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Comparative study between fascia lata and temporalis fascia in myringoplasty

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Abstract

Background: Repair of a perforated tympanic membrane (myringoplasty) can facilitate normal middle ear function, resist infection, and help re-establish normal hearing. Autogenous graft materials are the most popular graft materials used in myringoplasty because of their easy acceptability by the body. This study is conducted to compare between temporalis fascia graft and fascia lata graft in myringoplasty for patients with tubo-tympanic dry perforation.

Results: A total of 60 patients with persistent dry tympanic membrane perforation were included in our study during the period from January 2018 to May 2020. Patients underwent myringoplasty with temporalis fascia (30 patients as group A) or fascia lata (30 patients as group B). Patients were scheduled for follow-up visits concerning graft status, ear discharge, and audiograms. The mean postoperative air-bone gap in group A was 17.5 ± 4 after 1 month and 8.6 ± 6.9 after 3 months, while in group B, the mean postoperative air-bone gap was 17.6 ± 4.9 after 1 month and 9.4 ± 7.5 after 3 months. There was 90% success in graft uptake in group A, while there was 80% success in group B.

Conclusion: Using temporalis fascia is still the best and most trustworthy technique of myringoplasty compared to fascia lata graft. However, fascia lata can be a good alternative to temporalis fascia especially in cases of revision myringoplasty, ears having large perforation, or near-total perforation where the chances of residual perforation are high because of the limited margin of remnant tympanic membrane overlapping the graft.

Keywords: Fascia lata, Temporalis fascia, Myringoplasty

Background

The purpose of closing chronic dry perforations of the tympanic membrane is to improve hearing and prevent middle ear infections. Closure of the perforation isolates the middle ear from the external environment and prevents contamination by exposure to pathogens and restores the vibratory area of the tympanic membrane [1]. Skin grafts were the first graft materials used in myringoplasty by Horst Wullstein and Fritz Zollner [2, 3]. However, they were discontinued from use because of high failure rates and the formation of cholesteatoma [4]. Xenografts such as porcine dura and calf jugular vein were used to repair tympanic membrane perforations but were quickly abandoned because of their very high failure rates [5].

Autogenous graft materials are the most popular graft materials used in myringoplasty because of their easy acceptability by the body. Connective tissues like fascia lata, dura, temporalis fascia, and vein graft and perichondrium are preferable because they are easier to handle and more resistant to infection, and the problem of cholesteatoma formation is much less [6]. Such an abundance of materials implies that there is no clear-cut favorite and the choice of graft material depends on the individual surgeon's preference. Due to its anatomic proximity, translucency, and suppleness, temporalis fascia is the most preferred grafting materials among the otologists and successful closure is anticipated in approximately 90% of primary myringoplasty [7].

Fascia lata is a fibrous sheath that encircles the thigh subcutaneously. In 1999, preserved mashed fascia lata

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became approved as a tissue product designed to replace areas of lost fascia or collagen [8]. In the selection of graft tissue, several factors are considered including the biological properties, probability of survival, adequacy in size, and ease of procurement [9]. Graft displacement, improper placement, infection, hemorrhage, and Eustachian tube dysfunction are the known contributing factors for the failure of closure of perforation. Thus, consistent achievement of good results in myringoplasties is still a challenge and one of the most difficult tasks of otology surgery [6]. This study aimed to compare temporalis fascia graft versus fascia lata graft in myringoplasty for patients with tubo-tympanic dry perforation.

Methods

This prospective randomized controlled trial was conducted from January 2018 to May 2020 after the approval of the ethical committee of the hospital. This study was conducted on patients diagnosed with uncomplicated tubo-tympanic chronic suppurative otitis media selected from the outpatient clinics. Inclusion criteria included patients between the age group of 10–60 years with uncomplicated mucosal chronic otitis media and patients with dry perforation for at least 6 weeks before surgery. Exclusion criteria were age groups below 10 years or above 60 years, patients with a previous history of ear surgery, patients with sensorineural hearing loss or mixed hearing loss, or patients with squamous chronic otitis media.

