Comparison between overlay and underlay primary myringoplasty: retrospective analysis on anatomical and functional results in 497 adult patients

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Abstract. Background and aim: Retro-auricular approach using an autologous graft is the predominant surgical method for myringoplasty (MPL). Endaural and transcanal or endoscopic approaches are also used. There is no definitive consensus on the best MPL surgical technique. Aim of this study is to compare the two most used technique, over and underlay MPL, to evaluate the difference in anatomical and functional outcomes. Methods: We made a retrospective analysis of 497 adult patients who underwent underlay or overlay primary MPL, between 2010 and 2018, and evaluated the difference in anatomical and functional outcomes. Results: Successful functional results, evaluated after 18 months from surgery, were obtained in 380 patients (76,4%); in the underlay MPL, a successful result was obtained in 85%, in the overlay technique in the 68%. we observed anatomical failure in 13.4% patients; In detail 9,8% underwent MPL underlay and 17,2% MPL overlay. Conclusions: Our results indicate that underlay technique involves fewer complications. We believe that this remains the technique to prefer, except in subtotal or wide anterior perforations that could be better managed with the overlay technique. (www.actabiomedica.it)

Key words: myringoplasty, graft; tympanic membrane perforation, surgery, healing, hearing function

Introduction

Myringoplasty is a technique used to repair Tympanic Membrane (TM) perforations through graft material that can stimulate and lead its healing (1).

TM perforations can be a consequence of middle ear infections, traumatic injuries, or iatrogenic causes. Most of these perforations heal spontaneously restoring the natural protection between outer and middle ear, the others may need a surgical repair. MPL are used to restore TM integrity, and to preserve or improve hearing function. The most common surgical procedures are the “underlay” and the “overlay” techniques, in which the graft is placed under or over the tympanic remnants, respectively. Several factors may affect the outcome, such as the surgical technique, surgeon experience and perforation characteristics (2,3).
An analysis of the literature shows a failure rate between 12% and 26%, regardless of the MPL technique (4,5).

We made a retrospective analysis of 497 adult patients who underwent underlay or overlay primary MPL, to evaluate the difference in anatomical and functional outcomes of MPL techniques.

Materials and methods

The study included 497 adult patients who underwent MPL in ENT departments of three hospitals in Campania, from 2010 to 2018, according to the following criteria: age between 18 and 60 years old, absence of ossicular disorders, no acute ear inflammation in the month prior to surgery, primary MPL, with retroauricular surgical approach, at least 18 months of follow-up.

All patients underwent otomicroscopic evaluation before and after surgery, pure tone audiometry (PTA) before and after surgery (threshold level as mean of frequencies between 0.5 and 3 kHz, according to 1995’s Committee on hearing and equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss) (6). Criteria for successful functional restoration were ≥ 15 dB mean air-bone gap improvement for frequencies from 0.5 to 3 kHz. Criteria for anatomical failure were: early or late perforation recurrence, blunting, neotympanum lateralization (NL), granulomatous myringitis (GM), neotympanum medialization (NM), and iatrogenic cholesteatoma (IC).

Statistical analysis was performed using MedCalc Statistical Software version 19.1.7 (MedCalc Software bvba, Ostend, Belgium). Our data were tested with the t-Student test. P<0.05 was considered statistically significant. Incidence rate was estimated both in total sample and in the two surgical technique’s group.

Results

Our study population included 497 patients (260 males and 237 females) with mean age of 34.6±7.7 years old; underlay MPL was performed on 254 patients, overlay MPL on 243.

The underlay technique was performed in anterior (21.1%), posterior (68.2%) and subtotal perforations (10.7% of cases). The overlay MPL was performed in anterior (28.9%), posterior (7.3%), and subtotal perforations (63.8%). Successful functional results, evaluated 18 months after surgery, were obtained in 380 patients (76.4%); the underlay MPL obtained a successful result in 215 patients (85%), while the overlay technique obtained a successful result in 165 patients (68%). (Table 1)

In this study, we observed anatomical failure in 67 patients (13.4%); 9.8% of underlay MPL and 17.2% of overlay MPL had an anatomical failure, respectively. (Table 2).

Fifty patients (10%) obtained a successful anatomical result without achieving any functional improvement.

Early recurrent perforations (within 3 months from surgery) were observed in 5.6% (28/497) of patients: 5.1% (13/254) in underlay and 6.1% (15/243) in overlay MPL.

Late recurrent perforations (over 3 months from surgery) occurred in 2.2% (11/497) of patients; 3.1% (8/254) in underlay and 1.6% (4/243) in overlay MPL.

No blunting occurred in the underlay MPL, while it was observed in 3.2% (8/243) of patients in overlay MPL.

No NL occurred in underlay MPL, while it was observed in 4.9% (12/243) of patients in overlay technique.

