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Effect of Cortical Mastoidectomy on Audiological Outcomes in Mucosalchronic Otitis Media: A Randomized Controlled Trial

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ABSTRACT

Background: Otitis media is an inflammation of a part or whole of the mucoperiosteal lining of the middle ear cleft. The role of mastoidectomy in the treatment of mucosal chronic otitis media has remained controversial especially when there is no evidence of active infection.

Aim of the work: To evaluate the impact of cortical mastoidectomy in the management of mucosal chronic otitis media in terms of graft uptake and hearing improvement.

Patients and methods: A prospective, randomized controlled trial of 30 patients with uncomplicated mucosal chronic otitis media were allocated at random to either group of 15 patients each. Patients in group A underwent tympanoplasty without mastoidectomy and group B underwent tympanoplasty with cortical mastoidectomy. Patients were scheduled postoperatively for follow-up visits on 1, 3weeks, 3, 6 months and 1 year postoperatively for clinical assessment of the operated ear concerning graft status, ear discharge and hearing improvement.

Results: Tympanoplasty with cortical mastoidectomy has better graft uptake (93.3 %) as compared to without mastoidectomy (86.6 %). The mean air conduction threshold gain was 10.1 ± 10.2 dB in group A and 12.0 ± 9.2 dB in group B. The mean air-bone gap closure was 8.6 ± 6.9 dB in group A and 11 ± 9 dB in group B. There was no statistical significance among both groups.

Conclusion: Addressing the mastoid region by mastoidectomy did not show a statistically significant difference in the postoperative hearing gain and graft uptake rate in treating mucosal chronic otitis media.

Keywords*: Mucosal chronic otitis media; Tympanoplasty; Mastoidectomy; Mastoid pneumatization; Cortical mastoidectomy.*

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INTRODUCTION

Chronic otitis media is one of the commonest ear diseases of all age groups and it is caused by many factors including infections, eustachian tube dysfunction, nasal allergy and trauma. The disease has been classified based on its underlying pathology as active or inactive mucosal, active or inactive squamosal and healed chronic otitis media[1]. Tympanoplasty is a commonly performed surgical procedure to close perforations of the tympanic membrane. According to Jackler and Schindler [2]. Several factors contribute to success or failure of surgery which are divided into mastoid and non-mastoid factors. Non-mastoid factors are age, eustachian tube dysfunction, perforation site and size, cochlear reserve and ossicular chain status. Mastoid factors are the extent of pneumatization and the presence of inflammatory disease in the mastoid. Traditionally tympanoplasty with mastoidectomy has been identified as an effective method of treatment of chronic ear infection resistant to antibiotic therapy[3]. However, the effect of mastoidectomy on patients without evidence of active infectious disease remains an issue of debate.[4] Authors in favor of cortical mastoidectomy suggest that pneumatization increases the air reservoir in the mastoid and also helps in achieving the patency of aditus and eradicating the mastoid source of infection[4,5].

Others have argued that closure of tympanic membrane perforations and elimination of chronic ear drainage can be achieved effectively when performing tympanoplasty irrespective of mastoidectomy[6,7].It has been suggested that mastoidectomy is not only unnecessary, but it increases the risk of ingrowth of squamous epithelium together with the potential for injury to the inner ear structures and facial nerve during mastoid surgery with little or no significant clinical advantage[7]. The contribution of mastoid pneumatization remains controversial, and the role of mastoidectomy in treating tympanic membrane perforations continues to be debated, particularly in

cases of chronic suppurative otitis media in the absence of cholesteatoma.

Our objective is to detect the impact of cortical mastoidectomy in the management of mucosal chronic otitis media in terms of graft uptake and hearing improvement.

PATIENTS AND METHODS

This prospective randomized controlled trial was conducted in the Otorhinolaryngology Department, Al-Azhar University Hospitals. 58 non-pediatric patients with persistent mucosal chronic otitis media were included in the current study. 22 cases were excluded. 13 of which didn't meet the inclusion criteria and 7 cases refused to be a participant in this study. Two cases were excluded due to delays in the preoperative assessment and refusal of randomization. Another 6 cases were excluded from our study in the period of the postoperative follow up due to their attrition (2 from Group A and 4 from Group B).

Informed consent taken from every patient with explanation of the aim of the study. Approval from ethical committee of the hospital was taken.

