A comparative analysis of canal wall reconstruction mastoidectomy over canal wall down mastoidectomy

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Abstract

Aim: This study aims to investigate the advantages of canal wall reconstruction mastoidectomy (C.W.R.) over the canal wall down (CWD) mastoidectomy.

Material and method: A prospective study was conducted on sixty patients with cholesteatoma who underwent operation from September 2010 to October 2016. Patients were divided into two groups: “Group A,” posterior canal wall reconstruction group (C.W.R.) with 28 patients (28 ears) and “Group B” which included 32 patients (32 ears) in whom canal wall down mastoidectomy (CWD) was done without reconstruction. The patients were followed up at 3 months and 6 months postoperatively with otoendoscopy to look for recurrence or residual disease, the occurrence of any complications, and for hearing assessment.

Results: Group A (C.W.R.) patients were cosmetically better, and none had postoperative cavity problems. While in Group B (CWD), 16 patients (50%) had a cavity problem. Group A CWR group also had early epithelization. Both methods had hearing improvement postoperatively. Group A had more hearing improvement than Group B.

Conclusion: The C.W.R. method is a safe method for eliminating the problem of the mastoid cavity. This surgery can be easily taught and applied universally in all cholesteatoma patients as a primary treatment. The C.W.R. technique provides improved exposure to the middle ear without creating a mastoid bowl, which significantly reduces the incidence of residual and recurrent disease. These results indicate that the C.W.R. method is better than the CWD operation.

Keywords: Mastoidectomy, Cholesteatoma, Ear canal, Reconstruction

Background

Cholesteatoma treatment is mainly surgical. Surgeries for cholesteatoma are usually classified as closed or open procedures. The closed procedure [14], also called the canal wall-up (C.W.U.) procedure, results in a high rate of “dry ear” but can lead to a high cholesteatoma recurrence rate because of residual disease in hidden areas and due to incomplete clearance.

The open procedure, known as canal wall down mastoidectomy (C.W.D), ensures complete disease removal and has a low cholesteatoma recurrence rate. Mastoid cavity after surgery may develop complications, including cosmetic problems due to enlarged meatus, poor hearing aid fit, recurrent infection, impaction with debris, and frequent visits to the doctor for ear cleaning.

There are two methods to overcome the problems of the mastoid cavity: mastoid obliteration [4, 5] and canal wall reconstruction [1–3]. However, mastoid obliteration has a risk of trapping residual cholesteatoma, hinders postoperative surveillance, and can cause infection or resorption, or shrinkage of the graft materials. Canal
wall reconstruction is more practical for anatomic and physiologic reasons and can be performed by various techniques.

In this study, cases were divided into two groups, Group A included 28 patients (47% cases) who underwent canal wall down mastoidectomy with posterior canal wall reconstruction (C.W.R.), using conchal cartilage, and Group B included 32 patients (53% cases) who underwent canal wall down mastoidectomy (CWD) without posterior canal wall reconstruction.

Postoperatively, the patients were followed up at 3 months and 6 months with otoendoscopy to look for postoperative healing, recurrence of disease, and any complications. They were subjected to preoperative and postoperative audiometry. Here, the patient’s conchal cartilage [14] was used for reconstruction of the posterior canal wall (Figs. 1 and 2).

Aims and objectives

1. To investigate the advantages of canal wall reconstruction mastoidectomy (C.W.R.) over open procedures.
2. To evaluate the outcome of the soft wall reconstruction technique for canal wall down mastoidectomy.
3. To review the long-term hearing results and impact of posterior canal wall reconstruction in patients with cholesteatoma.

Material and method

A prospective study was conducted in the Department of Otorhinolaryngology & Head neck surgery, M.G.M. Medical College & M.Y. Hospital, Indore, from September 2010 to October 2016 on 60 patients who were
diagnosed with a squamosal type of chronic suppurative otitis media.

Exclusion criteria consisted of patients having the following:

1. Severe or profound SNHL.
2. Only functioning ear.
3. Intracranial complications.
4. Uncontrolled diabetes mellitus, hypertension, or other systemic illness.
5. Residual or recurrent cholesteatoma cases.
6. Patients not attending follow-up.

- After taking through history and clinical examination all the patients were subjected to examination under a microscope and otoendoscopy to confirm clinical findings. All of them underwent pure tone audiometry. HRCT temporal bone was also done. All the cases were thoroughly examined and investigated and proper informed consent. Findings were recorded in the proforma. After complete preoperative workup, these patients were taken for surgery.

