consent were included in the study. Patients with frank otorrhoea at the time of surgery, revision surgeries, patients with pure sensorineural hearing loss, patients who refuse to participate in the study, any systemic diseases or medications affecting wound healing and patients contraindicated for surgery were excluded from the study. Informed consent was taken from all the patients pre-operatively after explaining the procedure. Ethical approval was taken from the Institution Ethical Review Board (IERB) of B.P. Koirala Institute of Health Sciences, Dharan, Nepal. A successful Tympanoplasty was defined as full acceptances of the graft, and intact healing of the tympanic membrane without perforation, retraction, or lateralization within a follow up period of 90 days from the operation. Any residual perforation from pin point to total rejection was reported to be failure.

Pre-operative work up

All patients who fulfilled the inclusion mentioned criteria were included in the study and underwent clinical examinations for their ears. Pure tone audiometry test was performed by a certified trained audiologist within 1 week before surgery, 6th week (42nd post-operative day) after surgery and 3rd month (90th post-operative day) after surgery. Air conduction included frequencies at 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz and 8000 Hz and bone conduction included frequencies at 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz and 4000 Hz. Three frequencies pure tone average was calculated from 500 Hz, 1000 Hz and 2000 Hz. Air Bone gap (ABG) was measured by the difference of average of air conduction and bone conduction threshold done at the same time. It was documented both pre and post-operatively. The findings were noted in the audiological evaluation sheet. Patients were admitted or called on OPD basis according to the availability of bed in the ward. Oral antibiotic (Cefixime 8-10 mg/kg/day in two divided doses) were prescribed the day before surgery and continued for 10 days post-operatively. Part preparation was done in the morning on the day of surgery. Surgery was done either under local or general anaesthesia. Patient who underwent surgery in local anaesthesia were pre-medicated with injection pethidine 1 mg/kg (maximum of 50 mg) and injection promethazine 0.5 mg/kg (maximum of 25 mg) intramuscularly in gluteal region an hour before surgery for sedation. Four quadrant blocks were given with 2% xylocaine with adrenaline (1:200,000) to anaesthetise the operating ear. Examination under microscope was done before surgery & findings noted. Both type of tympanoplasty was performed by the faculty or senior residents.

Surgical technique

Either permeatal or postauricular approach was used to access the tympanic membrane and middle ear according to necessity or convenience of the surgeon. Operating microscope (Olympus OME 500 or Moller Wedel) was used to perform all surgeries.

Cartilage palisade tympanoplasty

After the assessment of tympanic membrane pathology, the tragus or the cymba concha was injected with local anaesthetic 2% xylocaine with adrenaline (1:200,000). An incision along the free edge of medial side of the tragus/concha was performed leaving 2 millimetre of cartilage in dome of tragus/concha for cosmetics and the subcutaneous tissue was dissected to the lateral border of the cartilage and its perichondrium. In cases of total perforation, conchal cartilage was preferred, owing to its curved shape. The cartilage was then widely exposed on both its lateral and medial surfaces and then harvested with its attached perichondrium. The donor site was closed with Ethicon (Ethilon) 3-0 cutting body. The perichondrium was removed from one side of the cartilage as shown in Figure 1. The cartilage was cut into several slices of about 1mm broad with the help of scalpel blade No. 23 as in Figure 2. The tympanomeatal flap and the fibrous annulus was elevated. After lifting the fibrous annulus, the middle ear and ossicular status was evaluated. Pieces of dry gel foam were kept in the middle ear. The first piece of the palisade cartilage was placed anterior to tubal entrance, medial to the bony annulus. Superiorly, the palisade reached the supratubual recess. A 2 mm piece of cartilage was placed inferiorly to support the first palisade and hold it close to the under surface of bony annulus, keeping the tunnel open. The next palisade was also placed under the bony annulus. The third palisade was in close contact with the handle of malleus. Inferiorly, it was placed on top of the bony annulus, but beneath the fibrous annulus, which was elevated. The next palisades were placed posteriorly to the handle of malleus but on top of the bony annulus. The most posterior piece of cartilage was placed with its posterior edge on top of the posterior bony annulus. While placing the palisades, the perichondrium was

turned towards the ear canal or middle ear, but it was placed in such a way that there is no space between them as given in Figure 3.

