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ORIGINAL ARTICLE

Cartilage Ossiculoplasty; a Comparative Study Between Single Versus Double Cartilage Block Techniques

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ABSTRACT

Background: There has been renewed interest in the use of cartilage for middle-ear reconstructions. There have been concerns regarding weakening of cartilage struts, from histological studies involving explants; as a result, cartilage struts for ossiculoplasty have not gained popularity. On the other hand, cartilage tympanoplasty is now an established procedure for tympanic membrane and attic reconstruction. The perceived benefit of cartilage tympanoplasty is to prevent retraction pockets at the grafted site. Our study aims to assess the cartilage as sound transmitter in ossiculoplasty by using two different techniques.

Methods: A randomized controlled trial was carried out on 18 patients at ENT Department, Zagazig University Hospitals, from Aug. 2018 to Aug. 2019 suffering from chronic suppurative otitis media with ossicular discontinuity “erosion” with or without cholesteatoma and presented by otorrhea and hearing loss. There were randomly divided into 2 groups with nine patients in each group. Group (A) included patients who undergo the Single Cartilage Block Ossiculoplasty and Group (B) included the patients underwent the Double Cartilage Block Ossiculoplasty.

Results: There is statistically significant difference between the studied groups regarding Hearing outcome. Eight cases (88.9%) out of nine with SCB group versus only three out of eight cases (37.5%) with DCB shows successful outcome with ABG <20 dB With p-value: <0.05.

Conclusions: The single cartilage block technique is a simple and effective method for ossicular reconstruction and associated with significant improvement in PTA-ABG in those with conductive hearing loss. Especially in patients with intact stapes super structure.

Keywords. Ossicular reconstruction, single cartilage block , double cartilage block



BACKGROUND

Over recent years, continuous improvement occurred in ossicular reconstruction to restore hearing as much as normal hearing. This is due to a better understanding of biomechanics of the ossicular chain, leading to an effective columellar effect, in addition to discovery of new types and new materials of prosthesis[1]. Currently, plenty of materials are utilized in ossiculoplasty. The advantages of use of autologous material (cartilage, ossicles or bone cortex) are easy availability, cheap and harvested from the patient. In a condition with absence of autologous material or in functional failure, ossicular prosthesis was subsequently developed. The role of this prosthesis is to transmit the sound waves from the tympanic membrane to the stapes head, either directly, or

indirectly. In spite of the presence of various types of materials (titanium, gold, hydroxyapatite, steel, ceramics, Teflon etc.), titanium and hydroxyapatite (HAP) prostheses are the most commonly used materials in ossiculoplasty[2]. For a successful ossicular chain reconstruction (OCR) an air-filled middle ear (ME) and a functioning Eustachian tube (ET) are very important prerequisites. The tympanic membrane (TM) must be intact, healthy and mobile postoperatively. The ossicular reconstruction must be secure and stable. Grafts and prostheses chosen for use in ME reconstruction ideally, should not induce a sustained foreign body reaction, extrude or bio-degrade. Most otologists prefer to use healthy, fresh, autologous tissues whenever possible and the success rate with these materials is high. The second choice has been

preserved allogenic grafts[3]. Other factors affecting postoperative hearing results include patient age, length of the prosthesis, revision surgery, otorrhea, TM perforation and cholesteatoma[4]. The ideal prosthesis for ossicular chain reconstruction should be biocompatible, stable, safe, easily insertable, and capable of yielding optimal sound transmission[5]. When the surgeon chooses a particular prosthesis, selection must be based on several factors, including compatibility and easiness of configuring the prosthesis during surgery[6]. The use of cartilage is controversial. Few studies show evidence of cartilage resorption over the long term. Yet other studies report long term stability with good functional results. Advantages include versatility, availability, cost, bio-compatibility, and low extrusion rates; however operative time may be prolonged as cartilage has to be harvested and molded. Tragal cartilage is most commonly used; conchal and chondral cartilages also have been used [7]. We aimed to assess the cartilage as sound transmitter in ossiculoplasty by using two different techniques.

