

Research Paper

## Socio-demographic & clinico-pathological correlates of chronic otitis media: a tertiary care govt. Hospital based epidemiological study in eastern India

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**Abstract**

**Background:** Chronic otitis media (COM) is the commonest disorder in Otorhinolaryngology practice, characterized by chronic inflammation of the middle ear cleft and mastoid cavity which presents with recurrent ear discharge and deafness. It results in considerable morbidity and may even cause extra-cranial and intra-cranial complications. Infections of the middle ear and complications caused by COM, are still a major public health problem in the developing countries like India. It is one of the main causes for preventable hearing loss when treated appropriately. It is important to review the changing trends in natural history of the disease, associated socio-demographic parameters & clinico-pathological findings in order to understand the pathogenesis & initiate definitive treatment.

**Objective:** The present article attempts to explore the socio-demographic profile of patients with COM, attending outpatient department in a tertiary care govt. hospital in eastern India & correlate the clinico-pathological features with types of disease, its severity & risk factors for development of complications.

**Material & Methods:** A prospective, cross-sectional, observational study was carried out including consecutive patients with clinical diagnosis of COM. Their socio-demographic profile were recorded through a pre-designed proforma incorporating epidemiologic parameters, clinical & radiological findings. Data was statistically analyzed & correlated with literature review.

**Results:** In the present study, mostly male patients, of lower & upper lower socio-economic class, in the age group 21-30 years were included. Overcrowding was found to be positively associated with the risk of development of COM. Cases were mostly unilateral, mucosal but with a good number of squamous COM. Bad ear hygiene practices were highly prevalent among study population with poor knowledge about the disease. Aural discharge was the commonest presenting symptom followed by deafness. Most of the patients were suffering from the disease for long periods. Mucosal COM mostly caused mild hearing loss, whereas squamous COM caused more severe to profound hearing loss. Most of the central perforations caused mild hearing loss, subtotal & postero-superior marginal perforation caused moderate hearing loss and squamous COM with attic perforation is mostly associated with severe hearing loss. Correlation between congested/ persistently discharging and granulations/polypoidal middle ear mucosa with cholesteatoma was found to be statistically significant. Incus long process was commonly eroded & in the cases without cholesteatoma, granulation tissue in the mastoid antrum was associated with almost all the cases of ossicular necrosis. Duration of disease have been found to possess statistically significant correlation with development of complications,

**Conclusion:** The present study indicates that prevalence of COM can be reduced by avoiding unhealthy habits, improving health status & knowledge about the disease,. Thorough clinical examination & early & definitive management of COM helps to give the patients better outcome & reduces the chances of complications.

**Keywords:** chronic otitis media(COM), mucosal COM, squamous COM, cholesteatoma, hearing loss, complications.

## Introduction

Chronic suppurative otitis media (CSOM) describes chronic middle ear (ME) disease and is defined as 'chronic inflammation of the middle ear and mastoid cavity, which presents with recurrent ear discharge or otorrhoea through a tympanic membrane perforation'. The term chronic otitis media (COM) is a better term to encompass the varied pathology seen as a result of chronic ME inflammation.<sup>[1]</sup> The disease pathogenesis may sometimes begin in childhood as a spontaneous tympanic membrane perforation due to acute infection of the middle ear known as acute otitis media, or as a sequelae of less severe forms of otitis media, associated with eustachian tube dysfunction & retraction pocket formation or perforation of the tympanic membrane. Onset of the disease may occur in adulthood as well and causes hearing impairment. Spectrum of COM ranges from a relatively benign condition to a cause of death from intracranial complications. Mostly it is painless otorrhoea, when water enters into ears or an episode of upper respiratory tract infection occurs, which subsides on medical management only to recur again. So most of the cases suffer little from annoyance of running ears, thereby delaying definitive management. The effect on hearing is variable; the hearing loss is often perceived as slight even though both ears are severely affected. Thereby negligence runs them into the risk of more advanced disease with bone destruction, threats of intra- or extra-cranial complications & severe degrees of hearing loss, even profound hearing loss which may be irreversible even after surgical treatment of the disease. On the other hand some of the patients have chronic ill health, headache, giddiness, deafness and continued presence of pus in ear, which is often offensive & distressing; thereby the patients are handicapped for various occupation. COM is an important cause of acquired and preventable hearing loss, especially in the developing countries. Incidence of COM varies from 0.5%–2% in developed countries whereas in developing countries it varies from 3%–57%. In

India, incidence of COM is up to 30%.<sup>[2]</sup> So in the present article we tried to encompass these factors for better understanding & management of COM, an important public health problem.