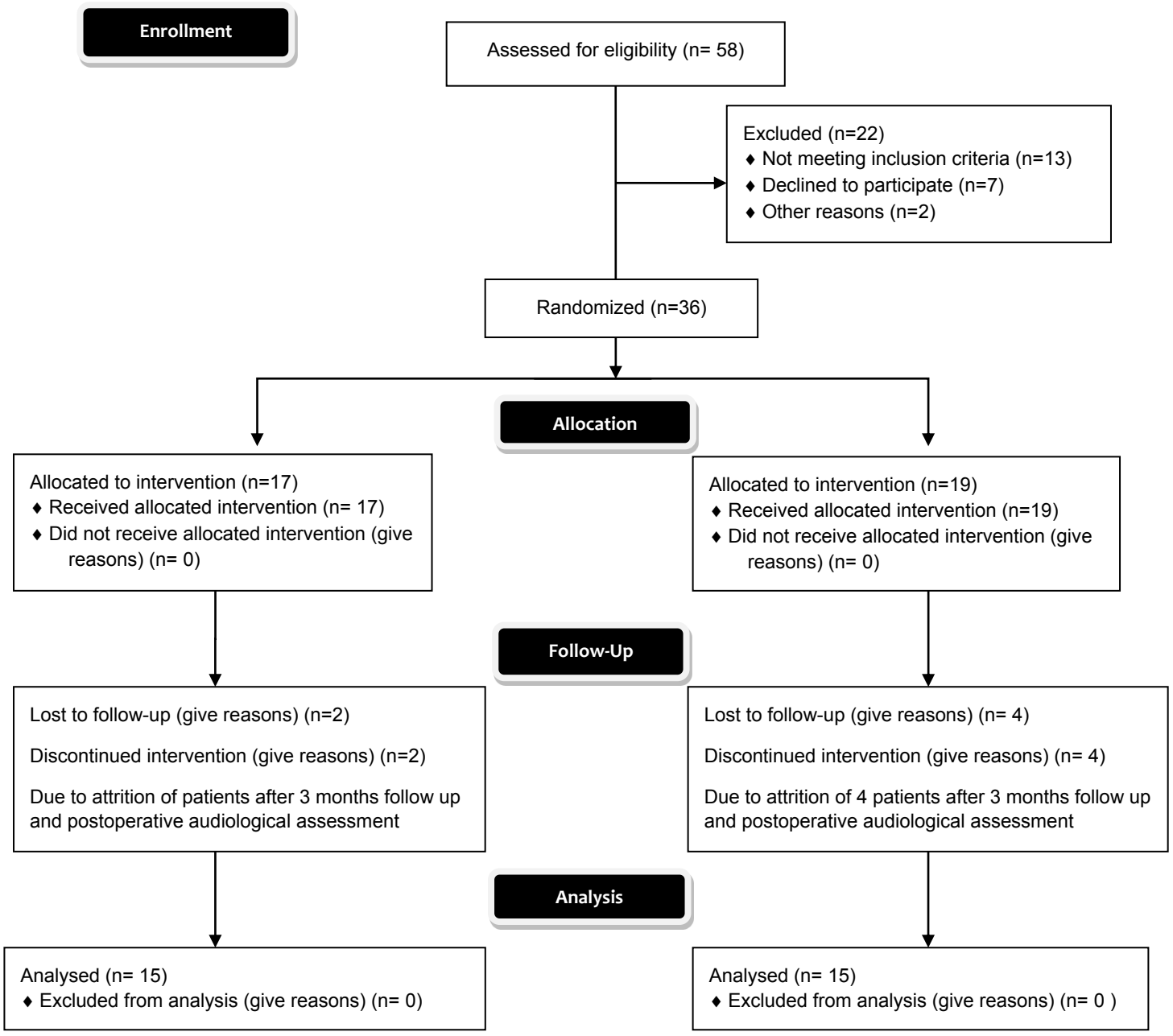

Fig. 1: Consort Flow Diagram.

The patients were selected parallel and arranged as two groups according to the different surgical modalities with allocation ratio (1:1). The patients were randomized into two groups (A and B) containing 15 patients each based on a computerized randomization table. All the patients were fully informed about the randomization. All the 30 patients included in the study were subjected to detailed otorhinolaryngological examination followed by pure tone audiometry, tympanometry with eustachian tube function, computerized tomography and routine preoperative investigations.

The study was a randomized controlled trial comparing 2 methods of management of mucosal chronic otitis media: cortical mastoidectomy and type 1 tympanoplasty. The study protocol was reviewed and approved by the Faculty of medicine Al-Azhar University council meeting.

Eligibility criteria:

Inclusion criteria were patients between the age group of 18-45 years from both sex with uncomplicated mucosal chronic otitis media and dry central perforation for at least 3 months. Patients with previous ear surgery, sensorineural or mixed hearing loss, and patients with cholesteatoma were excluded from this study. Those consenting to participate in the study were randomly assigned to two groups by a computerized table of random numbers. Group A consisted of tympanoplasty and group B consisted of tympanoplasty with cortical mastoidectomy. Full otological examination including assessment of the site, size of perforation, middle ear condition, presence of ear discharge and any abnormality of the external auditory canal. Classification of the size of tympanic membrane perforation depends on the extent of perforation, and they are divided into small, medium, large, subtotal, or total perforation[8].

