

COMPARATIVE STUDY BETWEEN TEMPORALIS FASCIA GRAFT WITH PLATELET RICH PLASMA OR HYALURONIC ACID VERSUS TEMPORALIS FASCIA GRAFT ALONE IN SIMPLE MYRINGOPLASTY

By

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ABSTRACT

Background: Tympanic membrane perforation (TMP) results mainly from infectious and traumatic causes. Perforations result from acute otitis media and trauma heal spontaneously in the majority of cases. But if there is a repeated infection or if the infection is persistent, there is less possibility of spontaneous healing of this perforation.

Objective: To assess the effectiveness of adding platelet rich plasma (PRP) or hyaluronic acid (HA) to temporalis fascia graft to enhance healing of tympanic membrane in comparing with temporalis fascia graft alone in case of simple myringoplasty.

Patients and methods: This was a prospective randomized comparative study on 90 patients [30 patients with temporalis fascia alone ,30 patients with temporalis fascia with PRP and 30 patients with temporalis fascia with HA] which was conducted at the Otolaryngology Department Al-Hussein Bab-Al-Shaaria Al-Azhar University hospital and Hearing and Speech institute from september 2020 till August 2021.

Results: There was a significant difference between the three groups regarding postoperative pure tone audiometry (PTA) only. Meanwhile, there was a significant decrease in pure tone audiometry (PTA) postoperatively in the three groups. There was a statistically significant difference in the results of tympanic membrane healing and pure tone audiometry (PTA) pre and post-operatively after using Esterified Hyaluronic acid and platelet rich plasma (PRP) with temporalis fascia graft. There were no statistically significant differences as regard the success rate between patients who underwent temporalis fascia graft platelet rich plasma (PRPG), temporalis fascia graft with Hyaluronic acid and patients who underwent temporalis fascia graft alone.

Conclusion: FGM with adding PRP or HA was slightly more successful in closure of TM perforation than pure FGM in case of TM perforation,

Keywords: Hyaluronic acid, central tympanic membrane perforation, The superficial temporalis fascia, Myringoplasty.

INTRODUCTION

The physiologic function of the tympanic membrane (TM) is not only transmission of sound waves to the middle ear sound conducting system, also it has an important role in middle ear protection against external environment and also against nasopharyngeal reflux “middle ear cushion” (Boedts *et al.*, 2014). This can explain why unrepaired TM perforations can significantly impair the quality of life.

A persistent TMP increases the patient’s risk of developing recurrent acute otitis media or chronic middle ear disease. These conditions are frequently associated with an unpleasant otorrhea. The myringoplasty is a surgical procedure closes a simple perforated tympanic membrane (Sankarnarayanan *et al.*, 2013).

Various grafting materials have been used to reconstruct the TM, including skin, fascia, vein, fat, perichondrium, dura mater, and cartilage. Temporalis fascia is the most frequently used grafting material (Alzahrani *et al.*, 2015).

Outcome of myringoplasty depends on various factors and has some limitations. Studies have shown that closure rates also depend upon the size of perforation also vary from surgeon to surgeon. Various studies show experimental use of some agents for healing of tympanic membrane perforation such as hyaluronic acid, pentoxifylline and fibroblast growth factors (Habesoglu *et al.*, 2014).

Platelet Rich Plasma (PRP) was developed in the 1970s and was first used by Ferrari in Italy in 1987 in cardiothoracic surgery. PRP therapy began gaining popularity in the mid-

1990s. It has since been applied to many different medical fields such as cosmetic surgery, dentistry, sports medicine, and pain management (Maria *et al.*, 2011).

PRP is an autologous product. Platelets are key factors in tissue repair mechanisms. They provide essential growth factors, which stimulate fibroblasts and endothelial cells to create extracellular matrix deposition and neovascularization. Plasma contains many factors essential for cell survival, including nutrients, vitamins, hormones, electrolytes, growth factors, and proteins. They serve as a promoter for cell migration and new tissue generation (Maria *et al.*, 2011).

Hyaluronic acid (HA) seems to play an important role during the healing process, Because HA is a component of the extracellular matrix of many tissues in the body, its biocompatibility is very high it was first used in its liquid form for middle ear packaging in otologic practice. Many studies applied topical HA to show the positive effect of the material on the healing of acute traumatic TM perforations and showed some good results (Saliba *et al.*, 2011).

These autologous biomaterials are easy, quick and cheap to produce and are biocompatible, safe and easily manipulated during surgical procedure. (Magdy *et al.*, 2018).

