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Does balloon Eustachian tuboplasty increase the success rate in repair of subtotal tympanic membrane perforations with resistant tubal dysfunction?

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Keywords
Subtotal perforation; Eustachian tuboplasty; Balloon; Dysfunction

Abstract
Objectives: To evaluate the effect of balloon Eustachian tuboplasty on the results of surgical reconstruction of subtotal tympanic membrane perforations in cases of resistant Eustachian tube dysfunction.

Design: Prospective randomized study.

Setting: Tertiary care university hospital.

Patients: Seventy-two patients with dry subtotal tympanic membrane perforations and resistant Eustachian tube dysfunction, aging 19–51 years, were distributed randomly in two groups A and B.

Interventions: Both groups underwent underlay myringoplasty using temporalis fascia graft. In group A, myringoplasty was preceded by balloon dilatation of the cartilaginous Eustachian tube.

Main outcome measures: Graft take rate, hearing results and middle ear pressure.

Results: Graft take rate at 12 months postoperative showed a significant difference between the two groups where it was 89.2% in group A (33 of 37 cases) and 80% in group B (28 of 35 cases). Pure tone audiometry results at 12 months postoperative showed a significant improvement of air conduction curves at all frequencies in both groups. The middle ear pressure was significantly better in group A at 6 months (mean pressure: −29 daPa in group A, −60 daPa in group B) and at 12 months postoperative (mean pressure: −55 daPa in group A, −79 daPa in group B).
1. Introduction

Chronic suppurative otitis media (CSOM) without cholesteatoma is an entity whose definition and surgical treatment are somewhat controversial. Chronic suppurative otitis media is considered to be a chronic inflammation of the middle ear and mastoid mucosa in which the tympanic membrane (TM) is not intact and discharge is present. Standard treatments for CSOM include debridement, ototopical therapy, and dry ear precautions. In those cases that do not resolve or result in spontaneous healing of the TM with conservative measures, surgical intervention is considered.

Repair of TM perforations includes the use of variable types of grafts. Although temporalis muscle fascia is the most frequently used grafting material, with a success rate of approximately 90% in primary tympanoplasties, lower success rates for larger perforations have been reported. In practice, the size actually affects the results where larger perforations are associated with lower success rates. These poor results may be related to factors including the regenerative power of the drum, mastoid cavity problems and/or chronic ET dysfunction.

Evaluation of ET dysfunction with balloon Eustachian tuboplasty in the results of reconstruction of subtotal tympanic membrane perforations in cases of resistant Eustachian tube dysfunction.

Eustachian tube function is an important prognostic factor for the success in tympanoplasty. Better results have been reported in patients with normal ET function, and higher failure rates after tympanoplasty have been observed in patients with ET problems. Many methods were designed to improve the ET function whether medical or surgical including the development of minimally invasive procedures such as the balloon dilation or Eustachian tuboplasty.

Balloon Eustachian tuboplasty is a recent advance in the management of ET dysfunction that proved to be safe and yields good results in restoring ET function. It involves the use of a special balloon to dilate the cartilaginous part of the Eustachian tube.

We designed this study to assess the impact of balloon Eustachian tuboplasty in the results of reconstruction of subtotal tympanic membrane perforations in cases of resistant Eustachian tube dysfunction.

2. Methods

After getting the approval of the university ethics committee and written consents from all enrolled patients, this study was conducted on 76 patients suffering from inactive chronic suppurative otitis media. Patients were prospectively selected from the otorhinolaryngologic outpatient clinic of Benha University Hospitals or referred from other hospitals in the same governorate from July 2009 to January 2012.

Preoperative assessment included otomicroscopy, pure tone audiometry (air conduction and bone conduction thresholds at frequencies: 250–8000 Hz), air-bone gap (ABG), Inflation-deflation test, CT scan of temporal bone (to exclude mastoid pathology) and routine preoperative investigations. The inflation–deflation test was done by introducing positive (or negative) pressure of approximately 400 daPa. If the ET opens as a direct result of the pressure (i.e. the pressure returns toward 0 daPa) the ET is most likely working properly. If the pressure does not equalize, the patient should swallow several times over 20 s. If the pressure still does not equalize, there is ET dysfunction.

