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Original Research Article

Clinical Outcomes of Tympanoplasty in Chronic Otitis Media: A Prospective Evaluation

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Abstract:

Background: Chronic otitis media (COM) is a frequent ear disorder that is related to the perforation of the tympanic membrane, and the conductive hearing loss. Tympanoplasty is a common operation that is meant to repair the tympanic membrane and reestablish the normal hearing ability.

Aim: To prospectively assess the clinical outcomes of tympanoplasty in patients with the chronic cases of otitis media with the focus on graft uptake and hearing improvement.

Methodology: The proposed study was an observational study that took place in the Department of ENT, Lord Buddha Koshi Medical College and Hospital in the span of one year. The number of patients was 130 patients with a diagnosis of COM, who received tympanoplasty. Demographic profile data, type of perforation data, surgical technique, graft uptake and hearing outcome data were gathered and evaluated with descriptive and inferential statistics.

Results: Most of the patients were 21-40 years (46.2%), and were mainly male (58.5%). There were 112 patients with successful graft uptake (86.2%). It was found that the improvement of hearing was significant in 104 patients (80%), with an average air-bone gap closing 12.4 ± 4.2 dB. More favorable results were reported with a dry ear state, less perforation size, and intact ossicular chain.

Conclusion: Tympanoplasty is a successful surgical procedure in chronic otitis media with high graft success, and considerable hearing gain. The choice of the patient and ear condition before the surgery is important in the outcome of the surgery.

Keywords: Chronic otitis media, Tympanoplasty, Graft uptake, Hearing improvement, Air-bone gap

Introduction

COM is an inflammatory disease of the middle ear that is chronic and is usually accompanied by perforation of the tympanic membrane and repeated or ongoing ear discharge [1]. It is a major health burden especially in the third world countries whereby early medical attention and preventive measures may not be readily available [2]. The condition does not only have impacts on auditory functioning, but extends to other aspects of communication, education, and quality of life. When not treated, the complications that may result because of the untreated COM include hearing loss, which is conductive and can disrupt the normal day-to-day routine and socialization [3].

Pathophysiology of COM is a complex interplay of infection, inflammation and dysfunction of the Eustachian tube. The continuous infection causes alterations in the mucosa of the middle ear cleft, which causes chronic discharge and inability to heal the tympanic membrane spontaneously [4]. The disease is also caused by environmental conditions, poor hygiene, frequent upper respiratory infections and socioeconomic conditions [5]. It is important to comprehend such underlying mechanisms to be able to manage them effectively and prevent their recurrence [6].

Tympanoplasty is a well proven surgery that aims at repairing the perforated tympanic membrane and regenerating the normal physiology of the middle ear [7]. The main aims of tympanoplasty are to eliminate disease, seal the perforation and to restore hearing function. Different types of surgery and graft materials have been proposed over the years, and the use of temporalis fascia has been largely accepted since it is easy to obtain, biocompatible and has a high success rate. Development of surgical procedures has also resulted in the improved results of this procedure [8].

Graft uptake and postoperative hearing improvement are considered to be two important parameters that can be used to measure the success of tympanoplasty [9]. The successful incorporation and healing of the graft material at the perforation point is known as graft uptake and improvement of hearing is measured in terms of audiometry like closure of air-bone gap [10]. Anatomy and functionality are vital measures of success and patient satisfaction during surgery. Regular monitoring of these parameters can be used to identify the efficacy of the procedure [11].

Various reasons have been stated, which affect the results of tympanoplasty. These are patient factors like age and health, disease factors like size and location of perforation and intraoperative factors like surgical procedure and the location of the graft [12]. The nature of the middle ear, i.e., whether it is dry or actively discharging at the time of surgery is a very important factor in defining postoperative success. Also, the presence of Eustachian tube functioning, and ossicular chain integrity should be considered when predicting the outcomes of hearing [13].

