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Original Research Paper

Influence of tympanosclerosis on the graft uptake and hearing results in patients undergoing underlay myringoplasty

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ABSTRACT:
Objective: - To observe the frequency of tympanosclerosis and assess its influence on the graft uptake and hearing results in patients undergoing underlay myringoplasty. **Material and methods**: - Patients 2>12 years of age with a diagnosis of chronic Suppurative otitis media tubo-tympanic type were included in the study. All the patients were recruited from the outpatient clinic (OPD) of the Department of Otorhinolaryngology and Head & Neck Surgery, Bheri Hospital from 18 October 2022 to 14 April 2024. Pre- operative and post-operative pure tone audiogram was performed to evaluate the bearing threshold. The sites of tympanosclerotic plaques were noted intraoperatively after otomicroscopic examination. The patients with tubo-tympanic diseases with tympanosclerosis were enrolled as study group and those without tympanosclerosis were kept in control group. Tympanosclerotic plaques from tympanic membrane were removed completely wherever possible and were either removed partially or left as such wherever they were located far away from the margins of the perforation. After 10th post-operative weeks graft uptake was noted and pure tone audiogram was performed. **Results:** - Frequency of tympanosclerosis was seen in 30% of cases of tubo-tympanic disease who were undergoing underlay myringoplasty. Graft uptake was seen in 96.1% cases of study group and in 94.9% cases of control group. In the same way, the graft uptake was noted in 96.36% of cases in whom tympanosclerotic plaques were completely removed compared to 95.23% cases in whom tympanosclerotic plaques were either partially removed or left as such. These differences in graft uptake rates were however statistically not significant. Post-operative average hearing gain in study and control group were 12.1dB & 15.9dB respectively which was also statistically not significant. Difference in post-operative average hearing improvement of 12.1dB & 15.9dB respectively seen in groups in which tympanosclerotic plaques were completely removed or partially, was also statistically not significant. However. Group with tympanosclerosis had more cases with longer duration of inactivity and less number of episodes of discharges as compared to group without tympanosclerosis and the difference was found to be statistically significant. **Conclusion**: - Tympanosclerosis if removed as far as practicable has no effect on either graft uptake or post-operative hearing result in patient undergoing underlay myringoplasty.

Keywords: tympanosclerosis, myringoplasty, tubo-tympanic

INTRODUCTION:

Chronic Suppurative otitis media is one of the commonest ear diseases in many of the developing countries of the world including Nepal. The prevalence of tubo-tympanic type chronic Suppurative otitis media in Nepal is 7.2%. Chronic Suppurative otitis media is defined as the chronic inflammation of the middle ear cleft lasting for more than 3 months duration caused by pus forming microorganisms. Chronic Suppurative otitis media is characterized by intermittent or persistent, chronic purulent drainage through a perforated tympanic membrane. As defined by Shenoi PM "Chronic Suppurative otitis media is a persistent disease, insidious in onset often capable of causing severe destruction of middle ear structure and irreversible sequelae, which is clinically manifested with deafness and discharge of ear for more than three months duration",

Different authors have classified chronic Suppurative otitis media in different ways and have used various terms to denote its different types. Usually chronic Suppurative otitis media is classified into two main groups: tubo-tympanic and attico-antral disease. Chronic Suppurative otitis media (tubo-tympanic disease) is also called a benign form of chronic middle ear infection. Usually patients with this type of disease have no danger of developing intracranial complications. This disease is characterised by a perforation in the pars tensa, with infection usually limited only to the middle ear mucosa. In Nepal it is a common cause of hearing disability.

A study done on deafness by the committee for the International Year of Disabled Person (IYPD) during 1980/1981, mentioned that deafness is the number one disability in Nepal and otitis media in its various forms is the important cause of this disability. Another study was carried out by the Department of Ear, Nose and Throat, TUTH, Community Medicine Department of the IOM, Kathmandu and Britain Nepal Otology Service (BRINOS), England in 1991, on the prevalence of deafness and ear diseases. It was found that prevalence of deafness in Nepal was 16.6% of the general population in age group 5 years and above. Out of 15,845 people examined, 7.2% had tubo-tympanic disease and 0.9% attico-antral disease.

The usual practice of treating chronic Suppurative otitis media tubo- tympanic type is either medical and/or surgical. The commonest surgical treatment is myringoplasty. Myringoplasty refers to a procedure in which the tympanic membrane perforation caused by an episode of trauma or infection is grafted without additional canal or middle ear surgery to prevent recurrent ear discharge and to improve hearing. Provided the ossicular chain is intact and mobile and cochlear reserve is adequate. The success of surgery of myringoplasty is evaluated in terms of graft uptake rate and hearing improvement. Sometimes chronic Suppurative otitis media is associated with a condition called tympanosclerosis which is characterized by hyaline degeneration of the fibrous layer of the tympanic membrane and middle ear mucosa. The incidence of tympanosclerosis in chronic Suppurative otitis media, varies from 3-43%, Tympanosclerosis usually involves the tympanic membrane alone but may involve the middle ear and ossicular chain as well. It is called myringosclerosis when the disease is limited only to the tympanic membrane. Tympanosclerosis is a benign condition and is generally considered to be the inactive end product of recurrent or chronic otitis media.

Tympanosclerotic plaques are common clinical finding and are rarely of significance. Hearing loss is uncommon unless the majority of the tympanic membrane or middle ear cleft is involved.

Myringoplasty is an operation with generally good results. A possible cause of failure of myringoplasty is thought to be the tympanosclerotic plaques in the tympanic membrane remnant.

Tympanosclerotic plaques are situated in the lamina propria, and because blood vessels are also situated in this layer, blood supply may be compromised, which could have a negative influence on epithelial immigration leading to graft failure.

Different literatures show that tympanosclerosis is a common clinical finding in ears with middle ear infection or inflammation particularly chronic Suppurative otitis media tubo-tympanic type. Literature is bountiful with studies as etiopathogenesis of tympanosclerosis and its clinical impact on hearing and on various modalities of management. However, so far we don't have any study to show the frequency of tympanosclerosis in patients with tubo-tympanic disease undergoingmyringoplasty.

In Nepal, there are several studies on graft uptake and post-operative hearing results following myringoplasty in patient with tubo-tympanic disease, But there is no study done so far either at our institution (Bheri Hospital) showing the frequency of tympanosclerosis in patients undergoing underlay myringoplasty or its influence on post- operative myringoplasty results after its complete or partial removal from tympanic membrane.

So this study has been aimed to compare the graft uptake and post- operative hearing starus in patients with tubo-tympanic disease with or without tympanosclerosis undergoing myringoplasty. It is also aimed to compare the graft uptake and post- operative hearing when the tympanosclerotic plaques are completely removed or left as such from the tympanic membrane.

