

Longitudinal Study of Type I Interlay Tympanoplasty

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Abstract The aim of the present study was to access success rate of tympanoplasty and complications with interlay technique of tympanoplasty. This Longitudinal Prospective study was carried out in the Department of Otorhinolaryngology and Head and Neck Surgery, Era's Lucknow Medical College, Lucknow. 50 patients aged between 10 and 50 years of chronic otitis media mucosal type disease with dry ears were selected. Otomicroscopic, tuning fork test, pure tone audiometry were done in all patients. All patients underwent interlay tympanoplasty. Patients were followed up regularly for a minimum period of 1.5 years. Successful graft uptake was noted in 48 (96%) cases. Interlay tympanoplasty results in excellent graft uptake and good post operative Air Bone Gap closure.

Keywords Chronic otitis media · Mucosal disease · Interlay · Type I tympanoplasty

Introduction

From seventeenth to nineteenth centuries, several attempts were made at closing the perforations of the tympanic membrane. Apart from discharge, perforation of tympanic

membrane also leads to considerable amount of hearing loss. Chronic otitis media (COM) has a major impact on the social life of a person in the form of ear discharge and hearing disability [1]. Definitive management of mucosal COM is tympanoplasty [2]. Tympanoplasty is a procedure done to repair the defect in the tympanic membrane after eradication of all the disease in the middle ear cleft with or without reconstruction of ossicular chain [3]. Blake used paper patch, a prosthetic material to close a perforation in 1887 [4]. In 1952, Wallstein [5] first published a method of closing perforation by split thickness skin graft. One year later Zollner [6] described his experiments with similar grafts. In 1956, Zollner [6] used fascia lata to close perforation. In 1958, Heerman [7] began to use temporalis fascia. Technique wise, on the basis of placement of graft in relation to the remnant tympanic membrane, it is classified as underlay, overlay and interlay. The objectives of the present study were to access success rate of tympanoplasty and complications with interlay technique of tympanoplasty.

Material and Method

This is a prospective study, which was carried out in the Department of Otorhinolaryngology, Era's Lucknow Medical College Hospital between May 2012 to May 2015. 50 patients aged 10–50 years with chronic otitis media mucosal type were included in the study. All the patients had dry ears before surgery. Patients undergoing revision surgery were excluded from this study.

Otomicroscopy, Tuning fork test, Pure tone audiometry (PTA) were done in all patients pre-operatively and was documented in the performa. All the patients were operated by a single surgeon. Patients were operated under general

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anaesthesia. Patients were admitted and single dose of intravenous ceftriaxone was given prior to surgery. Post-operatively ceftriaxone was continued for 3 days and thereafter patients were given oral antibiotics, antihistamine and nasal drops for next 4 days. Post aural sutures and endomeatal pack was removed on the 7th post-operative day. Topical ear drops containing ofloxacin and beclomethasone was started and continued for next 4 weeks. PTA and Tympanometry was done at the end of 3rd month.

Patients were followed up for a minimum period of 1.5 years. Follow up were done at 1st, 2nd, 3rd week after discharge, there after 3rd, 6th, 12th, 18th month respectively and in between if required. Examination under the microscope was done to assess the graft uptake and complications. The hearing levels of each frequency were recorded both in air conduction (0.5, 1, 2 and 4 kHz) and bone conduction (0.5, 1, 2, and 4 kHz). The mean hearing levels were defined as the average of hearing levels at frequencies of 0.5, 1, 2, and 4 kHz. The air–bone gap (ABG) was defined as the average of the air–bone conduction gap at 0.5, 1, 2, and 4 kHz.

Tympanometry was done at the end of 3rd month to evaluate the middle ear aeration for any atelectasis or otitis media with effusion (OME). 50 control patients whose mean ear volume value of 1.57 ± 0.013 was taken as reference value for comparison. Controls were the patients selected randomly from our outpatient department without any ear or nasal complaints or with any upper respiratory tract infection. All the patients in our study were having Type A curve on tympanometry.

With Ethics Committee approval, all patients were informed and consented for the surgery. A post auricular approach was used in all patients. Post auricular incision was started from the highest point of helix to mastoid tip approx 2 cm behind the post auricular groove. Temporalis Fascia was harvested and used as graft material. Tympanomeatal flap was elevated from 3 o'clock to 11 o'clock in right ear and vice versa in left ear. Fibro-squamous layer of remnant tympanic membrane was elevated leaving behind the mucosal layer. Oto-endoscopy was done to inspect the middle ear cleft and ossicular status with Karl Storz HOPKINS Telescope 0° and 45°. Round window reflex was assessed and present in all patients. Ossicles were healthy and mobile in all patients. Temporalis fascia graft was placed between the fibro-squamous layer and mucosal layer of drum tympanic membrane. Tympanomeatal flap was repositioned back. Graft was supported externally by abgel and EAC was packed with abgel and ear wick soaked in antibiotic solution. Post auricular incision was closed in layers. Mastoid dressing applied. Mastoid dressing as a routine was changed on the 2nd post-operative day.