Although there has been a tremendous advancement in the field of otologic surgery, there has still been variability in the outcome of tympanoplasty in various clinical situations [14]. This inconsistency emphasises the necessity of continuous monitoring of clinical outcomes and detection of clinical predictors, which can impact surgical success [15]. A more in-depth knowledge of these aspects can help to enhance patient selection, improve surgical procedures, and better the outcomes on the whole. Thus, the current study will be a prospective comparison of clinical outcomes of tympanoplasty in COM patients within a tertiary care environment.

Methodology

In this section, the study design, setting, participant selection, and procedures used to assess the clinical outcomes of tympanoplasty were outlined in patients with chronic otitis media. The approach was structured and systematic to ensure proper data collection, sound assessment of the outcome of the surgery and reduction of bias during the study period.

Study Design: This was planned to be a prospective observational study that was intended to determine the clinical outcomes of tympanoplasty on patients with chronic otitis media. A prospective design was employed to facilitate systematically gathering preoperative and postoperative clinical and audiological data, and thus provide valid measures of the outcomes of surgery in the long-term. This design was also suitable to provide real time follow-up and reduce recall bias.

Study Area: The research was carried out in the Department of ENT of Lord Buddha Koshi Medical College and Hospital, Saharsa, Bihar, India

Study Duration: The investigation was conducted in a one-year.

Study Participants

Inclusion Criteria

- Young adults (15-60 years old) with COM (mucosal type).
- Patients who report with perforation of the tympanic membrane and are to undergo tympanoplasty.
- Patients who will be eligible to take part in the research and give informed written consent.

Exclusion Criteria

- The patients who have cholesteatoma or atticoantral form of disease.
- Individuals who have sensorineural, or combined sensorineural, hearing loss.
- Patients that have undergone ear surgery previously.
- Patients who have a systemic disease like uncontrolled diabetes or immunocompromised conditions that may hamper wound healing.

Sample Size: In the study, 130 patients meeting the inclusion criteria were used. The size of the sample was chosen according to the mean cases of tympanoplasty done at the institution within a year, as this was enough to represent and have the findings to be statistically reliable.

Procedure: A thorough preoperative assessment was conducted on all enrolled patients and this included detailed history taking which focused on the period of ear discharge, hearing loss, and history of past treatments. The size, location, and integrity of the tympanic membrane perforation, and the health of the mucosa of the middle ear were examined through clinical examination (otoscopy and microscopy).

Audiological testing was conducted in terms of pure tone audiometry to find out the baseline audiological levels, air conduction and bone conduction thresholds. Air-bone gap was also calculated to determine the level of conductive hearing loss.

Type I tympanoplasty was performed on all patients incorporating normal surgical procedures under either local/general anesthesia according to the appropriateness of the patient and the choice of the surgeon. As a graft material, temporalis fascia was taken and utilized in all the cases, as it is an effective and compatible graft. Underlay or overlay technique was applied in placing the graft.

The postoperative therapy involved taking antibiotics, painkillers, and guidance against activities that

may undermine healing of the grafts. Follow up of the patients was done at a regular time, usually 2 weeks, 6 weeks and 3 months after surgery. Follow up visits were done to assess the graft uptake with the aid of otoscopic examination and repeat audiometry was done to measure the hearing improvement.

Statistical Analysis: Data collected were entered into SPSS version 27.0 (IBM, USA) which was analyzed. Demographic and clinical variables were summarized with descriptive statistics mean, standard deviation, frequencies, and percentages.

Paired t-tests were used to compare the preoperative and postoperative hearing thresholds to address the question of whether hearing improvement after surgery is significant or not. The relationships between clinical variables (perforation size and ear condition) and the outcomes of surgery were tested with the help of relevant statistical tests. The p-value of below 0.05 was deemed to be statistically significant meaning that there was a significant difference between the variables compared.

Results

The number of patients in the study was 130. The findings are expressed in terms of demographic variables, clinical outcomes and surgical outcomes.

