

CLINICAL STUDY OF SUCCESS RATE OF TEMPORALIS FASCIA GRAFT BY UNDERLAY TECHNIQUE

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ABSTRACT

Background: Temporalis fascia which is placed as an underlay graft is commonly used to repair tympanic membrane perforations. Graft failure is a well recognized complication. **Aim:** A total of 100 cases were selected based upon inclusion criteria for this study, which is done to know the effectiveness of temporalis fascia as graft material for myringoplasty and also to know the hearing gain following this procedure. **Materials and Methods:** The present study was conducted from the patients attending the outpatient department of E.N.T., Alluri Sita Rama Raju Academy of Medical Sciences from the month of August, 2010 to March, 2012. Patients between 18-48 years of age presenting with chronic suppurative otitis media, tubotympanic disease whose ear is dry for last 4 weeks and post operatively patient is followed till 6 months were the inclusion criteria. **Results:** This is a hospital based prospective study. Of the 100 cases, the age group of the patient varied from 18 to 48 years. There was no correlation between graft take rate and age. There were 58 females and 42 males. 70 cases belonged to lower socio-economic strata and 30 cases belonged to middle income group. Bilateral chronic suppurative otitis media was seen in 27 cases. 34 cases in our study had perforation of more than 50% in size, in which the graft take up rate was very poor. Site of perforation did not have much effect on the outcome of graft status. The preoperative pure tone average mean in our study was 31.85 dB and postoperative pure tone average mean was 16.10 dB, thus the hearing gain was 15.75 dB. The overall success rate of graft take up in our study is 87%, while 60 of them had hearing improvement of 10 to 20 dB, also hearing improvement of more than 20dB in 27 patients and improvement was less than 10dB in 13 patients. The most common cause for graft failure in our study was postoperative infection, the other cause being faulty technique of operation, Eustachian tube dysfunction. **Conclusion:** The study concluded that the outcome of myringoplasty does not depend on age and sex. Tympanic membrane with perforation of more than 50% have poor take up rates. Site of perforation did not have relevance with graft take up. There is a mean hearing gain of 15.75 dB in patients who had undergone myringoplasty with graft taken up. Postoperative infection, Eustachian tube dysfunction and faulty technique are the common reasons for graft failure.

Keywords: Tympanic Membrane, Myringoplasty, Eustachian tube.

INTRODUCTION:

Chronic suppurative otitis media is one of the common otological conditions in India for which patients seek advice from an otorhinolaryngologist. Poverty, illiteracy, poor hygiene and overcrowding are all factors which play an important role in causation of this disease. Various surgical modalities of treatment have been tried since ages, to repair the tympanic membrane perforation, with varying degrees of success rate. One such modality of treatment is Myringoplasty. The perforation seen in chronic suppurative otitis media may be the only sequelae remaining when the pathological process in middle ear cleft has healed.¹ It exposes the middle ear mucosa to exogenous source of infection and also produces conductive hearing loss, to address these issues the surgical technique of Myringoplasty was developed, which is reconstruction of tympanic membrane perforation.

Different materials have been used to reconstruct the tympanic membrane, most accepted of which is the temporalis fascia, because of its qualities of low metabolic rate, requiring lesser blood supply and is more resistant to infection.² In the present study an attempt is made to study the effectiveness of temporalis fascia as graft material and the improvement in hearing following its grafting. Preoperative symptom analysis, audiological assessment, graft uptake, postoperative symptom analysis, postoperative audiological assessment, complication and follow- up is presented in the study.

MATERIALS AND METHODS:

The present study was conducted from the patients attending the outpatient department of E.N.T., Alluri Sita Rama Raju Academy of Medical Sciences from the month of August, 2010 to March, 2012. One hundred cases were selected for this study. Patients presenting to the outpatient department and fulfilling the below mentioned criteria were taken up for study. Patients between 18-48 years of age presenting with chronic suppurative otitis media, tubotympanic disease whose ear is dry for last 4 weeks and post operatively patient is followed till 6 months were the inclusion criteria. Patients with active chronic suppurative otitis media. Patients of less than 18years or more than 48 years. Patients with perforation in an only hearing ear and presence of cholesteatoma. Presence of active otitis externa were excluded from the study. Hundred patients fulfilling these criteria were selected randomly for the study. These patients were evaluated audiological prior to enrolment, the ear drum perforation was quantified as small sized if the perforation involved less than 25% of the surface area of tympanic membrane, medium sized if it involved between 26%-50% and large sized if the perforation involved more than 50%.

