Open Access

Original Article

Outcomes of Type-1 Tympanoplasty with and without use of Topical Nasal Steroids; a Comparative Study

Ayesha Khan, Naeem Riaz, Faisal Manzoor, Kamran Zamurrad Malik, Sunarays Akhtar, Shahzad Hanif

Department of ENT, Combined Military Hospital /National University of Medical Sciences (NUMS) Rawalpindi Pakistan

ABSTRACT

Objective: To compare the outcome of Type-1 tympanoplasty procedure in patients given intranasal steroids post-operatively versus those not given intranasal steroids after procedure.

Study Design: Quasi-Experimental study.

Place and Duration of Study: Combined Military Hospital, Rawalpindi. Pakistan from May 2021 to May 2023.

Methodology: A total of 464 patients, 232 of which were given intranasal steroids (Group-A), and 232 who were not given intranasal steroids (Group-B) were made part of this research. Upon inclusion, all pre-operative demographics were documented. Patients in post-operative follow up period were assessed for condition of tympanic membrane and improvement of hearing ability.

Results: In current study, post-operatively, in patients who were given intranasal steroids, graft take-up frequency was 227(97.84%) and residual perforation was 5(2.16%) was better than in patients who were not given intranasal steroids, which came to 224(96.55%) and 8(3.45%), respectively (p=0.399). In terms of post-operative WHO grade of hearing impairment distribution (p<0.001) and post-op hearing status (p=0.005) difference between patients who were given intranasal steroids and those not given intranasal steroids was statistically significant.

Conclusion: Addition of intranasal steroid spray to the treatment regimen following tympanoplasty is provides better outcomes in terms of higher graft take-up frequency and an improvement in hearing from preoperative levels.

Keywords: Chronic suppurative otitis media, Deafness, Steroids, Tympanoplasty.

How to Cite This Article: *Khan A, Riaz N, Manzoor F, Malik KZ, Akhtar S, Hanif S. Outcomes of Type-1 Tympanoplasty with and without use of Topical Nasal Steroids; a Comparative Study. Pak Armed Forces Med J 2024; 74(5): 1374-1378. DOI: https://doi.org/10.51253/pafmj.v74i5.11037*

INTRODUCTION

Chronic Suppurative Otitis Media (CSOM) affects more than 300 million people across the globe with an annual incidence of 31 million.[1,2] CSOM is an infective process involving the middle ear, in which during the initial phase, patient presents with acute infection, which when remains unresolved results in perforation of the tympanic membrane with continuous discharge of chronic inflammatory fluid.[3] In less developed countries, CSOM constitutes a primary cause for medical consultations and the prescription of medications, while also significantly contributing to preventable cases of hearing impairment.[4]

Primarily, there are two types of CSOM: squamous type and mucosal type. Mucosal CSOM is usually associated with perforation of the tympanic membrane, which results in requirement of surgical treatment through tympanoplasty.[5,6]

The outcome of tympanoplasty has been extensively investigated with regards to several factors that may impact the success of the process. These factors include the age and gender of the patient undergoing the operation, the size and location of the perforation, the presence of comorbidities, and the patient's smoking status.[7] However, there is a significant lack of available data about the impact of using intranasal steroids as a component of the normal post-operative therapy regimen, which includes antibiotics and antihistamines, following Type-1 tympanoplasty In addition, it is widely acknowledged that a high standard of post-operative care plays a crucial role in enhancing the results of a surgical intervention.[8]

Hence, in order to fill the knowledge gap that persists in our local data pertaining to the advantages of post-operative use of intranasal steroid therapy among individuals after Type-1 tympanoplasty, it was crucial to undertake a research study on this subject matter.

METHODOLOGY

The quasi-experimental study was conducted at ENT Department of Combined Military Hospital Rawalpindi, Pakistan from May 2021 to May 2023 after

Correspondence: Dr Ayesha Khan, Department of ENT, Combined Military Hospital, Rawalpindi Pakistan

Received: 12 Oct 2023; revision received: 15 Dec 2023; accepted: 22 Dec 2023

obtaining approval from the Institutional Ethical Review Board (ERB No.: 417).

