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A comparative study of tragal cartilage and autologous incus for ossicular chain reconstruction in type IIB tympanoplasty at Dr. Hedgewar Hospital, Aurangabad

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ABSTRACT

Background: Tympanoplasty is the surgical operation performed for the reconstruction of the eardrum (tympanic membrane) and/or the small bones of the middle ear. Chronic otitis media is a very common condition of middle ear which not only has a high incidence in the world but also in our set up. So, in view of this, we decided to conduct a study on the surgical management of CSOM-tubotympanic type.
Methods: We conducted this study at ENT department of Dr. Hedgewar Rugnalaya, Aurangabad to compare air bone gap closure by using tragal cartilage and autologous incus in type IIB tympanoplasty in patients with chronic suppurative otitis media, (tubotympanic). 66 patients with central perforation of tympanic membrane, necrosed incus and mobile stapes requiring type IIB tympanoplasty, were included as a part of the study.
Results: We performed type IIB tympanoplasty with a routine post-aural incision in 66 patients. According to our observation, both incus and cartilage are good materials for ossiculoplasty, tragal cartilage being better.
Conclusions: After conducting this study we concluded that incus and tragal cartilage both are excellent materials for ossiculoplasty.

Keywords: Air bone gap, Chronic otitis, Chronic suppurative otitis media, Tragal cartilage, Tympanoplasty

INTRODUCTION

The importance of hearing and dry ear is no less. People often visit ENT specialists for discharging ear along with hearing problems and the most common reason being chronic otitis media. It leads to social distress for patients. Incidence rate of chronic suppurative otitis media is 4.76% with 22.6% of cases occurring annually under-fives.[1] According to WHO in 2004 CSOM prevalence in South East Asia is between 0.9% to7.8% and in India is > 4%.[2,3] Worldwide prevalence of CSOM is 65 to 330 million people.[1] Chronic otitis media is defined as permanent abnormality of pars tensa or flaccida most likely a result of acute otitis media, negative middle ear pressure or otitis media with effusion. Chronic otitis media is a very common condition of middle ear which not only has a high incidence in the world but also in our set up. So, in view of this, we decided to conduct a study on the surgical management of this pathology (CSOM-tubotympanic type).

Objectives

The objectives of the study were to do a comparative study using tragal cartilage and autologous incus for ossicular chain reconstruction in type-IIb tympanoplasty and to compare hearing improvements and AB gap closure using the two methods for ossicular chain reconstruction.

METHODS

This study was carried out as per the ICH (step 5), Guidance for Good Clinical Practices (GCP) and the principles of Declaration of Helsinki (Scotland, October 2000). Dr. Babasaheb Ambedkar Medical Research Society's Ethics Committee, Dr. Hedgewar Rugnalaya Garkheda, Aurangabad, had reviewed and approved the protocol and all study related documents. A Single center, open label, double arm, prospective, randomized controlled clinical trial study design was used. This study was conducted for period of August 2015 to February 2017. Study was conducted at ENT department, Dr. Hedgewar Hospital, Aurangabad, Maharashtra. Total 66 Patients was enrolled in this study. The study design is mainly based on the questionnaires provided to the patients. This questionnaire enlists the side effects caused by the drug which will be answered only in a binary format i.e., yes/no. The answers obtained for questions from each patient for the symptoms are then analyzed.

Inclusion criteria

- Age 18 to 60 years
- Both gender male and female
- Patients having central perforation
- Patients with necrosis of long process of incus
- Patients with intact and mobile malleus and stapes
- Patients with conductive deafness.

Exclusion criteria

- Patients with active ear discharge
- Patients having URI
- Patients with cholestatoma
- Patients with necrosed malleus/stapes
- Patients with absent suprastructure stapes
- Patients having tympanosclerosis
- Patients with any generalized disease or immunocompromised state
- Patients with sensory neural hearing loss in the ear to be operated

Method of collection of data

A total 66 patients with central perforation of tympanic membrane, necrosed incus and mobile stapes requiring type IIB tympanoplasty, were included as a part of the study.

Randomization method

A total 66 patients were divided in 2 groups. Group A consisted of 33 patients in whom tragal cartilage used as the material for ossicular reconstruction and group B was of 33 patients in whom autologous incus will be used as the material for ossicular reconstruction.

Now in order to do randomization we used "BLOCK randomization" as the method. We used computerized randomization for this study. All patients in our study underwent preoperative, intraoperative and postoperative criteria as per protocol.

RESULTS

Distribution of age

As per age distribution, we get maximum number from 15-30 age groups i.e. 43.9% of total.

Sex distribution

As per age distribution, out of 66 cases, 66% were females and 34% males.

Table 1: Middle ear mucosa.

Middle ear mucosa	Frequency	Percentage (%)
Edematous	14	21.2
Non edematous	52	78.8
Total	66	100.0

Middle ear mucosa

Table 1 denotes intra-operative middle ear mucosa status. In approximately 79% of cases it was non edematous and in 21% cases edematous. It was found that though middle ear mucosa was edematous, it was not significant. We tried to control upper respiratory tract infection in every case with antibiotics and ear drops prior to surgery.

Simple mastoidectomy was done in every case with edematous middle ear mucosa and patency was established.

Graft uptake at 3 months post-operative follow up

Table 2 denotes graft acceptance at 3 months of follow up. Out of 66 cases graft was not accepted in 5 cases.

Table 2: Graft uptake at 3 months post-operative follow-up.

Graft	Graft accepted	Graft rejected	Total
Autologous incus	29	4	33
Tragal cartilage	32	1	33
Total	61	5	66

Post-operative AB gap closure at 3 months post-operative follow up cases in which graft was not accepted have been excluded in this comparison.

