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INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI: 10.21474/IJAR01/15621

DOI URL: <http://dx.doi.org/10.21474/IJAR01/15621>



RESEARCH ARTICLE

A STUDY TO EVALUATE THE HEARING EFFICACY OF BONE CEMENT OSSICULOPLASTY FOR INCUDOSTAPEDIAL REBRIDGING

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Manuscript Info

Manuscript History

Received: 31 August 2022

Final Accepted: 30 September 2022

Published: October 2022

Key words:-

Hydroxyapatite Bone Cement,
Ossiculoplasty,
Incudostapedialrebridging

Abstract

Background:The goal of surgery in cases with chronic otitis media both safe and unsafe types is to achieve a maximal disease clearance and restore the near normal hearing. Various techniques of ossiculoplasty have been used to reconstruct the eroded ossicular chain. The ideal material to be employed in ossiculoplasty techniques should be bio active, bio compatible, safe, stable and with easier to apply. Hydroxyapatite, which is a calcium phosphate compound bone cement is similar in composition to living human bone and satisfies all the all above characteristics of an ideal ossiculoplasty material.

Objectives:The purpose of this study is to evaluate the hearing outcomes of hydroxyapatite bone cement ossiculoplasty done in patients with incudostapedial erosion in both safe and unsafe types of chronic otitis media. The study is also aimed to determine the ideal candidates for bone cement ossiculoplasty.

Methodology:A total of thirty patients of chronic otitis media with incudostapedial erosion were included in the study. Patients underwent ossicular reconstruction with hydroxyapatite bone cement. Preoperative and post operative hearing results with pure tone audiogram and impedance audiometry were recorded. One year period of follow up was done and reduction in air bone gap was analyzed.

Results:The post operative air bone gap was found to be significantly reduced after a period of follow up of one year. The mean preoperative and postoperative pure tone averages was found to be 47.46 and 36.86 respectively. The mean preoperative and post operative air bone gaps were 37.89 and 27.28 respectively with $p < 0.001$. No complications were recorded during the study in relation to the bone cement.

Conclusions:Incudostapedialrebridgingossiculoplasty with hydroxyapatite bone cement is a safe and reliable method that is cost effective and provides significant hearing outcomes in selected patients with no complications recorded.

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Introduction:-

Chronic otitis media is the leading cause of conductive hearing impairment particularly in developing countries. Due to the prevalence of this condition inspite of the advancements in medical sciences, WHO considers this as the commonest cause of persistent hearing loss among the pediatric and adult population of the developing countries [1].

The World Health Organisation estimated that 65-330 million people worldwide are affected by chronic suppurative otitis media of whom 50% are affected by hearing loss [2].

Chronic suppurative otitis media is defined as the chronic inflammation of the middle ear cleft which presents with recurrent ear discharges through a perforation in the tympanic membrane. It may be of two types – mucosal and squamous also called as safe and unsafe types respectively. In addition to the tympanic membrane perforations, erosion or discontinuity of the middle ear ossicles results in conductive type of hearing loss [3]. Ossicular erosion is more common in unsafe type of CSOM compared to the safe type. It is being reported in 14% of the safe ears. The long duration of the inflammatory process and the release of inflammatory mediators induce the activation of osteoclasts and bone resorption and results in ossicular erosion.

Incudal necrosis is the most prevalent ossicular pathology in CSOM involving most frequently the lenticular process followed by the long process resulting in incudostapedial discontinuity. Conductive hearing impairment of more than 40dB in pure tone audiogram and Ad type curve in tympanometry is suggestive of ossicular erosion. Radiological investigations like high resolution CT scan of the temporal bone and peroperative microscopic examination confirms the diagnosis. It is therefore necessary to restore hearing as close as possible to the physiological hearing in patients with ossicular discontinuity. Ossiculoplasty is a reconstructive procedure performed to rebridge the interruption in the middle ear ossicles.

