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COMPARATIVE ASSESSMENT OF SURGICAL OUTCOMES OF MICROSCOPIC TYMPANOPLASTY TO MINIMALLY INVASIVE ENDOSCOPIC TYMPANOPLASTY

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ABSTRACT

Background: CSOM (chronic suppurative otitis media) is a disease having high prevalence globally including India and usually affect subjects from low socio-economic background. It is treated with tympanoplasty where Hopkins Karl Storz Endoscope 0°, 30°, 2.7mm 18 cm and Carl Zeiss Opmi Surgical ENT Microscope has been used for performing ear surgeries owing to their cost-effectiveness, portability, and better optics.

Aim: The present study aimed to comparatively assess the surgical outcomes following microscopic tympanoplasty and invasive endoscopic tympanoplasty.

Methods: The present study assessed 120 subjects who underwent tympanoplasty in the institute. 120 subjects were randomly and equally divided into two groups namely the microscopic group and endoscopic group. For all the subjects, demographics, tympanic membrane perforation size, and pure-tone audiometry were assessed preoperatively and 8th week postoperatively. Also, graft uptake rate, postoperative morbidity, average surgical time, and anesthesia type were assessed in both groups.

Results: A graft uptake rate of 96% and 93% were respectively seen in the microscopic and endoscopic groups. Higher postoperative morbidity was seen in the microscopic group compared to the endoscopic group, whereas; mean surgical time was lesser in the endoscopic group. Endoscopic tympanoplasty was more economical and was done under local anesthesia. The mean air-bone gap was 16.05dB and 16.42 dB respectively in the microscopic and endoscopic group.

Conclusions: Minimally invasive endoscopic technique has equal graft uptake and hearing gain compared to conventional microscopic tympanoplasty with the benefit of less medical resource consumption and less postoperative morbidity making it easy to perform and cost-effective.

Keywords: Chronic suppurative otitis media, CSOM, endoscopic tympanoplasty, microscopic tympanoplasty

INTRODUCTION

COM or chronic otitis media is a common disease affecting the middle ear. Chronic otitis media is a common disease seen globally including in India, and commonly affects subjects from low socioeconomic status and seen in developing countries. Following the 2004 reports of the WHO (World Health Organization), India is among the nations that have the highest prevalence of CSOM (chronic suppurative otitis media) with a prevalence rate of more than 4%. Chronic otitis media is linked to the structural changes in pars flaccid or pars tensa along with the middle ear which is seen secondary to negative middle ear pressure, Eustachian tube dysfunction, and inadequately treated otitis media.[1]

Previous literature data has reported that the procedure of tympanoplasty is done to close the perforation in the tympanic membrane. Since the application of tympanoplasty in clinical practice, various surgical techniques and different graft materials have been developed and used. However, the technique used more widely and accepted on a large scale is post-aural microscopic tympanoplasty, and has a success rate of 80% to 90%. Post-aural microscopic tympanoplasty used the temporalis fascia as the most common grafting material.[2]

After the incorporation and use of the endoscope in the field of surgery, it is widely used in various surgeries involving the nasal complex and excellent results have been reported. Ear surgeries assisted with endoscopes are usually done by surgeons and have been increasing in the practice of surgeons in the past 10-20 years.[3]

The authors have reported that various benefits of using the endoscope include it being minimally invasive and can be done using a transcanal approach that eliminates unnecessary dissection of the soft tissues and allows better access to the hidden areas in the cavity of the middle ear. Endoscopes also have surgical advantages over the use of microscopes being ideal for use in camp surgeries, being cost-effective, and easy to transport.[4]

The present study aimed to assess the efficacy and role of using the rigid endoscopes in the tympanoplasty. The study had objectives of comparatively assessing the surgical outcomes concerning postoperative morbidity, hearing gain, graft uptake, and medical resource consumption including anesthesia type and surgical procedure duration in the two surgical procedures, and assessing any existing relationship between the two procedures.

MATERIALS AND METHODS

The present study aimed to assess the efficacy and role of using the rigid endoscopes in the tympanoplasty. The study had objectives of comparatively assessing the surgical outcomes concerning postoperative morbidity, hearing gain, graft uptake, and medical resource consumption including anesthesia type and surgical procedure duration in the two surgical procedures and to assess any existing relationship between the two procedures. The study was done at Department of ENT, Sri Venkateswara Medical College, Tirupati, Andhra Pradesh, after the clearance was given by the concerned institutional ethical committee. The study population was from the Department of Otorhinolaryngology of the Institute after obtaining informed consent from the study subjects.

