



Research Article

ISSN : 2277-3657
CODEN(USA) : IJPRPM

The comparison of Tympanoplasty with or without Mastoidectomy in patients with dry Chronic Otitis Media: A randomized superiority clinical trial

Hossein Rekabi¹, Mina Najarzadeh², Sara Lotfi³ and Nader Saki^{4*}

¹Assistant Professor of Otolaryngology, Head and Neck Surgery, Hearing and Speech Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

²Otolaryngologist, Hearing and Speech Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

³Resident of Otolaryngology, Head and Neck Surgery, Hearing and Speech Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

⁴Associate Professor of Otolaryngology, Head and Neck Surgery, Hearing and Speech Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

*Email: Ahvaz.ent@gmail.com

ABSTRACT

Tympanoplasty and mastoidectomy are the surgical interventions for chronic infection of the middle ear. Tympanoplasty is employed to eradicate the infections of the middle ear and to reconstruct the hearing mechanism. Otolaryngologists might also conduct mastoidectomy in addition to tympanoplasty when they are doubtful about the complete elimination of pathology, based on the preoperative audiometry and intraoperative observations. Mastoidectomy is also conducted to remove the granulation tissue of cholesteatoma and chronic refractory infections; however, there is controversy regarding the success of tympanoplasty with or without mastoidectomy when there is only a simple perforation in the eardrum without active infection or cholesteatoma. This study aimed to compare the effectiveness of tympanoplasty with and without mastoidectomy in patients with dry chronic otitis media. Seventy-six patients with dry chronic otitis media which had simple perforated tympanic membrane were randomly allocated in 2 groups (1:1 ratio) of intervention. Group one underwent tympanoplasty alone with graft (TP) and group two underwent tympanoplasty with mastoidectomy (T&M) surgery. The success rates of surgeries were compared between the intervention groups two month postoperatively. The success rates of TP group and T&M group were 57.9% and 65.8%, respectively. There were no significant differences between intervention groups regarding the improvements in hearing impairment and amount of graft uptake. Mastoidectomy with tympanoplasty was not superior regarding the success of surgical intervention in dry chronic otitis media, as compared to tympanoplasty without mastoidectomy.

Keywords: Tympanoplasty, Mastoidectomy, Chronic Otitis Media, Outcome

INTRODUCTION

Chronic otitis media is the unresolved inflammation of the middle ear and mastoid, which is almost always associated with perforated eardrum. It might manifest as an indolent dry disease or exhibit active discharges(1). Failure to timely treat these recurrent infections along with persistence of the middle ear pathology leads to sclerosis of ossicles, which might result in developmental psychosocial and cognitive disorders(2). Therefore, it is desired to employ any procedures concerning the improvement of success rates of tympanoplasty leading to decreased incidence of complicated chronic middle ear infection. It might also reduce the costs, and may prevent the unwanted

complex surgeries in cases of previous unsuccessful operations(1).The best and the most effective treatment option for chronic infections of middle ear is the surgical operation of eradicating the pathology by means of tympanoplasty(2). The goal of tympanoplasty is to successfully eliminate the pathology and to make a mucous access to middle ear, along with an intact tympanic membrane (TM) in order to have a conductive mechanism for hearing improvement (1). Although several non-invasive techniques have been developed for the treatment of various diseases and cancers, surgery is the gold standard option for most of life-threatening diseases.

Some authors consider the intact TM as an indicator for a successful surgery, while some others believe that postoperative hearing level and the aeration of middle ear correspond to successful tympanoplasty(1, 3). There is somewhat a consensus to perform mastoidectomy with tympanoplasty (T&M) for complicated otitis media; however we have not yet achieved such agreement for those otitis media with simple perforated TM. Mastoidectomy is demonstrated to augment the aeration of middle ear, which might consequently improve the success of tympanoplasty(4, 5) with no additional costs for patients. Although no major complications have been recognized for mastoidectomy, a recent study reported prolonged exposure to the noise generated by mastoid drilling might lead to permanent sensorineural hearing loss (SNHL) (6).

We conducted this randomized superiority trial to test this claim that mastoidectomy along with tympanoplasty might be more effective for clearing the source of infection from mastoid and to aerate the middle ear cleft(5, 7, 8) especially in cases of transient eustachian tube dysfunction, so that patients might better tolerate the postoperative negative pressure of middle ear.

