International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 14, No. 2, February 2025 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_14.2.2025.23

ORIGINAL RESEARCH

A Single-Blinded Randomized Prospective Study Comparing Dry Versus Wet Temporalis Fascia Grafting In Participants With Chronic Otitis Media Undergoing Type-1 Tympanoplasty

[1]Dr. Aishwarya Sridhar, [2]Dr. Sathish Kumar, [3]Dr. Soujanya Balaraj

[1]Senior Resident, Department of ENT, Ramaiah Medical College Hospital, Bengaluru,Karnataka, India.
[2]Professor, HOD, Department of ENT, Vydehi Institute of Medical Sciences and Research Centre, Bengaluru, Karnataka, India.
[3]Assistant Professor, Department of ENT, Ramaiah Medical College Hospital, Bengaluru, Karnataka, India.

Corresponding Author
Dr Aishwarya Sridhar
Senior Resident, Department of ENT, Ramaiah Medical College Hospital, Bengaluru,Karnataka, India.

Received: 22 December, 2024 Accepted: 27 January, 2025 Published: 05 February, 2025

ABSTRACT

Background: Chronic Otitis Media(COM) affects 65-330 million globally, 60% of whom have hearing impairment.[1] It presents as recurrent ear discharge through a perforated tympanic membrane. The perforation mostlystemsfrom middle ear infections, apart from trauma and iatrogenic factors.[2]Persistent infections lead to chronic perforation, necessitating tympanoplasty. Type-1 tympanoplastyis repair of tympanic membrane perforation, utilizing Temporalis Fascia(TF) grafts.The limited studies comparing dry versus wet TF graftsprompted us to pursue this study.

Objectives: Comparison ofhearing improvement and graft uptake and placement time between the two groups.

Materials &methods: Sixty blinded participants with COM were randomized into two groups one received the dry and the other received the wetTF graft.Graft placement time, pre and post-operative audiometry, and graft uptake were assessed.Descriptive statistics was used for categorical and continuous data. Chi-square and Mann-Whitney U tests were done to compare between groups.

Results: Our findings were similar between the dry graft and wet graft groups' concerning hearing loss improvement (mean±SD= 14.33±5.42 dB and 14.17±5.09 dB, respectively,$p<0.94$) and graft uptake [27(90%) and 26(86.7%) participants, respectively, $p<0.69$].On average the dry graft placements were completed earlier (mean±SD=5.77±1.07minutes) than the wet graft placement(mean±SD=10.47±1.48 minutes). This difference was significant($p<0.001$). Both groups experienced no postoperative complications.

Conclusion: Based on our study and existing research, we conclude that dry and wet TF grafts produce comparable hearing improvement and graft uptake. Dry grafting offers shorter placement times without compromising outcomes, providing surgeons with anexpeditious approach.

Keywords: Chronic Suppurative Otitis Media (CSOM), Audiometry, Pure Tone Audiometry(PTA), Conductive Hearing Loss, Tubo-Tympanoplasty, Grafts, Graft Placement Time.

INTRODUCTION

Hearing impairment is a significant societal challenge, impacting individuals emotionally, socially, and physically. Such impairment can arise from congenital or acquired causes. Chronic otitis media (COM) is a common ailment seen in ENT clinics among acquired conditions. Which disproportionately affects those hailing from lower socioeconomic groups. It is a prevalent and potentially preventable cause of conductive hearing loss.[3]COM is characterized by persistent middle ear and mastoid cavity inflammation, leading to recurring ear discharges via a perforated tympanic membrane. Global estimates indicate 65-330 million are affected, of whom 60 % have hearing impairment.COM accounts for 28000 deaths with a disease burden of more than 2 million DALYs.[1]

Infections of the middle ear predominantly cause tympanic membrane perforations, with trauma and iatrogenic factors also contributing. While many perforations heal naturally, chronic cases lead to non-healing perforations that necessitate surgical intervention like tympanoplasty.[4]Historically, tympanic membrane repair dates back centuries, with

DOI: 10.69605/ijlbpr_14.2.2025.23

type-1 tympanoplasty focusing on maintaining ossicular integrity. Several graft materials are available like temporalis fascia (TF), tragal perichondrium, fascia lata, split-thickness skin graft, and vein graft with varying success rates. In 1958 Heermann was the first to use temporalis fascia for the reconstruction of the tympanic membrane. Temporalis fascia is pivotal in such surgeries due to their availability in the same region, easy harvest, sufficient amount, and high success of graft uptake. However, concerns regarding graft longevity have prompted considerations of alternative materials like perichondrium or cartilage.[5,6,7]

The timing of temporalis fascia harvest during surgery-either dry (rigid) or wet (soft)-has intrigued researchers, prompting investigations into the success of graft uptake, procedure durations, and patient audiology results. Only a few studies have been done that compare dry graft with wet graft type-1 tympanoplasty. Hence, with this background, we designed this study to analyze and comparesuccess rates of graft uptake, procedural efficiency, and hearing outcomes between participantsreceiving dry versus wet temporalis fascia grafts during type-1 tympanoplasty.By exploring these variables, this research seeks to enhance our understanding of how temporalis fascia graft properties, including moisture levels during grafting, may influence surgical success and patient Hearing improvements.