Table 3 denotes that when tragal cartilage was used and total 32 cases were taken after excluding 1 case of graft failure, 87.5% (28) of patients had AB gap closure <20

dB, 12.5% (4) had AB gap closure from 20-30 dB, and none had closure >30 dB.

Table 3: Post-operative AB gap closure at 3 months post-operative follow-up.

Range		Ossiculoplasty material used	
		Tragal cartilage	**Incus**
0-20	Count	28	22
	%	87.5	75.9
20-30	Count	4	6
	%	12.5	20.7
>30	Count	0	1
	%	0.0	3.4
Total	Count	32	29
	%	100.	100.0
Chi-square test	**Value**	**Df**	**Asymp. Sig. (2-sided)**
	1.977a	2	0.372

When autologous incus was used and total 29 cases were taken after excluding 4 graft failures, 76% (22) patients had AB gap closure <20 dB, 20.7% (6) patients had AB gap closure between 20-30 dB, and 3.4% (1) patient had AB gap closure >30 dB. This shows that according to our study tragal cartilage is a better material for ossiculoplasty when compared to incus. Though this difference is not statistically significant. This may be due to small sample size as the study duration was less.

Table 4: Post-operative infections.

Graft	Yes	No	Total
Tragal cartilage	0	33	33
Incus	3	30	33
Total	3	63	66

Table 4 denotes that 3 out of 66 patients had post-operative infections and all were when incus was used. It was an incidental finding when related to incus.

Figure 1: Drilling facet in cartilage.

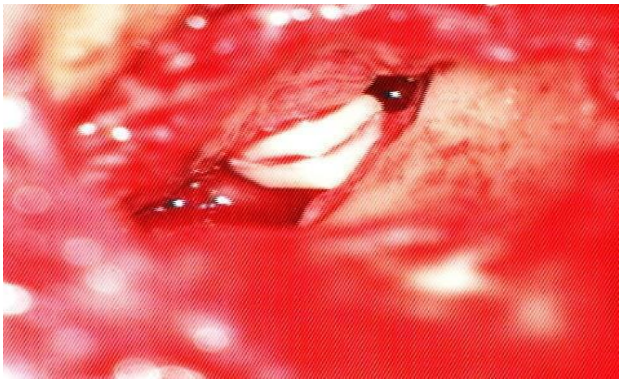

Figure 2: Two tier cartilage.

Figure 3: Facet made in incus.

DISCUSSION

Chronic otitis media is a very common condition seen in general population. As it is known that the procedure used to treat this condition is Tympanoplasty. Autologous incus and tragal cartilage are feasible, cost effective and are easy to use. Materials like TORP and PORP have a high extrusion rate. In view of this we decided to conduct a study based on incus and tragal cartilage. We did not find many studies which compared incus and tragal cartilage as materials for ossiculoplasty. So, we decided to conduct a study using these materials. In the present study involving 66 patients we did randomization and divided the patients in two groups, one of tragal cartilage with 33 patients and one of autologous incus with 33 patients. Block randomization was the method used.

We performed type IIB tympanoplasty with a routine post-aural incision. Temporalis fascia was the graft material used to close the perforations and autologous incus and tragal cartilage for ossiculoplasty. Amongst the previous studies, Mikaelian found a success rate of 72% using cartilage in ossiculoplasty.[1] Mundada and Jaiswal found a success rate of 75% when they used tragal cartilage for ossiculoplasty.[2] In our study when tragal cartilage was used and total 32 cases were taken after excluding 1 case of graft failure, 87.5% (28) of patients had AB gap closure <20 dB, 12.5% (4) had AB gap closure from 20-30 dB, and none had closure > 30 dB.

Malafronte and Giuseppe when used double-cartilage block they found that 81% patients had an AB gap closure within 20 dB.[3] In our study as well, we had to use double tier cartilage graft in few cases. Similarly, in previous studies when incus was used by Donaldson and Siddiq they found success rate of 74% and 70% respectively.[4,5] O'Reilly found that 64% patients had AB gap closure within 20 dB.[6] Gajjar et al had a success rate of 66.7% when AB gap was closure was within 20 dB.[7]

In our study when autologous incus was used and total 29 cases were taken after excluding 4 graft failures, 76% (22) patients had AB gap closure <20 dB, 20.7% (6) patients had AB gap closure between 20-30 dB, and 3.4% (1) patient had AB gap closure >30 dB. This shows that according to our study tragal cartilage is a better material for ossiculoplasty when compared to autologous incus. As it is seen that this difference is not statistically significant. This may be due to small sample size as the study duration was less. Amongst 66 cases graft was not accepted in 5 cases.

According to our observation we found that tragal cartilage was easy to handle. It is light in weight as compared to incus, has appropriate thickness and good stability. Hence both incus and cartilage are good materials for ossiculoplasty, tragal cartilage being better.

This study is limited by lack of long term follow up to see the long term results on audiogram because of short study duration.

This study is limited by small number of studies which have done comparison between incus and tragal cartilage.

CONCLUSION

Incus and tragal cartilage both are excellent materials for ossiculoplasty. Tragal cartilage being easy to handle and more stable material when compared to incus. Post-operative AB gap closure was more when tragal cartilage was used. Though the difference is not statistically significant, a greater number of patients had AB gap closure <20 dB when tragal cartilage (87.5%) was used as compared to autologous incus (76%).

We have found in few cases that when double-tier cartilage was used, stapes head and cartilage was a very stable assembly and approximation between cartilage and temporalis fascia graft was good.

Recommendations

With this study we recommend that; Tragal cartilage should be preferably used over incus as a material for ossiculoplasty. It is easy to handle and forms a more stable assembly.

We would like to suggest that further comparative study on this particular topic on large number of patients and long term follow up is necessary to establish superiority of cartilage over bone for ossiculoplasty.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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