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Success rate of tympanoplasty in chronic suppurative otitis media patients: A retrospective study

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Abstract:

Background:

Tympanoplasty is an orthodox surgical therapy for chronic suppurative otitis media (CSOM), an important public health problem characterized by persistent perforation of the tympanic membrane and ear discharge. Its success rate differs across settings markedly, & this study aimed to determine success rate of tympanoplasty in CSOM patients & its prognosticating factors.

Methods: Ninety patients who had undergone tympanoplasty in the year 2019 from a retrospective database were studied. Data was collected using a structured checklist and analysed using SPSS 25. Baseline profiles of participants were computed using descriptive statistics. Paired t-test was used to compare preoperative and postoperative ABG results. Multiple regression analyses of potential factors (intra-& pre-operative characteristics) were used to identify predictors for success of tympanoplasty while the level of significance was set at $p<0.05$. Anatomical success was defined as a complete integration of the graft and functional success as an ABG closure of ≤20dB after 6 months postoperatvely.

Results: The postoperative anatomical & functional success rates for tympanoplasty were 81.1% and 60%, respectively. According to the statistical results of the study, neither the anatomic success nor the functional was found to be prognosticated by the potential factors analyzed.

Conclusion: Tympanoplasty is an effective surgical procedure that can result in improved auditory function in patients and prevents complications satisfactorily irrespective of baseline characteristics. With tympanoplasty, the ear heals and the patient hears.

Keywords: Tympanoplasty; CSOM; success rate; SPHMMC

Introduction:

Chronic suppurative otitis media (CSOM) is a chronic inflammatory condition of the middle ear and mastoid cavity characterized clinically by perforation of the tympanic membrane and persistent ear discharge [1,2]. More particularly in developing countries, it is an important cause of acquired hearing impairment [2], the degree of which is related to the location and size of the tympanic membrane perforation, the status of the ossicles, as well as to the duration of chronic damage [3]. Despite all medical advancements, CSOM still remains a public health problem, predominantly in developing countries such as Ethiopia, where the prevalence of CSOM is estimated to lie between 1 and 6% [2].

While the optimal treatment strategy is selected with respect to the pathology of COM, CSOM is, every so often, managed by doing tympanoplasty, a surgical procedure that entails

grafting of the tympanic membrane with inspection of ossicular chain with/without reconstruction of the middle ear hearing mechanism [4]. The main goals of tympanoplasty are removal of the active disease and reduction of damage due to the complication [5], which are expected to be evidenced by reconstruction of healthier middle-ear cavity, closure of the perforation and optimal restoration of hearing [1,6].

The success rate tympanoplasty (measured both anatomically and functionally) varies noticeably from one study to another [7]. A number of factors such as age, gender, site & size of the perforation, drainage status of the ear at the time of surgery and surgeon's experience had been implicated to be associated with the surgical outcome of tympanoplasty in some countries [8,9,10]. Other studies including Onal et al [11] noted that smoking, pathology in the contralateral ear, size of the tympanic membrane perforation, and duration of the dry period have an effect on the success rates of tympanoplasty [7]. However, although the burden of the disease (for which tympanoplasty is done commonly) is estimated to be considerable in Ethiopia and the palpable fact that surgical procedure success rate differ across settings as a function of multiple proxy factors, there is still lack of research in the country that deals with success rate of the surgical procedure and analyze associated factors of success of tympanoplasty in CSOM patients. Therefore, this study was conducted in an attempt to rectify this paucity of data.

2. Methods and Materials

A retrospective study was conducted to assess the success rate of tympanoplasty in CSOM patients and its predictive factors. The study was conducted at Otorhinolaryngology–Head and Neck Surgery (ORL-HNS) department of SPHMMC, starting from January 1st to December 31st, 2019. Ethical clearance was secured from Institutional Review Board of the college. Moreover, in conditions where patients were needed for physical evaluation, all the WHO-approved precautionary measures were exercised to minimize the transmission of the COVID-19 pandemic. Inclusion criteria for this study were: 1) All patients who underwent tympanoplasty for the indication of CSOM in the specified period regardless of their age; 2) All patients who underwent tympanoplasty and had complete medical record. And exclusion from the study consisted of: 1) patients with traumatic tympanic membrane perforation; 2) patients with significant congenital anomaly of the ear; 3) patients with pre-operative sensorineural hearing loss; & 4) patients who did not come for follow-up audiological and otomicroscopic evaluation. A total of 90 patients were eligible as per the inclusion and exclusion criteria and hence were included in the study. Data were collected using a structured questionnaire. Data were entered, cleaned, coded and analyzed by using SPSS for Windows version 20.0 (IBM, USA). The data were cleaned by using sort cases tool and whenever missing and/or unexpected values were identified, that value was checked in the filled hardcopy data collection questionnaire to correct data entry mistakes. The socio-demographic & clinical characteristics of participants were computed using simple descriptive statistics (mean, percentage, frequencies, and standard deviation) whereas relationships between dependent and the selected independent variables were analyzed using multiple logistic regression wherein variable that showed p value of <0.25 in binary regression were taken to multiple regression. P-value of <0.05 and 95% confidence level were considered statistically significant.

