Section: Otorhinolaryngology

Original Research Article

A PROSPECTIVE STUDY ON THE INFLUENCE OF SINUSITIS ON ACTIVE MUCOSAL TYPE OF CHRONIC OTITIS MEDIA

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ABSTRAC

Background: Although many cases Chronic otitis media (COM) of the active mucosal type is often perpetuated by focal sepsis in the upper aerodigestive tract, Sinusitis is a known but under-evaluated contributor. This study aimed to determine the role of sinusitis in persistent ear discharge and to assess the improvement in middle ear mucosa after sinus disease clearance. The aim is to establish the role of sinusitis as a focal sepsis in patients with active mucosal type of chronic otitis media.

Materials and Methods: This prospective study was conducted from January 2020 to September 2020 in the Department of Otorhinolaryngology, Thanjavur Medical College, Tamilnadu. Forty patients aged 18–45 years with active mucosal COM and chronic sinusitis were included. All underwent diagnostic nasal endoscopy (DNE) and CT paranasal sinuses. Functional endoscopic sinus surgery (FESS) with or without septal correction was performed. Preoperative and postoperative middle ear mucosal status was monitored at three months.

Results: Among 40 patients, 19 (47.5%) were males and 21 (52.5%) females, most in the 26–35 years age group. On DNE, 12.5% had enlarged bulla and paradoxical middle turbinate. CT showed Grade I disease in 62.5%, Grade II in 20%, Grade III in 12.5%, and Grade IV in 5%. Preoperatively, 77.5% had moist edematous mucosa and 22.5% boggy polypoidal mucosa. Post-FESS, 35 (87.5%) patients showed improved middle ear mucosal status, while 5 (12.5%) had no improvement. Non-improvement was due to Eustachian tube hypofunction (n=1) or recurrence of sinus disease from surgical failure (n=4).

Conclusion: Sinusitis is a major etiological factor in persistent ear discharge in active mucosal COM. Diagnostic nasal endoscopy is mandatory in all such patients. FESS effectively improves middle ear mucosal status and should be considered early.

Keywords: Chronic otitis media active mucosal disease, Functional endoscopic sinus surgery, Septal correction, Enlarged middle turbinate & Chronic sinusitis.

INTRODUCTION

Chronic otitis media (COM) is defined as a persistent inflammatory condition of the mucoperiosteal lining of the middle ear cleft, often lasting for more than three months. The active mucosal type of COM is characterized by recurrent or persistent mucoid otorrhea through a tympanic membrane perforation, without the presence of cholesteatoma. The pathogenesis of this condition is multifactorial, involving Eustachian tube dysfunction, bacterial biofilms, and environmental factors. However, a crucial and often overlooked contributor is the presence of focal sepsis in the upper airway, including chronic sinusitis, adenoiditis, tonsillitis, and allergic rhinitis. These conditions perpetuate the inflammatory cycle by maintaining a reservoir of pathogens that continuously seed the middle ear via the Eustachian tube. An Indian study by Sengupta et al. (2019) emphasized that undiagnosed sinonasal pathology is present in nearly 60% of patients with refractory COM, yet routine otologic evaluation often bypasses nasal endoscopy.[1]

The pathophysiological link between sinusitis and active mucosal COM is primarily mediated by the Eustachian tube, which acts as a conduit for infection and inflammation from the nasopharynx to the middle ear. Chronic sinusitis leads to persistent mucosal edema and mucociliary clearance impairment in the nasopharynx, directly affecting the tubal opening. Furthermore, anatomical variations such as a deviated nasal septum, enlarged middle turbinate, paradoxical middle turbinate, and medialised uncinate process predispose individuals to recurrent sinusitis, which in turn sustains middle ear inflammation. A study by Kumar and Patil (2020) from Maharashtra reported that 72% of patients with active mucosal COM had at least one anatomical variation of the ostiomeatal complex on CT scan.[2] Despite this, many patients receive repeated courses of antibiotics and ear drops without addressing the underlying sinonasal focus. Therefore, this study was designed to systematically evaluate the role of sinusitis as a focal sepsis in active mucosal COM and to assess the clinical outcome following endoscopic sinus surgery.

Aim and Objectives

Aim: To establish the role of sinusitis as a septic focus in patients with active mucosal type of chronic otitis media.

Objectives:

1. To study the improvement in middle ear mucosal status following clearance of sinus disease.
2. To identify the anatomical variations of the nose and paranasal sinuses that predispose to sinusitis in these patients.
3. To emphasize the need for proper diagnostic endoscopic evaluation in all patients with active mucosal COM.

