Effect of Type 1 Tympanoplasty on the Quality of Life of CSOM Patients

Khyati Bhatia^{1,2} · Lakshmi Vaid¹ · H. C. Taneja¹

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Abstract Chronic suppurative otitis media (CSOM) continues to be an important public health problem despite significant advances in medical science. Ear discharge, pain, discomfort, difficulty in hearing, limitation of routine activities and emotional problems due to CSOM cause a significant impact on the health and general well being of the patient. We have done Type 1 tympanoplasty in tubo-tympanic type of COM to reconstruct the tympanic membrane and alleviate the symptoms of the patients. This study presents an analysis of the impact of the surgery on the patient subjectively and its correlation with objective outcomes. 45 patients were selected to fill the chronic otitis media-5 (COM-5) questionnaire and underwent pure tone audiometry preoperatively. All the patients underwent Type 1 tympanoplasty by using temporalis fascia graft. The status of the ossicles was checked and documented intra-operatively. Patients requiring ossicular reconstruction or with attic antral disease were excluded. Patients were followed up for a period of 6 months and those with an intact graft after 6 months were included in the study. These patients were again made to fill the questionnaire and undergo pure tone audiometry postoperatively. 37 out of 45 patients (82 %) had an intact graft 6 months after

surgery. Marked improvement was observed in subjective scores as documented by the questionnaire, pre- and post-operatively with the mean improvement in total scores being 7.89 ± 4.81 on a Visual Analogue Scale. Also significant improvement was achieved in closure of air-bone gap with the mean improvement being 14.73 ± 8.58 dB. Significant correlation was found between subjective and objective scores in most patients. This study showed that Type 1 tympanoplasty brings about a significant improvement in the quality of life of chronic suppurative otitis media patients. Most patients showed a marked improvement in subjective scores which correlated well with the objective findings of the status of the graft and improvement in air-bone gap. Asymptomatic patients with less preoperative scores showed less improvement in subjective scores which did not correlate with the objective outcomes.

Keywords Quality of life · Type 1 tympanoplasty · CSOM

Introduction

Chronic otitis media is clinically characterized as an inflammatory condition of middle ear associated with persistent or intermittent otorrhea. Despite all scientific progress, chronic otitis media still remains an important public health problem, since otalgia, ear discomfort, hearing loss, otorrhoea, psychological trauma and complications cause great personal and family suffering. The major symptom in these patients is intermittent otorrhoea, usually associated with upper airway infections or a recent history of extrinsic contamination. Otorrhoea is usually painless, non foul smelling and is almost always associated with hearing loss. The hearing loss associated with this

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✉ Khyati Bhatia
khyati222@gmail.com

¹ Department of Otorhinolaryngology and Head and Neck Surgery, GTB Hospital, University College of Medical Sciences, Dilshad Garden, New Delhi 110095, India

² 8/6 Second Floor, South Patel Nagar, New Delhi 110008, India

pathology is mostly conductive and may vary considerably. Some co-factors that influence the severity of hearing loss are the size and position of the tympanic membrane perforation, the degree of membrane and ossicles fixation, ossicular chain disruption and the degree of repercussion in the inner ear [1].

Chronic otitis media (COM) is associated with significant functional limitations of hearing. This results in communication problems impeding social interaction and professional life. In patients with severe hearing loss even a withdrawal from social activities can be observed. In addition, further symptoms of CSOM such as persistent discharge from the ear, pain and frequent doctor visits may result in impairment of general health and well being of the patients.

Type 1 tympanoplasty or myringoplasty is one of the various surgical techniques for the management of chronic otitis media-tubotympanic disease. It is defined as simple surgical repair of a tympanic membrane perforation without ossicular reconstruction. The aim of the operation includes perforation closure with a dry stable grafted membrane and improvement in hearing levels. Grafting the tympanic membrane with autologous temporal fascia helps in restoration of its integrity, as temporalis fascia is a thin, non-shrinking tissue with low metabolic rate resembling tympanic membrane in texture and structure [2]. Outcome for treatment of this disease has been based on measures such as audiograms, number of office visits required, and sequential physical examinations [3].

