Original Research Article

A prospective study on outcome of surgical management of tympanic membrane retractions

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Abstract

Background: The objective of the study was to analyze the outcome of surgery in patients with retracted tympanic membrane in context to hearing improvement and dry ear. Additionally, the study also aimed to determine possible complications during surgery. **Methods:** The study was carried out on 50 patients in the department of Otolaryngology at a tertiary care hospital in India. Patients with grade 3 and 4 tympanic membrane retraction with or without cholesteatoma and patients with grade 1 and grade 2 tympanic membrane retraction with recurrent or persistent discharge and with conductive hearing loss were included. Surgery was carried out with Temporalis fascia graft following standard protocol. Patients were followed up for a period of 6 months. Audiological evaluation was performed on all the patients before the surgery and on completion of 3rd month and 6th month post surgery. Kruskal Wallis test was used to compare mean hearing improvement. **Results:** Of the total 50, 46 patients had successful graft uptake. Post-operative complications including post aural wound infection (n=2) and residual perforation (n=2) were observed. The difference in mean hearing score preoperatively and postoperatively (at the end of 6th month) was found to be statistically significant ($P=7.66e^{-10}$). **Conclusion:** Surgical intervention using a temporalis fascia graft in patients with retracted tympanic membrane provides excellent results with respect to hearing improvement and dry ear. The procedure was found to be safe with minimal complications.

Keywords: Middle ear surgery, Temporalis fascia graft, Tympanic membrane retraction

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INTRODUCTION

Retraction pocket, which is a localized retraction of the tympanic membrane is characterized by the inward displacement of tympanic membrane caused due to the presence of fragile portion of pars tensa or pars flaccida. [1] It is a well-defined clinical entity, affecting either pars tensa or flaccida and at times affects both. Many a times, it can be asymptomatic, small and self-cleansing. [2] It can also erode the adjacent structures resulting in otalgia and hearing loss. [2] Retractions of tympanic membrane are subject to dynamicity.[3] Retraction is inactive squamous chronic otitis media.[3] Pathological invagination of tympanic membrane into middle ear space is known as tympanic membrane retraction.[4] They have potential to become active with retained debris – cholesteatoma.[3] Retractions are precursors to cholesteatoma.[4] Chronic Eustachian tube dysfunction is a very important predisposing factor.[4] Posterosuperior pars tensa and pars flaccida are vulnerable areas.[5] Long process of incus and stapes superstructure are most commonly eroded ossicles.[5] Retractions pockets range in severity from stable, self cleansing, shallow to deep, adherent, symptomatic

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pockets.[3] Retractions may present with recurrent otorrhoea, persistent hearing loss, cholesteatoma.[5] Most widely accepted classification for grading of retraction pockets are Sade's classification for pars tensa retractions and Tos's classification for pars flaccida (attic) retractions.[3,5]

Tympanic membrane retraction is a dynamic process, so it is difficult to predict its course. Timing of intervention remains controversial. Earlier intervention is easy to perform but may predispose patients to post operative complications. Wait and watch policy may increase extent of adhesions, increase hearing impairment, progress to cholesteatoma and its complications. Surgery will become more difficult.[5]

Therefore, the study emphasizes on the outcome of underlay fascia tympanoplasty in patients with retracted tympanic membrane in the context of hearing improvement and dry ear. The study also aimed to determine possible complications during surgery.

