

Endoscopic Versus Microscopic Tympanoplasty: A Randomized Control Trial

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Abstract:

Background: Chronic otitis media (COM) refers to an inflammatory condition affecting the middle-ear space, characterized by lasting and irreversible alterations in the tympanic membrane. Tympanoplasty is a procedure to remove disease from middle ear and reconstruct hearing with or without tympanic membrane grafting.

Objective: The main aim of surgery is to eradicate infection and decrease the hearing disability in the patient.

Materials and Methods: This hospital based randomized control trial study was carried out among all patients attending the OPD in ENT and Head & Neck Surgery Department of Rohilkhand Medical College & Hospital, Bareilly Uttar Pradesh in the stipulated period fulfilling the inclusion criteria.

Results: There was no significant relevance in age of patients in between group A and Group B. There was no significant divergence in type of diagnosis of patients in between Group A and Group B. There was no significant difference in perforation size of patients in between Group A and Group B. The graft uptake rate was more in Group A as compared to Group B but there was no significant difference between Group A and Group B. There was no significant difference in graft uptake time of patients in between Group A and Group B.

Conclusion: Although the graft uptake and hearing improvement were similar between the endoscopic and microscopic groups, the differences observed were not statistically significant. Furthermore, no complications were detected in either group. Therefore, this study affirms that both endoscopic and microscopic tympanoplasty procedures demonstrate comparable success rates in grafting and hearing enhancement.

Keywords: Endoscopic, Microscopic, Tympanoplasty.

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Introduction

Tympanoplasty is the surgery of choice amongst mucosal type chronic otitis media. Tympanoplasty is a procedure to remove disease from middle ear and reconstruct hearing with or without tympanic membrane grafting [1]. The use of microscope was a revolutionary advance as it allows the surgeon to view the limited confines of temporal bone. Conventionally Microscopic tympanoplasty is being used and still in practice for surgery for TM perforations. But since the introduction of endoscopes in the 1990s, endoscopic tympanoplasty is emerging as an alternative for microscopic tympanoplasty by opening up opportunities for minimally invasive surgeries with wide angled vision and higher magnification [2].

Endoscopic approach has made it easier to access middle ear and understand the ventilation pathways. The introduction of miniaturized charged camera device microchips has eliminated the use of long lens system and provides steerability and excep-

tional optics. Endoscopic surgery is typically a transcanal approach facilitating minimally invasive surgery, avoiding unnecessary incision and soft tissue dissection. It gives panoramic view and magnification without loss of resolution on zooming the view. Endoscope comparatively gives wide field of view along with angulations of view which can be achieved by placing prisms at the end providing direct and quick access to the nook and corners of middle ear cavity not properly visualized by microscopes allowing complete removal of disease with decrease in recurrence rates [3].

Endoscopes provide movie camera type of picture due to its easy mobility at the site of surgery [4]. Microscopes provide the benefit of using both hands to perform surgery but with the limitation of narrow view of the surgical field, straight line vision and inability to access deeper areas [5]. Microscopic tympanoplasty is performed by giving a post auricular incision which increases hospital stay and

discomfort of the patient postoperatively whereas the endoscopic approach uses transcanal route which reduces surgery time, anaesthesia time, hospital stay, post-operative pain, and use of medical resources and cost of surgery due to its minimally invasive procedure [6].

The concerns regarding depth perception, steeper learning curve and chance of injury by the light source, heat induced caloric effect with vertigo, fogging of the lens during surgery, is a limitation to endoscopic surgery.

Insufficient microscopic enlargement & focus, common surgical site infection due to bleeding and crowding of instrument in surgical area, fogging of lens with blood due to trauma, inability to directly access the traumatized area with endoscope are some of the drawbacks of endoscopic tympanoplasty. Since, there is limited literature present on this topic which compares both endoscopic and microscopic tympanoplasty. There are comparable benefits and drawbacks of both the surgeries. So, to fill this lacunae and study the advantages and disadvantages of endoscopic tympanoplasty over microscopic tympanoplasty the present study has been undertaken.

