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Original Article

Comparative Study Between Perichondrium and Composite Cartilage/Perichondrium in Endoscopic Myringoplasty for Total and Subtotal Perforations

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Abstract

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Background: Perforations of the tympanic membrane [TM] are frequently encountered problems, often as a result of middle ear infections, traumatic injury, or complications following surgery. Although the TM has the ability to heal itself, surgical intervention may be required for chronic perforations.

The aim of the work: We aimed to compare the graft take rates and the postoperative hearing results in endoscopic trans-canal Myringoplasty operations using the tragal cartilage and perichondrium composite graft technique with those of tympanoplasties using perichondrium graft technique for total and subtotal TM perforations.

Methods: This prospective study was conducted on 40 patients who had non-cholesteatomatous chronic suppurative otitis media and had total or subtotal perforations. The patients were divided randomly into two groups for comparison in the study.

Results: There was higher closure rate/graft take in composite cartilage/perichondrium group compared to the perichondrium group; however, the difference was of no statistically significant value. The case was considered to be successful if there is complete healing of TM with hearing improvement [decrease ABG]. Cases with residual perforation or those who showed no hearing improvement postoperatively are considered failed.

Conclusion: There was higher success and hearing improvement postoperatively in composite cartilage/perichondrium group compared to the perichondrium group; however, the difference was of no statistically significant value. Further research with larger sample size is necessary in the detection of the efficacy of using the tragal cartilage and perichondrium composite graft technique for repairing TM perforation.

Keywords: Tympanic Membrane; Perichondrium; Endoscopic; Myringoplasty.



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INTRODUCTION

Perforations of the tympanic membrane [TM] are a frequent occurrence, primarily caused by middle ear infections, traumatic injury, or complications following surgery. While the TM has the ability to regenerate on its own, chronic perforations may require surgical intervention for repair [1,2]. Tympanoplasty is a surgical procedure that involves transferring tissue. Several types of graft materials, such as temporalis fascia, cartilage, perichondrium, periosteum, vein, fat, or skin, have been utilized to repair perforations in the tympanic membrane [TM] [3,4]. Endoscopic Tympanoplasty offers several benefits, including a shorter surgery time. Compared to other approaches, the endoscopic method results in superior cosmetic outcomes, less postoperative pain, and reduced dressing requirements [5]. The goal of utilizing fascia or perichondrium in Tympanoplasty is to achieve both anatomical and functional success, while also maintaining these outcomes over time. However, when dealing with larger defects of the TM, successful healing becomes more challenging due to the increased technical difficulty and the larger area that must be vascularized and epithelialized. In such cases, the use of cartilage as a grafting material has been recommended to improve the chances of success and reduce the likelihood of surgical failures [6].

Perichondrium/cartilage composite graft is an easy-taking graft for tympanoplasty and tympanomastoidectomy with high efficiency and reliability. It is effective in the majority of patients with large perforations ^[7].

We aimed to compare the graft take rates and the postoperative hearing results in endoscopic trans-canal Myringoplasty operations using the tragal cartilage and perichondrium composite graft technique with those of tympanoplasties using perichondrium graft technique for total and subtotal TM perforations.

PATIENTS AND METHODS

This comparative prospective study was carried out on 40 patients with non-cholesteatomatous chronic suppurative otitis media and having subtotal perforation [when it involves the four quadrants of TM] or total perforation [when there is no TM remnant]. Patients were selected from general population including patients reporting to Otorhinolaryngology [ORL] outpatient clinics at Al-Azhar University Hospitals [Al- Hussein and Sayed Galal].

Patients were randomly allocated into two groups. Group A consisted of 20 patients who received a composite graft of cartilage and perichondrium harvested from the tragus, while Group B was comprised of 20 patients who received only a perichondrium graft harvested from the tragus. Full history taking has been concluded to all patients, examination included general and ENT examination, and investigations included hearing evaluation [pure tone audiometry] which was done in ENT department [audiology unit] to assess hearing acuity and recording of air bone gap [ABG]. The laboratory tests conducted included ESR, CBC, FBS, SGPT, serum creatinine, coagulation assay, HCV core antigen, HBVs antigen, and ECG and/or chest X-ray if deemed necessary.