AIM AND OBJECTIVE:

1. To find out the frequency of tympanosclerosis in patientsundergoing underlay myringoplasty.
2. To assess the graft uptake rate and post-operative hearing results of underlay myringoplasty in ears with tympanosclerosis after its complete or partial removal.
3. To assess the graft uptake rate and post-operative hearing results of underlay myringoplasty in control ears without tympanosclerosis.
4. To compare the results of underlay myringoplasty between ears with tympanosclerosis and ears without tympanosclerosis.

MATERIAL AND METHODS:

Place of Study:

Department of Otorhinolaryngology and Head & Neck Surgery,Bheri Hospital

Study Design:

Prospective and longitudinal

Duration of Study:

The study was conducted for a period of 18 months starting from 18October to 14 April 2024.

Inclusion Criteria:

1. Ears with chronic Suppurative otitis media tubo-tympanic (inactive stage) undergoing underlay myringoplasty.
2. Age: > 12 years
3. Sex: Patients of either sex.

Exclusion Criteria:

1. Ears with active tubo-tympanic disease (Middle ears with pus, edema, granulation tissue and glue detected per operatively were considered as active)

2. Patients with chronic Suppurative otitis media tubo-tympanic with pure sensory neural hearing loss (SNHL) were excluded from the study.
3. Revision cases of myringoplasty.

Sampling Method:
The sampling technique used in this study was a non-probability convenient sampling method. All the patients participated in this study had fulfilled the above mentioned criteria.

Pre-operative Workup:
All patients of tubo-tympanic disease with and without tympanosclerosis planned for myringoplasty were evaluated either by residents or consultants. Both ears were examined otoscopically and findings were noted. From all the patients, local as well as permanent addresses were noted for correspondence. At the time of admission, duration of dryness of ear before operation and number of discharges during last one year, for the ear planned for myringoplasty was asked and noted.

Pure Tone Audiometric (PTA) Evaluation:
The pure tone audiogram was done for all patients undergoing myringoplasty one day prior to surgery. Pure tone audiometry done within 7 days of surgery was also accepted. The test was conducted by a qualified senior audiologist in a sound treated room. The test was performed applying Hughson and Westlake method which was done at 5 decibel intensity interval. During procedure stimulus was presented for few seconds to elicit the responses from the subject and yields undapted level of hearing acuity. In a sound treated room, patient was asked to seat comfortably and instructed to respond for the faintest sound and then to press the button detected through earphones.

The test was performed through Air conduction and bone conduction mode. Air conduction threshold was measured with pure tone of 250, 500, 1000, 2000, 4000 and 8000 Hz frequencies whereas bone
conduction threshold was measured with 250. 500, 1000, 2000, 4000 Hz frequencies. Air conduction threshold was calculated taking the average of 500, 1000, 2000 Hz frequencies. Post-operative air conduction threshold was reassessed after 10th week of operation taking the average frequencies of 500, 1000, 2000 Hz.
The instruments used for measuring hearing threshold were wellcalibrated.

Surgical Intervention:
All patients underwent myringoplasty under sedation and local anaesthesia. Operations were done routinely by permeatal approach, but in few cases myringoplasty was also done by post aural and end aural approaches as well. Temporalis muscle fascia graft was harvested in all the cases. Graft was supported using gel foam inside middle ear cavity as well as in external auditory canal. At the end of operation, ear canal was packed with Bismuth Iodide paraffin paste, which was removed on 10th postoperative day. During this period allpatients were kept on oral amoxicillin.
Intraoperatively, tympanic membrane & middle ear was evaluated for tympanosclerotic patches and size and site of the perforation. In myringosclerosis. Quadrants involved were also noted. Middle ear cavity was evaluated and its ossicular chain status and status of the middle ear mucosa was also noted.

Data Collection:
Depending upon the presence or absence of tympanosclerotic plaques, all the patients were divided into two groups i.e. study and control groups. All the patients of chronic Suppurative otitis media with tympanosclerosis were enrolled as study group while amongst those without tympanosclerosis, almost equal number of age matched patients were assigned as control group. All the patients were especially requested to come for follow up at 10th week of operation.

Postoperative Follow up and Outcome Measurement:

a. Graft Uptake and Failure
Postoperative follow up was done specifically at 10th day and 10th week of operation. On 10th postoperative day Bismuth Iodide Paraffin Paste (BIPP) Pack was removed and patients were asked forsome aural precautions. On 10th postoperative week. Status of graft uptake was noted. On doing otoscope examination, it was noted whether the graft was taken up totally (successful graft uptake) or whether there was residual perforation (graft failure). The patients with total rejection of graft, residual perforation or even inflamed graft with pus formation were taken as graft failure.

b. Post-Operative Hearing Outcome
Regarding post-operative hearing evaluation, all patients underwent post-operative pure tone audiogram. It was done at 10th week or laterby senior audiologists. Average air conduction threshold was measured at 500, 1000, 2000 Hz frequencies. Both pre- operative and post-operative audiometric values were compared.
For the purpose of evaluation of post-operative hearing results of the total cases with tympanosclerosis, those with ossicular chain discontinuity and fixation were excluded from the study group.

RESULTS:

The total number of myringoplasty done during 18 months of study period was 194 out of which 187 were the cases of chronic Suppurative otitis media (tubo-tympanic type) without tympanosclerosis and 92 with tympanosclerosis.

Among 187 cases of tubo-tympanic disease without tympanosclerosis, 95 (fulfilling the inclusion criteria) were included in control group among which 78 (82.10%) completed the follow up. Out of 92 cases of tubo-tympanic disease with tympanosclerosis, 81 (fulfilling the inclusion criteria) were included in the study group, among which 76 (93.82%) completed the follow up. Thus, out of 176 patients enrolled in the study. 154 completed the follow up & were analysed, i.e. 76 from study group and 78 from control group.

Average Age Distribution of Study and Control Groups

In the study group maximum number of patients were seen in age group 12-20 years i.e.36 (47.4%), followed by 27 (35.5%) in 21-30 years age groups, 7 (9.2%) in 31-40 years age group and 6 (7.9%) in age group above 40 years. The average age of patients in this group was 24±8.5 years the range being 12 to 45 years.