The study included 120 subjects from both genders having central perforation in the tympanic membrane. The inclusion criteria for the study were subjects with inactive mucosal type chronic suppurative otitis media and exclusion criteria were subjects with a history of ear trauma, sensorineural hearing loss, and cases with ear discharge.

The 120 subjects were randomly divided into two groups of 60 subjects each using software for randomization. All 120 subjects were surgically treated under GA (general anesthesia) or LA (local anesthesia). TIVA (total intravenous anesthesia technique) was used in a few subjects. All the surgeries were performed by two surgeons, experts in the field.

For Group I subjects, Hopkins Karl Storz Endoscope 0°, 30°, 2.7mm 18 cm and Carl Zeiss Opmi Surgical ENT Microscope was utilized to perform the tympanoplasty. The transcanal approach and tragal perichondrium graft were used in the endoscopic surgery procedure. In the microscopic tympanoplasty technique, a postaural approach with a temporalis fascia graft was used. Subjects were followed after the procedure at 2^{nd} week, 4^{th} week, and 8^{th} week postoperatively following surgery. For all the subjects, demographic data, clinical profile, complications during and following the surgery, postoperative and intraoperative complaints, mean surgical time, anesthesia type, mean postoperative air-bone gap, preoperative mean air-bone gap, and perforation size were noted. VAS (visual analog scale) scores were used for the postoperative complaints in the form of a questionnaire.

The surgery for all the subjects was done using TIVA, general anesthesia, or local anesthesia as needed. In the use of local anesthesia, 30 mg pentazocine injection was used along with 25 mg promethazine via the intramuscular route to induce sedation, and 2% lignocaine infiltration was done. In the subjects where general anesthesia was used, endotracheal intubation was used along with intravenous and inhalational anesthesia drugs. In TIVA, an oxygen mask was utilized to maintain proper oxygenation, and vitals monitoring was done throughout the procedure.

In the subjects where a microscope was used, after doing infiltration with 2% lignocaine with adrenaline, 1:80,000 in the external auditory canal and post-aural region, the external auditory canal was exposed using the Wilde's incision followed by dissection of the post-aural soft-tissues to harvest the temporalis fascia graft. Pinna retraction was then done anteriorly with a Mollison retractor and a sickle knife was used to freshen the perforation margin. The tympanomeatal flap was then elevated 5mm away from the tympanic annulus and skeletonization of the malleus handle was done. In all the subjects, the ossicular chain was seen to be intact. The harvested temporalis fascia graft was then spread uniformly and placed below the malleus handle. Zohler and Wullstein's classification was used to perform type 1 tympanoplasty. The tympanomeatal flap was spread over the temporalis fascia. Gel foam pieces were placed inferiorly and anteriorly in the middle ear cavity below the graft and over the tympanomeatal flap to support the graft. The postaural incision was sutured and sutures were removed after 1 week.

In the endoscopic group, infiltration in the postaural region was done with 2% lignocaine with adrenaline, 1:80,000 in the external auditory canal, and tragus. Endoscopes used for the surgery were 0° and 30°, 2.7 mm, and 11 cm. The sickle knife was used to freshen the perforation margin. From the same ear tragus, a tragal perichondrium graft was harvested with minimal dissection of the soft tissues. With a circular knife, 5mm lateral to the annulus, an incision was made followed by the elevation of skin from the bone of the external auditory canal. After elevation of the annulus, mucosa of the middle ear was incised followed by tympanomeatal flap elevation from the malleus handle to reach the middle ear cavity. After malleus handle skeletonization, an underlay technique was used to place the temporalis fascia graft, and the flap was placed back over the fascia. Gel foam was placed inferiorly and anteriorly below the graft in the middle ear to support the graft over the tympanomeatal flap.

In the microscopic group, subjects were observed for two days following the procedure, whereas, in the endoscopic group, subjects managed with local anesthesia were discharged the same day and under TIVA, and general anesthesia was observed for 1 day. The subjects were followed till 8 weeks following surgery.

The data gathered were analyzed statistically using SPSS software version 21.0 (IBM Corp., NY Armonk, USA), an independent t-test for qualitative variables, and a chi-square test for categorical variables. The data were expressed in mean and standard deviation and frequency and percentage. The significance level was taken at $p<0.05$ value.

