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Efficacy of Ossicular Chain Reconstruction in Improvement of Air Conduction in Chronic Suppurative otitis Media with Ossicular Pathology

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Abstract : *The management of chronic suppurative otitis media had witnessed a profound change over the last 100 years. Most ear reconstruction can be done after successful removal of the disease. However, the main primary aim of any surgical procedure is the complete removal of bone destroying disease. This could be either Canal wall up or Canal wall down Mastoidectomy. For a successful ossicular reconstruction an air-filled middle ear and a functioning eustachian tube are very important prerequisites. The tympanic membrane must be intact, healthy and mobile. The ossicular reconstruction must be secure and stable. Grafts and biomaterials chosen for use in middle ear reconstruction ideally should not induce a sustained foreign body reaction, extrude or biodegrade. In the present study the results of ossiculoplasty are compared with 4 standard criteria (Belfast rule of thumb) for successful out come of ossiculoplasty*

Keywords: *CSOM, Ossicular reconstruction, Belfast rule of thumb, Grafts, Biomaterials.*

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I. Introduction

Hearing is one of the vital senses of man. When such a great vital sensation is lost, life naturally loses its charm. In India, especially in Andhra Pradesh, the incidence of Chronic Suppurative otitis media (CSOM) is very high. About 30% of patients who attend ENT Outpatient Department suffer from CSOM. The management of chronic suppurative otitis media had witnessed a profound change over the last 100 years, from the early attempts at surgical exposure of the middle ear in 1889 to the present day techniques of tympanoplasty. The ear surgeons of today, have at their disposal, a wide range of surgical procedures for the treatment of CSOM, with and without Cholesteatoma. Most ear reconstruction can be done after successful removal of the disease. However, the main primary aim of any surgical procedure is the complete removal of bone destroying disease. This could be either Canal wall up or Canal wall down Mastoidectomy. For a successful ossicular reconstruction an air-filled middle ear and a functioning eustachian tube are very important prerequisites. The tympanic membrane must be intact, healthy and mobile. The ossicular reconstruction must be secure and stable. Grafts and biomaterials chosen for use in middle ear reconstruction ideally should not induce a sustained foreign body reaction, extrude or biodegrade.

II. Aims and Objectives

1. Identifying commonest ossicular pathology in CSOM.
2. Reconstruction of ossicular chain using different graftmaterials .
3. To compare pre-operative and post-operative hearing thresholds (air bone gap dB) in patients who underwent ossiculoplasty.
4. Subjective evaluation is also involved in post operative assessment.

III. Materials and Methods

Forty ossiculoplasties were performed over 2 year period i.e., from August 2010 to August 2012 at Government E.N.T. Hospital, Koti, Hyderabad. Patients of both safe and unsafe type of chronic suppurative otitis media with good cochlear reserve and good eustachian tube function were selected. Both intact canal wall and canal wall down procedures were included. The operations were performed under local or general anaesthesia. Post aural or endaural incision used. After clearing of disease from the middle ear and mastoid as necessary, the status of ossicular chain was assessed and found that necrosed incus in 95% of cases, necrosis of malleus in 27.5%,necrosis of stapes suprastructure in 22.5%of patients. Ossicular reconstructive procedure was planned according to the status of the ossicular chain. Temporalis fascia was used to reconstruct the tympanic membrane. In this study, the cases where autogenous cartilage(conchal) or autogenous bone(incus remnant), homograft septal cartilage, was used-between

1. Stapes head and newly constructed tympanic membrane (short columella).
2. Footplate and newly constructed tympanic membrane (long columella)

All patients underwent thorough history taking, examination under microscope, hematological and radiological investigations, audiometry assessment before surgery and three months and six months after surgery. Pure tone averages (500Hz, 1000Hz & 2000Hz) were compared between pre-operative and post-operative results.

IV. Observations

A total of 40 patients with chronic suppurative otitis media with and without cholesteatoma requiring surgical treatment were treated in the Government ENT Hospital, Koti, Hyderabad within a period of 36 months, were taken into study. The detailed information regarding age, sex, clinical findings, pre-operative air bone gap findings, intra-operative ossicular pathology, type of reconstruction and post-operative air bone gap findings were given in the master chart.