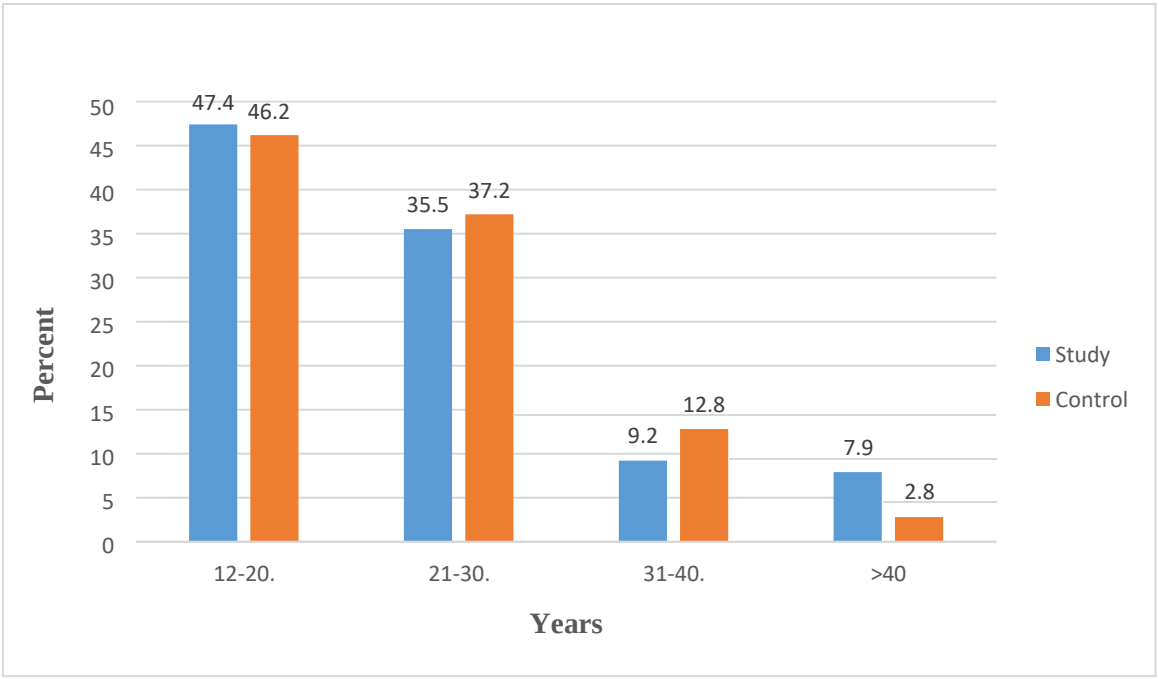
In control group, the maximum number of patients were seen in age group 12-20 i.e. 36 (46.2%) followed by 29 (37.2%) in 21-30 years age groups, 10 (12.8%) 31-40 years age group and 3 (3.8%) in age group above 40 years. The average of patients in this group was 23±8 years the range being 13 to 48 years (Table I, Fig. 1)

Table 1: - Average Age distribution of study group (n = 76) andcontrol groups (n = 78).

Age (Years)	Groups	
	Study (n=76)	Control (n=78)
12-20	36	36
	47.4%	46.2%
21-30	27	29
	35.5%	37.2%
31-40	7	10
	9.2%	12.8%
>40	6	3
	7.9%	2.8%
Total	76	78
	100%	100%
P value		

P= 0.67 (NS)

Figure 1. Average Age distribution of study and control groups.

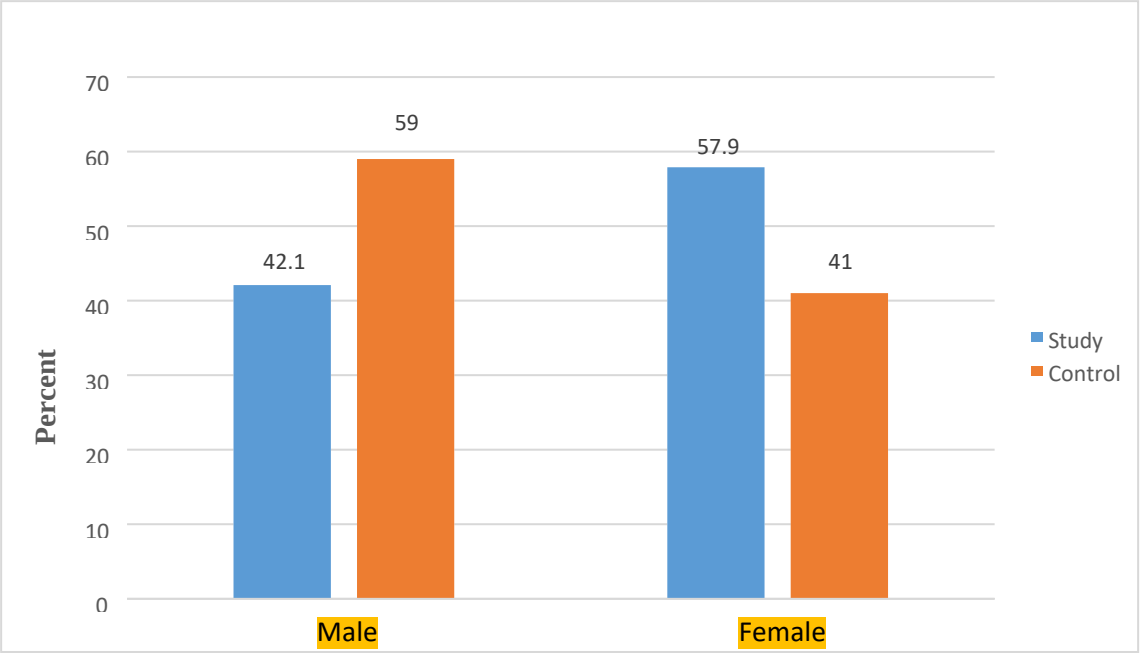


Sex Distribution of Study and Control Groups:
In study group, out of total 76 patients 3 (42.1%) were male and 44 (57.9%) were female with male to female ratio of (0.72:1) showing female preponderance, where as in control group out of 78 patients 46 (59%) were male and 32 (41%) were female with male to female ratio1.4:1 (Table II. fig. 2).

Table II: Sex Distribution in Study and Control Groups.

