IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 20, Issue 7 Ser.13 (July. 2021), PP 36-41
www.iosrjournals.org

A prospective study of wet type of tympanoplasty at Narayan Medical College & Hospital . Rohtas

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Abstract:
Introduction : The onset of CSOM is early in life and the condition represents one of the most common infectious diseases during childhood. The prevalence of CSOM in urban school children is 2.32% and in rural children it is about 5.11%. The prevalence of CSOM in adults varies according to the geographical location though its exact prevalence in India is not known
Aim and Objective: To study results of type -1 tympanoplasty in wet ear interms of graft uptake, hearing improvement and recurrence.
Material and Methods: This study is a prospective type of study done at Narayan Medical College and Hospital, Department of ENT during October 2020 to April 2021 on 100 patients of CSOM undergoing wet type-1 tympanoplasty. Patients who were diagnosed with chronic otitis media were invited to take part in the study. This study, done on them was explained in detail to them. An informed consent was obtained.
Results: The mean ± SD pre-op and post-op 3-months AB GAP was 38.63 ± 6.09 dB and 28.75 ± 6.67 dB. Distribution of mean post-op 3-months AB GAP is significantly lower (improved) compared to mean pre-op AB GAP (P- value<0.00). The % improvement in the AB GAP at 3- months from the pre-op stage was 24.82%. The mean ± SD pre-op and post-op 6-months AB GAP was 38.63 ± 6.09 dB and 22.00 ± 7.49 dB. Distribution of mean post-op 6-months AB GAP is significantly lower (improved) compared to mean pre-op AB GAP (P-value<0.00). The % improvement in the AB GAP at 6- months from the pre-op stage was 42.84%.
Conclusions: There is significant improvement in hearing score and rinne test in pre-op and post –op outcome for type 1 tympanoplasty in wet ear in safe (mucosal) type of chronic suppurative otitis media.
Key words: *Tympanoplasty, wet ear, CSOM, AB Gap*

Date of Submission: 09-07-2021 Date of Acceptance: 24-07-2021

I. Introduction

Chronic suppurative otitis media (CSOM) is a common occurrence in children and adults in developing countries. The usual presentation is of recurrent otorrhoea as a result of persistent tympanic membrane (TM) perforation, accompanied by conductive hearing loss, which may vary in severity. The onset of CSOM is early in life and the condition represents one of the most common infectious diseases during childhood. The prevalence of CSOM in urban school children is 2.32% and in rural children it is about 5.11%. The prevalence of CSOM in adults varies according to the geographical location though its exact prevalence in India is not known.(1)

There are five sub types of chronic otitis media

1. Inactive mucosal COM- In this there is permanent perforation of pars tensa but middle ear mucosa is not inflamed.
2. Active mucosal COM- Permanent defect of pars tensa with an inflamed middle ear mucosa which produces mucopus that may discharge.
3. Healed COM-Thinning and/or local or generalised opacification of pars tensa without perforation or retraction.
4. Inactive squamosal COM- Retraction of pars flaccida or pars tensa (usually posteriosuperior) which has potential to become active with retained debris.
5. Active squamosal COM (Cholesteatoma)- Retraction of pars flaccida or pars tensa that has retained squamous epithelial debris and is associated with inflammation and production of pus.(2)

The aim of chronic otitis media treatment is to improve the symptoms of otorrhoea, close the perforation, improve hearing and reduce the number of complications, with the minimum of adverse effects. Tympanoplasty is a common procedure for treating these patients.(3)

The term Tympanoplasty was introduced in 1953 by Wullstein. "Tympanoplasty is a procedure to eradicate disease in the middle ear cleft and to reconstruct hearing mechanism, with or without tympanic membrane grafting"(2). Tympanoplasty can be performed on dry or wet perforations. Dry central perforation means ear should be dry for at least 6 weeks and tympanic membrane remnant should be of normal color with normal middle ear mucosa. Wet perforation means congestion of drum remnant, congestion of middle ear mucosa, presence of mucoid discharge in middle ear, and polypoidal or mucosal hypertrophy of middle ear mucosa.(4)

Usually, surgeons perform tympanoplasty on ears with active discharge after the ear becomes dry, but in many cases this is practically impossible because the discharge from the ear continues despite receiving medical treatment. The discharging ear presents the otologists with the dilemma of operating on it or not. In contrast to the common perception that tympanoplasty result in the patients with wet ear is poorer than those with dry ear, the studies show that there was little difference in the results of the operations performed on two groups.(KULWINDER)

In the present study we had assessed the wet type of tympanoplasty and find out the hearing improvement in these study subjects.