## Aims & Objective

1. To record the socio-demographic profile of the COM patients
2. To document the type & degree of hearing loss in relation to disease pathology
3. To correlate clinical & pre-operative findings with per-operative findings, thereby establishing factors predicting high risk or advanced disease with impending complications
4. To assess the gap between knowledge & practice of the patients, thereby identifying the needs of change in healthcare delivery system to reduce the disease burden.

## Material & Methods

**Period of study:** October 2017 to September 2018

**Nature of study:** Prospective, cross-sectional, observational study over a period of 12 months.

**Place of study:** Department of Otorhinolaryngology (ENT) & Head-Neck Surgery, IPGME&R and SSKM Hospital, Kolkata.

**Sample size:** Institutional ethical committee clearance was obtained prior to commencement of the study. A pre-designed & pre-tested questionnaire was followed to interview all the patients attending the ENT out-patient department (OPD) with clinical diagnosis of COM. Written informed consent in their own language was obtained from the patients (or from their guardians, as the case may be) for participating in the study. Being a tertiary care govt. hospital, our hospital caters to a huge population of cases attending from urban as well as rural areas. The questionnaire was structured, open-ended revealing socio-demographic profile of the COM patients & their perception about the disease process was also recorded. Thorough history

taking & clinical examination was performed on the patients who consented to participate in the study. The patients were tested with X-ray mastoid, pure tone audiometry & general medical check up to rule out any other systemic illness. Computerised Tomography (CT) scan was done in selected cases with aural polyp, suspected COM complications, children with extensive cholesteatoma etc.

After initial medical management, patients were operated for definitive management of COM & per-operative findings were recorded to corroborate with the clinical findings. Thus 160 cases were included in the study, who were operated during the study period with close follow up. We excluded patients with medical co-morbidities, recurrent COM cases & patients with history of previous operations from our present study.

Patients included in the study were classified into four groups:

Group A: COM (mucosal) –unilateral- 66 cases (41.3%)

Group B: COM (mucosal) - bilateral- 56 cases (35%)

Group C: COM (squamous)- unilateral- 24 cases (15%)

Group D: COM (squamous)- bilateral- 14 cases (8.7%)

We recorded information regarding age, gender, socio-economic status, place of residence, overcrowding, personal habits, knowledge about the disease, presenting symptoms, duration of disease, type of perforation of tympanic membrane, degree of hearing loss, skiagram of mastoid, middle ear mucosal status, mastoid antral findings per-operatively, types of surgery performed, presence of intra-cranial or extra-cranial complications etc.

Statistical Framework: After recording data were tabulated and analyzed using Statistical Package for the Social Sciences (SPSS) software version 16. We calculated statistical parameters mean, standard deviation, median etc., and independent t test, Chi square/Fisher exact test were performed for describing the results of our study. Odds ratio (OR) with 95 % confidence interval (CI) were used to explore association between the variables. p value of  $\leq 0.05$  at 5 % level of accuracy was considered as significant.

## Result Analysis

**Table 1:** showing distribution of cases according to socio-demographic parameters

Attributes		Group A (n=66)	Group B (n=56)	Group C (n=24)	Group D (n=14)
Age(years)	1-10	3	1	0	1
	11-20	4	5	3	2
	21-30	25	23	9	6
	31-40	28	20	7	3
	41-50	3	3	2	1
	51-60	2	4	2	1
	>60	1	0	1	0
Gender	Male	36	35	15	9
	Female	30	21	9	5
Socio-economic status (Modified Kuppusswamy Scale)	Upper	3	2	0	1
	Upper middle	4	3	1	0
	Lower middle	7	5	4	2
	Upper lower	23	25	8	7
	Lower	29	21	11	4
Place of residence	Urban	29	34	10	5
	Rural	37	22	14	9
Overcrowding	Present	40	35	15	10
	Absent	26	21	9	4