Surgical procedures:

All surgeries were performed under local anesthesia and sedation. Most of the surgeries were performed by residents under close supervision by faculty surgeons. However, difficult cases and pediatric ones were conducted by the senior surgeons. The surgical approach employed was either transcanal, postaural, or endaural, with endaural being the most common approach. In all the studied cases, graft was taken from incision site and was dried using a hair dryer before grafting. The graft was inserted using underlay technique and supported on both sides with Gelfoam. Postoperatively, a head bandage was applied for 24 hours. Although administration of prophylacticantibiotics is not a norm in the setting, ciprofloxacin ear drop was applied postoperatively for a week on operated ear after the bandage had been removed, and patients were instructed to keep their ears dry.

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Patients were followed-up one week after surgery for stitch removal and surgical site infection. Then after, patients were seen successively by the end of 1st month, 3rd month, & 6th month for otomicroscopic and audiologic assessment. PTA was assessed using average measures of 500, 1000, 2000 and 4000 Hz.

3. Results

3.1 Baseline characteristics of studied subjects

This study included data derived from 90 chronic CSOM patients who had undergone tympanoplasty, two-third of whom (65.6%) were females and the remaining (34.4%) were males. Patients' age ranged from 9 to 52 years, with an average age of 24.3 ± 9.4 years. Of all the study participants, majority (91.1%) aged 15 years or older, & most patients (77.8%) were dwellers of Addis Ababa, Ethiopia. Only four patients (4.4%) had history of previous tympanoplasty, as shown in Table 1.

Table 1: Distribution of baseline characteristics patients with anatomical and hearing success rate of tympanoplasty at SPHMMC, AA, Ethiopia, from Jan 1st to Dec 31st, 2019.

Variable Yes		Graft uptake		Hearing success	
		No	Yes	No	
Age range	<15 years	7	1	5	3
	≥15 years	66	16	49	33
Duration of dry period	<3 months	14	3	13	4
	>3 months	59	14	41	32
Size of perforation	≥50%	56	12	42	26
	< 50%	17	5	12	10
Site of perforation	Central	20	5	15	10
	Subtotal	51	11	37	25
	Total	2	1	2	1
Surgical approach	Endaural	64	11	45	30
	Transcanal	6	5	7	4
	Retroauricular	3	1	2	2
Graft placement technique	Underlay	73	17	54	36
Graft material used	Temporalis fascia	66	14	50	30
	Cartilage	1	0	1	0
	Perichondrium	2	1	1	2
	Cartilage with perichondrium	4	2	2	4
Status of the TM	Normal	67	16	48	35
	Myringosclerosis	6	1	6	1
Status of the middle ear mucosa	Normal	65	14	49	30
	Granulation tissue	1	2	0	3
	Tympanosclerosis	5	1	4	2
	Cholesteatoma	2	0	1	1

Using the Middle Ear Risk Index (MERI 2001) scoring system, patients were stratified to three groups to assess preoperative and intraoperative risk factors for tympanoplasty. Accordingly, most (83.3%) of the study patients had mild risk (0-3 score), while 12 (13.3%) had moderate risk (4-6 score), and only 3 (3.3%) had severe risk (7-12 score).

3.2 Success rate of tympanoplasty

An intact graft in proper position and an ABG closure of ≤ 20dB at the end of six months was considered a success. The graft uptake was examined by ear microscopy and the hearing improvement was gauged by pure tone audiometry. The overall successful perforation closure rate was 81.1% (73 of 90 patients). Significant hearing improvement (air–bone gap ≤ 20 dB) was achieved in 60% (54 of 90) of patients and more than 10 dB air conduction gain in 64(71.1%) of the studied patients (Fig. 1). The mean preoperative air–bone gap was 30.8 dB±1.2 SD with an average air–bone gap improvement of 17.6 dB±13 SD.