Table 1: WHO classification of hearing loss:

Hearing threshold in better ear	Degree of impairment
0-25 dB	Not Significant
25-40 dB	Mild impairment
41-55 dB	Moderate impairment
56-70 dB	Moderately severe impairment
71-91 dB	Severe impairment
>91 dB	Profound impairment

Preoperative assessment included, complete clinical history, through ENT examination, X-ray mastoids, audiogram and routine blood and urine investigations as per the proforma. Anaesthesia used was local anaesthesia. The technique employed in all the patients was post-aural underlay technique of Myringoplasty. Harvesting the temporalis fascia graft, freshening of edges of perforation, elevation of tympanomeatal flaps along with annulus and entry into middle ear by incising the middle ear mucosa. Then skeletonising the

handle of malleus and placing graft medial to it such that it covers the entire perforation. Postoperatively the patients were discharged on 7th post-operative day. Systemic antibiotics and antihistaminics were routinely administered for 7 days. Analgesics were prescribed symptomatically. Antibiotic ear drops are prescribed for 2 – 3 weeks. Metal pack was removed after 3 weeks, neodrum was inspected, and patients were told to follow up regularly at weekly intervals to note the uptake of graft for 6 months. Audiological evaluation was done post-operatively after 2 months. The outcome was taken as successful: if at the end of 3 months the graft was still in situ and acted as a scaffold for the epithelial healing and an effective hearing gain of at least more than 10 dB. Failure: if there is remnant perforation or graft rejection after 3 months, or if there is hearing gain of less than 10 dB. Early failure is graft rejection within 3 weeks of surgery and late failure is graft rejection after 1 year of surgery.

RESULTS:

Table 2: Distribution based on demographics such as age, sex, socio-economic status,

Age group	Number of patients	Percentage
18 to 27	43	43
28 to 37	40	40
38 to 48	17	17
Sex	Number of patients	Percentage
Male	58	58
Female	42	42
Income Group	Number of patients	Percentage
Low income	70	70
Middle income	30	30
High income	0	0
Total	100	100

Table 2 shows that of the 100 cases that were operated, the age of the patient varied between 18 and 48 years, i.e. the youngest of the patient was 18 years and the eldest was 48 years. In the present study of 100 patients, 58 were female patients and 42 were male with male: female ratio of 1:1.3. 70 cases (70%) belonged to low income group and 30 cases (30%) belonged to middle income group. None of the patients were in the high income group.

Table 3: Ear Involved

Side	Number of patients	Percentage
Righ	40	40
Left	33	33
Bilatera	27	27
Tota	100	100

Table 3 shows that the incidence of bilateral ear discharge was, seen in 27% of the patient, in right ear it was 40%, and in left ear it was 33%.

Table 4: Perforation Size

Size	Number of cases	Percentage
Small	16	16
Medium	50	50
Large	25	25
Subtotal	9	9
Total	100	100

Table 4 shows that 16 cases (16%) had small size perforation, 50 cases (50%) had medium size perforation, 25 cases (25%) had large size perforation and 9 cases (9%) had subtotal perforation.

Table 5: Preoperative hearing loss (Pure tone Average)

Loss in dB	Number of patients	Percentage
16 - 25	33	33
26 - 40	43	43
>40	24	24

Table 5 shows that 33 patients (33%) had no significant deafness (16 – 25 dB), 43 patients (43%) had mild deafness (26-40 dB), and 24 patients (24%) had moderate to severe deafness (> 40 dB).

Table 6: Graft Status

Graft	Number of cases	Percentage
Taken up	87	87
Not taken	13	13

Table 6 shows that who had undergone Myringoplasty in our hospital, there was graft take up in 87 cases (87%) and in 13 cases (13%) graft did not take up.

Table 7: Post-operative hearing gain

Hearing gain	Number of patients
<10dB	1
	3
	6
10 – 20dB	0
> 20dB	2
	7

Table 7 shows that 60 of them had hearing improvement of 10 to 20 dB ,there was hearing improvement of more than 20dB in 27 patients and the improvement was less than 10dB in 13 patients.

Table 8: Mean hearing gain

Pure tone average mean		Hearing gain
Pre operative	Post operative	
31.85 dB	16.10dB	15.75dB

Table 8 shows that the mean preoperative hearing threshold is 31.85dB and the mean post operative hearing threshold is 16.10dB and the mean hearing gain after surgery is 15.75dB.

DISCUSSION:

The present study was conducted from the patients attending the outpatient department of E.N.T., Alluri Sita Rama Raju Academy of Medical Sciences from the month of August, 2010 to March, 2012. One hundred cases were selected for this study. Out of which (58) were male and (42) were female. The age of patients varied from 18 to 48 years. Ages below 27 years were 43, age group between 28 to 37 years was 40 in number and age group above 38 years is 17 cases. Children were not taken up for study. Michael and Glasscock et al. (1982)³ reported in their study of 1556 tympanic membrane grafting that there was no difference in take rate of graft based upon age of the patient. In the present study of 100 cases, the age of patient varied between 18 and 48 years, the take up rate of graft for different age group was the same, which suggests that age did not made any difference in take rate. Browning GG (1997)⁴ states that there is a close relationship of chronic otitis media and low socio economic group. Higher incidence is because of poor general health, malnutrition and overcrowding. In the present study of 100 cases, 70 cases (70%) belonged to low income group. Low income group in our country is associated with ignorance and illiteracy, and the thus there is more prevalence of chronic otitis media in this group.