On analysis of socio-demographic parameters, it was found that most of the patients were male (59.4%), with male: female ratio of 1.46, mostly

belonging to lower (40.6%) and upper lower (39.4%) socio-economic status as per Modified Kuppusswamy Scale. Average age of the patients

included in the study was estimated to be 25.87±12.29 years (median= 19, range= 7-65). Age was found not to vary across gender (mean ± SD = 25.76± 11.97 years vs. 26.04±13.09 years, unpaired t = 0.093 and p = 0.915 at df 37). Most of the patients (39.4%) were in the age group 21-30 years closely followed by patients in the age group 31-40 years (36.3%). Place of residence did not show any significant effect on the disease process (51.3% rural vs. 48.7% urban population,

p = 1.0 as per Fisher exact test). Overcrowding was found to be positively associated increasing the risk of development of COM (present in 62.5% of our study population, chi-square value= 20.881, P= 0.03). In our study 56.3% patients suffered from unilateral disease compared to 43.7% cases with bilateral disease. The distribution of cases showed 76.3% cases were mucosal COM as compared to 23.7% cases were squamous COM.

**Table 2:** showing personal habits & knowledge of the patients about the disease

Parameters	Response (Yes)	Response (No)
<b>Personal Habits</b>		
Bathing in pond/river	97 (60.6%)	63 (39.4%)
Pouring oil in ear	107 (66.9%)	53 (33.1%)
Unhygienic ear picking	113 (70.6%)	47 (29.4%)
<b>Knowledge about COM</b>		
COM is contagious	95 (59.4%)	65 (40.6%)
COM is inherited	89 (55.6%)	71 (44.4%)
COM is preventable	73 (45.6%)	87 (54.4%)
COM is curable	69 (43.1%)	91 (56.9%)
Deafness occurs from COM	65 (40.6%)	95 (59.4%)
COM can be life threatening	53 (33.1%)	107 (66.9%)

On analyzing personal habits, bad ear hygiene practices like bathing in pond/ river (60.6%), pouring oil in ear (66.9%) & unhygienic ear picking (70.6%), were found to be highly

prevalent among study population. Regarding knowledge of the patients about the disease, there were lots of misconceptions like COM is contagious (59.4%) & can be inherited (55.6%) as responded by our patients. Most of the patients were unaware of the fact that COM is preventable (54.4%) & can be cured by proper treatment (56.9%). Knowledge regarding COM can cause deafness was also lacking (59.4%) and poor knowledge about the fact that COM can cause life threatening complications (66.9%)

While considering clinical and operative data we clubbed the mucosal disease cases in one group (n= 122 cases) & squamous disease cases in the other group (n= 38 cases).

**Table 3:** Showing presenting symptoms, duration of disease, clinical & radiological variations of cases as well as operative & complication patterns of the study population

Parameters		COM mucosal disease (n= 122)	COM squamous disease (n=38)
Presenting symptoms	Aural discharge	103 (84.4%)	38 (100%)
	Deafness	94 (77%)	33 (86.8%)
	Itching in ears	33 (27%)	5 (13.2%)
	Rotatory sensation (vertigo)	7 (5.7%)	11(28.9%)
	Ringling sound (Tinnitus)	15 (12.3%)	12 (31.6%)
	Pain in ears	34 (27.9%)	18 (47.4%)
Duration of disease	< 2 years	29 (23.8%)	3 (7.9%)
	2-5 years	43 (35.2%)	6 (15.8%)
	> 5 years	50 (41%)	29 (76.3%)
Hearing loss	Mild	76 (62.3%)	5 (13.2%)
	Moderate	25 (20.5%)	9 (23.7%)
	Severe	14 (11.5%)	18 (47.4%)
	Profound	7 (5.7%)	6 (15.7%)
Skiagram of mastoid	Pneumatic	97 (79.5%)	3 (7.9%)
	Sclerotic	15(12.3%)	31 (81.6%)
	Diploic	10 (8.2%)	4 (10.5%)
Types of surgery performed	Tympanoplasty	95 (77.9%)	0
	Cortical mastoidectomy + tympanoplasty	27 (22.1%)	0
	Canal wall down mastoidectomy	0	38 (100%)
Complications	None	119 (97.6%)	22 (57.9%)
	Facial palsy	2(1.6%)	5 (13.2%)
	Lat SCC fistula	1(0.8%)	6 (15.8%)
	Brain abscess	0	2 (5.2%)
	Mastoid abscess	0	3 (7.9%)