Furthermore, as it is displayed in Table 2, there was significant improvement in hearing level after tympanoplasty with a p value of <0.001 and mean SD of 1.4.

MD= mean difference

Table 2: Paired sample t-test on hearing level in dB of CSOM patients before and after tympanoplasty at SPHMMC, AA, Ethiopia, from Jan 1st to Dec 31st, 2019.

	Preoperatively (N=90)	Postoperatively (N=90)	Paired sample t-test		
			MD	t	P value(95% CI)
Normal	3	38	15.7	11.5	<0.001(13-18.4)
Mild HL	24	30			
Moderate HL	44	19			
Moderately severe	16	3			
Severe	2	0			
Deafness	1	0			

3.3 Factors associated with success of typmanoplasty

Among all the potential factors analyzed in the studied populations, none appeared to be significantly associated with the tympanic membrane closure success or hearing success. Although the socio-demographic and clinical variables such as duration of dry ear prior to surgery, the surgical approach employed, status of tympanic membrane and type of

tympanoplasty showed association in binary logistic regression, none of them proved to be prognosticate success likelihood of tympanoplasty suffering from CSOM, as detailed in Table 3.

Table 3: Binary and multiple logistic regression model showing predictors of tympanoplasty success at SPHMMC, AA, Ethiopia, from Jan 1st to Dec 31st, 2019

Variable		COR at 95% CI	P value	AOR at 95% CI	P value
Surgical approach	Endaural	1 (Reference)	-	-	-
	Transcanal	4.8(1.3,18.7)	0.22	-	-
	Retroauricular	1.9(0.2,20.4)	0.5	-	-
Duration of dry ear	<3 months	2.5(0.8,8.5)	0.13	-	-
	>3 months	1 (Reference)	-	-	-
Status of the TM	Normal	4.4(0.5.37.9)	0.18	-	-
	Myringosclerotic	1 (Reference)	-	-	-
Type of tympanoplasty	Microscopic	4.4(0.5.37.9)	0.18	-	-
	Endoscopic	1 (Reference)	-	-	-

N.B: These variables are from the total variables statistically significant while cross tabulation done (p<0.25)

4. Discussion

4.1 Characteristics of patients

In this study, a 1:2 male to female ratio was noted, a finding similar to that of the study done in Iranian population by Naderpour, et al. [6] in their study that aimed to assess factors affecting the surgical outcome in tympanoplasty and that of the study done by Gamra and his colleagues in pediatric population of Tunisia [12]. Although several studies including [13] conclude that there is no marked difference in sexual predilection of CSOM, the female predominance of this study might be underpinned by factors such as their delayed health-seeking behavior, as was observed in Rwanda [14]. It could also be due to that women seek more help for their health problems and are used to go clinic for antenatal care or accompanying family members to the hospital.

Regarding the size and site of TM perforation, most (68.9%) of the studied patients were observed to have a subtotal perforation in line with Gamra's finding [12] in Tunisa where the author noted subtotal perforation to be most common among the studied pediatric cases. The higher prevalence of larger perforations in the present study can be ascribed to low socioeconomic factors such as delayed care (as a result of financial constraints & access) and traumatic traditional practices and very limited access to ear health in the past.

With regard to the duration of the dry ear prior to the surgery, most (81.1%) of the patients' ears were kept dry for more than three months prior to the operation. This was consistent with a study conducted by Yurttas et al. who noted that about two-third (64.6%) of patients' ears was kept dry for more than three months prior to surgery [4]. The higher number of dry ear before surgery is mainly attributed to the surgeons' preference & their wish to optimize outcomes.

In this study, the technical preference of using underlay technique routinely is in line with the practice in most parts of the world [15].The surgeons' preference for underlay technique may also be due to the evidence that overlay technique calls for surgical experience, extended time for operation, and it entails certain potential risks, such as graft lateralization, blunting and cholesteatoma formation [7].