A successful ossiculoplasty requires a stable connection between the remnant parts of the ossicular chain so as to reduce the air bone gap and increase the efficacy of hearing [4]. Various ossiculoplasty techniques have been employed to reconstruct the ossicular chain and to achieve near normal hearing. Ideal materials for ossiculoplasty should be biocompatible, stable, safe, affordable and easily available. In our study we used hydroxyapatite bone cement to bridge the erosion between incus and stapes. The objective of our study is to evaluate the hearing outcome after using hydroxyapatite bone cement to rebridge the theincudostapedialerosiom and to know the ideal cases of ossicular erosion to use bone cement [5]. We analysed the preoperative and postoperative air bone gap and tympanometry results in the included study group.

Materials And Methods:-

This is a prospective observational carried out in the Department of ENT, Govt. Rajaji hospital and Madurai Medical College, Madurai from August 2020 to July 2021, after obtaining approval from the Institutional Ethics committee.

Inclusion and exclusion criteria:

30 patients with ossicular erosion diagnosed by otomicroscopy and HRCT temporal bone between 18 years and 50 years were included. Patients with sensorineural hearing loss and patients with complications were excluded.

A total of 30 patients who attended the outpatient department satisfying the above criteria were selected for the study. Complaints and a detailed otologic and medical history was elicited and they were subjected to a detailed clinical examination of the ear, nose and throat.

The size and site of the perforation, middle ear mucosal status, ossicular chain status were examined using otoscope and findings were recorded. Otoendoscopy was done to confirm the clinical findings. Tuning fork tests were done using 256 Hz, 512 Hz and 1024 Hz tuning fork and findings were documented.

All patients were subjected to pure tone audiometry, and graphical recordings of their hearing thresholds were made. Pure tone averages and air bone gap were calculated. Impedance audiometry was done and findings documented.

Diagnostic nasal endoscopy was done to assess the pharyngeal end of the Eustachian tube and to rule out nasal and nasopharyngeal foci of infection. HRCT scan of the temporal bone was taken for each and every patient before undergoing surgery to know about middle ear and ossicular status and also to rule out cholesteatoma and congenital anomalies of the ear if any.

Systemic examination and investigations were done to assess fitness for surgery. Patients were explained about the surgery and informed written consent was obtained. Patients were posted for cortical mastoidectomy with tympanoplasty and ossiculoplasty using hydroxyapatite bone cement under general anaesthesia.

Tympanomeatal flap was elevated and ossicular chain and middle ear mucosal status was examined under microscope. The mastoid cortex was opened through McEwans triangle using a micromotor drill. Mastoid antrum was reached and disease clearance was done. Aditus was widened and patency achieved.

After thoroughly evaluating the ossicular defect, hydroxyapatite bone cement was applied between the incus remnant and stapes. The cement paste was obtained by mixing the powder component (an hydroxy apatite based mixture of tetracalcium phosphate) with the liquid component (a dilute citric acid) in the ratio of 1:1. The temporalis fascia graft was placed by underlay technique medial to the handle of malleus and tympanomeatal flap was repositioned.

Results:-

Weekly follow up of the patient was done with otoendoscopic examination for the first three weeks thereafter monthly once. Uptake of the graft was checked and recorded. Tuning fork tests were done at the end of 3 months and hearing improvement if present was recorded. Pure tone audiogram and impedance audiometry was done at the end of 3rd month, 6th month and 12th month. Pure tone average, air bone gap, hearing gains were assessed. The results were analyzed in tables and graphs and conclusions were drawn from the data collected.