Steps of surgery
General anesthesia was used in all cases. All cases were operated under Zeiss operating microscope. The retroauricular approach was used in all cases. A postauricular skin incision is given in all cases. An anteriorly based, wide Musculo periosteal flap was created. The mastoid cortex was exposed. Posterior meatotomy was done. Tympanomeatal flap elevated and middle ear inspection was done prior to mastoidectomy to check any middle ear disease and to look for ossicular status. Any cholesteatoma or granulation tissue in the middle ear was dissected free from the ossicles, leaving behind the ossicular chain intact if possible. Whenever the malleus and incus were found eroded, the pseudostapedial joint was disarticulated first, to avoid damage to the inner ear from subsequent drilling.

Drilling was done by the inside-out technique, and the disease was followed posteriorly. Drilling was initiated at attic and bone drilling continued posteriorly. The antrum was opened and the extent of cholesteatoma was appreciated. The sac was followed posteriorly, and complete cholesteatoma removal was ensured. An endoscope and angled telescope were used wherever necessary to clear disease from hidden areas like the sinus tympani area.

Drilling is done over the facial bridge. The bridge is broken and the facial ridge lowered. Some portion of the anterior and posterior buttress of the facial ridge was preserved as a guideline for reconstruction.

To reconstruct the defect in the posterior canal wall, a 1-mm diamond burr was used to form grooves in the bone at the anterior buttress area antero-superiorly and posterior buttress part of the facial ridge posteroinferiorly. Conchal cartilage was harvested and shaped according to the defect present in the posterior canal wall. Conchal cartilage has a natural curvature, which helps to fit in easily. We generally kept the size of cartilage 1mm or 2mm larger than the defect, so that it snugly fits in the defect.

Cartilage ossiculoplasty was done wherever required. Larger-sized Temporalis facia was harvested and placed over the middle ear and also covering the reconstructed canal wall. A tympanomeatal flap was then repositioned.

Meatoplasty was not done in the CWR group, while wide meatoplasty was done in the CWD and open group. Antibiotic-soaked gel foam is filled in the external auditory canal. The wound is closed in layers using vicryl 3-0 suture, and skin incision is sutured using Nylon 3-0 suture, and a mastoid dressing is applied.

Patients were followed up with otoendoscopy and pure tone audiometry to look for the rate of healing and epithelization, any residual disease or recurrent disease, and for hearing assessment.

Main outcome measures
- The postoperative period required for complete epithelization (dry ear), postoperative hearing, and incidence of recurrent cholesteatoma were compared between the groups.
- Hearing results: Preoperative audiometry was done in every case. Postoperative pure tone audiometry was done at 3 months and 6 months after surgery in every case.

Results
In the present series of 60 cases, 33 were males (55%), and 27 were females (45%). The mean age was 22.07 years. Median age = 19 years. Most of the cases have been children and young adults with a history of otorrhea. The youngest patient was 5 years old, and the oldest was 56 years.

In this study, CT scan was done in 49 cases out of 60 cases, and on CT scan sclerosis of mastoid air cells was seen in 47 cases (95.91%), soft tissue shadow in 49 cases (100%), malleus erosion in 28 cases (57.14%), incus erosion in 32 cases (65.31%), stapes erosion in 2 cases (4.08%), lateral cortex breach in 8 cases (16.33%), tegmen breach in 3 cases (6.12%), fallopian canal erosion in 5 cases (10.20%), LSSC erosion in 6 cases (12.24), sinus
plate erosion in 9 cases (18.37%), and dural plate erosion in 2 cases (4.08%).

Overall, the most common CT scan finding was a soft tissue shadow in 100% (49/49) and sclerotic mastoid in 95.91% (47/49).

The most common ossicular erosion was incus erosion in 65.31% of cases (32/49) followed by the malleus erosion in 57.14% of cases (28/49).

Fallopian canal erosion was seen in 10.20% of cases (5/49), most commonly involving the horizontal part of the facial canal (Table 1).