Table 1: Age Distribution

SI.No	Age group (years)	No. of Cases	Percentage
I	11-20	2	5%
11	21-30	30	75%
lll	31-40	6	15%
IV	41-50	2	5%
V	>50	-Nil	0%

All patients were divided into 5 age groups. Group 1: (11-20 year) 5%, GroupII (21-30years)75%, GroupIII:(31-40 years)15%,Group IV:(41-50years)5%, Group V: >50 years 0%.

Table 2: Sex distribution Total No. of Patients (n) = 40

Sl.No.	Sex	No. of Patients	Percentage
1	Males	28	70%
2	Females	12	30%

Table 3: Distribution by involved ear (n=40)

Sl.No.	Ear involved	No. of Patients	Percentage
1	Right	12	30%
2	Left	21	52.5%
3	Both	7	17.5%

In the present study of the 40 cases, 12 patients (30%) patients had disease in the Rt. Ear,21 patients(52.5%) had disease in Lt. Ear and 7 cases, (17.5%) had disease in both ears. Of the 7 patients with bilateral disease, 5 patients had safe type of disease and two patients had unsafe disease. Of the 5 patients with safe type of disease, one patient had got both ears operated and ossicular reconstruction done. Of the 2 patients with unsafe type of disease, the ear with active and extensive disease was operated on first.

Table 4: Symptom Distribution (n=40)

Sl.No.	Symptoms	No. of Patients	Percentage
1	Otorrhoea	40	100%
2	Hearing loss	37	92.5%
3	Ear ache	2	5%
4	Vertigo	1	2.5%
5	Tinnitus	4	10%

In the present study Commonest presenting complaint was otorrhoea in 40 patients(100%) followed by hearing loss in 37 patients (92.5%) & tinnitus in 4 patients(10%), later earache in 2 patients (5%) & vertigo in 1 patient (2.5%) in descending order. One patient got relieved of tinnitus after medical management.

Table 5: Duration of symptoms (n=40)

Sl.No.	Duration (in years)	Otorrohea		Hearing loss	
		No. of Patients	Frequency	No. of Patients	Frequency
1	0 – 3	19	47.5%	27	67.5%
2	3.6 – 6	6	15%	6	15%
3	6.1 – 9	14	10%	-	-
4	9.1 – 1.2	6	15%	3	7.5%
5	> 12	5	12.5%	1	2.5%

Minimum duration of otorrhoea-8months
Maximum duration of otorrhoea- 45 years,
Minimum duration of hearing loss-2months,
Maximum duration of hearing loss -20 years

Overall mean duration of symptoms:
Hearing impairment - 2.8 years
Otorrhoea - 7.25 years.

Table 6: Distribution by ear findings (n=40)

Sl.No.	Ear findings	No. of Patients	Percentage
1	Central perforation	28	70%
2	Postero superior Marginal perforation	5	12.5%
3	Attic perforation	7	17.5%

In the present study on examination under microscope the presence of central perforation was the commonest finding in 28 patients (70%). Attic perforation seen in 7 patients(17.5%) and Postero Superior Marginal perforation in5 patients(12.5%).

Table 7: Pre-operating hearing threshold (n=40)

Sl.No.	Air-bone gap dB	No. of Patients	Percentage
1	0 – 10	0	0%
2	11 – 20	1	2.5%
3	21 – 30	4	10%
4	> 30	35	87.5%

In the present study it is observed that 35 patients(87.5%) had hearing threshold more than 30 dB.

Table 8: Distribution of type of procedure (n=40)

Sl.No.	Procedure	No. of Patients	Percentage
1	Intact canal wall technique	32	80%
2	Canal wall down	8	20%

Table 9: Pre-operative hearing loss in patients with type of surgery (n=40)

Sl.No.	Air bone gap (dB)	Intact canal wall		Canal wall down	
		No. of Patients	percentage	No. of Patients	Percentage
1	0 – 10	-	-	-	-
2	11 – 20	-	-	1	12.55%
3	21 – 30	3	9.37%	1	12.5-
4	> 30	29	90.62%	6	75%

All the patients taken in the study had pure conductive type of hearing loss. Pre-operative Air bone gap >30 dB in intact canal wall procedures was seen in 29 cases (90.62%). while in canal wall down procedures it is seen in 6 patients (75%).

