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Endoscopic tympanoplasty: single versus double flap technique

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Introduction:

The aims of tympanoplasty are elimination of disease and restoration of function. Restoration of function requires a healthy tympanic membrane, an air-containing, mucosal-lined middle ear and a connection between the tympanic membrane and the inner ear fluids (*Harris et al., 2016*)

Underlay (medial) and overlay (lateral) techniques are two traditional methods for repair of TM perforations. The underlay technique is easier to perform and less time consuming (*Fayad and Sheehy, 2009*), thus it is often preferred by otologists (*Harris et al., 2016*)

The graft is placed medial to the entire TM remnant and the malleus handle and is suitable for posterior perforations (*Jackson et al., 2010*)

Some of the commonly faced problems in underlay technique include decreased mesotympanic space and a lesser success rate in anterior perforations (*Gerlinger et al., 2006*)

In the overlay technique, which is frequently applied to anterior perforations, the epithelial layer is elevated precisely, and the graft is placed lateral to the fibrous layer of TM remnant and annulus (*Fayad and Sheehy, 2009*)

Although the overlay technique has a higher success rate in repairing anterior perforations, it is more technically demanding, and specific potential complications may occur such as graft lateralization, anterior blunting, slower healing, stenosis of the external auditory canal, epithelial pearls, and iatrogenic cholesteatoma (*Gersdorff et al., 2002*)

Therefore, repairing anterior perforations remain a challenge, especially when using the underlay technique. Factors influencing failure of the underlay technique in those cases include inadequate blood supply lack of residual TM as a source of epithelium, lack of support for the graft anteriorly, and poor exposure (*Applebaum and Deutsch, 1986*),.

Underlay and overlay technique of myringoplasty have been used for several years, and both have their advantages and disadvantages. When the underlay technique is used to repair the subtotal tympanic membrane perforation, the anterior portion of graft may fall away resulting in reperforation, and obliteration of the anterior part of middle ear cavity. The overlay technique has a higher success rate for the reconstruction of the subtotal tympanic membrane perforation, but lateralization of the graft may occur (*Kartush et al., 2002*).

These problems have been managed by a variety of surgical techniques such as the use of William's microclip, sandwich graft tympanoplasty, loop overlay tympanoplasty, and over-underlay tympanoplasty (*Lee et al., 2010*).

Over-underlay tympanoplasty is a safe, simple and easy procedure with low rate of graft failure and better hearing improvement (*Prakas et al., 2014*).

Yet, a still better method is needed to repair anterior tympanic membrane perforations (*Kartush et al., 2002*)

As a solution, this study aims to apply a modification of several previously reported techniques by using endoscopic double anterior and posterior tympanomeatal flaps and compare it with single posterior tympanomeatal flap as regard success rate in the challenging total and subtotal perforations.

Hypothesis:

To test the role of graft placement under the anterior flap in success rate of tympanoplasty.

Aim of work

The aim of this work is to compare outcome between endoscopic single and double flap technique in repairing total and subtotal tympanic membrane perforations.

Outcomes:

Primary outcome:the difference in graft taking rate between the two techniques.

Secondary outcomes:1-Post operative hearing results.

2-Benefits of endoscope in tympanoplasty.

Patients and methods:

A prospective randomized controlled clinical study will be conducted in Otorhinolaryngology Department, Mansoura University Main Hospital, on 40 patients with total and subtotal tympanic membrane perforations attending in the department.

Period of study:

1 year from July 2017 to July 2018.

Method of randomization:

Randomized according to random table design.

Patients will be divided randomly into 2 groups A and B:

Group A:will undergo single posterior tympanomeatal flap.

Group B:will undergo double anterior and posterior tympanomeatal flaps.

Inclusion criteria:

-Age group (20-50)

-Chronic otitis media with total or subtotal tympanic membrane perforation.

-No active inflammation of middle ear and no epithelial invagination or cholesteatoma mass.