Inclusion Criteria: Patients of either gender aged over 16 yearsdiagnosed with Chronic Suppurative Otitis Media (CSOM), with centrally located tympanic membrane perforation were included.

Exclusion Criteria: We excluded the patients who had previous history of diabetes, immunosuppression, hypertension or structural otic disease, those with perforation on the margins of tympanic membrane, smokers, who presented with active ear infection, platelet/coagulation disorders and those who were not fit for commencement of surgery.

Sample size was calculated using WHO sample size calculator by assuming anticipated frequency of intact tympanic membrane after tympanoplasty in intranasal steroid Group 92.31%[10] and anticipated frequency of intact tympanic membrane after tympanoplasty in no intranasal steroid Group 85.0%.[9] This came to 464 patients of which 232 patients were placed in intranasal steroids Group (Group-A) and 232 patients in no intranasal steroids Group (Group-B).

Study population was recruited using non-probability consecutive sampling. Participants were required to sign written, informed consent before participating in the study. Chronic suppurative otitis media (CSOM) was defined by the presence of "otorrhoea (discharge from ear) of over two to six weeks duration coming through a defect/perforation in the tympanic membrane.[11,12] Baseline characteristics of patients including age in years, gender (male/female), ear involved (left/right) and duration of discharge (in weeks) were documented. Additionally, pre-operative assessment of hearing was performed through "pure tome audiometry" and degree of hearing impairment (in dB) was also documented. Patients were classified based on "WHO Grades of Impaired Hearing" as follows: normal hearing (≤25dB), mildly impaired (26-40 dB), moderately impaired (41-60 dB), severely impaired (61-80 dB) and deaf (≥ 80dB).[13]

After anesthesia fitness all patients underwent Type-1 tympanoplasty by Underlay technique. This technique was used as it has been reported to yield best outcomes.[14] For the procedure, temporalis fascia was used as graft material, as it has been shown to be associated with a significantly higher rate of success.[15] Post procedure, patients were divided into two equal Groups (232 each) based on their medical registration (MR) number. Single blinding was done, in which patients were blind to the Group distribution. Patients with even MR numbers were placed in Group-A (intranasal steroid) and were treated with the combination of antibiotic (tablet co-amoxiclav 625mg x BD for 10 days), antihistamine (tab Levocetirizine 5mg once daily for six weeks) and intranasal steroid spray (Fluticasone 200mcg/day for six weeks), while patients with odd MR numbers were placed in Group-B (no intranasal steroid) and were given standard therapy only with combination of antibiotic (tablet co-amoxiclav 625mg x BD for 10 days) and antihistamine (tablet Levocetirizine 5mg once daily for six weeks) (Figure) . Patients were followed up in the outdoor ENT department at the end of six weeks, where an otoscopic examination was performed to visualize the status of tympanic membrane being intact (named as successful graft take-up), the primary outcome measure. For secondary outcome measures, presence of any residual perforation was documented. Hearing assessment was repeated through Pure Tone Audiometry to assess any improvement in hearing ability after operation from the baseline.

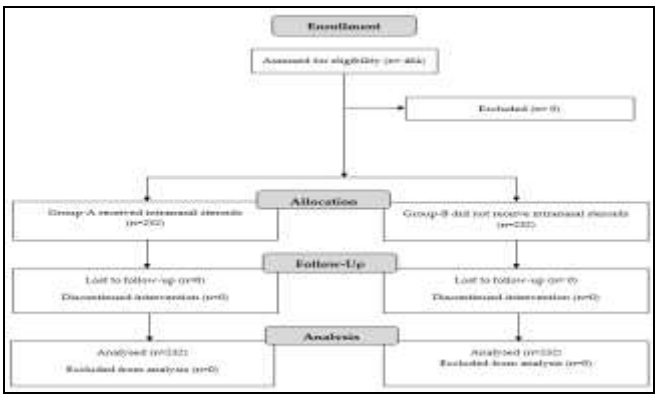

Figure: Patient Flow Diagram (n=464)

Data was analyzed using Statistical Package for Social Sciences (SPSS) 22.00. Normality of data was checked by Shapiro-Wilk test, which showed that quantitative data was not normally distributed, hence it was represented using median and IQR. Qualitative data was represented using frequencies and percentages. Chi-square test and Mann-Whittney U-test were applied depending on the type of data, and *p*-value of ≤0.05 was considered as statistically significant.