AIM OF THE STUDY

1. To study outcome of type – 1 tympanoplasty in discharging ear.
2. To study results of type -1 tympanoplasty in wet ear interms of graft uptake, hearing improvement and recurrence.

II. Material And Methods

This study is a prospective type of study done at Narayan Medical College and Hospital, Department of ENT during October 2020 to April 2021 on 100 patients of CSOM undergoing wet type-1 tympanoplasty. Patients who were diagnosed with chronic otitis media were invited to take part in the study. This study, done on them was explained in detail to them. An informed consent was obtained.

Patients of COM aged between 10-60 years of age with central perforation and purely conductive hearing loss were selected for this study. Patients with squamous disease or sensorineural hearing loss and those unwilling to participate in the study were excluded. Individuals with pus or smelly discharge were initially treated with a course of antibiotics based on culture sensitivity reports along with topical ear drops and antihistamines. Criteria for wet ear: Congestion in remnant of tympanic membrane; congested middle ear mucosa; presence of mucoid discharge but no frank pus in the middle ear and/or polypoidal change in middle ear mucosa.Institutional ethics clearance was obtained before conducting this study. Written Study proforma consisting of name, age, sex, type of perforation, pre and post-operative hearing status (measured in decibel), graft uptake and re-perforation was constructed. All cases underwent thorough clinical evaluation and those individuals found to be having known factors (deviated nasal septum, chronic sinusitis etc) which influence the outcome of tympanoplasty were initially treated for the same before definitive surgery was undertaken. Examination under microscope was done in all cases to evaluate the status of the ear pre- operatively including the colour of the middle ear mucosa. Each individual was advised a skiagram of the mastoids (lateral oblique view). Pure tone audiometry (using Bracketing method) and impedance audiometry (to assess Eustachian tube function) was performed (by the same audiologist) in a sound proof audiometry booth using the same audiometer both pre and post operatively. Routine preoperative investigations were performed.The surgical procedure was performed by the first author in all of the cases in a single institution. The surgery was carried out under local anesthesia in most of the cases; general anaesthesia being used for those who could not co-operate under local anaesthesia. Endaural or post aural incision was made; margins of perforation were made raw; undersurface of tympanic membrane remnant was scraped to remove any epithelium; tympanosclerotic patch over the remnant of tympanic membrane, if any, was removed; tympanomeatal flap was elevated; any polypoidal or granulation tissue found was removed from the middle ear; type 1 tympanoplasty was performed using temporalis fascia graft by underlay technique. Details of intra operative findings including status of ossicular chain, chorda tympani nerve and any facial nerve injury were recorded. Follow up was done at the end of 1st, 3rd, 6th and 12th month. Graft uptake or rejection at the end of 12 post-operative months along with post-operative audiogram were taken for calculating the results. The data was analyzed using Microsoft Excel software; statistical tests like paired and unpaired T tests were performed using the same software.