Methodology

The prospective study was conducted in the department of Otolaryngology at tertiary care hospital in Kolhapur, India. The study was approved by the Institutional Ethics and Research Committee (DMCK/131/2017). The minimum sample size was calculated (n=~ 23) considering 80 % power with 95 % level of significance in R studio (v 1.2.5001) software using appropriate R code (pwr.t.test (effect size = 0.85, power = 0.80, sig.level = 0.05, type ="two.sample")). A total of 50 patients aged 15 to 50 years with retractions of the tympanic membrane of grades 3 and 4 with or without cholesteatoma and the patients with grades 1 and 2 retractions with persistent or recurrent ear discharge and with conductive hearing loss were included in the study. Patients below 15 years or above 50 years of age, with sensorineural hearing loss or mixed hearing loss and cases of revision ear surgery were excluded. On obtaining written consent from the patients, routine investigations, audiometry, tympanometry, CT of temporal bone and preanaesthetic evaluation were carried out. Ear microscopy was performed and the ear was cleaned of any debris. Intramuscular injection of tetanus toxoid 0.5 ml was administered to the patient. The patients were subjected to lignocaine sensitivity test using 0.1 ml of 2% lignocaine. An inch of the post auricular region was shaved and prepared. Oral antibiotics and antihistaminics were administered to the patient. Patients were pre-medicated with Glycopyrrolate injection 0.2 mg, Ranitidine injection 50 mg, Midazolam injection 1 mg and Ondansetron injection 4 mg via IV route. Diclofenac 75 mg intramuscular injection was also administered to control pain and inflammation. For local infiltration, 2% Lignocaine with Adrenaline (1:2 lacs) was injected in post-aural region and in external auditory canal (EAC). All the patients were placed in a supine position with head turned to the opposite side and the post aural incision was done. Temporalis fascia was used as graft material. Temporalis fascia graft was harvested and spread evenly for drying. Posterior meatotomy was done at the level of spine of Henle. Elevation of full cuff tympanomeatal flap till annulus was done. Canalplasty was performed if necessary. Retraction pocket was identified and elevated. Middle ear was entered. Ossicular chain was inspected for continuity and mobility. Cortical mastoidectomy was done in cases without cholesteatoma. In patients with cholesteatoma, Canal wall down mastoidectomy along with cavity obliteration was done. In cases of ossicular erosion, ossiculoplasty was done either with allograft or artificial prosthesis. Middle ear was packed with antibiotic-steroid soaked gel-foam. Temporalis fascia graft was placed by underlay technique. Tympanomeatal flap was repositioned. Antibiotic-Steroid soaked gel-foam was placed in external auditory canal. Post aural incision was sutured in layers using absorbable suture material. Mastoid bandage was applied. Post-surgery, patients were discharged on the second day and were prescribed antibiotics and antihistamines for three weeks. On the seventh post-operative day, endomeatal wick and stitches were removed. Patients underwent otomicroscopy to assess graft uptake and post-operative complications. All the patients were followed up weekly for a month And Thereafter, monthly for the next three months. On completion of the sixth post-operative month, they underwent Pure Tone Audiometry to assess hearing improvement.

Statistical Analysis

Data was collected and compiled. Results were tabulated and statistical analysis was done in . SPSS (23.0) statistical software. To compare mean hearing improvement Kruskal Wallis test was used. $P<0.05$ was considered significant.

RESULTS

The mean age of the patients was 36.6 ± 9.62 years. High number of patients belonged to the age group of 36-45 years (46%). A slight male preponderance was observed with 54% (n=27) males and 46% (n=23) females. Frequency distribution analysis of the Nature of tympanic membrane retractions among the study subjects is summarized in Table 1.

Table 1: Frequency distribution analysis (n=50)

VARIABLES	FREQUENCY	PERCENTAGE
EAR AFFECTED		
Right	26	52%
Left	24	48%
GRADE OF PT		
I	24	48%
II	06	12%

III	12	24%
IV	08	16%
GRADE OF PF		
I	09	18%
II	10	20%
III	02	04%
NIL	29	58%
OSSICLE ERODED		
Long process of incus	15	30%
Long process of incus and	05	10%
Stapes superstructure	30	60%
Nil		
HEARING LOSS		
31-40 dB	08	16%
41-50 dB	22	44%
51-60 dB	11	22%
>61 dB	09	18%

PT- Pars Tensa ; PF- Pars Flaccida

Majority of patients underwent Cortical mastoidectomy with type I tympanoplasty (60%). Table 2 summarized the type of surgery done along with frequency.