Inclusion criteria: Age ranged from 10-50 years. Sex included both male and female. Mucosal type chronic suppurative otitis media with subtotal perforation [when it involves the four quadrants of TM] or total perforation [when there is no TM remnant]. All patients were primary tympanoplasty cases with conductive hearing loss and intact ossicular chain. At least one-month dry middle ear mucosa.

Exclusion criteria: Age less than 10 years and more than 50 years. Other middle ear pathologies. Previous otological surgery. Smaller TM perforation. Ossicular discontinuity. Sensorineural hearing loss.

Surgical technique:

Anaethesia: All surgeries were conducted using general anesthesia and involved the use of straight $[0^{\circ}]$ and angled $[30^{\circ}]$ telescopes with diameters of 2.7 mm and 4 mm.

In Group A, the tragal cartilage/perichondrium graft was obtained by making a 1-cm incision 2-3 mm medial to the free border of the tragus. The cartilage with its perichondrium was obtained and the perichondrium was removed from both sides as one piece. The cartilage was then cut into an L-shaped graft, while the remaining cartilage was cut into one U-shaped piece for later use in replacing the dome of the tragus, along with other small pieces to support the graft. The margin of the perforation was then freshly trimmed circumferentially using a pick or a sickle knife under endoscopic guidance. In subtotal perforation, the perforation was freshened by resection of the epithelialized perforation edges. In total perforation, the perforation was refreshed by scratching the annulus edges. For support of the anterior part of the graft, to create an anterior tunnel, a small horizontal incision of approximately 3 mm was made about 3 mm lateral to the annulus using a round knife. The annulus, along with a small cuff of deep meatal skin along the anterior bony wall, was then elevated at approximately one o'clock for the right side and eleven o'clock for the left side. A posterior incision was then made 5 mm from the tympanic annulus, after which the tympanomeatal flap was elevated. The integrity and movement of the ossicles were examined. Two small pieces of cartilage were placed below the Eustachian tube opening in the hypotympanum. The L-shaped cartilage was then placed over these pieces, medial to the anterior inferior aspect of the remaining tympanic membrane [TM]. It was important to ensure that the cartilage was in close proximity to the anterior margin of the perforation. The perichondrium was then positioned anteriorly with curved forceps and needle, medial to the malleus umbo to prevent the graft from moving laterally and lateral to the L-shaped cartilage. Through the anterior tunnel, the tip of the perichondrium was pulled out using a micro suction cannula or alligator forceps, and the graft was placed between the skin cuff and meatal bony wall. The posterior part of the perichondrium was placed over the posterior wall of the external auditory canal, and the tympanomeatal flap was repositioned to cover the posterior part of the perichondrium. Gel-foam was then placed lateral to the grafts, and the U-shaped cartilage was repositioned through the tragus incision, with one or two stitches performed.

Group B: To obtain the tragal perichondrial graft, a 1-cm incision was made 2-3 mm medial to the free border of the tragus by cutting through the skin and cartilage. The perichondrium was then separated from the cartilage and prepared as a graft, after which the incision was sutured. The margin of the perforation was then freshly trimmed circumferentially as previously described. The tympanomeatal flap was elevated as before, and the integrity and mobility of the ossicular chain were assessed. An anterior tunnel was created as before, and a graft of appropriate size was placed medial to the malleus handle. Absorbable gelatin sponges were packed in the middle ear cavity to support the graft, and the tympanomeatal flap was repositioned to its original position. The external auditory canal was then filled with absorbable gelatin sponge pledgets up to the level of the isthmus.