METHODS

A randomized controlled trial was carried out on 18 patients at ENT Department, Zagazig University Hospitals, from Aug. 2018 to Aug. 2019 suffering from chronic suppurative otitis media with ossicular discontinuity “erosion” with or without cholesteatoma and presented by otorrhoea and hearing loss. There were randomly divided into 2 groups with nine patients in each group. Group (A) included patients who undergo the Single Cartilage Block Ossiculoplasty and Group (B) included the patients underwent the Double Cartilage Block Ossiculoplasty. Inclusion Criteria: Chronic suppurative otitis media with or without cholesteatoma. Conductive hearing loss of 35db and more. Exclusion Criteria: Mixed and SNHL. Patient not fit for surgery or anesthesia. Patient with middle ear tumor. Extensive disease with intracranial complications. Patients with absent stapes superstructure. Revision ear surgery

All studied subjects were subjected to: Full history taking. Complete physical examination for all patients. Complete ENT examination with full otological examination (Otoscope, Endoscope), as well as nasal examination, and Facial nerve examination. Pure tone audiogram and tympanogram were done for all cases. Preoperative temporal bone CT scans were done for all cases. Routine laboratory investigations were done preoperatively (CBC, FBS, coagulation profile, liver and kidney function tests, viral markers and complete urine analysis).

Randomization: Randomization was performed in

blocks of 2 using random numbers generated by sas function uniform (SAS Institute, Cary, NC, USA). Randomization was stratified according to Middle Ear Risk Index (MERI) [8]. Middle Ear Risk Index combines the known preoperative and intraoperative risk factors for tympanoplasty (presence of otorrhea, perforation, cholesteatoma, middle ear granulations and ossicular status) and generates a numeric value that correlates with severity of disease and prognosis. A MERI of 6 was chosen as the cut-off point between two groups of patients: MERI < 6 represents moderate disease, while MERI above 6 corresponds to severe disease. The MERI score was computed on the day preceding the reconstruction. Subjects with MERI < 6 were assigned randomization numbers in ascending sequential order using the lowest numbers available. Subjects with MERI > 6 were assigned randomization numbers in descending sequential order. The randomization was performed by the principal investigator (SA) on the day preceding the planned surgery.

Surgical Steps: All cases were operated under GA in the following steps: Post auricular incision, Elevation of tympanomeatal flap, exploration of middle ear and mastoid cavity, removal of all granulation tissue and cholesteatoma sac with CWU procedure, examination of ossicular continuity, removal of eroded incus, clearance of Eustachian tube orifice, Reconstruction of ossicular continuity using autologous cartilage that is harvested from tragus. Group A, was operated by using Single Cartilage Block (SCB) technique, optimum size cartilage strip tailored according to the gap between anteroinferior part of the hypotympanum and the head of stapes. Temporalis fascia graft is harvested and applied over the cartilage block to close the middle ear and Gel foam was applied in the middle ear cavity and in external canal. In Group B, Double Cartilage Block (DCB) technique is applied; the rectangular block of cartilage was folded on itself to be fixed on the stapes head. Gel foam packing of the middle ear and tympanoplasty is performed with temporalis fascia or cartilage graft. The fascia is draped over the DCB. One case of canal wall down was reconstructed by Cartilage and temporalis fascia.

Postoperative management and follow up:

Antibiotics (systemic), analgesic, anti-inflammatory & nasal decongestant. Removal of the outer aural pack after one week, and the inner pack after two weeks, with continuity of antibiotic and steroid ear drops and regular ear examination. Post-Operative otoscopic examination. Post-Operative Pure Tone Audiogram & Tympanogram (for assessment of hearing outcome): These tests were held at the 6th month postoperatively. Ethical

Clearance: Written Informed consent was taken from the patient to participate in the study. Approval for performing the study was obtained from Otorhinolaryngology Departments, Zagazig University Hospitals after taking Institutional Review Board (IRB) approval. The work has been carried out in accordance with the code of ethics of the world medical association (Declaration of Helsinki) for studies involving humans.

Statistical Analysis: Data analysis was performed using the software SPSS (Statistical Package for the Social Sciences) version 20. Quantitative variables were described using their means and standard deviations (mean \pm SD). Categorical variables were described using their absolute frequencies and were compared using fisher exact test. To compare means of two groups, Independent sample t test or Mann Whitney test were used. To compare medians of the same group before and after surgery, Wilcoxon signed rank test was used. The level statistical significance was set at 5% ($P < 0.05$). Highly significant difference was present if $p \leq 0.001$.

