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Comparision of graft uptake and audiological outcomes in dry and wet ears with chronic suppurative otitis media; a prospective observational study

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Abstract

Background: Chronic otitis media (COM) is a routinely occurring health problem that causes a multitude of symptoms ranging from purulent ear discharge to reduced human functionality due to impaired hearing. This study is done to determine the rate of graft uptake and post operative hearing improvement in dry and wet ear in mucosal COM, where dry group had no discharge for >3 months and “wet” group comprised patients with scanty mucoid/mucopurulent discharge at the time of surgery. In our study, patients of age <18 years and >55 years, squamous COM, complications and revision tympanoplasty were excluded.

All 50 cases underwent Underlay Type-1 Tympanoplasty with the use of temporalis fascia for neo-tympanum reconstruction. The graft uptake and improvement in hearing were compared based on otoscopic findings and pure tone audiograms at second and third months post-operatively. Intact graft was seen in 22 patients in dry (88%) and 20 patients in wet group (80%). 3 in dry and 5 in wet group showed residual perforation. Graft uptake rate was better in dry group, but not statistically significant.

Results : Pre-operatively, mean pure tone threshold (PTT) in wet and dry groups was 31.6 dB and 31.8 dB respectively. In the second post-operative month, mean PTT was 22.4 dB in wet and 21.2 dB in dry groups. After 3 months, mean PTT of 20.6 dB in wet and 21 dB in dry group was observed. Hearing improvement was seen in 88% cases in dry ear and 80% in wet ear, but *p value* yet again showed no statistical significance.

Conclusion: presence of discharge in the ear at the time of surgery does not interfere with the success rate of type-1 tympanoplasty in terms of re-epithelialization of graft and subsequent establishment of improved audiological function

INTRODUCTION

Chronic otitis media (COM) is defined as a chronically discharging ear for 3 months or more, which fails to respond to medical management (1). Patients typically complain of otalgia, purulent otorrhea and a decrease in day-to-day functionality due to a reduced hearing. A dry ear suggests an ‘inactive mucosal type of COM’ where no discharge is present at the time of surgery, whereas wet ear suggests an ‘active mucosal type of COM’ wherein the ear is discharging at the time of surgery. The indication of surgery in both scenarios is to halt disease progression, prevent recurrence as well as restore hearing. In both categories of patients, the most prioritized concern remains impaired hearing. To bridge this impairment, irrespective of the outcome of medical management, the only option is surgical (1).

Surgical procedures for chronic ear diseases are designed to achieve a safe ear through disease clearance, prevention of further progression of the disease and provide imrpoved hearing by reconstructing the tympanic membrane (neo-tympanum) and ossicular chain mechanism. The most commonly exhausted surgical technique is a type 1 tympanoplasty, which aims at closing the defect in the tympanic membrane by construction of a new tympanic membrane. For this, with the use of

autografts like, temporalis fascia, fascia lata, perichondrium, cartilage, dura mater, vein graft and rarely split thickness skin graft (STSG) are used, all with varying surgical results (2).

Temporalis fascia is a free graft which has been used the most frequently in the last thirty years (3) with varying degrees of success. While it is accepted that a discharging ear is not a contraindication to tympanoplasty (3), the success rate of surgery on a pre-operatively discharging ear in terms of graft uptake and functional outcomes has not been studied at length. Hence, in this study, we aim to assess post-operative outcomes on patients with both inactive and active mucosal COM and compare their rates of graft uptake and improvement in audiological function.

MATERIALS AND METHODS

The present prospective observational study involves fifty patients enrolled by purposive sampling, divided into two groups (dry and wet mucosal types of COM) of twenty-five patients each, during period from December 2015 to November 2016 at a tertiary care hospital in Pune, India. Approval was obtained by the Institutional Ethics Committee prior to the participant recruitment process.

Dry group included patients with no ear discharge for a minimum of three months and at the time of surgery. Wet group included patients with purulent/mucopurulent ear discharge at the time of surgery. The success of surgery was studied based on presence and absence of discharge in varying sizes of central perforations in the pars tensa (small, moderate, large and subtotal perforation) and status of middle ear mucosa at the time of surgery.