Table 2: Types of surgery

SURGERY TYPES	FREQUENCY (n=50)	PERCENTAGE
CM and T1	30	60%
CWD and T3a	15	30%
CWD and T3b	05	10%

CWD = Canal wall down, T3a = Type 3a tympanoplasty, T3b = Type 3b tympanoplasty, CM = Cortical mastoidectomy, T1 = Type I tympanoplasty. At the end of the 3rd post-operative month, hearing loss within 30 dB, between 31-40 and between 41-50 dB were observed in 42% (n=21), 46% (n= 23) and 10% (n=5) cases respectively. However, at the end of 6 months, 56% (n=48) patients had hearing loss between 11-20dB and 44% (n=22) had hearing loss between 21-30dB.

The mean difference observed between Pre-op PTA (DB) and Post-op PTA (dB) was statistically significant (Table 3).

Table 3: Hearing improvement

VARIABLE	MEAN ± SD	P-VALUE
Pre-Op PTA (dB)	50.98 ± 9.83	$7.66e^{-10}$
Post-Op PTA (dB)	21.38 ± 2.97	

Pre-op PTA (DB) = Pre-operative pure tone audiometry, Post-op PTA (DB) = Post-operative pure tone audiometry. Post-operative complications were not observed in majority of cases (92%). Post-operative complications such as perforation (4%) and post aural wound infection (4%) were observed. (Table 4).

Table 4: Post-operative complications

VARIABLES	SUBCATEGORIES	FREQUENCY	PERCENTAGE
COMPLICATIONS	Infection	2	4%
	Perforation	2	4%
	Nil	46	92%

DISCUSSION

Tympanic membrane retraction may be regressive, progressive or stagnant and is thus considered as dynamic pathological condition. Secretory otitis media persistence and negative pressure in the middle ear cleft defines the resolution or further deterioration of retraction.[16] Development of negative pressure in the middle ear cleft may be due to small volume of epitympanum and small area of tympanic isthmus resulting in epitympanic dysventilation.[17] Timing of the treatment largely depends upon further progression of the condition and worsening of symptoms. In such conditions, early and accurate diagnosis along with monitoring is vital. Conservative management of the condition is offered in cases of asymptomatic, self-cleansing retractions where the full extent is visible. In cases where the full extent is not visible and have an obvious keratin accumulation and persistent or intermittent otorrhoea, surgical interventions is required.[18] Literature provides mixed results in context to timing of surgery as well as outcome and complication of such interventions. Further, use of temporalis fascia graft in surgery of retracted tympanic membrane has also not been extensively studied in the literature. Thus, there was much need for a prospective cohort clinical study that evaluates the outcome of tympanic membrane retraction surgery. The main aim of the study was to examine the effect of surgical interventions on retracted tympanic membrane in context to dry ear and hearing improvement. The study also evaluated the occurrence of complications during and after the surgery in these patients. Age of subjects in the study was in the range of 15 to 50 years. However, the literature shows the age groups to vary vastly from 8-73 years.[18,19,20] . Mean age was found to be 36.6 ± 9.62 years. This is comparable with the results obtained in the study done by Kasbekar *et al.* [18] However, the mean age of study subjects in the study conducted by Comacchio *et al.* and Levinson was 47.56 years and 16 years respectively.[19,20] Low mean age in Levinson indicate that the tympanic membrane retraction may also occur in young people. In fact, 19 patients out of 79 patients in the study conducted by Levinson were less than 12 years of age.[20] Variation in mean age in studies can be attributed to the inclusion criteria of 15 to 50 years in context to patients' age. A slight predominance of male was observed. This concurs with the findings of the study conducted by Cassano *et al.* and Barbara. [21,22] However, Comacchio *et al.* reported high male predominance with 7 females and 17 males.[19] For more than 50 years, cartilage has been used as a material for grafting in tympanoplasty. Cartilage has greater strength than temporalis fascia and thus, their use should be recommended.[18] A second look surgery or computed tomography of high resolution of the middle ear should be performed when cartilage is used as graft material because