Table 10: Intra-operative ossicular status (n=40)

Sl.No.	Ossicular status	No. of Patients	Percentage
1	Necrosed malleus	11	27.5%
2	Necrosed incus	38	9.5%
3	Absent stapes Suprastructure	9	22.5%

Commonest overall ossicular pathology is necrosis of incus in38 patients (95%) with next necrosed malleus in 11 patients(27.5%,) least ossicular pathology seen is absence of stapes suprastructure in 9 patients (22.5%). In intact canal wall technique incus was absent in 96.8% of cases, stapes suprastructure absent in 12.5% of cases, absent malleus in 9.3% of cases. In canal wall down procedures combined malleus and incus were absent in 87.5% of cases and stapes suprastructure were absent in 75% of cases.

Table:11 pre operative air conduction thresholds with type of procedure

SI.NO	Air conduction thresholds	No.of patients inintact canal wall procedure	percentage	No.of patients in canal wall down procedure	percentage
1	0-10	-	-	-	-
2	11-20	-	-	1	12.5%
3	21-30	15	37.5%	1	12.5%
4	>30	17	42.5%	6	75%

In the present study 15 patients(37.5%) had air conduction threshold with in 30db in intact canal wall procedure and in canal wall down procedure 6 patients had air conduction threshold >30 db.

Table 12: Results according to type of reconstruction in intact canal wall technique (n=32)

Sl.No.	Reconstruction	Closure within 20 dB		Closure within 30 dB	
		No. of Patients	Frequency	No. of Patients	Frequency
1	Short columella	18	56.25%	29	100%
2	Long columella	-	-	3	100%

In the present study ,the results varied according to the type of reconstruction, A closure of air bone gap within 20 dB was achieved in 18(56.25%) patients with short columella reconstruction. All the patients had air bone gap closure with in 30db.

Table 13: Reconstruction in canal wall down (n=32)

Sl.No.	Reconstruction	Closure within 20 dB		Closure within 30 Db	
		No. of Patients	Frequency	No. of Patients	Frequency
1	Short columella	-	-	1	100%
2	Long columella	1	12.5	2	25%

In the present study patients air bone gap less than 20 dB is seen in 1(12.5 %.) patient using long columella technique.

Table 14: Results according to the type of graft material (ICW technique) (n=32)

Sl.No.	Type of graft material	Closure within 20 dB		Closure within 30 dB	
		No. of Patients	Frequency	No. of Patients	Frequency
1	Incus remnant (A)	17	74.07%	25	92.59%
2	Conchal cartilage	1	100%	-	-
3	Septal cartilage (H)	-	-	4	100%

A = Auto graft ,H = Homo graft

In the present study as the results were assessed according to the type of graft material used, it is evident that the air bone gap closure less than 20 dB is seen in 17 patients(74.07%) using incus remnants.

Table 15: Results according to the type of graft material(CWD) (n=08)

Sl.No.	Type of graft material	Closure within 20 dB		Closure within 30 dB	
		No. of Patients	Frequency	No. of Patients	Frequency
1	Incus remnant (A)	1	-	2	100%
2	Septal cartilage (H)	1	-	2	28.56%

In the present study In canal wall down technique, closure within 20 dB using septal cartilage is seen in one patient(14.28%).

Table:16 Post op air conduction thresholds according to type of procedure

SI.NO	Air conduction thresholds	Intact canal wall procedure	percentage	Canalwall down procedure	Percentage
1	With in 20db	28	87.5%	1	12.5%
2	With in 30db	4	12.5%	4	50%
3	>30db	-	-	3	37.5%

In the present study air conduction thresholds with in 20db is seen in 28 patients(87.5%) in intact canal wall procedures and in canal wall down procedures air conduction thresholds with in 20db is seen in 1 (12.5%)patient.

IV. Discussion

The present study was conducted to know the commonest ossicular pathology in patients with CSOM. It is conducted to try the different available graft materials in Ossicular reconstruction in order to review the post operative results in comparison with pre-operative audiological assessment. This study includes 40 patients clinically diagnosed as CSOM of both safe and unsafe types. Among the 40 patients males were 28 and females were 12.Patients who had CSOM in Left ear were (52.5%) and (30%) had in the right ear. 7 patients 17.5% had bilateral ear disease.