MATERIALS AND METHODS

Trial Design and study population

The present study is a randomized superiority clinical trial with a parallel design (1:1 ratio of intervention arms). All patients with chronic otitis media in ENT ward of Emam Khomeini Hospital, Ahvaz jundishapur University of Medical Sciences were enrolled during 2012-2014. Written informed consent was obtained from all participants according to the Declaration of Helsinki, after comprehensive elucidation of the research purposes. The Ethics Committee of Ahvaz jundishapur University of Medical Sciences approved the protocols of this trial (Grant. No.: U-90207).

Study Settings

Clinical data including physical examinations and audiometric assessments were recorded. The discharging versus dry status of ears and the presence of cholesteatoma was determined. Patients with air bone gaps (ABG) higher than 30, cholesteatoma, and discharging ears were not included. Patients were excluded based on intraoperative observations suggesting cholesteatoma, problems of ossicles, granulation tissue of the middle ear, and suspicious mucosal surfaces.

Interventions

Patients were randomly allocated in two groups: the first group underwent tympanoplasty alone (TP), and tympanoplasty with mastoidectomy was performed for the second group of patients. Audiometric assessments were conducted for all patients pre- and post-intervention. All patients were operated by one surgeon, and their medications were similar pre- and post-intervention. Patients were followed 3 months postoperatively regarding the graft placement status.

Sample Size and Statistical Analysis

Considering a study power higher than 80% and type I error probability (α) of 0.05, the sample size of trial was determined as 36 patients for each arm based on the formula:

$$n = \frac{(z(1-\frac{\alpha}{2}) + z(1-\beta))^2 \cdot [p_1(1-p_1) + p_2(1-p_2)]}{(p_1 - p_2)^2}$$

Quantitative variables are presented as mean (SD), and were tested by independent t-test or Mann-Whitney U, where indicated. Categorical variable are expressed as frequencies, and were tested by Chi-square or Fisher Exact, where

appropriated. Statistical analysis was performed using SPSS 16 software (SPSS Inc., Chicago, IL, USA). P-values less than 0.05 were considered statistically significant.

RESULTS

Participants Flow

During the study course, 118 eligible patients underwent surgery. Figure 1 represents the participants' trial profile. Among them, 23 person were excluded because of ABG>30, 13 patients due to discharging ears, and 6 patients because of cholesteatoma. Finally, 76 patients were remained for trial (37 men and 39 women), which were randomly (1:1) allocated in two groups of tympanoplasty alone (TP) and tympanoplasty with mastoidectomy (T&M).

Participants Characteristics

The mean \pm SD age of individuals of TP group was 30.4 ± 7.6 and was 28.2 ± 8.9 in T&M group, which were not statistically different ($p=0.295$). No differences regarding gender or disease duration was found across intervention groups.

Post-intervention Outcomes

The patients were categorized in three groups regarding the size of TM perforation: 1) less than 50% perforation in TN; 2) more than 50% perforation; and 3) Totally perforated TM. Intervention groups did not reveal differences with respect to the size of TM perforation ($p=0.258$). Concerning the site of TM perforation (including anterior, posterior, central, and undetermined), intervention groups were not statistically significant ($p=0.614$). Table 1 shows the patients' post-intervention characteristics.

Most importantly, TP (57.9%) and T&M (65.8%) groups were not significantly ($p=0.497$) different regarding the success rates of surgery. It is of particular importance that individuals of both groups did not reveal postoperative complications.

Table 1. The post-intervention characteristics of patients with dry chronic otitis media who were randomly allocated in two groups of tympanoplasty alone (TP) and tympanoplasty with mastoidectomy (T&M)

Characteristics	Tympanoplasty alone (N=38)	Tympanoplasty with Mastoidectomy (N=38)	Difference*
Perforation Size			0.258
< 50%	20 (52.63%)	13 (34.21%)	
\geq 50%	13 (34.21%)	17 (44.74%)	
Total Perforation	5 (13.16%)	8 (21.05%)	
Site of Perforation			0.614
Anterior	10 (26.32%)	11 (28.95%)	
Posterior	10 (26.32%)	10 (26.32%)	
Central	13 (34.21%)	8 (21.05%)	
Undetermined	5 (13.16%)	9 (26.38%)	
Postoperative Outcome			0.497#
Successful	22 (57.89%)	25 (65.79%)	
Failed	16 (42.11%)	13 (34.21%)	

