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Post-Operative Hearing Assessment in Tympanoplasty and Factors Affecting the Outcome

Manisha Sharma^{1*}, Nilam Sathe¹ and Ninad S. Gaikwad²

¹Department of ENT, Seth G. S. Medical College and KEM Hospital, Mumbai, India

²HBT Medical College and RN Cooper Hospital, Mumbai, India

*Corresponding author

Abstract

Tympanoplasty refers to any operation with/ or without reconstruction of tympanic membrane, with/ or without ossicular chain reconstruction with or without mastoidectomy to eradicate infection and disease so as to make the ear safe, dry and restore hearing. Different materials have been used to construct the tympanic membrane, the most accepted of which is temporalis fascia autograft and almost always the most favorable graft for its immunologically compatibility. Pure tone audiometry is the gold standard to record pre and postoperative hearing assessment and to compare the result postoperatively. This prospective study is focussed on Tympanoplasty and reconstruction of the hearing mechanism analyzing the audiometric pattern of hearing loss in COM pre- operatively, and assessing the outcome of the surgery after 6 weeks postoperatively. Prospective observational study carried out for One year 8 Months from February 2018 to October 2019 in a sample size of 50 patients. Detailed history and clinical examination of all these patients were done. Patients were assessed by pure tone audiometry (PTA) and eustachian tube patency was assessed by eustachian tube function test- Toynbee test. Based on the investigations, the necessary intervention were performed as per the existing standards of care and protocols. Patients were followed up in opd at weekly intervals after surgery. All the data was compiled and used for the study. Results-Variou pre & postoperative parameters like age, sex, otorrhoea, types of tympanoplasty, hearing assessment were compared. The mean pre and post-operative air conduction threshold in the successful cases are 48.96 and 33.62 respectively with a mean audiological improvement of around 15 db. Thus, our findings are consistent with other studies. In our study, differences between Pre and Post mean values of Air Conduction when tested with Paired T test showed P value <0.01 which is highly significant. Type 1 tympanoplasty is a safe and effective technique to achieve intact tympanic membrane and improve hearing in patients of chronic otitis media tubotympanic type. It helps in improving the quality of life of patients. The most common approach is post aural. The graft uptake rate is better at six weeks. Many factors have been investigated to determine their effect on the tympanic membrane closure rate and hearing improvement. Some studies demonstrated that surgical outcome depends on several factors including size and location of the perforation, ossicular status, type of surgical technique, graft type and function of the Eustachian tube. The study had limitation of small sample size, future study with large sample size and prospective in nature will be more useful. Even though many different factors can influence the results of a tympanoplasty operation, according to the statistical results of the study, there is no significant difference in the outcome of the operation, neither in the health of the tympanic membrane after surgery nor in hearing development.

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Introduction

Chronic otitis media (COM) is a long-standing infection of a part or whole of the middle ear cleft characterized by ear discharge and a permanent perforation in tympanic membrane. It manifests as ear discharge and deafness. Chronic otitis media of mucosal variety, inactive is the main indication of Tympanoplasty. Other indications are long standing traumatic perforation and iatrogenic perforation.

Tympanoplasty refers to any operation with/or without reconstruction of tympanic membrane, with/or without ossicular chain reconstruction with or without mastoidectomy to eradicate infection and disease so as to make the ear safe, dry and restore hearing (Adoga et al., 2010).

It was introduced by Berthold in 1878, but it was only in 1956 when Wullstein developed fundamental principles for modern practice. The underlay technique, has become widely recognized as one of the most successful techniques (Acuin, 2007). Hough modified this technique by utilizing temporalis fascia (Okafor, 1984) (Hough, 1970).

Different materials have been used to construct the tympanic membrane, the most accepted of which is temporalis fascia autograft and almost always the most favorable graft for its immunologically compatibility. Since the fundamental principles of tympanoplasty were introduced by Wullstein and Zollner, surgery of the ear has been directed toward the restoration of function as well as providing a stabilized trouble-free ear. There are several major reasons why the complete closure of a chronic tympanic membrane perforation is desirable. With a closed tympanic membrane perforation, patients experience dramatic improvement in hearing, avoid the occurrence of otitis media, and tolerate water in the ear canal. In addition, with complete closure of the defect, recurrent otorrhea is unlikely to occur with upper respiratory tract infections and otitis media (Okafor, 1984; Olusesi *et al.*, 2005-2009)

The most common surgical techniques used are underlay and overlay grafting, with transcanal, end aural and post auricular approaches. The underlay technique is most preferred because, compared with the overlay technique, the graft is placed entirely medial to the remaining drum and malleus while with regard to surgical approach, post-auricular approach is more preferable than transcanal route, because the grafting via ear canal through a

speculum is regarded as more technically difficult (Okafor, 1984).

There are five types of tympanoplasty according to Wullstein.

Type I: With restoration of normal middle ear

Type II: Ossicular chain partially destroyed but preserved and continuity restored. Skin graft laid against the ossicles after removal of the bridge

Type III: Myringostapediopexy producing a shallow middle ear and a columella effect

Type IV: Round window protection with a small middle ear mobile foot plate left exposed.

Type V: Closed middle ear with round window protection; fenestration in the horizontal semicircular canal covered by a skin graft.

The tympanic membrane perforations mainly result from middle ear infections, trauma or iatrogenic causes, and hearing loss from tympanic membrane perforation is usually less than 45 dB and of conductive type. More severe hearing loss is usually associated with ossicular abnormalities (Lasisi *et al.*, 2007)

Pure tone audiometry is the gold standard to record pre and postoperative hearing assessment and to compare the result postoperatively.

This prospective study is focussed on Tympanoplasty and reconstruction of the hearing mechanism analyzing the audiometric pattern of hearing loss in COM pre-operatively, and assessing the outcome of the surgery after 6 weeks postoperatively.

Materials and Methods

Study design

Prospective observational study

Study Period

One year 8 Months

February 2018 to October 2019

Sample Size: 50

Based on our records of the last one year, the number of patients undergoing tympanoplasty was 40. Hence the sample size was kept as maximum of 50 patients over the study period.

Materials and Methods

All patients who presented (from February 2018 to October 2019) to the ENT department with complaints of ear discharge and hearing loss who satisfied the inclusion/exclusion criteria were enrolled in the study after obtaining a valid written informed consent.

Detailed history and clinical examination of all these patients were done and relevant information regarding their presenting complaints and past illnesses were recorded in the case record form (CRF).

Patients presenting with these complaints were assessed by pure tone audiometry (PTA) and eustachian tube patency was assessed by eustachian tube function test-Toynbee test.

Based on the investigations, the necessary intervention were performed as per the existing standards of care and protocols.

Patients paid routine hospital charges for the investigations performed for this study.

Patients were not liable to pay any additional expenses. No incentive were provided to the patients.

Patients were asked to follow up in opd at weekly intervals after surgery. All the data was compiled and used for the study.

Outcome Measures

Hearing assessment with Pure Tone Audiogram (PTA) – preoperative and postoperative.

Subjective improvement in hearing.

Tuning fork tests.

Assessment parameter

The success rate is judged by the standard parameters like the Gain in A–B gap to within 20 dB, Gain in Air Conduction and Gain in hearing more than 15 dB post-operatively.

Surgery is regarded as successful if ear is dry and the tympanic membrane healed and mobile at the end of six weeks follow up.

The data obtained from all the patients was entered into a worksheet.

The findings of the study were analyzed by appropriate statistical tests in consultation with a statistician. Student’s paired ‘T’ tests was used to compare the pre-operative and post-operative results. Microsoft excel for windows was used for data entry and SPSS version 25 for windows was used for statistical analysis.

Results and Discussion

Weber test

It was towards operated side preoperatively in all patients. Postoperatively it was towards operated side in 32 patients, Central in 9 patients and towards non-operated side in 9 patients.

Absolute Bone Conduction (ABC) test

All the patients had normal ABC test since patients with Sensorineural hearing loss were not included in the study.

Change of pressure during swallowing is recorded as step ladder type of graph that is normal. If some residual pressure persists even after five swallows, tubal function considered as partially impaired.