RESULTS

The present clinical study aimed to assess the efficacy and role of using rigid endoscopes in tympanoplasty. The study had objectives of comparatively assessing the surgical outcomes concerning postoperative morbidity, hearing gain, graft uptake, and medical resource consumption including anesthesia type and surgical procedure duration in the two surgical procedures and to assess any existing relationship between the two procedures. The included 120 subjects were randomly divided into two groups of 60 subjects each where Group I subjects were managed with microscopic tympanoplasty and Group II subjects with endoscopic tympanoplasty. The mean age of study subjects was 26.71±13.07 years and 24.91±9.25 years in the microscopic tympanoplasty and endoscopic tympanoplasty group respectively. There were 63.33% (n=38) females and 36.66% (n=22) males in the microscopic tympanoplasty group and 50% (n=30) males and 50% (n=30) females in the endoscopic tympanoplasty group as shown in Table 1.

The lesion was on the right ear in 53.33% (n=32) subjects and was on the left side in 46.66% (n=28) subjects from the microscopic tympanoplasty group. The right side was operated in 60% (n=36) subjects and on the left side in 40% (n=24) subjects in subjects that underwent endoscopic tympanoplasty. The mean size of perforation was small, medium, and subtotal in 33.33% (n=20), 40% (n=24), and 26.66% (n=16) subjects respectively in microscopic tympanoplasty group, whereas, the perforation size was small, medium, and subtotal in 16.66% (n=10), 40% (n=24), and 43.33% (n=26) subjects from endoscopic tympanoplasty group (Table 1).

It was seen that in subjects managed with endoscopic tympanoplasty, at the 4^{th} week postoperative, 56 subjects had eardrum intact and it remained intact in 56 subjects at the 8^{th} week postoperatively. In 4 subjects where graft failure was seen, all 4

subjects were irregular at follow-up recalls and had postoperative infections. In the microscopic tympanoplasty group, 58 subjects were reported with intact eardrum at the 4th week postoperatively and it remained intact in 58 subjects at the 8th week postoperatively. All 2 subjects were irregular at follow-up recalls and had postoperative infections with graft failure.

The study results showed that mean surgical time in TIVA, LA, and GA groups in microscopic tympanoplasty was 42.2±2.4, 40.5±5.6, and 60.4±3.2 minutes respectively, whereas it was significantly lower in endoscopic tympanoplasty group with 38.73±1.5, 33.62±2.7, and 43.24±3.3 minutes respectively in TIVA, LA, and GA groups with respective p-values of 0.006, 0.0005, and 0.0001. The consumption of medical resources was 16.66% (n=10), 33.33% (n=20), and 50% (n=30) in TIVA, LA, and GA in microscopic tympanoplasty group, and was 23.33% (n=14), 46.66% (n=28), and 30% (n=18) in TIVA, LA, and GA in endoscopic tympanoplasty group which was statistically non-significant in two groups with p=0.26. The graft uptake was seen in 96.6% (n=58) subjects from the microscopic tympanoplasty group and was 93.33% (n=56) in the endoscopic tympanoplasty group which was non-significant with p=0.57 as depicted in Table 2.

Concerning the postoperative complications and complaints in study subjects, granulation of the external auditory canal was seen in 3.33% (n=2) of subjects from the microscopic tympanoplasty group and in no subjects from the endoscopic tympanoplasty group. Urine retention was seen in 3.33% (n=2) of subjects from the microscopic tympanoplasty group and in no subjects from the endoscopic tympanoplasty group. Bat ear was seen in 6.66% (n=4) of subjects from the microscopic tympanoplasty group. The tragal hematoma was seen in 10% (n=6) of subjects from the endoscopic tympanoplasty group and no subjects from the microscopic tympanoplasty group. Ear pain was seen in 10% (n=6) of subjects from the microscopic tympanoplasty group. Neck pain was seen in 6.66% (n=4) of subjects from the microscopic tympanoplasty group. Bleeding during graft harvesting was seen in 3.33% (n=2) of subjects from the microscopic tympanoplasty group. Nausea was seen in 10% (n=6) and 6.66% (n=4) subjects from microscopic tympanoplasty and endoscopic tympanoplasty groups respectively. The complications were significantly higher in the microscopic tympanoplasty group compared to the endoscopic tympanoplasty group with p=0.004 as summarized in Table 2.