Statistical Analysis

Results were tabulated and statistical analysis was done. Chi square test was applied for the statistical analysis of pre-operative and post-operative air–bone gap. The *p* value smaller than 0.0001 was taken as significant.

Results

Interlay tympanoplasty was done on 50 patients between May 2012 and May 2015. Minimum age of the patient was 10 years and maximum 50 years with mean age of 24.8 years. Females comprised of 58% (29 cases) and males 42% (21 cases).

80% (40 cases) of patients had complaint of both ear discharge and hearing loss, 12% (6 cases) had only ear discharge and 8% (4 cases) had only hearing loss.

The status of graft was observed at regular intervals. Successful graft uptake was seen in 48(96%) patients. Successful graft uptake was defined as one that had (1) integrity of the graft; (2) post-operative gain of minimum of 10 dB in the auditory threshold, or conservation of hearing; and (3) complete healing, with the space of the aerated middle ear manifested by the graft located in the correct anatomical position, with neither atelectasis nor otitis media with effusion (OME).

Post-operative improvement in hearing was evaluated by pure tone audiometry at 3rd month. Out of the 50 patients, 2(4%) had a pre-op air bone gap (ABG) in the range 11–20 dB, 8(16%) had ABG range 21–30 dB, 24(48%) had ABG range 31–40 dB and 16(32%) had ABG range above 40 dB. The maximum number of cases in our study were with a pre-operative ABG range >30 dB. The mean pre-operative air bone gap (ABG) in our study was 35.24 ± 6.82 (Table 1).

The ABG closure at the end of 3rd month, 39(78%) patients had ABG range within 10 dB, 8(16%) had ABG range 11–20 dB, 2(4%) had range 21–30 dB and 1(2%) had range of 31–40 dB. In this study overall 94% patients had reduced mean air bone gap. The mean post-operative air bone gap (ABG) at the end of 3rd month was

Table 1 Pre and post operative air bone gap (ABG)

Range (dB)	No. of patients	
	Pre op ABG	Post op ABG
≤10	0	39 (78%)
11–20	2 (4%)	8 (16%)
21–30	8 (16%)	2 (4%)
31–40	24 (48%)	1 (2%)
≥40	16 (32%)	0

Table 2 Graft uptake in various studies

Study	Technique	Graft up take (%)	<i>p</i> value
Sengupta et al. [9]	O + U + combined technique (N = 40)	92.5	0.484
Umar et al. [29]	U(N = 85)	92.95	0.437
Mokhtarnejad et al. [30]	Subannular grafting (N = 38)	97	0.798
	U(N = 25)	100	0.149
Lima et al. [27]	U(N = 39)	95	0.822
Sergi et al. [21]	U(N = 52)	94.2	0.673
	O(N = 63)	91.5	0.315
Lee et al.[20]	Loop overlay (N = 42)	98.8	0.388
Mehta et al. [31]	U(N = 50)	94	0.646
Singh et al. [22]	U (with temporalis fascia) (N = 80)	95	0.786
Karela et al. [32]	U(N = 211)	91.5	0.182
Kartush [15]	Over-underlay (N = 100)	100	0.149
Mishra et al. [33]	U(N = 100)	97	0.759
Mangal singh et al. [34]	O(N = 30)	93.3	0.613
	U(N = 30)	93.3	
Stage et al. [35]	U(N = 39)	97	0.797
Glasscock [36]	O(N = 57)	91	0.287
	U(N = 180)	96	1.000
Fadl et al. [37]	U	85.4%	
	O	66.7%	
Gupta et al. [38]	O	86.6%	
Brown et al. [39]	U	74%	
	O	100%	
Guo et al. [16]	I(N = 53)	96.2	0.959
	U(N = 168)	85.7	0.008
Komune et al. [17]	I(N = 69)	94.2	0.649
Patil [24]	I(N = 100)	96	1.000
Our study	I(N = 50)	96	1.000

U underlay, *O* overlay, *I* interlay

10.52 ± 5.20 ($p < 0.0001$) which was statistically significant.

Tympanometry was done at 3rd month post-operatively to evaluate the middle ear aeration for atelectasis or otitis media with effusion. The mean ear volume post operatively in our study was 1.56 ± 0.015 . 50 control patients whose mean ear volume value of 1.57 ± 0.013 was taken as reference value for comparison, which is statistically insignificant.