Caye–Thomasen et al. (2007)⁵ in their study of 26 cases, male to female ratio was 1.36. John Mathai (1999)⁶ in his study of 200 cases, the male to female ratio was 1:23. In the present study of 100 cases, we had 58 females and 42 males who underwent Myringoplasty, with male to female ratio of 1:1.3, which correlates with studies. Robert K Jackler and Robert A Schindler (1984)⁷ in their study of 48 patients, bilateral tympanic membrane perforation was seen in 25% of patients. John B Booth (1974)⁸ in his study of 284 cases, found the incidence of bilateral discharge to be 30%. In the present study of 100 cases, 40 cases (40%) had right ear disease, 33cases (33%) had left ear disease, and 27 cases (27%) were having bilateral disease. This correlates well with the quoted literature.

John B Booth (1974)⁸ in a large series of Myringoplasties demonstrated that for perforations which involved less than 50% of tympanic membrane, higher closure rate were achieved than the perforation of more than 50%. Adkins WY, White B (1984)⁹ in their study of 71 cases found that high failure rate in graft take up in cases with presence of a near total or total perforation. In the present study, out of 100 cases, small size perforations were 16, medium sizes were 50, and large were 25 Subtotal perforations in 9 cases. In all cases handle of malleus was healthy and well covered. Other features like aural polyp, granulations and cholestoma were absent. Tuning fork tests revealed conductive type of deafness. X-ray paranasal sinuses showed haziness in 20 cases. Preoperative pure tone threshold ranged from 16 to 45dB. The foci of infection removed prior to surgery. Halik, Smyth (1988),¹⁰ in their study, found higher risk of failure of graft in anteroinferior quadrant because of poor visualization. In the present study, the site of perforation carried no significance.

Caye–Thomasen et al. (2007)⁵ in their study of 26 cases, noted that the mean preoperative pure tone average to be 26.1 dB, the mean postoperative pure tone average of 11.5 dB and thus the mean hearing gain of 18.6 dB. Brown C et al. (2002)¹¹ in their study of 193 cases of Myringoplasty, the mean preoperative air conduction average was 35.20dB, while the mean

postoperative air conduction average was 25.87dB, thus average air conduction improvement was 10.33dB. In the present study of 100 cases, the preoperative pure tone average showed that 43 cases (43%) had PTA of 26-40 dB, 33 cases (33%) had PTA of 16 – 25 dB and 24 cases (24%) had PTA of more than 40 dB. The mean being 31.85 dB. The post operative PTA was taken 2 months after the surgery, which shows that, 87 cases (87%) of the total cases in which graft was taken had PTA average gain of more than 10dB. The postoperative pure tone average mean was 16.10 dB. Thus hearing gain in our study was 15.75 dB.

Palva T and Vistanen H (1982)¹² in their study of 172 cases, found a number of successfully repaired tympanic membrane of 153 (89%). Albera R et al. (2006)¹³ in their study of 212 patients, found a graft take rate of 86% (182 cases). In the present study of 100 cases of Myringoplasty, all patients underwent postauricular underlay temporalis fascia grafting, in which the graft take up was seen in 87 cases and so the graft take rate in our study was 87%, which very nearly correlates with the quoted literature.

Michel E Glasscock (1993)¹⁴ in his study of 100 cases, reported 7 cases of graft failure. In which 4 were due to immediate postoperative infection and 2 were due to technical error at the time of graft placement. In the present study of 100 cases, there were 13 cases of graft failure; the most common cause for failure was post-operative infection, which was seen in 5 cases, 5 cases failed due to eustachian tube dysfunction and 3 cases failed due to faulty technique. This is in correlation with the quoted literature.

Conclusion:

The conclusions drawn from this study are as follows; the outcome of myringoplasty does not depend on age and sex. Tympanic membrane with perforation of more than 50% have poor take up rates. Site of perforation did not have relevance with graft take up. There is a mean hearing gain of 15.75 dB in patients who had undergone myringoplasty with graft taken up. Postoperative infection, Eustachian tube dysfunction and faulty technique are the common reasons for graft failure. Local anaesthesia has the following advantages such as less bleeding, the greater overall safety of the patient, risk to larynx and trachea eliminated, post operative nausea and vomiting are less, under LA hearing can be tested and reduced cost to patients. Temporal fascia is a standard graft because of its easy availability, availability near the site of the operation, sufficient material, immunological inertness and low nutrients requirements. Post aural route approach was easy graft and can be taken same incision and superior functional results. Underlay technique of myringoplasty the meatal flap help the stability, fixation and vascularisation of graft and also prevent lateralization of the graft as well as anterior blunting. Long term result of graft behavior appears excellent. Post aural underlay technique myringoplasty will yield fewer complications as well as superior functional results.

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