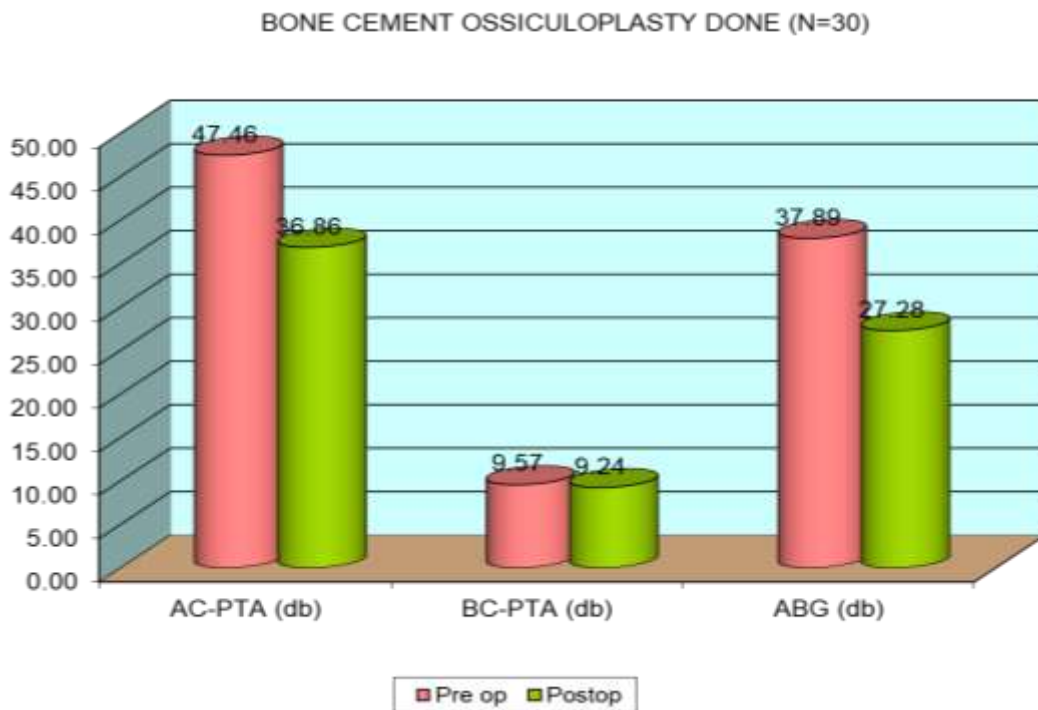


Fig 1:- Chart showing the comparison of air bone gap in preoperative and post operative patients.

BONE CEMENT OSSICULOPLASTY DONE (N=30)	Preop		Postop		p-value
	Mean	SD	Mean	SD	
AC-PTA (db)	47.463	3.713	36.86	6.305	<0.001
BC-PTA (db)	9.57	2.925	9.243	2.898	0.665
ABG (db)	37.893	4.014	27.283	5.775	<0.001

Fig 2:- Table showing the comparison of air bone gap between the preoperative and post operative patients

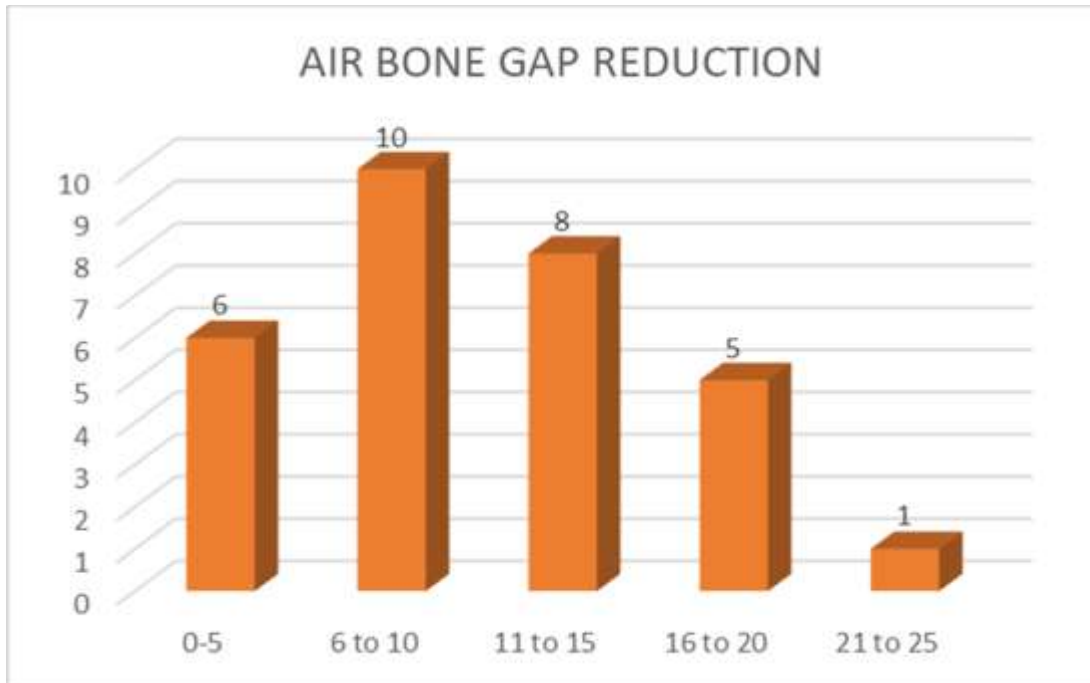


Fig 3:- Graph showing the percentage of patients with air bone gap reduction.