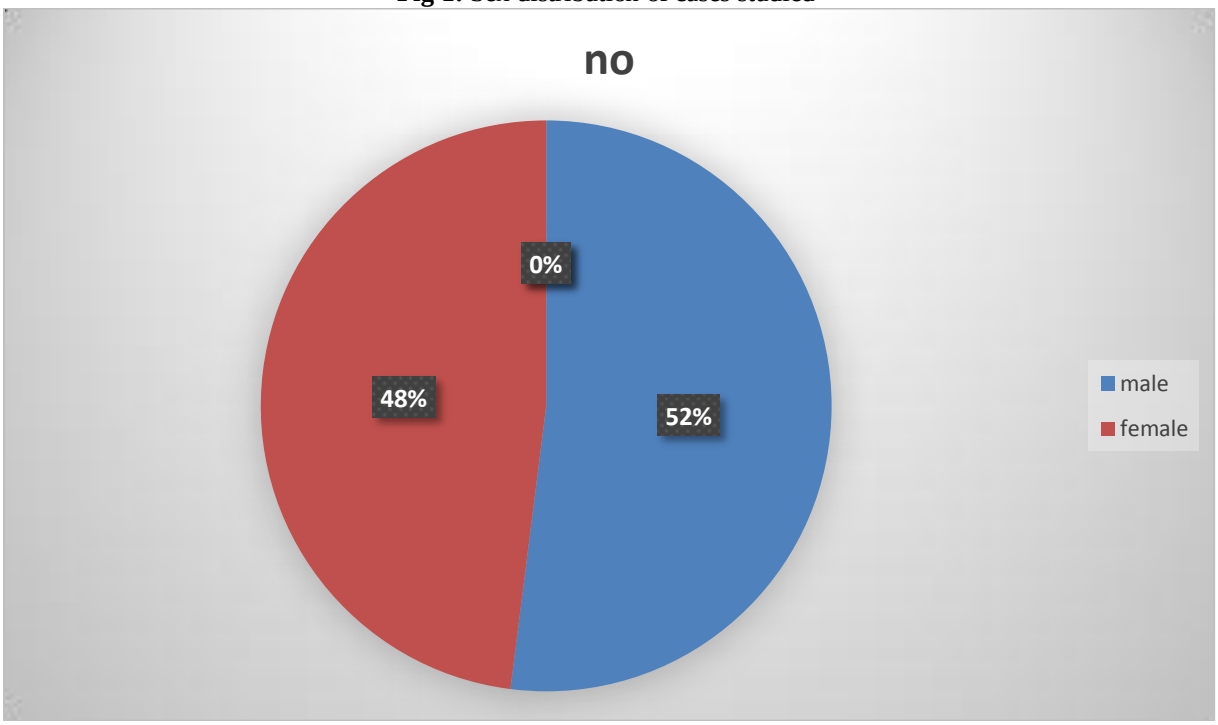
III. Results

Table 1:

Age group (years)	No. Of cases	% of cases
<20	10	10.0
20-29	32	32.0
30-39	30	30.0
40-49	18	18.0
50-59	10	10.0
Total	100	100.0

In the present study of 100 cases studied, 10 (10.0%) had age less than 20 years, 32 (32%) had age between 20 – 29 years, 30 (30.0%) had age between 30 – 39 years, 18 (18%) had age between 40 – 49 years and 10 (10.0%) had age above 50 years. The mean ± SD of age of the entire group of cases studied was 32.8 ± 11.1 years and the minimum age of the study subjects was 16 yrs whereas maximum age was 55 yrs.

Fig 1: Sex distribution of cases studied



Of 100 cases studied, 52 (52%) were males and 48 (48%) were females. In the entire study group, the male to female sex ratio was 1.10: 1.00.shows slight greater no of male than female.

Table 2: Distribution of operative side among the cases studied

Operative side	No. of cases	% of cases
Right	54	**54**
Left	46	**46**
Total	**100**	**100**

In the present study of 100 cases studied, 54 (54%) had right side operated and 46 (46%) had left side operated in the study group. hence there is right side dominance in the tympanoplasty and is greater than left side.

Table 3: Distribution of mean graft harvesting time, graft placement time and total operating time among the cases studied

	Time (Mins)		
	Mean	**SD**	**Min – Max**
Graft harvesting time	4.72	0.90	**4 – 7**
Graft placement time	4.72	1.36	**3 – 8**
Total operating time	**49.28**	**4.58**	**40 – 60**

The mean ± SD of graft harvesting time was 4.72 ± 0.90mins and the min – max time range was 4 – 7 mins. The mean ± SD of graft placement time was 4.72 ±1.36 mins and the min – max time range was 3 – 8 mins. The mean ± SD of total operating time was 49.28 ±4.58 mins and the min – max time range was 40 – 60 mins.

Table 4 : Distribution of mean pre-op and post-op hearingscore (AB GAP) among the cases studied

	AB GAP (dB)	
	Mean	**SD**
Pre-op	38.63	**6.09**
Post-op 3-Months	28.75	**6.67**
Post-op 6-Months	22.00	**7.49**
% Improvement at 3-Months	24.82%	
% Improvement at 6-Months	42.84%	
P-value (Paired data)		
Pre-op v Post-op 3-Months	0.001***	
Pre-op v Post-op 6-Months	0.001***	
P-value by paired t test. P-value<0.05 is considered to bestatistically significant. ***P-value<0.001.		