Sixty patients were included and were divided randomly into 2 groups as temporalis fascia graft was used in group A and fascia lata graft was used in group B. All patients were fully informed about the randomization. All the patients were subjected to detailed otorhinolaryngological examination followed by pure tone audiometry, tympanometry with Eustachian tube function, computerized tomography of the temporal bone, and routine hematological and biochemical investigations.

Patients of both groups underwent myringoplasty under general anesthesia using postaural approach which facilitates a large area of tympanic annulus exposure for placing graft with underlay technique. Also when using temporal fascia graft, a single incision approach can help in harvesting the graft. For harvesting fascia lata graft, an incision was made at the junction of the middle and upper 1/3 of the lateral part of the thigh after giving local anesthesia. An incision about 5 mm away from the postauricular groove was made, and dissection was done till the bone was reached. The spine of Henle is palpated, and the posterior wall of the external auditory canal was dissected in a way to expose the tympanic annulus. The rim of the annulus was freshened by a sickle knife. A tympanic meatal flap was raised, and the middle ear cavity is examined for ossicular mobility. The

pre-dried graft (either temporal fascia or fascia lata) was then placed under the annulus after filling the middle ear cavity by gel foam. The gel foam keeps the graft in place and helps in early take-up. The tympanomeatal flap was replaced back, and the external auditory canal was packed with antibiotic ointment soaked gauge piece.

Outcomes measured were success rate and hearing improvement. This was done by an independent professional who was unaware of the randomization. Pure tone audiometry and tympanometry were performed at the end of the first and the third month for all the patients.

Statistical analysis

After collecting the data, the statistical analysis was performed using Excel 2017 and SPSS software (version 15.0, SPSS, Inc., Chicago, IL). The categorical variables were compared using a chi-square test. *P* values of 0.05 were considered to be statistically significant based on the Bonferroni correction.

Results

A total of 30 patients were considered in every group of this study. The mean age of patients was 28.4 years, 56.7% of cases were male, and 43.3 % were female. Forty percent of patients had a perforation of the right tympanic membrane, and 60% of patients had a perforation of the left tympanic membrane (Table 1).

There was a non-statistically significant difference among studied groups according to the site, size, or shape of perforation (Table 2).

There was 90% success in graft uptake in group A while there was 80% success in group B with a non-statistical significant difference between results of graft uptake between both groups (Table 3).

Regarding the relation between the size of the perforation and the success rate, group A had 100% graft uptake success in patients with medium-sized perforation of the tympanic membrane, 71.4% success in patients with large perforation, and 66.7% success in patients with subtotal perforation, while group B had 83.3% graft uptake success in patients with medium-

Table 1 Epidemiological study of study cases

Variables	Patients with CSOM = 60	
	No.	%
Age (years), mean ± SD	10–55 years old, 28.4 ± 9.8	
Gender		
Female	26	43.3
Male	34	56.7
Side of perforation		
Right	24	40
Left	36	60

Table 2 Comparison between both study groups regarding criteria of the perforation

Parameter		No. of CSOM cases = 60				χ^2 test	P value
		Group A, no. = 30		Group B, no. = 30			
		No.	%	No.	%		
Site of perforation	Central part of TM in pars tensa	18	60	10	33.3	4.705	0.319 <i>NS</i>
	Antero-inferior part of TM in pars tensa	7	23.3	12	40		
	Postero-inferior part of TM in pars tensa	5	16.7	8	26.7		
Shape of perforation	Rounded shaped	9	30	14	46.7	2.865	0.581
	Oval shaped	14	46.7	12	40		
	Kidney shaped	7	23.3	4	13.3		
Size of the perforation	Medium sized	20	66.7	18	60	2.865	0.581
	Large	7	23.3	10	33.3		
	Subtotal	3	10	2	6.7		

χ^2 chi-square test, *NS* non-significant (P value > 0.05), *S* significant (P value \leq 0.05), *HS* highly significant (P value \leq 0.001)

sized perforation of the tympanic membrane, 80% success in patients with large perforation, and 100% success in patients with subtotal perforation. There was a non-statistically significant difference between results of graft uptake among different perforation sizes of both studied groups (Table 4).