Even though Eustachian tube function was partially impaired, based on middle ear mucosa and ossicular findings two were taken for type I tympanoplasty and one was taken for type II Tympanoplasty

Tympanoplasty is the preferred surgical procedure in surgery for chronic otitis media. 66% of our population was young adult population between 18-30 years. The mean age was 30.38 with std. deviation of 11.83. In a study conducted by Lasisi and Afolabi the majority of patients were aged 21–34 years which was in concurrence with present study. Some studies show age as a prognostic factor and stated that the success of the graft integration in children is slightly lower than in adults and that this is due to the fact that children have persistent dysfunction of the Eustachian tube, recurrent infections of the respiratory tract with otorrhea, and lack of development of the immune system (Faramarzi *et al.*,

2012; Lee *et al.*, 2002). In our study, we selected age criteria as above 18 years, therefore, children were not included in the study. As discussed above, there is no significant hearing improvement as compared to age groups hence indicating age is not a prognostic factor.

CSOM as the major indication for tympanoplasty has also been published in previous studies (Olusesi *et al.*, 2005-2009; Sergi *et al.*, 2011; Faramarzi *et al.*, 2012; Flint *et al.*, 2010; Angeli *et al.*, 2006; Black and Wormald, 1995). Other indications for tympanoplasty have been reported in literature (Lee *et al.*, 2002; Pinar *et al.*, 2008; Kageyama-Escobar *et al.*, 2001).

In our study, males were predominant over females with ratio of 2.1:1 which was consistent with other studies. However, there was no statistically significant correlation between sex and success rate, which was similar in other studies. Emir and *et al.*, showed that being male was a good prognostic factor.

Karela *et al.*, indicated hearing improvement in 91.5% of cases and stated that myringoplasty is a procedure that can be successful in many cases, regardless of age, gender, location, and size of the perforation.

The Right (14): Left (16) ear ratio was 0.78.

Otorrhea was the most common presenting complaint, seen in (97%) of the patients followed by hearing loss with which 78% of the patients presented. This was consistent with the previous studies where otorrhea and hearing loss were most common presenting complaints.

42% of patients had mild conductive hearing loss and 40% had moderate conductive hearing loss which formed the maximum patients.

All underwent type 1 tympanoplasty by underlay technique with temporalis fascia graft and were followed up for at least six weeks postoperatively. In the study we observed the graft take rate of 94%. Study by Mallikarjun S. *et al.*, on audiometric evaluation of type 1 tympanoplasty for hearing results indicated graft uptake of 88%.

Most of the study population had long standing ear discharge for more than 10 years. This suggested chronic nature of disease in majority of the patients.

Although there are controversies concerning the benefit of tympanoplasty in improving the functional hearing results in affected patients (Yung, 1995; Kotecha *et al.*, 1999), published studies reported its benefit based on the subjective and objective improvement on patients' hearing function (Olusesi *et al.*, 2005-2009; Faramarzi *et al.*, 2012; Flint *et al.*, 2010; Angeli *et al.*, 2006; Mane *et al.*, 2013; Raghuwanshi and Asati, 2013; Mohamad *et al.*, 2012). Sergi *et al.*, (2011) reported that tympanoplasty resulted in a 57–97% improvement in patients' hearing function and that myringoplasty can improve hearing independent of the site and size of perforation, and thus concluded that hearing improvement can be used as an indication for myringoplasty.

Mishra *et al.*, reported hearing gain of 10–30 dB in 95% of their cases. Faramarzi *et al.*, (2012) reported that approximately 24% patients that had ABG within 25 dB before intervention; increasing to 71% post-operatively. In our study, 20% patients were within 25db which increased to 84% post-operatively. Demirpehlivan *et al.*, in their study on the comparison of different TM reconstruction techniques in type I tympanoplasty reported improvement in average PTA post-operatively, regardless of the materials used for the reconstruction.

Small CP (40%) followed by moderate CP (38%) was the most common finding on the tympanic membrane. Studies by Indorewala *et al.*, reported that TM perforations were small (<30%), medium/large (30–60%) and subtotal/total (>60%). Our findings were against this study.

Cohn *et al.*, in 1979 assessed ETF by using Impedance audiometry (Toynbee's test). Those with normal ETF a graft uptake of 95percent, 75 percent graft uptake in partially impaired ETF and 69 percent graft uptake totally impaired ETF. Sen *et al.*, in 1998 assessed with normal ETF a graft uptake of 80 percent, 80 percent graft uptake in partially impaired ETF and 66 percent graft uptake in totally impaired ETF. In our study, the overall success rate of graft uptake after 6 weeks was 95 percent in normal ETF and 66 % in partially impaired ETF. In a study done by Mackinnon *et al.*, the success rate was 29% in obstructed Eustachian tube. In a study by Virtanen *et al.*, the success rate was 80 percent in patients who had normal pre-operative tubal function whereas in our study it came out as 95 percent.

Table.1 Age distribution amongst study population

Age groups (in years)	Frequency	Percentage
18-30	33	66
31-45	11	22
45-60	5	10
61 and above	1	2
Total	50	100

Table.2 Showing hearing results vs. age group

Age group(years)	No of patient	Improvement	No Change	P-Value 0.67
18-30	33	18	15	
31-45	11	9	2	
45-60	5	4	1	
>61	1	1	0	

As seen from the table above, there is no significant hearing improvement as compared to age groups.

Table.3 Sex distribution amongst study population

Gender	Frequency	Percentage
Male	34	68
Female	16	32
Total	50	100

Table.4 Showing hearing results vs Gender

Gender	Improvement	No Change	P-Value 0.067
Female	7	9	
Male	25	9	

As seen above, there is no significant improvement in hearing with respect to gender.

Table.5 Involvement of side amongst study population

Side	%
Left	56
Right	44
Total	100

Table.6 Distribution of symptoms

Symptoms	Frequency	Percentage
Otorrhoea	47	94
Hearing loss	39	78
Earache	11	22
Tinnitus	7	14

Table.7 Duration of otorrhoea

Duration	Frequency	Percentage
< 6 months	8	16
7 months -1 year	9	18
2-5 Years	6	12
6-10 Years	6	12
> 10 years	21	42
Total	50	100

Table.8 Showing characteristics of Ear discharge

Character	Frequency	Percentage
Mucopurulent	46	92
Continuous	1	2
Intermittent	45	97
Foul smelling	25	50
Non Foul smelling	21	42
Non-Blood Stained	46	92
Scanty	2	4
Moderate	32	64
Profuse	12	24

As seen in the table, 46 patients (92 %) had mucopurulent discharge, 4 of them never had any history of discharge. Amongst those, 45 patients (97 percent) had intermittent discharge.

Table.9 Showing hearing results vs duration of Dry Ear before Surgery

Duration	Improvement	No Change	P-Value
≥4 weeks	<u>26</u>	<u>8</u>	0.07
≤4 weeks	<u>6</u>	<u>10</u>	

As shown in table above, there is no significant improvement in hearing with respect to duration of dry ear before surgery.

Table.10 Tympanic membrane findings

Operated Ear

TM findings	Frequency	Percentage
Small CP	20	40
Moderate CP	19	38
Large CP	9	18
Dual CP	1	2
Subtotal CP	1	2
Total	50	100

Table.11 Hearing results vs size of perforation

Size Of perforation	Improvement	No Change	P-value
Small CP	8	12	
Moderate CP	14	5	
Large CP	8	1	
Subtotal CP	1	0	

From the above table, it is inferred that there is no significant improvement in hearing with respect to size of perforation.