This was a prospective study aimed to assess the effectiveness of adding platelet rich plasma (PRP) or Hyaluronic acid (HA) to temporalis fascia graft to enhance healing of tympanic membrane in comparing with temporalis fascia graft alone in case of simple myringoplasty.

PATIENTS AND METHODS

This was a prospective randomized comparative study which was conducted in the Otolaryngology department, Al-Azhar University elhussein Hospital bab el-shearia hospital and hearing and speech institute

A written consent was obtained from each participant prior to enrolling him/her in the study which was approved by the ethical committee of the Faculty of Medicine, Al-Azhar University.

Inclusion criteria: The subjects of this study consist of 90 patients with TM perforation; will be conducted as candidates for simple myringoplasty using temporalis fascia graft causing any of the following: Patients belonging to both sexes, with ages ranging from 16 to 50 years. Patients with small to medium sized dry central TM perforation. Patients with apparently healthy middle ear mucosa for one month at least before surgery.

The exclusion criteria are: Age up to 16 years and of at least 50 years, patients with previous failed myringoplasty, patients with cholesteatoma, retraction pockets or associated mastoiditis, known eustachian tube dysfunction (diagnosed by Valsalva test and tympanogram, patients with wet or attic perforations.

Clinical assessments of these patients included:

1. History taking
2. General examination in the form of Vital signs (Blood pressure, Temperature, Heart rate, Respiratory rate), Signs of (Pallor, Cyanosis, Jaundice, and Lymph node enlargement).

3. Full ENT examination including: Oropharyngeal examinations, nasal examination, ear examination searching for otitis media with effusion and adhesive otitis media and neck examination with assessment of cervical lymph nodes.

Pre-operative investigations included:

1. Laboratory investigations in the form of Complete Blood Count (CBC) and bleeding profile which includes prothrombin concentration (PC), prothrombin time (PT) and activated partial thromboplastin time (APTT).
2. Radiological investigations in the form of plain X-Ray soft tissue lateral view to nasopharynx.
3. Pre-operative pediatric assessment (Fitness) which includes general, cardiovascular, neurological and chest examination.
4. Pure tone audiometry: Pure tone audiometric air conduction testing is performed by presenting a pure tone to the ear through an earphone and measuring the lowest intensity in decibels (dB) at which this tone is perceived 50% of the time. This measurement is called threshold. The testing procedure is repeated at specific frequencies from 250 to 8000 hertz (Hz, or cycles per second) for each ear, and the thresholds are recorded on a graph called an audiogram.
5. Tympanometry: After an otoscopy (examination of the ear with an otoscope) to ensure that the path to the eardrum is clear and there is no perforation, the test is performed by

inserting the tympanometer probe in the ear canal.

The subjects of this study consist of 90 patients with TM perforation, will be conducted as candidates for simple myringoplasty using temporalis fascia graft, they will be arranged into 3 groups and treated as follow:

1. The first group: (30 patients) will be treated by simple myringoplasty using temporalis fascia graft and PRP.
2. The second group: (30 patients) will be treated by simple myringoplasty using temporalis fascia graft and Hyaluronic acid.
3. The third group: (30 patients), the control group, will be treated by simple myringoplasty using only temporalis fascia graft alone.

Post-operative assessment: Whether the tympanic membrane perforation was closed or not was checked during the post-operative course and finally at six months after surgery. The relationships between the rate of closure and the size of perforation, between the rate of closure and the cause of perforation, and between the rate of closure and the presence of otorrhoea were analysed by the chi-square test. For post-operative hearing, the air-bone gap was assessed at an average of three speech frequencies at least six months after surgery.

Postoperative Assessment Data:

1. Post-operative pain: Early post-operative pain which was measured 6 hours' post-operative, assessed by a visual analogue scale (VAS). A score of one means "no pain", while a score

of ten is "maximal pain" (*Puura et al., 2006*).

2. Recovery time was defined as the number of days taken to return to normal activity as judged by patient/parents during the routine post-operative follow-up at 7 days.

Follow up: Outcome of surgery was regarded as successful if the ear was dry and the tympanic membrane intact and mobile. The ear drum was considered adhesive if at least half of it couldn't be moved with a pneumatic otoscope. Audiometric tests were performed with a Madsen OB-70 or Madsen OB-822 audiometre calibrated according to ISO Standards. The results are presented as air-bone gaps before operation and at the last follow up examination comparing the preoperative and postoperative mean thresholds of air conduction at 0.5, 1 and 2 kHz with the preoperative mean thresholds of bone conduction in the same frequency range

Ethical consideration: Study protocol had been submitted for approval by ethical committee and Institutional Review Board (IRB) of Al-Azhar University.

