

## A Prospective Observational Study to Determine the Surgical Outcome in Chronic Otitis Media with Cholesteatoma

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### Abstract

**Aim:** The aim of this study to evaluate the surgical outcome in chronic otitis media with cholesteatoma.

**Methods:** This prospective observational study was carried out in the Department of ENT, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India, for 1 year. All patients of chronic otitis media with cholesteatoma - new cases, and previously operated cases with residual or recurrent disease. A written informed consent was taken from all patients included in the study. Detailed history-taking, thorough clinical examination was done for these patients. The data collected was entered into a specially designed case record form.

**Results:** The mean preoperative ABG was 36 dB and the mean postoperative ABG was 22 dB with an improvement in mean ABG of 14 dB. 57% of the study population underwent ICW mastoidectomy and 43% underwent CWD mastoidectomy. The mean improvement in ABG in ICW mastoidectomy was 16dB whereas it was 11.4dB in CWD mastoidectomy showing a statistically significant difference. All patients in the study population underwent ossicular reconstruction of which 52% underwent myringo platinopexy (MP) and 48% underwent myringo- stapedopexy (MS). The mean improvement in the ABG in subjects who underwent MP was 13.5dB and in MS was 14.6 dB. Postoperative complications were noted in 15% of the study population. Our study had 6 patients undergoing revision surgery, all of which were after a period of 1 year from the previous surgery undergone by the patients for cholesteatoma. From this the recurrence rate for cholesteatoma can be determined at 14%.

**Conclusion:** The controversy of ICW vs. CWD surgery is here to stay for long. However, it can be noted that both procedures have their own advantages and disadvantages and when performed meticulously both serve the purpose of rendering the patient a safe ear.

**Keywords:** COM, Cholesteatoma, Hearing outcome, Residivism, Post-operative complications.

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## Introduction

Chronic suppurative otitis media has been an important cause of middle ear disease since prehistorical time[1] It is a worldwide health problem and is still prevalent in the modern antibiotic era[2] It is one of the most common ear disease in developing countries[3] Chronic otitis media (COM) is an inflammatory process in the middle ear space that results in long-term, or more often, permanent changes in the tympanic membrane including atelectasis, dimmer (formerly “monomer”) formation, perforation, tympanosclerosis, retraction pocket development, or cholesteatoma[4] Cholesteatomas that arise from retraction pockets are known as primary acquired cholesteatomas on the basis that infection has not given rise to the cholesteatoma. Several theories have been advanced to explain the formation of primary acquired cholesteatomas, including invagination of the pars flaccida, basal cell hyperplasia, otitis media with effusion, and perforation of the pars flaccida membrane with epithelial ingrowth. Patients with cleft palates are particularly prone to the development of primary acquired attic cholesteatomas[5] Like primary acquired cholesteatomas, several pathogenic mechanisms may contribute to the formation of secondary acquired cholesteatomas. The implantation theory, the metaplasia theory, and the epithelial invasion theory have all been advanced as possible mechanisms involved in cholesteatoma formation.

A unique feature that cholesteatoma and tympanic membrane epithelium have in common is migration. No other epithelium tested, including skin, vocal cord, and oral epithelium, has shown the locomotion present with tympanic membrane epithelium and cholesteatoma[6]

Once a retraction pocket develops, the epithelial migratory pattern is altered and keratin accumulates. This is the second stage in the development of a cholesteatoma. The sac slowly enlarges by

accumulation of keratin and other debris until the walls of the attic are reached. Once this point is reached, bone resorption occurs.

Congenital and acquired cholesteatomas can be eradicated from the temporal bone only by surgical resection.[7]

The primary goal of surgery for COM is to eradicate disease and obtain a dry, safe ear. Restoration of hearing is by necessity a secondary consideration[8]

### Surgical approach

Canal wall-down procedure[9]

These procedures have as their unifying theme a surgical strategy involving removal of varying portions of the bony EAC to obtain improved access to the epitympanic and mesotympanic spaces for management of chronic ear disease. These approaches also leave some or all of the diseased spaces of the temporal bone permanently exteriorized to help avoid recurrent disease: Following canal-wall-down mastoidectomy, the patient is left with a cavity. The keratinizing squamous epithelium that lines the mastoid bowl is prone to collecting debris and should be cleaned on a regular basis. Many patients must adhere to lifelong water precautions to minimize risk of infection.