Table.12 Intraoperative middle ear findings

Status of ossicles

Status of Ossicles	No of Patients
Ossicular Chain Intact	47
Necrosed Handle of malleus	3

Table.13 Pre-op Hearing Grade in operated Ear

Grades of Hearing	No of patients	Percentage
Mild Conductive Hearing loss	21	42
Moderate Conductive Hearing loss	20	40
Moderately severe conductive hearing loss	7	14
Moderately severe mixed hearing loss	1	2
Severe Mixed hearing loss	1	2
Profound mixed hearing loss	1	2
Total	50	100

Table.14 Post-operative hearing grade in Operated Ear

Hearing Grade	No of patients	Percentage
Normal	14	28
Mild Conductive hearing loss	27	54
Moderate conductive hearing loss	4	8
Moderately severe conductive hearing loss	1	2
Mild sensorineural hearing loss	1	2
Moderate mixed hearing loss	1	2
Moderately severe mixed hearing loss	2	4
Total	50	100

Table.15 Hearing Grades in Non-Operated Ear

Hearing Grade	Pre-Operative		Post-Operative	
	No of Patients	Percentage	No of Patients	Percentage
Normal	26	52	26	52
Mild CHL	14	28	14	28
Moderate CHL	6	12	6	12
Moderately severe CHL	1	2	1	2
Moderate MHL	1	2	1	2
Moderately severe MHL	1	2	1	2
Severe to profound MHL	1	2	1	2
Total	50	100	50	100

Paired t test using 95% confidence interval in SPSS showed significant difference in the PTA ACT (Pure Tone Average Air Conduction Threshold), yielding p value of <0.01. Thus significant change in hearing loss was observed postoperatively.

Table.16 Comparison of Preoperative & Postoperative hearing loss

Hearing loss	Mean	Std. Deviation	P Value
Preoperative hearing loss in dB (PTA ACT)	48.96	14.652	<0.01
Postoperative hearing loss in dB (PTA ACT)	33.62	10.660	

Preoperatively 12 percent of patients had air bone gap below 20 dB which increased to 64 % post-operatively. None of the patient had ABG <10dB pre-operatively, and the proportion increased to 4% post-operatively.

Table.17 Comparison of Preoperative & Postoperative Air Bone Gap(ABG)

ABG	Mean	Std Deviation	P value
Pre-operative ABG in dB	34.54	11.187	<0.01
Post-operative ABG in dB	19.58	8.109	

Paired T test using 95% confidence interval in SPSS showed significant difference in the ABG (Air Bone Gap), yielding p value of <0.01 . Thus significant change in hearing loss was observed postoperatively in terms of ABG.

Table.18 Comparison of Preoperative & Postoperative Air Bone Gap(ABG)levels

ABG	Pre-op		Post-op	
	Frequency	%	Frequency	%
<25	10	20	42	84
26-40	27	54	6	12
41-60	13	26	2	4
Total	50	100	50	100

Majority of the patients had ABG of 26-40 dB preoperatively consisting of 54 % which was formed by 12 % of patients postop. 26 % of patients had preoperatively ABG between 41-60 dB which was formed by 4 % of the patients postoperatively. 20 % of pre-op patients had ABG less than 25dB which increased to 84 dB post-operatively.

Table.19 Postoperative ABG closure

ABG change	Interpretation	Frequency	Percentage
>+15 db Change	A	18	36
<15 db Change	B	32	64
Total		50	100

The change in ABG was categorized into 2 groups. ABG closure was calculated subtracting postoperative ABG from preoperative ABG as shown in the table. Change within 15 dB was regarded as Significant improvement in which 36 % of the patients belonged. 64% of patients had improvement but it was less than 15 db.

Table.20 Subjective perception of effect on hearing by patients

Hearing	Frequency	Percentage
No Change	18	36
Improved	32	64
Total	50	100

At 6 weeks postoperatively, 36 % of the patients did not feel there is any change in the hearing status. 64 % said there was improvement in the hearing.

Rinne’s test

Table.21 Operated Ear

	512 Hz	
	Pre-Op	Post-Op
Positive	8	30
Negative	42	20

Table.22 Non-Operated Ear

	512 Hz	
	Pre-Op	Post-Op
Positive	36	36
Negative	14	14

Rinne’s test at 512 Hz showed change in 22 patients from preoperative to postoperative.

Table.23 Closure of Perforation

Closure Of Perforation	No of patients	Percentage
Yes	47	94
No	3	6
Total	50	100

Table.24 Closure of perforation and Eustachian tube function

H/o Ear drops reaching throat	Closure of perforation (%)
No(9 patients)	77
Yes(41 patients)	97

Table.25

Eustachian Tube Function (Toynbee test)	No of patients	%
Normal	47	94
Partially Impaired	3	6
Total	50	100

Amongst patients in whom ETF was normal, 45 patients (95.7 percent) and amongst partially impaired ETF, 2 patients (66 percent) had closure of perforation at 6 weeks follow up.

Table.26

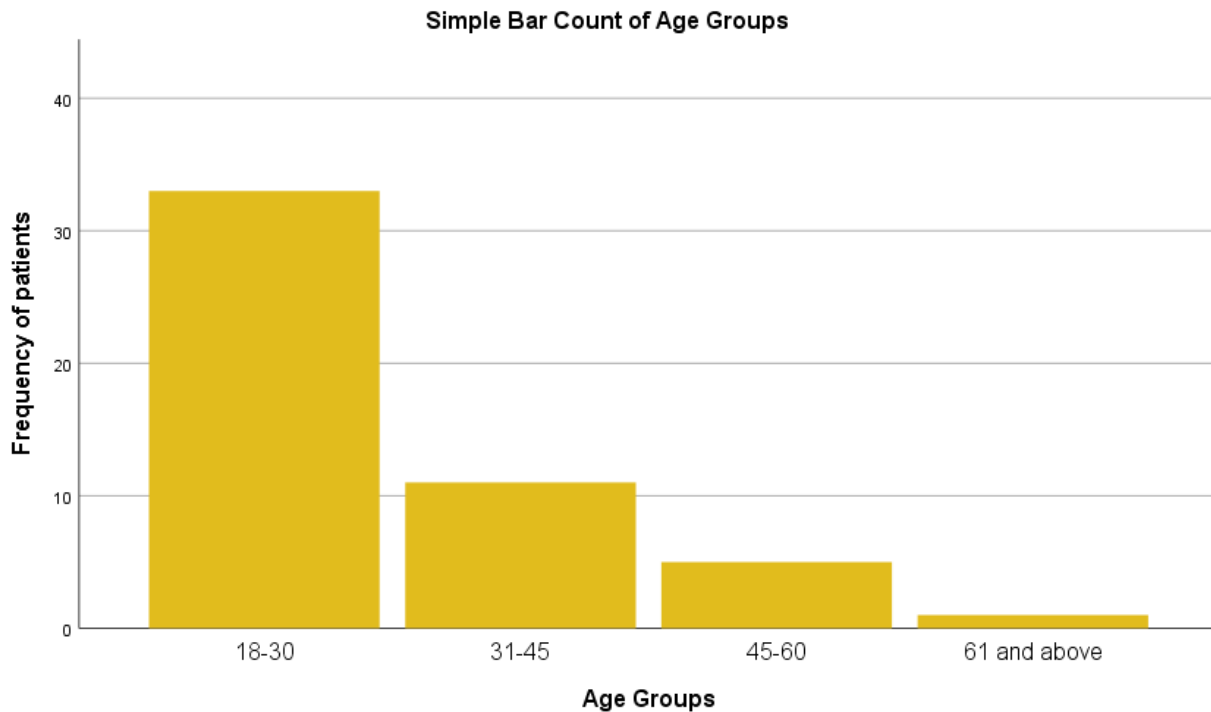
Eustachian tube Function	% of Closure
Normal	95.7
Partially Impaired	66

Table.27

Eustachian tube function	Post- op ABG closure (>15db change) Frequency %		Post-op ABG closure (<15 db change) Frequency %	
	Normal(47)	18	38	29
Partially impaired(3)	0	0	3	100

As seen above, 38 percent of patients amongst normal pre- operative ETF had >15 db change in Air bone Gap as compared to patients with partially impaired ETF in which none have >15 db change.

Fig.1



18 to 30 years (66%) was the most common age group amongst study population followed by 31 to 45 years (22%).