The results for the air-bone gap are summarized in Table 3. Preoperatively, the mean air-bone gap was 30.72±3.06 dB and 32.02±3.37 dB for microscopic tympanoplasty and endoscopic tympanoplasty groups respectively which was statistically non-significant with p=0.07. At the 8th week postoperative, the mean air-bone gap was 14.23±2.72 dB and 15.23±4.44 dB for microscopic tympanoplasty and endoscopic tympanoplasty group respectively depicting the non-significant difference with p=0.12. The mean gain in the air-bone gap was 16.05±4.44 dB and 16.42±4.56 dB for the microscopic tympanoplasty and endoscopic tympanoplasty group respectively. This difference was statistically non-significant with p=0.36 as shown in Table 3.

DISCUSSION

The present study included 120 subjects who were randomly divided into two groups of 60 subjects each where Group I subjects were managed with microscopic tympanoplasty and Group II subjects with endoscopic tympanoplasty. The mean age of study subjects was 26.71±13.07 years and 24.91±9.25 years in the microscopic tympanoplasty and endoscopic tympanoplasty group respectively. There were 63.33% (n=38) females and 36.66% (n=22) males in the microscopic tympanoplasty group and 50% (n=30) males and 50% (n=30) females in the endoscopic tympanoplasty group. These data were similar to the studies of Mohindra S et al[5] in 2010 and Yadav SP et al[6] in 2009 where authors assessed subjects with demographic data comparable to the present study.

It was reported that the lesion was on the right ear in 53.33% (n=32) subjects and was on the left side in 46.66% (n=28) subjects from the microscopic tympanoplasty group. The right side was operated in 60% (n=36) subjects and on the left side in 40% (n=24) subjects in subjects that underwent endoscopic tympanoplasty. The mean size of perforation was small, medium, and subtotal in 33.33% (n=20), 40% (n=24), and 26.66% (n=16) subjects respectively in microscopic tympanoplasty group, whereas, the perforation size was small, medium, and subtotal in 16.66% (n=10), 40% (n=24), and 43.33% (n=26) subjects from endoscopic tympanoplasty group. These results were consistent with the previous studies of Basak B et al[7] in 2014 and Vikram BK et al[8] in 2008 where authors suggested similar demographic and clinical profiles in their study subjects with CSOM.

The study results showed that in subjects managed with endoscopic tympanoplasty, at the 4th week postoperative, 56 subjects had eardrum intact and it remained intact in 56 subjects at the 8th week postoperatively. In 4 subjects where graft failure was seen, all 4 subjects were irregular at follow-up recalls and had postoperative infections. In the microscopic

tympanoplasty group, 58 subjects were reported with intact eardrum at the 4th week postoperatively and it remained intact in 58 subjects at the 8th week postoperatively. All 2 subjects were irregular at follow-up recalls and had postoperative infections with graft failure. These results were in agreement with the findings of Migirov I[9] in 2015 and Parelkar K et al[10] in 2015 where authors suggested similar graft success in their study subjects as seen in the present study.

It was seen that the mean surgical time in TIVA, LA, and GA groups in microscopic tympanoplasty was 42.2±2.4, 40.5±5.6, and 60.4±3.2 minutes respectively, whereas it was significantly lower in endoscopic tympanoplasty group with 38.73±1.5, 33.62±2.7, and 43.24±3.3 minutes respectively in TIVA, LA, and GA groups with respective p-values of 0.006, 0.0005, and 0.0001. The consumption of medical resources was 16.66% (n=10), 33.33% (n=20), and 50% (n=30) in TIVA, LA, and GA in microscopic tympanoplasty group, and was 23.33% (n=14), 46.66% (n=28), and 30% (n=18) in TIVA, LA, and GA in endoscopic tympanoplasty group which was statistically non-significant in two groups with p=0.26. The graft uptake was seen in 96.6% (n=58) subjects from the microscopic tympanoplasty group and was 93.33% (n=56) in the endoscopic tympanoplasty group which was non-significant with p=0.57. These results were in line with Fernandes NV[11] in 2003 and Quraishi MS et al[12] in 1995 where medical resource consumption in endoscopic and microscopic tympanoplasty was reported similar to the present study by the authors.