Intact canal wall/canal wall up procedures[10]

The canal wall up mastoidectomy involves removing the mastoid air cells lateral to the facial nerve and otic capsule bone while preserving the posterior and superior external auditory canal walls. This technique affords access to the epitympanum while maintaining the natural barrier between the external auditory canal and mastoid cavity. This approach is preferred generally to avoid the long-term problems associated with canal wall down procedures. This approach can be combined with a facial recess dissection for:

- Removal of disease in the recess.
- Better exposure of the posterior mesotympanum around the oval and round windows.
- Better visualization of the tympanic segment of the facial nerve.
- Better middle ear aeration postoperatively.

For increased exposure, the facial recess can be extended inferiorly or superiorly to gain complete access to the hypotympanum and epitympanum.

The decision to remove the wall is most often made during surgery, when the extent of disease is fully appreciated. This study compares the surgical outcome of these procedures done for cholesteatoma in terms of hearing outcome, residivism and post-operative complications.

### Material and methods

This prospective observational study was carried out in the Department of ENT, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India, for 1 year. after taking the approval of the protocol review committee and institutional ethics committee.

### Inclusion criteria

All patients of chronic otitis media with cholesteatoma - new cases, and previously operated cases with residual or recurrent disease. A written informed consent was taken from all patients included in the study. Detailed history-taking, thorough clinical examination was done for these patients. The data collected was entered into a specially designed case record form. The patients were followed up for a period of 6 months. The pre-operative and 1 month, 3 months and 6 months post-operative Pure-tone average was recorded

for each patient along with detailed examination to look for any post-operative complications. This study comprised of 42 patients who were admitted and who underwent surgical management in the Department of ENT. All the 42 patients who underwent surgical management for cholesteatoma in this study were, in their own language, explained in detail about the nature of the disease, the anaesthetic procedure, the operative procedure and possible complications and consent was obtained from them. In all the patients" thorough examination, routine investigations, relevant audiological (pure-tone audiometry) and radiological tests (X-ray mastoid, HRCT-temporal bone) were performed.

### Data analysis

The data was analyzed using the IBM SPSS v25.0 software with the significance determined using the Chi square test and the independent t test.

### Results

The study comprised 42 patients who underwent surgical management for cholesteatoma.

All patients underwent satisfactory removal of the disease (mastoidectomy) and hearing reconstruction (tympanoplasty) in a single stage surgery. Temporalis fascia graft was used for reconstruction of the tympanic membrane defect by underlay technique.

The following is the surgical outcome of these patients.

### Hearing outcome

The mean preoperative ABG was 36 dB and the mean postoperative ABG was 22 dB with an improvement in mean ABG of 14 dB.

**Table 1: Comparison of ABG in the mastoidectomy procedures**

| Mastoidectomy        | Net improvement in ABG (Mean±Sd) |
|----------------------|----------------------------------|
| ICW (N=24)           | 16.03±7.5                        |
| CWD (N=18)           | 11.39±7.4                        |
| Independent 't' test | P value=0.04 (significant)       |

57% of the study population underwent ICW mastoidectomy and 43% underwent CWD mastoidectomy. The mean

improvement in ABG in ICW mastoidectomy was 16dB whereas it was 11.4dB in CWD mastoidectomy showing a statistically significant difference.

**Table 2: Comparison of ABG in the tympanoplasty procedures**

| Tympanoplasty              | Net improvement in ABG (Mean±SD) |
|----------------------------|----------------------------------|
| Myringoplastinopexy (N=22) | 13.53±6.6                        |
| Myringostapediopexy (N=20) | 14.60±8.9                        |
| Independent 't' test       | P value=0.60 (not significant)   |

All patients in the study population underwent ossicular reconstruction of which 52% underwent myringo-platinopexy (MP) and 48% underwent myringo- stapedopexy (MS). The mean improvement in the ABG in subjects who underwent MP was 13.5dB and in MS was 14.6 dB.

There is an improvement in the AC threshold, which had maximum distribution of subjects between 41-60 dB preoperatively to 21-40 dB postoperatively.

#### Residivism

In the 6 months follow up, 3 patients were found to have residual disease and none had recurrence. For these 6 months follow up

the residual rate was determined at 7% with no recurrence noted. All patients who had residual disease had undergone ICW mastoidectomy. Thus, the residual disease rate for ICW mastoidectomy was determined as 12% whereas recurrence rate was nil. CWD mastoidectomy had no patients presenting with residual or recurrent disease in the 6 months follow-up period, but to note is that 5 of the 6 patients who underwent revision surgery for recurrent cholesteatoma had previously undergone CWD mastoidectomy. 6 months being too short a follow-up period, the residivism rates are not significant. A long-term follow-up study will be required to determine the same.