Postoperative follow-up: During hospitalization: Antibiotics [IV], anti-inflammatory [IM], oral metronidazole, oral decongestant and antihistaminics, dressing was changed after 24 hours. The patient was

allowed to return home within 2-3 days, and home treatment was continued until removal of the pack. The list of instructions was given and explained to the patients [water is kept away from the ear, and nose blowing is discouraged, the graft must be kept free from infection, activities that change the tympanic pressure are forbidden, such as sneezing with the mouth closed, heavy nose blowing]. All patients were called for regular follow up. The stitches were removed after 7 days, the pack was removed after 14 days, the gel foam in the external auditory canal was not disturbed for 3 weeks, inspection of the TM for healing of the graft weekly for one month, then monthly for 6 months. The wanted data was collected in the case sheet of every patient.

Both groups were subjected to endoscopic examination during each follow-up visit to observe any changes in the graft. An audiometric evaluation was conducted to measure the air-bone gaps [ABGs] at the end of the sixth postoperative month. The success of the graft was determined by the presence of an intact graft without perforation, retraction, lateralization, significant blunting, or medialization. A residual perforation was defined as one that was observed following the removal of gel foam fragments. On the other hand, re-perforation was defined as the occurrence of a new perforation at postoperative six months, despite the complete healing of the tympanic membrane following the surgery.

Statistical analysis: The data collected were tabulated and analyzed statistically using IBM personal computer with Statistical Package of Social Science [SPSS] version 22, IBM Corp, Armonk, NY, USA. Descriptive statistics were used to present quantitative data in terms of mean [¬X] and standard deviation [SD], while qualitative data were presented in terms of numbers [No.] and percentages [%]. The Kolmogorov-Smirnov test indicated that the data were non-normally distributed. To compare the quantitative data of both groups, the Mann-Whitney U test was used. The Chi-squared [χ2] and Fisher Exact tests were used to examine the relationship between two qualitative variables. The Wilcoxon signed-rank test was used to compare preoperative and

postoperative quantitative data for each group. A two-sided p-value of less than 0.05 was considered statistically significant.

RESULTS

In the current work, there was no significant differences between study groups [composite and perichondrium] regarding patient age, body mass index [BMI], gender, smoking and diabetes mellitus [DM] [Table 1]. For example, patient age ranged between 14 to 47 years in composite group and from 12 to 48 years in the perichondrium group. Males represented 65% and 50.0%, while smoking was reported in 45% and 50% of composite and perichondrium groups respectively.

In addition, there was no significant difference between study groups regarding perforation characteristics. The majority of perforation type was subtotal [95.0% and 90.0% in composite and Perichondrium groups respectively]. It was on the right side in 60.0% and 50.0% in composite and Perichondrium groups respectively [Table 2].

Furthermore, there was no significant differences between study groups regarding the results of preoperative air bone gap [19.78 ± 4.93 and 20.82 ± 5.47 , respectively]. In addition, comparable results were reported 6 months after surgery [Table 3]. However, air bone gap was significantly reduced in each study group at 6 months when compared to preoperative values [Table 4].

In the current work, complete success [Closure rate/ graft take] was reported among 90.0% of the composite group, compared to 75.0% in the perichondrium group. However, this difference did not reach statistical significance [Table 5]. A case is deemed successful if there is complete healing of the tympanic membrane and an improvement in hearing [i.e., decrease in air-bone gap]. Cases that have residual perforation, re-perforation, or those that do not exhibit hearing improvement after the surgery are considered failed.

		Composite cartilage/perichondrium	Perichondrium	test	P-value
		No. = 20	No. = 20		
Age [year]	Min. – Max.	14 – 47	12 – 48	-0.162	0.872
	Median [IQR]	32.5 [21.75]	29.5 [15.25]		
	Mean ± SD	30.40 ± 11.05	30.95 ± 10.37	_	
BMI	Min. – Max.	22 – 33	20 – 32	1.315	0.197
	Median [IQR]	29 [3.75]	28.5 [4.75]		
	Mean ± SD	28.90 ± 2.86	27.55 ± 3.59		
Sex	Male	13 [65%]	10 [50%]	0.921	0.337
	Female	7 [35%]	10 [50%]		
Smoking	Yes	9 [45%]	10 [50%]	0.100	0.752
	No	11 [55%]	10 [50%]		
DM	Yes	3 [15%]	2 [10%]	0.229	0.633
	No	17 [85%]	18 [90%]		

 Table [1]: Comparison between study group regarding patient demographics and risk factors.