Exclusion criteria

-Recurrent perforation after previous myringoplasty.

-Active inflammation of middle ear.

-Narrow external auditory canal.

-Ossicular disruption or fixation.

-Immunocompromised patients including uncontrolled diabetics, chronic liver and kidney diseases.

Preparation:

-All patients are subjected for pre-operative pure-tone audiograms with planned post-operative audiograms for follow up.

-Written consent will be obtained from patients.

Surgical technique:

-Surgery will be applied under local or general anesthesia via endoscopic trans-canal approach.

-Group A(Single tympanomeatal flap group):-

- The procedure begins with a transcanal endoscopic examination of the TM.
- A temporalis fascia graft is harvested in standard fashion, pressed, and then dried.
- A rim of tissue is removed from the edges of the perforation to ensure complete de-epithelialization of the medial surface of the TM remnant.
- A posterior canal wall incision is made 6-8 mm from annulus from 6 to 12 O'clock, then posterior tympanomeatal flap is elevated with the posterior tympanic annulus to enter middle ear space.
- Tympanic membrane is dissected from handle of malleus.
- The status of the middle ear and ossicular chain are examined.
- The previously harvested fascia graft is trimmed to appropriate size for full coverage of the perforation and placed over handle of malleus, below remnant of tympanic membrane.
- The graft is draped properly to provide complete coverage of the TM perforation.
- The tympanomeatal flap is then laid back down in native position.

-Group B(Double tympanomeatal flaps group):-

- Posterior tympanomeatal flap is elevated like group A.
- Then, the anterior tympanomeatal flap is initiated.
- A horizontal incision is made just lateral to the anterior portion of the annulus .
- The canal skin and anterior annular ring are carefully elevated medially with a Rosen Needle.
- The middle ear is entered medial to the annulus using a 1mm right-angle hook to penetrate the middle ear mucosa until the tip of the instrument is visible through TM perforation
- Care is taken to preserve the integrity of the annular ring when making this anterior canal skin tunnel.
- The previously harvested fascia graft is trimmed to appropriate size for full coverage of the perforation and tailored to have anterior tip that will be later pulled from the middle ear through the anterior tympanomeatal flap.
- The posterior tympanomeatal flap is then moved anteriorly.
- The trimmed fascia graft is then placed into the middle ear through the posterior flap.
- The posterior tympanomeatal flap is placed back down into native position, and the fascia graft is draped properly to cover TM perforation with the anterior tip is directly in line with the anterior canal skin tunnel.
- The anterior tip is picked up with the right-angle hook and pulled through the tunnel underneath the tympanic annulus, and out through the canal skin incision and left as a tag which is laid up against the normal anterior canal skin.

In both groups:

- The middle ear is then packed with dry gel foam followed by gel foam soaked with antibiotic solution and antibiotic soaked ribbon gauze.
- A standard ear pressure dressing is applied for the first 24h and then removed.
- The outer canal packing (ribbon gauze) is removed in 1 week at the first post-operative visit
- Antibiotic drops are initiated twice a day for a week until the second post-operative visit.
- Endoscopic follow up evaluation will be carried out after 3 weeks & follow up PTA&Tympanogram will be done after 3 month.
- The 2 groups will be compared as regard middle ear pressure, hearing assessment& success rate.

Data collection and statistical analysis:

Patients' data including preoperative assessment, operative details and postoperative follow up will be recorded, tabulated, analyzed and discussed.

Sample size: Based on a pilot trial, a convenient sample size was calculated to achieve 80% power to compare outcome between endoscopic single and double flap technique in repairing total and subtotal tympanic membrane perforations with an alpha level of 0.05. Twenty patients per arm will be included in the study.

Data distribution will be analyzed by computer by SPSS program.

Statistical analysis will be performed by using the suitable statistical methods and tests of significance and differences will be considered significant at $P \leq 0.05$.

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