Chart.1

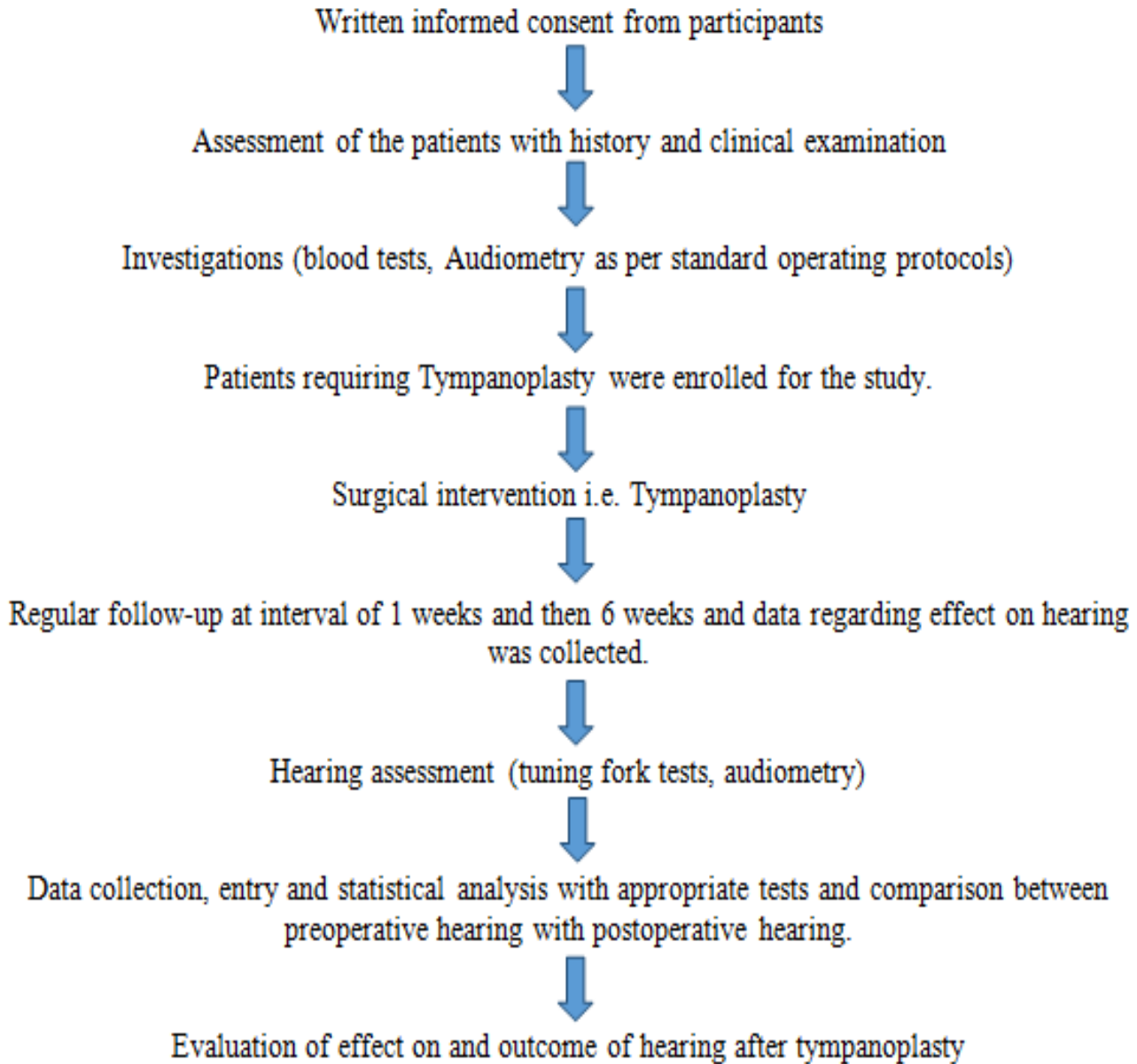
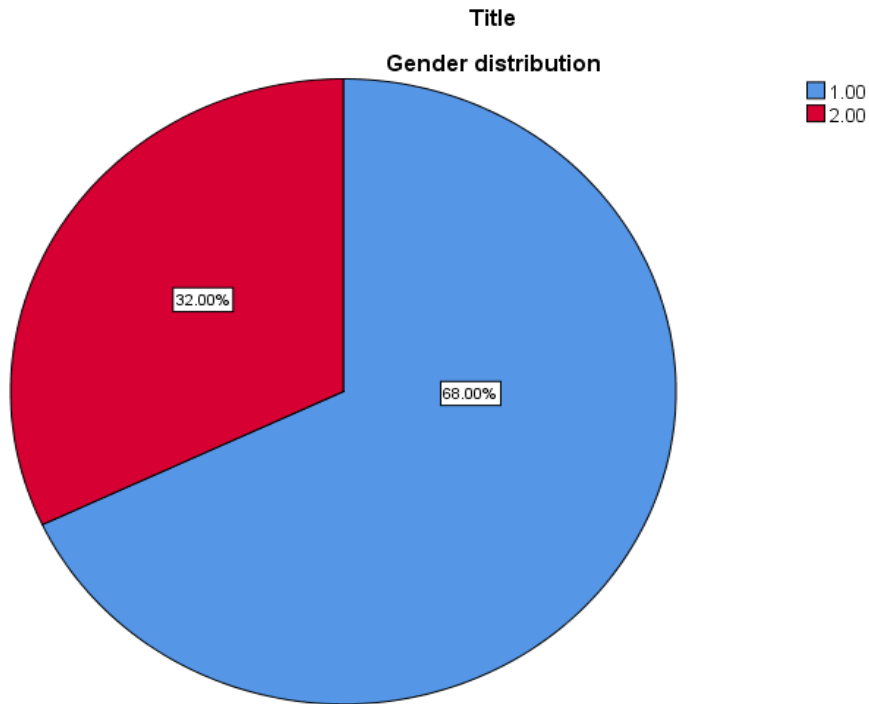
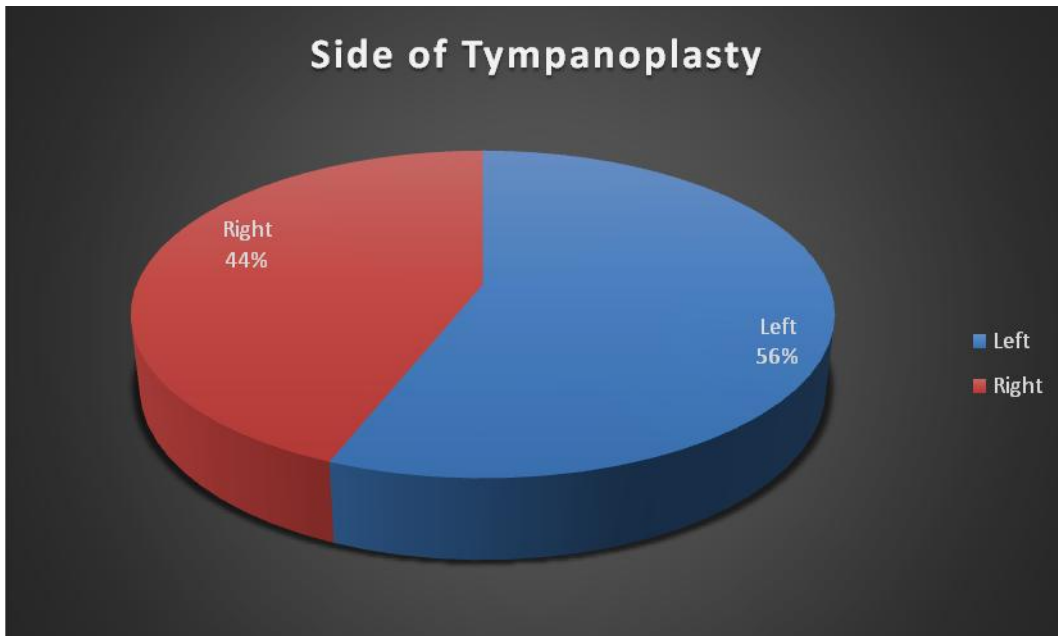


Fig.2



As shown in above chart where 1 is represented by Percentage of males (68 %) and 2 by percentage of females(32 %) with male :female ratio is 2.1:1

Fig.3



As shown above, there was little left side predominance (56%) in our study as compared to right (44 %) with Right : Left ratio of 0.78