Table [2]: Perforation characteristics among study groups

		Composite cartilage/perichondrium	Perichondrium	test	P-value
		No. = 20	No. = 20		
Type of perforation	Subtotal	19 [95%]	18 [90%]	0.360	0.459
	Total	1 [5%]	2 [10%]		
Side of perforation	Right	12 [60%]	10 [50%]	0.404	0.525
	Left	8 [40%]	10 [50%]		

Composite cartilage/perichondrium Audiogram Perichondrium P-value air bone gap No. = 20No. = 2010 - 25 0.531 Preoperatively 10 - 30 0.632 Range 19.78 ± 4.93 20.82 ± 5.47 Mean ± SD 0.194 After 6 months Range 5 - 25 5 - 30 1.321

Table [3]: Comparison between study groups according to the audiogram [air bone gap].

Table [4]: Comparison between pre- and post-operative air bone gap in each of study groups

 11.32 ± 5.33

Audiogram air bone gap		Composite cartilage/perichondrium	Perichondrium	
		No. = 20	No. = 20	
Before procedure	Mean ± SD	19.78 ± 4.93	20.82 ± 5.47	
After procedure [6 month]	Mean ± SD	11.32 ± 5.33	13.79 ± 6.44	
Difference	Mean [change %]	8.04 [40.65%]	7.11 [34.15%]	
Paired comparison	t	5.509	3.721	
	P-value	<0.0001	0.0001	

Table [5]: Outcome among study groups

		Composite cartilage/perichondrium	Perichondrium	test	P-value
		No. = 20	No. = 20		
Graft taking/ Closure rate	Complete [successful]	18 [90%]	15 [75%]	1.558	0.693
	Re-perforation	2 [10%]	5 [25%]		

DISCUSSION

Mean ± SD

In the current study, demographic characteristics of the studied patients showed that, in composite cartilage/perichondrium group, there were 13 [65%] male and 7 [35%] female, the mean age and BMI were 30.40 \pm 11.05 years and 28.90 \pm 2.86 Kg/m² respectively; while, in perichondrium group, there were 10 [50%] male and 10 [50%] female, the mean age and BMI were 30.95 \pm 10.37 years and 27.55 \pm 3.59 Kg/m² respectively. No statistically significant difference has been found between the two studied groups as regard age, sex, BMI, smoking and DM [P-value > 0.05]. Also, no statistically significant difference has been indicated between the studied groups as regard the type of perforation and side of perforation [P-values were 0.459 and 0.525 respectively].

In a study by **Lou** *et al.* ^[8], a total of 134 patients [81 females, 53 males] with an average age of 35.1 ± 1.29 years were included. Of the 134 ears, 72 [53.7%] affected the left ear, while 62 [46.3%] affected the right ear. The patients were randomized into two groups: Group A, which consisted of 67 ears treated with a double-layer cartilage-perichondrium graft, and Group B, which consisted of 67 ears treated with a single graft. The two groups were matched in terms of age, sex, affected ear side, size and location of the perforation, pre-existing myringosclerosis, status of the non-operated ear, smoking status, and presence of diabetes [p > 0.05].

Shakya *et al.* ^[9] [a previous study] examined 65 patients who had undergone surgery for anterior perforation, with an overall mean age of 29.24 ± 10.38 years, ranging from 12 to 57 years old. In group A, which

involved a single perichondrium being applied over the barred cartilage, there were 10 males and 11 females, with a mean age of 29.14 \pm 10.25 years.