PRE OP ABG - POST OP ABG	No. of Cases	Percentage
< 5	6	20.00
5.1 - 10	10	33.33
10.1 - 15	8	26.67
15.1 - 20	5	16.67
> 20	1	3.33
TOTAL	30	100.00

Discussion:-

Hearing impairment due to chronic otitis media poses a major disability worldwide. Ossicular discontinuity is the important pathology behind the hearing impairment in patients with chronic otitis media both safe and unsafe type. In the earlier days surgical correction was done as a staged procedure [6]. The first sitting was aimed at disease clearance. Reconstruction of the ossicles and restoring of the hearing mechanism was planned in the second sitting. Our study was aimed to overcome the drawbacks by combining the disease clearance and ossicular reconstruction as a singled staged procedure [7].

The material used for ossicular reconstruction in our study was hydroxyapatite bone cement. Calcium phosphates are minerals made out of calcium cations and phosphate anions [8] [9]. They are known as the major inorganic material in around 60% of all local human bones. The presence of calcium phosphates in bones was first found in 1769, and during the 1800s, calcium phosphates that exist in bones were partitioned into various classes [10].

Hydroxyapatite (HAP) has been generally utilized in bone recovery [11]. It is a normally happening type of calcium phosphate that establishes the biggest measure of inorganic parts in human bones [12]. The synthetic equation of

HAP is $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ with a Ca/P proportion of 1.67. HAP is the most steady calcium phosphate with low solvency in physiological conditions characterized by temperature, pH, body liquids, and so forth and the outer layer of HAP can go about as a nucleating site for bone minerals in body liquids [13] [14]. Also, HAP doesn't cause fiery responses when applied clinically

HAP is known to be osteoconductive however not osteoinductive. Therefore, particles like fluoride, chloride, and carbonate particles are subbed depending on the situation [15]. For instance, the utilization of fluoride as an anionic replacement expanded the security and the utilization of magnesium as a cationic replacement expanded the natural impact [16].

In our observational study, outcome of the patients of chronic otitis media with incus erosion who underwent canal wall up or canal wall down mastoidectomy procedure with ossiculoplasty. As an end result of this procedure desirable hearing results were able to be made out. On analyzing, this study proved significant difference between pre and postoperative ABG with value 37.89 dB and 27.28 dB respectively when the patients were followed up for a period of 6 months.

Conclusion:-

This study was conducted mainly to analyze the hearing outcome of bone cement ossiculoplasty in cases of chronic otitis media with incudostapedial erosion. Final analysis of this study showed significant p value on comparing preoperative and postoperative ABG in which there is a postoperative gain. Our study was based on usage of a calcium phosphate bone cement – HYDROXYAPATITE.

To conclude, there is a gain in ABG following surgery. To make this analytical study still definitive, further long term follow up of cases is necessary to analysis the longevity, effectiveness and persistence of gained hearing, disease recurrence and resurgence.

With this available data, this method of ossiculoplasty is worth of trying in patients of chronic otitis media with evident incudostapedial erosion. To conclude, Ossiculoplasty invariably gives a better hearing outcome in cases of chronic otitis media with ossicular erosion when compared to patients who don't undergo ossiculoplasty. Ossiculoplasty should be performed in all cases with hearing loss of the conductive type due to ossicular erosion. Since bone cement has the ease of application and requires minimal expertise, it can be done along with mastoidectomy as a single stage procedure, thus avoiding staged reconstruction. Hydroxyapatite being similar in composition to the human bone, has good osseointegrative properties, biocompatible and nil adverse reactions. It showed significant gain in the air bone gap. No Post operative complications were recorded in the study group.

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