* Chi-square test.
Observed power was 76.16%

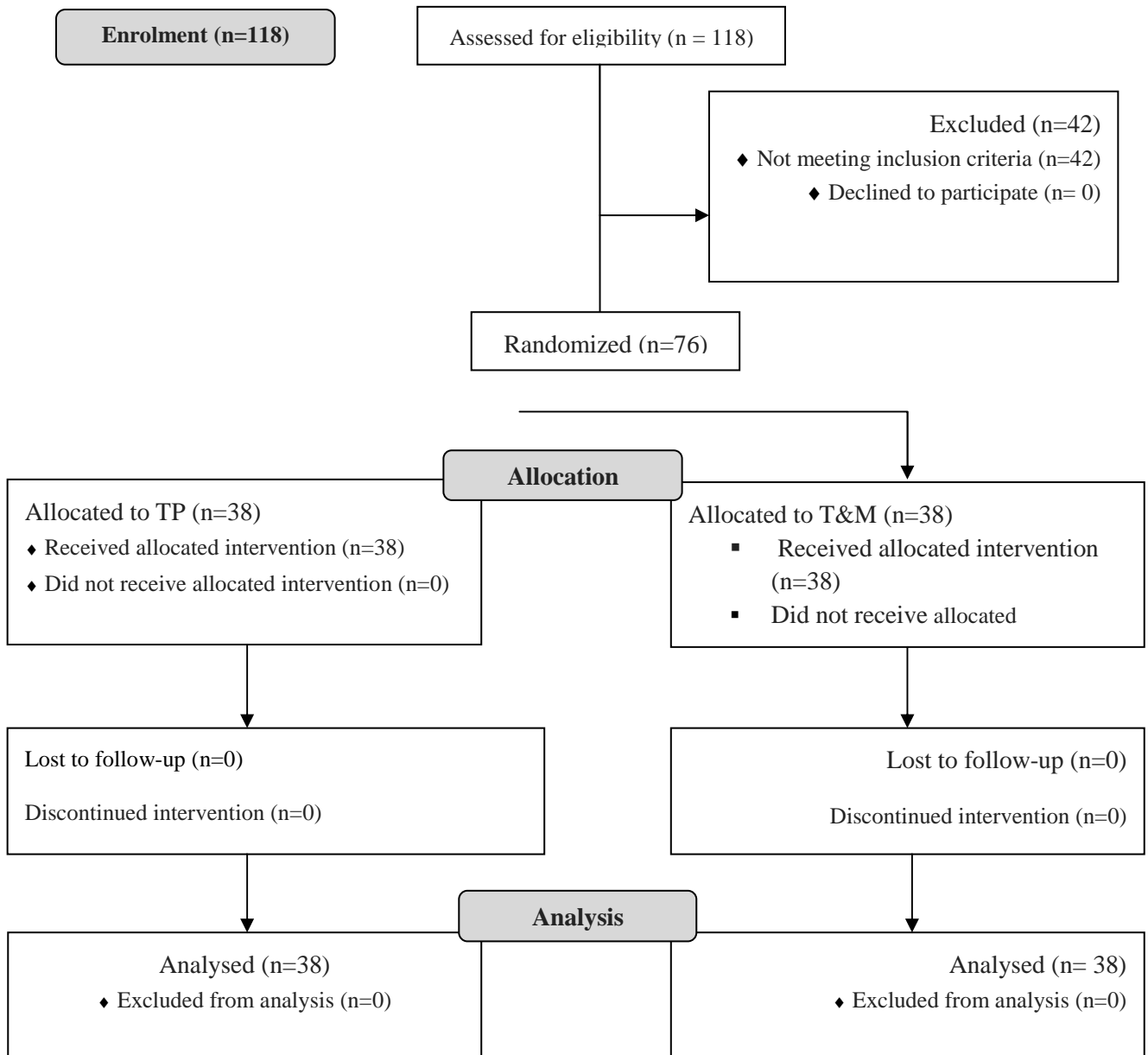


Fig.1. The CONSORT of the present study

DISCUSSION

We conducted this randomized superiority trial to compare the effectiveness of TP and T&M on dry chronic otitis media. The main findings of this study are as follow: TP (57.9%) and T&M (65.8%) did not reveal significantly different success rates of surgery with fair study power. Both interventions were similarly safe with no postoperative complications.

