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A comparative study of sequential vs. simultaneous type I tympanoplasty in patients with bilateral chronic otitis media – Mucosal type

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ABSTRACT

Background: Patients with bilateral chronic otitis media – mucosal type have been conventionally treated with sequential tympanoplasty. Bilateral simultaneous tympanoplasty is usually not preferred because of the theoretical risk of iatrogenic sensorineural hearing loss. With the advent of modern surgical instruments and surgical techniques, the risk is expected to be lower. This study compares the clinical outcomes in type I tympanoplasty performed simultaneously and sequentially.
Materials & methods: This randomized prospective study was carried out in a tertiary care hospital between August 2015 and July 2017. A total of 30 patients were divided into two groups of 15 each. This study analyzed the graft uptake, pure tone audiogram findings pre- and post-operatively, duration of surgery and number of hospital visit for each patient and the outcomes were compared between both the groups.
Result: Patients undergoing bilateral simultaneous tympanoplasty had significantly lesser mean duration of surgery and number of hospital visits than the patients undergoing sequential tympanoplasty. Graft uptake and postoperative wound infections were similar in both the groups. Postoperative hearing improvement was significantly better in the bilateral simultaneous tympanoplasty group. However, further studies are needed to authenticate this observation. None of the patients had a postoperative deterioration of hearing or sensorineural hearing loss.
Conclusion: Bilateral simultaneous tympanoplasty is not only feasible but also better than sequential tympanoplasty, especially in terms of operating time, follow-up and overall financial implications on the patient.

1. Introduction

Patients with chronic otitis media (COM) – mucosal type usually present with unilateral disease. However, bilateral disease is also known to occur with an incidence as high as 12% in the general population. The treatment of COM focuses on the mucosal infection in the tympanomastoid compartment. Surgical treatment is indicated when it is certain that a chronic discharging ear cannot be cured by conservative treatment and after ruling out tubal discharge resulting from nasopharyngeal or sinus suppuration or allergies. Based on the pure tone audiogram (PTA), the hearing loss of the patient is estimated to determine the severity of the disease. A tympanic membrane defect (central perforation) alone can lead to hearing loss of up to 45 dB. Hearing loss of more than 45 dB or the presence of granulation (Jayakumar et al., 2016) would indicate disease involving the ossicular chain. Hence, when no ossicular chain involvement is suspected and the middle ear mucosa is found to be normal, myringoplasty is performed, where only the defect in

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the tympanic membrane is repaired and the middle ear is not opened. Alternatively, in type I tympanoplasty the middle ear is inspected for ossicular chain integrity and mucosal status under the microscope and tympanic membrane is repaired. In cases of bilateral COM, sequential tympanoplasty is conventionally performed. Bilateral simultaneous tympanoplasty is not preferred because the risk of iatrogenic sensorineural hearing loss (SNHL) is 1.2%–4.5% after ear surgeries (Palva et al., 1973). However, with the advent of advanced instruments and modification of surgical techniques, the risk is found to be much lower. Many studies attempted to perform bilateral myringoplasty simultaneously and have found good surgical outcomes (Caye-Thomasen et al., 2007).

This study aims to compare the clinical outcomes in type I tympanoplasty performed simultaneously and sequentially in patients diagnosed with bilateral COM – mucosal type.