of its property to obscure keratin pearls behind the graft.[18] Malhotra *et al.*, in a literature review, concluded that due to light material, strength and anatomic proximity, temporalis fascia was the preferred material followed by tragal perichondrium and tragal cartilage. [23] Previous reports suggest that there is no statistically significant difference in the results while using any of the materials for tympanic membrane graft.[14,23] Therefore, temporalis fascia was used as for graft in this study. All patients suffered from pars tensa retraction. Both Pars tensa and Pars flaccida retraction was seen in 42 % of the patients. Cholesteatoma was noted in 40 % of the casesHearing loss between 42-50 dB was seen in 44 % of the cases. Comacchio *et al.* had also reported high occurrence of cholesteatoma with 44% cases.[19] Whereas, a lower rate of cholesteatoma was reported by Kasbekar *et al.* (31%) and Levinson (19%).[18,20] Otitis media is disease commonly seen due to bacterial infection. Persisting otitis media can result in disruption of the ossicular chain. Presence of cholesteatoma along with otitis media may worsen the condition. [24] This is reflected in this study where 40% of cases showed ossicle erosion. Levinson and Comacchio *et al.* have reported ossicle erosion in 30% and 48% of the cases in their study respectively. [19,20] Higher rate of ossicle erosion was observed in Kasbekar *et al.* (83%). [18] The variation in the prevalence of ossicle erosion can be attributed solely to persistence of otitis media and presence of cholesteatoma. A broad spectrum of grafting materials and procedures managing tympanic membrane retraction are known. [18-22,25-27] However, majority of the cases in this study underwent cortical mastoidectomy with type I tympanoplasty (60%). Forty percent of the cases were at advanced stage of hearing loss and hence were managed with Canal wall down with type 3a or 3b tympanoplasty. At the end of 6 months, all subjects had improved hearing and 96% cases had dry ear. However post-operative complications such perforations (4%) and post aural wound infection (4%) were found. Perforation of the tympanic membrane was the consequence of acute otitis media in the early postoperative period. The cases of acute otitis media were managed conservatively but perforation persisted. The cases of post aural wound infection were managed with broad spectrum antibiotics for 10 days. There was no retraction pocket recurrence and cases of cholesteatoma during the 6-month follow-up. Interestingly, 1 case of retracted pocket was observed each in the studies by Cassano *et al.* and Kasbekar *et al.*[18,21] Cassano *et al.* and Comacchio *et al.* also reported one and three cases of cholesteatoma respectively. [19,21] Graft uptake was observed in 48 cases. Therefore, success rate of this technique was 96%. Interestingly, lower success rate was reported by Cassano *et al.* (79%), Spielmann *et al.* (84%) and Jesic *et al.* (86.1%). [21,25,27] Whereas, Barbara reported a higher success rate (100%).[22] This variation in outcomes can be due to multiple reasons such as duration of symptoms, severity of disease, errors in surgical procedure and individual's response towards the treatment. The study comprised of a small group of patients. Keeping in account the development of complications due to delay in surgical interventions in patients with tympanic membrane retractions, studies on large patient group can be done in future. Further studies are required to identify the timing of surgery and determining efficacy of observational and monitoring strategies in comparison to surgical interventions in patients with retracted tympanic membrane. Studies with long-follow-up period, , should be conducted to evaluate the long-term efficacy of surgery in tympanic membrane retraction. Comparative studies using various graft materials may also be performed to analyse the advantages and disadvantages of graft materials used in surgery of retracted tympanic membrane.

CONCLUSION

Surgical intervention in cases of retraction pocket gives excellent graft uptake and hearing improvement with dry ear and has minimal complications. Management of retraction pocket should be tailored for individual patients. Treatment modality depends on grading of retraction pocket, anatomic status and regular follow up to monitor disease progression. Follow up of patients after any treatment modality is necessary as additional intervention may be required in future.

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