Materials & Methods

This hospital based randomized control trial study was carried out among all patients attending the OPD in ENT and Head & Neck Surgery Department of Rohilkhand Medical College & Hospital, Bareilly Uttar Pradesh in the stipulated period fulfilling the inclusion criteria. Duration of Study was One year (1st November 2022 to 31st October 2023)

The sample size calculated for each group was 105. Total sample size for both the groups came out to be 210 or till the sample size reached.

Inclusion Criteria

- All patients willing to participate in the study.
- All patients including both the gender below the age of 60 yrs. [10]

Exclusion Criteria:

- All patients above the age of 60 years.
- Patients suffering from diabetes, hypertension, tuberculosis, any immunocompromised disease.

Methodology:

After IEC approval, I applied for CTRI registration. Once approved by the CTRI study was started as per the following methodology:

- Patients selected for the study were explained the procedure and a written consent were taken from them. Detailed history and examination was done as per the performance. The patients fitting the inclusion criteria were randomly divid-

ed in two groups by random selection.

- Group A underwent microscopic tympanoplasty.
- Group B underwent endoscopic tympanoplasty.
- Pure tone audiometry was performed on all the patients before and after the surgery.
- All the investigations required for local anaesthesia were done and patients underwent endoscopic and microscopic tympanoplasty.
- Post-operative assessment was done at 6 weeks and 3 months in respect of Graft uptake, Hearing Status, hearing time and complications were compared with various laid down prognostic factors.

Statistical Analysis: The data was recorded in patient information sheet and Statistical Package for Social Sciences (SPSS) version 23.0 was used for Statistical Analysis. The data was analysed by applying frequency, mean and standard deviation. Appropriate statistical test based on distribution and type of data. $P < 0.05$ was considered significant.

Results:

In our study, age of patients was in range from 18 to 60 years. The youngest was 15 years and the eldest was 60 years. In group A, maximum number of cases were in between 31-40 years age group is 47 cases (44.8%). followed by 19-30 years is 32 cases (30.5%), 41-50 years with 15 cases (14.3%), 15-18 years age group are 6 cases (5.7%) and in age group of 51-60 years 5 cases (4.8%). Over all, mean age of cases in group A was 34.79 ± 9.25 years.

In Group B maximum number of cases were in between 31-40 years age group is 46 cases (43.8%). followed by 19-30 years is 39 cases (37.1%), 15-18 years age group are 11 cases (10.5%), 41-50 years with 9 cases (8.6%), and in age group of 51-60 years none cases (0%). Over all, mean age of cases in group B was 34.83 ± 8.29 years. There was no significant difference in age of patients in between group A and Group B.

In Our study out of 105 cases in Group A, 50.5% were male and 49.5% were female and out of 105 cases in Group B, 47.6% were male and 52.4% were female. There was no significant difference in gender of patients in between Group A and Group B.

In Our study out of 105 cases in Group A, 51.4% cases of right inactive mucosal disease, 35.2% cases of left inactive mucosal disease and 13.3% cases of B/L inactive mucosal disease and out of 105 cases in Group B, 54.3% cases of right inactive mucosal disease, 34.3% cases of left inactive mucosal disease and 11.4% cases of B/L inactive mucosal disease. There was no significant difference in type of diagnosis of patients in between Group A and Group B. In Our study 105 cases in Group A

underwent microscopic intervention and 105 cases in Group B underwent endoscopic intervention. In Our study out of 105 cases in Group A, Perforation size was medium in 50.5% of cases and Perforation size was small in 49.5% of cases and out of 105 cas-

es in Group B, Perforation size was medium in 39.0% of cases and Perforation size was small in 61.0% of cases. There was no significant difference in perforation size of patients in between Group A and Group B.

Table 1: Compare Graft Uptake at 6 Weeks

Compare graft uptake or success at 6weeks	Group A		Group B		P-Value
	Number	%	Number	%	
Graft Uptake	39	41.50%	36	37.10%	0.536

In Our study in Group A, the graft uptake rate at 6 weeks was 41.50% and in Group B, the graft uptake rate was 37.10%. The graft uptake rate was more in Group A as compared to Group B but there was no significant difference between Group A and Group B.

