

COMPARATIVE STUDY BETWEEN PATCHING AND CONSERVATIVE TREATMENT OF TRAUMATIC TYMPANIC MEMBRANE PERFORATION

By

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ABSTRACT

Background: Trauma remains a regular occurrence relating to activities and lifestyle of humans and it can affect any part of the body. The ear is located within the cranio-facial skeleton which is exposed to environmental trauma that can occur as blunt injuries like contusion, concussion, decompression, and penetrating injuries as fractures.

Objective: The aim of the present work was to investigate the effect of patching of traumatic TMP either with gel foam or steri-strips, and to compare it with conservative treatment depending on closure rate, closure time, hearing gain, and rate of otorrhea.

Patients and Methods: This prospective study was carried out on sixty patients who attended to outpatient clinic of Al-Hussien and Sayed Galal Hospitals, Al-Azhar University from February 2019 to December 2019. All patients who came with traumatic tympanic membrane perforation were screened. They were divided randomly into three equal groups; group A was treated conservatively, group B was treated by steri-strip patch, and group C was treated by gel foam patch.

Results: The closure rates of the perforations in conservative group, Steri-Strips patching and gel foam patching groups were 80%, 95%, and 100%, respectively. There was no statistically significant difference in tympanic membrane closure rate between the 3 groups. Steri-Strip and gel foam patching groups showed shorter healing times compared with the conservative group. However, there was an increased rate of otorrhea in the Steri-Strip group and conservative group compared with gel foam patching group.

Conclusion: Steri-strip and gel foam patching accelerated the closure of small, moderate and large traumatic tympanic membrane perforations, closure rates and closure times did not differ significantly among the steri-strip and gel foam groups. The closure time increased in steri-strip and gel foam groups in comparison to conservative group and this difference is highly significant.

Keywords: conservative, patching, Traumatic tympanic membrane perforation.

INTRODUCTION

Major injuries affecting the ears can lead to disturbances in hearing and difficulties in maintenance of balance especially when the inner ear is affected (*Eagles et al., 2013*). Treatment of TTMP range from inactive watchful waiting,

active intervention to surgical intervention (*Jellinge et al., 2015*). Otolaryngologists have however been advised to be reluctant in offering surgical intervention in cases of TTMP without significant symptoms as most patients will heal spontaneously within two months (*Smith et al., 2012*).

Active interventions include topical application of substances like epidermal growth factor, enoxaparin, and ascorbic acid to stimulate epithelization for quick closure or to prevent formation of sclerotic plaques in the perforated membrane (*Lou et al., 2016*).

Surgical intervention is indicated in cases of complications like perilymph fistula, facial paralysis, severe vertigo, or profound sensorineural hearing loss. Such diagnosis should be made early and treatment offered promptly (*Smith et al., 2012*).

It included exploration and tympanoplasties, closure of the perforation with stents in the form of simple patches or as patches laden with substances in the form of silk fibroin membranes or steri-strips patching (*Park et al., 2011*)

The aim of the present work was to investigate the effect of patching of traumatic TMP either with gel foam or steri strips and to compare it with conservative treatment depending on closure rate, closure time, hearing gain, and rate of otorrhoea.

PATIENTS AND METHODS

This prospective study was carried out on sixty patients who attended to outpatient clinic of Al-Hussien and Sayed Galal University Hospitals from February 2019 to December 2019. All patients who came with traumatic tympanic membrane perforation were screened. They were divided randomly into three equal groups; group A was treated conservatively, group B was treated by steri-strip patch and group C was treated by gelfoam patch. All

patients signed informed consents before the study.

Exclusion criteria: Otitis media, granulation tissue in the ear, persistent otorrhea, severe vertigo, profound hearing Loss, facial palsy and temporal bone fracture.

All patients were submitted to full history, general and ENT examinations. Pure tone audiometry is performed. In observation group, there was no intervention, but the patients underwent medical treatment including systemic antibiotics, nasal decongestant and analgesics then regular follow-up.

Transcanal approach was under local anesthesia. Under the otomicroscope, the external auditory canal was injected with 2% lidocaine and 1:100,000 epinephrine at the bony cartilaginous junction. A small piece of a Steri-Strips was trimmed to provide a 1- or 2-mm overlapping margin around the perimeter of the perforation. Gel foam a highly absorbent, non-elastic sponge manufactured from neutral gelatine of pharmaceutical grade material around 4 mm thick was used in group C. Minimal amount of gel foam of appropriate size and shape was applied over the perforation and held firmly in place. No ear drops or packing of the auditory canal were used in either group.

Statistical analysis:

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done:

- Chi-square (x²) test of significance was used in order to compare proportions between qualitative parameters.
- A one-way analysis of variance (ANOVA) when comparing between more than two means.
- Post Hoc test: Least Significant Difference (LSD) was used for multiple comparisons between different variables.

- The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:
 - P-value <0.05 was considered significant.

RESULTS

No statistically significant difference between both groups according to demographic data (Table 1).