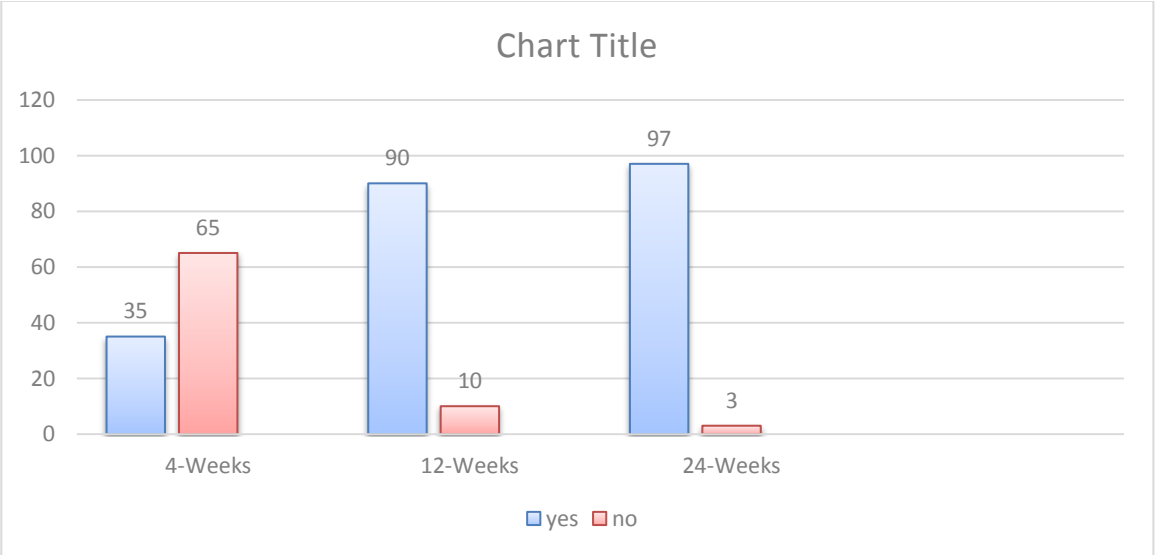
The mean ± SD pre-op and post-op 3-months AB GAP was 38.63 ± 6.09 dB and 28.75 ± 6.67 dB. Distribution of mean post-op 3-months AB GAP is significantly lower (improved) compared to mean pre-op AB GAP (P- value<0.00). The % improvement in the AB GAP at 3-months from the pre-op stage was 24.82%. The mean ± SD pre-op and post-op 6-months AB GAP was 38.63 ± 6.09 dB and 22.00 ± 7.49 dB. Distribution of mean post-op 6-months AB GAP is significantly lower (improved) compared to mean pre-op AB GAP (P-value<0.00). The % improvement in the AB GAP at 6- months from the pre-op stage was 42.84%.when we assess pre-op vs post-op at 3 month then there is significant association with p value- 0.001, at 6 month also there is significant association pre-op and post-op with p value-0.001.

Table 6: Distribution of pre-op and post-op outcome ofRinne's test among the cases studied

	Post-op (Rinne's test)						
	Positive		**Negative**		**Total**		
Pre-op (Rinner'stest)	n	%	n	%	n	%	**P-value**
Positive	1	100.0	0	0.0	1	100.0	**0.736**^{NS}
Negative	35	89.7	4	10.3	39	100.0	
Total	36	90.0	4	10.0	40	100.0	
P-value by Wilcoxon's signed rank test. P-value<0.05 is considered to be statistically significant. NS-Statistically non-significant.							

Of 1 Positive case pre-operatively, 1 (100.0%) had positive post-op Rinne's test and none had negative post-op Rinne's test. Of 39 Negative cases pre-operatively, 35 (89.7%) had positive post op Rinne's test and 4 (10.3%) had negative post-op Rinne's test. The overall Post-op % improvement in Rinne's test was 89.7%. Distribution of Post-op Rinne's test improved significantly compared to Pre-op Rinne's test (P-value<0.001).

Fig 2: Distribution of uptake of graft among the cases studied.



In the present study Of 40 cases studied, 14 (35.0%) had uptake of graft and 26(65.0%) did not have it at 4-weeks.when we assess this also at 12 wks we found Of 40 cases studied, 36 (90.0%) had uptake of graft and4 (10.0%) did not have it at 12-weeks and 24 wks. Of 40 cases studied, majority i.e. 39 (97.5%) had uptake of graft and1 (2.5%) did not have it at 24-weeks.

IV. Discussion

Chronic suppurative otitis media is a disorder in which the mucoperiosteal lining of the middle ear cleft is inflamed. The tubotympanic variety is more prevalent and is defined by perforation of the tympanic membrane's pars tensa. Middle ear infections, trauma, and iatrogenic causes are the most common causes of perforation. The patient has ear drainage and a loss of hearing. It is uncommon for chronic perforations of the tympanic membrane to close spontaneously, necessitating surgical treatment. The surgery's goal is to cure the condition and restore hearing.

One of the most common operations in otorhinolaryngology is type 1 tympanoplasty. The surgeons use cutting-edge microsurgical procedures and equipment. Graft uptake success rates of 90 to 97 percent have been reported. There are a number of elements that influence the success rate of a project, as reported.