Table 1 demonstrates the demographic distribution of the study population where most of the patients were aged 21-40 years and 41-60 years (60, 46.2% and 50, 38.4% respectively) with 20 patients representing 15-20 years (15.4%). The number of males was higher at 76 patients (58.5%) as compared to 54 females (41.5%). These data suggest that younger and middle-aged adults with COM and the need to have a tympanoplasty are more common than males. These demographic features are graphically presented in Figure 1.

Table 1: Demographic Characteristics of Study Participants (n = 130)

Parameter	Category	Frequency (n)	Percentage (%)
Age (years)	15–20	20	15.4
	21–40	60	46.2
	41–60	50	38.4
Gender	Male	76	58.5
	Female	54	41.5

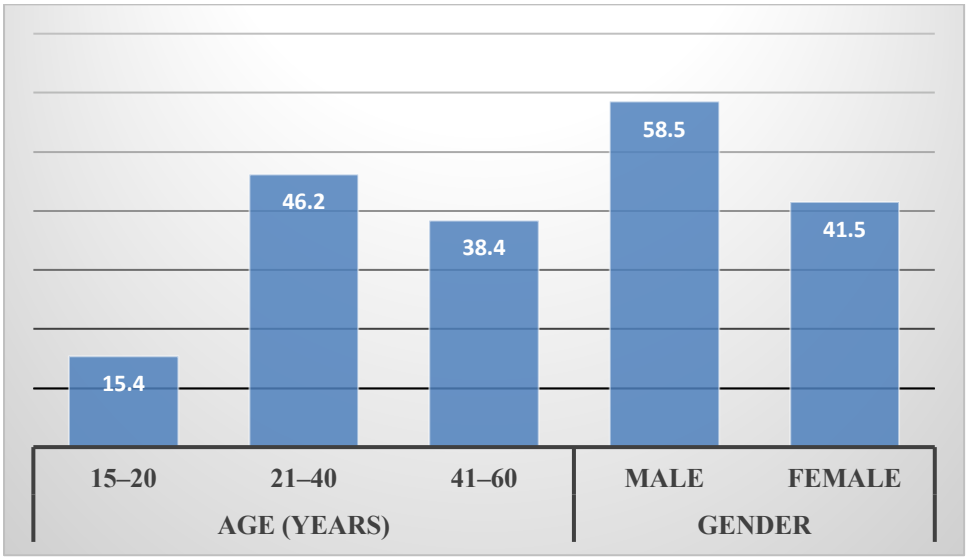

Figure 1: Visual Representation of Demographic Characteristics of Study Participants (n = 130)

Table 2 summarizes the clinical features of the patients where medium sized perforations were seen in 55 patients (42.3%), small sized perforations in 45 patients (34.6%), and large sized perforations in 30 patients (23.1%). Also most of the patients were experiencing a dry ear (90, 69.2%) as opposed to wet ear (40, 30.8%). The distribution indicates that the majority of the patients were in a good preoperative state, with dry ears and moderate sizes of perforations being usually linked to increased success rates in surgery. These clinical characteristics are graphically represented in Figure 2.

Table 2: Clinical Characteristics (n = 130)			
Parameter	**Category**	**Frequency (n)**	**Percentage (%)**
Type of perforation	Small	45	34.6
	Medium	55	42.3
	Large	30	23.1
Ear condition	Dry ear	90	69.2
	Wet ear	40	30.8