The hearing loss associated with TM perforation is demonstrated to range from 0-40 dB (9). Tympanoplasty (TP) is the surgical procedure for the restoration of the middle ear hearing mechanism. It was firstly described by Wulstein and its various types in 1953 (9). In type-I tympanoplasty the graft is placed over or under the intact malleus handle (10). TP is usually conducted to reconstruction of the small, medium, subtotal or sometimes for the total perforation of the ear drum (5, 9, 10). Successful repair of TM perforation and consequent hearing improvement are typically achieved in greater than 90% of patients(9).Simple mastoidectomy is successfully performed in various otologic operations and in acute coalescent mastoiditis(11). Nowadays, the majority cases of mastoidectomy are performed for complicated chronic ear disease or as a part of complicated surgeries (12).Some otologists still conduct T&M to treat uncomplicated chronic otitis media, in order to clear the pathological source of infection from mastoid and to

re-aerate the middle ear cleft (5). Altogether, tympanoplasty with or without mastoidectomy is enigmatic for restoration of tympanic membrane. The functional benefits of a large aerated mastoid system was firstly introduced by Flisberg et al.(13) and Holmquist and Bergström(14). Hypothetically, when a surgical opening in the mastoid pneumatic system is operated it might exert a buffering action for pressure changes in the middle ear according to Boyle's Law. It consequently allows surgeons for the debridement of infections and to devitalize the bone (5). This mechanism might help patients with intermittent Eustachian dysfunction to overcome the disadvantages of negative pressure of middle ear(3, 15). One retrospective study on 484 patients who had underwent TP at ENT ward of Birmingham, Alabama revealed that mastoidectomy is not necessary for better outcomes of TMs with simple perforations (3). When mastoidectomy is performed in addition to tympanoplasty in cases with simple perforations of TM, the surgeon has to be informed of the possible complications (3). The simple mastoidectomy operation has no particular complications when it is conducted by a skilled surgeon, because the experiences and manual skills of surgeons are the most important attributors for intra- and post-operative complications. The other problem is that mastoidectomy increases the operation time, but to a small extent so that it might be considered as a part of tympanoplasty surgery. However, the safety assessment of T&P requires more studies with long-term follow-ups. Indorwala et al.(4) investigated 789 patients, in which 91% and 9% of tympanoplasties were performed without and with mastoidectomy, respectively. The complete graft take was reported to be in 98.6% of cases, and 86% of patients showed improvement in their hearing outcome post-operatively (mean= 12.5 ±9.5dB), which was influenced by ossicular erosion as and mastoid surgery. They concluded that optimal outcome is achieved with appropriate surgical technique.

To the best of our anecdotal and empirical evidence, these hypothetical effects for T&M have been described. However, recent studies have refuted the claim that mastoidectomy improves graft takes or otologic outcomes, especially in cases of simple perforation repair. In our study all of patients had simple perforations in TM, so we did not encountered ossicular problems, granulation tissue cholesteatoma, or active discharges intraoperative. T&M was not superior to TP with respect to important outcomes. In another study in ENT department of Osaka University Mastoidectomy in addition to TP is not beneficial (15). It is in line with our findings regarding audiometric results and graft takes, so that we did not observe significant superiority for T&M as compared to TP. Moreover, for cases of chronic suppurative otitis media, no significant differences were demonstrated regarding audiologic examination and graft uptake (5). Chavan SS et al revealed there was no significant difference regarding the graft uptake between tympanoplasty with cortical mastoidectomy (97.33%) and tympanoplasty without mastoidectomy (93.33%), four month postoperatively(16). Also, they reported that tympanoplasty along with aerating the sclerosed mastoid did not show significant superiority with respect to the improvement of hearing status compared to TP(16). Hall et al also concluded that TP is sufficient for the reconstruction of simple uncomplicated perforations of TM (17). In line with them, Krishnan et al.(18) found out that when TP is conducted by experienced hands with particular attention for complete removal of pathology from the middle ear along with Eustachian tube function restoration, the outcomes do not differ from that of T&M concerning graft uptake and hearing improvement.