RESULTS

In this study, a total of 464 patients were included. Median (IQR) age was 39.00 (19.00–65.00) years. There were 274(59.05%) male subjects while

remaining 190(40.95%) subjects were female. In 245(52.80%) cases, right ear was involved while in 219(47.20%) cases left ear was involved. Median (IQR) duration of ear discharge was 5.00 (4.00–9.00) weeks. Median (IQR) Pure Tone Audiometry (PTA) score was 53.00(32.00–65.00) dB. Based on PTA results, 86(18.53%) had mild, 310(66.81%) had moderate and 68(14.66%) had severe impairment of hearing as per WHO grade of Impaired Hearing.

Upon comparison of these baseline characteristics between study Groups, it was found that there was a significant difference between study Groups in terms of median age (p=0.001), median pre-operative pure tone audiometry score (p=0.027) and WHO grade of hearing impairment distribution (p=0.016) while it was insignificant in terms of gender distribution (p=0.571), ear involved (p=0.926) and median duration of ear discharge (p=0.289). This is demonstrated below in Table-I.

Upon assessment of status of tympanic membrane at follow up visit it was found that in Group-A (n=232), frequency of intact tympanic membrane was 227(97.84%) and of residual perforation was 5(2.16%) while in Group-B (n=232), frequency of intact tympanic membrane was 224(96.55%) and of residual perforation was 8(3.45%), (p=0.399). Median post-operative PTA (Pure Tone Audiometry) score in Group-A was 35.00 (20.00–61.00) dB while in Group-B it was 36.00 (20.00–85.00) dB, (p=0.016). In terms of post-operative WHO grade of hearing impairment distribution (p<0.001) and post-op hearing status (p=0.005) difference between Group-A and Group-B was significant. This data is demonstrated in Table-II:

Table-I: Comparison of Baseline Characteristics Between Groups (n=464)

Parameters	Intranasal steroid Group (Group-A) n = 232		No intranasal steroid Group (Group-B) n = 232		p-value
Age in years (Median, IQR)	36.00 (19.00–65.00)		42.00 (21.00–65.00)		0.001
Gender	Male	Female	Male	Female	0.571
	140(60.35%)	92(39.65%)	134(57.76%)	98(42.24%)	
Ear involved	Right	122(52.59%)	123(53.02%)		0.926
	Left	110(47.41%)	109(46.98%)		
Median duration of ear discharge (weeks)	5.00 (4.00–9.00)		5.00(4.00–9.00)		0.289
Median PTA score (dB)	51.00 (32.00 – 65.00)		54.00 (34.00–65.00)		0.027
WHO grade of hearing impairment	Normal	0(0.00%)	0(0.00%)		0.016
	Mild	55(23.71%)	31(13.36%)		
	Moderate	145(62.50%)	165(71.12%)		
	Severe	32(13.79%)	39(16.82%)		
	Deaf	0(0.00%)	0(0.00%)		

**PTA: Pure Tone Audiometry*

Table-II: Comparison of Post-Operative Parameters between Groups (n=464)

Parameters	Intranasal steroid Group (Group-A) n=232		No intranasal Steroid Group (Group-B) n=232	p-value
Tympanic membrane status	Intact	227 (97.84%)	224 (96.55%)	0.399
	Residual perf-oration	5(2.16%)	8(3.45%)	
Median post-op PTA score (dB)	35.00 (20.00 – 61.00)		36.00 (20.00–85.00)	0.016
Post-op WHO grade of hearing impairment	Normal	55(23.71%)	32(13.79%)	< 0.001
	Mild	146(62.93%)	154(66.38%)	
	Moderate	30 (12.93%)	27(11.64%)	
	Severe	1(0.43%)	15(6.47%)	
	Deaf	0(0.00%)	4(1.72%)	
Post-op hearing status	Improved	224(96.55%)	209(90.09%)	0.005
	Not-improved	8(3.45%)	23(9.91%)	