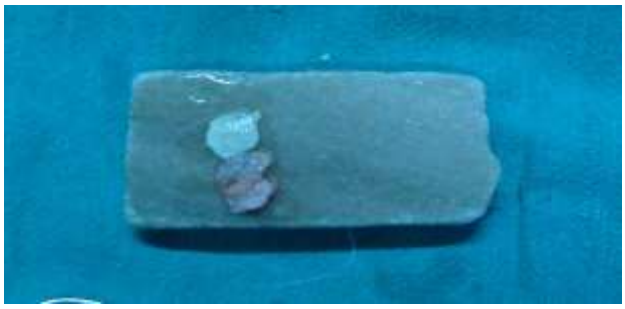

Figure 1: Separated perichondrium from one side of the cartilage.

Figure 2: Slicing of palisade cartilage.

Figure 3: Placing of palisade cartilage.

Temporalis fascia tympanoplasty

Fascia of the ipsilateral temporalis muscle was harvested by a transverse supra-auricular incision just above the superior attachment of pinna during permeatal approach and temporalis fascia graft was harvested from the same incision site in post-aural incision as approached to the middle ear and tympanic membrane. Any remaining muscle fibres were removed from the fascia bluntly and were cut into an appropriate size after it had been dried up. Temporalis fascia was kept by underlay technique after elevating the tympanomeatal flap. The tympanomeatal flap was replaced, and the annulus was fixed all around by gel foam balls in both the groups. Antibiotic soaked (Neomycin, Polymixin B Sulfates and Bacitracin Zinc) gauge, was kept in the ear canal.

Follow up

Patients were given oral antibiotics (tablet Cefixime 8-10 mg/kg/day) in two divided doses for 10 days after food, oral antihistamics (tablet Fexofenadine: >2-11 years: 30 mg twice daily; >/= 12 years: 60 mg twice daily) after food, oral proton pump inhibitors (tablet Ranitidine - children: 5-10 mg/kg/24hour; tablet Pantoprazole 40 mg/24hour) in empty stomach in morning for 10 days, oral analgesics (combination of tablet Ibuprofen 5-10 mg/kg/dose with tablet Paracetamol 10-15 mg/kg/dose) every 8 hourly for 3 days. Patients were advised to avoid lifting heavy things, blowing of nose, drinking liquids with straw and sneezing. If patient was to sneeze at all, then were directed to sneeze with open mouth. They were also advised not to drive their own car to home from the hospital on the day of the operation and to undergo daily dressing of external wound with betadine solution and application of mastoid bandage.

Patients were reviewed in the on 6^{th} postoperative day, 6^{th} postoperative week (42^{nd} postoperative day) and 12^{th} postoperative week (90^{th} postoperative day). In 6^{th} postoperative day, suture and pack were removed. Topical antibiotic and steroid ear drop (Neomycin 0.5% w/v and Betamethasone 0.1% w/v) 3 drops thrice daily for 2 weeks in the operated ear were given. Aural precaution was advised. They were followed on 6^{th} postoperative week (42^{nd}post-operative day) and 12^{th} postoperative week (90^{th} post-operative day). Graft uptake results were noted and pure tone audiometry was performed.

Analysis and statistics

Results were analysed as graft uptake rate and change between pre and post-operative hearing. All data were entered in Microsoft XP excel spread sheet and analyzed by the statistical package for social sciences (SPSS 17.0, SPSS Inc., Chicago, IL, U.S.A.). Fischer's exact test, student's t-test and Pearson χ^2 value were calculated. Statistical significance was considered at $p < 0.05$.

RESULTS

From April 2014 to March 2015, 76 patients were enrolled in the study who met the inclusion mentioned criteria. Group A comprised of 38 subjects with temporalis fascia and Group B comprised of 38 subjects with perichondrial-cartilage palisade. Eight subjects were lost in follow up at the end of the study. Hence, 92.1% (n=35) and 86.8% (n=33) subjects completed the study in the temporalis fascia and palisade cartilage group. There were 29 (42.65%) males and 39 (57.35%) females in the study. In the temporalis fascia group, 9 (25.7%) subjects were males and 26 (74.3%) subjects were females. In the cartilage group, 20 (60.6%) subjects were males and 13

(39.4%) subjects were females. Table 1 shows the gender distribution in the study group.