In group A patients, postauricular incision followed by harvesting of temporalis fascia graft and elevation of tympanomeatal flap. In group B, cortical mastoidectomy was performed along with widening of aditus add antrum. A free flow of saline ensured patency of aditus. An underlay graft was placed in all the cases after the middle ear was inspected for pathology (fibrous band, granulations and ossicular erosion) and the ossicular chain for continuity. All the patients who were randomized into two groups were analyzed i.e. intention to treat analysis was followed. The patients were followed up for a period of 1 year. Outcomes were measured in terms of graft success rate and hearing improvement. This was done by an independent professional who was unaware of the randomization. Pure tone audiometry and tympanometry were performed at the end of 6 months in all the patients.

RESULTS

A total of 30 were divided into two groups A and B containing 15 patients each. Patient characteristics are shown in table 1.

Variables		**Total No. of cases = 30**	
Age (Years) Mean ± SD		28.8 ± 10.8	
		Group A No. (%)	**Group B No. (%)**
Gender			
Male		9 (60%)	5 (33.4%)
Female		6 (40%)	10 (66.8%)
Site of TM peroration	Central part of TM	6 (40%)	8 (53.3%)
	Antero-inferior part	6 (40%)	5 (33.4%)
	Postero-inferior part	3 (20%)	2 (13.3%)
Size of TM perforation	Small	3 (20%)	5 (33.4%)
	Medium sized	8 (53.3%)	6 (40%)
	Large	4 (26.7%)	4 (26.7%)
Side of TM perforation	Right	7 (46.7%)	6 (40%)
	Left	8 (53.3%)	9 (60%)

Table 1: Patient's characteristics in both groups.

In group A (tympanoplasty) there were 9 males and 6 females whereas in group B (tympanoplasty with cortical mastoidectomy) there were 5 males and 10 females.

Central and antero-inferior part of the tympanic membrane were equally distributed at 40% in group A in comparison to 53.3% and 33.4% in group B respectively. Postero-inferior part of TM was the least part to be affected in both groups at 20 % in group A and 13.3 % in group B. No statistically significant difference was observed among studied groups according to the site of perforation.

The right ear was involved in 18 (60 %) cases whereas the left ear involved in 12 (40 %) of the cases. The most common size of perforation seen was large at 47.5 %, followed by medium, subtotal

and small perforations at 27.5, 15 and 10 % of the patients respectively.

Table 2 demonstrates Preoperative and 6 months postoperative Air-Bone Gap (ABG), Air conduction threshold (AC Th) and ear canal volume (ECV) in each studied group.

Variables		Group A	Group B	P-value
ABG	**Preoperative**	37.8 ± 9.76	39.5 ± 8.44	0.495 **NS**
	Postoperative	29.2 ± 7.13	28.5 ± 7.52	0.094 **NS**
ACTh	**Preoperative**	24.4 ± 9.92	26.4 ± 8.90	0.45 **N S**
	Postoperative	13.7 ± 4.5	14.9 ± 4.1	0.75 **NS**
ECV	**Preoperative**	4 ± 0.4	4 ± 1.4	0.0001 HS
	Postoperative	1.5 ± 0.9	1.5± 0.8	0.0001 HS

P value: NS=Non-significant (P-value > 0.05), S=significant (P -value ≤ 0.05), HS= highly significant (P-value ≤ 0.001), ABG =Air-Bone Gap, AC Th=Air conduction threshold ECV=ear canal volume (ECV)

Table 2: Postoperative audiological outcomes.

The preoperative mean air-bone gap in Groups A and B was (24.4 ± 9.9 dB) and (26.4 ± 8.9 dB) respectively. The preoperative air conduction threshold was (37.8 ± 9.7) and (39.5 ± 8) for Group A and Group B respectively. There are significant differences among studied groups as regards preoperative and postoperative air-bone gap and air conduction threshold after 6 months. There are highly significant differences among studied groups as regards preoperative and postoperative ECV after 6 months.

As regards the complications rate, there were two failures in group A and one failure in group B. The difference was not significant statistically. Wound hematoma and chorda tympani nerve injury showed more chance with group B. Tinnitus wasn't improved in two cases in group A compared with only one case in group B, one patient in each group developed tinnitus after the operation.

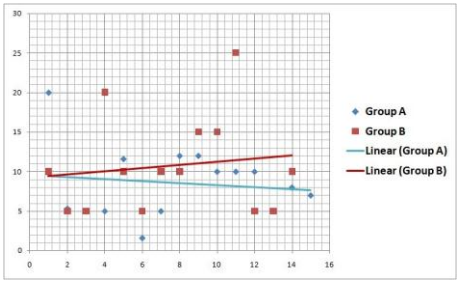

Fig. 2: Air conduction threshold between both groups.