MATERIALS AND METHODS

Study Design and setting: This was a prospective, interventional, single-center study conducted in the Department of Otorhinolaryngology, Thanjavur Medical College, Thanjavur, Tamilnadu, from January 2020 to September 2020.Duration: January 2020 to September 2020 (9 months).

Sample Size: The sample size was calculated based on the expected proportion of patients showing improvement in middle ear mucosal status following functional endoscopic sinus surgery (FESS). From a pilot study conducted on 10 patients prior to the main study, the proportion of improvement was estimated to be 85%. With a desired precision (margin of error) of 12% and a 95% confidence interval, the minimum required sample size was calculated using the formula:

$n = (Z^2 \times p \times (1-p)) / d^2$

Where:

Z = 1.96 (for 95% confidence level)

p = 0.85 (expected proportion of improvement from pilot study)

d = 0.12 (margin of error)

Calculation:

$n = (1.96^2 \times 0.85 \times 0.15) / (0.12^2)$

$n = (3.8416 \times 0.1275) / 0.0144$

$n = 0.4898 / 0.0144$

$n = 34.01 \approx 34$ patients

Anticipating a dropout rate of approximately 15%, the final sample size was rounded up to 40 patients. This sample size was also consistent with previous Indian studies in similar settings, such as the study by Sengupta et al. (2019), which included 35 patients, and Reddy et al. (2018), which enrolled 42 patients.

Inclusion Criteria

- Age between 18 and 45 years, both sexes
- Clinically diagnosed case of active mucosal type of chronic otitis media (central tympanic membrane perforation with persistent or intermittent mucoid otorrhea for more than 3 months)
- Associated chronic sinusitis diagnosed by diagnostic nasal endoscopy and confirmed by CT scan of paranasal sinuses
- Willing to undergo surgical intervention and follow-up for 3 months

Exclusion Criteria

- Cholesteatoma or unsafe (squamous) type of chronic otitis media
- Acute upper respiratory tract infection at the time of enrollment
- Prior history of sinus surgery or ear surgery (tympanoplasty or mastoidectomy)
- Immunocompromised status (HIV, uncontrolled diabetes mellitus with HbA1c >8%, chronic steroid use)
- Pregnancy or lactation
- Presence of nasopharyngeal mass or malignancy

Study Procedure and Data Collection

Clinical Examination: All patients underwent a detailed history taking followed by general physical and otorhinolaryngological examination. Otoendoscopy was performed using a 0° 4mm rigid endoscope (Karl Storz, Germany) to document the middle ear mucosal status, which was categorized as either (a) moist edematous mucosa or (b) boggy polypoidal mucosa.

Diagnostic Nasal Endoscopy (DNE): DNE was performed using 0° and 30° rigid endoscopes (4mm) after decongestion with 10% xylometazoline spray and topical anesthesia with 4% lignocaine. Anatomical variations including enlarged bulla, paradoxical middle turbinate, enlarged middle turbinate (Type 1), medialised uncinate, deviated nasal septum, and concha bullosa were recorded.

Radiological Evaluation: All patients underwent high-resolution computed tomography (HRCT) of the paranasal sinuses in coronal and axial planes (slice thickness 1.25 mm). Sinus disease was graded as:

- Grade I: Mucosal thickening <3 mm
- Grade II: Incomplete opacification of one or more sinuses
- Grade III: Complete opacification of one or more (not all) sinuses
- Grade IV: Total opacification of all sinuses

Surgical Intervention: All patients underwent Functional Endoscopic Sinus Surgery (FESS) under general anesthesia by a single experienced surgeon to avoid inter-operator bias. The extent of surgery included uncinectomy, middle meatal antrostomy, anterior ethmoidectomy, and, when indicated, frontal recess clearance and sphenoidotomy. Septal correction (septoplasty) was performed when deviated nasal septum was causing significant obstruction of the ostiomeatal complex. Postoperatively, all patients received nasal saline irrigation twice daily, intranasal mometasone furoate spray for 6 weeks, and a 7-day course of oral amoxicillin-clavulanate.

Follow-up: Patients were followed up at 2 weeks, 1 month, and 3 months postoperatively. At each visit, otoendoscopic examination was repeated, and middle ear mucosal status was reassessed at the final 3-month visit.

Outcome Measures

Primary Outcome: Improvement in middle ear mucosal status, defined as conversion from moist edematous or boggy polypoidal mucosa to healthy, dry mucosa at 3 months post-FESS.

Secondary Outcome: Identification of anatomical variations predisposing to sinusitis in these patients.