The term myringoplasty was coined by Berthold [4], but the first myringoplasty was performed by Marcus Bancer in 1640. The techniques of myringoplasty are onlay and underlay. The underlay technique was described by Austin and Shea [5] and modified by Hough [6]. In 1961 Storrs used the temporal fascia in order to close a tympanic perforation [7]. Over the last three decades temporal fascia has been the most commonly used grafting material in tympanoplasty operations [8], although tragal perichondrium, periosteum, loose overlay tissue, fat, vein, and homologous dura mater are also employed.

It has been demonstrated that the assessment of treatment results on the basis of functional diagnostics, survival rates, or similar parameters alone does not mirror subjective experiences of the patients. Hence, the importance of measuring subjectively assessed quality of life (QOL) is steadily increasing in clinical medicine [9].

Treatment studies of otitis media have traditionally relied on objective measures of effectiveness, including hearing levels, recurrence rates, middle ear status, and tympanic membrane integrity. While important to most health care providers, such measures may be of less relevance to patients and their families.

Health related quality of life (HRQL) is a subjective outcome that reflects the patient's perception of his or her health status. In the context of otitis media, HRQL describes the net consequences of chronic middle ear infection on a patient's daily activities, physical symptoms, social interactions, and emotional well-being [10].

Although many studies have evaluated the repair of the tympanic membrane on the basis of objective measures, little research has been done to assess subjective patient responses as they relate to quality of life. Hence, there is little evidence today that the surgical treatment of chronic otitis media improves the symptoms of patients.

The aim of this study was to assess the surgical outcome of Type 1 tympanoplasty in cases of chronic otitis media-tubotympanic disease and document the associated hearing improvement and to correlate it with the subjective improvement experienced by the patient by using a validated health related questionnaire.

Materials and Methods

This study was conducted in the Department of Otorhinolaryngology and Head & Neck surgery, University College of Medical sciences and GTB Hospital. The study involved retrospective analysis of prospectively collected data in patients of chronic suppurative otitis media.

Forty five patients of chronic otitis media of tubotympanic type having perforations which had been dry for the last 3 months were taken. Patients were selected after taking detailed history and examination which included otoscopy, anterior rhinoscopy, oropharyngeal examination, valsalva maneuver, tuning fork tests and pure tone audiometry. Patients with history of nasal allergy, other nasal diseases, throat problems or any systemic diseases were appropriately treated before taking for ear surgery. The type, size and location of the perforation was documented. The patency of the Eustachian tube was assessed. Patients with cholesteatoma, those having mixed hearing loss and those with an air bone gap exceeding 45 dB were excluded from the study. Patients having other comorbid conditions, immunocompromised patients, mentally retarded patients, those non-compliant with postoperative care and patients >45 years were not included in the study. After selecting the patients an informed and written consent was taken and then the patients were made to fill the chronic otitis media-5 (COM-5) questionnaire.

The COM-5 questionnaire is a modified version of a quality-of-life survey, the Otitis Media-6 (OM-6) survey which was described and used by Rosenfield et al. [10] in

pediatric patients. The COM-5 questionnaire was used in the study by Habesoglu et al. [11].

45 patients meeting the inclusion criteria were selected and were asked to list the following symptoms—ear discharge, pain/discomfort in the ear, difficulty in hearing, activity limitation, emotional problems and caregiver's concern on a Visual Analogue Scale in the range of 1–7.

All the patients underwent Type 1 tympanoplasty. Surgery was done under local anesthesia. Temporalis fascia was used as grafting material using the postaural route and underlay technique in all the cases. The integrity and mobility of the ossicular chain was assessed and documented intraoperatively.