MATERIALS & METHODS

Study Design: This was a single-blinded prospective randomized study.

Ethics and Selection Criteria

The study was conducted in accordance with the Declaration of Helsinki and following the approval from the institutional ethics committeeof Vydehi Institute of Medical Sciences and Research Centre, Whitefield, Bangalore.A written informed consent was taken from participants who were enrolled during the period between September 2018 to August 2020. Consentingparticipants aged 16 years and above of either gender with central perforation (of any size) of the tympanic membrane, along with mild to moderate conductive hearing loss attending the ENT clinic were enrolled. Those with attic perforation, cholesteatoma, contraindications to undergo surgery, undergoing revision tympanoplasty, having COM with complications, experiencing sensorineural hearing loss, and those who withdrew consent were excluded from the study.

Methodology

Enrolled participants were randomized into dry and wet grafting groups by a computer-generated randomization table. The selected participants were subjected to detailed clinical examination, audiological evaluation, and laboratory investigation before and after type-1 tympanoplasty. All the surgeries were done by a single surgeon to reduce inter-surgeon bias.

Outcome Measures: Hearing improvement in terms of pure tone audiometry (PTA) results, graft uptake, and graft placement time were measured in both groups for comparison.

Statistical Analysis

Both descriptive and inferential statistics were applied to the data collected. All categorical data were expressed as proportions (%) and continuous data as mean±SD. The chi-square test was used to detect any association between disease characteristics and the type of graft used and to compare graft uptake between the groups. Mann-Whitney U Test was used to compare Hearing Improvement and graft placement time, between the two groups. Data entry was done using Microsoft Excel and all analyses were done at 5% significance using Microsoft Excel and SPSS version 22.0.

RESULTS

Demographics

Overall, 60 participants with COM needing type-1 tympanoplasty were enrolled, 50%(n=30) were randomized into the dry graft group and 50%(n=30) into the wet graft group.The mean agein the drygraftgroup was 34.53 years,whereas in the wet graftgroup, it was 30.50 years. An equal distribution of gender and age between the two groups was observed as depicted in table no 1

.

		Dry graft n (%)	Wet graft n (%)	P value
Gender	Male	15 (50%)	16 (53.3%)	0.80
	Female	15 (50%)	14 (46.7%)	
Age (years)	≤20	03 (10%)	07 (23.3%)	0.66
	21-30	13 (43.3%)	11 (36.7%)	
	31-40	06 (20%)	06 (20%)	
	41-50	04 (13.3%)	04 (13.3%)	
	>50	04 (13.3%)	02 (6.7%)	
Table 1: Gender and age distribution across the dry and wet graft groups				
Chi-square test, p <0.05 is statistically significant				

DOI: 10.69605/ijlbpr_14.2.2025.23

Association between Disease Characteristics and Type of Graft Utilized

It was found that disease characteristics such as the ear involved (laterality), duration of ear discharge, size of tympanic membrane perforation, ear ossicles involvement, the middle ear mucosa status, and the pre-operative Pure Tone Audiometry (PTA) were equally distributed amongst the participants between the dry graft and wet graft groups as depicted in table no.2.

	Dry Graft n (%)	Wet Graft n (%)	P value
Laterality or Side Affected			
Right	10 (33.3%)	12 (40.0%)	0.56
Left	13 (43.3%)	09 (30.0%)	
Bilateral	07 (23.3%)	09 (30.0%)	
Duration of ear Discharge (years)			
≤1	10 (33.3%)	09 (30.0%)	0.90
2-5	08 (26.7%)	10 (33.3%)	
6-10	02 (6.7%)	01 (3.3%)	
>10	10 (33.3%)	10 (33.3%)	
Size of Tympanic Membrane Perforation			
Small	07 (23.3%)	02 (6.7%)	0.12
Medium	10 (33.3%)	16 (53.3%)	
Large	13 (43.3%)	12 (40.0%)	
Ear Ossicles Left Intact			
Maleus + Incuas + Stapes	26 (86.7%)	27 (90.0%)	0.69
Maleus + Stapes only	04 (13.3%)	03 (10.0%)	
Middle Ear Mucosa Status			
Normal	24 (80.0%)	26 (86.7%)	0.43
Hypertrophic	05 (16.7%)	02 (6.7%)	
Oedematous	01 (3.3%)	02 (6.7%)	
Pre-operative Pure Tone Audiometry (PTA)			
Normal hearing	05 (16.7%)	01 (3.3%)	0.14
Mild hearing loss	19 (63.3%)	25 (83.3%)	
Moderate hearing loss	06 (20.0%)	04 (13.3%)	