Patients were enrolled after taking due informed written consent. A detailed history of the patients was charted along with specific histories of immunocompromised status or comorbidities which may confound results of graft uptake. The type of ear and size and location of perforation were documented. Exclusion criteria included patients of age less than 18 years and more than 55 years, with marginal/ attic perforation/ cholesteatoma or any evidence of a squamous type of COM, with one or more intracranial and extracranial complications of COM, with immunosuppressive illness or immunosuppressive therapy which may interfere with the quality of the results. Patients undergoing revision tympanoplasty were also excluded from our study.

Detailed clinical examination - which included general examination and a thorough ENT examination - was done and disease status noted. Examination of the tympanic membrane under microscope and pure tone audiogram (PTA) was done for assessment of hearing loss and degree of hearing loss. Under suitable anesthesia, an underlay technique of Type-1 Tympanoplasty through post-aural approach with the use of temporalis fascia as a graft material was performed.

These patients were then followed up monthly for three months. At every monthly visit, an otological examination of the ear was undertaken to assess the status of the thus placed temporalis fascia graft and the rate of its uptake as the neotympanic membrane. In the second and third post-operative months, PTA was repeated to assess post-operative improvement in audiological function.

RESULTS

The data thus collected was subjected to statistical analysis using SPSS software version 20 and test of significance was applied to confirm whether the post-operative results thus obtained had any statistical significance. In the present study, it was observed that graft was well-taken in 22 patients and failed in 3 patients of dry group whereas graft was accepted in 20 patients of and failed in 5 patients with wet ear. As the *p-value > 0.05* using unpaired t-test, there is no statistical significance established between graft uptake in both groups (Table 1). Combining both groups, uptake is observed in a total of 84% patients (N1=42) and failure in 16% patients (N2=8).

Graft uptake	Dry ear	Wet ear	Total (N)
	No. (%)	No. (%)	No. (%)
Taken (N1)	22 (88%)	20 (80%)	42 (84%)
Failure (N2)	03 (12%)	5 (20%)	8 (16%)

Table 1: Comparision of graft uptake between dry and wet ears

The size of the perforation was studied to explain the reason for graft uptake or failure. Out of 50 patients, 29 patients (58%) had a moderate central perforation (MCP) , 11 patients (22%) had large central perforation (LCP), 3 patients (6%) had small central perforation (SCP) and 7 patients (14%) had subtotal perforation (STP) (Table 2). On applying the Chi-square test, the differences were statistically insignificant, with p value=0.3609 {p>0.05}, which meant that while failure of uptake was noted across sizes, it negatively affected the overall outcome in both the groups.

	Dry ear		Wet ear		Total (N)	
Size of perforation	Taken (N1a)	Failure (N2a)	Taken (N1b)	Failure (N2b)	Taken (N1)	Failure (N2)
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
MCP	11 (22%)	01 (02%)	15 (30%)	02 (04%)	26 (52%)	03 (06%)
LCP	05 (10%)	01 (02%)	03 (06%)	02 (04%)	08 (16%)	03 (06%)
SCP	03 (06%)	-	-	-	03 (12%)	-
STP	03 (06%)	01 (02%)	02 (04%)	01 (02%)	05 (04%)	02 (04%)
Total cases	22 (44%)	03 (06%)	20 (40%)	05 (10%)	42 (84%)	08 (16%)

Table 2 : Comparision of graft uptake in dry and wet ears with different perforation sizes

On microscopic examination during surgery, status of middle ear mucosa was assessed and recorded. 2 patients (4%) in wet group (total 50% patients) had edematous mucosa with 1 patient (2%) experiencing graft failure, 3 (6%) patients had inflamed mucosa, 6 (12%) had pale mucosa and rest 14 patients (28%) had healthy mucosa. In the dry group (50%), 16 patients (32%) had healthy mucosa, 9 patients (18%) had pale mucosa. No inflammation or edema was noted in the dry group. Graft uptake (total 84%) was found in 54% of healthy, 24% of pale, 4% of inflamed and 2% of edematous middle ear mucosa (Table 3). Statistically no significant difference was observed based on middle ear mucosa between the two groups, with p value = 0.1253 {p>0.05}