Patients with bad ET function received medical treatment as a trial for at least one month. They received nasal decongestants, antihistaminics and corticosteroids. They also received systemic antihistaminics, gradually declining doses of corticosteroids and mucoregulators.

Inclusion criteria were: adult patients with subtotal perforations (defined as perforation > 75% of TM size and not reaching the annular ligament), dry for at least 3 months, bad Eustachian tube function resistant to full courses of medical treatment, conductive hearing loss correlating with the perforation, normal contralateral ear with normal hearing, no mastoiditis or cholesteatoma, no nasal or nasopharyngeal masses, no chronic sinus infection, no velopharyngeal insufficiency, no patulous ET, no pregnancy, normal mental faculties and absence of uncontrolled systemic diseases.

Using sealed envelopes, patients were randomly divided into two groups: A and B. Group A included 38 patients in whom the TM was reconstructed by myringoplasty combined with balloon Eustachian tuboplasty. Group B included 38 patients in whom the TM was reconstructed by myringoplasty without any other procedure.

2.1. Interventions

All cases underwent underlay myringoplasty using temporalis fascia graft. Under general anesthesia, a postauricular incision was performed and a large piece of the true temporalis fascia was harvested and prepared. The tympanomeatal flap was elevated till the annulus after fine trimming of the perforation edge. The ossicles were inspected for integrity and mobility.

The middle ear was packed with gel foam pieces before accurate placement of the graft medial to the drum remnants and the handle of malleus. Another layer of gel foam pieces was placed on the graft and the external canal was then packed with a gauze containing antibiotic ointment.

In group A, myringoplasty was preceded by balloon dilation of the Eustachian tube. Under transnasal endoscopic vision, a balloon catheter (Bielefeld Balloon Catheter, Germany) (Fig. 1); 6 mm in diameter and 16 mm in length was introduced into the pharyngeal orifice of the Eustachian tube. Once the catheter was correctly positioned in the pharyngeal orifice, the balloon was carefully advanced into the cartilaginous tube while avoiding any resistance (Fig 2a). The tube should not be advanced beyond its length to avoid entrance in the bony part of the ET. Once the balloon was positioned correctly inside the cartilaginous tube, a saline solution was used...
to apply the dilation up to a pressure of 10 bars (Fig. 2b) using balloon inflator. Pressure was maintained for 2 min, then the solution was aspirated from the balloon and the catheter was carefully removed with the endoscope to complete the procedure. No mastoidectomy was done.

**Outcome measures** included the graft take rate, hearing results (PTA, ABG), and middle ear pressure. Graft take success was defined as a complete closure of the TM at 12 months postoperative.

**Follow up visits** were assigned after the 1st week, 2, 4 weeks then after 6 and 12 months. In each visit; the TM was inspected for healing and for any complication. PTA and middle ear pressure were measured at 6 and 12 months postoperatively.

**Statistical analysis** A variance analysis with repeated measures and χ² tests were performed for statistical analysis. A $P < .05$ was considered statistically significant.

### 3. Results

This study included 76 patients; only 72 patients fulfilled the required data and period. Table 1 shows the general characteristics of both groups. Group A included 37 patients (18 males, 19 females) with mean age of 33.6 years. Group B included 35 patients (19 males and 16 females) with mean age of 28.4 years. All patients did not have previous ear surgeries.

**Graft take rate** at 12 months postoperative showed a significant difference between the two groups where it was 89.2% (33 cases of 37) in group A and 80% in group B (28 cases of 35) ($P < 0.05$) (Table 2).

**Pure tone audiometry** results at 12 months postoperative showed a significant improvement of air conduction curves at all frequencies in both groups with slight better results in group A; yet statistically insignificant difference between the two groups. (Table 3) There were no significant changes in the bone conduction curves.
Table 1: General characteristics of the studied groups.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cases</td>
<td>37</td>
<td>35</td>
</tr>
<tr>
<td>Age; mean (SD) years</td>
<td>33.6 (6.6)</td>
<td>28.4 (3.76)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>18</td>
<td>19</td>
</tr>
<tr>
<td>Female</td>
<td>19</td>
<td>16</td>
</tr>
<tr>
<td>Side (%)</td>
<td></td>
<td></td>
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<tr>
<td>Right</td>
<td>16</td>
<td>21</td>
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<tr>
<td>Left</td>
<td>21</td>
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Table 2: The take rate in the studied groups.