In this study, intraoperatively, sclerotic mastoid was found in 57 cases (95%), cholesteatoma in 51 cases (85%), granulation in 42 cases (70%), polyp in 5 cases (8.33%), malleus head erosion in 37 cases (61.66%), incus erosion in 42 cases (70%), stapes erosion in 2 cases (3.33%), lateral cortex breach in 7 cases (11.67%), tegmen breach in 4 cases (6.67%), fallopian canal erosion in 5 cases (8.33%), LSSC erosion in 7 cases (11.67%), sinus plate erosion in 15 cases (25%), and dural plate erosion in 4 cases (6.67%).

Overall, the most common intraoperative finding was sclerotic mastoid in 95% of cases (57/60), followed by cholesteatoma in 85% of cases (51/60).

The most common ossicular erosion was seen in incus in 70% of cases (42/60) followed by malleus erosion in 61.66% (37/60).

Fallopian canal erosion was seen in 8.33% of cases (5/60) mostly involving the horizontal segment (Table 1).

A total of 49 patients underwent preoperative CT scan exposure. Their CT findings and intraoperative findings were compared (Table 3).

On CT scan, 95.91% of cases (47/49) had sclerotic mastoid, which was also found intraoperatively in 95.91% (47/49). The soft tissue mass was seen in 100% of cases (49/49) on CT scan and was confirmed intraoperatively.

CT cannot differentiate between cholesteatoma, granulation, or polyp, and all were seen as soft tissue mass on CT scan. Intraoperatively, cholesteatoma was the most common in 83.67% of cases (41/49) followed by granulation in 69.39% (34/49) and polyp in 8.16% (4/49).

On CT scan, the most common ossicular erosion was incus erosion in 65.31% (32/49), followed by malleus erosion in 57.14% (28/49). Intraoperatively also, similar findings were obtained but in more no. of cases: incus erosion in 71.43% (35/49) and malleus erosion in 63.27% (31/49). Fallopian canal erosion was seen in 10.20% (5/49) on CT scan and in 8.16% (4/49) intraoperatively.

Sinus plate erosion was seen in 18.37% of cases on CT scan and in 28.57% of cases intraoperatively.

Overall, CT scan and intraoperative findings were comparable, but intraoperatively the findings were seen in more no. of cases.

In Group A, the CWR group, the preoperative mean AB gap was 40.39 ± 6.1dB and the postoperative mean AB gap was 15.32±4.8 dB. In Group B, the CWD group, the preoperative mean AB gap was 42.22 ± 6.7dB, and the postoperative mean AB GAP was 22.81±8.1dB (Table 4). There is a statistically significant reduction in AB gap postoperatively in both groups (p value=0.001). The p value of clinical examination findings at 6 months for graft in situ, retraction pocket formation, disease recurrence, and graft displacement were p=0.923, i.e., (p>0.05). There is no significant difference between the two groups for postoperative complications rate (Table 5).

The cavity problem required frequent cleaning and frequent visit to the doctor, which was more in group B (CWD). Since p value =0.002 (p<0.05) for cavity

| Table 1 Preoperative CT findings |
| SN | CT findings | No.of patients n=49 |
| 1 | Sclerosis of mastoid air cells | 47 | 95.91% |
| 2 | Soft tissue shadow (cholesteatoma, granulation, polyp) | 49 | 100% |
| 3 | Malleus erosion | 28 | 57.14% |
| 4 | Incus erosion | 32 | 65.31% |
| 5 | Stapes erosion | 2 | 4.08% |
| 6 | Lateral cortex breach | 8 | 16.33% |
| 7 | Tegmen breach | 3 | 6.12% |
| 8 | Fallopian canal erosion | 5 | 10.20% |
| 9 | LSSC erosion | 6 | 12.24% |
| 10 | Sinus plate erosion | 9 | 18.37% |
| 11 | Dural plate erosion | 2 | 4.08% |

CT scan was done in 49 cases (out of 60 cases)

| Table 2 Intra-operative findings |
| SN | Intraoperative finding | No.of patients n=60 |
| 1 | Sclerosis of mastoid air cells | 57 | 95% |
| 2 | Cholesteatoma | 51 | 85% |
| 3 | Granulation | 42 | 70% |
| 4 | Polyp | 5 | 8.33% |
| 5 | Malleus head erosion | 37 | 61.66% |
| 6 | Incus erosion | 42 | 70% |
| 7 | Stapes erosion | 2 | 3.33% |
| 8 | Lateral cortex breach | 7 | 11.67% |
| 9 | Tegmen breach | 4 | 6.67% |
| 10 | Fallopian canal erosion | 5 | 8.33% |
| 11 | LSSC erosion | 7 | 11.67% |
| 12 | Sinus plate erosion | 15 | 25% |
| 13 | Dural plate erosion | 4 | 6.67% |
problems in 2 groups, there is a significant difference in cavity problems in groups A and B.