Complications took place in 5 patient in the form of perforation and discharge in 2 patients. They were treated conservatively. Culture sensitivity of discharge was done and culture sensitive antibiotic was given. After a week of treatment, the discharge subsided but they had developed perforation. Remaining 3 patients developed granulations in the external auditory canal at the meatotomy site, which completely subsided after administering culture sensitive

antibiotic therapy. Graft lateralization, medialization and atelectasis were not found in any of our patient.

Discussion

Tympanoplasty is the simplest operative procedure performed to repair the perforation in ear drum by repairing the tympanic membrane only. There are at least a dozen techniques to repair membrane defect, among these the Underlay and Overlay is quite common and are widely used. In underlay technique graft is placed medial to the mucosal layer whereas in overlay technique, graft is placed lateral to fibrous layer of tympanic membrane. In the last few years, a new technique Interlay has also emerged and is being successfully used with promising results [8]. In Interlay technique the graft is supported

Table 3 Pre-operative Air Bone Gap in different studies

ABG range (dB)	Lee et al. [20] (%)	Yadav et al. [23] (N = 50)(%)	Lima et al. [27] (%)	Sergi et al. [21]		Patil [24] (%)	Our study (%)
				U%	O%		
<10	9.1	0	0	22.4	29.6	0	0
11–20	35.9	20	31	36.7	33.3	8	4
21–30	34	70	43	36.7	20.3	26	16
≥30	21	10	26	18.3	16.6	66	80

U underlay, O overlay

medially by mucosal layer and laterally by fibro squamous layer.

Sengupta et al. [9] in his study found maximum number of patients to have complaints of hearing loss and discharge (57.5%) followed by complaint of only ear discharge in 25% cases and only hearing loss in 12.5%. In our study, 80% (40 cases) of patients had complaint of both ear discharge and hearing loss, 12% (6 cases) had only discharge and 8% (4 cases) had only hearing loss.

Labatut Pesce et al. [10] had undertaken post aural route approach in 66% of his cases. In our study post aural approach was used in 100% of cases.

Successful tympanoplasty was defined as the one that should include (1) integrity of the graft; (2) post-operative gain of minimum of 10 dB in the auditory threshold, or conservation of hearing; and (3) complete healing, with the space of the aerated middle ear manifested by the graft located in the correct anatomical position, with neither atelectasis nor otitis media with effusion (OME) [11–14]. In our study successful graft uptake was noted in 48(96%) patients. Residual perforation in the antero-inferior quadrant and pulsatile discharge following an episode of upper respiratory tract infection was noted in 2 (4%) patients. In various other tympanoplasty related studies either by overlay, underlay or combined technique the successful graft take up rate was 85.7–100% [15, 16]. Komune [17] observed a success rate of 94.2%, while Guo [16] reported 96.2%, Wandong She [18] reported 87.5%, Hay and Blanshard [19] reported 91% showing high success rate in Interlay Myringoplasty. In our study we had a success rate of 96% which is in close proximity with the results of above mentioned studies (Table 2).

Lee et al. [20] reported in their study that postoperative air–bone gap less than 10 dB was in 80.4% cases, between 10 and 20 dB was in 13%, between 21 and 30 dB was 5.6%, and more than 30 dB was in 0.9% cases. Sergi et al. [21] by underlay technique reported for 31 patients the post-op ABG was 10 dB (63.2%), for 16 was from 11 to 20 dB (32.6%), for 1 from 21 to 30 dB (0.6%) and for another 1 it was more than 30 dB (0.6%). But for overlay technique, for 16 patients, the ABG was 10 dB (29.6%), for 18 was from 11 to 20 dB (33.3%), for 11 from 21 to 30 dB

Table 4 Mean pre-operative Air Bone Gap in different studies

Study	Mean ABG (dB) (standard deviation)	<i>p</i> value in comparison with present study
Sengupta et al. [9]	29.15 ± 5.56	<0.0001
Saha et al. [28]	30.61 ± 10.49	<0.0001
Fouad et al. [25]	37.3 ± 6.3	0.033
Patil et al. [24]	36.42 ± 12.01	0.221
Our study	35.24 ± 6.82	

Table 5 Mean Post-operative Air Bone Gap in different studies

Study	Post op mean ABG(dB)	<i>p</i> value in comparison with present study
Fouad et al. [25]	13.7 ± 4.6	<0.0001
Lima et al. [27]	10.3	0.765
Sergi et al. [21]		
Underlay	9.9	0.400
Overlay	17.5	<0.0001
Patil et al. [24]	9.7 ± 6.71	0.265
Our study	10.52 ± 5.20	<0.0001

