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Original Research Article

A COMPARATIVE STUDY ON MASTOID CAVITY OBLITERATION VERSUS OPEN MASTOID CAVITY IN MODIFIED RADICAL MASTOIDECTOMY PATIENTS

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Abstract

Background: Modified radical mastoidectomy, which is performed for unsafe type of chronic otitis media, ends up with an 'open' mastoid cavity. This often remains as a source of chronic discharge and harbours debris and therefore requires periodic cleaning. Difficulties in fitting the hearing aid is another issue related with this condition. To overcome these problems, surgeons today prefer to obliterate the cavity. The aim is to compare mastoid cavity obliteration versus open mastoid cavity in post modified radical mastoidectomy patients. **Materials and Methods:** 40 patients with chronic otitis media scheduled to undergo canal wall down mastoidectomy were randomized either to open mastoid cavity technique (n=20) or mastoid cavity obliteration technique group (n=20). Demographic, clinical profile and intraoperative complications were noted and post-operative evaluation was done at regular intervals. The two groups were compared for parameters like pain (VAS), discharge, bleeding/aural granulation, wax deposition, perichondritis, healing etc. Data was compared statistically. **Result:** The two groups were comparable for age, sex, laterality, side and pure tone audiometry. Post-operatively, patients operated with open mastoid cavity technique had significantly higher pain score at day 7 and day 15 follow-up. There was no significant difference between two groups for any of the other outcomes studied. At day 90, none of the patients in either of two groups had pain and perichondritis. Discharge, bleeding/aural granulation and wax deposition was seen in 5 (25%), 1 (5%) and 2 (10%) of with open mastoid cavity technique as compared to 2 (10%), 0 (0%) and 0 (0%) of mastoid cavity obliteration technique group patients respectively. At day 90 healing rate was higher in mastoid cavity obliteration technique group (75%) as compared to the other group (50%) (p=0.102). **Conclusion:** Mastoid cavity obliteration had an edge over open mastoid cavity technique with respect to higher healing rate and lesser pain in early post-operative period.

INTRODUCTION

Modified radical mastoidectomy for total excision of cholesteatoma ends up in an 'open' mastoid cavity. Despite being a common procedure being performed by this open cavity is at a risk of breakdown of skin and recurrence of infection as it remains to be a source of chronic discharge and harbours the debris. This open cavity is sometimes cause of dizziness as a result of exposure of semicircular canals to direct caloric stimulation by cold air/water entering the cavity. Moreover, it frequently requires cleansing under medical supervision apart from having esthetic issues too.[1] Difficulties in fitting the hearing aid is another issue related with open mastoid cavity.[2]

Owing to these limitations, surgeons today prefer to overcome these disadvantages of leaving the mastoid cavity open. Various strategies needed to overcome the limitations of open mastoid cavity include reducing the number and size of cavities.[2] Though these strategies are helpful, yet they are not able to completely overcome all the limitations related with open mastoid cavity.

As such mastoid obliteration seems to be the only viable option that has capability to overcome all the

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limitations of open mastoid cavity that can be accomplished using both biological as well as non-biological grafts apart from use of local flaps, viz. fat, cartilage, bone, dust, variety of flaps (myofascial and fascial-periosteal flap), hydroxyapatite and bio-active glass.[3]

Although mastoid obliteration is a useful strategy to overcome the limitations of open mastoid, it also suffers from a shortcoming restricting its universal use. The shortcoming associated with mastoid obliteration is difficulty to monitor the mastoid cavity for recurrence of an infection.

As noted above the choice of leaving the mastoid cavity open or to carry out mastoid obliteration is very difficult and needs to be examined in the light of clinical evidence. Hence, the present study was planned to carry out a comparative assessment of mastoid cavity obliteration and open mastoid cavity in post modified radical mastoidectomy patients at a tertiary care centre in North India.