Table 2: Distribution of disease characteristics across the dry and wet graft groups

Chi-square test, p <0.05 is statistically significant

Comparison of outcome Measures between the Two Groups

Post-Op Pure Tone Audiometry (PTA) done 3 months after surgery showed that 49 participants (81.67%)had >10 dB hearing gain, of which 24 participants belonged to the dry graft group and 25 participants were from the wet graft group and the mean PTA gain was 14.33±5.42 and 14.17±5.09 dB in the dry and wet graft group respectively which is not statistically significant (p = 0.94) [Table no. 3 & 4].

		Dry Graft Group n(%)	Wet Graft Group n(%)	P-Value
PTAGain	<10 Db	06 (20.0%)	05 (16.7%)	0.74
	>10 dB	24 (80.0%)	25 (83.3%)	

Table 3: Comparison of PTA gain between the two groups

Chi-square test, p <0.05 is statistically significant

Group	N	PTA Gain (dB)[Mean±SD]	P-Value
Dry graft group	30	14.33 ± 5.42	0.94
Wet graft group	30	14.17±5.09	

Table 4: Comparison of mean Post-Op PTA gain between the two groups

Mann-Whitney U test, p <0.05 is statistically significant

On otomicroscopic examination done one-month post-surgery, 27 participants (90%) in the dry graft group and 26 participants (86.7%) from the wet graft group had intact grafts while the remaining experienced graft failure. The graft uptake was better in the dry graft group, but this was not statistically significant (p=0.69) [Table no.5]. Also, the mean graft placement time was 5.77±1.07 minutes and 10.47±1.48 minutes in the dry and wet graft group respectively, the difference was statistically significant (p<0.001) [Table no.6]. Neither group experienced significant postoperative side effects.

DOI: 10.69605/ijlbpr_14.2.2025.23

		Dry Graft Group n(%)	Wet Graft Group n(%)	P-Value
Graft uptake	Graft intact	27 (90.0%)	26 (86.7%)	0.69
	Graft failure	03 (10.0%)	04 (13.3%)	
Table 5: Comparison of graft uptake between the two groups				
Chi-square test, p <0.05 is statistically significant				

Group	N	Graft placement time (min)[Mean±SD]	P-Value
Dry graft group	30	05.77 ± 1.07	<0.001*
Wet graft group	30	10.47 ±1.48	
Table 6: Comparison of mean graft placement time between the two groups			
Mann-Whitney U test, p <0.05 is statistically significant *The difference in the graft placement time between the groups is statistically significant			

DISCUSSION

In our study, 60 participants were divided into dry and wet temporalis fascia graft groups, each with 30 cases. The gender distribution was comparable between the groups, with males and females almost equally represented. This is comparable to the study conducted by Singh GB et al., 2016; in which there were 27 males (54%)and 23 females (46 %) in the dry graft group and thewet graft group had24 males (48 %)and 26 females (52 %). Showing equal gender distribution.[8] The age range of 18 to 60 years was considered in this study, with mean ages of 34.53 years in the dry graft group and 30.50 years in the wet graft group. A study done by Deosthale NV et al., 2015; also observed a comparable mean age of 27.87±9.79 years.[9]In this study we observed an equal distribution of disease characteristics like laterality, duration of ear discharge, size of tympanic membrane perforation, which ear ossicles were leftintact, middle ear mucosa status, and pre-op PTA amongst the participants in both the groups. This implies that the two groups have comparable baseline characteristics and none of the disease characteristics significantly affect the outcome measures.

Post-Op PTA at 3 months was done for all the participants. A hearing improvement of more than 10dB was recorded in 49 participants, 24 (80%) in the dry graft group and 25 (83.33%)in the wet graft group. The remainder showed only less than 10dBhearing improvement. The mean gain after 3 months was 14.33 dB in the dry graft group and 14.17dB in the wet graft group(p= 0.94).Thereby suggesting no significant difference in hearing improvement regardless of whether a dry or wet graft was used. Similar audiology results were obtained when Singh GB et al., 2016; tried to study the factors influencing type-1 tympanoplasty. He observed that only 25 out of the 41 cases in the dry graft group and 29 out of 45 cases in the wet graft group showed audiological improvement, which was statistically insignificant (p=0.369).[8]

On carrying out an otomicroscopic examination one-month post-surgery, it was observed that 27 (90%) participants in the dry graft group and 26 (86.67%) participants in the wet graft group had intact graft, the remainder which included 3 (10%) and 4 (13.33%) participants in the dry and wet graft group experienced graft failure respectively. The graft uptake was slightly better in the dry graft group, but this was not statistically significant (p=0.69).