Statistical Analysis: Data were entered into Microsoft Excel (version 2019) and analyzed using SPSS software (version 22.0, IBM Corp., Armonk, NY, USA). Descriptive statistics were expressed as frequencies (n) and percentages (%) for categorical variables. The preoperative and postoperative middle ear mucosal status were compared using the Chi-square test (χ^2 test) for categorical paired data. A p-value of less than 0.05 was considered statistically significant. The Chi-square test was chosen because the variables were categorical (moist edematous, boggy polypoidal, healthy dry) and the observations were independent.

Ethical Considerations:

Institutional Approval: Prior approval was obtained from the Institutional Ethics Committee of Thanjavur Medical College, Thanjavur.

Informed Consent: Written informed consent was obtained from all participants in their preferred language (Tamil or English) after explaining the purpose, procedures, potential risks, and benefits of the study. The consent form was approved by the Institutional Ethics Committee.

Confidentiality: All patient data were anonymized and assigned unique identification numbers. No personal identifying information was used in any publication or presentation arising from this study.

Risk and Benefit Assessment: Potential risks of FESS included bleeding, infection, cerebrospinal fluid leak, and recurrence of sinus disease. All patients were thoroughly counseled regarding these risks. The anticipated benefits included resolution of ear discharge, improvement in hearing, and reduced need for long-term antibiotics. No financial incentive was provided to participants; however, all surgical procedures and postoperative medications were provided free of cost through the hospital's public health system.

Right to Withdraw: Participants were explicitly informed of their right to withdraw from the study at any time without affecting their subsequent medical care.

Conflict of Interest Declaration: The authors declare no conflicts of interest. No external funding was received for this study.

RESULTS

A total of 40 patients were included in the study: 19 (47.5%) males and 21 (52.5%) females. The maximum number of patients (42.5%) belonged to the 26–35 years age group (third decade).

Table 1: Age and Sex Distribution among study participants

Age Group (years)	Male (n=19)	Female (n=21)	Total (n=40)	Percentage (%)
18 – 25	5	7	12	30.0%
26 – 35	9	8	17	42.5%
36 – 45	5	6	11	27.5%
Total	19	21	40	100%

A total of 40 patients were enrolled in the study, comprising 19 males (47.5%) and 21 females (52.5%). The majority of patients belonged to the 26–35 years age group, which included 9 males and 8 females, accounting for 17 patients (42.5% of the total cohort). The second most common age group was 18–25 years, with 5 males and 7 females, totaling 12 patients (30.0%). The 36–45 years age group had 5 males and 6 females, making up 11 patients (27.5% of the total). No patient was below 18 years or above 45 years as per the inclusion criteria. The female-to-male ratio was approximately 1.1:1, indicating a nearly equal sex distribution across all age groups. Among males, the highest proportion (9 out of 19, or 47.4%) was seen in the 26–35 years bracket, while among females, the same age group also contributed the maximum (8 out of 21, or 38.1%). Overall, the third decade of life (26–35 years) was the most

commonly affected period for active mucosal chronic otitis media with associated sinusitis in this study cohort.

Table 2: Anatomical Variations on Diagnostic Nasal Endoscopy (DNE)

Anatomical Variation	Number of Patients	Percentage
Enlarged bulla + Paradoxical middle turbinate	5	12.5%
Enlarged middle turbinate (Type 1)	4	10%
Medialised uncinate	4	10%
Deviated nasal septum alone	3	7.5%
Concha bullosa	2	5%
No significant variation	22	55%
Total	40	100.0%

The majority of patients, 22 out of 40 (55.0%), had no significant anatomical variation on endoscopic evaluation. Among those with identifiable variations, the most common finding was a combination of enlarged bulla with paradoxical middle turbinate, observed in 5 patients (12.5% of the total cohort). Enlarged middle turbinate (Type 1) and medialised uncinate process were each seen in 4 patients (10.0% respectively). Deviated nasal septum alone, without other associated variations, was present in 3 patients (7.5%). Concha bullosa was the least common identifiable variation, found in only 2 patients (5.0%). Thus, among the 18 patients who exhibited anatomical variations (45.0% of the total cohort), the combined finding of enlarged bulla and paradoxical middle turbinate was the single most frequent abnormality, followed equally by enlarged middle turbinate and medialised uncinate. No patient had more than two concurrent variations documented on routine diagnostic nasal endoscopy.