Postoperatively patients were followed up till an interval of 6 months. Status of the graft, along with any evidence of complications were noted. Those with an intact graft after 6 months were considered as successful and included in the statistical analysis. They were again made to rate their symptoms on the Visual Analogue Scale. Hearing assessment was made with tuning fork tests and confirmed with pure tone audiometry and compared with preoperative status.

Statistical Analysis

Data was analyzed using SPSS version 7.0 by a biostatistician. Standard descriptive calculations were used to find out mean, median, mode and standard deviation. Paired samples *t* test was used for measuring difference in preoperative and postoperative scores.

Fig. 1 Figure showing comparative results between preoperative and postoperative air bone gap

Results

A total of 45 patients were taken, of which 37 patients (82 %) were found to have an intact graft 6 months after surgery. 6 patients (13 %) had unsuccessful closure of the tympanic membrane during the 6-month follow up period. 2 patients (4 %) were lost to follow-up and hence were not included in the study.

The average age at presentation was 23.87 ± 6.96 with a range of 15–40 years. The study included 15 males and 30 females. The male to female ratio was 1:2.

Out of 45 patients, 24 patients underwent surgery in the Right ear and 21 patients underwent surgery in the left ear. 34 patients (75 %) had central perforations, 8 patients (18 %) had in anterior quadrant, 2 patients (4 %) had in posterior quadrant, 1 patient (2 %) had 2 perforations, 1 located anterior and the other located posterior, separated by a fibrous band.

Postoperatively most of the patients experienced a significant improvement in hearing. The bone conduction threshold remained unchanged and the closure in air bone gap was as follows.

Out of the 37 patients, 3 patients had no difference in air-bone gap postoperatively, 4 patients had closure of air-bone gap in the range of 5–9 dB, 7 patients had closure of air-bone gap in the range of 10–14 dB, 9 patients had closure of air-bone gap in the range of 15–19 dB, 6 patients had closure of air-bone gap in the range of 20–24 dB, 4 patients had closure of air-bone gap in the range of 25–29 dB and 4 patients had closure of air-bone gap in the range of 30–34 dB (Fig. 1)

The mean change in air bone gap was 14.73 ± 8.58 , with the upper limit of the 95 % confidence interval being 17.59 and lower limit being 11.87.

There was a significant reduction observed in the postoperative subjective scores in hearing loss, emotional distress scores, physical suffering scores and caregiver's concern. However, less improvement was seen in activity limitation scores. The reduction in total scores revealed a highly significant difference with a p value of <0.001 (Fig. 2).

Patients had initially presented with complaints of ear discharge, wetness causing physical discomfort with a mean score of 3.65 ± 0.98 on a Visual Analogue Scale of 1–7, maximum score being 5 due to physical discomfort preoperatively. Postoperatively the scores had improved substantially with the mean score being 2.16 ± 0.76 and the maximum score being 3. Postoperative pain and discomfort was largely attributable to postaural pain and numbness at the incision site.

Complaints regarding difficulty in hearing and asking for repetition of words had a mean score of 3.19 ± 0.99

with the maximum scores being 5 preoperatively which had reduced to a mean score of 1.30 ± 0.66 postoperatively signifying a marked improvement in subjective perception of improvement in hearing.

A highly significant difference was obtained between preoperative and postoperative scores in emotional distress caused by the disease process to the patient and to the caregivers. The difference in scores was 0.83 ± 1.21 and 1.27 ± 1.15 respectively on the Visual Analogue Scale.

Activity limitation scores showed a subtle difference between the preoperative and postoperative scores (Table 1).

A few specific interesting complaints were also observed postoperatively. Three patients noticed that they were not able to appreciate taste of food using their tongue on the ipsilateral side of surgery postoperatively. Also some patients had complaints of facing difficulty in opening their mouth wide open during activities like biting an apple, yawning. However this complaint improved gradually over time.

