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Endoscopic Fascia-Cartilage Composite Grafting in Chronic Suppurative Otitis Media

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ABSTRACT

Objective: To evaluate perforation of an air-bone gap closure success using fascia-cartilage composite graft in endoscopic Trans canal tympanoplasty.

Study Design: Randomized Control Trial (Clinical Trials.gov Identifier: NCT04945811)

Place and Duration of Study: ENT Department Combined Military Hospital, Quetta Pakistan, from Apr 2020 to May 2021

Methodology: One hundred and thirty-three cases of chronic Suppurative otitis media fulfilling the selection criteria were operated upon, and an endoscopic fascia-cartilage composite graft was used. A successful outcome in terms of perforation closure and air-bone gap closure was evaluated in all patients.

Results: In the 138 patients operated, complete fascia-cartilage composite graft uptake was achieved in 129 (93.5%) patients. Nine (6.5%) patients had graft failure. The pre-operative mean air-bone gap was 36.49±4.61 decibels, and the postoperative mean air-bone gap was 12.57±5.09 decibels. This improvement was found to be significant, with the *p*-value < 0.001.

Conclusion: Endoscopic per-meatal fascia-cartilage composite grafting has a high graft uptake and air-bone gap closure percentage in chronic Suppurative otitis media cases.

Keywords: Air-bone gap, Cartilage, Chronic suppurative otitis media.

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INTRODUCTION

Chronic suppurative otitis media is one of the leading causes of preventable disabling hearing loss in the developing World. World Health Organization reports a prevalence of nearly 43% in the western pacific region for chronic suppurative otitis media.[1] In the early stages, chronic suppurative otitis media leads to reversible hearing loss, with complications developing in the latter stages in neglected cases.[2]

The hallmark of chronic suppurative otitis media is central tympanic membrane perforation. Depending upon the size and location of the perforation, conductive hearing loss varies from 25 to 45 decibels. The waveform formed on a pure tone audiogram shows a difference between bone and air conduction known as air-bone gap.[3] The presence of sensory neural hearing loss indicates the involvement of cochlea in the disease process and reduces the chances of hearing improvement with tympanoplasty.[4]

Conventional tympanoplasty involves raising a tympanomeatal flap in either postauricular or end aural approach. Posterior tympanomeatal flap elevation carries the risk of secondary canal stenosis and scarring.[5] The traditional choice of graft is temporalis fascia, albeit with lower nutritional requirements but having a higher failure rate and poorer hearing restoration rates. Cartilage grafts carry much higher rates of air bone-gap closure but have physiologically higher nutritional demands and are difficult to manipulate.[6] A fascia-cartilage composite graft composed of fascia (perichondrium) with a central cartilage island provides the strength of both tissues.[7] Performing the surgery using the endoscopic route gives better visualization and control with lesser disruption of metal wall integrity while giving better results comparable to conventional technique. This study was carried out to evaluate perforation of an air-bone gap closure success using fascia-cartilage composite graft in endoscopic Trans canal tympanoplasty.

METHODOLOGY

This randomized control trial (Clinical Trials.gov Identifier: NCT04945811) was carried out to determine the hearing restoration in terms of postsurgical air-bone gap closure in cases of chronic suppurative otitis media that underwent tympanoplasty at the department of ENT, at CMH Quetta after approval of Institutional Review Board (File No: CMH QTA-IRB/531) from April 2020 to May 2021.

A sample size of one hundred and thirty-eight patients was calculated with the Raosoft sample size calculator (power of test 80% and margin of error 9%), with a prevalence of 46 % of chronic suppurative otitis media in the western pacific reported by WHO.[8] The

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patients were selected by non-probability consecutive convenience sampling technique.

Inclusion Criteria: Patients aged 18 to 55 years of either gender with dry central perforation were included from the study.

Exclusion Criteria: Any patient with actively discharging ear, sensory neural hearing loss on pure tone audiogram, sclerotic mastoid bone erosion or suspicion of cholesteatoma (on computerized tomogram petro mastoid area), with diabetes and hypertension were excluded from the study.

All patients had pre-operative computerized tomogram petro mastoid area and pure tone audiogram with bone conduction to determine the hearing loss and degree of air-bone gap and to rule out pre-existing ear diseases. One hundred and thirty-eight consenting patients of chronic suppurative otitis media were included according to inclusion criteria.

Per-operatively all cases were managed under general anaesthesia. The head of the patient was rotated towards the opposite side, bringing the operated ear to 70 degrees. A zero-degree wide angle endoscope was used for surgery via meatus approach without posterior meatus flap elevation. Perforation margins were freshened, and composite cartilage facial graft was taken from the concha bowel using a posterior incision on the pinna. An approximately 1.5 x 1 cm fascia-cartilage composite graft was harvested and placed in saline.

Depending upon the perforation size, cartilage was trimmed in half thickness according to the perforation size to give a snug fit, and the fascia was kept up to 03 mm beyond the dimensions of cartilage all around. Using a permeatus approach middle ear was packed with sponge stone. The composite graft was placed in a manner that cartilage assumed a lateral position and fascia was medial. The lateral surface of the tympanic membrane remnant and graft was secured with sponge stone dipped in Ciprofloxacin ear drops. The external auditory canal was packed with ear wick soaked in Fusidic acid cream. The incision on the pinna was closed with 2/0 Ethicon in a single layer.