2. Methodology

This is a randomized prospective study carried out at the ENT department of a University hospital from August 2015 to July 2017. The study was approved by the institutional ethics committee. Using RAS software, 30 patients were randomly divided into two groups – Group A (simultaneous tympanoplasty) and Group B (sequential tympanoplasty). The objective of the study is to determine the graft uptake, to analyze the PTA findings pre- and postoperatively and compare the duration of surgery and the number of hospital visits in both the groups. Patients with bilateral COM – mucosal type with conductive or mixed hearing loss were included in the study. Other inclusion criteria considered were patients who underwent only type I tympanoplasty and had dry ears for atleast 4 weeks before the surgery. The study excluded patients undergoing revision surgeries, patients with granulation, or patients who presented with COM with complications. After obtaining a thorough history, the patients were subjected to otomicroscopy to assess the site and size of the perforation, middle ear status, and the presence of discharge or granulation. Anterior and posterior rhinoscopy was performed to rule out nasal and nasopharyngeal etiology of COM – mucosal type. Patients then underwent PTA. After preoperative evaluation, patients underwent Type I tympanoplasty either simultaneously or sequentially. The procedure was performed under general anesthesia and under the vision of a 0° endoscope. The graft used was a temporalis fascia graft harvested through a supra-aural incision. In patients undergoing simultaneous type I tympanoplasty, a large temporalis fascia graft was harvested on the side that was operated first. The temporalis fascia was divided into two as per the requirement of the tympanic membrane perforation. One portion of the temporalis fascia graft was used in the first ear. After securing hemostasis, the wound was closed with a sterile cotton pad. The head was turned to the other side. The other ear was painted and draped. With a change of gloves by the surgeon and scrub nurse, and a new set of tympanoplasty instruments, endoscopic tympanoplasty was performed in the other ear with the remaining part of the temporalis fascia, adhering to all universal precautions. The external auditory canals were packed with gelfoam bilaterally. Dressing was applied after closing the supra-aural wound. In Group B (Sequential group), the surgery was done in one ear with the use of an endoscope as described above. The second surgery was done after an interval of at least 3 months. For the second ear, during the surgery, the supra-aural incision was made on the ipsilateral side for harvesting the temporalis fascia graft and endoscopic tympanoplasty was carried out. The duration of the surgery was measured from the start of infiltration until the end of dressing.

The patients were started on intravenous antibiotics one day prior to surgery and the antibiotic cover was continued until one week after surgery along with antihistamines and nasal decongestants. Suture removal was done on the seventh postoperative day. The patients were followed up for three months. The post-aural wound was assessed at the end of one week. Patients were assessed for the graft uptake and postoperative PTA at the end of one and three months. Statistical analysis was carried out using IBM SPSS version 22. P-value <0.05 was considered statistically significant.

3. Results

48 patients were originally included in the study. 15 of them underwent simultaneous type I tympanoplasty (Group A). 15 patients underwent sequential type I tympanoplasty (Group B). The data of these 30 patients are included in the following results.18 patients were dropped from the study because 2 patients failed to turn up for follow-up in group A, and 16 patients in group B dropped out of the study after their first surgery citing various medical and personal reasons. Hence their data is not included in the following results.

The mean age of the patients in Group A was 42 years and that in Group B was 36 years. Group A had 9 male and 6 female patients and group B had 6 male and 9 female patients.

In group A, the mean preoperative PTA was 37.29 ± 11.3 dBHL. The mean 1 month postoperative PTA was 27.22 ± 10.7 dBHL. The mean 3 months postoperative PTA was 22.18 ± 9.01 dBHL. In group B, the mean preoperative PTA was 42.74 ± 10.55 dBHL. The mean PTA 1 month after surgery improved to 36.12 ± 9.13 dBHL and 30.08 ± 9.98 dBHL 3 months after the surgery.

The improvement in hearing at the end of one month in group A was 10.07 dB. Hearing improved by 15.11 dB at the end of 3 months after the surgery. In group B, the hearing improved by 6.62 dB at the end of 1 month and 12.66 dB at the end of 3 months after the surgery. The preoperative Air-Bone Gap (ABG) was found to be 21.72 ± 7.3 dB in group A and 29.86 ± 23.12 dB in group B. The postoperative ABG was found to be 15.28 ± 6.07 dB in group A and 24.38 ± 10.3 dB in group B at the end of 3 months.

There was a statistically significant improvement in postoperative hearing between group A and group B. Patients undergoing bilateral simultaneous tympanoplasty showed better improvement in hearing than patients undergoing bilateral sequential tympanoplasty.

The supra-aural wound was examined at the end of 1 week for wound infection. None of the patients in group A had wound infection. Two patients in group B had wound infection which was statistically insignificant.

The graft uptake was 96.7% in group A and 90% in group B. There was no statistical significance in the rate of graft uptake among both the groups ($p = 0.3$).

The mean duration of surgery in group A was 120.67 ± 31.840 min. The mean duration of surgery in group B was 195 ± 28.221 min. This difference in the duration of surgery between group A and group B was statistically significant.

The average number of hospital visits for each patient in group A was 4 ± 1 and in group B was 9 ± 2. This difference is the number of visits to the hospital is statistically significant ($p = 0.003$).