Aural discharge was the commonest presenting symptom in mucosal COM (84.4%) & present in all cases of squamous COM (100%). This was followed by deafness which was more prevalent in squamous COM group (86.8%) vs 77% in mucosal COM group. Rotatory sensation (vertigo) was complained by 11 patients suffering from squamous COM (28.9%) of whom 9 cases were found to have lateral semicircular canal (SCC) erosion & fistula by cholesteatoma during mastoid exploration, thus correlating the clinical symptoms with per-operative findings. On the other hand, only 1 case of lateral SCC erosion was found in the mucosal COM group per-operatively (0.8%), may have been caused by inflammatory granulation tissue, which is rare in mucosal disease. Majority of the patients in the mucosal group were suffering from the disease for long periods (41% for > 5years & 35.2% for 2-5 years), indicating lack of awareness & low perceived threat regarding the disease. The disease was more neglected in the squamous COM as 76.3% cases were suffering for > 5 years, due to scanty discharge which although intermittent was

recurrent. Mucosal COM mostly caused mild hearing loss (62.3% cases), also contributing to delay in seeking definitive treatment, whereas squamous COM caused more severe (47.4%) to profound hearing loss (15.7%) due to extensive bone destruction, ossicular erosion & inflammatory mediators related inner ear damage. Radiological features showed mostly pneumatic mastoid in mucosal COM (79.5%) & mostly sclerotic (81.6%) in squamous COM, although mastoid pneumatisation pattern could not be directly correlated to disease process as 12.3% cases of mucosal COM had sclerotic mastoid.

**Table 4:** Showing distribution of cases according to types of perforation

Type of Perforation	Number (%)
Central	76 (47.5%)
Subtotal	25 (15.6%)
Attic	38 (23.8%)
Postero-superior marginal	21 (13.1%)
Total	160

Clinical examination showed most of the cases had central perforation (47.5%) whereas attic perforation was noted in 38 cases (23.8%) which were the squamous COM cases.

**Table 5:** Correlating types of perforation with resultant hearing loss

Type of Perforation	Hearing Loss			
	Mild	Moderate	Severe	Profound
Central	67 (41.9%)	5 (3.1%)	3 (1.9%)	1(0.6%)
Subtotal	3 (1.9%)	13 (8.1%)	7 (4.4%)	2 (1.2%)
Attic	7 (4.4%)	6 (3.8%)	17 (10.6%)	8 (5%)
Postero-superior marginal	4 (2.5%)	10 (6.3%)	5 (3.1%)	2 (1.2%)
Total	81	34	32	13

While considering the type of hearing loss in relation to the type of perforation, most of the central perforations caused mild hearing loss (41.9%) whereas subtotal perforations mostly caused moderate hearing loss (8.1%). Postero-superior marginal perforation also correlated with moderate hearing loss (6.3%), mostly due to increased chances of ossicular erosion. Squamous COM with attic perforation is mostly associated with severe hearing loss (10.6%).

**Table 6:** Showing variations of middle ear mucosal status pre-operatively

Middle ear mucosal status (pre-op)	Number (%)
Normal	95 (59.4%)
Congested/ discharging	18 (11.3%)
Oedematous	27 (16.8%)
Granulations/ polypoidal	20 (12.5%)
Total	160

Another important clinical finding was the middle ear mucosal status noted pre-operatively by examination under microscope. Most of the cases had normal middle ear mucosa (59.4%) whereas 16.8% showed oedematous mucosa followed by granulations/ polypoidal mucosa & congested/

discharging mucosa respectively. These had been correlated with the per-operative mastoid antral

findings per-operatively, as summarised in the next table.

