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Outcome of Myringoplasty with Temporal Fascia and With Sliced Tragal Cartilage Graft-A Comparative Study

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Abstract

Introduction: Myringoplasty is the surgical procedure to repair tympanic membrane perforations and thereby improving hearing, providing a dry ear, and reducing susceptibility to infections. Although there are many kinds of techniques and graft materials used, no methods have proven indisputably superior to the other. Therefore, to find out the outcome of myringoplasty using temporal fascia and sliced tragal cartilage in chronic inactive mucosal otitis media was set as an objective of the study. Materials and Methods: This cross-sectional observational study was conducted at the department of Otolaryngology & Head-Neck surgery, Shaheed Suhrawardy Medical College Hospital (ShSMCH) for six months from July 2018 to December 2018, after acceptance of the protocol and approval from IRB. Patients attending in the ShSMCH with complaints of chronic inactive mucosal otitis media were approached for inclusion of the study and final selection were done in according to the selection criteria. Ethical issues were ensured properly throughout the study period and inclusion was confirmed following signing written informed consent. All patients were randomly allocated into two groups where one group were received myringoplasty with temporalis fascia graft and another group received sliced tragal cartilage. Total 50 patients (25 patients in each group) were included, and they were subjected to details history taking, physical examination and necessary investigations. The researcher conducted all the interview and collected data were recorded into a case record form for each patient. Data analysis was done by SPSS 17. Results: Of total, 50 study population, mean age of the 32.30±10.93 SD (years) with 58% male and 42% females respectively. No significant age and gender difference is noted across the group (p>0.05). Patients having temporal fascia graft had significantly higher proportion of graft uptake in comparison to patients having sliced tragal graft (p < 0.05). Both groups of the patient improve significantly in term of hearing after operation (p < 0.05 in each group) but comparison in between groups showed that the improvement was significantly higher in temporal fascia graft group (p < 0.001). Conclusion: Myringoplasty with temporal fascia graft could be a better option than sliced tragal cartilage graft in our population. However, further larger study with longer follow up is necessary to finalize the comment.

Keywords: Myringoplasty, Temporal fascia, Tragal cartilage graft. Number of Tables: 06 ; *Number of Figure:*01 ; *Number of References:* 19; *Number of Correspondences:* 03.

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Introduction:

Chronic otitis media (COM) is the major community ear disorder in our country. It is the chronic inflammation of the middle ear cleft which is composed of eustachian tube, hypotympanum, mesotympanum, epitympanum, aditus and mastoid air cells and presents with recurrent ear discharge through tympanic perforation. Continuing mucosal infection of the middle ear by resistant organisms, continuing infection of the nasopharynx with secondary infection of the middle ear cleft and changes in the mucosa of the middle ear secondary to eustachian tube dysfunction may all