MATERIALS AND METHODS

This single blind randomized controlled study was carried out at Department of ENT, Teerthankar Mahaveer Hospital and Research Centre (TMHRC), Moradabad after obtaining permission from Institutional Ethics Committee (TMU/IEC/20-21/063,DATED- 25/01/2022) and consent from the participants. The sample size projections were based on a previous study by Hembrom et al.4 who reported the difference in time taken for reepithelization between the two groups to be 5.2 weeks. The rounded off sample size was calculated as 40, at 95% confidence, 80% power with an estimated pooled standard deviation of 8 weeks and a contingency allowance of 10%.

Inclusion Criteria

- Consenting patients with chronic otitis media (COM) undergoing canal wall down mastoidectomy.

Exclusion Criteria

- Patients already undergoing treatment for post-mastoidectomy problems.
- Patients with history of otogenic intracranial complications.

Method of Data Collection

All the eligible patients were invited to participate in the study and after obtaining the consent they were enrolled in the study.

Following enrolment, demographic details were noted and history was taken followed by general, systemic and otorhinolaryngological examination.

Routine investigations including complete hemogram (Hb, TLC, DLC, Platelet count) were performed. Urine analysis was done. Blood sugar, urea and creatinine were noted.

Aural swab was obtained and was sent for culture sensitivity assessment.

Imaging studies including X-ray both mastoids and CT-temporal bones was performed.

Pre-anesthetic check-up was done.

The patients were then randomized to one of the following two study groups:

Group A (n=20): Patients undergoing modified radical mastoidectomy (MRM) using open mastoid cavity technique.

Group B (n=20): Patients undergoing MRM using mastoid cavity obliteration technique.

Operative Procedure

All the patients underwent MRM under general anesthesia. In patients having bilateral involvement, worse of the two ears was selected for operative intervention.

Operation was performed by post aural approach. Middle ear was evaluated for cholesteatoma and ossicular chain status. Cholesteatoma sac was removed surgically using the drill, from the mastoid and middle ear. All diseased air cells were accessed till dural plate superiorly, sinus plate posteriorly, sinodural angle posterosuperiorly and tip cells inferiorly were removed. Exteriorization of cavity was done by lowering the facial bridge till the ridge. Complete removal of disease was done from middle ear cleft including sinus tympani and facial recess.

In the patients assigned to the Group A, the temporalis fascia graft was used to cover the mastoid bowl and middle ear and the former was kept open. Adequate meatoplasty was done. Haemostasis was achieved. The postaural incision was closed in layer followed by mastoid dressing.

For Group B the mastoid cavity was obliterated with muscle pedicle graft. Muscle pedicle graft is a composite flap compromising temporalis fascia superiorly and the periosteum of outer mastoid cortex inferiorly. The pedicle was sited inferiorly near the mastoid tip and was based on a branch of the postauricular artery. Adequate meatoplasty was done. The post auricular incision was closed in layers. This was followed by application of a pressure dressing.

Post-operative Care

All the patients were placed on oral antibiotics, analgesics, and antihistaminics in the postoperative period. They were instructed to take adequate precautions to prevent entry of water into the ear canal. Antibiotics were continued for 10 days and antihistaminics for 3 weeks.

Skin sutures were removed after 7 days.

Follow-up

All the patients were followed in the OPD on 7th, 15th, 21st, 30th, 60th and 90th day. The following outcomes were noted:

- Pain at a VAS scale ranging from 0 (No pain) to 10 (extreme unbearable pain).
- Discharge from surgical site
- Bleeding/aural granulation
- Wax deposition
- Perichondritis
- Healing
- Recurrence

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Data Analysis

Data was analyzed using IBM Statistical Package for Social Sciences (SPSS Stats) version 21.0. Chi-square and Independent samples 't'-tests were used to compare and analyze the data. If the 'p' value obtained was less than 0.05 then the association was considered as significant.

RESULTS

Age of patients ranged from 11 to 67 years. Mean age of patients in Groups A and B was 26.80±12.91 and 28.90±12.91 years respectively. Majority of patients in Group A were males (65%) whereas majority of patients in Group B were females (60%). Bilateral involvement was seen in 2 (10%) of Group A and 4 (20%) of Group B patients. Among unilateral cases, in Group A, right side was more commonly involved (66.7%) whereas in Group B, both sides were equally involved (50% each). Mean PTA for left and right ears were 54.80±15.34 and 48.66±19.60 dB respectively in Group A as compared to 54.19±20.17 and 51.43±24.81 dB respectively in Group B. Statistically, there was no significant difference in demographic and clinical profile of patients in two study groups ($p>0.05$) [Table 1].