Sex	Groups	
	Study (n=76)	Control (n=78)
Male	32	46
	42.1%	59%
Female	44	32
	57.9%	41%
Total	76	78
	100%	100%
P value	0.04	

Fig 2: Sex Ditribution in study and control group



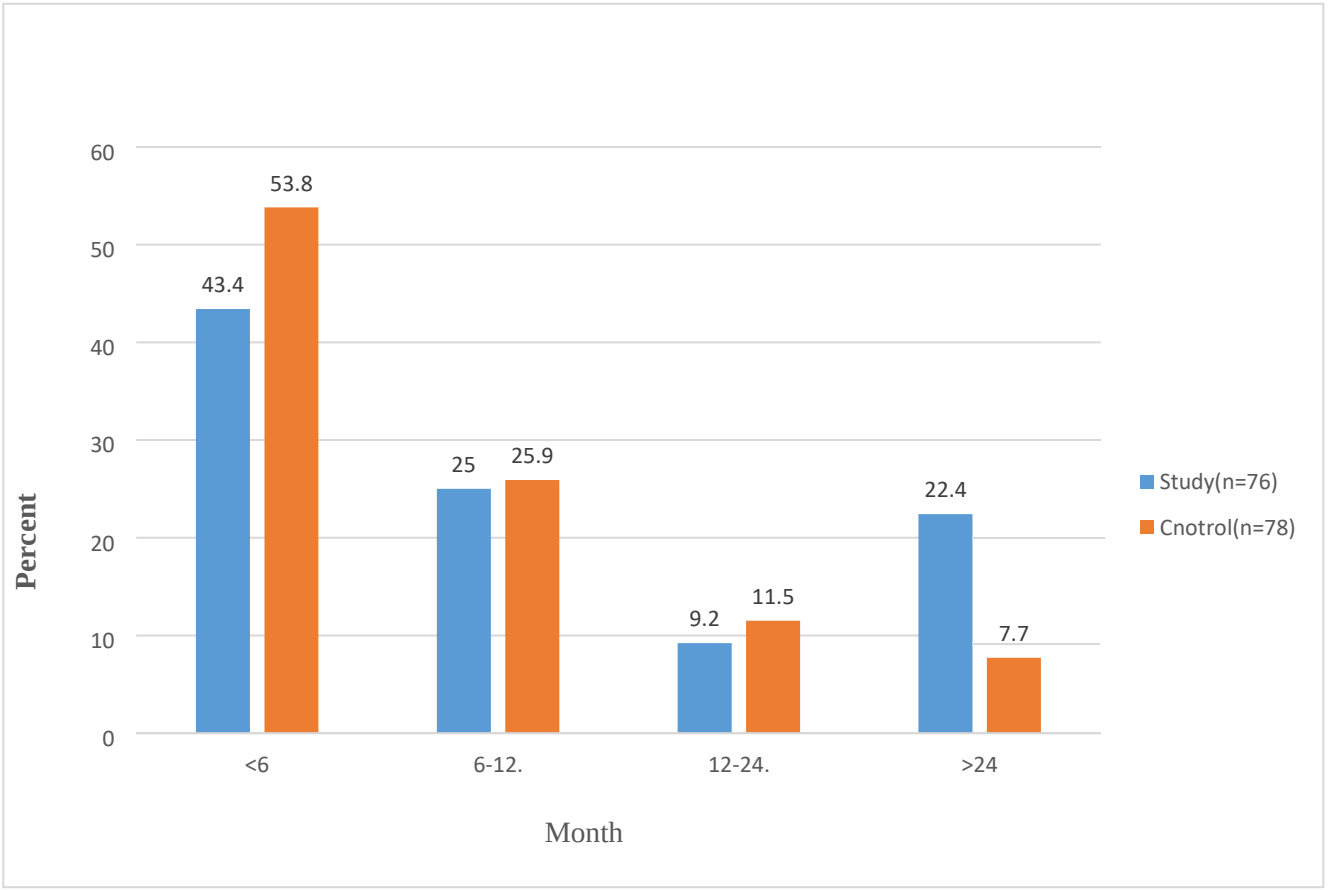
Period of Dryness of Ear before Surgery in Study and ControlGroups:
In study group, the period of dryness of ear before surgery was of lessthan 6 months duration in 33 (43.4%) ears; of 6-12 months duration in 19 (25.0%) ears; of 12-24 months duration in 7 (9.2%) ears; of more than 24 months duration in 17 (22.4%) cars.

In control group the period of dryness of ears before surgery was ofless than 6months duration in 42 (53.8%) ears; of 6-12 months duration in 21 (26.9%) ears; of 12-24 months duration in 9 (11.5%)ears; of more than 24 months duration in 6 (7.7%) ears. The difference in period of dryness of more than 24 months durationseen in 17 (22.4%) ears of study group when compared to 6 (7.7%) ears of control group was found to be statistically significant (p=0.01), (Table III. Fig. 3).

Table III: Period of Dryness of Ear before Surgery in Study andControl Groups.

Period of Dryness(months)	Groups		P value
	Study(n=76)	Control (n=78)	
<6	33	42	**0.20**
	43.4%	53.8%	
6-12	19	21	**0.79**
	25.0%	25.9%	
12-24	7	9	**0.64**
	9.2%	11.5%	
>24	17	6	**0.01**
	22.4%	7.7%	
Total	76	78	**0.08**
	100%	100%	

Fig 3: Period of dryness of ear before surgery in study and control groups



Episodes of Ear Discharge during Last One Year in Study andControl Groups:

In study group. 33 (43.4%) cases had no episodes of any ear discharge; 16 (22.1%) cases had 1-2 episodes of ear discharge; 11 (14.5%) cases had 3-4 episodes & 16 (21.1%) cases had more than 4episodes of ear discharge during last one year period of time.