Table 2: Graft Uptake Time (In Weeks)

Graft Uptake (In Weeks)	Group A		Group B	
	Number	Percentage%	Number	Percentage%
3	2	1.9	2	1.9
4	7	6.7	6	5.7
5	9	8.6	9	8.6
6	20	19.0	20	19.0
7	15	14.3	13	12.4
8	15	14.3	19	18.1
9	8	7.6	19	18.1
10	14	13.3	4	3.8
11	1	1.0	2	1.9
12	3	2.9	3	2.9
Failure	11	10.5	8	7.6
Total	105	100.0	105	100.0

In Our study out of 105 cases in Group A, graft uptake time was 6-10 weeks in 68.6% of cases, 4-5 weeks in 15.2% of cases, 11-12 weeks in 3.8% of cases and minimum 3 weeks in 1.9% of cases and out of 105 cases in Group B, graft uptake time was 6-9 weeks in 67.6% of cases, 4-5 weeks in 14.3% of

cases, 10-12 weeks in 8.6% of cases and minimum 3 weeks in 1.9% of cases.

Graft uptake time was less in Group B as compared to Group A but there was no significant difference in graft uptake time of patients in between Group A and Group B.

Table 3: Graft Uptake Week Wise

Graft Uptake	Group A		Group B		P-Value
	Number	Percentage%	Number	Percentage%	
3-5 weeks	18	17.1	17	16.2	0.953
6-8 weeks	50	47.6	52	49.5	
9-12 weeks	26	24.8	28	26.7	

In Our study out of 105 cases in Group A, graft uptake time was 3-5 weeks in 17.1% of cases, 6-8 weeks in maximum 47.6% of cases and 9-12 weeks in 24.8% of cases and out of 105 cases in Group B, graft uptake time was 3-5 weeks in 16.2% of cases, 6-8 weeks in maximum 49.5% of cases and 9-12 weeks in 26.7% of cases. There was no significant difference in graft uptake time of patients in between Group A and Group B.

Table 4: Graft Uptake & Failure Rate

Graft Uptake	Group A		Group B		P-value
	Number	Percentage%	Number	Percentage%	
Failure	11	10.5	8	7.6	0.470
Success	94	89.5	97	92.4	
Total	105	100.0	105	100.0	

In Our study in Group A, graft uptake Success rate was 89.5% and graft uptake failure rate was 10.5%, in Group B, graft uptake Success rate was 92.4% and graft uptake failure rate was 7.6%. graft uptake Success rate was more in Group B as compared to Group A & graft uptake failure rate was less in Group B as compared to Group A but there was no significant difference in graft uptake Success & failure rate of patients in between Group A and Group B.

Table 5: Comparison of Mean ABG at Pre- Op In Between Group A and Group B

Group	N	ABG at PRE- OP		t-value	P-value
		Mean	Std. Deviation		
Group A	105	28.73	4.66	1.008	0.315
Group B	105	29.42	5.16		

Mean ABG at pre- op in Group A was 28.73 and in Group B was 29.42. There was no significant difference in mean ABG at pre- op in between Group A and Group B.

The mean ABG at post-op at 6 weeks in Group A was 21.31 and in Group B were 21.35. There was

no significant difference in mean ABG at post-op at 6 weeks in between Group A and Group B.

Mean ABG at post- op in Group A was 17.32 and in Group B were 17.46. There was no significant difference in mean ABG at post- op in between Group A and Group B.