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
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<tr>
<td>Number of cases</td>
<td>37</td>
<td>35</td>
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<tr>
<td>Take number</td>
<td>33</td>
<td>28</td>
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<tr>
<td>Percentage</td>
<td>89.2%</td>
<td>80%</td>
</tr>
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</table>

Table 3: Mean of air conduction averages at 250–8000 Hz preoperative and 12 months postoperative.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Group</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>P value</th>
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<tr>
<td>250</td>
<td>A</td>
<td>36.45 ± 4.28</td>
<td>20.20 ± 3.18</td>
<td>Significant</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>35.9 ± 4.65</td>
<td>22.6 ± 4.35</td>
<td>Significant</td>
</tr>
<tr>
<td>500</td>
<td>A</td>
<td>38.5 ± 3.5</td>
<td>16.00 ± 3.65</td>
<td>Significant</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>35.00 ± 3.80</td>
<td>21.60 ± 3.25</td>
<td>Significant</td>
</tr>
<tr>
<td>1000</td>
<td>A</td>
<td>36.75 ± 3.55</td>
<td>18.33 ± 4.24</td>
<td>Significant</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>38.55 ± 2.67</td>
<td>19.20 ± 3.55</td>
<td>Significant</td>
</tr>
<tr>
<td>2000</td>
<td>A</td>
<td>33.25 ± 3.8</td>
<td>18.59 ± 3.70</td>
<td>Significant</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>34.50 ± 2.9</td>
<td>19.40 ± 5.50</td>
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</tr>
<tr>
<td>4000</td>
<td>A</td>
<td>39.08 ± 4.8</td>
<td>23.80 ± 3.96</td>
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<tr>
<td></td>
<td>B</td>
<td>36.65 ± 3.9</td>
<td>21.00 ± 2.65</td>
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<tr>
<td>8000</td>
<td>A</td>
<td>35.45 ± 3.75</td>
<td>18.70 ± 2.60</td>
<td>Significant</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>36.75 ± 5.05</td>
<td>19.90 ± 3.25</td>
<td>Significant</td>
</tr>
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</table>

The means of ABG in groups A and B showed a significant improvement from 30.08 to 9.25 dB in group A and from 29.65 to 9.85 dB in group B as shown in Table 4. There were no significant differences between postoperative means in both groups.

The middle ear pressure was significantly better in group A at 6 months (mean pressure: −29 daPa in group A, −60 daPa in group B) and at 12 months postoperative (mean pressure: −55 daPa in group A, −79 daPa in group B). Table 5.

Failed cases: Incomplete graft take with residual small-sized perforations ranging from pin-point perforation to size <25% of the TM occurred in four cases in group A and in seven cases in group B. They were managed by inlay cartilage tympanoplasty under local anesthesia.

Complications: No SNHL, facial palsy, blunting, and lateralization occurred in both groups. No occurrence of patulous tube in any case. Tympanic membrane retraction of grade II occurred in two cases of group A (5.4%) and in nine cases of group B (25.7%).

The surgeries were performed by senior MD staff members. The mean operative time in group A was 49 ± 6.5 min including the dilatation procedure while it was 38.5 ± 7.2 min in group B.

4. Discussion

Up to our best knowledge, balloon Eustachian tuboplasty was never used in combination with myringoplasty in the management of subtotal perforations. Balloon Eustachian dilation, through the pharyngeal orifice, was proved as a safe procedure and presented success in restoring ET function.

Combining balloon tuboplasty to myringoplasty resulted in a significantly higher graft take and normal middle ear pressure while it did not add to the hearing gain. The middle ear pressure was within or near normal during the follow up period. This reflects an effective restoration of Eustachian tube function after tuboplasty. However, soft tissue balloon dilation of stenotic vessels, biliary tree, urinary strictures, and other tubular organs has been demonstrated to have lasting benefits and this could be expected after Eustachian tuboplasty.