On assessing postoperative complications and complaints in study subjects, granulation of the external auditory canal was seen in 3.33% (n=2) of subjects from the microscopic tympanoplasty group and in no subjects from the endoscopic tympanoplasty group. Urine retention was seen in 3.33% (n=2) of subjects from the microscopic tympanoplasty group and in no subjects from the endoscopic tympanoplasty group. Bat ear was seen in 6.66% (n=4) of subjects from the microscopic tympanoplasty group. The tragal hematoma was seen in 10% (n=6) of subjects from the endoscopic tympanoplasty group and no subjects from the microscopic tympanoplasty group. Ear pain was seen in 10% (n=6) of subjects from the microscopic tympanoplasty group. Neck pain was seen in 6.66% (n=4) of subjects from the microscopic tympanoplasty group. Bleeding during graft harvesting was seen in 3.33% (n=2) of subjects from the microscopic tympanoplasty group. Nausea was seen in 10% (n=6) and 6.66% (n=4) subjects from microscopic tympanoplasty and endoscopic tympanoplasty groups respectively. The complications were significantly higher in the microscopic tympanoplasty group compared to the endoscopic tympanoplasty group with p=0.004. These results correlated to the studies of Jyothi AC et al[13] in 2017 and Choi N et al[14] in 2017 where similar complications were reported by the authors following tympanoplasty as seen in the results of the present study.

Preoperatively, the mean air-bone gap was 30.72±3.06 dB and 32.02±3.37 dB for microscopic tympanoplasty and endoscopic tympanoplasty groups respectively which was statistically non-significant with p=0.07. At the 8th week postoperative, the mean air-bone gap was 14.23±2.72 dB and 15.23±4.44 dB for microscopic tympanoplasty and endoscopic tympanoplasty group respectively depicting the non-significant difference with p=0.12. The mean gain in the air-bone gap was 16.05±4.44 dB and 16.42±4.56 dB for the microscopic tympanoplasty and endoscopic tympanoplasty group respectively. This difference was statistically non-significant with p=0.36. These findings coincided with the results of Raj A et al[15] in 2001 and Karhuketo TS et al[16] in 2001 where air-bone gap results similar to the present study were reported by the authors in their studies.

CONCLUSIONS

Considering its limitations, the present study concludes that the minimally invasive endoscopic technique has equal graft uptake and hearing gain compared to conventional microscopic tympanoplasty with the benefit of less medical resource consumption and less postoperative morbidity making it easy to perform and cost-effective.

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TABLES

Characteristics	**Microscopic tympanoplasty n=60 (%)**	**Endoscopic tympanoplasty n=60 (%)**
Mean age (years)	26.71±13.07	24.91±9.25
Gender		
Females	38 (63.33)	30 (50)
Males	22 (36.66)	30 (50)
Lesion side		
Right	32 (53.33)	36 (60)
Left	28 (46.66)	24 (40)
Mean perforation size		
Small	20 (33.33)	10 (16.66)
Medium	24 (40)	24 (40)
Subtotal	16 (26.66)	26 (43.33)

Table 1: Demographic data of the two groups of study subjects

S. No	**Factors**	**Microscopic tympanoplasty**		**Endoscopic tympanoplasty**		**p-value**
		n=60	**%**	**n=60**	**%**	
1.	**Mean surgical time (min)**					
a)	TIVA	42.2±2.4		38.73±1.5		**0.006**
b)	LA	40.5±5.6		33.62±2.7		**0.0005**
c)	GA	60.4±3.2		43.24±3.3		**0.0001**
2.	**Postoperative complications and complaints**					
a)	External auditory canal granulation	2	3.33	0	-	**0.004**
b)	Bat ear	4	6.66	0	-	
c)	Urine retention	0	-	2	3.33	
d)	Tragal hematoma	0	-	6	10	
e)	Ear pain	6	10	0	-	
f)	Neck pain	4	6.66	0	-	
g)	Bleeding during graft harvesting	2	3.33	0	-	
h)	Nausea	6	10	4	6.66	

3.	**Medical resources consumption**					
a)	TIVA	10	16.66	14	23.33	0.26
b)	LA	20	33.33	28	46.66	
c)	GA	30	50	18	30	
4.	**Graft outcomes**					
a)	Failure	2	3.33	4	6.66	0.57
b)	Uptake	58	96.6	56	93.33	

Table 2: Mean surgical time, postoperative complications, and medical resource consumption in two groups of study subjects

S. No	Air-bone gap	Microscopic tympanoplasty	Endoscopic tympanoplasty	p-value
1.	**Preoperative**	30.72±3.06	32.02±3.37	0.07
2.	**Postoperative in 8th week**	14.23±2.72	15.23±4.44	0.12
3.	**Gain at 8th week**	16.05±4.44	16.42±4.56	0.36

Table 3: Preoperative, postoperative, and gain in air-bone gap in two groups of study subjects