**Table 3: Residivism – ICW vs. CWD surgery**

| Residivism              | ICW (N=24) | CWD (N=18) |
|-------------------------|------------|------------|
| Residual disease        | 3          | 0          |
| Recurrent disease       | 0          | 0          |
| Total % in 6 months F/U | 12.5       | 0          |

In 1 patient who underwent canal wall down mastoidectomy in our study there was recurrent disease noted in the form of retraction with squamous ingrowth noted at one-year follow-up. This patient had preoperative facial nerve palsy grade III with complete recovery noted at 3<sup>rd</sup> month follow-up but at 1-year follow-up patient had hard of hearing and on examination had tympanic membrane retraction. Intraoperatively patient was noted to have displacement of the ossicular graft with squamous ingrowth.

Our study had 6 patients undergoing revision surgery, all of which were after a period of 1 year from the previous surgery undergone by the patients for cholesteatoma. From this the recurrence rate for cholesteatoma can be determined at 14%.

#### Post-operative complications

Postoperative complications were noted in 15% of the study population.

**Table 4: Post-operative complications– ICW vs. CWD surgery.**

| Post-operative complications                 | ICW (N=24) % | CWD (N=18) % |
|--|--------------|--------------|
| Significant external auditory canal stenosis | 8.33         | 0            |
| Post-aural wound dehiscence                  | 0            | 5.55         |
| Significant medialization of pinna           | 0            | 83.33        |

**Table 5: Hearing outcome in study by Dodson et al.**

| Closure of ABG (dB) | ICW | CWD |
|---------------------|-----|-----|
| -10-1               | 25  | 36  |
| 0-10                | 36  | 07  |
| 11-20               | 17  | 21  |
| 21-30               | 14  | 21  |
| >30                 | 08  | 14  |

Significant external auditory canal stenosis was noted in patients undergoing ICW mastoidectomy determined at 8.33%. 1 (2.4%) patient who underwent revision CWD had post aural wound dehiscence. Incidentally this patient was noted to have excessive blood loss intraoperatively. It remains unclear whether the complication could be attributed to the CWD procedure or to other patient related factors.

No patient in our study developed facial nerve palsy and sensorineural hearing loss postoperatively owing to the strict vigilance, meticulous approach and proper identification and respecting of the anatomical landmarks at surgery.

Also, there were no occurrences of perichondritis noted in these patients who underwent surgery for cholesteatoma.

Of mention is the cosmetic defect caused by the significant change in the position of the pinna following a CWD procedure. The pinna was more medialized, and patients had a concern of loss of symmetry of the ears. One patient who had undergone a CWD mastoidectomy on the opposite ear previously had a special request for having the same surgery to be done on the presenting ear in order to have symmetrical appearance of the ears.

### Discussion

The ICW and CWD mastoidectomy procedures each have inherent advantages and limitations that involve ease of disease

removal, incidence of recurrent or residual disease, and extent of postoperative care[11]

Several studies have compared the surgical outcomes of the two procedures, each author favouring one, and some studies favour both procedures. In our study we have compared the surgical outcome in terms of hearing outcome, residivism and post-operative complications.

### Hearing outcome

In a study done by Dodson et al on pediatric cholesteatoma, statistical analysis of the means for postoperative air-bone gap, closure of the air-bone gap, change in bone conduction, and postoperative SRT revealed no significant differences between groups at a 95% confidence interval[12] The hearing outcomes in terms of closure of air-bone gap in this study were as depicted in the following table.

In our study we have noted that closure of air-bone gap was better in the ICW group. Excellent closure of air-bone gap was noted in 2 patients who had air-bone gap of less than 10dB in the ICW group.

In a CWD mastoidectomy, the bony tympanic annulus and much of the ear canal is removed, and the tympanic membrane graft is placed onto the facial ridge and medial attic wall. This results in a significant reduction in the size of the residual middle ear space. However, as long as this air space is  $\geq 0.5$  cc, the resultant loss

of sound transmission should be less than 10dB. Since the average volume of the tympanic cavity is 0.5–1cc, a CWD procedure should create no significant acoustic detriment, so long as the middle ear is aerated[13] Indeed, clinical studies comparing the acoustic results of CWD vs ICW mastoidectomy have shown no significant difference[14,15]

Our study shows a statistically significant difference in the hearing improvement between the 2 groups. The mean improvement in ABG in ICW mastoidectomy was 16dB whereas it was 11.4 dB in CWD mastoidectomy showing a statistically significant difference as determined by the independent t test with a p value of

0.04. However, it can be further noted that most patients requiring a CWD procedure also had stapes supra- structure erosion requiring a MP.