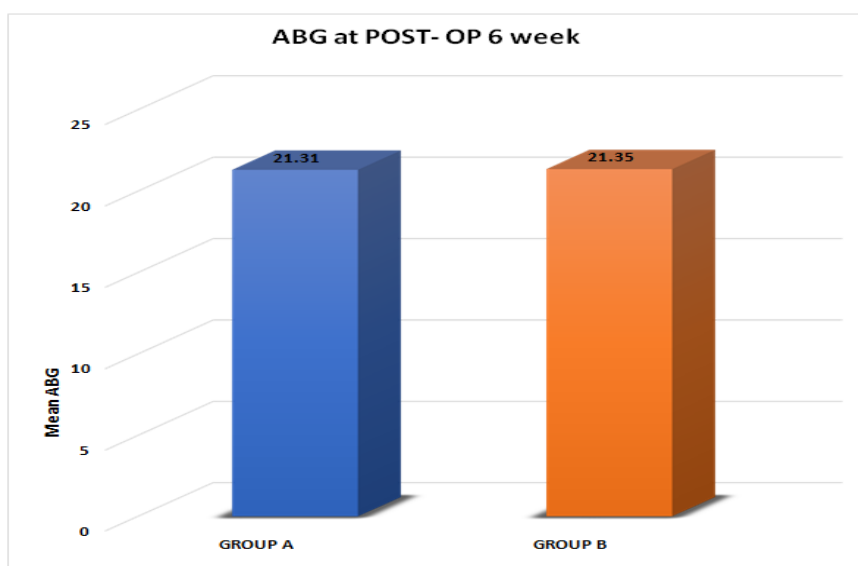


Figure 1: ABG at POST-OP 6 week

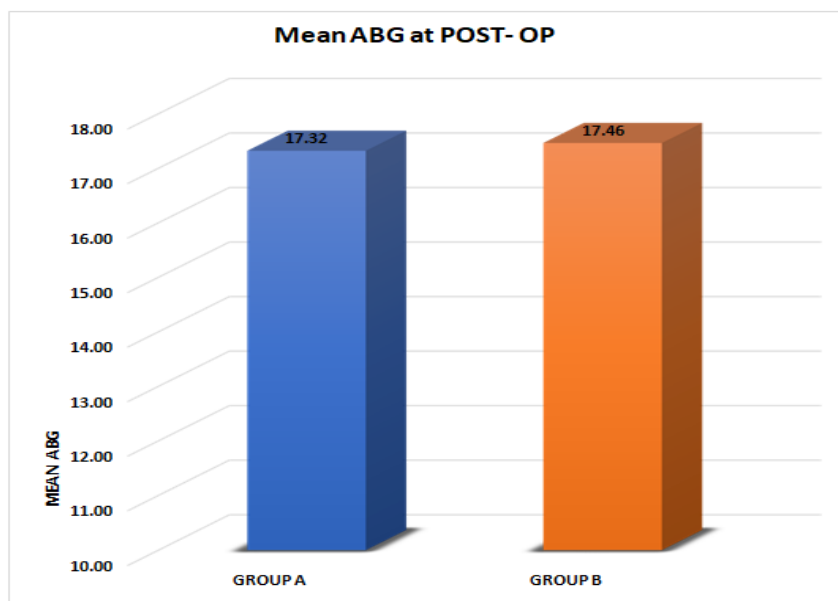


Figure 2: Mean ABG at POST-OP

Discussion

Mean age of cases in group A was 34.79± 9.25 years. Over all, mean age of cases in group B was

34.83 ± 8.29 years. Our finding is in accordance with the study done by, Maran RK et al [7], Patel J et al [8] where maximum cases were seen in 2nd and 3rd decade of life. In our study out of 150 pa-

tients, 111 patients had disease in right ear, 73 in left ear, and 26 in both the ears. Our finding was in accordance with study conducted by Huang TY et al [3]

Patients only with small and medium sized perforation were selected for the study. In Our study out of 105 cases in Group A, perforation was medium size in 50.5% of cases and small size in 49.5% of cases and out of 105 cases in Group B, perforation size was medium in 39.0% of cases and perforation size was small in 61.0% of cases.

Our finding was in accordance with a study conducted by Lakpathi G, Sudarshan Reddy L, Anand [5], Gaur RS, Tejavath P, Chandel S [11] performed a comparative study where 30 patients of each group underwent microscopic and endoscopic tympanoplasty. Patients were followed up at 1st, 3rd and 6th month.