Balloon tuboplasty appears to give a better chance for graft healing and restoration of middle ear integrity. For ventilation and pressure regulation within the middle ear, gas exchange via the middle ear mucosa and the mastoid is important, in addition to exchange via the ET. The presence of ET obstruction/dysfunction is a poor prognostic sign, indicating interference with gas exchange. Overall, good ET function facilitates better hearing, improves restoration of middle ear aeration, and leads to fewer post-operative complications.

The take rate of the study group was significantly higher than the control group. This rate was comparable with the success rate of other studies using cartilage grafts, allograft, and hyaluronic acid fat grafts.

Preoperative assessment of ET function was not helpful for comparing pre and postoperative functions of the ET but it highlighted the preoperative state of the Eustachian tube and guided the choice of patients. No single non-invasive test can assess ET function by the same way in cases of intact and perforated TMs.

Temporalis fascia graft was used in all cases to be able to monitor postoperative middle ear pressure that might not be correctly measured if cartilage grafts were used. Normal middle ear aeration is reflected in type A tympanography, whereas a thick tympanic membrane (e.g. after cartilage...
Balloon Eustachian tuboplasty in myringoplasty

Balloon Eustachian tuboplasty is a safe, easy and effective procedure that yields better results in reconstructions of subtotal TM perforations in cases of resistant Eustachian tube dysfunction without noticeable complications.

5. Conclusion

Balloon Eustachian tuboplasty is a safe, easy and effective procedure that yields better results in reconstructions of subtotal TM perforations in cases of resistant Eustachian tube dysfunction without noticeable complications.

References

Does balloon Eustachian tuboplasty increase the success rate in repair of subtotal tympanic membrane perforations with resistant tubal dysfunction?

هل تزيد توسع قناة استاحكيوس بالبالون من نسبة النجاح في إصلاح الثقوب الشبه هل تزيد توسع قناة استاحكيوس بالبالون من نسبة النجاح في إصلاح الثقوب الشبه

اسم المجلة: المجلة المصرية للأنف والأذن والحنجرة والعلوم المشتركة

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د/ أحمد محمد عبد الغني

رئيس قسم الأذن و الأنف والحنجرة

أ/ أحمد محمود سلطان

التقدم للتقيمة

جهود توجيه محمد موفق

28/3/2018
المتلخص العربي:

الأهداف: تقييم أثر توسيعة قناة استئكسيوس بالبالون على نتائج جراحة إصلاح ثقب طبلة الأذن الشبه كامل.

التصميم: دراسة مستقبيلة عشوائية.

التجهيزات: مستشفى جامع.

المريض: واحد وثمانين مصاباً مصاب بثقب طبلة الأذن الشبه كامل، الأعمار من 19 - 51 عاماً، تم توزيعهم عشوائياً على مجموعتين: أ - ب.

التدخل: تم إجراء جراحة إصلاح للثقب باستخدام غشاء العضلة الصدغية. في المجموعة الأولى سبق ذلك توسيعة قناة استئكسيوس باستخدام البالون.

قياسات النتائج الرئيسية: معدل نجاح الرقعة، النتائج السمعية، ضغط الأذن الوسطي.

النتائج: معدل نجاح الرقعة بعد 12 شهراً من الجراحة أظهر تفوقاً ملموساً للمجموعة الأولى حيث كانت النتيجات 90% للمجموعة الأولى و 80% للمجموعة الثانية. قياس السمع بعد 12 شهراً من الجراحة أظهر تحسناً ملموساً في جميع المجموعتين في جميع الترددات. ضغط الأذن الوسطي كان أفضل في المجموعة الأولى بصورة ملموسه بعد 6 شهور من الجراحة واستمر بنفس الصورة بعد الشهر الثاني عشر.

الاستنتاج: توسيعة قناة استئكسيوس باستخدام البالون تدخل آمن وسهيل وفعال ويؤدى لتحسن ملحوظ في نتائج الإصلاح الجراحي لثقوب الأذن الشبه كاملاً.

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