contribute to the development of chronic otitis media. The diagnosis on COM implies a permanent abnormality of the pars tensa or flaccida, Various time related definitions have been applied to COM; however, generally a perforation for more than 3 months is deemed chronic¹. In India, prevalence rate is 7.8% which is very high. In Bangladesh prevalence rate is $5.2\%^2$. A study over 4260 subjects was conducted by Department of Otolaryngology and Head-Neck Surgery, Bangabandhu Sheikh Mujib Medical University, Dhaka, World Health Organization, Dhaka, and Head-Neck Cancer Hospital and Institute, Dhaka, Bangladesh stated that 6.2 per cent had COM³ (tubotympanic in 3.6 percent, atticoantral in 0.6 percent and dry perforation variety in 2.0 percent). Worldwide, there are nearly 65 to330 million sufferers. Risk factors for the chronic otitis media are early nasopharyngeal acquisition of otological pathogens due to high rate of cross-infection, more siblings under the age five, more crowded accommodation, higher number of siblings with a history of ear inflammation, age at first episode of acute otitis media, poorer nutritional status, reduced exposure to medical services and supportive therapies⁴. Otoscopy with the aid of a microscope is the 'gold standard' for the diagnosis of COM. History taking and investigations are an aid to management rather than to diagnosis. Pure tone audiometry assesses the magnitude of conductive hearing impairment due to the disease. The degree of air bone gap depends on- size of the perforation of tympanic membrane, erosion of the ossicular chain. Standard treatment of active mucosal COM is conservative management with aural toilet, topical antibiotics, systemic antibiotics, and advice. In case of inactive mucosal COM, other prerequisites are dry ear, good Eustachian tube function. Myringoplasty is the main stay of treatment for chronic otitis media of inactive mucosal disease. In a study the overall success rate of myringoplasty was 86 %. Posterior & inferior perforations had a 90% success rate for repair, compared to only 67% of anterior perforations⁵. The success rate of subtotal perforation closure (92.5%)was as good as the closure rate for small perforation (94.1%). But the poorer results were in younger patients. Vrabec et al⁶ found better success with advancing age. This is due to lower incidence of upper airway infections and better eustachian tube function in later age and relative immaturity of the immune system in younger children. Caylon et al⁷ found no statistical difference in the success rate between two sex groups. No significant difference was found when comparing the two surgical techniques of overlay and underlay; the success rate was 79.1% in the former & 82.3% in the later⁸. When hearing improvement was the main indication for surgery it was improved in 67%. A study was done by Mani Lal Aich et al⁹ at Dhaka Medical College on 100 cases in 2009. The overall graft take rate was 84%. The mean preoperative and postoperative air conduction threshold in the successful cases were 35.2dB & 24.1dB respectively with

a mean audiological improvement of 11.1dB & air bone gap improvement was 12.4dB. Various types of grafts are being used to repair the tympanic membrane. The most widely used graft in tympanoplasty is temporal fascia graft followed by cartilage, skin, vein graft, fat, perichondria etc. Temporal fascia graft is considered to be a better graft in terms of hearing outcome owing to its thinness and more pliable texture. Tragal cartilage with perichondrium fulfills all the required qualities of an ideal graft material namely low rejection rate, sufficient quantity, good tensile strength, conductive properties similar to that of tympanic membrane and easy availability. Fernandes from Newcastle. Australia published the technique of composite chondroperichondrial clip tympanoplasty using the tragal cartilage10. Tragal cartilage is a fibroelastic cartilage and being composed of collagen type II is also similar nature of the tympanic membrane, temporal muscle fascia consists primarily of collagen type I. Collagen type II has higher tensile strength than other types. Nowadays, several institutes preferred cartilage not only hard cases but also simple tympanic membrane perforations. A study was done by Mubarak M. Khan¹¹ at Department of Otorhinolaryngology, MIMER Medical College, Pune, India was performed on 223 cases by using slice tragal cartilage as graft during myringoplasty. The overall success rate was 98.20% in terms of perforation closure and airbone gap closure within 7.06 ± 3.39 dB. The success rates in the various age groups are as follows: 11 to 20 years, 97.67%; 21 to 40 years, 99.12%; and 41 to 60 years, 96.96%. So ultimate management for chronic mucosal otitis media is myringoplasty. To evaluate the outcome of the surgery postoperative graft, take rate and audiological assessment is essential.

Materials and Methods:

This cross-sectional observational study was conducted at the department of Otolaryngology & Head-Neck surgery, Shaheed Suhrawardy Medical College Hospital (ShSMCH) for six months from July 2018 to December 2018, after acceptance of the protocol and approval from IRB. Patients attending in the ShSMCH with complaints of chronic inactive mucosal otitis media were approached for inclusion of the study and final selection were done in according to the selection criteria. Ethical issues were ensured properly throughout the study period and inclusion was confirmed following signing written informed consent. All patients were randomly allocated into two groups where one group were received myringoplasty with temporalis fascia graft and another group received sliced tragal cartilage. Total 50 patients (25 patients in each group) were included, and they were subjected to details history taking, physical examination and necessary investigations. The researcher conducted all the interview and collected data were recorded into a case record form for each patient. Data analysis was done by SPSS 17.