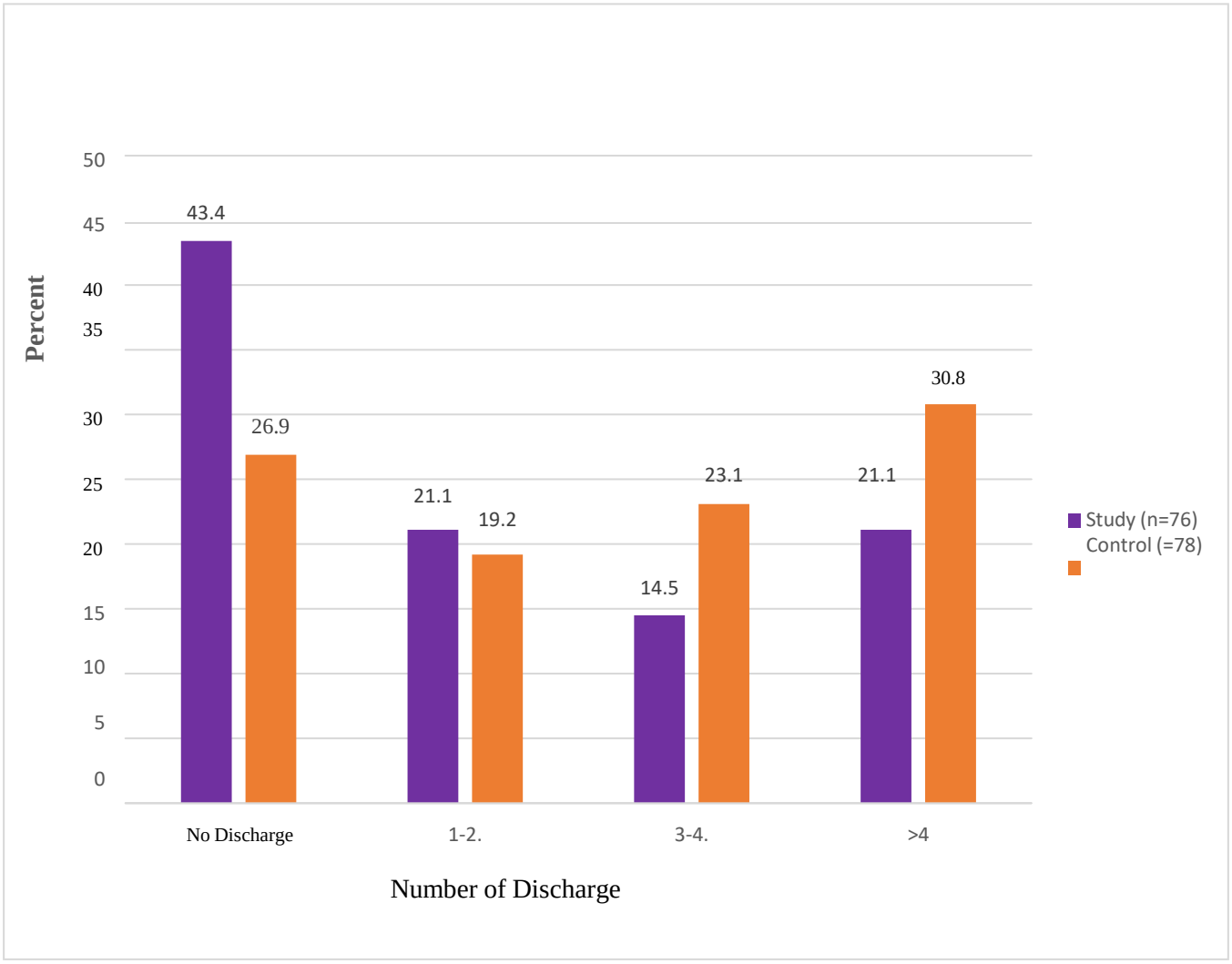
In control group, 21 (26.9%) cases had no episodes of any ear discharge: 15b (19.2%) cases had 1-2 episodes of ear discharge: 18 (23.1%) cases had 3-4 episodes & 24 (30.8%) cases had more than 4 episodes of ear discharge during last one year period of time.

Difference between the two groups was found to be statistically notsignificant with p value 0.11. (Table IV, Fig.4.)

Table IV: Episodes of Ear Discharge during Last One Year in Studyand Control Groups.

Episodes of ear discharge duringlast one year	Groups		P value
	Study(n=76)	Control (n=78)	
No Episodes	33	21	0.11(NS)
	43.4%	26.9%	
1-2	16	15	
	21.1%	19.2%	
3-4	11	16	
	14.5%	23.1%	
>4	16	24	
	21.1%	30.8%	
Total	76	78	
	100%	100%	

Fig 4: Episodes of Ear Discharge during Last One Year in Study and Control Groups.



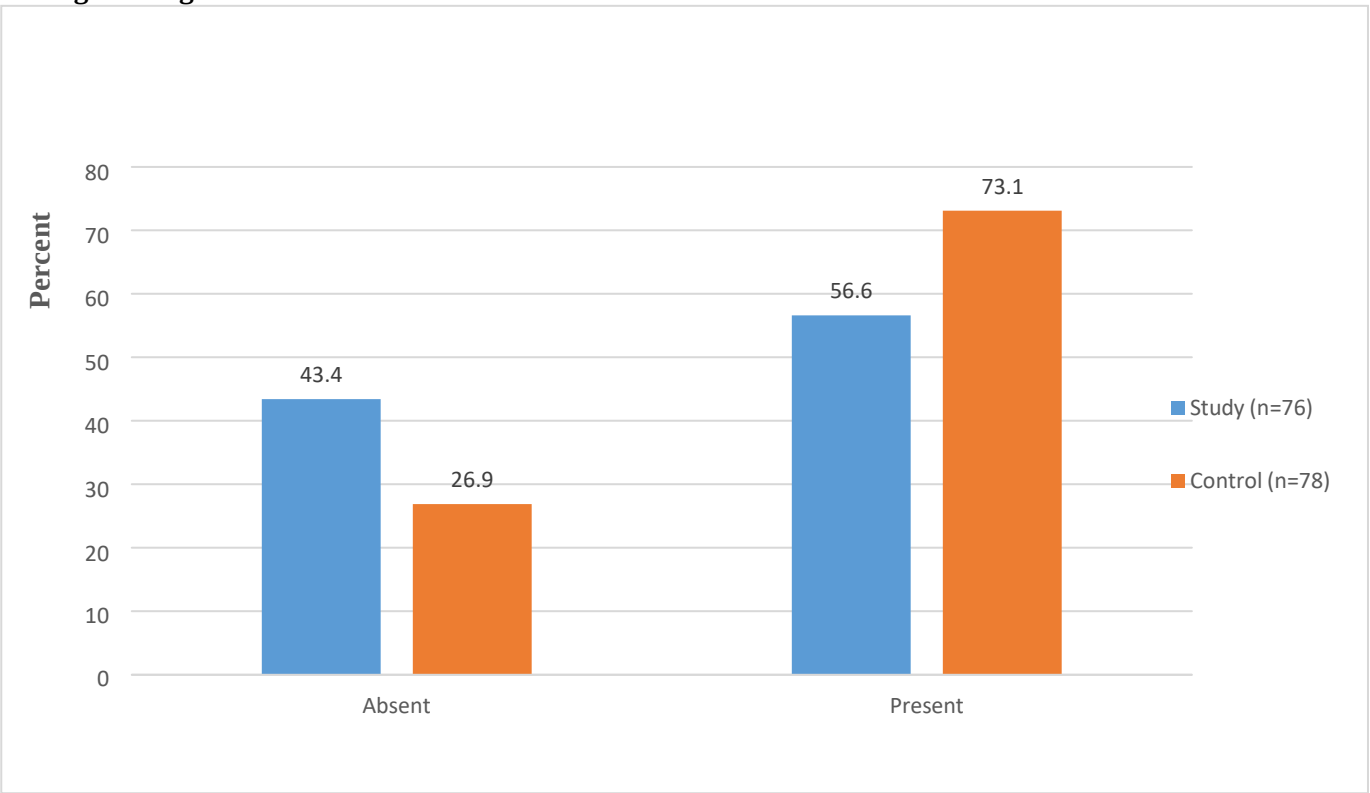
In study group, 33 (43.4%) cases had absence of episodes and 43 (56.6%) cases had presence of episodes of ear discharge in last one year where as in control group 21 (26.9%) cases had absence of episodes & 57 (73.1%) cases had presence of episodes of ear discharge in last one year of period. This observed difference was found to be statistically significant with p value of 0.03. (Table V, Fig.5)