Period of epithelization, i.e., the time required to be dry ear, in Group A, the mean ± S.D. was 49.28±6.62 days, and in Group B, it was 64.22±9.51 days. Since the p value = 0.001, i.e., p<0.05, there is a statistically significant difference in Group A and Group B epithelization. Hence, there is early epithelization in group A soft wall reconstruction compared to the CWD and open groups (Table 6).

Table 3 Comparison between preoperative CT findings and intraoperative findings

| SN | Findings                          | Preoperative ct finding | %     | Intraoperative finding | %     |
|----|-----------------------------------|-------------------------|-------|------------------------|-------|
| 1  | Sclerosis of mastoid air cells    | 47                      | 95.91%| 47                     | 95.91%|
| 2  | Soft tissue mass                  | 49                      | 100%  | 49                     | 100%  |
|    | Cholesteatoma                      |                         |       | 41                     | 83.67%|
|    | Granulation                        |                         |       | 34                     | 69.39%|
|    | Polyp                              |                         |       | 4                      | 8.16% |
| 3  | Malleus head erosion               | 28                      | 57.14%| 31                     | 63.27%|
| 4  | Incus erosion                      | 32                      | 65.31%| 35                     | 71.43%|
| 5  | Stapes erosion                     | 2                       | 4.08% | 2                      | 4.08% |
| 6  | Lateral cortex breech             | 8                       | 16.33%| 7                      | 14.29%|
| 7  | Tegmen breach                     | 3                       | 6.12% | 4                      | 8.16% |
| 8  | Fallopian canal erosion            | 5                       | 10.20%| 4                      | 8.16% |
| 9  | LSSC erosion                       | 6                       | 12.24%| 7                      | 14.29%|
| 10 | Sinus plate erosion                | 9                       | 18.37%| 14                     | 28.57%|
| 11 | Dural plate erosion                | 2                       | 4.08% | 4                      | 8.16% |

Table 4 Comparison of pre-operative A.B. gap and post-operative A.B. gap between 2 groups

|                         | Mean preoperative A.B. gap | Mean postoperative A.B. gap (3 months) | Mean postoperative A.B. gap (6 months) |
|-------------------------|-----------------------------|----------------------------------------|----------------------------------------|
| Group A (C.W.R.)        | 40.39±6.07                  | 22.32±4.32                             | 15.32±4.79                             |
| Group B (CWD)           | 42.22±6.68                  | 30.22±5.86                             | 22.81±8.07                             |

Table 5 Clinical findings of patients during follow-up at 3 months and 6 months comparing Group A and Group B

| SN | Follow-up findings                          | Group A (n=28) CWR | Group B (n=32) CWD | p value at 6 months |
|----|---------------------------------------------|--------------------|--------------------|---------------------|
|    |                                             | 3 months           | 6 months           | 3 months           | 6 months           |                      |
| 1  | Graft in situ                               | 28 (100%)          | 27 (96.4%)         | 32 (100%)          | 31 (96.9%)         | 0.923               |
| 2  | Well epithelized (dry ear)                  | 28 (100%)          | 28 (100%)          | 25 (78.1%)         | 30 (93.8%)         | 0.178               |
| 3  | Retraction pocket                           | 0 (0%)             | 1 (3.6%)           | 0 (0%)             | 1 (3.1%)           | 0.932               |
| 4  | Disease recurrence                          | 0 (0%)             | 1 (3.6%)           | 0 (0%)             | 1 (3.1%)           | 0.923               |
| 5  | Persistent discharge                        | 1 (3.6%)           | 1 (3.6%)           | 6 (18.8%)          | 3 (9.4%)           | 0.369               |
| 6  | Graft displacement                          | 0 (0%)             | 1 (3.6%)           | 0 (0%)             | 1 (3.1%)           | 0.923               |
| 7  | Hearing improvement                         | 28 (100%)          | 27 (96.4%)         | 31 (96.9%)         | 31 (96.9%)         | 0.923               |
| 8  | Cavity problem requiring frequent cleaning  | 0 (0%)             | 0 (0%)             | 16 (50%)           | 9 (28.1%)          | 0.002               |