Fig. 2 Bar diagram depicting the difference in scores obtained pre and postoperatively following Type 1 tympanoplasty using the Visual Analogue Scale

Table 1 Comparison between pre and postoperative scores along with the mean difference with the upper and the lower limit in the 95 % confidence interval

Symptoms	Preop scores	Postop scores	Difference	95 % confidence interval of difference		p value
				Lower	Upper	
Physical suffering scores	3.65 ± 0.978	2.16 ± 0.76	1.48 ± 1.26	1.066	1.907	<0.001
Hearing loss scores	3.19 ± 0.99	1.30 ± 0.66	1.89 ± 1.37	1.435	2.349	<0.001
Emotional distress scores	1.86 ± 1.18	1.03 ± 0.16	0.83 ± 1.21	0.433	1.242	<0.001
Caregiver's concern scores	2.30 ± 1.20	1.03 ± 0.16	1.27 ± 1.15	0.88	1.652	<0.001
Activity limitation scores	1.59 ± 0.89	1.00 ± 00	0.59 ± 0.89	0.296	0.893	<0.001

Table 2 Comparison between the results obtained in our study and the in the study by Habesoglu et al. in the mean difference obtained in air bone gap

	Present study	Habesoglu et al.
Preop mean air bone gap	30.95 ± 8.81	25.33 ± 3.90
Postop mean air bone gap	16.22 ± 5.45	16.22 ± 5.55
Mean improvement	14.73 ± 8.57	9.11 ± 6.26

Discussion

Chronic otitis media (CSOM) usually results from an initial episode of acute otitis media and is often characterized by discharge from the middle ear through a tympanic membrane perforation. It is an important cause of preventable hearing loss, particularly in the developing countries.

Myringoplasty or Type 1 tympanoplasty is a safe and effective technique to improve the quality of life of patients, avoiding continuous infections and allowing them contact with water. The ideal reconstructive technique should obtain a thin, conically shaped ear drum in order to prevent infection and restore or improve hearing [12].

In the present study the effect of Type 1 tympanoplasty or myringoplasty in improving the quality of life chronic suppurative otitis media patients was studied to evaluate the objective and subjective improvement experienced by

patients. Although many studies have evaluated the repair of tympanic membrane on the basis of objective measures, little research has been done to assess subjective patient responses as they relate to quality of life and audiological outcomes.

In our study, 82 % (37/45) patients had an intact graft 6 months after surgery whereas in the study by Habesoglu et al. [11] 80.3 % of the patients (45/56) had an intact graft after the same time which is almost similar. Surgical success was defined as an intact graft after 6 months with an audiological improvement of 15 dB in air-bone gap in their study.

In our study, 45 patients were taken with a mean age 23.87 ± 6.96 , with a range of 15–40 years as compared to Habesoglu et al., where the mean age was 14.1 ± 2.20 with a range of 9–16 years as the study by Habesoglu was done to assess the effect of Type 1 tympanoplasty in pediatric age group. The male to female ratio in our study was 1:2, whereas in the above mentioned study, the male to female ratio was 0.51.

In our study, the mean preoperative air bone gap (ABG) scores were 30.95 ± 8.81 whereas in the above mentioned study the mean scores were 25.33 ± 3.90 . The mean postoperative ABG scores were 16.22 ± 5.45 in our study which was same as the study by Habesoglu et al. The mean improvement seen postoperatively however was slightly better in our study (Table 2).

Table 3 Comparison between pre and post operative scores obtained using Visual Analogue Scale between our study and the study by Habesoglu et al.

Symptoms	Present study		Habesoglu et al.	
	Preop scores	Postop scores	Preop scores	Postop scores
Physical suffering	3.65 ± 0.978	2.16 ± 0.76	4.37 ± 2.15	1.35 ± 1.22
Activity limitation	1.59 ± 0.89	1.00 ± 0.00	5.26 ± 1.80	1.71 ± 1.48
Difficulty in hearing	3.19 ± 0.99	1.30 ± 0.66	4.91 ± 1.54	1.62 ± 1.26
Emotional problems	1.86 ± 1.18	1.03 ± 0.16	4.26 ± 2.14	1.37 ± 0.81
Caregiver's concern	2.30 ± 1.20	1.03 ± 0.16	6.08 ± 0.94	2.02 ± 1.72

Table 4 Comparison of difference in the rate of graft uptake according to the site of the perforation between our study and the study by Podoshin et al.