**PTA: Pure Tone Audiometry*

DISCUSSION

Chronic suppurative otitis media (CSOM) is a fairly common disease of the ear encountered in the Otorhinolaryngology department of hospital all across the globe with younger population (especially those of lower socioeconomic strata) being affected much more as compared to the older population.[15,16] It has been reported in a previous study that when it comes to prevalence of CSOM that male patients are more likely

to have this otic disease as compared to their female counterparts and mostly left ear is found to be affected much more as compared to the right ear.[17] When we compared the finding of our study with this study we found that in terms of male predominance, our findings were congruent were consistent with this study, however, in terms of ear involvement, we found that right ear was affected more with CSOM as compared to left ear. It is a well-known fact that CSOM is a reversible (in most cases) cause of impairment in the ability of hearing.[18] This was also demonstrated by the patients of our study Group in which all patients who were included in our study had some degree of loss of hearing ability with moderate degree of hearing loss being most common occurrence. Prompt and appropriate treatment is essential to prevent permanent damage to the hearing ability.

For this purpose, tympanoplasty is a highly beneficial surgical procedure which if performed timely, appropriately and skillfully, has the ability to improve the hearing loss in patients who have suffered some degree of hearing impairment secondary to CSOM.[19] This property of tympanoplasty was also observed by us in our study where more that 90% of patients had improvement in their ability to hear from preoperative levels. When it comes to use of intranasal steroids during post-operative period and its impact on the outcome of tympanoplasty, not much data is available. Although, it has been reported in previous studies that intranasal steroids are highly beneficial and efficacious in the conservative treatment of patients who have middle ear infection.[20,21] Yet, its impact on post-operative outcome is still a field to be explored. In this instance, one study has been recently conducted by Shah *et al*.[9] in which it was found that use of intranasal steroids significantly improved the post-operative outcomes in patients who underwent tympanoplasty in terms of frequency of intact ear drum, lesser frequency of residual perforation and higher proportion of patients who had improvement in the hearing as compared to baseline levels. In our study, we also observed these beneficial effects of adding intranasal steroids to the standard post-operative regimen of treatment.

The overall paucity in the availability of literature on this important management aspect of Chronic Suppurative Otitis Media makes it imperative that further studies should be carried out in this regard to improve management plans for CSOM which will eventually provide improved patient outcomes.

ACKNOWLEDGEMENTS

We are thankful to our seniors of ENT department for their support and guidance throughout our research which was very helpful to us in completion of our research project. We are also thankful to the whole surgical team as well as the study participants who have helped us thoroughly in addressing this public health problem and conduct this research.

CONCLUSION

In terms of a higher frequency of intact tympanic membrane graft and an improvement in hearing from preoperative levels, adding topical intranasal steroid spray to the normal regimen used following tympanoplasty is advantageous.

Conflict of Interest: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

AK & NR: Data acquisition, data analysis, critical review, approval of the final version to be published.

FM & KZM: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

SA & SH: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

REFERENCES

1. Khairkar M, Deshmukh P, Maity H, Deotale V. Chronic suppurative otitis media: a comprehensive review of epidemiology, pathogenesis, microbiology, and complications. Cureus 2023; 15(8): e43729. https://doi.org/10.7759/cureus.43729
2. Uddén F, Filipe M, Reimer Å, Paul M, Matuschek E, Thegerström J, et al. Aerobic bacteria associated with chronic suppurative otitis media in Angola. Infect Dis Poverty 2018; 7(1): 42. https://doi.org/10.1186/s40249-018-0422-7
3. Verhoeff M, van der Veen EL, Rovers MM, Sanders EA, Schilder AG. Chronic suppurative otitis media: a review. Int J Pediatr Otorhinolaryngol 2006; 70(1): 1-12. https://doi.org/10.1016/j.ijporl.2005.08.021
4. Singer AEA, Abdel-Naby OG, El-Kader RMA, Mohamed AR. Risk factors of sensorineural hearing loss in patients with unilateral safe chronic suppurative otitis media. Am J Otolaryngol 2018; 39(2): 88-93. https://doi.org/10.1016/j.amjoto.2018.01.002
5. Chavan RP, Ingole SM, Birajdar SN. Overview of tympanoplasty techniques and results. Int J Otorhinolaryngol Head Neck Surg 2017; 3(2): 170-175. https://doi.org/10.18203/issn.2454-5929.ijohns20170360
6. Patil BC, Misale PR, Mane RS, Mohite AA. Outcome of interlay grafting in type 1 tympanoplasty for large central perforation. Indian J Otolaryngol Head Neck Surg 2014; 66(4): 418-424. https://doi.org/10.1007/s12070-014-0741-3