(20.3%) and for 9 was more than 30 dB (16.6%). Overall total of 62.9% from overlay group had post op ABG to be <20 dB. Singh et al. [22]. by underlay technique showed 11–20 dB ABG closure in 63% cases, 21–30 dB ABG closure in 24% cases and more than 30 dB ABG result in 13% cases. Yadav et al. [23] reported post operative ABG as ≤10 dB in 68% cases, 26% cases had ABG in the range of 11–20 dB, 6% cases had ABG in the range of 21–30 dB and 0% cases had ABG ≥ 30 dB. Patil [24] by interlay technique reported post operative 76 (76%) cases had ABG within 10 dB, 4 (4%) cases had ABG in the range of 21–30 dB, 2 (2%) cases had ABG between 31 and 40 dB and no case (0%) had ABG >40 dB. In our study, 24(48%) pts had a pre-op air bone gap (ABG) in the range 31–40 dB, 16(32%) pts had ABG range above 40 dB, 8(16%) had ABG range 21–30 dB and 2(4%) had ABG range 11–20 dB. In comparison to the various studies discussed above (Tables 3, 4), the maximum number of cases in our study were with a pre-operative ABG range

Table 6 Complications in various studies

Complications	Sengupta [9]	Umar [29]	Mishra [33]	Singh [34]		Lee [20]	Patil BC [24]	Our study
				U	O			
Medialisation	7.5%	1.17%	–	–	–	–	–	–
Lateralisation	7.5%	–	1%	–	6.6%	–	–	–
Perforation/rejection of graft	12.5%	5.88%	2%	6.6%	6.6%	1.2%	4%	4%
Post aural wound infection	7.5%	–	–	–	–	–	–	–
Partial flap necrosis	–	–	–	–	–	–	2%	–
Granular myringitis	10%	–	–	–	6.6%	–	–	–
Alteration of taste	–	2.35%	–	–	–	–	–	–
Granulation in EAC	5%	–	–	–	–	–	–	6%
Deterioration in hearing	–	1.17%	–	–	–	–	–	–
Retraction pockets	–	3.52%	2%	–	–	–	–	–
Otitis media with effusion	–	–	2%	–	–	2%	–	–
Epithelial pearls	–	–	–	–	–	2.3%	–	–

U underlay, *O* overlay

>30 dB. The ABG closure at the end of 3rd month: 39(78%) pts had ABG range within 10 dB, 8(16%) pts had ABG range 11–20 dB, 2(4%) pts had range 21–30 dB and 1(2%) pt had range 31–40 dB. The two pts with post-op ABG of 21–30 dB and one pt with 31–40 dB were having pre op ABG of more than 40 dB, so these cases also had a hearing improvement post-operatively (Table 1).

Fouad et al. [25]. observed a mean post op ABG to be 13.7 ± 4.6 dB. In our study, the mean post-op ABG was 10.52 ± 5.20 (Table 5).

In a study by Yigit et al. [26], the rate of atelectasis by underlay was greater than overlay technique. No patient had atelectasis in our study. The mean ear volume post operatively in our study was 1.56 ± 0.015 which was compared with the controls having mean ear volume of 1.57 ± 0.013 , which is statistically insignificant. Controls were the patients selected from out patient department without any complaint of ear discharge and upper respiratory tract infection. All the patients in our study were having Type A curve on tympanometry (Table 6).

Anterior canal wall blunting chances are very less by the interlay technique as the fibrous annulus which is elevated during the procedure is meticulously placed back onto the bony annulus all around and secured with small pieces of gelfoam. There is no medialisation or lateralisation of the graft as the graft is supported medially by the mucosal layer and laterally by the fibro-squamous layer.

As the mucosal layer is below the graft there are no chances of endothelium overgrowing on the graft leading to myringitis. The fibro-squamous layer of the tympanic membrane is elevated completely hence there is no fear of leaving residual epithelium behind leading to the formation of epithelial pearls or an iatrogenic cholesteatoma if it gets buried under the graft.

Conclusion

Interlay tympanoplasty results in excellent graft uptake and good post operative ABG closure. A main advantage of this technique includes prevention of anterior blunting, lateralization and medialisation of graft. Interlay tympanoplasty abolishes chances of epithelial cyst formation as in overlay technique and myringitis due to endothelium overgrowth as in underlay technique. This technique although, is more difficult and time consuming and requires expertise but the chances of complication are very less and results are as good as with other techniques. We would like to emphasize that this technique should be practiced more and more among the surgeons and residents.

Compliance with Ethical Standards

Conflict of interest The authors have no conflicts of interest to disclose.

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