Post-operative mean pain scores peaked at day 7 in both the groups and thereafter showed a declining trend. Pain scores were significantly higher in Group A as compared to that in Group B at day 7 and day 15 ($p<0.05$) however, there was no significant difference between the two groups at subsequent follow-up intervals ($p>0.05$). At day 60 and 90, none of the patients in either of two groups reported of pain. Discharge from surgical site was maximum at day 15, however, by day 90 only 5 (25%) of Group A and 2 (10%) of Group B patients had discharge from surgical site. Bleeding/aural granulation peaked at day 15 and day 21 when 3 (15%) of Group A and 1 (5%) of Group B patients showed this sign. At day 90, only 1 (5%) patient in Group A and no patient in Group B had bleeding/aural granulation. None of the cases in Group B showed wax deposition at any follow-up interval, however, in Group A, one patient (5%) at day 60 and two patients (10%) at day 90 showed wax deposition. Perichondritis peaked at day 15, with 3 (15%) of Group A and 2 (10%) of Group B patients showing this sign. However, by day 60 onwards, none of the patients in either of two groups showed perichondritis. Statistically, there was no significant difference between the two groups for outcomes like discharge, bleeding/aural granulation, wax deposition and perichondritis at any of the follow-up intervals ($p>0.05$) [Table 2].

In Group A, healing was not seen in any case by day 30. At day 60 and 90, there were 2 (10%) and 10 (50%) cases respectively showing healing. In comparison, healing was seen from day 30 itself in Group B when 2 (10%) patients showed healing. In Group B, the healing rate was 20% and 75% respectively at day 60 and 90 respectively. Though the healing was earlier and seen in higher proportion of Group B as compared to Group A cases yet there was no statistically significant difference between the two groups at any of the follow-up intervals ($p>0.05$). There was no case of recurrence in either of two groups at any follow-up interval [Table 3].

Table 1: Comparison of demographic and clinical profile of cases in two study groups

SN	Variable	Group A (n=20)	Group B (n=20)	Statistical significance
1.	Mean age±SD (Range) in years	26.80±12.91 (11-63)	28.90±12.91 (18-67)	t=0.514; p=0.610
2,	Sex			
	Male	13 (65%)	8 (40%)	$\chi2$=2.506; p=0.113
	Female	7 (35%)	12 (60%)	
3.	Bilateral involvement	2 (10%)	4 (20%)	$\chi2$=0.784; p=0.376
4.	Side involved (Unilateral)			
	Left	6/18 (33.3%)	8/16 (50%)	$\chi2$=0.971; p=0.324
	Right	12/18 (66.7%)	8/16 (50%)	
5.	Mean PTA ±SD (dB)			
	Left ear	54.80±15.34	54.19±20.17	t=0.108; p=0.915
	Right ear	48.66±19.60	51.43±24.81	t=0.392; p=0.697

Table 2: Follow-up Evaluations

SN	Follow-up interval	Group A (n=20)	Group B (n=20)	Statistical significance
Pain				
1.	Day 7	2.05±1.43	1.10±1.21	t=2.287; p=0.029
2.	Day 15	1.25±1.45	0.40±0.99	t=2.165; p=0.037
3.	Day 21	0.70±1.17	0.20±0.52	t=1.739; p=0.090
4.	Day 30	0.15±0.67	0.05±0.22	t=0.632; p=0.531
5.	Day 60	0	0	-
6.	Day 90	0	0	-
Discharge				
1.	Day 7	18 (90%)	17 (85%)	$\chi2$=0.229; p=0.633
2.	Day 15	19 (95%)	18 (90%)	$\chi2$=0.360; p=0.548
3.	Day 21	15 (75%)	13 (65%)	$\chi2$=0.476; p=0.490
4.	Day 30	11 (55%)	7 (35%)	$\chi2$=1.616; p=0.204