Data management and Statistical Analysis: Data entry, processing and statistical analysis were carried out using Statistical package for social sciences (IBM-SPSS), version 24 (May 2016); IBM- Chicago, USA. Quantitative data were presented as frequency and percentage and compared by Chi2 test, Kruskal –Wallis test and Wilcoxon's test. Qualitative data were presented as mean \pm standard deviation and were compared by one – way ANOVA, and paired test. P-values less than 0.05 (5%) was considered to be statistically significant.

RESULTS

Three studied groups were comparable in demographic data without statistical significance difference (Table 1).

Table (1): Demographic characteristics between the studied groups

Parameters		Group A (n=30)	Group B (n=30)	Group C (n=30)	P
Age (years) Mean ± SD		34.05 ± 10.64	32.7 ± 6.85	35.1 ± 8.81	0.581
Gender	Female	14 (46.7%)	17 (56.7%)	15 (50%)	0.733
	Male	16 (53.3%)	13 (43.3%)	15 (50%)	
BMI (kg/m ²) Mean ± SD		25.49 ± 2.75	26.78 ± 3.44	26.35 ± 3.28	0.281

There was no significant difference found between the groups as regard comorbidities (Table 2).

Table (2): Comorbidities distribution between the studied groups

Parameters		Group A (n=30)	Group B (n=30)	Group C (n=30)	P
Smoking		12 (40%)	15 (50%)	17 (56.7%)	0.429
HTN		8 (26.7%)	9 (30%)	7 (23.3%)	0.843
Diabetes Mellitus		9 (30%)	11 (36.7%)	10 (33.3%)	0.861

There was no significant difference found between the groups as regard main complaints (Table 3).

Table (3): Main complaint distribution between the studied groups

Parameters		Group A (n=30)	Group B (n=30)	Group C (n=30)	P
Diminution of hearing		8 (26.7%)	6 (20%)	7 (23.3%)	0.844
Tinnitus		11 (36.7%)	11 (36.7%)	9 (30%)	
Ear discharge		0	2 (6.7%)	1 (3.3%)	
Ear fullness		10 (33.3%)	9 (30%)	11 (36.7%)	

There was no significant difference found between the groups as regard clinical characteristics (**Table 4**).

Table (4): Clinical characteristics between the two studied groups

Parameters		Group A (n=30)	Group B (n=30)	Group C (n=30)	P
Side	Right	19 (63.3%)	16 (53.3%)	18 (60%)	0.725
	Left	11 (36.7%)	14 (46.7%)	12 (40%)	
Causes	Infection	24 (80%)	20 (66.7%)	23 (76.7%)	0.468
	Trauma	6 (20%)	10 (33.3%)	7 (23.3%)	
Perforation location	Central ant.	13 (43.3%)	9 (30%)	11 (36.7%)	0.563
	Central post.	17 (56.7%)	21 (70%)	19 (63.3%)	

There was a significant difference between the three groups regarding postoperative PTA only. Meanwhile, there

was a significant decrease in PTA postoperatively in the three group (**Table 5**).

Table (5): PTA between the studied groups preoperatively and postoperatively

Parameters	Group A (n=30)	Group B (n=30)	Group C (n=30)	P
Preoperative Mean \pm SD	23.21 \pm 4.62	24.11 \pm 5.09	24.27 \pm 5.23	0.676
Postoperative Mean \pm SD	15.43 \pm 6.85	15.17 \pm 6.43	19.82 \pm 5.34	0.007
^t	4.35	5.73	3.09	
p	<0.001	<0.001	0.002	

There was no significant difference found between the groups as regard results outcomes (**Table 6**).

Table (6): Results distribution between the studied groups

Parameters	Group A (n=30)	Group B (n=30)	Group C (n=30)	P
Success	25 (83.3%)	27 (90%)	22 (73.3%)	0.236
Failure	5 (16.7%)	3 (10%)	8 (26.7%)	

DISCUSSION

The aim of the current study was to assess the effectiveness of adding platelet rich plasma (PRP) or Hyaluronic acid (HA) to Temporalis fascia graft to enhance healing of tympanic membrane in comparing with temporalis fascia graft alone in case of simple myringoplasty.