Table V: Comparison between Study and Control Groups in Relation to Presence or Absence of Episodes of Ear Discharge during the Last One Year

Episodes of Ear Discharge during the Last One Year	Groups		P value
	Study (n=76)	Control (n=78)	
Absent	33	21	0.03*
	43.4%	26.9%	
Present	43	57	
	56.6%	73.1	
Total	76	78	
	100%	100%	

***Significant**

Fig 5: Comparison between Study and Control Groups in Relation to Presence or Absence of Episodes of Ear Discharge during the LastOne Year.



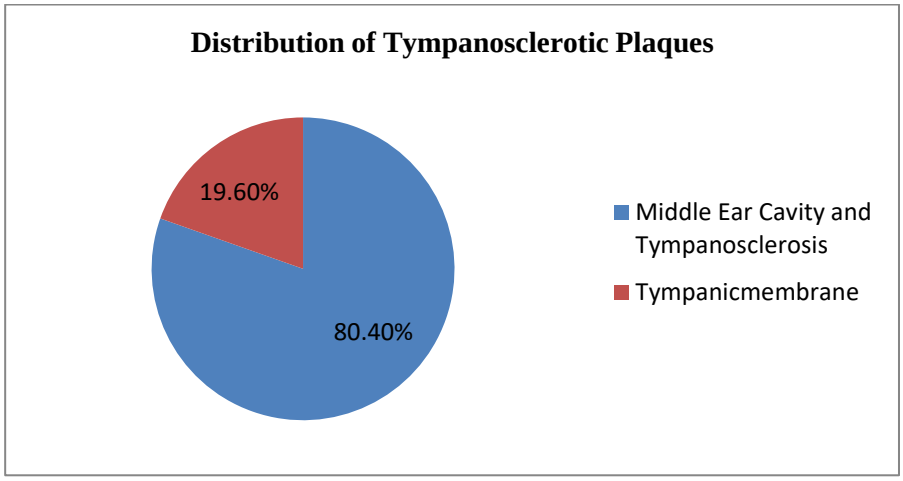
Distribution of Tympanosclerotic Plaques:

74 (80.43%) cases had presence of tympanosclerotic plaques in tympanic membrane only and 18 (19.56%) cases had presence of tympanosclerotic plaques in both tympanic membrane & middle ear.(Table VI, Fig.6)

Table VI: Distribution of Tympanosclerotic Plaques (n=92)

Tympanosclerotic Plaques	Number of Patients	Percent
Tympanic membrane only	74	80.43
Tympanic membrane and MiddleEar Cavity	18	19.56
Total	92	100

Fig 6: Distribution of Tympanosclerotic Plaques

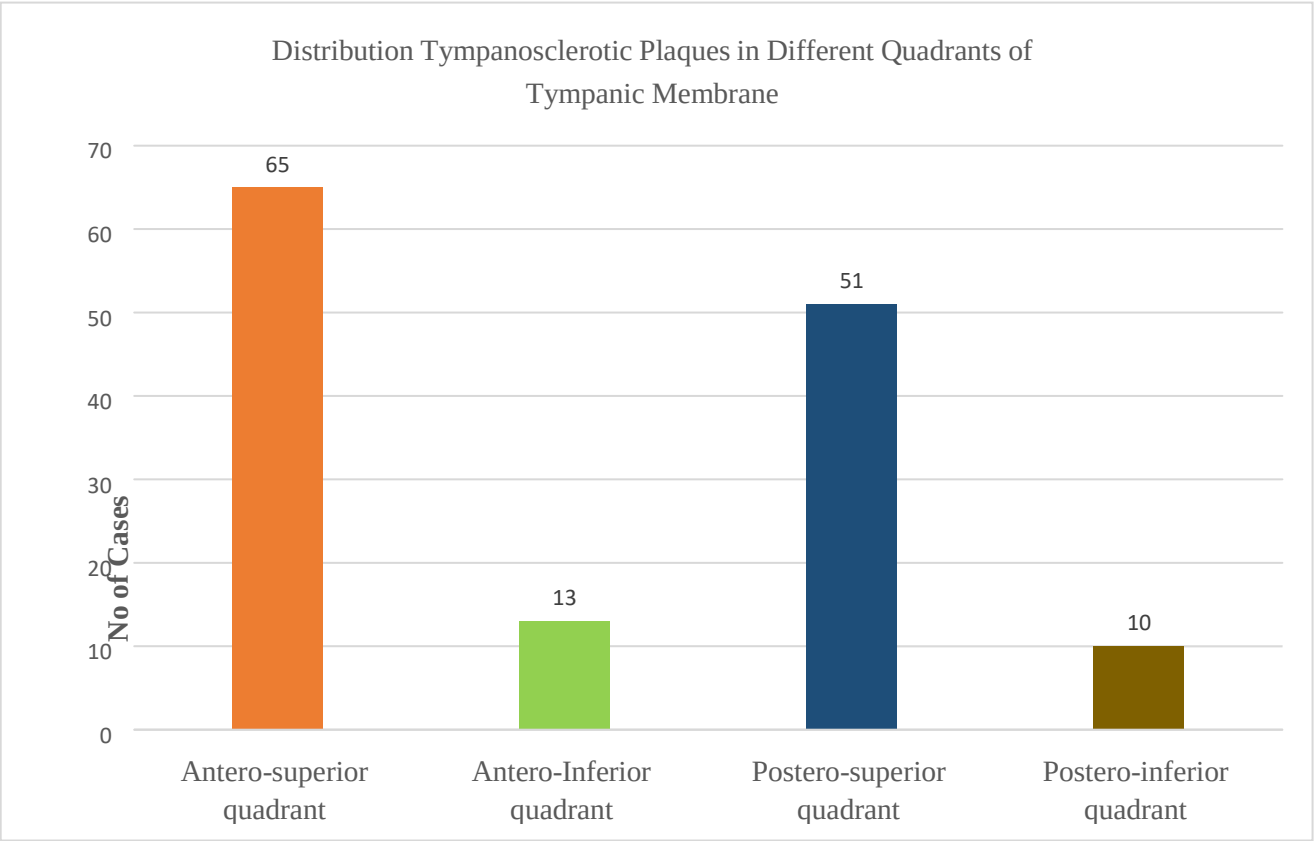


Distribution of Tympanosclerotic Plaques in Different Quadrants ofTympanic membrane:
Regarding the distribution of tympanosclerotic plaques in different quadrants of tympanic membrane, the most commonly involved quadrant was antero-superior quadrant in 65 (70.65%), followed by postero-superior quadrant in 51 (55.43%), antero-inferior quadrant in 13 (14.13%) and postero-inferior quadrant in 10 (10.86%) cases. (Table VII. Fig. 7)