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5.	Day 60	7 (35%)	3 (15%)	$\chi2$=2.113; p=0.144
6.	Day 90	5 (25%)	2 (10%)	$\chi2$=1.558; p=0.212
C. Bleeding/Aural Granulation				
1.	Day 7	2 (10%)	0 (0%)	$\chi2$=2.105; p=0.147
2.	Day 15	3 (15%)	1 (5%)	$\chi2$=1.111; p=0.292
3.	Day 21	3 (15%)	1 (5%)	$\chi2$=1.111; p=0.292
4.	Day 30	2 (10%)	0 (0%)	$\chi2$=2.105; p=0.147
5.	Day 60	1 (5%)	1 (5%)	$\chi2$=0; p=1.000
6.	Day 90	1 (5%)	0 (0%)	$\chi2$=1.026; p=0.311
D. Wax Deposition				
1.	Day 7	0 (0%)	0 (0%)	-
2.	Day 15	0 (0%)	0 (0%)	-
3.	Day 21	0 (0%)	0 (0%)	-
4.	Day 30	0 (0%)	0 (0%)	-
5.	Day 60	1 (5%)	0 (0%)	$\chi2$=1.026; p=0.311
6.	Day 90	2 (10%)	0 (0%)	$\chi2$=2.105; p=0.147
E. Perichondritis				
1.	Day 7	3 (15%)	1 (5%)	$\chi2$=1.111; p=0.292
2.	Day 15	3 (15%)	2 (10%)	$\chi2$=0.229; p=0.633
3.	Day 21	3 (15%)	1 (5%)	$\chi2$=1.111; p=0.292
4.	Day 30	3 (15%)	0 (0%)	$\chi2$=3.243; p=0.072
5.	Day 60	0 (0%)	0 (0%)	-
6.	Day 90	0 (0%)	0 (0%)	-

Table 3: Healing pattern and recurrence

SN	Follow-up interval	Group A (n=20)	Group B (n=20)	Statistical significance
Healing				
1.	Day 7	0	0	-
2.	Day 15	0	0	-
3.	Day 21	0	0	-
4.	Day 30	0	2 (10%)	$\chi2$=2.105; p=0.147
5.	Day 60	2 (10%)	4 (20%)	$\chi2$=0.784; p=0.376
6.	Day 90	10 (50%)	15 (75%)	$\chi2$=2.667; p=0.102
Recurrence				
1.	Day 7	0	0	-
2.	Day 15	0	0	-
3.	Day 21	0	0	-
4.	Day 30	0	0	-
5.	Day 60	0	0	-
6.	Day 90	0	0	-

DISCUSSION

The present study included a relatively younger profile of almost even representation of two genders with a mean age of 27.85 years and sex-ratio (M:F) of 1.11:1. Although, there are workers who have reported the mean age of patients to be as low as 9.2 years and an equal representation of two genders,[5] however, there are studies that have reported the mean age of patients to be as high as 38 years and a male dominance (M:F=1.94:1).[6] The age and sex profile of the patients in the present study is close to that reported by Roy et al,[7] and Das et al,[8] who reported the mean age of patients within ±5 years range as compared to the present study and reported sex-ratio as 1.22 and 1.57 respectively. In the present study, there were 15% cases with bilateral involvement, however, procedure was done in only worse of the two ears. Right side was more commonly involved than the left side. Involvement of a particular side may be incidental as some workers report a dominance of right side as in the present study,[9] however, some others report dominance of left side.[6]

In the present study, pure tone audiometry showed mean intensity ranging from 48.66±19.60 dB to 54.80±15.34 dB. Maiti and Sinha10 in their study reported it to range from 41.8 to 47.6 dB while Das et al,[8] reported them in 37 to 37.27 dB range, thus showing it to be slightly lower than that in the present study. The reason for this was the fact that in the present study the average depicted both the affected as well as unaffected ear and hence the functional measures were slightly better than that in the previous studies. As such, evaluation of functional outcome was not our objectives and hence the audiometric measures were primarily to ascertain the comparability of two groups rather than measure of a treatment need or functional gap.