Table 1: Gender distribution in the groups.

Group	Male	Female	Total
Temporalis fascia	9(25.71%)	26(74.29%)	35
Cartilage	20(60.60%)	13(39.40%)	33

The age of the subjects ranged from 16 years to 48 years. Majority of the subjects in both the age groups were from 21-30 years. Table 2 shows age distribution in both the groups.

Table 2: Age distribution of subjects in both groups.

Age group (in years)	Group Temporalis fascia	Group Cartilage
13 – 20	8	9
21 – 30	24	18
31 – 40	2	4
>41	1	2
Total	35 (92.10%)	33 (86.84%)

Post-operative graft status

On the 42nd post-operative day, failure of graft uptake was observed in both the groups and there was no difference in the success and failure rates between the groups. Table 3 shows post-operative graft uptake on 42nd post-operative day. 9 subjects had graft failure on the 90th post-operative day, with 3 cases in the temporalis fascia group and 6 in the Cartilage group. There was no difference in the failure rates between the groups. Table 4 shows post-operative graft uptake on 90th post-operative day. When we followed up subjects from 42nd to 90th day we observed that 3 cases of residual perforations in Temporalis fascia (T. fascia) group and 1 case of residual perforation in cartilage group healed and there was intact tympanic membrane at the end of study.

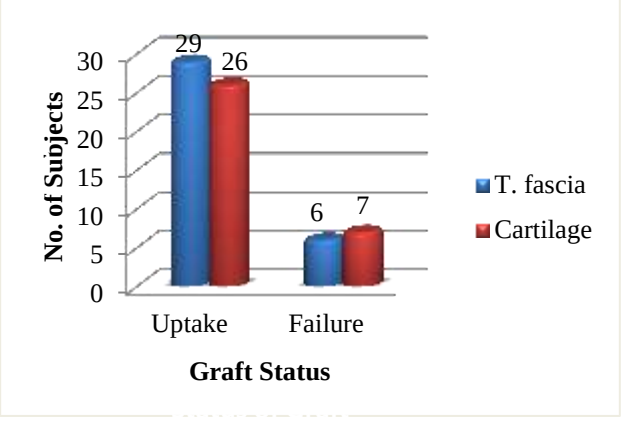

Figure 4: Post-operative graft status on 42nd day.

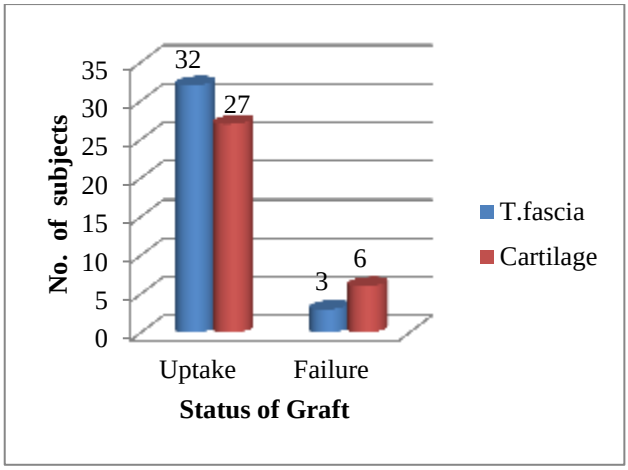

Figure 5: Post-operative graft status on 90th day.

Post-operative hearing results

Successful graft uptake was seen in 29 cases in temporalis fascia group and 26 cases in cartilage group in the 42nd postoperative day. 1 subject in temporalis fascia and 5 subjects in cartilage group had no hearing gain inspite of successful graft uptake. Closure of air-bone gap within 10 dB was achieved in 20.69% in temporalis fascia group and 13.79% in cartilage group. Closure of air-bone gap within 20 dB was achieved in 55.17% in temporalis fascia group and 46.15% in cartilage group. Similarly, closure of air-bone gap within 30 dB was achieved in 79.31% in temporalis fascia group and 73.08% in cartilage group. However there was no statistically significant difference observed (p=0.819).