4. Discussion

It is imperative to treat COM because it may lead to serious complications if left untreated. It is necessary to rule out nasal and nasopharyngeal etiology of COM, especially when the patient presents with bilateral disease. Patients can be considered for simultaneous bilateral surgery if posterior rhinoscopy or diagnostic nasal endoscopy is normal. The incidence of iatrogenic SNHL has been

found to be 1.2%–4.5% (Palva et al., 1973) (Tos et al., 1984). Due to the theoretical risk of iatrogenic injury to the inner ear, bilateral surgeries were not advocated in the past. However, recent studies indicate that the incidence of SNHL following type I tympanoplasty is minimal. Tos et al. studied the nature of SNHL after otosurgery and found no case of severe high tone sensorineural damage after transcanal myringoplasty and tympanoplasty in ears with an intact chain (Tos et al., 1984). Better outcomes are also attributed to improved operating techniques and the availability of better instruments (Sharma and Saroch, 2013). There is also a theoretical risk of upper respiratory tract infection in the immediate postoperative period leading to simultaneous graft rejection on both sides. However, this is extremely unlikely with the routine postoperative effective use of antimicrobials (Raghuwanshi and Asati, 2013). Patients in this study also received nasal decongestants and antihistamines in the postoperative period. In this study, the temporalis fascia graft uptake was successful in 96.7% of patients undergoing bilateral tympanoplasty simultaneously and 90% of patients undergoing the procedure sequentially. In their study, Sharma and Saroch have obtained graft uptake rate of 90% following bilateral simultaneous myringoplasty (Sharma and Saroch, 2013). Rai et al. recorded a 93% success rate after bilateral tympanoplasty with autogenous temporalis fascia graft (Rai et al., 2014). Ihsan & Ranjana documented 86% graft uptake at the end of 3 months after bilateral ear surgery for COM- Mucosal type (Ihsan and Ranjana, 2017).

In this study, no patient had any deterioration in hearing or SNHL post-operatively in either groups.

The mean duration of surgery for patients undergoing bilateral simultaneous tympanoplasty was 120.6 min, and for patients undergoing sequential tympanoplasty, it was 195 min for both the ears. This difference is of statistical significance. The difference in time taken for the operation is mainly because of the need for harvesting temporalis fascia graft twice and the subsequent wound closure. The average time taken for bilateral surgery was 118 min in a study conducted by Rai et al. (2014). This is comparable to the time taken for bilateral surgery in our patients. Thus, patients undergoing bilateral simultaneous tympanoplasty need to be under general anesthesia for a much lesser time than patients undergoing sequential tympanoplasty.

The average number of hospital visits in group A was 4 and in group B, it was 8.7. There is a statistically significant difference in the number of hospital visits between both the groups mainly because patients undergoing sequential tympanoplasty had to visit the outpatient department for preoperative work up and postoperative follow-up twice. Patients undergoing bilateral simultaneous tympanoplasty had the advantage of going through the routine of surgical work up only once.

Patients in group A were explained about the possibility of transient loss of hearing in the immediate postoperative period because of the packing of the external auditory canal. However, the patients did not complain of occlusion in the postoperative period, despite the aural packing.

Few patients who were initially enrolled in group B were lost to follow up after the first surgery. Some patients refused surgery in the second ear once they started having improvement in hearing from the first surgery. This puts the patients in group A at advantage, and the surgeon also has reduced workload of scheduling surgeries.

Onal et al. had observed that tympanoplasty was less successful in patients with bilateral COM (Onal et al., 2012). But in our study, the outcome of tympanoplasty in bilateral COM has been comparable with that of tympanoplasty in unilateral COM.

We have observed in this study that bilateral simultaneous tympanoplasty is not only feasible, but also better than sequential tympanoplasty especially in terms of operating time, follow-up and overall financial implications on the patient.

5. Conclusion

The result of graft uptake in patients undergoing bilateral tympanoplasty is similar to that of patients undergoing tympanoplasty for unilateral disease. We have recorded a significant difference in the time spent by the patient in the operating theatre and the number of hospital visits. Thus, patients undergoing bilateral simultaneous tympanoplasty have an advantage. In our study, we have observed that bilateral simultaneous tympanoplasty is a feasible option and a good alternative to obviate multiple hospital visits for patients. However, more evidence-based research data are needed to authenticate the finding that bilateral simultaneous tympanoplasty is associated with a significant improvement in postoperative hearing compared with bilateral sequential tympanoplasty.

Declaration of competing interest

There is no conflict of interest among the authors. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.joto.2019.12.005.

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