Fig.4

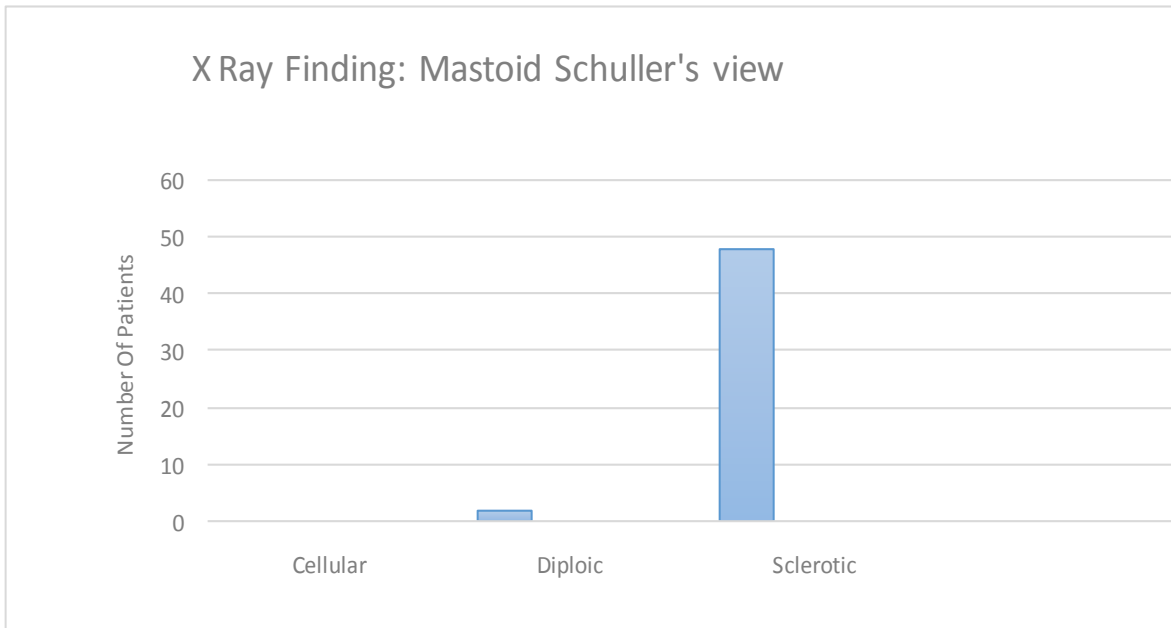


Fig.5

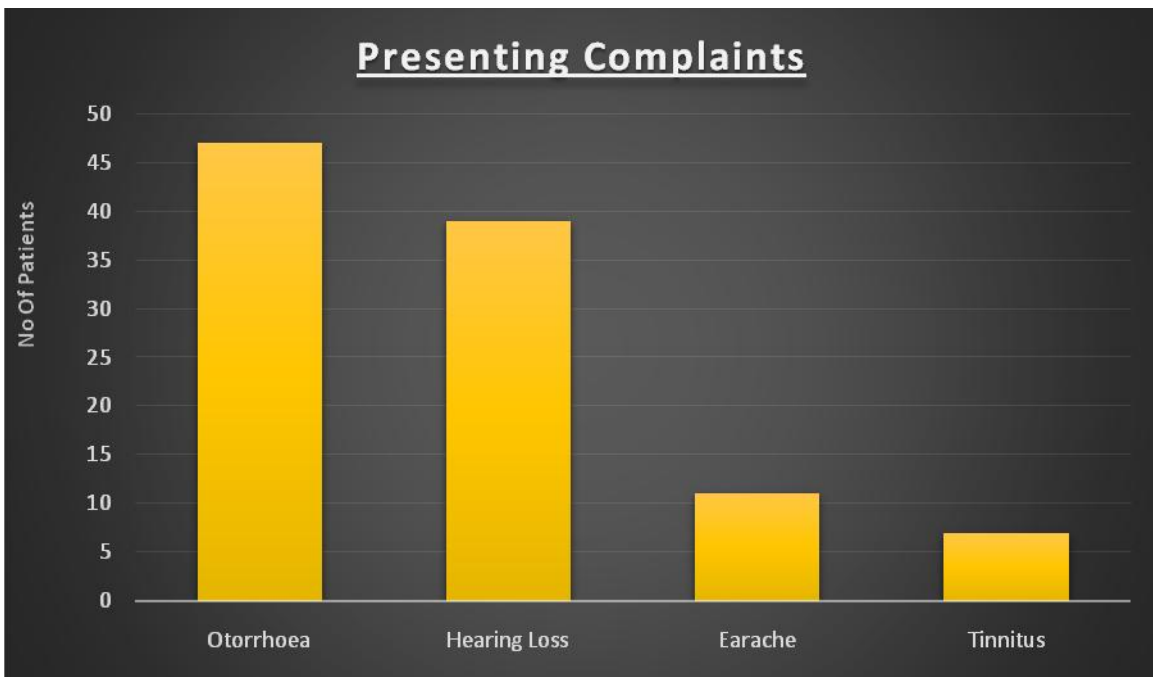
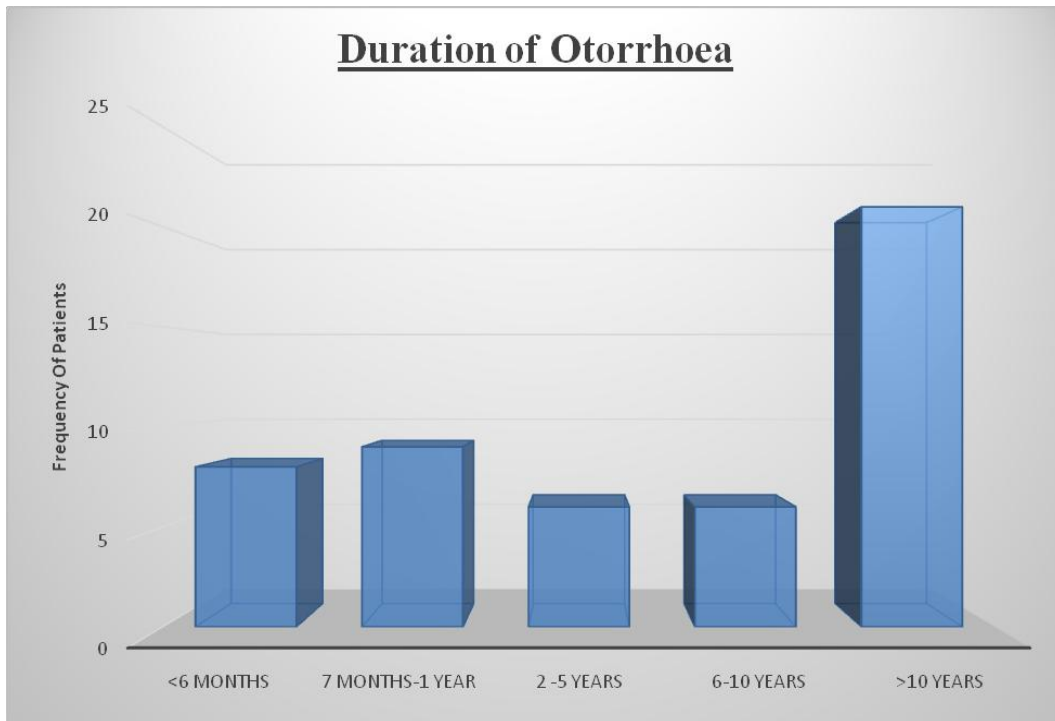
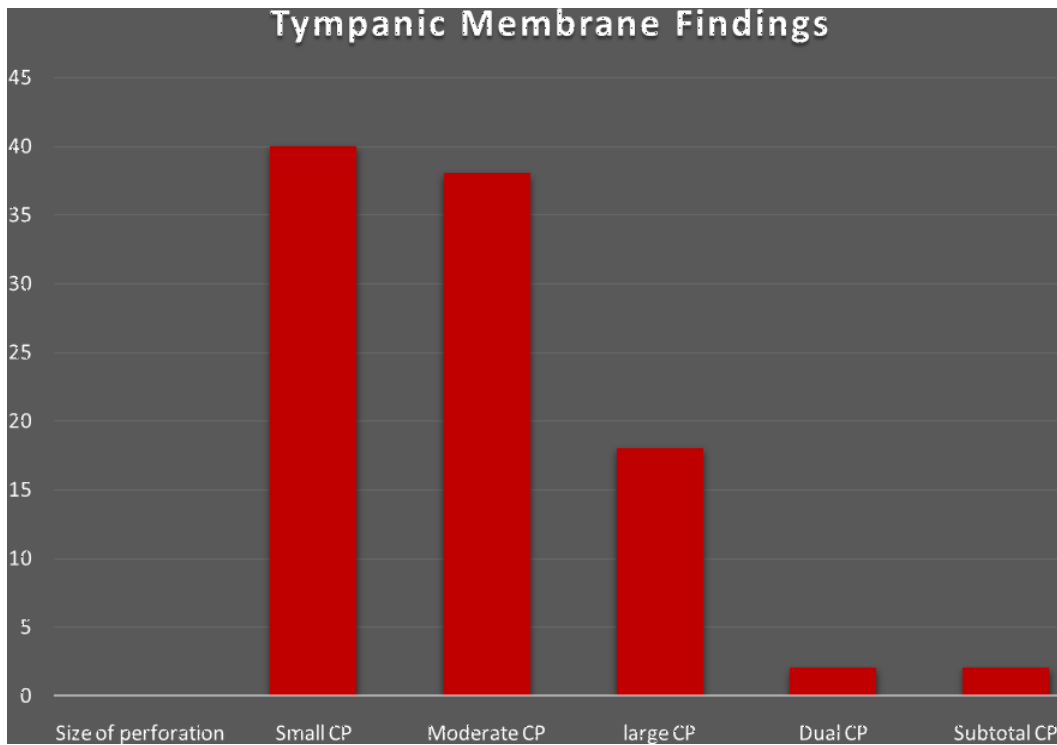