Successful graft uptake was seen in 32 cases in temporalis fascia group and 27 cases in cartilage group in the 90th post-operative day. 3 subjects in temporalis fascia and 2 subjects in cartilage group had no hearing gain inspite of successful graft uptake. Closure if air-bone gap within 10 dB was achieved in 18.75% in temporalis fascia group and 25.93% in cartilage group. Closure of air-bone gap within 20 dB was achieved in 53.13% in temporalis fascia group and 51.85% in cartilage group. Similarly, closure of air-bone gap within 30 dB was achieved in 71.87% in temporalis fascia group and 88.89% in cartilage group. However there was no statistically significant difference observed (p=0.153).

Table 3: Comparative closures of Air bone gaps at 42nd and 90th post-operative days for temporalis fascia/cartilage (T/S).

Post-operative day	<10 dB	<20 dB	< 30 dB	p
42nd (T/S)	13.79/20.69	46.15/55.17	73.08/79.31	0.819
90th (T/S)	25.93/18.75	51.85/53.13	88.89/71.87	0.153

DISCUSSION

The use of cartilage is experiencing a renaissance in ear surgery. Temporalis fascia remains the most frequently used graft material, with tympanic membrane closure rates of 70-90% for primary tympanoplasties in different hands.[14] Advantages of cartilage graft include its very low metabolic rate and ability to receive nutrients by diffusion. It is very easy to work with because it is pliable, resists deformation from pressure variations and incorporates well into the tympanic membrane.[15] Cartilage retains its rigidity and resists retraction, resorption and re-perforation, even with continuous eustachian tube dysfunction.[16]

In our study, which is the first of its kind in Nepal has compared graft uptake and hearing results after 6 weeks and 3 months of tympanoplasty. Prasad et al had also used 6 weeks as the minimum post- operative follow up period after myringoplasty, the time required for complete healing and good hearing results.[17] In order to prevent the shortcoming of the study as a short period of follow up, we included 3months also to assess the status of the graft and hearing results. Success was defined as anatomical intactness of the tympanic membrane and hearing improvement by post-operative ABG closure.

Tympanic membrane intactness

The results in our study, at the end of 6 weeks and 3 months follow ups, successful closure of tympanic membrane was achieved in 82.86% and 91.43%, respectively, of the temporalis fascia group with 78.79% and 81.82%, respectively in palisade cartilage group. In a recent study by Khan et al at the end of two year and four year follow ups, successful closure of tympanic membrane was achieved in 98.20% and 97.75%, respectively, of the sliced cartilage group compared with 87.42% and 82.63%, respectively, of the temporalis fascia group.[18]

Air bone gap closure

Our results of closure of air bone gap on 42nd and 90th days were achieved but it was not statistical significant. Table 5 shows comparative air bone gap closures on 42nd and 90th post-operative days for the two groups. These results are similar to Gamra et al where they observed good functional hearing results (ABG <20 dB) in 89% with cartilage graft and 82.8% with temporalis fascia graft (p >0.005).[19]

The current study suggests that palisade cartilage graft and temporalis fascia graft for tympanic membrane perforation closure are comparable. The disadvantage of using thicker cartilage, thought to interfere with hearing and sound conduction, was overcome by slicing them to achieve a thickness comparable with that of the temporalis fascia. The comparable post-operative ABG closure with both the palisade cartilage graft and temporalis fascia graft (p >0.05) indicates that palisading the cartilage does not interfere with sound conduction, thus providing an advantage over the use of thick un-sliced cartilage.

CONCLUSION

The rate of graft uptake in palisade cartilage group and temporalis fascia group are comparable. The hearing results in palisade cartilage and temporalis fascia following surgery were statistically significant postoperatively, signifying that the hearing was better after surgery. On comparing the hearing results among palisade cartilage and temporalis fascia there was statistically significant difference on post-operative hearing in the palisade cartilage group in 42nd post-operative day but on longer follow up at 90th post-operative day there was no statistical significance observed between the two groups. A longitudinal follow-up of the subjects would further strengthen the study to elucidate the long-term results of this technique.

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