Postoperatively all patients have been advised injection of Ceftriaxone intravenous for two days followed by capsule Cefixime 400 mg for seven days. Post auricular stitches and ear wick were removed after seven days. A reassessment of tympanic membrane status was done after four weeks of surgery. One hundred thirty-eight cases after four weeks were reassessed for air-bone gap using a pure tone audiogram.

Statistical analysis was conducted on the Statistical Package for Social Sciences (SPSS), version 26. Paired sample t-test was used to test the significance of air-bone gap closure in the patients. The *p*-value of ≤0.05 was considered statistically significant.

RESULTS

A total of 138 adult patients volunteered for the study. All 138 patients, both pre and postoperatively, underwent pure tone audiometry with bone conduction. Among the study group were 39 (28.3%) females and 99 (71.7%) males. Age varied from 18 to 55 years, with a mean age of 36.54±11.24 years.

Among the 138 patients in this study, four weeks of postoperatively tympanic membrane perforation closure was achieved in 129 (93.5%). Nine (6.5%) patients had graft failure. The pre-operative average air-bone gap was 36.49±4.61 decibels, and the postoperative air-bone gap was 12.57±5.09 decibels. This improvement was significant (*p*-value <0.001), as shown in the Table. After surgery, patients with partial tympanic membrane closure did not require any auditory augmentation.

Table: Comparison of Pre and Post-Operative Air Bone Gap Closure (n=138)

Parameters	Study Group (n=138)	*p*-value
Pre-Operative Air-Bone Gap	36.49±4.61 decibel	<0.001
Post-Operative Air-Bone Gap	12.57±5.09 decibel	

DISCUSSION

Pure tone audiometry checks two pathways of auditory conduction, i.e., bone conduction, which shows the cochlear threshold and air conduction which demonstrates the tympanic-ossicular chain integrity.[8] Normally, air and bone conduction lie at the same intensity level, or bone conduction is slightly better than air conduction (up to a 10-decibel difference). An air-bone gap of more than 10 decibels shows a disruption in the tympanic-ossicular chain.[9] The use of fascia has been the earliest choice of graft material. The main advantage of using fascia in the form of temporalis or vein graft is that it has low nutritional requirements leading to the relatively high uptake of graft material.[10] However, this advantage is negated regarding healed tympanic membrane strength and hearing rehabilitation in air-bone gap closure.[11]

Cartilage as an alternative to fascia was first introduced in the forms of palisades. These cartilage

palisades as a graft material increase the strength of the tympanic membrane but have more nutritional requirements. Additionally, cartilage grafts are thicker and more tedious to manipulate in the tympanic cavity.[12] Using a composite fascia and cartilage graft gives the advantage of a robust graft with easier manipulation per operatively. Traditionally posterior meatal wall flap is raised to access the tympanic cavity. This approach carries the risk of post-operative external auditory canal scarring and stenosis apart from increased per-operative time and bleeding. The use of an endoscopic approach minimizes these risks.[13] Anatomically strength of the tympanic membrane comes from the middle fibrous layer. Recovery with fascia graft promotes endothelium and epithelium layer formation without forming the middle fibrous layer. The resultant neo tympanic membrane is weaker structurally, giving way early to minor infections and the movement in response to auditory signals is weaker, thereby not achieving air bone gap.[14]

Debasish *et al.* in an original article comprising 30 cases, repaired the tympanic membrane using a composite cartilage-fascia graft with a cartilage rim. This composite grafting system gave a 93% success rate with tympanic membrane reconstruction and nearly 80% air-bone gap closure rate.[15]

Gozeler *et al*. in a prospective study spanning over three years, compared fascia grafting with composite fascia-cartilage graft in Type-I tympanoplasty of 113 patients. Tympanic membrane closure rate and air bone-bone gap closure rates were statistically better in composite fascia cartilage grafting compared to fascia alone grafts.[16]

In a prospective case series of 31 patients who used composite fascia cartilage graft using an endoscopic approach, Lou *et al*. achieved a 90% tympanic membrane perforation closure rate and better air-bone gap closure rates when compared with post-operative audiometry findings.[17]

Shekharappa *et al.* in a study of 30 patients, achieved a perforation closure rate of 93 % and an air-bone gap closure rate of 90% using cartilage-only grafting. They used sliced tragal cartilage with conventional posterior meatal wall flap technique.[18]

In a retrospective clinical study, 116 patients used both temporalis fascia and cartilage grafts in two groups. They achieved a statistically significantly better perforation closure rate with cartilage grafting. Dinc *et al.* also found cartilage grafts to have higher endurance than fascia grafts. Air-bone gap closure rates were comparable with both techniques, with slightly better results with cartilage grafting.[19]

Varma *et al*. in a prospective study of 60 patients, divided the patients equally using tragal perichondrium graft in 30 patients and tragal perichondrium-cartilage graft in 30 patients for endoscopic tympanoplasty. They found perichondrium-cartilage composite graft to be slightly superior to fascia-only graft with fewer post-operative complications with endoscopic technique.[20]

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CONCLUSION

Endoscopic per-meatal composite fascia-cartilage tympanoplasty significantly improves auditory thresholds and graft uptake in cases with CSOM.

Conflict of Interest: None.

Author's Contribution

ZA:, AAK: Conception, design, AR:, IS: Data analysis, JA: Substantial.

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