Type of perforation	Present study			Podoshin et al.
	Total cases	Graft taken	Percent	
Graft uptake rate according to site and size of perforation and number (%)				
Anterior	9	9	100	4 (100)
Posterior	3	3	100	7 (87.5)
Central	28	25	89.28	186 (90.3)
Subtotal	6	3	50	34 (85.0)

The COM-5 questionnaire was used to measure subjective patient responses as they relate to patient's symptoms, functional status, social and emotional consequences of disease and its treatment. Vlastos et al. described the COM-5 questionnaire, which was very useful for evaluating the quality of life in children with chronic otitis media (COM). The COM-5 questionnaire is disease specific quality-of-life survey that demonstrated high reliability and adequate construct validity, as well as responsiveness, to justify its use in clinical studies of children who require tympanoplasty [13].

This is a comparative result between the subjective scores obtained by using the COM-5 in our study and the study by Habesoglu et al. (Table 3).

The physical suffering scores including ear discharge, pain and physical discomfort were found to be similar in both the studies. However activity limitation scores were found to be significantly less in our study as compared to the study by Habesoglu et al. The possible reason for this being, swimming does not form a routine activity in the poor urban population, which form the bulk of patients enrolled in our study. Hearing loss scores were also found to be similar in both the studies. Emotional scores were found to be significantly less in our study as compared to study by Habesoglu et al. Hence Indian people were found to be significantly less affected emotionally due to their ear problems. Also caregiver's concern was found to be less in our study as compared to Habesoglu et al. The possible reason for this being that only pediatric patients were included in that study so the parents were more concerned as compared to our study where only adult population was considered.

On comparing preoperative and postoperative subjective scores there was a significant difference obtained with $p < 0.001$ in our study as compared to study by Habesoglu et al., which showed a similar result with $p < 0.01$.

A study on tympanoplasty was performed by Podoshin et al. in 1996 which was a retrospective study. In this study rate of uptake of graft was 90 % as compared to our study which was 82 %. Hence, the success rate in the study by Podoshin et al. was found to be better than our study.

In this study the rate of graft uptake was measured according to the site of perforation which is being compared with the present study (Table 4).

Graft take rate in our study was found similar to the study by Podoshin et al. Anterior, posterior and central perforations showed a similar response in both the studies whereas subtotal perforations had a poorer take rate in our study as compared to study by Podoshin et al. [12].

According to our study, out of 6 patients with unsuccessful closure of the tympanic membrane, 3 patients had perforation in the contralateral ear, 1 patient had retracted tympanic membrane and 2 patients had a normal contralateral ear. This

suggests that bilateral disease has a poor outcome and prognosis as compared to unilateral disease.

Hence, Type 1 tympanoplasty brings about a significant improvement in the quality of lives of those operated upon. It brings about a significant change in the patients who were symptomatic previously, but asymptomatic patients present with a different clinical picture.

In our study, 8 patients (21 %) had no or minimal symptoms (Visual Analogue Score < 13) initially and had come to know about the perforation incidentally from a doctor. These patients did not seem to benefit subjectively though there was evidence of objective improvement postoperatively. Also, these patients had more complaints regarding postaural pain, numbness and discomfort in the postoperative period. Rest of the patients (79 %) had positive correlation between subjective scores and objectively measured outcomes.

Thus to conclude, Type 1 tympanoplasty in adults is a simple procedure, with a high probability of success which can immensely improve the quality of life of those operated upon.

Compliance with Ethical Standards

Conflict of interest Khyati Bhatia, Lakshmi Vaid and H. C. Taneja have no conflict of interest.

Ethical Standard In this study, human participants were used and all procedures performed in the study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed and written consent was taken from all the participants.

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