The incidence of middle ear disease in India as shown There is 12.45 million (39.30%) out of 31.70 million suffering from chronic otitis media diseases in India. Rest of 2.64 million (8.32%) out of 31.70 million suffering from various other types of middle ear diseases in India.[44]In our hospital the incidence chronic suppurative otitis media attending the out patient department of govt ENT hospital is 30%. It is observed in the present series that majority of the patients belonged to the age group of 21 to 30 years i.e. 75% followed by the age groups of 31 to 40 i.e 15% and 11 to 20 years 5%. V.K. Poorie and Aarti Iyer found the incidence more common in the age group of 0 to 10 years. This may be because this study includes those patients who underwent surgery of mastoid, unlike their study which is a bacteriological study.C.S.O.M is found to be more common in males. The ratio of M: F is 1.5:1 in the present study. It was 1.4:1 in the study by **V.K. Poorie**. A similar study by

Eugenijus Lesinskas et al of Lithuania showed incidence in M: F as 1.4: 1. Prevalence in Britain, 0.9% of children and 0.5% of adults have chronic suppurative otitis media with no difference between the sexes (Paul Hewish et al).

David parry et al (46) studied that otorrhoea is the most common presentation followed by hearing loss, ear ache ,giddiness which is similar to our study where 100% of patients presented with otorrhoea .

Homograft prosthesis was used exclusively in ossicular reconstruction from 1972 to 1986(35) as revised by **wehrs.**

O'Reilly, Robert C*; Cass, Steven P (2005)[36] and others proposed Sculpted autologous incus interposition provides hearing success comparable with current allograft prosthesis studies, has a very low extrusion rate, and remains stable over time.

In the present study 74.07% of patients had air bone gap closure with in 20 db using incus remnant in intact canal wall technique and closure within 30db is seen in 100 % (out of 8) in canal wall down technique.

According to

Dornhoffer JL[45] Canalwall-up mastoidectomy, with Ossicular reconstruction gave good hearing results when compared to canal wall down

In the present study 70% of the patients achieved closure of air bone gap with in 20db with intact canal wall technique when compared to canal wall down.

Shrikrishna B H[37] (2011),and others proposed Ossiculoplasty results are best with autologous incus, followed in descending order by homologous septal cartilage and Teflon PORP .In our study results are best with autologous incus followed by homograft septal cartilage.

Austin (1972), Fisch (1994) and Pennington[38](1948) in their extendedperiod of study(2-10) reported good stability of hearing results with auto grafts. In the present study hearing improvement with in 20db is seen in 70% of patients using autograft.

Black[39] compared the results of malleus stapes assembly with malleus foot plate assembly and achieved the closure of air bone gap within 20db in 86 % of patients in the former and 80% in the later.

In the present study the results of ossiculoplasty are compared with 4 standard criteria for successful out come of ossiculoplasty

Belfast rule of thumb(40)

- The operated ear must reach an air conduction level of 30 db at speech frequencies or be with in 15 db of other ear for the patient to benefit (smyth and Peterson 1985)
- Closure of air bone gap with in or equal to 20 db.In the present study closure of air bone gap within 20db using incus is seen in 17cases(74.07%) and using septal cartilage closure with in 30db is seen in 4 patients(100%).
- Improvement in air conduction more than 40db.
- Gain in postoperative hearing of 15db.

In the present study air conduction thresholds within 20db is seen in 28 patients (87.5%) in intact canal wall procedure and in canal wall down closure with in 20 db is seen in 1 patient(12.5%).

Bauer[41] (2000) analyzed his 34 years of experience of autogenous incus and cortical bone to form a collumella between stapes head and tympanic membrane. In their study 85% showed an air bone gap closure < 20 dB and 43% showed closure < 10 dB when the tympanic membrane was normal.

We analyzed our results according to the type of reconstruction and found that short columella assembly gave

result within 20 dB in 18 patients and within 30 dB in 29(100%)patients and followed by long collumella with 3 patients within 30dB in intact canal wall technique,

Kartush[42](1994) found that the results of incus remnants and cortical bone were similar. They also found that the autogenous bone provides better sound transmission than cartilage. In our study also, we achieved better results with autogenous bone as compared to homograft cartilage.

Guildford[47] and others recommended transposing the residual auto graft incus on to its side so that it lies on the stapes capitulo and beneath the manubrium.