In the case of chronic otitis media, tympanoplasty is an operation that eliminates infection and restores middle ear function. This procedure is carried out using surgical techniques and the materials chosen by the surgeon for the tympanic membrane graft. A number of studies have been conducted to determine the impact of various characteristics such as age, sex, perforation size, opposite ear state, ear discharge status at the time of surgery, surgical approaches and procedures, and graft materials. According to these findings, most centres primarily employ the procedures and techniques that their own surgeons favour.

This study mainly focuses on surgical outcome and audiological improvement in the patients undergoing type 1 tympanoplasty using wet temporalis fascia graft. In our study, we used wet temporalis fascia graft i.e. weharvested the graft just before putting it. Although initially itis a little difficult to put wet temporalis fascia graft as it gets rolled. Using an operating microscope, harvesting graft becomes easy and comfortable, as you can take only the temporalis fascia without any muscle or soft tissue. In the present study mean age of the included patients was 32.8 ± 11.1 years and the minimum – maximumage range was 16 – 55 and the male to female sex ratio was 1.10: 1.00. In a study by **Amit Bikram Maiti** et al 2020(1) about comparison between dry and wet tympanoplasty included patients of mean age 28.2 years in the wet group and female to male in the ratio 1:1.5. In study by **Naveen K** et al 2019(8) mean age was 37.96± 8.27years, with a slight female prepondance. In age incidence both the studies are in accordance with our present study but differ in sex prepondance. Thus we can say that age after 25 years is more prone to com. In our study right side operation (52.5%) was more than left side(47.5%). These findings are almost similar to the study of **Naveen K** et al 2019(8) where there was slight predominance for the Right sided disease is noted in 29 patients in comparison with 21 cases of left sided disease. Similar findings by **Naveed Aslam** et al 2001(9) stating right side (59%) predominance than left side(41%).

In the present study of 40 cases studied, 34 (85.0%) had unilateral disease and 6(15.0%) had bilateral disease in the study group. In a study by **Dr. S. SUGANTHI** et al 2018 (5)reported bilateral involvement in 34% cases and 66% cases had unilateral involvement. In the present study the mean ± SD of graft harvesting

time was 4.72 ± 0.90minutes. The mean ± SD of graft placement time was 4.72 ±1.36 minutes. The mean ± SD of total operating time was 49.28 ±4.58 minutes. In a study by **Naveen K** et al 2019 (8)mean graft placement time was recorded to be 9.76 ± 1.58 minutes.

In our present study the mean ± SD pre-op and post-op 3-months AB GAP was 38.63 ± 6.09 dB and 28.75 ± 6.67 dB. The % improvement in the AB GAP at 6-months from the pre-op stage was 42.84%. Almost similar findings in a study by **Naveed Aslam** et al 2001(9) mean pre-op and post-op AB GAP was 30db and 15db respectively and the hearing improvement was recorded to be 74%. Good hearing improvement was also seen in a study by **O. Ben Gamra** et al 2016 (10)where 62% hearing improvement was recorded. In a study **Masoud Naderpour** et al 2016(11) based on air bone gap (measured by PTA), moderate hearing loss in patients with wet ears was 41.5 dB (SD=10.09) before the surgery, but this number reached 16.33 dB (SD=10.90) after the surgery. There was also a statistically significant difference between hearing levels observed before and after the surgery in wet ears (P= 0.001). 92% cases reported a hearing gain of >10db in a study by **Dr. S. SUGANTHI** et al 2018.(5)

In our study we found 35% uptake of graft at 4 weeks, 90% uptake at 12 weeks and 97.5% uptake at 24 weeks. In a study by **Sadarudheen Ahmed Mohammed Islah** et al 2016(12) recorded 63.33% of graft uptake. 95% graft uptake was noticed in a study by **Dr. S. SUGANTHI** et al 2018(5) on 50 wet ears. **Masoud Naderpour et al**(11) in their study assess The perforated membrane had been closed in 88 percent of dry eared patients and 74 percent of wet eared patients after surgery, according to the findings. This distinction, however, was not statistically significant. Patients' hearing status improved significantly in both groups, albeit there was no statistically significant difference between them in this regard.

V. Conclusions

Based on above observations we conclude that there is significant improvement in hearing score and rinne test in pre-op and post –op outcome for type 1 tympanoplasty in wet ear in safe (mucosal) type of chronic suppurative otitis media.

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Dr. Chandrakant diwakar, et. al. "A prospective study of wet type of tympanoplasty at Narayan Medical College & Hospital . Rohtas." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS),* 20(07), 2021, pp. 36-41