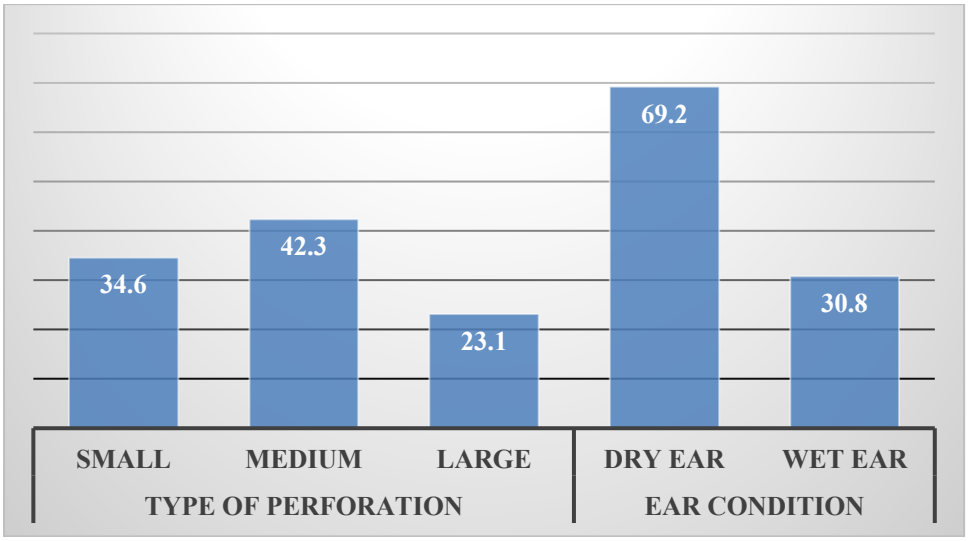

Figure 2: Visual Representation of Clinical Characteristics (n = 130)

Table 3 presents the surgical outcomes and shows that a successful graft uptake was obtained in 112 patients (86.2%) and graft failure was experienced in 18 patients (13.8%). An improvement in hearing was observed in 104 patients (80%), and there were 26 patients (20%), who did not improve. Such findings suggest that tympanoplasty has a good anatomic and functional success rate, thus supporting its effectiveness as a treatment modality in chronic otitis media. These surgical results are presented graphically in Figure 3.

Table 3: Surgical Outcomes (n = 130)		
Outcome	**Frequency (n)**	**Percentage (%)**
Successful graft uptake	112	86.2
Graft failure	18	13.8
Hearing improvement	104	80
No improvement	26	20

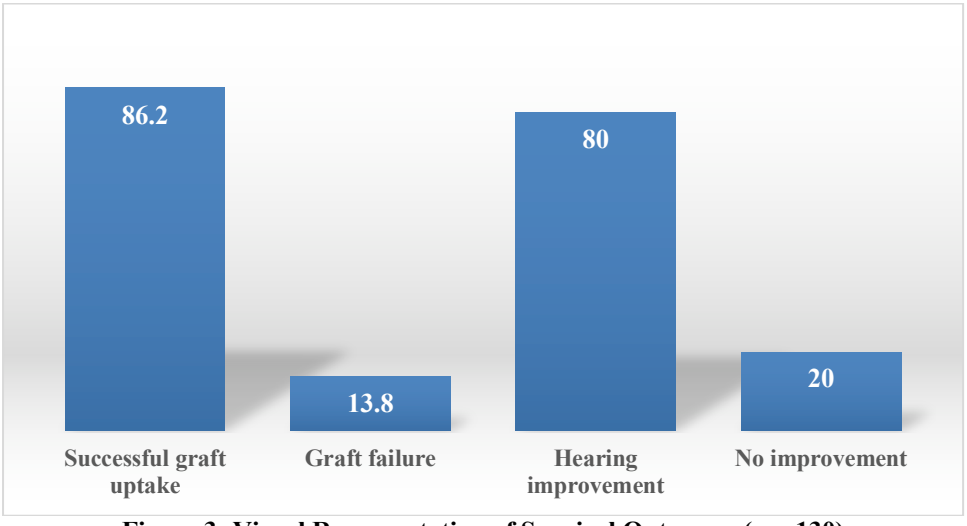

Figure 3: Visual Representation of Surgical Outcomes (n = 130)

The results of the hearing measured in air-bone gap are shown in Table 4, with the mean level of 28.6 ± 6.3 dB before the operation, and 16.2 ± 4.5 dB after, and the mean of the difference was 12.4 ± 4.2 dB. This large improvement signifies successful change in hearing ability in the aftermath of tympanoplasty, and it is statistically significant ($p < 0.05$).