Study procedure: This is a cross-sectional study which involve interviewing all patients and or his/her attendant who underwent myringoplasty by using temporal fascia and sliced

tragal cartilage in the Department of Otorhinolaryngology and Head Neck surgery, Shaheed Suhrawardy Medical College Hospital (ShSMCH), Dhaka. All patients were interviewed using a standard questionnaire. After admission history was taken and physical examination was done. Then all the investigations including pure tone audiometry and impedance audiometry were done. Then informed written consent was taken from the patient. The operation was performed under general anesthesia. A Per-operative microscopic examination was done. Incision site was infiltrated with two percent lignocaine with 1:200000 adrenaline in both cases. Temporalis fascia graft was harvested in the first group by a standard postauricular incision. The margin was freshened by a curved needle and the handle of the malleus was denuded. Graft was placed in underlay technique (under the remnant tympanic membrane medial to the handle of malleus) and gel foam was placed on either side of the graft. Sliced tragal cartilage was used as graft material in the second group. A horizontal incision was given at 2-3 mm below and behind the tip of tragus. Cartilage along with perichondrium was taken. Thin cartilage slices (with perichondrium) of 0.5 mm thickness were created with the Slice its cartilage slicer. Rosen incision was given transmeatally. The incision was made in the meatus from 12 to 6 o'clock on the posterior side, parallel to the tympanic annulus at a distance between 5 and 8 mm. At 12 and 6 o'clock the incision nearly joins the annulus. Margin freshening was done. Tympanomeatal flap was elevated. Sliced cartilage of 0.5mm was placed medial to the handle of the malleus. Gel foam was placed, and the flap was repositioned. Sofratulle packs were given in both cases. After the operation first follow up on 7th postoperative day, during which skin sutures were removed. The second follow-up visit will be done on the 2nd week, during which pack were removed. Assessment of graft uptake was done by using microscope in all visits of the patient. Graft uptakes were considered successful if there is no residual perforation seen after the end of follow up period at 6 weeks. After 12 weeks, a pure tone audiogram was done to evaluate the post-operative hearing status.

Results:

Fifty patients of chronic inactive otitis media were included in the final analysis. Among the respondents 50% underwent myringoplasty using temporal fascia graft and another 50% underwent myringoplasty using sliced tragal cartilage.

The mean age of 50 patients was 32.30 ± 10.93 years, ranging from 16 to 58 years. Distribution was similar in both groups of patients (Table I).

Table-I: Distribution of respondents according to age (n=50)

| Age group (years) | Temporal Fascia Graft | Sliced Tragal Cartilage Graft | Total | |
|----------------------|-----------------------|----------------------------------|---------|--|
| | N (%) | N (%) | N (%) | |
| ≤20 | 7 (28) | 3 (12) | 10 (20) | |
| 21-30 | 5 (20) | 8 (32) | 13 (26) | |
| 31-40 | 7 (28) | 11 (44) | 18 (36) | |

| Age group (years) | Temporal Fascia Graft | Sliced Tragal Cartilage Graft | Total |
|----------------------|-----------------------|----------------------------------|--------|
| 41-30 | 5 (20) | 1 (4) | 6 (12) |
| 51-60 | 1 (4) | 2 (8) | 3 (6) |

Among all patients, majority were male (58%) and 42% were female. Distribution was similar across groups (Table II).

Table II: Distribution of respondents according to sex (n=50)

| Sex | Temporal Fascia Graft | Sliced Tragal Cartilage Graft | Total | |
|--------|-----------------------|----------------------------------|---------|--|
| | N (%) | N (%) | N (%) | |
| Male | 15 (60) | 14 (56) | 29 (58) | |
| Female | 10 (40) | 11 (44) | 21 (42) | |

74% of patients had hearing loss, 12% had tinnitus, 18% had vertigo and 10% had earache (Figure 1).