Table (1): Comparison between three groups according to demographic data

| Demographic data \ Groups | Conservative (n=20) | Steri-strip (n=20) | Gel foam (n=20) | p-value |
|---------------------------|---------------------|--------------------|-----------------|---------|
| Age (years) | | | | |
| Range | 15-59 | 17-59 | 16-59 | >0.05 |
| Mean±SD | 29.97±5.69 | 28.77±5.46 | 29.37±6.07 | |
| Sex | | | | |
| Male | 9 (45%) | 8 (40%) | 10 (50%) | >0.05 |
| Female | 11 (55%) | 12 (60%) | 10 (50%) | |
| Laterality | | | | |
| Right | 6 (30%) | 8 (40%) | 7 (35%) | >0.05 |
| Left | 14 (70%) | 12 (60%) | 13 (65%) | |

F-One Way Analysis of variance; #x²: Chi-square test

No statistically significant difference between groups according to etiology (Table 2).

Table (2): Comparison between three groups according to etiology

| Etiology \ Groups | Conservative (n=20) | Steri-strip (n=20) | Gel foam (n=20) | p-value |
|-------------------|---------------------|--------------------|-----------------|---------|
| Slap injury | 9 (45%) | 11 (55%) | 8 (40%) | >0.05 |
| Self cleaning | 6 (30%) | 5 (25%) | 7 (35%) | |
| RTA/ Fall | 2 (10%) | 1 (5%) | 2 (10%) | |
| Blow | 1 (5%) | 1 (5%) | 1 (5%) | |
| Iatrogenic | 2 (10%) | 2 (10%) | 2 (10%) | |

x²: Chi-square test;

No statistically significant difference between groups according to healing outcome of traumatic TM perforations (Table 3).

Table (3): Comparison between three groups according to healing outcome traumatic TM perforations

| Healing outcome of traumatic TM perforations | Groups | | |
|--|---------------------|--------------------|-----------------|
| | Conservative (n=20) | Steri-strip (n=20) | Gel foam (n=20) |
| Small | 5 | 6 | 5 |
| Healing | | | |
| No. | 5 | 6 | 5 |
| % | 100.0% | 100.0% | 100.0% |
| Medium | 11 | 10 | 12 |
| Healing | | | |
| No. | 9 | 10 | 12 |
| % | 81.8% | 100.0% | 100.0% |
| Large | 4 | 4 | 3 |
| Healing | | | |
| No. | 2 | 3 | 3 |
| % | 50.0% | 75.0% | 100.0% |
| p-value | >0.05 | | |

x²: Chi-square test;

No statistically significant difference between groups according to occurrence of infection and No. of patients with healed TM perforation after control of infection. (Table 4).

Table (4): Comparison between three groups according to occurrence of infection and numbers of patients with healed TM perforation after control of infection

| Parameters | Groups | | | p-value |
|---|---------------------|--------------------|-----------------|---------|
| | Conservative (n=20) | Steri-strip (n=20) | Gel foam (n=20) | |
| Occurrence of infection | 2 (10%) | 5 (25%) | 1 (5%) | >0.05 |
| No. of patients with healed TM perforation after control of infection | 0 (0%) | 4 (80%) | 1 (100%) | |

x²: Chi-square test;

Higher closure rates in steri-strip and gel foam groups compared to conservative group, but insignificant statistically significant difference present between groups according to closure times. No

statistically significant difference between groups according to hearing gain (dB) statistically significant higher of otorrhea in steri-strip compared to conservative and gel foam groups (Table 5).

Table (5): Comparison between three groups according to outcome of closure rates, closure time, hearing gain and rate of otorrhea

| Parameters \ Groups | Conservative (n=20) | Steri-strip (n=20) | Gel foam (n=20) | p-value |
|----------------------------|---------------------|--------------------|-----------------|---------|
| Closure rates,(%) | | | | |
| Yes | 16 (80%) | 19 (95%) | 20 (100%) | 0.058 |
| No | 4 (20%) | 1 (5%) | 0 (0%) | |
| Closure time (days) | | | | |
| Mean±SD | 32.96±7.09 | 25.37±7.44a | 23.89±8.51a | 0.011* |
| Hearing gain, (Db) | | | | |
| Mean±SD | 13.18±2.78 | 13.91±2.78 | 14.03±2.68 | >0.05 |
| Otorrhea,(%) | 2 (10%) | 5 (25%) | 1 (5%) | >0.05 |

x2: Chi-square test;

DISCUSSION

Tympanic membrane perforations may occur as the result of a pressure wave in the external ear canal, or by direct penetration. About 50% are attributable to slap injuries or direct blows (*Lou et al., 2012*).

An overview on traumatic TM perforations reported most common complaint was tinnitus followed by aural fullness and reduced hearing (*Wani et al., 2016*).

In our study, the most common symptom was hearing loss followed by pain and ear buzzing. The most distressing symptom was ear buzzing.