In the present study, the follow-up period was limited to three months (90 days) only and hence post-operative complications like pain, discharge, bleeding, wax deposition and pericondritis and wound healing were used as the outcome measures. Although some workers have included functional outcomes in terms of changes in pure tone audiometry as the outcomes of interest,[5,11,12] however keeping in view the instability of functional outcomes over the short duration of

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follow-up in the present study, we preferred to exclude it as an outcome of interest and limited our study to evaluation of wound healing and other post-operative complications.

Among different outcomes, we found a statistically significant difference between the two groups for post-operative pain during the first two follow-up intervals (Days 7 and 21) when mean pain scores were significantly higher in open mastoid cavity as compared to obliterated mastoid cavity group. However, beyond that period, the two groups did not differ significantly for pain and by day 60 onwards all the patients in both the groups did not experience any pain. The findings of the present study are in agreement with the observations of Chhapola and Matta,[1] who also reported the incidence of pain in open cavity group to be higher as compared to obliterated cavity group during the first two follow-ups (day 30 and day 45), however, they did not find it to be significant statistically. In their study too, though the follow-up lasted till 6 months, they did not report of pain as a complication for follow-ups beyond day 45. The reason for emergence of a statistically significant difference in pain profile of two groups could be attributed to relatively early follow-up (days 7 and 15) and recording of pain on a continuous VAS scale instead of recording it as an event. Recording pain on VAS score helped us to get an objective assessment and also helped to differentiate between the two groups. As such irrespective of the method of measurement of pain, other workers have also found that obliteration of the canal helps to reduce the post-operative pain substantially.[10,12]

In the present study, no statistically significant difference between the two groups was observed for findings like discharge, bleeding/aural granulation, wax deposition and perichondritis during the entire clinical course as observed on different follow-up intervals. At final follow-up findings like pain, discharge, bleeding/aural granulation, wax deposition and perichondritis were seen in 0%, 25%, 5%, 10% and 0% of open mastoid cavity group as compared to 0%, 10%, 0%, 0% and 0% of obliterated cavity group patients. Overall healing rate at day 90 was 50% in open as compared to 75% in obliterated mastoid cavity group. We did not witness recurrence in any case in either of the two groups. In essence, despite absence of a statistically significant difference between the two groups for different outcomes of interest (except for pain on day 7 and day 21 follow-up), obliterated group seemed to have an edge over open cavity group both in terms of fewer complications as well as faster healing. A similar observation was also made by Das et al,[8] who remarked that "cavity obliteration in post-canal wall down setting significantly reduced the post-operative cavity volume and need for cavity debridement with better epithelisation, less incidence of discharge, vertigo on caloric stimulation when compared to open cavity". In another study, Mathur et al,[12] also found similar results and found that cavity obliteration was helpful to reduce the problems like pain and discharge as compared to open cavity. They also found healing to be faster in obliterated cavity as compared to open cavity group and healing/reepithelization rates at 6 months to be higher in obliterated (88%) as compared to open cavity group (68%). They also reported the functional outcomes in terms of AC gain to be better in obliterated as compared to open cavity group. However, in the present study owing we did not compare the functional outcomes owing to limitation of follow-up period as already explained earlier. In another recent study, Roy et al,[7] also found that canal wall reconstruction ensures fewer post-operative complications, better esthetics, faster healing and better functional outcome as compared to open mastoid cavity. Chhapola and Matta1 too made similar observations. A number of other workers also endorsed the observations of the present study with respect to different post-operative complications and/or faster healing.[5,8,10,13-15]

Although in the present study we have attempted to objectively evaluate the outcomes of concern, however, there were few limitations such as a shorter follow-up duration, non-inclusion of functional outcomes and some non-pathologic complications like giddiness. Moreover, a larger sample size could have yielded a statistically significant outcome. The findings of the present study open up the door for comparison of two methods on a larger sample size with a focus on quantification of outcomes and inclusion of more variables for evaluation. Further, comparative studies between different materials used for obliteration could also be carried out.

CONCLUSION

The findings of the present study suggest that mastoid cavity obliteration following modified radical mastoidectomy helps to reduce the complications and ensures a faster healing.

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