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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. It primarily aims to reconstruct the tympanic membrane, restoring protection to the middle ear and alleviate the difficulty in hearing. Thus, the aim of this study was to determine success rate of tympanoplasty in CSOM patients & its associated factors.

Methods: A total of 90 Patients who had undergone tympanoplasty from Jan 1st, 2019 to Dec 31st, 2019 at SPHMMC, Ethiopia were included in this study. A retrospective medical chart review was carried out. Data was collected using a structured checklist and entered using Microsoft Excel 2010 and later transferred to SPSS for analysis. The socio-demographic and clinical characteristics of participants were computed using descriptive statistics (frequencies, percentage, mean and standard deviation). Paired t-test was used to compare preoperative and postoperative ABG results. Relationship between dependant and certain independent variables were analysed using chi-square. A p value of <0.05 and 95% confidence level were considered statistically significant.

Results: 59 of the participants were females and 31 were males, with an overall age range of 9 to 52 years. The postoperative anatomical & functional success rates for tympanoplasty were 81.1% and 60%, respectively. The surgical approach employed was the only variable that exhibited significant association with the tympanoplasty outcome; the endaural approach had better graft uptake rate (p value=0.049).

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

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

Keywords Tympanoplasty; Chronic Suppurative Otitis Media; Success rate; Endaural surgical approach; St. Paul's Hospital Millennium Medical College

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 [8-10]. 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 is conducted in an attempt to rectify this paucity of data.

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 were included in the study. Data were collected using a structured questionnaire. Data entering, coding and clearing for the quantitative data and the analysis was performed using Microsoft Excel 2010 and SPSS version 25. 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 chi square. 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 prophylactic antibiotics 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. 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, and 12th month, for otomicroscopic and audiologic assessment. PTA was assessed using average measures of 500, 1000, 2000 and 4000 Hz.

Results

This study included data derived from 90 chronic CSOM patients who underwent 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 years & SD of 9.4. Of all the study participants, majority (91.1%) aged 15 years or older, & most patients (77.8%) were dwellers of Addis Ababa. Only four patients (4.4%) had history of previous tympanoplasty, as shown in Table 2.

Using the Middle Ear Risk Index (MERI 2001) scoring system, patients were stratified to three groups to stratify patients according to known 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).

Success Rate of Tympanoplasty

An intact graft in proper position and hearing gain 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 patients. 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.

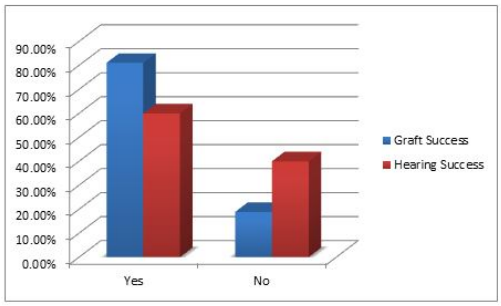

Figure.1: Graft success (TM closure rates) and hearing success rates

Furthermore, as it is displayed in Table 1, there was significant improvement in hearing level after tympanoplasty with a p value of <0.001 and mean SD of 1.4.

	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			

Table 1: 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. MD= mean difference.

Factors associated with success of tympanoplasty

Among all the factors analyzed in the studied populations, only the surgical approach employed by the surgeon appeared to be significantly associated with the tympanic membrane closure success. The rate of graft success was 85.3 % in patients with endaural approach, whereas it was 54.5% in transcanal approach and 75% in post auricular approach with p value of 0.049. However, the surgical

approach didn't show a significant improvement in postoperative audiological evaluation.

The remaining socio-demographic and clinical variables such as duration of dry ear prior to surgery, size and site of perforation, type of tympanoplasty and type of graft showed no statistically significant association with any form of the two tympanoplasty success rate: anatomical and functional ones. Some of the variables are shown in Table 2 as follows.

Variable		Graft uptake		Hearing success	
		Yes	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
	Central	20	5	15	10
Site of perforation	Subtotal	51	11	37	25
	Total	2	1	2	1
	Endaural	64*	11	45	30
Surgical approach	Transcanal	6	5	7	4
	Retroauricular	3	1	2	2
Graft placement technique	Underlay	73	17	54	36
	Temporalis fascia	66	14	50	30
	Cartilage	1	0	1	0
Graft material used	Perichondrium	2	1	1	2
	Cartilage with perichondrium	4	2	2	4
	Normal	67	16	48	35
Status of the TM	Myringosclerosis	6	1	6	1
	Normal	65	14	49	30
Status of the middle ear	Granulation tissue	1	2	0	3
Mucosa	Tympanosclerosis	5	1	4	2
	Cholesteatoma	2	0	1	1

Table 2: Factors associated with anatomical and hearing success rate of tympanoplasty at St. Paul's Hospital Millennium Medical College, AA, Ethiopia, from Jan 1st to Dec 31st, 2019, *p value <0.05.

Discussion

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, 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 delayed health-seeking behavior, as was observed in Rwanda [14].It could be also 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 he noted subtotal perforation to be the 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.

In this study, the technical preference of using underlay technique routinely is in line with 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].

Success Rate of Tympanoplsty

This study revealed that 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≤20dB) which was achieved in 60% of the studied patients. 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.

Factors associated with success of tympanoplasty

In this study, the surgical approach significantly affected the rate of postoperative graft success in CSOM patients who had undergone tympanoplasty. The rate of graft success was 85.3 % in patients who were approached endaurally, while it was 75% in post auricular approach and only 54.5% in transcanal approach, respectively (p=0.049).While some authors such as Halim et al. & Nayyar et al. found no significant difference in success rate between the surgical approaches [22-24], many otologists have long promoted postaural approach as a standard approach to the middle ear [22,24].

Postaural approach is commonly used to expose the mastoid area during the same procedure, enabling mastoidectomy to be performed if necessary. It generally preserves more usable tissues, provides a better viewing angle of the entire tympanic membrane and the middle ear [22].The transcanal approach restricts access to tympanic membrane margin in patients with narrow ear canals whereas endaural approach is good in all types of tympanic perforation and easy to harvest fascia from incision site [1]. However, the finding of the present study is in contrast with the previous data. The researcher believes that it is not the approach itself, but the surgeon's preference and experience that may be attributable to this contradiction. In our setting, transcanal operation was done using endoscopic technique which is new in our practice and the surgeons are therefore still on the early phases of their learning curve [25]. This may lead to the low success rate associated with transcanal approach noted in the current study.

Limitations

This study was strongly affected by the 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 training facility to train ENT resident physician's tympanoplasty skills. All of the registrars are newbie's in tympanoplasty, none of the registrars were totally confident in doing tympanoplasty by independently. There were only few surgeries done by experienced surgeon for the very complicated cases. All other cases were completed/supervised by experienced surgeon after a registrar started. This might affect the outcome if compared to a set up where only experienced surgeons perform tympanoplasty.

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. Endaural surgical approach was the only factor that proved to improve the success rate of tympanoplasty.

Therefore, given its efficacy, tympanoplasty should be delivered to a larger population. 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 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.

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