Table VII: Distribution Tympanosclerotic Plaques in DifferentQuadrants of Tympanic Membrane (n=92)

Tympanosclerosis	Number	Percent
Antero-superior quadrant	65	70.65
Antero-Inferior quadrant	13	14.13
Postero-superior quadrant	51	55.43
Postero-inferior quadrant	10	10.86

Fig 7: Distribution Tympanosclerotic Plaques in Different Quadrantsof Tympanic Membrane



Comparison between Study & Control Groups in Relation to Average Pre-operative & Post-operative Air Conduction Threshold:

In study group, the average pre-operative air conduction threshold was 31.0 dB: while average post- operative air conduction threshold at 10 week of operation it was found to be 18.9 dB with a net average hearing gain of 12.1dB. On the other hand, in control group average pre & post-operative air conduction threshold was found to be 34.3 dB &18.4 dB respectively with a net average hearing gain of 15.9 db. The difference between the two groups was statistically not significant. (Table. VIII)

Table VIII. Comparison between Study & Control Group in Relation to Pre- operative & Post-operative Air Conduction Threshold.

Group		Pre-Operative pure tone audiogram (dB)	Post-operative pure tone audiogram (dB)	Net gain (dB)
Study	Mean±SD	31.0±12.9	18.9±15.0	12.1±13.4
Study	Mean±SD	34.3±16.1	18.4±13.4	15.9±13.5
P value from Z test		0.17 (NS)	0.81 (NS)	0.08 (NS)

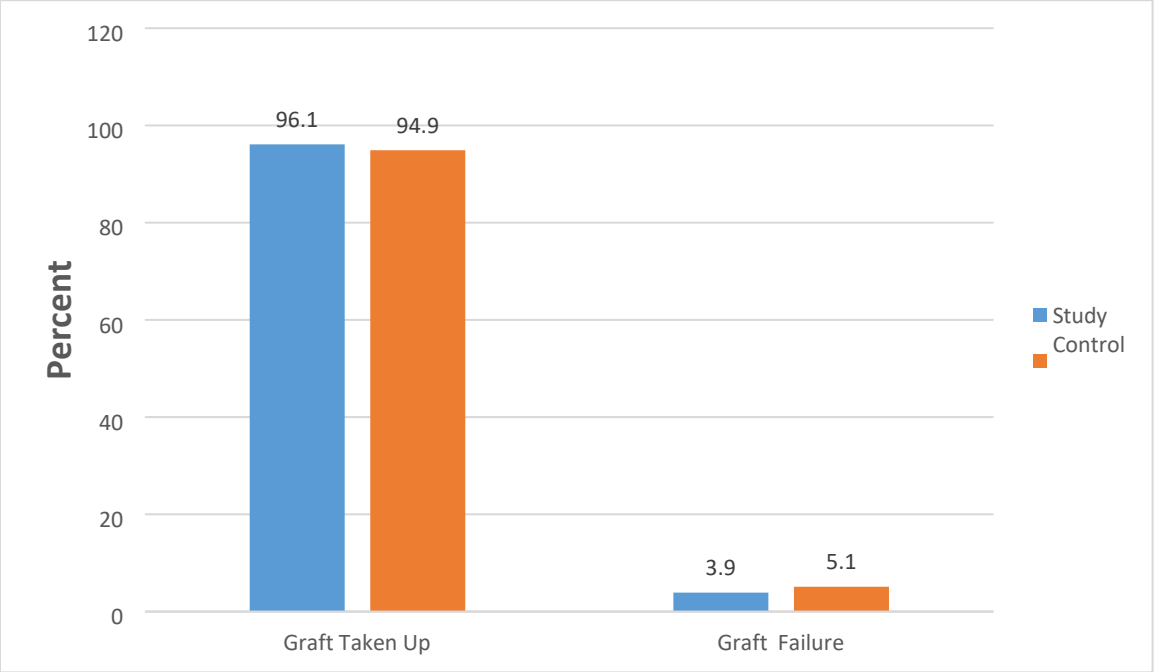
Graft Uptake in Study and Control Groups:

In study group, graft uptake was seen in 73 (96.1%) of patients where as it was seen in 74 (94.9%) of patients under control group. This difference is found to be statistically non-significant with p value 1.0 (Table IX. Fig.8)

Table IX: Graft Uptake in Study and Control Groups.

Graft	Group		P value
	Study	Control	
Taken up	73	74	1.0 (NS)
	96.1%	94.9%	
No Taken up	3	4	
	3.9%	5.1%	
Total	76	78	
	100.0%	100.0%	

Fig 8: Graft uptake in study and control groups



Graft Uptake Rates after Complete and Partial Removal of Tympanosclerotic Plaques:

Among 76 cases of chronic Suppurative otitis media with tympanosclerosis, tympanosclerotic plaques were completely removed in 55 cases; whereas in 21 cases tympanosclerotic plaques were left as such. After 10 weeks of follow up; the graft uptake rate was found in 53 (96.36%) cases in which the tympanosclerotic plaques were completely removed where as it was seen in 20 (95.25%) cases in which tympanosclerotic plaques were either partially removed or were left as such (Table X). This difference was found to be statistically not significant with p value of 1.0

Table X: Graft Uptake Rates after Complete and Partial Removal ofTympanosclerotic Plaques.