4.2 Success rate of tympanoplsty

This study revealed that the overall perforation graft uptake rate was 81.1%. The anatomical success achieved in the current study was in concordance with a recent meta-analytic review [16], which aimed to determine factors that influence the efficacy of type I tympanoplasty in both adult and pediatric populations, & revealed an average success rate for closure of perforations of 86.6%. However, most of the success rates in the existing literatures range from as low as 75% to as high as 98%. For example, Naderpour et al. [6] found an overall graft success rate of 93.3%, in Iranian patients who had undergone tympanoplasty while Gamra et al. found 92.8% successful graft uptake in Tunisian children who had tympanoplasty for CSOM [12]. On the other hand, two separate studies done in Turkish population by Yurttas et al. [4] and Pinar [17] revealed that a lesser overall success rate for full postoperative graft success of 75% and 74.4%, respectively. Of note, a study conducted by Isaacson & Abebe [18] in Ethiopian pediatric patients even observed a much lower success rate (intact tympanic membrane) of 54.5% at six months after surgery.

The other important success parameter evaluated in this study was improvement in hearing (air bone gap closure ≤20dB) which was achieved in 60% of the studied patients, with even higher rate of significant

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hearing gain. Findings in close proximity to our finding include a study conducted in Tunisian children, which revealed a functional improvement in 65% postoperatively [12] and a study performed in Indian population where 60% and 73.6% functional success rate were recorded [19,20]. Higher hearing success rates were documented in similar Iranian studies which discovered 86% and 83.8% hearing improvement [15,21]. We found significant hearing improvement in our study as demonstrated by a mean ABG gain in pure tone audiometry (PTA) of 17.6 dB while a previous study by Isaacson & Abebe [18] documented a mean improvement of 14 dB in their study done in Ethiopian population. However, a better hearing outcome of 86% (with mean= 12.5±9.5dB) was demonstrated by Indorewala along with other authors in their retrospective review of patients [15].

In general, the discrepancies both in the anatomical and functional forms of tympanoplasty success noted across different literatures can be attributed multiple factors such as characteristics of study patients, the methodology used, the operational definition used to gauge anatomical and functional successes, and the inter-institutional surgical advancement dissimilarities. Also, the possible presence of overlooked factors including Eustachian tube dysfunction, adhesive otitis media, and revision surgery can impair the surgical closure of a TM perforation.

4.3 Factors associated with success of tympanoplasty

In contradiction to several otologists [eg. 22,23,24] who have long promoted certain factors to be associated with success odds of tympanoplasty, this study noted no any factor to be statistically sound to predict tympanoplasty outcomes. This divergence can be justified by the smaller sample size of this study and the need to consider postoperative factors including surgical site infection.

5. Limitations

- This study was affected by the emergence of COVID-19 pandemics. The COVID-19 crises reduced regular client follow up postoperatively, especially for those who were expected to come for oto-microscopic and/or audiological examination postoperatively during the early months of the crises. Exclusion of the patients with incomplete medical data decreased the total sample size, which has a potential impact on the statistical power of the tests used.
- All surgeries were done in a teaching facility where most tympanoplasty surgeries are done by senior ENT resident physicians. There were only few surgeries done by experienced surgeon for the very complicated cases. This might have affected the outcome if compared to a set up where only experienced surgeons perform tympanoplasty.

6. Conclusion and Recommendation

This study showed that endaural approach, underlay technique, and temporalis fascia grafts were used predominately. It highlighted that tympanoplasty is an effective surgical procedure that leads to reconstruction of ear drum and restoration of auditory function in CSOM patients irrespective of the potential factors considered in this study. Successful surgical outcomes are influenced by factors other than the intra- & pre-operative factors.

Therefore, given its efficacy, tympanoplasty should be delivered to a larger population regardless of their baseline characteristics. It is recommended that all concerned stakeholders make the procedure more accessible to the needy. Further large-scale studies should be conducted in similar settings to pinpoint the factors that can enhance the efficacy of the procedure and have a deeper exploration of attributing factors for the sizeable failure rate in tympanoplasty across settings.

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Authors' contributions

All four authors conceived the study, participated in the design and coordination of the study, and helped to draft the manuscript. SAY and SMH performed the statistical analysis. All authors read and approved the final manuscript.

Abbreviations

ABG: Air Bone Gap; CSOM: Chronic Suppurative Otitis Media; dB: Decibel; ENT: Ear, Nose and Throat; ORL-HNS: Otorhinolaryngology-Head and Neck Surgery; PTA: Pure Tone

Average: SPHMMC: St. Paul's Hospital Millennium Medical College: SPSS: Statistical Package for Social Sciences; TM: Tympanic membrane

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