GM occurred in 0.6% (3/497) patients, 0.8% in underlay MPL (2/254) and 0.4% in overlay technique (1/243).

Table 1. Successful functional results 18 months after surgery

| Overall success rate | Underlay technique | Overlay technique | Statistical analysis |
|----------------------|--------------------|-------------------|---------------------|
| 76% (380/497)        | 85% (215/254)      | 68% (165/243)     | p=0.0001            |

Table 2. Anatomical failure rate

| Overall Failure rate | Underlay technique | Overlay technique | Statistical analysis |
|----------------------|--------------------|-------------------|---------------------|
| 13.4% (67/497)       | 9.8% (25/254)      | 17.2% (42/243)    | P=0.00124           |
Any subsequent complications are not attributable to the technique but secondary to patients-related factors.

Sade found early and late perforation in 19% and 8% of his sample, he also found that site of perforation did not influence the success rate. (12). Sheehy and Anderson reported this complication in 9.5% of the overlay MPL (13). In our study, overall early perforation occurred in 5.6% of cases, while late perforation occurred in 2.2% of cases. Early perforations may be secondary to post-operative infection with graft necrosis, incorrect positioning of the fascia especially in the anterior and lower quadrants, insufficient graft re-epithelialization. Late perforations can be due to upper respiratory tract inflammation, which leads to otitis, or neotympanum dystrophy. To avoid this complication the following precautions are essential: graft dimensions suitable for ensuring contact with the anulus, the hammer and the posterior wall of external acoustic canal (EAC) (about 2.5 x 4 cm); careful positioning of the graft (absence of bleeding, calibration of the EAC to achieve a clear view on the anterior angle, anchoring to the hammer, conservative preparation of the skin flaps); appropriate front and lower support of the graft in underlay MPL (ensuring enough surface tension to makes the graft adhere to TM residues); graft hooking to the hammer (in overlay MPL).

The anterior tympanomeatal angle is normally a 50° acute angle that optimizes TM vibration. The blunting of this angle provokes a conductive hearing loss, mainly on low frequencies. Our data showed blunting as an overlay MPL complication, due to the graft thickness, its “lift” on the anterior wall or an inadequate stretching of the cutaneous anterior flap.

**Discussion**

According to literature the anatomical and functional integrity of the neotympanum is essential to protect the middle ear and restore audiological functions (1,4,7,8).

In 2012, Nardone described a series of 1000 MPL in adult, showing an 81% success rate in 2 years and 78% in 10 years (9). In 1988 Halik JH described a success rate of 74% in 11 years in a series of 605 patients (10). In our opinion, an 18-month follow-up is enough to validate the results of MPL, in fact, after this period; any anatomical and functional complications are well manifested already, except IC which, according to different studies, ranges between 0.1 and 0.7% (9,11).

We observed that a follow-up interval of 18 months is adequate to consider the anatomical-functional results consolidated, except for the possible onset of a CI which, however, has minimal clinical and statistical significance (several studies estimate it between 0.1 and 0.7%).

| Table 3. Graft failures rates and statistical analysis |
|------------------------------------------------------|
| Early Recurrence Perforation | Late Recurrence Perforation | Blunting | Neotympanum Lateralization |
|--------------------------------|-------------------------------|---------|----------------------------|
| UL | OL | Statistical analysis | UL | OL | Statistical analysis | UL | OL | Statistical analysis |
| 5.1% | 6.1% | p=0.34212 | 3.1% | 1.6% | p=0.2149 | - | 3.2% | p=0.00634 | - | 4.9% | p=0.00034 |

**Granulomatous Myringitis**

| Ul | Ol | Statistical analysis |
| 0.8% | 0.4% | p=0.69965 |

**Neotympanum Medialization**

| Ul | Ol | Statistical analysis |
| 0.8% | 0.4% | p=0.69965 |

**Iatrogenic Cholesteatoma**

| Ul | Ol | Statistical analysis |
| - | 0.4% | p=0.1470 |

NM occurred in 0.6% (3/497) patients: 0.8% (2/254) in underlay MPL and 0.4% (1/243) in overlay technique.

We found only one IC, in the overlay MPL (0.4%).

Underlay and overlay MPL techniques showed comparable effectiveness in early and late recurrence of perforation, NM, GM and IC, while there is a statistically significant difference between the two techniques regarding blunting (p=0.00634) and NL (p=0.00034) where the overlay technique presented a higher failure rate. (Table 3)
According to Packer, there is an increased failure rate in the overlay MPL (14). The anulus plays an important anatomic and trophic role for the graft. Our experience showed that a wide calibration of the EAC is preferable because it allows to stretch out the graft on the anterior bone frame, without over-edging the anulus. For this reason, it is mandatory to carefully cover anteriorly the graft using a skin flap.