RESULTS

There was statistically non-significant difference between the studied groups regarding age, gender or otorrhoea duration (SCB group had non-significantly younger age and lower discharge duration than DCB group). Table (1) There was statistically non-significant difference between the studied groups regarding side of ear lesion, presence of chronic suppurative otitis media, TM lesion, and presence of cholesteatoma or granulation tissue. Equal number was had attic perforation and cholesteatoma (88.9%) and granulations (11.1) in both groups. Only one patient in SCB group versus three with DCB group had bilateral ear involvement. Table (2) There was non-significant difference between the studied groups regarding presenting symptoms (discharge color, amount, odour and hearing loss). All patients had yellow discharge. Table (3) There was non-significant difference between the studied groups regarding intraoperative findings. All patients had eroded incus (necrosed) and intact stapes. Two thirds of patients with SCB group versus 55.6% of patients within DCB group had eroded malleus. There was non-significant difference between both groups regarding operative approach where all patients within SCB group underwent CWU technique and only 1 patient in DCB group underwent CWD. Table (4) There was a significant difference between the studied groups regarding Hearing outcome. Eight cases (88.9%) out of nine with SCB group versus only three out of eight cases (37.5%) with DCB shows successful outcome with $ABG < 20$ dB. There was non significant difference

between the studied groups regarding recurrence of cholesteatoma. Where only one patient (11.1%) out of nine with SCB group was reported as a case of recurrent cholesteatoma (Recurrent cholesteatoma was defined as a newly formed disease process secondary to a retraction pocket.). On the other hand, no case of recurrence was reported in DCB group. Table (5) There was non-significant difference between the studied groups regarding ABG values preoperatively. On the other hand a significant difference in regard to ABG six months postoperatively was noted between the two groups (with SCB had significantly lower ABG than DCB group). N.B one case was lost in group B during follow up period. On assessing change in ABG in each individual group over time, there was a significant decrease in it in both groups. Regarding pre- and post-operative audio-logical assessment, our results showed that the PTA was significantly improved along our study and good results were obtained at 6th month postoperatively. Table (6) Regarding ABG improvement in our patients, the improvement in PTA-ABG was 57.14% and 41.61% Six months postoperatively in group A and B respectively. Table (7)

DISCUSSION

In patients with COM the treatment objectives are to provide a dry ear, to ensure the function of Eustachian tube, and to restore the sound-conducting system of the middle ear. Ossicular chain reconstruction represents a challenge even for experienced otologists and the success is achieved with good and long-lasting audiometric outcome, represented by closure of postoperative ABG less or equal to 20dB [9]. Achieving all of these parameters in COM patients is difficult and controversial. Although ear surgery has been developing quite fast in the last 20-30 years, the choice of most appropriate surgical procedure is not clear in some patients with COM. Hearing results are affected by many parameters like current otorrhoea, perforation type, ossicular status, and granulation tissue or cholesteatoma in the middle ear [10]. CWU or CWD techniques were preferred for eradication of disease according to these changing conditions, with advantage and disadvantage of each technique [11]. Regarding presenting complain, our results showed that otorrhoea and hearing loss were the most common complaint were seen in 100% of the patients. Tinnitus was considered the second prevalent complain, 14 (77.8%) cases were complaining of tinnitus while the other 4(22.2%) cases were not. Vertigo, headache, ear pain and facial nerve problems were not reported in any of our patients. In the study done by Kumar et al., [12] the commonest complaint of patients was otorrhoea,

seen in 100% of cases. Second common presenting complaint was hearing impairment which was seen in 84% of patients. A minority of patients also complained of tinnitus (5.68%), earache (20%), and vertigo (3.4%). All patients were complaining of (CSOM). Cholesteatoma was presented in 16 (88.9%) of our patients. While the other 2 (11.1%) cases were presented with granulation tissue. On the other hand 16 (88.9%) cases were presented with attic perforation, while the other 2 (11.1%) cases were presented with aural polyp. These findings were in agree with that reported by Patel et al., [13] that in COM, (85.3%) cases were of atticointral type and (14.7%) cases were of tubotympanic type. Varshney et al., [14] reported that ossicular erosion was found to be much more common in Cholesteatoma (51.67%) cases vs. (7.77%) cases without. However, in another studies that were carried by Zhu et al., [15] and Yorgancilar et al., [16]. They were found cholesteatoma as primary disease. Regarding the side involved, in this study unilateral involvement of the ear was seen more than bilateral involvement. Olowookere et al., [17] also found unilateral involvement was seen more than the bilateral involvement. Abou-Elhamd et al., [18] found that the other ear is normal in 63% and Kumar et al., [19] in 72% cases. In this study the left ear was involved more than the right ear. Rai, [20] found right ear was involved more than the left one. In contrast Olowookere et al., [17] and Chavan et al., [21] found left ear to be more affected. No knowledge of anatomical differences in the ear structures of right and left ear has been reported. The involvement of one side to other is due to random selection of cases. Regarding ossicular erosion, in our study the incus was reported to be the most eroded ossicle in 18(100%) cases, followed by erosion of malleus in 11(61.11%) cases. While the stapes was intact in all cases. Gomaa et al., [22] and Chavan et al., [21] reported that, incus was, involved in 100% cases. Also Austin, Reported that most common ossicular defect to be erosion of incus with intact malleus and stapes in 29.5% of cases Mathur et al., [23] reported incus erosion was the most common in their study. Regarding hearing assessment, "PTA" and Tympanogram were done to all cases in both groups pre- and six months post-operatively. ABG was calculated as the difference between the postoperative air conduction (AC) and bone conduction (BC) thresholds at frequencies of 0.5, 1 and 2 kHz. Our results showed that; the Mean \pm SD of pre-operative PTA-ABG was 37.78 ± 4.41 dB and 41.11 ± 6.01 dB in groups A and B respectively. The Mean \pm SD of PTA-ABG six months Post-operatively was found as 16.56 ± 7.86