Status of Middle Ear Mucosa	Graft uptake (N1)		Graft failure (N2)		Total cases (N)	
	Dry	Wet	Dry	Wet	Dry	Wet
Healthy	15 (30%)	12 (24%)	01 (02%)	02 (04%)	16 (32%)	14 (28%)
Pale	07 (14%)	05 (10%)	02 (04%)	01 (02%)	09 (18%)	06 (12%)
Inflamed	-	02 (04%)	-	01 (02%)	-	03 (06%)
Edematous	-	01 (02%)	-	01 (02%	-	02 (04%)
Total cases	22 (44%)	20 (40%)	3 (06%)	05 (10%)	25 (50%)	25 (50%)

Table 3 : Comparision of Middle ear mucosa with status of graft uptake

In our study, hearing improvement was assessed by repeat pure tone audiometry in second and third post-operative months. Preoperatively, mean pure tone threshold (PTT) in wet group was 31.6 dB and 31.8 dB in dry group. Hearing improvement was seen in 22 out of 25 patients in dry ear and 19 out of 25 patients in wet ear. At second month, mean PTT was 22.4 dB in wet and 21.2 dB in dry groups. PTA after three months of follow-up showed mean PTT of 20.6 dB in wet and 21 dB in dry group (Table 4). Postoperatively hearing gain was 0-5 dB in none of the patients with dry or wet ear; 6-10 dB in 12 patients with dry ear and 6 patients with wet ear; more than 10 dB in 10 patients with dry ear and 14 patients with wet ear, earning a statistical p-value = 0.2734 (p>0.05) which is insignificant. There was an average hearing improvement of 10.8 dB in dry ear group and 11 dB in wet ear group. For test of significance, we used the test of significance difference between two means and the results were found to be statistically insignificant.

Duration	Mean (dB) ± Standard deviation S.D	Mean (dB) ± Standard deviation S.D
	Dry ear (N_d=25)	Wet ear (Nw=25)
Pre operative	31.8 ± 5.75	31.6 ± 5.35
2nd month	21.2 ± 8.45	22.4 ± 7.79
3rd month	21 ± 8.42	20.6 ± 8.33
Mean improvement	10.81	11.0

Table 4: Comparison of PTA (in dB) between wet and dry ear at 2 months and 3 months

DISCUSSION

Type-1 tympanoplasty is a commonly performed procedures in Otorhinolaryngology. With advanced microsurgical techniques and modern equipments, the state of the art facility has now developed to an extent that good graft success rates are to be expected. Several studies conducted in the past have reported good results with type – 1 tympanoplasty with respect to hearing improvement, graft uptake and the overall achievement of a safe, functional ear.

Various factors influencing the success rate of this procedure have been discussed in the literature. The presence of active ear discharge at the time of surgery presents the surgeon with the dilemma of whether to operate or not. But since discharge is not a contraindication to an impending operative decision (1, 3), the important factors which decide the rate of graft uptake and the subsequent success are the size of the perforation and the intra-operative status of middle ear mucosa which have been considered in our study.

In both groups, size of the perforation adversely affects graft uptake. This can be attributed to thin nature of the remnant tympanic membrane, hampered visibility, failed graft overlap and reduced vascularity to the margins of perforation in dry group and thick residual tympanic membrane and increased vascularity of the inflamed tympanic membrane respectively (4). Higher failure rates in subtotal perforations have been attributes to a larger area that needs to be vascularized and epithelialised

Sudhanshu SB (5) found that medium sized perforation was the commonest one in their study and with graft uptake of 91.3%. Emir et al (6) found bigger perforations had the success rate of 75.8% while the smaller perforations had the success rate of 87.5% and the difference, statistically significant. Suprisingly, Benjamin D (7) found success rates for small and large perforation were 93.0% and 85.1% which was stark, yet not statistically significant.

Dhar et al found that graft uptake rate was seen in 96% cases of dry ear and 84% cases in wet ear and there was no significant difference between the two groups. However, better graft uptake rate was observed in small and medium sized perforations (8). Overall, in cases with perforated tympanic membrane, perforations less than 50% of the drum surface performed significantly better than the larger ones in relation to hearing improvement (9).