In Our study out of 105 cases in Group A, graft uptake time was 3-5 weeks in 17.1% of cases, 6-8 weeks in maximum 47.6% of cases and 9-12 weeks in 24.8% of cases and out of 105 cases in Group B, graft uptake time was 3-5 weeks in 16.2% of cases, 6-8 weeks in maximum 49.5% of cases and 9-12 weeks in 26.7% of cases. Our results are in accordance with the study conducted by Patel J et al [8], Maran RK et al [7]

Maran RK et al [7] conducted a prospective study comparing 30 patients in each group operated for endoscopic and microscopic tympanoplasty. Majority of the patients belonged to 15 to 30 years of age group. 90% of the patients in endoscopic group and 96% of the patients in microscopic group had successful graft uptake at 3 months. The air bone gap pre and post operatively in microscopic group was 22.05 ± 2.04 db and 9.05 ± 1.36 db respectively. The air bone gap in endoscopic group preoperatively was 21.81 ± 1.85 db and post operatively was 8.55 ± 1.44 db. Neither the graft uptake nor the hearing gain between the groups was significant.

In our study 39 cases (41.50%) in group A and 36 cases (37.10%) cases in group B had successful graft uptake with no significant difference between the groups. In Our study in Group A, graft uptake rate was 89.5% and graft failure rate was 10.5% In Group B, graft success rate was 92.4% and graft failure rate was 7.6%. Graft Success rate was more in group B as compared to group A & graft failure rate was less in group B as compared to Group A but there was no significant difference. Lade H, Choudhary SR, Vashishth [10] conducted a study on 60 patients where 30 patients were allotted in each group. The graft success rate of both the groups was 83.3%. The post op air bone gap of endoscopic group was 18.13dB and microscopic group was 16.87db. The post-operative graft success rate and hearing gain between both the groups were not significant.

Choi N et al [11] did a retrospective relative study where the graft success rate of endoscopic and microscopic group was 100% and 95.8% independently. The mean preop hearing in both the groups was 18.9 ± 7.8 dB and 18.6 ± 7.1 dB which improved to 9.2 ± 1.4 dB and 12.5 ± 1.3 dB independently. There was no significant difference between the two groups post operatively.

Pre and Post OP ABG

In our study we found that mean ABG at pre- op in group A was 28.73dB and in group B was 29.42dB. At 6th week post op the mean ABG in Group A was 21.31dB and in Group B was 21.35Db. Mean ABG at post- op in Group A was 17.32 and in Group B were 17.46. Our findings are in accordance with the study conducted by Patel J et al [8], Lakpathi G, Sudarshan Reddy L, Anand [4], Jyothi AC et al [12] divided 60 patients in each group and compared the hearing gain, graft uptake between microscopic and endoscopic approach. The graft uptake was 91.67% in endoscopic and 93.3% in microscopic group. The post-operative hearing gain was 11 to 20 in all of the success cases with no significant difference between the two groups.

Hsu YC, Kuo CL, Huang [13] did a retrospective comparative study of endoscopic and microscopic tympanoplasty which compared air bone gap and graft success rate on 153 ears where 100 ears were operated for microscopic and 53 ear were operated for endoscopic tympanoplasty. There was no statistical difference between the graft success rate and hearing outcome of the cases in both the groups at 3 months.

Plodpai Y, Paje N [14] investigated graft success rate and hearing gain in microscopic and endoscopic tympanoplasty on 181 patients. Graft uptake was 96.7% in the endoscopic group and 91.2% in the microscopic group which was statistically not significant. The post-operative hearing gain was 13dB and 15dB in endoscopic and microscopic group. The results between both the groups were not significant.

Another study by Salam et al [15] compared between endoscopic and microscopic group of 20 patients each. The graft success rate was 95% in both the groups at post-operative 3 months. The pre and post-operative air bone gap between both the groups was statistically insignificant other study by Jino ME et al [16] analyzed the perforation healing and hearing gain in patients who underwent microscopic and endoscopic tympanoplasty with 30 patients in each group. 86% of cases in microscopic group and 83% patients in endoscopic group had successful graft uptake. Average hearing gain in endoscopic group was 13.96dB and 15.03dB in microscopic group. The difference between both the groups was not significant.

Conclusion:

Chronic otitis media poses a substantial public health challenge, bearing significant economic and societal burdens due to its associated hearing loss and complications. Although the graft uptake and hearing improvement were similar between the endoscopic and microscopic groups, the differences observed were not statistically significant, this study affirms that both endoscopic and microscopic tympanoplasty procedures demonstrate comparable success rates in grafting and hearing enhancement.

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