dB and 24.63 ± 4.37 dB in groups A and B respectively. Statistical analysis of these results showed that there was a significant difference between these findings with good results were obtained at the end of 6 months Post-operatively in the group A (SCB) indicating success of the procedure in achievement of good ossicular reconstruction and restoring hearing function. Regarding hearing outcomes and PTA-ABG postoperatively, a successful reconstruction was defined as a postoperative PTA-ABG <20 dB. Calculation of hearing results was in accordance with the American Academy of Otolaryngology Head and Neck Surgery 1995 guidelines for reporting CHL. Hearing results in our study revealed a mean post-operative ABG of 16.56 ± 7.86 dB. In 8(88.9%) cases within group A versus only 3(37.5%) cases within group B. While mean post-operative ABG of 24.63 ± 4.37 dB, was reported in 5(62.5%) cases in group B versus only 1(11.1%) case in group A. A significant difference between the previous two groups regarding ABG six months postoperatively was noted (with SCB had significantly lower ABG than DCB group). Regarding percent improvement in ABG postoperatively, in group A, the improvement was 57.14%. While in group B, it was 41.61%. In a similar study by Mahanty et al., [24] when success was defined as <20 dB. PTA-ABG was done 6 months postoperatively, the success rate was 60% for cartilage ossiculoplasty and 56.25% for PORP. In a comparative study done by Pathan et al., [25] they reported nearly similar results when they used the tragal cartilage as a rectangular piece that is placed over the stapes head and the other end at the annulus of the tympanic membrane in 50 cases versus 50 cases were reconstructed with Teflon prostheses, they found that success was reported in cartilage group with PTA-ABG of <20 dB in 60% cases and 56.25% for Teflon (PORP) group. Our results were in agreement with the study done by Gugliani et al., [26] in a comparative study on 60 cases using tragal cartilage and TORP. They reported that in group A, when using the tragal cartilage as reconstruction prostheses with medial end placed over stapes head and the lateral end kept at the tympanic annulus. They noted the success rate for cartilage was 63.3% and for polyethylene PORP was 53.3% after 6 months of post-operative hearing assessment by PTA. In another study carried out by Ayache et al., [27] when they used the cartilage ossiculoplasty from stapes to tympanic membrane in one stage-intact canal wall tympanoplasty for cholesteatoma surgery, they reported a reduction in PTA-ABG <20 dB in 85.2% postoperatively. Our results were in agree with the study done by Mobashir et al., [28] on 36

cases to compare cartilage ossiculoplasty by lever method with ossiculoplasty by (PORP) during cholesteatoma surgery, they reported that significant improvement in ABG either 6 or 12 months after surgery. The main ABG at 6 months after surgery was 16.3 ± 7.6 dB and the main ABG at 12 months after surgery was 21.3 ± 6.4 dB. And they concluded that Cartilage ossiculoplasty by lever method is an easy procedure for using an autogenous material in ossiculoplasty with no reaction, no extrusion, and also with acceptable hearing outcome.

CONCLUSIONS

Single cartilage block technique is a simple and effective method for ossicular reconstruction and associated with significant improvement in PTA-ABG in those with conductive hearing loss. Especially in patients with intact stapes super structure.

Recommendations:

It is important to perform the SCB technique in a larger series of long-term outcomes

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