Table 6 The average period of epithelization

| Type of operation | N  | Mean period of epithelization in days | Std deviation | Std error of the mean |
|-------------------|----|--------------------------------------|---------------|-----------------------|
| Group A (CWR)     | 28 | 49.29                                | 6.625         | 1.252                 |
| Group B (CWD)     | 32 | 64.22                                | 9.513         | 1.682                 |
In Group A (C.W.R.), none developed postoperative cavity problems, like dizziness, and deafness. Thus, there was freedom from requiring frequent visits to the doctor. Only one patient developed a persistent postoperative discharge, which was comparable with other studies. Group A (CWR), patients were also cosmetically satisfied because they had no big cavity problem, unlike Group B (CWD), who were cosmetically dissatisfied. The period of water restriction was also lesser in Group A (CWR).

Discussion
The patients were divided into Group A (C.W.R.) and Group B (C.W.D). Patients were followed up at 3 months and 6 months with otoendoscopy, CT scan, and pure tone audiometry, to look for the occurrence of any complications, to check epithelization, and for hearing assessment.

Inadequate exposure and dysfunction of the Eustachian tubes increase the risk of the postoperative formation of a retraction pocket in the pars flaccida. Our study removed the posterior canal wall integrally, resected the cholesteatoma tissue completely, and then reconstructed the posterior canal wall to reduce the risk of recurrence.

Autologous cartilage is one of the most suitable materials for posterior canal wall reconstruction and is used in this study. After shaping cartilage to fit the reconstruction site, it can easily be used. In various Otologic surgeries, cartilages (auricular cartilage and tragal cartilage) in the same surgical field have been widely used, as an additional incision is not required. The use of septal or costal cartilage has been found to produce similar postoperative results in other studies [10].

Weber and Gantz [13] reported that auricular cartilage is thinner than tragal cartilage and has a constant thickness and natural curvature, and is thus suitable for reconstruction. In addition, they found that the rate of formation of a retraction pocket was significantly lower for reconstruction with cartilage than for no reconstruction.

In the present study, we reconstructed posterior canal walls by inserting conchal cartilage. In Group A (C.W.R.), 25 (89.29%) of the 28 study subjects had an ABG of less than 25 dB after surgery, and one patient developed a postoperative retraction pocket. Thus, surgical outcomes were considered to be satisfactory and similar to other studies.

In the study by Smith et al. [11] in 1986, on *Soft-Wall Reconstruction of the Posterior External Ear Canal Wall*, a variable amount of soft-wall retraction was noted postoperatively in 47% of the ears. They used an autogenous bilaminar membrane to reconstruct the posterior canal wall defect.

In the study by Hosoi and Murata et al. [7, 8] in 1998 on long-term observation after soft posterior meatal wall reconstruction in ears with cholesteatoma, none of the patients experienced postoperative narrow-neck retraction pocket formation. No severe cavity or hearing problems have occurred since surgery.

In the study by Baek et al. [1] in 2016, postoperative otorrhea occurred in 5 patients (11.9%). In the study by Hatano et al. [6], some cases of tympanic membrane perforation and otitis media with effusion occurred during the follow-up period.

Canal wall down mastoidectomy with soft posterior canal wall reconstruction significantly lowers the cholesteatoma recurrence. The 3.57% (1/28 cases) of cholesteatoma recurrence rate in the Group A CWR group is an acceptable outcome in the 6-month follow-up period. It is comparable to the study by Dornhoffer et al. [2, 3]. The average follow-up period in his study was 7.8 years (6.7–9 years), with recurrence occurring in 8 ears (16%). He considered the results to be acceptable long-term results.

In the study by Takahashi et al. [12], there was no significant difference in the incidence of residual and recurrent cholesteatoma between the two groups. Postoperative pure tone audiometry was done at 3 months and 6 months after surgery in every case.

**Pre-op A.B. gap**
In Group A, mean± S.D., preoperative A.B. gap was 40.39±6.07 dB.
In Group B, mean± S.D., preoperative A.B. gap was 42.22±6.68 dB.

**Postoperatively at 3 months**
In Group A, mean± S.D., AB gap was 22.32±4.32 dB.
In Group B, mean± S.D., AB gap was 30.22±5.86 dB.