The mean preoperative air-bone gap was 34.6 ± 6.7 dB in group A and 35.3 ± 6.4 dB in group B with no statistically significant difference among studied groups. Postoperative air-bone gap in group A was 17.5 ± 4 dB after 1 month and 8.6 ± 6.9 dB after 3 months, while in group B, the mean postoperative air-bone gap was 17.6 ± 4.9 dB after 1 month and 9.4 ± 7.5 dB after 3 months. There was no statistically significant difference among studied groups regarding the postoperative air-bone gap after 1 and 3 months (Table 5).

The mean operative duration in group A was 46.5 ± 12.7 min, while in group B, it is 59.8 ± 9.2 with a statistically significant difference between both groups (P value = 0.039) (Table 6).

Discussion

Surgical repair of the tympanic membrane and tympanic membrane grafting has traveled a long way since the time of Berthold [10] who coined the term

"myringoplasty" [11]. These years have been filled with numerous technical advances that have improved surgery for tympanic membrane repair to a high level of accuracy. A critical problem early in the development of tympanoplasty was finding a suitable material for tympanic membrane grafting. This evolution of the tympanic membrane grafting has been based on biological tissues of mesodermal origin which contain collagen matrix [12].

Many autologous graft materials such as temporalis fascia, tragal perichondrium, cartilage, fat, and fascia lata have been used in repairing tympanic membrane perforations [6]. Various studies have been done comparing different graft materials and techniques. The main aim of utilizing different autografts in the study was to evaluate and compare the anatomic and functional results of various autografts.

Due to its anatomic proximity, translucency, and suppleness, temporalis fascia is the most preferred grafting materials among the otologists and successful closure is anticipated in approximately 90% of primary tympanoplasty [7]. Temporalis fascia is easy to harvest, and it can be used as an overlay or underlay graft for

Table 3 Comparison of graft uptake results among study groups

Graft uptake	Cases with graft failure = 9		χ^2 test	P value	
	No.	%			
Group A	Uptake	27	90	4.074	0.396 <i>NS</i>
	Failed	3	10		
Group B	Uptake	24	80		
	Failed	6	20		

χ^2 chi-square test, *NS* non-significant (P value > 0.05), *S* significant (P value \leq 0.05), *HS* highly significant (P value \leq 0.001)

Table 4 Assessment of graft uptake success/failure with respect to size of perforation

Size of perforation	Group	Success		Failure		Total no.	P value
		No.	%	No.	%		
Medium sized	Group A	20	100	0	0	20	0.37
	Group B	15	83.3	3	16.7	18	
Large	Group A	5	71.4	2	28.6	7	0.731
	Group B	8	80	2	20	10	
Subtotal	Group A	2	66.7	1	33.3	3	0.3378
	Group B	2	100	0	0	2	

χ^2 chi-square test, *NS* non-significant (P value > 0.05), *S* significant (P value \leq 0.05), *HS* highly significant (P value \leq 0.001)

Table 5 Preoperative and postoperative air-bone gap (ABG) at 1 and 3 months in both study groups

ABG	Mean \pm SD		t test	P value
	Group A	Group B		
Preoperative ABG	34.6 \pm 6.7	35.3 \pm 6.4	0.379	0.710
Postoperative ABG after 1 month	17.5 \pm 4	17.6 \pm 4.9	0.029	0.997 HS
Postoperative ABG after 3 months	8.6 \pm 6.9	9.4 \pm 7.5	0.457	0.654 HS

ABG air-bone gap, NS non-significant (P value $>$ 0.05), S significant (P value \leq 0.05), HS highly significant (P value \leq 0.001)

primary operations as there are no size limitations. Temporalis fascia also has a certain advantage of being similar in structure to the missing tunica propria of the drum. Although there are high success rates with temporalis fascia graft, poor results may be obtained in the late postoperative period, and in case of perforations in anterior and wide perforations. The cause of the failure is attributed to a lack of elasticity and decreased resistance to pressure changes in the middle ear and external ear [13].

The use of fascia lata as a graft material in myringoplasty was reported to have better dimensional stability and subsequently leads to a better outcome, particularly with respect to achieving an intact tympanic membrane and hearing improvement [14]. Fascia lata is thicker and stiffer than temporalis fascia. It is easier to manipulate in the middle ear as it does not get folded on itself and thus has better handling qualities.