Hinting that the type of graft used did not affect the success rate of the graft uptake. Similar results were seen in other studies as well. For example, in the study by Singh GB et al., 2016; graft uptake in dry grafting was 41(82%) out of 50 cases and 45 (90%) out of 50 in wet grafting which shows no significant difference and in another study by Alkan S et al., 2009; it was observed that out of 495 participants, graft uptake between dry and wet grafting was 94.2% and 90.3% respectively.[8,10]

What was noticed in this study to be statistically different between the two groups was the graft placement time. In our study, we found that the mean graft placement time in the dry graft group was 5.77 minutes while in the wet graft group, it was 10.47 minutes. The difference was statistically significant (p <0.001). Consequently,indicating that it takes a longer time to place the wet graft. This was in contrast to the study carried out by Alkan S et al., 2009; who saw that the dry graft group took a longer time, with a difference of 6.78 minutes between the groups (p<0.05).[10]

While another study carried out by K N et al., 2019;saw that most of the dry grafting was done in 3-6 minutes while the wet grafting took10-12 minutes.[11] The probable reason for the similar finding in our study could be due to the rigidity of the dry graft, making the placement easier when compared to the more moist wet graft, especially during anterior tucking procedures.

CONCLUSION

Based on our study and comparisons with similar research, we find no difference in success rates between dry and wet temporalis fascia grafting with regard to hearing improvement and graft uptake. Nevertheless, dry grafting is quicker, offering surgeons a viable option without compromising results.

Financial Support and Sponsorship
Nil.

DOI: 10.69605/ijlbpr_14.2.2025.23

Conflict of Interest

There are no conflicts of interest.

REFERENCE

1. Organization WH. Chronic suppurative otitis media: burden of illness and management options. iris.who.int. World Health Organization 2004.
2. Dolhi N, Weimer AD. Tympanic membrane perforation. StatPearls - NCBI Bookshelf 2023.
3. Sooriyamoorthy T, De Jesus O. Conductive hearing loss [Internet]. StatPearls - NCBI Bookshelf 2023.
4. Brar S, Watters C, Winters R. Tympanoplasty [Internet]. StatPearls - NCBI Bookshelf. 2023.
5. Glasscock ME, GulyaAJ. Glasscock & Shambaugh's Surgery of the ear: Closure of Tympanic Membrane Perforations. 5th edn. Glasscock ME, edr. Vol. 1. Ontario: BC Decker Inc; 2003 [cited 2019 Dec 10]. Available from: https://books.google.co.in/books?id=IvYbOyS6_i0C&printsec=frontcover&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false
6. Lierle DM. Standard classification for surgery of chronic ear infection: I. of the Technical Procedures in Surgery for Chronic Ear Infection: II. Of the Gross Pathology Found at Such Operations: III. For the Reporting of Postoperative Results of the Surgical Procedures Mentioned: The Committee on Conservation of Hearing of The American Academy of Ophthalmology and Otolaryngology. Archives of Otolaryngology 1965;81(2):204-5.
7. Devnath D, Ghosh D, Prakash D. Vein Graft Myringoplasty in small and medium sized Perforations. International Journal of Scientific and Research Publications 2017;7(7).
8. Singh GB, Kumar D, Aggarwal K, Garg S, Arora R, Kumar S. Tympanoplasty: does dry or wet temporalis fascia graft matter? The Journal of Laryngology & Otology 2016;130(8):700-5.
9. Deosthale NV, Kumar P, KhadakkarSP, HarkareVV, Dhoke PR, Dhote KS, et al. Outcome of Type I tympanoplasty in tubotympanic chronic suppurative otitis media in relation to site and size of tympanic membrane perforation. Journal of Evolution of Medical and Dental Sciences 2015;4(93):15834-8.
10. Alkan S, Baylanĉiĉek S, Sözen E, Baŝak T, Dadaŝ B. Effect of the use of dry (rigid) or wet (soft) temporal fascia graft on tympanoplasty. Journal of otolaryngology - head & neck surgery = Le Journal d'oto-rhino-laryngologie et de chirurgiecervico-faciale2009;38(1):126–32.
11. K N, Swarup R J. Comparative study of use of dry and wet temporalis fascia Graft in type-1 Tympanoplasty. Res J Med Allied Health Sci 2019;2(2):6-10.