7. Kim HC, Park KS, Yang HC, Jang CH. Surgical results and factors affecting outcome in patients with fat-graft myringoplasty. Ear Nose Throat J 2021: 1455613211063243. https://doi.org/10.1177/01455613211063243
8. Bowyer A, Royse C. The importance of postoperative quality of recovery: influences, assessment, and clinical and prognostic implications. Can J Anaesth 2016; 63(2): 176-183. https://doi.org/10.1007/s12630-015-0508-7
9. Shah RK, Shrestha K, Sapkota S, Giri S. Outcome of type 1 tympanoplasty with and without the use of topical nasal steroid: A comparative study from Eastern Nepal. Birat J Health Sci 2018; 3(1)5: 377-380. https://doi.org/10.3126/bjhs.v3i1.19765
10. Charan J, Biswas T. How to calculate sample size for different study designs in medical research? Indian J Psychol Med 2013; 35(2): 121-126. https://doi.org/10.4103/0253-7176.116232
11. Morris P. Chronic suppurative otitis media. BMJ Clin Evid 2012; 2012: 0507.
12. Neogi R, Dan A, Maity K, Basak B, Basu D, Acharya M, et al. Clinico-epidemiological profile of chronic suppurative otitis media patients attending a tertiary care hospital. J Indian Med Assoc 2011; 109(5): 324-326.
13. Olusanya BO, Davis AC, Hoffman HJ. Hearing loss grades and the International classification of functioning, disability and health. Bull World Health Organ 2019; 97(10): 725-728. https://doi.org/10.2471/BLT.19.230367
14. Khawaja M, Sajid T, Aziz T, Ashfaq U, Khan A. Comparison of graft uptake by underlay and overlay technique in myringoplasty. J Ayub Med Coll Abbottabad 2020; 32(Suppl 1)(4): S640-S643.
15. Lee JC, Lee SR, Nam JK, Lee TH, Kwon JK. Comparison of different grafting techniques in type I tympanoplasty in cases of significant middle ear granulation. Otol Neurotol 2012; 33(4): 586-590. https://doi.org/10.1097/MAO.0b013e31824b78ba
16. Mahdiani S, Lasminingrum L, Anugrah D. Management evaluation of patients with chronic suppurative otitis media: A retrospective study. Ann Med Surg 2021; 67: 102492. https://doi.org/10.1016/j.amsu.2021.102492
17. Abraham ZS, Ntunaguzi D, Kahinga AA, Mapondella KB, Massawe ER, Nkuwi EJ, et al. Prevalence and etiological agents for chronic suppurative otitis media in a tertiary hospital in Tanzania. BMC Res Notes 2019; 12(1): 429. https://doi.org/10.1186/s13104-019-4483-x
18. Acuin J. Chronic suppurative otitis media. BMJ Clin Evid 2007; 2007: 0507.
19. Tahir H, Ali I, Malik SA. Hearing assessment and status of tympanic membrane pre and post-operated tympanoplasty in cases of CSOM. Professional Med. J 2020; 27(12): 2581-2585. https://doi.org/10.29309/TPMJ/2020.27.12.4624
20. El-Anwar MW, Nofal AA, Khazbak AO, Sayed AE, Hassan MR. The efficacy of nasal steroids in treatment of otitis media with effusion: a comparative study. Int Arch Otorhinolaryngol 2015; 19(4): 298-301. https://doi.org/10.1055/s-0035-1548535
21. Butler CC, Van Der Voort JH. Oral or topical nasal steroids for hearing loss associated with otitis media with effusion in children. Cochrane Database Syst Rev 2002; (4): CD001935. https://doi.org/10.1002/14651858.CD001935