Our study is a comparative observational (cohort) prospective study carried on 60 patients (60 ears) diagnosed to have an uncomplicated tubo-tympanic type of chronic suppurative otitis media who underwent myringoplasty. In 30 patients, temporalis fascia was used as a graft material (group A), and in 30 patients, fascia lata was used as a graft material (group B). Both groups were matched with no statistically significant difference among studied groups according to shape, size, or site of perforation.

The overall graft uptake success rate of fascia lata graft in our study was 80% which is comparable with Patil et al. (85%) [15]. However, it was lower than the study of Indorewala et al. (96%) and Verma et. al. (92%) [8, 16].

The temporalis fascia had an overall graft uptake success rate of 90% which is lower than the study conducted by Verma et al. (96%) and Indorewala et al. (95%) [8, 16]. But Dabholkar et al. in underlay tympanoplasty achieved a graft success rate of 84% for temporalis fascia

[17]. However, the difference in graft success rate between the two groups of our study was not statistically significant. Thus, our results suggest that type of graft material does not influence the successful graft take-up.

The study of surgical outcome for these graft materials with respect to the size of the perforation showed that the success rate in group A decreased from 100% in patients with medium-sized perforation to 71.4% in patients with large perforation and 66.7% in patients with subtotal perforation. On the other hand, the success rate in group B decreased from 83.3% in patients with medium-sized perforation of the tympanic membrane to 80% in patients with large perforation. However, it reached 100% success in patients with subtotal perforation. A non-significant association was observed between the graft success in both groups and the size of perforation revealing that the successful graft take-up with respect to graft materials does not depend on the size of the perforation.

Hearing in our study was judged pre- and postoperatively by pure tone audiometry. The mean pre-procedure ABG was 34.6 \pm 6.7 dB in group A (temporalis fascia graft myringoplasty) and 35.3 \pm 6.4 in group B (fascia lata graft myringoplasty).

Postoperatively, the mean postoperative ABG in group A was 17.5 \pm 4 dB after 1 month and 8.6 \pm 6.9 after 3 months, while in group B, the mean postoperative ABG was 17.6 \pm 4.9 after 1 month and 9.4 \pm 7.5 after 3 months. There was no statistically significant difference among studied groups regarding the pre- or postoperative air-bone gap.

In the study conducted by Verma et al., audiological closure of the air-bone gap in the range of 0–30 dB was achieved in 88% cases of temporal fascia and 80% in fascia lata after surgery with no significant difference [16]. In 2014, Patil et al. found that the mean gain in air-bone gap postoperatively for temporalis fascia was 9.36 dB and for fascia lata was 12.1 dB which also was not significant [15].

The duration of the operation is an important parameter in terms of the duration of anesthesia, the surgeon's concentration, and the increased risk of iatrogenic complications. In our study, myringoplasty done using fascia lata took more time than temporalis fascia with a statistically significant difference.

Table 6 Comparison of operative duration among study groups

	Duration of the operation in minutes (\pm SD)	t test	P value
Group A	46.4 \pm 6	2.169	0.044 S
Group B	49.6 \pm 6.2		

χ^2 chi-square test, NS non-significant (P value $>$ 0.05), S significant (P value \leq 0.05), HS highly significant (P value \leq 0.001)

Conclusion

Although temporalis fascia had better overall graft uptake success and air-bone gap closure, it was statistically non-significant. The operative duration was significantly less using temporalis fascia than fascia lata. Using temporalis fascia is more simple due to anatomic proximity, and only single incision is needed; however, fascia lata had better dimensional stability and it was easier to handle and manipulate in the middle ear compared to temporalis fascia because of its physical characteristics and texture. So, fascia lata can be a good alternative to temporalis fascia especially in cases of revision myringoplasty, ears having large perforation, or near-total perforation where the chances of residual perforation are high because of the limited margin of remnant tympanic membrane overlapping the graft.

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Authors' contributions

All operations were done by AA and TA and observed by AH. AE, AH, and TA shared in the data collection and interpretation of the results. AE and AA were major contributors in writing the manuscript. All authors finally read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed in the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

An informed written consent to participate in the study was provided by all participants and the parent or legal guardian in the case of children under 16 before operation and before investigations according to the Research Ethics Committee of the Faculty of Medicine, Menoufia University. Ethics committee reference number is 12/2017ENT/639.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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