Fig.6



As seen in the table, most of the study population had long standing ear discharge for more than 10 years (42%) followed by those having seven months to one year (18% of patients).

Fig.7



As seen in the table, 40 percent of the patients had small Perforation, followed by 38 percent having moderate Perforation.

Fig.8

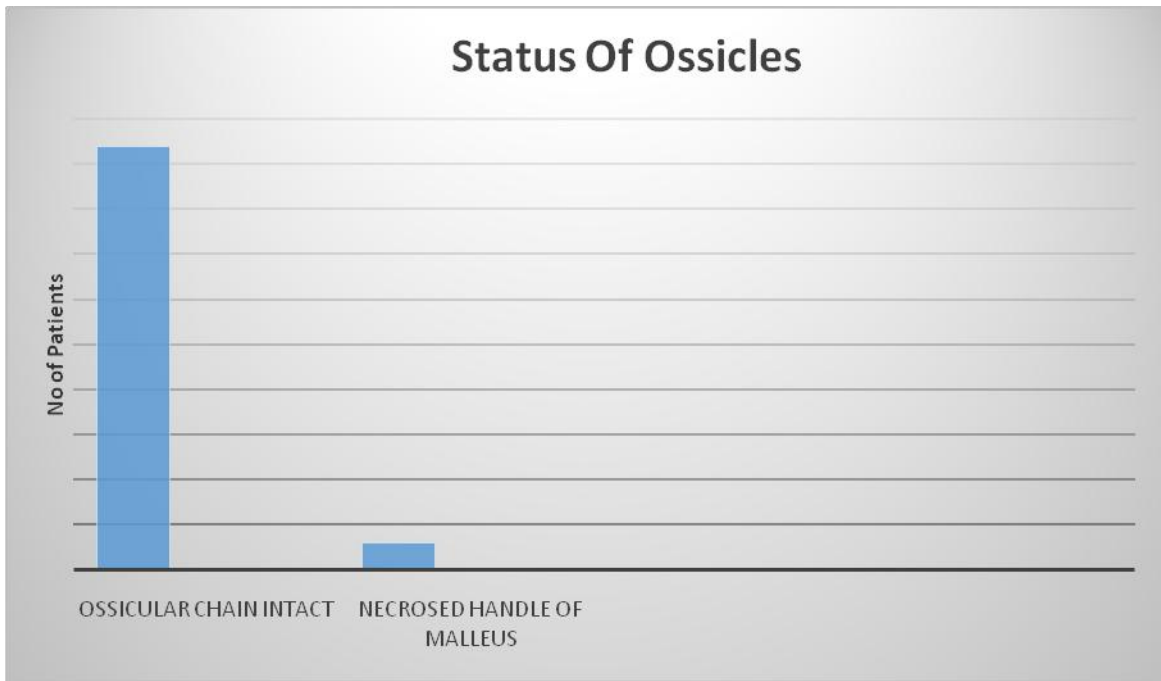


Fig.9 Type of Tympanoplasty

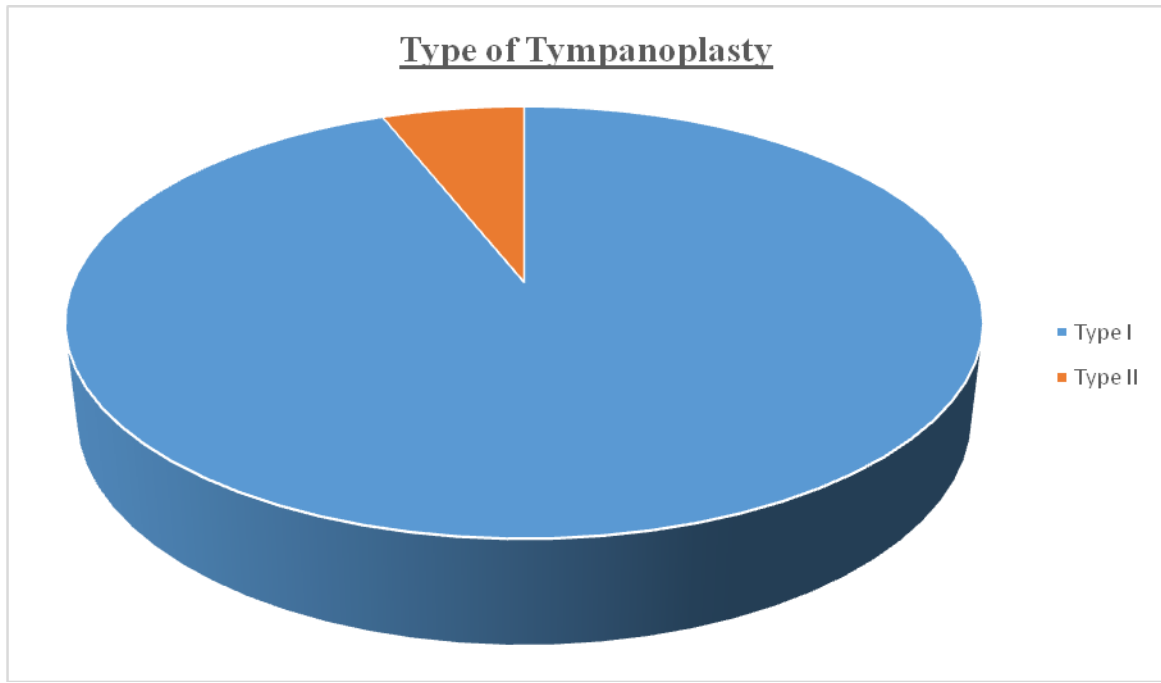
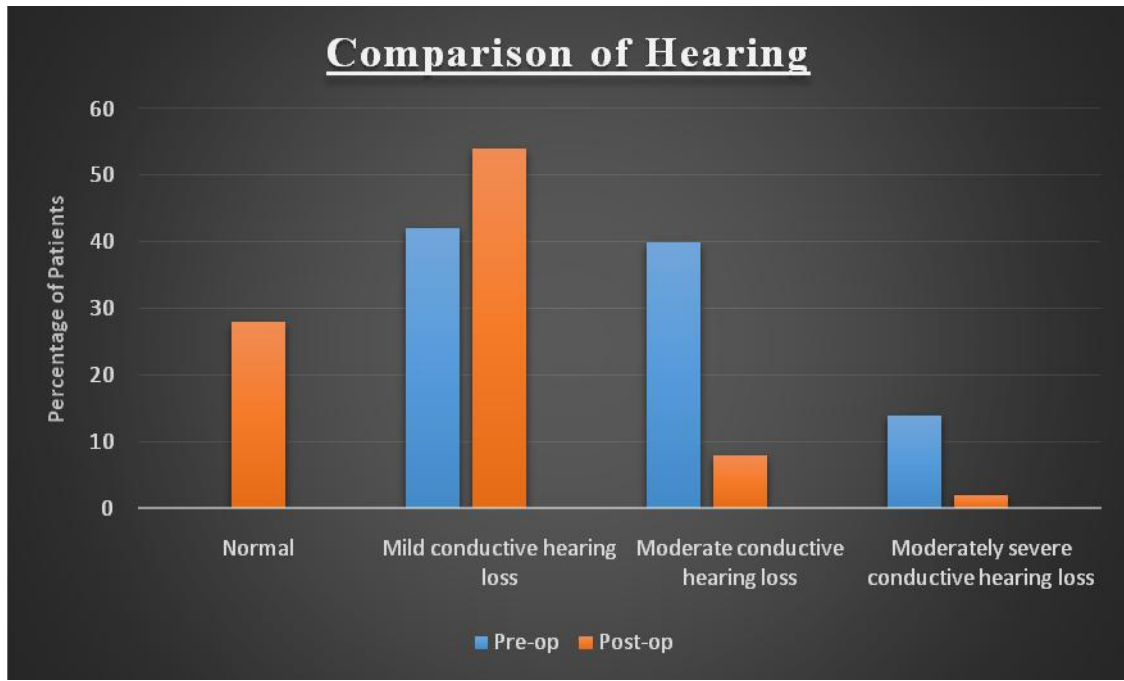
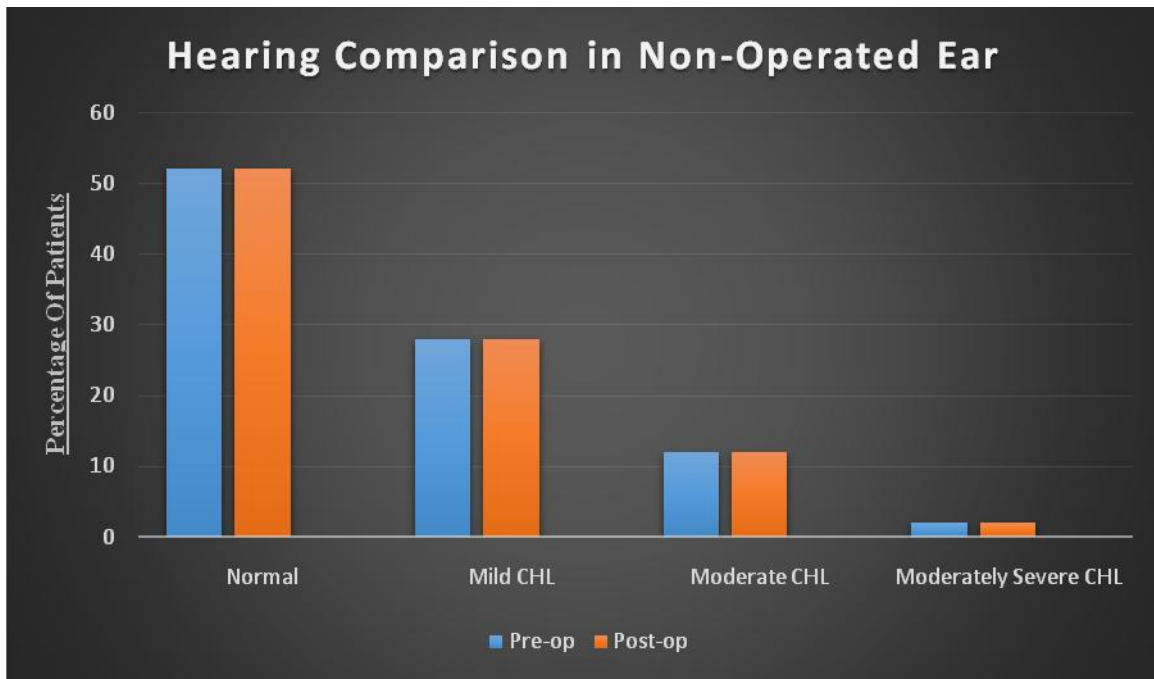


Fig.10



Most of the study population had mild conductive hearing loss (42 %) followed by moderate conductive hearing loss (8%) preoperatively. Postoperative hearing status after 6 weeks was used for comparison. Postoperatively most of them had mild Conductive hearing loss (54%) followed by normal grade (28 %).

Fig.11



In the non-operated ear, 52% had normal hearing, 28 % had mild CHL and 12% had mod CHL. Postoperatively there was no change in the hearing grade pattern.