Zollner[48] described the benefits of sculpturing the autologous incus in order to obtain better assembly and reduce subsequent ankylosis..In the present study also autologous incus was used 26 patients achieving closure with in 20db in 17 patients.

In this era, where a large variety of innovative artificial prosthtic materials are being used to replace and reconstruct the ossicular chain, auto grafts still play a significant role. In our study, in patients with safe chronic suppurative otitis media, we have found fairly good hearing results in patients implanted with autogenous cartilage and bone. These are easily available and cost effective. Moreover, they are stable and are easily accepted by the body and never extruded out.

V. Conclusions

40 ossiculoplasties were performed at Government E.N.T. Hospital, Koti, Hyderabad, A.P., during August 2010to august 2012 (over a period of 2 years) in patients with chronic suppurative otitis media (both safe and unsafe type of disease) presenting with pure conductive hearing loss.

1. Majority of the patients (95%) were more than 20 years of age with male predominance (Male: Female 70:30) and left ear 21 patients(52.5%) is involved more frequently compared to the right ear.

2.Commonest complaints were otorrhoea 40patients (100%) and hearing loss in 37 patients (92.5%)with average duration of hearing impairment is 2.8 years and otorrhoea is 7.25 years.

3.Central perforation was the commonest ear finding seen in 28 patients (70%) followed by attic Perforation in 7 patients (17.5%) and postero-superior marginal perforation 5 patients (12.5%).

4.In the present study it is observed that35 patients(87.5%) had hearing threshold greater than 30dB.

5. 32 (80%) patients underwent intact canal wall procedure while 8(20%) patients had undergone canal wall down modified radical mastoidectomy.

6. Necrosis of incus noted in 38 patients(95%) -the most common ossicular abnormality, followed by absent malleus in 11 patients(27.5%)and stapes absence in 9 patients(22.5%). All ossicles were present in one patient,both malleus and incus were absent in 5% of cases and incus, stapes suprastructure absent in 5% of cases.. In 17.5% of cases all ossicles were absent.

7.In intact canal wall technique, the commonest ossicular pathology seenwas incus necrosis (96.87%) followed by absence stapes suprastructure (27.5%),necrosed malleus in 9.37% of cases.

8. In canal wall down procedures both malleus and incus were lost in 87.5% of cases while stapes suprastructure was abscent in 75% of cases.

9.The overall success rate of the operations were assessed according to the closure of the Air Bone gap within 20dB and closure of A-B gap within 30dB. In intact canal wall technique Air Bone closure within 20dB is achieved in 72.72% of cases and closure within 30 db achieved in 100% of cases. In Canal Wall down technique, closure within 20dB is seen in 12.5% of cases and less than 30dB Air Bone gap closure seen in 37.5% of cases.

10. The results varied according to the type of material used in ossicular reconstruction. In Intact Canal wall technique, for autogenous incus A-B gap < 20 dB was seen in 17 patients(74.07%) of cases and A-B gap < 30 dB is seen in 25 patients(92.59%) of cases. For homologous septal cartilage - A-B gap < 30 dB was seen in 100% of cases. We used conchal cartilage in one case where the success rate is 100% i.e.. closure of air bone gap within 20 dB. In Canal Wall down technique for homologous septal cartilage closure within 30 dB is seen in 2 patients(25%) and closure within 20 dB is seen in patient(12.5%) of cases.

11. The results varied according to the type of ossicular reconstruction.

In Intact Canal wall technique

For short columella procedure

Air bone gap < 20 dB is seen in18 patients(56.25%) of cases and air bone gap < 30dB seen in29 patients (100%) of cases.

For long columella procedure

Air bone gap < 30 d8 is seen in 3 patients (100%).In Canal wall down procedures, patients with Long columella air bone gap less than 20 dB is seen in1 patient(12.5 %).The operated ear reached air conduction threshold with in 20db in 28(87.5%) patients in canal wall up procedure and air conduction closure with in

30db in 4(50%) patients in canal wall down procedure satisfying bellfast rule of thumb.

In this era, where a large variety of innovative artificial prosthetic materials are being used to replace and reconstruct the ossicular chain, autografts still play a significant role.in the present study, in patients with safe chronic suppurative otitis media, we have found fairly good hearing results in patients implanted with autogenous cartilage and bone. These are easily available and cost effective. They are stable and are easily accepted by the body and never extruded out.

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