Previous studies have noted higher prevalence of traumatic TM perforation in female population consistent with our findings (*Lou et al., 2012*).

Traumatic perforations of the tympanic membrane have a very high chance of spontaneous healing. So, early surgical intervention of traumatic perforations is not indicated by few studies (*Al-Juboori, 2014*).

In our study, the healing outcome with conservative management was very good. However, ear buzzing still present for initial few weeks till the perforation reduced or healed. Though two of them developed a secondary infection later on; their healing outcome was 100%. They were treated by simple dry ear mopping and the infection was controlled. Presence of infection did not affect the healing process.

In this study, Steri-Strips patching showed a relatively increased rate of otorrhea. No difference has been found between Steri-Strips and sutures or tissue adhesives in terms of infection in closure of surgical incisions (*Coulthard et al., 2010*).

In this study, the TMP closed in 4 of 5 Steri-Strips patching patients after otorrhea stopped. This may have occurred as a result of angiogenesis induced by infection. In this study, closure rates and closure times in patients with otorrhea were not different from closure rates and closure times in patients without otorrhea.

Gel foam is highly purified neutral gelatin of pharmaceutical grade material.

It is non-toxic, non-allergic, non-immunogenic and non-pyrogenic. It is usually absorbed completely in 4-6 weeks without inducing excess scar tissue. In a recent study it was also concluded that gel foam patching helps epithelial migration, promotes edema, granulation tissue formation at the edges and aids in ear drum healing (*Huang et al., 2017*).

In this prospective study, we compared the healing of TM perforations in steri-strip, gel foam groups and conservative group. We found that the overall healing rate differed insignificantly between the three groups at different time points. The application of steri-strip and gel foam patches promoted the healing of TM perforations.

CONCLUSION

The findings of this study revealed that steri-strip and gel foam patching accelerated the closure of small, moderate and large traumatic tympanic membrane perforations, and that closure rates and closure times did not differ significantly among the steri-strip and gel foam groups. The closure time showed highly significant difference between conservative group, steri-strip and gel foam groups. Hearing gain and rate of otorrhea were not statistically significant among three groups, but possibility of otorrhea occurring when using Steri-Strips patching.

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دراسة مقارنة بين ترقيع وعلاج ثقب غشاء طبلة الأذن الرضحي

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خلفية البحث: تعتبر الإصابات حدث منتظم متعلق بأنشطة ونظام معيشة الإنسان وتؤثر على أي جزء في الجسم. تقع الأذن في الهيكل الوجهي المخي وهي تتعرض للإصابات الخارجية التي قد تحدث مثل الإصابات الحادة ومن أمثلتها الكدمات والرج والإصابات النافذة مثل الكسور

الهدف من البحث: مقارنة ترقيع ثقب غشاء طبلة الأذن الناتج عن الإصابات باستخدام الجيل فوم أو شرائط ستري أو العلاج فقط، وذلك من حيث معدل الالتئام وزمن الالتئام وتحسن السمع ومعدل خروج الإفرازات.

المرضي وطرق البحث: أجريت هذه الدراسة الاستطلاعية علي ستين مريضاً والذين حضروا الي العيادة الخارجية في مستشفى الحسين الجامعي ومستفى سيد جلال الجامعي من فبراير ٢٠١٩ الي ديسمبر ٢٠١٩. وقد كان جميع المرضي يحضرون بثقب في غشاء طبلة الأذن ناتج عن الإصابات. وقد تم تقسيم المرضي بشكل عشوائي الي ثلاث مجموعات متساويات: المجموعة (أ) تم علاجهم بالأدوية فقط، والمجموعة (ب) تم عمل ترقيع طبلة الأذن باستخدام شرائط ستري، والمجموعة (ج) تم عملية ترقيع طبلة الأذن باستخدام الجيل فوم.

النتائج: معدل إلتئام الجروح بعد العلاج فقط كان ٨٠%، وبعدها الترقيع باستخدام شرائط ستري كان ٩٥%، وبعدها الترقيع باستخدام الجيل فوم

كان ١٠٠%، وهذا الاختلاف فى معدل إلتئام الجروح بين الثلاث مجموعات غير ملحوظ إحصائيا. ويقلل الترقيع باستخدام شرائط ستري او الجيل فوم زمن إلتئام غشاء طبلة الأذن مقارنة بالعلاج فقط ولكن معدل حدوث الإفرازات من الأذن يزيد فى مجموعة الترقيع باستخدام شرائط ستري ومجموعة العلاج فقط مقارنة بمجموعة استخدام الجيل فوم.

الاستنتاج: الترقيع باستخدام شرائط ستري والجيل فوم تسرع من زمن إلتئام ثقب غشاء طبلة الاذن الرضحي الصغير والمتوسط والكبير ومعدل وزمن الالتهام لا يختلف بشكل كبير بين استخدام شرائط ستري والجيل فوم ولكن زمن الالتهام يزيد بشكل كبير فى مجموعات شرائط ستري والجيل فوم مقارنة بالعلاج فقط.