Table 3: Preoperative and Postoperative Middle Ear Mucosal Status (with p-value)

Middle Ear Mucosal Status	Preoperative	Postoperative at 3 months	p-value*
Moist edematous mucosa	31 (77.5%)	5 (12.5%)	<0.001
Boggy polypoidal mucosa	9 (22.5%)	0 (0%)	<0.001
Healthy, dry mucosa	0 (0%)	35 (87.5%)	<0.001
Total	40	40	

Preoperative otoendoscopic assessment of the middle ear mucosa revealed that the majority of patients, 31 out of 40 (77.5%), had moist edematous mucosa, while the remaining 9 patients (22.5%) exhibited boggy polypoidal mucosa. No patient (0%) had healthy, dry mucosa at baseline. Following functional endoscopic sinus surgery (FESS) with or without septal correction, a marked improvement in middle ear mucosal status was observed at three months of follow-up. Postoperatively, the proportion of patients with moist edematous mucosa dramatically decreased to only 5 out of 40 (12.5%). Notably, none of the patients (0%) continued to have boggy polypoidal mucosa after surgical clearance of sinusitis. Conversely, healthy, dry middle ear mucosa was achieved in 35 out of 40 patients (87.5%) at the end of the study period. The improvement from preoperative to postoperative status was statistically highly significant for all three categories, with a p-value of less than 0.001.

Table 4: CT Grading of Sinus Disease

CT Grade	Description	Number of Patients	Percentage
Grade I	Mucosal thickening <3mm	25	62.5%
Grade II	Incomplete opacification of one or more sinuses	8	20%
Grade III	Complete opacification of one or more (not all) sinuses	5	12.5%
Grade IV	Total opacification of all sinuses	2	5%
Total		40	100.0 %

The majority of patients, 25 out of 40 (62.5%), had Grade I disease, defined as mucosal thickening of less than 3 mm without significant opacification of any sinus. Grade II disease, characterized by incomplete opacification of one or more sinuses, was observed in 8 patients (20.0% of the cohort). Grade III disease, which denotes complete opacification of one or more major sinuses but not all sinuses, was present in 5 patients (12.5%). The most severe form, Grade IV disease representing total opacification of all sinuses, was found in only 2 patients (5.0%). Thus, mild to moderate sinus disease (Grades I and II combined) accounted for 33 patients (82.5% of the total cohort), while advanced disease (Grades III and IV) was seen in only 7 patients (17.5%).

DISCUSSION

The present study demonstrates a strong association between chronic sinusitis and persistent activity in mucosal type of COM, with an improvement rate of 87.5% following endoscopic sinus surgery. This finding aligns with the concept that the middle ear and the paranasal sinuses are interconnected via the Eustachian tube and nasopharynx, forming a single functional unit often termed the "sinus–middle ear reflex". In our cohort, the majority of patients (62.5%) had mild to moderate sinus disease (Grade I and II), yet this was sufficient to perpetuate ear discharge. This suggests that even low-grade sinus inflammation can maintain middle ear pathology,

possibly through bacterial translocation or inflammatory mediators. A similar observation was made by Reddy et al. (2018) in a study from Hyderabad, where 68% of patients with persistent otorrhea had endoscopic evidence of sinusitis, and clearance of sinus disease led to dry ears in 84% of cases.[3] Our results are slightly higher (87.5%), which may be attributed to the inclusion of only active mucosal type and exclusion of squamosal disease.

The anatomical variations identified in our study – enlarged bulla with paradoxical middle turbinate (12.5%), enlarged middle turbinate (10%), and medialised uncinate (10%) – are consistent with the Indian population's sinonasal anatomy. These variations narrow the ostiomeatal complex, impair mucociliary drainage, and predispose to recurrent sinusitis. In a multicentric Indian study by Sharma et al. (2021), the most common variation in COM patients was paradoxical middle turbinate (15.2%), followed by concha bullosa (11.8%), which matches our findings.[4] The high percentage of patients requiring septal correction (67.5%) in our study indicates that septal deviation is a major comorbid factor. This is supported by a study from Delhi by Gupta and Mehta (2019), who reported that 71% of patients with COM and chronic sinusitis had a significantly deviated nasal septum requiring correction during FESS.[5] Therefore, a combined approach addressing both septal and sinus pathology is often necessary.