Our results showed a confidence interval (95%) according to the outcome of this study, and were recorded as positive if the graft was taken up and negative if it was untaken. In Group A graft take-up rate was 86.67 %; in Group B it was 93.33 %. There was a mean gain of air conduction threshold 10.1 ± 10.2 dB in group A and 12.0 ± 9.2 dB in group B which showed no significant difference between the two groups (figure 2).

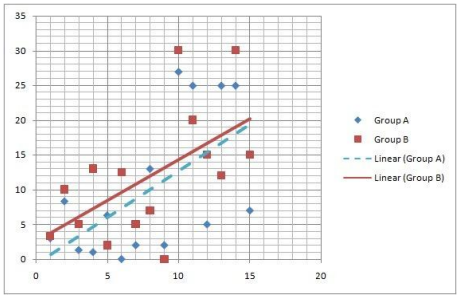

Fig. 3: Air bone gap closure between both groups.

The mean ABG closure was 8.6 ± 6.9 dB in group A and 11 ± 9 dB in group B which showed no significant difference between the two groups (figure 3). The mean ECV changes were 2.5 ± 0.4 in group A and 2.4 ± 0.9 dB in group B which showed no significant difference between the two groups.

Most studies did not report the number or nature of complications resulting from surgery beyond graft failures and persistent otorrhea. Complications in both groups were reviewed. Two cases of group A and one case of group B showed graft failure. Chorda tympani nerve showed more chance to be injured with group B. Wound hematoma occurred postoperatively in 1 case in group A.

DISCUSSION

Mastoidectomy was first described by Louis Petit in the 1700s, although the idea did not gain wider acceptance until cortical mastoidectomy was popularized by William House in 1958[9].Tympanoplasty with mastoidectomy is an effective method of treatment of chronic ear infection, but the effect of mastoidectomy on patients without evidence of active infectious disease in mastoid remains highly debated and unproven [10].

Holmquist and Bergstrom [11]first suggested that mastoidectomy improves the success rate of tympanoplasty for patients with mucosal chronic otitis media. Since then many literatures highlighted the advantages and disadvantages of performing cortical mastoidectomy in the surgical treatment of mucosal chronic otitis media supporting the argument that mastoid pneumatic system acts as a buffer to middle ear pressure changes[12-15]. Thus failure to create a pneumatized air cell system in a patient with mucosal chronic otitis media may increase the chance of surgical failure.

The present study is a randomized controlled trial for evaluating the role of cortical mastoidectomy in the surgery of mucosal chronic otitis media. In a study

done by Varshneyet al.[16]medium-sized perforation was the commonest one, while in our study we found large perforation to be the commonest at 47.5 %. Sex Distribution In our series in group A (tympanoplasty) there were 9 (60%) males and 6 (40%) females whereas in group B (tympanoplasty with cortical mastoidectomy) there were 5 (33.4%) males and 10 (66.8%) females. In a study carried by Kontantinidis et al. [17]male preponderance in the subjects was seen. There were 66.7 % males and 33.3 % female.

In our study, the graft uptake was 86.67 % and 93.33 % in group A and group B respectively. These findings were consistent with those of the study done by Chavan et al. [18]It was observed that the success rate of graft uptake was also seen to be 93% with tympanoplasty 97 % with tympanomastoidectomy. However, in the study conducted by Yasuo et al. [15], the graft uptake was seen to be slightly better with tympanoplasty (94.4 %) than with tympanomastoidectomy (90.7 %)

Postoperatively, the mean gain of air conduction threshold was 10.1 ± 10.2 dB in group A and 12.0 ± 9.2 dB in group B. The mean ABG closure was 8.6 ± 6.9 dB in group A and 11 ± 9 dB in group B. The mean ECV changes were 2.5 ± 0.4 in group A and 2.4 ± 0.9 dB in group B. The hearing improvement showed no significant difference between the two groups. Similar to the present study, Balyan et al.[7] found no significant difference in graft failure rates or hearing results compared with the literatures, or any difference in outcome measures whether or not drainage was present. They also concur that the addition of mastoidectomy adds increased effort and risk to the surgery.

Similarly, Mishiro et al.[19] compared their own surgical experience with and without mastoidectomy in mucosal chronic otitis media and found no significant difference in graft success rates, regardless of otorrhea or whether computed tomography showed an antral block. Furthermore, they concluded that performing mastoidectomy adds time, cost, and increased risk of postoperative complications.

CONCLUSION

The graft uptake rate, air-bone gap closure and air conduction threshold were better in the cortical mastoidectomy with tympanoplasty group than tympanoplasty alone however, this did not show a statistically significant difference between the two groups. A large sample size and multicenter study with a longer duration of follow up are required to prove a strong indication and statistical significance about the role of mastoidectomy in treating mucosal chronic otitis media.

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