Tympanosclerotic plaques	Graft uptake rate	p value
Completely removed(n=55)	53 (96.36%)	**1.0 (NS)**
Partially removed or left assuch(n=21)	20 (95.23%)	

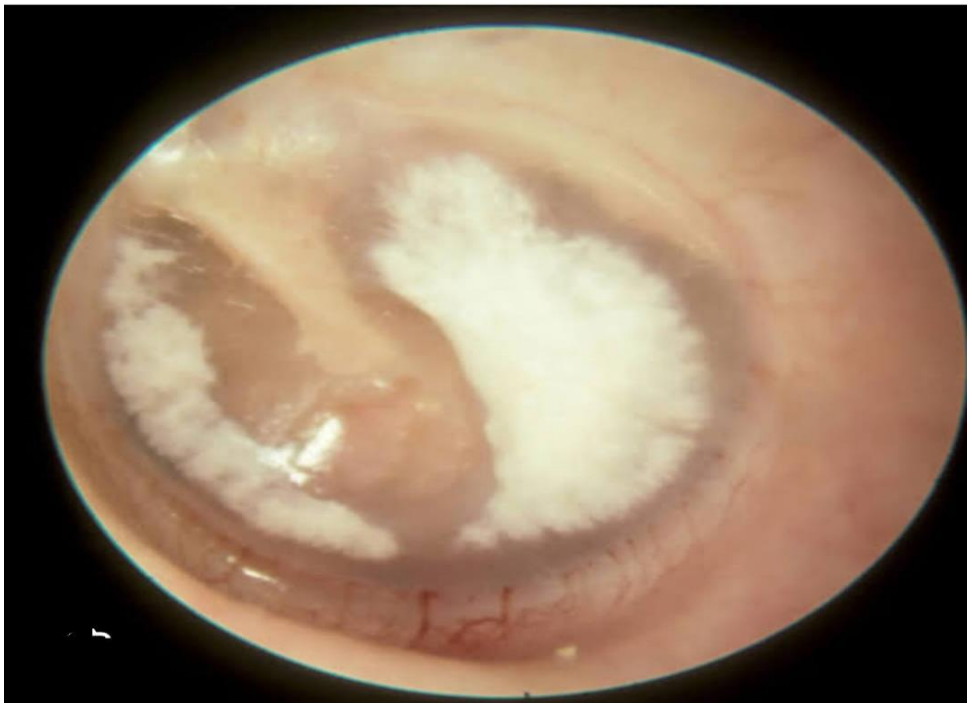
Comparison between Pre-operative & Post-operative Air Conduction Hearing Threshold after Partial or Complete Removal ofTympanosclerotic Plaques:

The average pre-operative & post-operative air conduction threshold in group with complete removal of tympanosclerotic plaques from tympanic membrane was 31.76dB & 19.45dB respectively with net average hearing gain of 12.31dB, whereas the average pre-operative & post-operative air conduction threshold in group in which tympanosclerotic plaques were either partially removed or left as such was 31.19 dB &17.52 dB with a net hearing average gain of 13.67dB.This observed difference was found statistically not to be significant. (Table.XI)

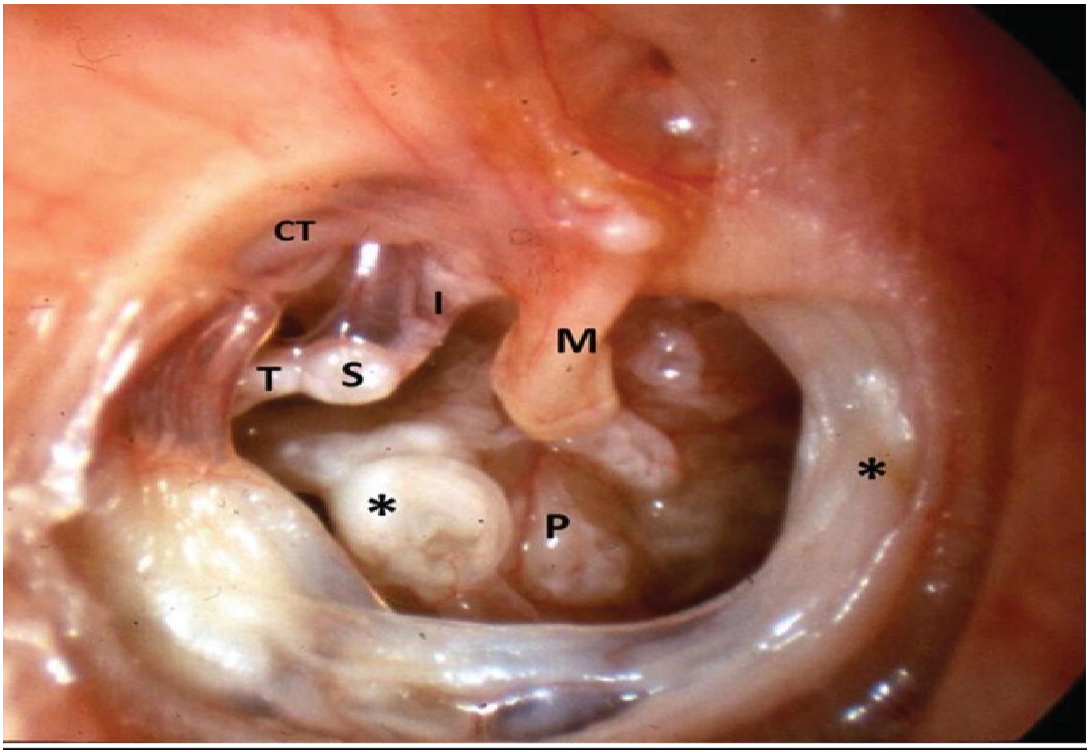
Table XI: Comparison between Pre-operative & Post-operative Air Conduction Hearing Threshold after Partial or Complete Removal ofTympanosclerotic Plaques.

Removal of tympanosclerotic plaques		Pre-operative pure tone audiogram (dB)	Post-operative pure tone audiogram (dB)	Net gain (dB)
Complete	Mean ± SD	31.76 ±11.98	19.45 ±15.52	12.31 ±13.29
Partial or left as such	Mean ± SD	31.19±16.31	17.52 ±13.64	13.67±14.11
p value from Z test		0.87 (NS)	0.62 (NS)	0.83 (NS)

p =0.83(NS)



Tympanosclerosis Involving Tympanic Membrane



Tympanosclerosis involving ossicular chain

CONCLUSION:

1. Frequency of tympanosclerosis was seen in 30% of cases of tubo-tympanic disease undergoing myringoplasty.
2. Ears with tympanosclerosis had a female preponderance with amale female ratio of (0.72:1).
3. Longer period of dryness of ear of more than 24 months was seen in ears with tympanosclerosis as compared to ears without tympanosclerosis. This difference was also statistically significant.
4. Absence of episodes of ear discharges in last one year was found more associated with tympanosclerotic ears compared to ears withouttympanosclerosis. This difference was again statistically significant.
5. Pre-operative and post-operative pure tone average air conduction threshold were similar in ears with tympanosclerosis and without tympanosclerosis.
6. Graft uptake rates after underlay myringoplasty between two groups were also similar and this difference also statistically was notsignificant.
7. Removal of tympanosclerotic plaques partially or completely did not have significant difference in graft uptake rate and postoperativehearing results.

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