 13.79 ± 6.44

In the current study, the comparison of the audiogram before & after procedure in the studied groups showed that, despite of decrease in the audiogram air bone gap after procedure in composite cartilage/perichondrium group more than perichondrium group, but this difference is of no significant value [p>0.05]. After 6 months, in Group A, 18 out of 20 patients had successful grafts [90%], while 2 patients had persistent perforation post-surgery. In Group B, 15 out of 20 patients had successful grafts [75%], while 5 patients had persistent perforation after the surgery.

In a Chinese study titled "Perichondrium/cartilage composite graft for repairing large tympanic membrane perforations and hearing improvement" done by **Chen et al.** [7], the audiometric results in 76 tympanoplasty patients observed that, the preoperative ABG was 41.66 \pm 10.22 dB.

In in a different study that aimed to compare the surgical outcomes of endoscopic myringoplasty using double-layer cartilage-perichondrium grafts versus single grafts, no significant difference was found between Group A and Group B in terms of preoperative [P value = 0.794] or 6-month post-operative air-bone gap [ABG] values [P value = 0.832] ^[6].

The present study demonstrated that there was high difference in audiogram ABG before and after procedure in both composite

cartilage/perichondrium group and perichondrium group that was statistically significant [P-value <0.0001].

In a recent study, the Wilcoxon signed-rank test showed that the mean preoperative ABG [28.61±3.14 dB] has been significantly greater than the mean postoperative ABG [12.15+3.98 dB; P value <0.05] [10].

According to the comparison of the outcome in the studied groups, we found that there was higher closure rate/graft take in composite cartilage perichondrium group compared to the perichondrium group; however, the difference was of no statistically significant value [P value = 0.693].

In a prior study, a total of 31 patients were followed up for more than 24 months, with an average follow-up period of 27.9 months [range: 24.2-36.4 months]. The success rate of the graft was 96.7% [30/31] at 6 months and 90.3% [28/31] at 24 months [8].

Our findings are consistent with those of **Linares** *et al.* ^[11] who reported that the rate of perforation closure in transcanal endoscopic tympanoplasty is superior to endoscopic tympanoplasty with classical underlay graft, with similar audiometric outcomes. After 6 months, in Group A, 34 out of 36 patients had successful grafts [94.4%], while in Group B, 29 out of 37 patients had successful grafts [78.3%].

In this investigation, a case is deemed successful if there is complete healing of the tympanic membrane and an improvement in hearing [i.e., decrease in air-bone gap]. Cases that have residual perforation or do not exhibit hearing improvement after the surgery are considered unsuccessful. The comparison of the failure rate in the studied groups showed that, there was higher success in composite cartilage/perichondrium group compared to perichondrium group; however, the difference was of no statistically significant value [P value =0.693].

Cartilage is a highly effective material for grafting, particularly in the repair of complex perforations, where the use of a cartilage-perichondrium graft can result in a stable neotympanum and decrease the likelihood of perforations/retractions, and the need for revision surgeries [12].

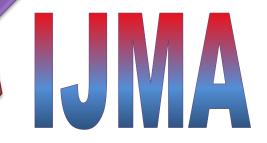
A study was conducted with the aim of exploring a new method that involved using a perichondrium cartilage composite graft for the repair of large tympanic membrane perforations in patients with chronic suppurative otitis media [CSOM]. The study found that successful closure was achieved in 92% of the ears, and post-surgery, 85.8% of patients experienced an improvement in their hearing ^[7].

Conclusion: Perichondrium/cartilage composite graft is an-easy taking graft for tympanoplasty and tympanomastoidectomy with high efficiency and reliability, it is effective in the majority of patients with large perforations. There was higher success and hearing improvement postoperatively in composite cartilage/perichondrium group compared to the perichondrium group; however, the difference was of no statistically significant value. Further research with larger sample size is necessary in the detection of the efficacy of using the tragal cartilage and perichondrium composite graft technique for repairing TM perforation.

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