**Postoperatively at 6 months**
In Group A, mean± S.D., AB gap was 15.32±4.79 dB.
In Group B, mean± S.D., AB gap was 22.81±8.07 dB.
Postoperatively, the A.B. gap was reduced in both Group A and Group B. There is a statistically significant reduction in postoperative A.B. gap since the \( p \) value < 0.05 at 3 months and 6 months.

In the present series, hearing improvement occurred in both groups, significantly reducing the postoperative A.B. gap in both groups. The hearing improvement was better in the posterior canal wall reconstruction group.

In the study by Takahashi et al. [12] in 2000, there was no significant difference in the two groups postoperative hearing.

Baek et al. [1] studied the efficacy of posterior canal wall reconstruction, using autologous auricular cartilage and bone pate in chronic otitis media with cholesteatoma. For all the 42 subjects, the mean preoperative
and postoperative A.B. gap values were 29.4±12.8 dB and 23.4±11.7 dB, respectively. It represents a significant average improvement of 6.0 dB (p<0.05).

In the study by Dornhoffer [2, 3], C.W.R. was done in 75 patients, the recurrent disease occurred in 5%, and hearing improvement was statistically significant (p<0.05), average preoperative PTA=27.2 dB improving to 11.5 dB. No patient had worsened hearing.

Dornhoffer [2, 3] in 46 patients (50 ears), reconstruction was done using cymba cartilage. Average preop P.T.A. was 25.6±11.2 dB, short-term postoperative P.T.A. 11.0±5.7, and long-term post-operative P.T.A. 12.4±6.4 dB. There was a significant difference between pre-op and post-op values (p<0.5). Recurrent cholesteatoma was seen in 8 ears (16%), pressure-equalizing tube insertion was performed in 9 ears (18%), perforation was seen in 1 ear (2%), and poor hearing results required second-look surgery in 2 ears (4%).

Sadooghi [9] conducted a study to reevaluate the soft-wall reconstruction technique for CWD mastoidectomy. In his research, there was no recurrent cholesteatoma in the soft wall reconstruction group. He concluded that soft wall reconstruction is a safe method for eliminating the problems of radicalized mastoid cavities.

Period of epithelization, the time required to be dry ear, in Group A (CWR), mean ± S.D. was 49.28±6.62 days, and in Group B (CWD), it was 64.22±9.51 days. Since the p value = 0.001, i.e., p<0.05, there is a statistically significant difference in Group A and Group B epithelization.

Hence, there is early epithelization in group A soft wall reconstruction compared to the CWD and open groups.

Thus, the period of restriction from water activities is significantly lower in the C.W.R. group. The results of our study for a period of epithelization are similar to the study by Takahashi et al. [12]. The postoperative period to be dry ear was significantly shorter in the soft wall reconstruction group than in the canal wall down and open group (Student’s t test, t=2.99, p<0.01). There was no significant difference in the postoperative hearing or incidence of residual or recurrent cholesteatoma between the two groups. The limitation of this study is short-term follow-up.

**Conclusion**

The C.W.R. method is a safe method for eliminating the problem of the mastoid cavity. It is a single-stage technique for cholesteatoma removal and canal wall reconstruction. This surgery can be easily taught and applied universally in all cholesteatoma patients including children, as a primary treatment. The C.W.R. technique provides improved exposure of the middle ear (especially the anterior epitympanum) without creating a mastoid bowl, which reduces the incidence of residual and recurrence significantly. These results indicate that the C.W.R. method is better than the CWD operation.

**Abbreviations**

CWR: Canal wall reconstruction; CWD: Canal wall down; CSOM: Chronic suppurative otitis media; A.B. gap: Air-bone gap.

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**Authors’ contributions**

RR: Project development, data Collection and manuscript writing. YG: Data Collection and manuscript writing. PKR: Data Collection and manuscript writing. The author(s) read and approved the final manuscript.

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**Availability of data and materials**

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Declarations**

**Ethics approval and consent to participate**

The institutional ethical clearance is taken from the Ethics and Scientific Review Committee MGM Medical College & M.Y Hospital, Indore, having No EC/MGM/ JUN-16/231. Informed written consent to participate in the study was provided by all participants (or their parent or legal guardian in the case of children under 16).

**Consent for publication**

Written informed consent for the publication was obtained from the participants (or from their parent or legal guardian in the case of children under 16).

**Competing interests**

The authors declare that they have no competing interests.

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