Through literature, it was also observed that the status of the middle ear mucosa at the time of surgery also aided in providing adequate results leading to graft uptake. Chopra H et al observed graft uptake in 100% of normal, 85.7% of congested and 58.8% of congested *and* edematous middle ear mucosa (10). In a similar study done by Warren et al (11) and Debora et al (12), where former observed success in temporalis fascia graft uptake in 89% cases with congested mucosa, the latter found results similar to the former under normal mucosal conditions

Despite of the high success rate and routine nature of the procedure, the effect of many influencing factors still remains questionable. It is often advocated by few authors to render the ear absolutely dry before attempting tympanic membrane repair to obtain more favorable results (13).

Glasscock et al's study showed better results than our study (14), however with no statistical significance. He opined that good results were independent of the status of the ear. Ceylan (15) studied 865 cases and found only marginally better results in 88.6% of patients with wet ear and 88% cases with dry ear, inferring that the status of the operated ear did not influence the graft success rate and that the most significant factor influencing the results was the surgical skill.

In a case study of 100 patients by Nagle SK et al (16), it was observed that complete graft uptake in was seen 44 (88%) of cases with dry ear and 37 (74%) cases in wet ear. Both Ceylan and Nagle's studies showed results which were comparable to our study wherein in 50 patients equally divided, 80% showed graft success in wet ear and 88% in dry ear.

91% patients with wet ear and 89% of those with dry ear had successful graft uptakes in a study Sinha et al (17), Raj A, Vidit T (18), Booth et al (19) and Naderpour (20) confirmed that the preoperative presence of a dry ear did not affect surgical success or complication rates. Vartiainen E found that necrosis of the graft and anterior blunting were the main causes of early failures and could not be attributed to the status of middle ear mucosa, size of the perforation or discharge (21).

Not only graft uptake but in these studies even the audiograms pre-operatively and post-operatively were compared. Ceylan et al's (15) study used a post-operative air-bone gap of less than 25 dB and hearing gain of > 10dB as a benchmark for physiological success and in his study, this was achieved by 77.7% cases in dry and 78.4% in wet ears. Results on improvement on audiological function have been varying. Where Benjamin D et al (7) found post operative hearing gain for dry and wet ear were not statistically significant, Tos M (22) observed more than 10 dB hearing gain in 87% in dry ears and 66% in wet ear group. Raj et al (18) too observed in patients undergoing myringoplasty in wet ear showed improvement in hearings in 68% of the patients while Eero Vartiainen et al (21) observed that the pre-operative ear

status whether dry or wet did not significantly affect the closure of air-bone gap. Deosthale et al found statistically insignificant differences between hearing in both groups (23). Naderpour (20) and Hosny (24) also found no statistical hearing improvement between two groups.

Thus, the success rate of tympanoplasty in terms of graft take up rate and hearing improvement, as found in our study, was consistent with the results of most studies in the literature. Even so, it should be reaffirmed that post-operative care follow-up along with meticulous graft placement will go a long way in achieving surgical success (25).

CONCLUSION

With the p-value consistently insignificant, it can be concluded that the presence of discharge, status of middle ear mucosa and size of perforation at the time of surgery does not interfere with the success rate of type-1 tympanoplasty with respect to re-epithelialization of graft and establishment of an improved audiological function.

LIMITATIONS OF THE STUDY

The present study has certain limitations. With respect to epidemiology, our study was conducted at a single centre with a limited sample size (N = 50), which may have reduced the statistical power to detect subtle differences between the dry and wet ear groups. Hence, the findings may not be generalizable to broader populations and multiple multicentric studies may be needed to calculate and extrapolate generalizable results. Socioeconomic factors and habits such as smoking and nutritional status were not considered in the our study. On the surgical front, only one graft material (temporalis fascia) and a single surgical technique (underlay type-1 tympanoplasty via post-aural approach) were employed. The success rates with other techniques and graft materials can neither be commented upon nor can be extrapolated. Follow-up period was limited to three months, precluding assessment of long-term graft integrity, late failures due to hidden disease nidus, and raising questions about sustained audiological outcomes. Finally, audiological assessment was limited to pure tone audiometry without inclusion of air–bone gap closure or speech audiometry.

Declarations

HUMAN ETHICS AND CONSENT TO PARTICIPATE

All procedures performed in the study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed Consent Informed and written consent was taken from all the participants

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Author Contribution

The chief operating surgeons in this study were Dr P Khairnar, Dr A More, Dr S Joshi with Dr Mishal I as second surgeon. The analysis was performed and compiled by Dr Amit Morey, Dr Mishal Ibji

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