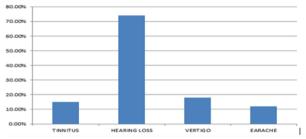


Figure 1: Clinical presentation of patients (n=50)

Majority 48% patients had inferior perforation, 28% had posterior perforation and 24% had anterior perforation. Majority 56% patients had medium sized perforation and 44% had small sized perforation. Patients were followed up in the 1st week, 2nd week and 12th week after surgery. Graft uptake was assessed after 6 weeks of treatment. Patients having temporal fascia graft had significantly higher proportion of graft uptake in comparison to patients having sliced tragal graft (p<0.05) (Table III).

| Table | III: | Distribution | of | respondents | according | to | graft |
|--------|-------|--------------|----|-------------|-----------|----|-------|
| uptake | ; (n= | 50) | | | | | |

| Graft uptake | Temporal Fascia Graft | Sliced Tragal Cartilage Graft | Total | P value |
|-----------------|--------------------------|----------------------------------|---------|---------|
| | N (%) | N (%) | N (%) | |
| Yes | 22 (88) | 15 (60) | 37 (74) | 0.024 |
| No | 3 (12) | 10 (40) | 13 (26) | 0.024 |

P value obtained by Chi-squared test

At admission mean Pure Tone Audiometry Air-Bone Gap (PTA-ABG) of all patients was 34.17 ± 2.86 , ranging from 30 to 40 (mild to moderate hearing impairment). Both surgical group had similar audiometry result at admission (p>0.05) (Table IV).

Table IV: PTA-ABG before surgery (n=50)

| | Temporal Fascia Graft | Sliced Tragal Cartilage Graft | P value |
|--------------------------|--------------------------|----------------------------------|---------|
| ABG (dB) | Mean±SD | Mean±SD | |
| Small sized perforation | 24.17±2.86 | 26.17±2.56 | 0.286 |
| Medium sized perforation | 32±3.15 | 34.17±3.02 | 0.304 |

P obtained by unpaired t test

Both temporal fascia graft and sliced tragal cartilage graft group of patients showed improvement in ABG 6 weeks after treatment (p<0.001) (Table V).

Table V: PTA-ABG result before and six weeks after myringoplasty (n=50)

| Graft type | | PTA-ABG (d | | |
|-------------------------------|-----------------------------|------------------|-------------------------|---------|
| | | Before operation | 6 Weeks after operation | P value |
| | | Mean±SD | Mean±SD | I value |
| Temporal fascia graft | Small Sized Perforation | 24.17±2.86 | 15±2.58 | < 0.001 |
| | Medium Sized Perforation | 32±3.15 | 20±3.13 | < 0.001 |
| Sliced tragal cartilage graft | Small Sized Perforation | 26.17±2.56 | 16±2.27 | < 0.001 |
| euronage grait | Medium Sized Perforation | 34.17±3.02 | 22±3.29 | < 0.001 |

Audiometry results showed a 12.19 ± 1.27 dB reduction in temporal fascia graft group and $6.55\pm.090$ dB reduction in sliced tragal cartilage graft group. The improvement was significantly higher in temporal fascia graft group (p<0.001) (Table VI).

Table VI: Comparison of improvement in audiometry results between two surgical groups. (n=50)

| | Tempora fascia gra | | Sliced cartilag | P value | |
|-------------|-----------------------|---------|--------------------|------------|--------|
| | Mean±S | D | Mean±SD | | |
| Improvement | Small | Medium | Small | Medium | <0.001 |
| in ABG | 9.17±0.32 | 12±0.02 | 10.17±0.29 | 12.17±0.27 | <0.001 |

P obtained by unpaired t test

Discussion:

Various graft materials including temporalis fascia, perichondrium, skin, vein, cartilage etc. have been used to repair the tympanic membrane perforation for a long time. There are variable results having merits and demerits of each graft material used in tympanoplasty. In this study sliced tragal cartilage and temporalis fascia were used as graft materials. In this study 50 patients of chronic inactive otitis media with small to medium sized perforation were surgically treated. Twenty-five patients were selected for repair with temporal fascia graft and another 25 with sliced tragal cartilage graft. The mean age of the patients studied was 32.30±10.93 years. Most patients were aged between 31 - 40 years (36%). Majority patients were male (58%) and 42% patients were female. Similarly, 54.76% patients were male and 45.23% where female were found in the study by Mazumder and colleagues¹². Santoshi Kumari et al found that 58.4% male and 41.4% female in their study involving patients with otitis media¹³. In the study 74% of patients had hearing loss, 72% had tinnitus, 60% had aural fullness, 18% had vertigo and 32% had earache. In comparison Islam et al found hearing loss in 83.3% patients of otitis media in a rural setting, earache in 15.6%, vomiting in 5.2%, vertigo in 5.2% and tinnitus in 2.1% among others¹⁴. The present study found that 48% of patients had inferior perforation, 28% had posterior perforation and 24% had anterior perforation. This is similar to the findings of Naderpur et al.¹⁵ They found central perforation in 56.7%, posterior perforation in 23.3% and anterior perforation in 20%. Graft uptake was significantly higher among patients who underwent myringoplasty with temporal fascia in comparison myringoplasty with sliced tragal cartilage graft (88% vs. 60%, p<0.05). This is nearly similar to the findings of Dabholkar et al¹⁶ who found respectively 84% and 80% graft uptake in patients who underwent myringoplasty with temporal fascia and sliced tragal cartilage. This is dissimilar to the findings of Kumar et al who noted graft uptake in 86.7% cases of temporal fascia graft and 93.3% cases of sliced tragal cartilage graft¹⁷. Initial PTA-ABG was similar in both types of surgical groups. In case of small sized perforation, ABG improved from 24.17±2.86 dB before surgery to 15±2.58 dB in temporal fascia graft patients and from 26.17±2.56 dB to 16±2.27 dB among sliced tragal cartilage graft patients. In case of medium sized perforation, ABG improved from 32±3.15 dB before surgery to 20±3.13 dB in temporal fascia graft patients and from 34.17±3.02 dB to 22±3.29 dB among sliced tragal cartilage graft patients. The improvement was significant in both group of patients (p<0.001). But temporal fascia graft group showed slightly higher improvement than cartilage group (p<0.001). Khan and Parab also found improvement in ABG of cartilage group (31.47±3.98 dB to 7.19±2.99 dB after surgery) and temporalis fascia group (30.98±3.54 dB to 6.86±2.39 dB after surgery)¹⁸. But the improvement slightly higher in tragal cartilage group in their study. No statistical analysis was done in their study. Another study by Telang et al¹⁹ found ABG improvement from 22.33±6.24 dB before surgery to 12.33±4.72 dB after surgery in temporal fascia group and from 20.77±5.75 dB to 10.50±4.46 dB after surgery in sliced cartilage group. Improvement was significant in both groups of patients. None of the procedures were found to be superior to one another. No major intraoperative and immediate postoperative complications like wound infection, sensory neural hearing loss, facial nerve palsy etc. were found in any patient of either group in the procedures. No cosmetic deformity of tragus was observed in reinforcement cartilage group. The present study endorses the finding that temporal fascia graft is superior to sliced tragal cartilage graft in the repair of tympanic membrane as it was a first-time study regarding cartilage using in tympanoplasty in our center, surgical expertise and post operative pt care may be an issue for lower graft uptake in cartilage group. The thickness of cartilage may be an issue for hearing outcome. 0.1mm thickness may give better hearing outcome in case of using sliced tragal cartilage.

Conclusion:

In conclusion, the study findings revealed that myringoplasty with temporalis fascia graft is superior to sliced tragal cartilage in chronic inactive mucosal otitis media patients. Temporalis fascia has shown its superiority in terms of graft intake and hearing improvement in subsequent follow up. However, this finding should be used with caution and further larger cohort is needed to conclude this finding.

Conflict of Interest: None.

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