Preoperative otoendoscopy revealed that 77.5% of our patients had moist edematous mucosa and 22.5% had boggy polypoidal mucosa. After FESS, none had polypoidal mucosa and only 12.5% remained moist. This dramatic improvement can be explained by the elimination of the septic focus in the sinuses, which reduces the bacterial load reaching the middle ear. A prospective study from Karnataka by Anitha and Ramesh (2020) reported similar findings: 82% of patients with active mucosal COM became dry within 12 weeks of FESS, and they noted a significant reduction in the need for topical antibiotics.[6] In our study, the 12.5% non-improvement rate warrants attention. Of these, one patient had isolated Eustachian tube dysfunction (hypofunction on dye test), which is a known independent risk factor for COM. The other four had recurrence of sinus disease due to surgical failure – a reminder that FESS requires skill and adequate postoperative care, including saline irrigation and follow-up endoscopy.

Comparing the study results with recent Indian literature, a study by Patnaik and Mohanty (2022) from Odisha found that 90% of patients with COM and associated chronic sinusitis benefited from FESS, with improvement in both ear and sinus symptoms.[7] However, their study included a younger population (mean age 24 years) and had a shorter follow-up (2 months). Our three-month follow-up is more robust. Another study from Punjab by Singh et al. (2021) reported an 80% improvement rate, but they performed only antral lavage rather than complete FESS, which is less effective.[8] This highlights that complete endoscopic clearance of all diseased sinuses is superior to limited procedures. The role of anatomical variations is further emphasized by a study from Kerala by Nair and George (2020), who noted that patients with COM and uncinate process hypertrophy had a 3.5 times higher risk of persistent ear discharge.[9] We observed medialised uncinate in 10% of cases, all of whom improved after uncinectomy.

Interestingly, not all patients with sinusitis and COM improve spontaneously after FESS; some require additional Eustachian tube interventions. In our study, one patient had persistent discharge despite a patent sinus ostium, and dye test confirmed poor tubal function. This aligns with the findings of a recent Indian trial by Bose et al. (2021), which recommended that preoperative Eustachian tube function testing be done in all patients with COM and sinusitis to predict surgical outcomes.[10] They reported that patients with normal tubal function had a 94% success rate after FESS, compared to only 45% in those with hypofunction. Our study had a small number of such cases, but it underscores the importance of multidisciplinary evaluation. The recurrence rate due to surgical failure (10% in our series) is comparable to the national average; a systematic review of Indian FESS outcomes by Venkatesh and Rao (2020) found a recurrence rate of 8–15% for chronic sinusitis with COM, often due to residual disease in the frontal or sphenoid sinuses.[11]

A major strength of the present study is the prospective design and the use of objective CT grading and endoscopic assessment. However, limitations include a small sample size (n=40), short follow-up (3 months), and single-center design. Long-term studies with larger cohorts are needed to confirm whether middle ear improvement is sustained beyond one year. Additionally, we did not perform microbiological correlation between sinus and middle ear cultures, which could have strengthened the causal link. An Indian study by Joshi et al. (2021) found that 65% of sinus and middle ear isolates were concordant (mainly Pseudomonas and Staphylococcus), suggesting direct spread.[12] Future research should include such microbiological mapping. Nevertheless, our study provides strong evidence that otologists should not treat the middle ear in isolation; a thorough nasal endoscopic examination is mandatory before labeling a case as refractory COM.

From a clinical practice perspective, our findings advocate for early referral of COM patients with nasal symptoms to a rhinologist. The practice of repeated ear toileting and antibiotic drops without addressing sinusitis is futile and contributes to antimicrobial resistance. A cost-effectiveness analysis by Thomas and Mathew (2019) from Tamilnadu found that performing FESS in COM patients with sinusitis reduced overall treatment costs by 35% over one year, by preventing repeated clinic visits and hospitalizations.[13] Therefore, integrating

FESS into the management algorithm of active mucosal COM is not only clinically beneficial but also economically sound. Surgeons should also be trained to recognize and correct anatomical variations such as paradoxical middle turbinate and medialised uncinate, as these are often missed on routine examination. In conclusion, sinusitis is a major treatable cause of persistent ear discharge, and functional endoscopic sinus surgery should be offered early to eligible patients.[14,15]

CONCLUSION

Sinusitis plays a major role in the etiology of persistent ear discharge in chronic otitis media active mucosal disease patients. Diagnostic nasal endoscopic examination is mandatory in all patients of chronic otitis media active mucosal disease which leads to proper management of disease. The most common anatomical variations which predispose to infection and inflammation of paranasal sinuses are deviated nasal septum, enlarged middle turbinate and medialised uncinate. The clearance of pathology in sinuses leads to improvement in the middle ear mucosal status. The clearance of sinusitis by functional endoscopic sinus surgery (FESS) leads to better outcome of middle ear disease clearance. Functional endoscopic sinus clearance is continuing as the best procedure for clearance of sinusitis.

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