There were non-statistical significant differences between the studied groups as regard age, sex, and body mass index, so they were matched groups. In agreement with our findings, the study of *Sayed et al. (2018)* showed no statistical significance difference between the two groups as regard age and sex.

In another recent study done by *Ersozlu and Gultekin (2020)* who showed that there was no statistically significant difference in gender between the 2 groups, and there was no statistically significant difference in age between the 2 groups.

In the current study, majority of cases in both groups were smokers, followed by diabetics then hypertensive, and there was non-significant difference found between the groups as regard comorbidities. These findings came in harmony with the findings of the study of *Abd El-Gelil and Dawod (2020)* reported that in PRP group (45%) and in control group (50%). Patients had underlying diseases like hypertension, dyslipidemia, hypothyroidism and diabetes mellitus. There was no significant difference for underlying disease between two groups.

Chronic suppurative otitis media (CSOM) represents one of the most common infections of the ear. It is a worldwide health problem that is still prevalent in the modern antibiotic era. Chronic suppurative otitis media is characterized by chronic purulent discharge through a perforated tympanic membrane, which is intermittent or persistent, and which can be associated with cholesteatoma (*Gopen, 2010*).

In the current study, tinnitus and ear fullness were the main complaints in the three studied groups, followed by Diminution of hearing and then ear discharge, and there was no significant difference found between the groups as regard Main complaint. Similar to our findings, the previous study of *Kadah et al. 2018* reported that, in group A, the complaint in (27%) was diminution of hearing and 36% of patients of ear

discharge. In group B, the main complaint of 18% of patients was diminution of hearing and 36% of patients complain of tinnitus, and there was no significant difference found between the groups as regard main complaint.

In the current study, it was found that there was no significant difference found between the groups as regard side of lesion where right side was the major side in the three groups. Also as regard causes of perforation where infection is major cause in all groups, there was no significant difference found between the groups as regard Perforation location where central posterior was the most affected site in all three groups.

Abd El-Gelil and Dawod (2020) reported that in PRP group, 60% were right and 40% were left, and in control group, 65% were right and 35% were left ears were enrolled.

In the current study, we found that there was a significant difference between the three groups regarding postoperative pure tone audiometry only. Meanwhile, there was a significant decrease in PTA postoperatively in the three groups. *Alhabib and Saliba (2017)* found that pure tone average (PTA) was statistically significant at 6 and 12 months postoperatively in HAFGM and not in PRPM. The air-bone gap (ABG) improved at 6 and 12 months postoperatively in the HAFGM group and the ABG of PRPM was not improved postoperatively; This was different from the current study and in which the air-bone gap was significantly improved in both groups. The hearing improvement when comparing between the two groups was found to be better in the HAFGM group

this was similar to the present study, where the group A achieve improvement in the air-bone gap post-operatively.

Yung et al. (2011) found postoperative air-bone gaps and hearing gains at 24 months were 16.97 dB and 13.63 dB, respectively in the fascia group and 20.63 dB and 12.60 dB, respectively in the cartilage group. There was no significant difference in the graft uptake rates or postoperative hearing between the two groups.

In the study of *Kadah et al. (2018)*, the air-bone conduction gap improved post-operatively in [81.82%] of group (A), and [72.73%] of group (B). There was no statistically significant difference between both groups. However, hearing improved significantly when either of the technique was used; preoperative mean air-bone conduction gap.

Hyaluronic acid has been found to accelerate tympanic membrane perforation closure, shorten the period of healing, and improve hearing; Hyaluronic acid is biodegradable, safe and biocompatible in the ear (*Maria e al., 2011*). Hyaluronic acid improves tympanic membrane wound healing by inducing the production of keratin, which serves as a scaffold for migrating epithelium and preventing dehydration of the perforation margin. Hyaluronic acid also enhances hearing by producing better quality neo-membrane with a well-organized fibrous layer (*Liu et al., 2013*).

In the current study, there was no significant difference found between the groups as regard success of Myringoplasty by the different methods. In agreement with our findings, the study of reported that hearing improved significantly, Also,

Sayin et al. (2013) concluded that the use of HA ester patching resulted with earlier closure time but not resulted with higher closure rates and this was different from the current study which shows increase rate of closure when esterified HA was used. *Ersozlu and Gultekin (2020)* reported that respectively, and there was no statistically significant difference in these gains. The FGM with PRPG technique resulted in a significantly higher success rate for large perforations than FGM alone.