Table 4: Hearing Outcome (Air-Bone Gap)

Parameter	Mean ± SD
Preoperative ABG (dB)	28.6 ± 6.3
Postoperative ABG (dB)	16.2 ± 4.5
ABG Closure	12.4± 4.2

Discussion

The current prospective trial compared clinical outcomes of tympanoplasty in patients with COM and showed high success rate in graft uptake (86.2%), as well as, hearing improvement (80%). These results show that tympanoplasty is a useful surgery that can be used both to fix the anatomy and restore the functionality (Panetti et al., 2017) [16]. The high rate of graft uptake in this study indicates a good surgical environment and the appropriate selection of patients whereas the high percentage of patients experiencing hearing improvement indicates the effectiveness of the procedure in improving auditory functions and general quality of life.

Demographic profile of the study population showed that most patients were aged between 21 and 40 years (46.2%), then 41-60 years (38.4%) with fewer being younger with the age group of 15-20 years (15.4%). This distribution indicates that the chronic cases of otitis media that need surgical interventions are more common among young and middle-aged adults, probably because of the heightened awareness, work requirements, and the effect of hearing loss on everyday life (Ramya, 2018) [17]. There was also a male preponderance (58.5%) in relation to females (41.5%) which could be attributed to the disparity in healthcare seeking behaviour and access to healthcare facilities.

The clinical features of the patients revealed that the most frequent ones were medium-sized perforations (42.3%) then small perforations (34.6%) and large ones (23.1%). Moreover, most of the patients had a dry ear (69.2) and 30.8% had a wet ear during the surgery. The fact that most of the patients had dry ears implies that they were operated under the best possible conditions which is known to enhance the outcome of surgery (Sharma et al., 2017) [18]. Dry middle ear endothelium offers an improved graft adherence and healing response, whereas chronic discharge can impair graft uptake, and predispose it to failure.

The results of the surgeries in the study showed that 112 patients (86.2%) had a successful graft uptake, and 18 patients (13.8%) had a graft failure. It showed an improvement in hearing in 104 patients (80%), with 26 patients (20%), showing no significant improvement. These results support the idea that tympanoplasty can be very effective to repair the integrity of the tympanic membrane and even enhance hearing (Sousa et al., 2017) [19]. The low rate of graft failure is also a good indication of the effectiveness of the surgery process and aftercare services.

Audiological evaluation revealed that the mean preoperative air-bone gap was 28.6 ± 6.3 dB which decreased to 16.2 ± 4.5 dB after the operation with the mean change being 12.4 ± 4.2 dB. Such a considerable decrease suggests considerable enhancement of the conductive hearing loss after operation (Suzuki et al., 2016) [20]. The extent of air-bone gap closure that was achieved in this trial represents a success of the restoration of the sound conduction apparatus in the middle ear and the success of tympanoplasty, as well as anatomy repair.

A number of variables were also identified to have an effect on the results of tympanoplasty, such as ear condition, perforation size and middle ear status. Patients whose ears were dry and with smaller perforations had better outcomes as compared to wet patients and larger perforations. Moreover, complete ossicular chain, no infection, and good technique in the surgery also led to better graft uptake and hearing outcomes. In general, the results of this research support the significance of proper patient selection, proper preoperative preparation and careful surgical performance to attain the best results in tympanoplasty.

Conclusion

This prospective study indicates that tympanoplasty is a very effective surgery in the treatment of COM with a high graft uptake rate of 86.2% and marked improvement in hearing in 80% of patients. The surgery led to significant decrease in the average air-bone gap, which verified the success of the procedure both anatomically and functionally. The results were better in patients who have dry ears, smaller perforations and good middle ear conditions, which underscores the significance of proper patient selection and preoperative preparation. All in all, tympanoplasty is a trusted procedure that could be used to restore the integrity of the tympanic membranes and enhance auditory performance,

and therefore, the quality of life of the affected individuals.

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