Hearing outcomes were also better in patients who underwent Myringostapediopexy (MS) vs. myringoplastinopexy (MP). The mean improvement in ABG in MS was 14.6 dB and in MS was 13.5 dB, however this was not statistically significant, as determined by the independent t test with a p value of 0.06. Autologous ossicles gave the best results for reconstruction in terms of air-bone closure.

### **Residivism**

Residivism includes residual and residual disease. Residual disease indicates the persistence of disease after incomplete removal as revealed during the second stage surgery. Recurrent cholesteatoma was defined as a newly formed disease process secondary to a retraction pocket.

Following an initial surgery, regardless of whether an ICW or CWD technique is used, both residual and recurrent disease- recidivism are possible. Canal wall defects, created by the original disease process or by the surgeon during removal of the initial cholesteatoma, predispose to retraction

pockets. Recurrent cholesteatoma is primarily a concern with ICW mastoid surgery. To minimize these problems adequate surgical expertise is required. All our patients who underwent ICW mastoidectomy had reconstruction of the lateral attic defect with autologous cartilage and soft tissues as required.

Detection of residual disease after surgery is easier with a CWD mastoidectomy. When the canal wall has been removed, only disease in the mesotympanum, hidden by the tympanic membrane, may be difficult to see. An exception to this condition would be cases in which tissue flaps and/or bone pate have been used to partially obliterate the mastoid cavity. With an ICW, the mastoid and epitympanum are not accessible to postoperative inspection. Planned second-stage surgery may mitigate postoperative concern in ICW mastoid surgery.

One particularly large patient population was assembled by Tos and Lau to evaluate the late results of surgery for cholesteatoma[16] This series included 740 patients of all ages (mean age, 39 years) followed for an average of 9.2 years. The ICW procedure was used in 324 patients and the CWD in 262. The group found no significant differences in either recurrent or residual cholesteatoma when comparing the two approaches.

The authors found that the rate of recidivism was more dependent on anatomical position of the cholesteatoma and concluded that ICW is the procedure of choice based on improved hearing profiles and fewer postoperative complications.

This study was concluded way back in 1989, with the advancements in technology ever-since the surgeon being equipped with angles scopes and a wide variety of angled instruments should be able to preserve the posterior canal wall as much as possible and our study advocates the same.

### **Post-operative complications**

The principal advantages of the ICW technique are the more rapid healing and, most importantly, the obviation of many long-term postoperative concerns. Epithelialization of the mastoid cavity in CWD cases may be a slow process (taking months) and certain areas may require special attention to promote healing[11] In our study most patients (90%) had satisfactory healing of the mastoid cavity at 6 months follow-up but required special attention and extra care. Once healing is complete, the mastoid bowl may require periodic cleaning because of irregular contours and the inability of desquamated epithelium to migrate effectively to the meatus. This condition predisposes to mastoid bowl infection (especially if water exposure has occurred). Our centre has also seen many patients who had undergone CWD procedures in the past with recurrent discharge and cavity problems. Meticulous surgery mitigates these issues. The facial ridge has to be reduced adequately with complete saucerization of the mastoid bowl. Also, the meatoplasty has to be adequate to minimize post-operative cavity problems.

By contrast, healing of the ICW mastoidectomy is usually rapid, periodic ear cleanings are not necessary, the incidence of external ear infections is not increased, and no limitations of water activities are imposed. In addition, an ICW approach provides more options for a hearing aid (e.g., canal type), if required, and its use is usually more trouble free (e.g., involving fewer canal infections).

### Conclusion

The controversy of ICW vs. CWD surgery is here to stay for long. However, it can be noted that both procedures have their own advantages and disadvantages and when performed meticulously both serve the purpose of rendering the patient a safe ear. The ICW procedure leaves behind an anatomically normal appearing ear and when quality of life concerns needs to be addressed this should be the procedure of

choice, with advancement in technology and availability of angled endoscopes which have marched well into otology. The CWD procedure should be reserved to cases presenting with complications and in patients who are more likely to be lost to follow-up.

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