CONCLUSION

Myringoplasty for the closure of a perforation in patients with TM perforation is an effective procedure and can produce good results in terms of hearing improvement, closure of defect and psychosocial betterment if diagnosed and treated early. It has a good success rate as compared to fascia alone and temporalis fascia graft with Hyaluronic acid, with minimal or no morbidity, and no complications.

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دراسة مقارنة بين استخدام الصفائح المشبعة بالبلازما او
حمض الهيالويورنيك مع رقعة اللفافة الصدغية او عدم
استخدامهم في نتائج عمليات ترقيع طبلة الاذن
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خلفية البحث: ترقيع طبلة الاذن. واحدة من العمليات الجراحية الشائعة في طب الاذن لعلاج التهاب الاذن الوسطى القيحي المزمن ويشير راب الطبلة إلى إغلاق جراحي بسيط لثقب في غشاء الطبلة بدون إعادة بناء عظمي. والبلازما الغنية بالصفائح الدموية ذات عوامل النمو المختلفة تحسن التئام الجروح.

الهدف من البحث: هو تقييم فعالية إضافة الصفائح الدموية المشبعة بالبلازما أو حمض الهيالورونيك إلى لفافة الصدغ لتعزيز التئام الغشاء الطبلي بالمقارنة مع رقعة اللفافة الصدغية وحدها في حالة راب الطبلة البسيطة.

المرضي و طرق البحث: تم اجراء البحث على تسعين مريضا مقسمة إلى ثلاث مجموعات: **المجموعة الاولى** مكونة من ثلاثين فرداً باستخدام رقعة اللفافة الصدغية فقط، و**المجموعة الثانية** مكونة من ثلاثين فرداً باستخدام رقعة اللفافة الصدغية مع حمض الهيالويورينك، و**المجموعة الثالثة** مكونة من ثلاثين فرداً باستخدام رقعة اللفافة الصدغية مع الصفائح المشبعة بالبلازما، وتم اجراء البحث بمستشفى الحسين وباب الشعرية الجامعي ومعهد السمع والكلام ابتداءً من شهر سبتمبر 2020 حتى شهر أغسطس 2021.

نتائج البحث: كانت هناك فروقاً ذات دلالة إحصائية بين المجموعات المدروسة من حيث العمر والجنس ومؤشر كتلة الجسم. كانت غالبية الحالات في المجموعتين من المدخنين، ويليهم مرضى السكري ثم مرضى ارتفاع ضغط الدم، ولم يكن هناك فرقاً معنوياً بين المجموعتين فيما يتعلق بالأمراض المصاحبة وكان

طنين الأذن وامتلاء الأذن هما الشكاوي الرئيسية في المجموعات الثلاث المدروسة، ويليهما ضعف السمع ثم إفرازات الأذن، ولم يكن هناك فرقاً معنوياً بين المجموعتين فيما يتعلق بالشكاوي الرئيسية ولم يكن هناك فرق كبير بين المجموعات فيما يتعلق بجانب الآفة حيث كان الجانب الأيمن هو الجانب الرئيسي في المجموعات الثلاث، وكذلك فيما يتعلق بأسباب الانتقاب حيث تكون العدوى سبباً رئيسياً في جميع المجموعات، علاوة على ذلك، لم يكن هناك فرقاً كبيراً بين المجموعات فيما يتعلق بموقع التنقيب حيث كان المركز الخلفي هو الموقع الأكثر تضرراً في المجموعات الثلاث و كان هناك فرقاً كبيراً بين المجموعات الثلاث فيما يتعلق بقياس السمع النقي بعد العملية الجراحية فقط. وفي الوقت نفسه، وكان هناك انخفاضاً كبيراً في قياس السمع النقي بعد الجراحة في المجموعات الثلاث ولم يتم العثور على فرق كبير بين المجموعات فيما يتعلق بنجاح ترقيع طبلة الأذن بالطرق المختلفة. كان متوسط العمر في المجموعة الأولى 10.64 ± 34.05 سنة، وكان 6.85 ± 32.7 في المجموعة الثانية، و 8.81 ± 35.1 سنة في المجموعة الضابطة.

الاستنتاج: أن إضافة حمض الهيالويورينيك أو الصفائح المشبعة بالبلازما إلى رقعة اللفافة الصدغية يعطي نتائج أفضل من استخدام رقعة اللفافة الصدغية بمفردها في عمليات ترقيع طبلة الأذن.

الكلمات الدالة: حمض الهيالويورينيك، رقعة اللفافة الصدغية، ترقيع طبلة الأذن، ثقب وسطي بطبلة الأذن.