Moreover, in our sample, NL occurred mostly as a late failure of overlay MPL, due to an inadequate positioning of the graft (especially for failed graft attachment to malleus handle). Our experience, consistent with literature, showed that the precautions suggested to prevent blunting are also effective in preventing NL (13).

As a postoperative complication of MPL, an incidence of GM up to 5% has been reported. It is characterized by granulation tissue on the TM outer surface (15). We observed that GM is due to an incomplete graft re-epithelisation following an inadequate stretching, it mostly complicates the underlay MPL technique.

Our data show that IC mainly occurred as late failure (3 to 6 months after surgery) of the overlay MPL, due to an incorrect TM de-epithelisation or incomplete stretching of the inferior cutaneous flap (16). IC is clinically characterized by superficial epidermal cyst, which is easy to threat, and proper cholesteatoma, a severe disease that needs further surgical treatment. Avoiding the persistence of squamous epithelium on the fibrous residue during detachment could be effective to prevent IC.

NM can occur more frequently in underlay MPL, as an early failure due to inadequate graft positioning or excessive EAC tamponade. It can occur as a late failure due to scar retraction or tube dysfunction. In our study, NM occurs less than other case series (17).

In our case series, according to literature, functional results are lesser to anatomical results (17-19). It becomes a subject of debate why a favourable anatomical result provides a poor functional outcome. Our experience points to several reasons: endotympanic adhesions and scar bridles which limitates TM compliance, neotympanum retraction due to endotympanic effusion, underestimated ossicular damages, low neotympanum performance compared to normal TM compliance.

In the comparison of techniques retro-auricular approach using an autologous graft is still the main surgical method for MPL. Endaural and transcanal or endoscopic approaches are also used. There is no definitive consensus on the best MPL surgical technique. The choice often depends on the training of the surgeon, as well as on the anatomical characteristics of the perforation (20).

Our study aims to make a comparison between overlay and underlay MPL techniques, based on our results and on literature. Analysis of our data showed a statistically significant success rate for underlay MPL, both anatomical and functional. Sergi et al. suggested that better results are due to ossicular less handling with faster healing; moreover, in overlay MPL graft lateralization is more common (21). Singh and Coll., in a prospective randomized study, found comparable anatomical and functional results between the two techniques; however, underlay MPL is easier, needs shorter surgery time (55 vs 90 minutes) and a faster post-surgical course (6 vs 8 weeks) (22). Nardone et al. reported better results for overlay MPL both short-term (92% vs 82% after 1 year) and long-term (85% vs 74% after 10 years), remarking that overlay MPL is performed in fewer cases because of its complexity, execution time, and complications (9).

Perforation type and surgeon attitude affects surgery choice, perforation type and size must be considered. Overlay MPL is preferred in subtotal and wide anterior perforations (23,24). Based on our experience, we identified some key-points for a successful MPL: management of flaps, EAC sizing, and graft placement.

The muscle-periosteal and the tympanic flaps must be as long and wide as possible to cover EAC posterior wall and reach the fascia, obtaining a quicker canal re-epithelialization, avoiding its stenosis. During the preparation of the flap, inflammatory areas must be detected and removed. The repositioning of the vascular fascia must be careful, to avoid scarring stenosis and small cholesteatomas. Tympanosclerosis plaques secondary to chronic inflammation can affect surgical outcomes causing recurrent perforations, due to inefficient absorption of the graft. For this reason, all tympanosclerotic plaques must be removed. In both techniques, insufficient exposure of anterior angle requires EAC calibration, to improve visibility and prevent defects of suture and bone plug. This will allow an
easier graft uptake and a better post-operative management. The fascia harvesting must be adequate, and, in the underlay MPL, embedded as much as possible toward the protympanum and under the anterior annulus, then stabilized filling the canal with absorbable gelatine sponges.

In the overlay technique, the length of fascia on the anterior wall should not exceed two millimeters, and the edge of the graft must be covered with flap. Once prepared, the anterior angle must be stuck with absorbable gelatine sponges to guarantee an adequate pressure for its stabilization and avoid blunting. During the rebuilding, the manubrium of malleus must be lateral to the fascia.

Conclusion

MPL is still the most practiced otological surgery, it is safe and effective to improve patient’s quality of life, avoiding recurrent infections. Best results depend on proper indication and approach. The ideal approach is based on six key points: adequate size of graft, respect for canal skin, respect for annulus, correct placement on the anterior edge of the graft, adequate EAC sizing and accurate ear tamponade. Our data indicate that the underlay technique is less burdened with complications. We believe that this remains the technique to prefer, except in subtotal or wide anterior perforations that could be better managed with the overlay technique.

Research involving human participants and/or animals: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

Conflicts of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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Received: 11 October 2021
Accepted: 23 October 2021

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