Our results confirm the previous findings of studies indicating that mastoidectomy is not necessary for tympanoplasty to achieve better outcomes in cases of simple perforations in TM. In this study we faced with some limitations as we could not follow patients for longer periods. However, a homogenous population with dry chronic otitis media with simple perforations was studied with fair study power and appropriate sample size.

In conclusion, mastoidectomy is not necessary to be added in the tympanoplasty surgery of dry chronic otitis media with simple perforations of tympanic membrane to achieve better outcomes concerning graft uptake with neotympanum formation rate, and hearing improvement.

REFERENCES

- [1] Canalis RF, Lambert PR. The ear comprehensive otology: Lippincott Williams & Wilkins; **2000**.
- [2] Flint PW, Haughey BH, Lund VJ, Niparko JK, Richardson MA, Robbins KT, et al. Cummings otolaryngology head and neck surgery. 5th ed: Mosby Elsevier; **2010**.
- [3] McGrew BM, Jackson CG, Glasscock ME. Impact of mastoidectomy on simple tympanic membrane perforation repair. *The Laryngoscope*. 2004;114(3):506-11.
- [4] Indorewala S, Adedeji TO, Indorewala A, Nemade G. Tympanoplasty Outcomes: A Review of 789 Cases. *Iranian journal of otorhinolaryngology*. **2015**;27(79):101.
- [5] Islam MT, Rafiquzzaman M. Comparative study of tympanoplasty with or without cortical mastoidectomy. *Journal of Armed Forces Medical College, Bangladesh*. 2015;10(1):69-73.
- [6] Kazikdas KC, Onal K, Yildirim N. Sensorineural hearing loss after ossicular manipulation and drill-generated acoustic trauma in type I tympanoplasty with and without mastoidectomy: A series of 51 cases. *ENT: Ear, Nose & Throat Journal*. **2015**;94(9).

- [7] Akinpelu OV, Amusa YB, Komolafe EO, Adeolu AA, Oladele AO, Ameye SA. Challenges in management of chronic suppurative otitis media in a developing country. *The Journal of laryngology and otology*. **2008**;122(1):16-20.
- [8] Dubey SP, Larawin V. Complications of chronic suppurative otitis media and their management. *Laryngoscope*. **2007**;117(2):264-7.
- [9] Glasscock M, Gulya A. Glasscock-Shambough surgery of the ear. Ontario: BC Decker Inc; **2003**.
- [10] Wullstein H. Theory and practice of tympanoplasty. *The Laryngoscope*. **1956**;66(8):1076-93.
- [11] Sanna M. Middle ear and mastoid microsurgery: Thieme; **2003**.
- [12] Adunka OF, Buchman CA. Otology, neurotology, and lateral skull base surgery: an illustrated handbook: Thieme; **2011**.
- [13] Flisberg K, Ingelstedt S, Örtengren U. The Relationship of Middle Ear Disease to Mastoid Hypocellularity: A working hypothesis. *Acta Oto-Laryngologica*. **1963**;56(S182):69-72.
- [14] Holmquist J, Bergström B. The mastoid air cell system in ear surgery. *Archives of Otolaryngology*. **1978**;104(3):127-9.
- [15] Mishiro Y, Sakagami M, Takahashi Y, Kitahara T, Kajikawa H, Kubo T. Tympanoplasty with and without mastoidectomy for non-cholesteatomatous chronic otitis media. *European archives of oto-rhino-laryngology*. **2001**;258(1):13-5.
- [16] Chavan SS, Deshmukh SD, Pawar VG. Tympanoplasty with or without cortical mastoidectomy. *Gujrat Medical Journal*. **2011**;8(1):8-10.
- [17] Hall JE, McRackan TR, Labadie RF. Does concomitant mastoidectomy improve outcomes for patients undergoing repair of tympanic membrane perforations? *The Laryngoscope*. **2011**;121(8):1598-600.
- [18] Krishnan A, Reddy E, Chandrakiran C, Nalinesha K, Jagannath P. Tympanoplasty with and without cortical mastoidectomy—a comparative study. *Indian Journal of Otolaryngology and Head and Neck Surgery*. **2002**;54(3):195-8.