Fig.12

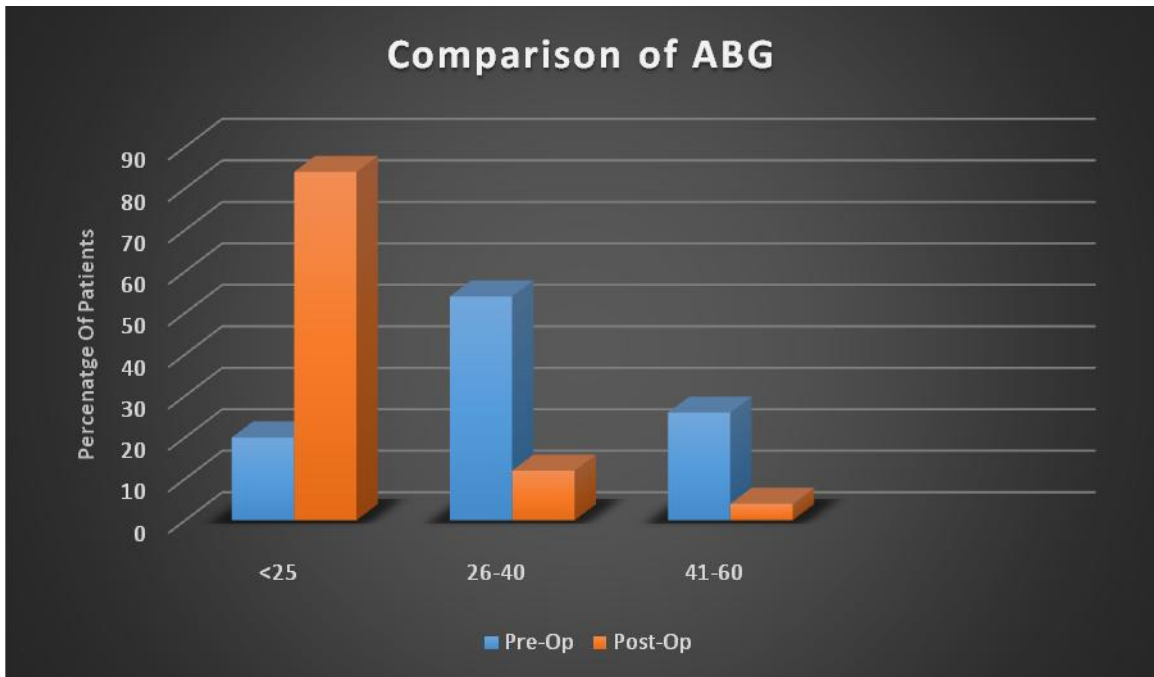


Fig.13

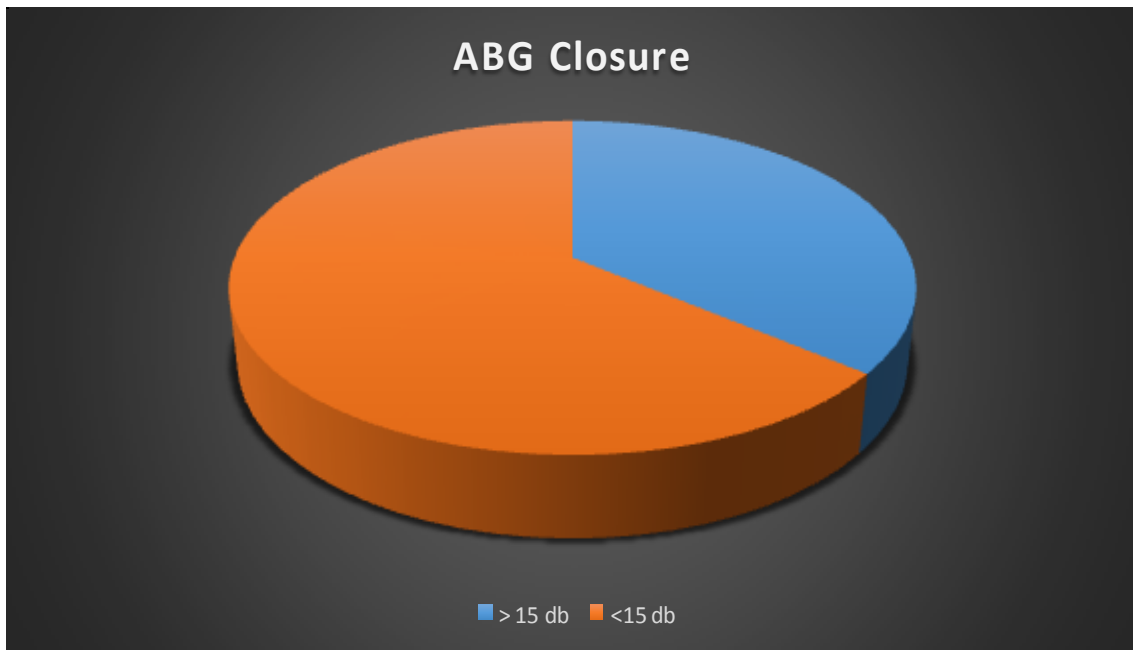
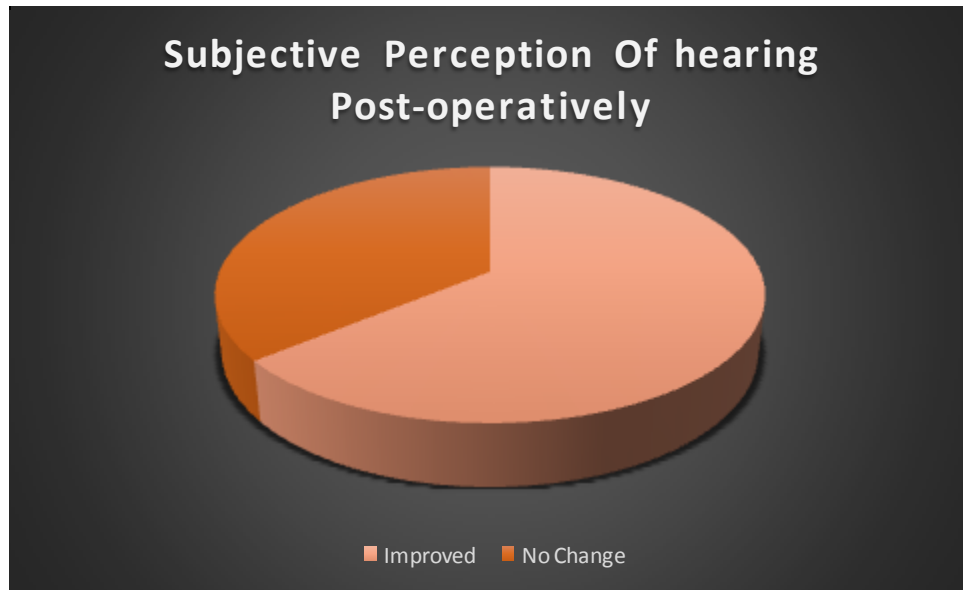
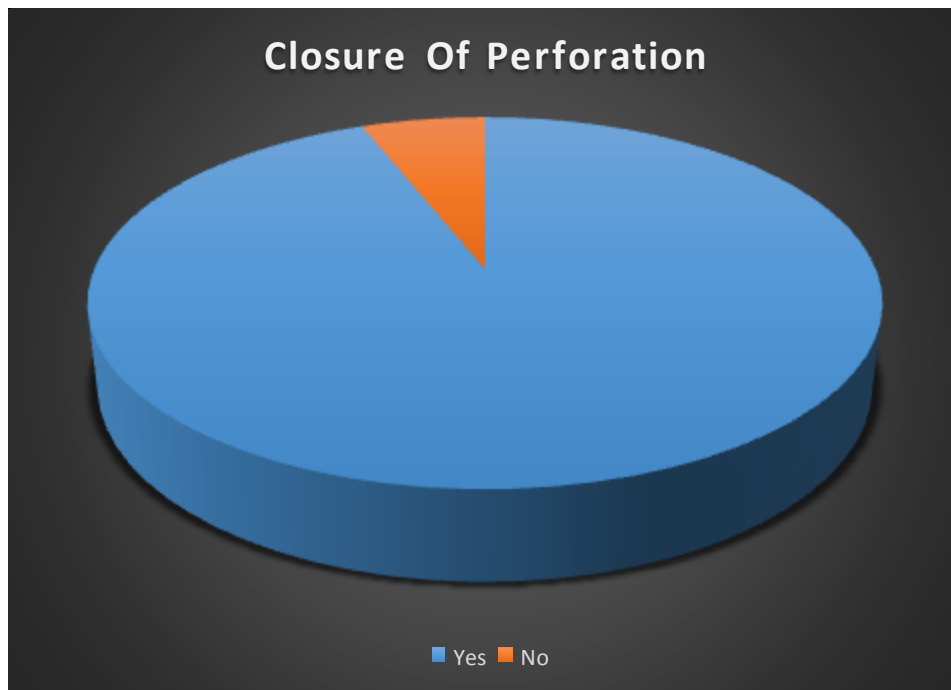


Fig.14



□ Tuning Fork tests

Fig.15



Also, in 38 percent of patients of normal pre-operative tubal function there is an improvement of >15 dB improvement in Air- Bone Gap as compared to pre-op partially impaired tubal function in which none of the patients had >15 dB improvement.

In terms of subjective perception of effect on hearing at 6 weeks postoperatively, 64% of the patients felt improved hearing status. 36% said there was no change in hearing. Hence changes in ABG and ACT postoperatively did not correlate with patients' perception in all the cases. In our

study, 82% of the patients had a gain in hearing function which were consistent with other studies. Indorewala *et al.*, reported 86.6% of the patients had a gain in hearing function. Olusesi *et al.*, (4) and Ogisi *et al.*, in Nigeria reported 88.2% and 77.0% gain respectively in hearing function in type I tympanoplasty without mastoidectomy (Perkins and Bui, 1996).

The mean pre and post-operative air conduction threshold in the successful cases are 48.96 and 33.62 respectively with a mean audiological improvement of around 15 db. Indorewala *et al.*, reported in their study pre-op and post-op with 33.34 dB and 20.20 dB respectively with a mean audiological improvement of around 13 dB. Hamans *et al.*, found a median hearing gain of 10 db. While Lee *et al.*, and Palva and Ramsay stated mean hearing improvement of 8 db in their series. Thus, our findings are consistent with other studies.

In our study, differences between Pre and Post mean values of Air Conduction when tested with Paired T test showed P value <0.01 which is highly significant. Type 1 tympanoplasty is a safe and effective technique to achieve intact tympanic membrane and improve hearing in patients of chronic otitis media tubotympanic type. It helps in improving the quality of life of patients. The most common approach is post aural. The graft uptake rate is better at six weeks. Many factors have been investigated to determine their effect on the tympanic membrane closure rate and hearing improvement.

It is difficult to compare these studies because of differences in age, definition of success, the method used, and the experience of the surgeon. Thus, the factors affecting tympanoplasty must be studied independent of the conditions of each study.

The study had limitation of small sample size, future study with large sample size and prospective in nature will be more useful. Even though many different factors can influence the results of a tympanoplasty operation, according to the statistical results of the study, there is no significant difference in the outcome of the operation, neither in the health of the tympanic membrane after surgery nor in hearing development. However, more studies on more samples in various centers should be conducted in order to make an acceptable conclusion.

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