**Table 7:** Corroborating the pre-operative mucosal status with per-operative mastoid antral findings

Middle ear mucosal status (pre-op)	Mastoid Antral Findings (per-op)			
	Healthy	Oedematous	Granulation tissue	Cholesteatoma
Normal	95 (59.4%)	0	0	0
Congested/ discharging	0	0	1 (0.6%)	17 (10.6%)
Oedematous	0	5 (3.1%)	16 (10%)	6 (3.8%)
Granulations/ polypoidal	0	1 (0.6%)	4 (2.5%)	15 (9.4%)

It was found that normal middle ear mucosal status directly correlated with healthy mastoid antral mucosa (59.4% cases) whereas congested/persistently discharging mucosa cases mostly turned out to be cases with underlying cholesteatoma (10.6%) and only few cases with granulation tissue in mastoid antrum (0.6%). Another pre-operative mucosal status with high risk of turning out as cholesteatoma cases was granulations/polypoidal middle ear mucosa (9.4% cases). On the contrary cases with only oedematous mucosa turned out to have mostly granulations in mastoid antrum (10% cases) rather than frank cholesteatoma (3.8%). On applying Fisher exact test the correlation between congested/persistently discharging and granulations/polypoidal middle ear mucosa with cholesteatoma was found to be statistically significant [  $p=0.035$  at  $df$  1, OR (95%)= 11.11]. All the cases with squamous COM underwent canal wall down mastoidectomy operation whereas for 77.9% cases with mucosal COM, tympanoplasty was sufficient and in rest of the cases with mucosal COM (22.1% cases) cortical mastoidectomy was combined with tympanoplasty as a part of definitive management. Among the 27 cases of mucosal COM, 22 cases (13.8%) showed ossicular necrosis, along with the 38 cases of squamous COM with ossicular erosion & engulfment by cholesteatoma. Thus overall 37.5% cases had ossicular necrosis, of which incus long process was eroded in 20 cases (12.5%) followed by erosion of stapes superstructure in 14 cases (8.1%), It is also worth mentioning that in the cases devoid of cholesteatoma, granulation tissue

in the mastoid antrum was associated with almost all (95.5%) the cases of ossicular necrosis.

**Table 8:** Depicting relation between duration of disease & occurrence of complications

Complications	Duration of disease		
	< 2 years	2-5 years	> 5 years
Facial palsy	0	2 (10.5%)	5 (26.3%)
Lat SCC fistula	0	3 (15.8%)	4(21.1%)
Brain abscess	0	0	2 (10.5%)
Mastoid abscess	0	0	3 (15.8%)

In the present study only 19 cases (11.9%) showed complications. While we searched about the duration of disease in these patients, both the brain abscess cases had duration of disease > 5 years (10.5% of overall cases with complication). 4 cases of lateral SCC fistula (21.1%), 3 cases of mastoid abscess (15.8%) and 5 cases of facial palsy (26.3%) also suffered from the disease longer than 5 years. Thus duration of disease have been found to possess statistically significant correlation with development of complications [Fisher exact test,  $p=0.048$  at  $df$  1, OR (95%)= 1.312].

## Discussion

The present study on COM has attempted to explore the patient characteristics using standard epidemiological parameters to have better understanding & management of COM, the commonest disorder in Otorhinolaryngology clinical practice. The study comprised of 160 patients, with male predominance (male: female ratio of 1.46). Similar male predominance has been noted by several authors.<sup>[3-6]</sup> However one study demonstrated marginal female preponderance.<sup>[7]</sup> This may be related to the

prevalent socio-demographic dynamics with male patients attending medical facility more commonly than females. Most of the patients (39.4%) in our study were in the age group 21-30 years closely followed by those in the age group 31-40 years (36.3%). This coincides with the results found by Berron<sup>[8]</sup>, Kalapana et al.<sup>[9]</sup> & others.<sup>[3,5]</sup> This age group variations also points to delay in seeking proper treatment as patients suffered from the disease for prolonged periods.

Prevalence of the disease was found to be more in lower & upper lower socio-economic status in the present study. This socio-demographic distribution of cases corroborated to results of different authors.<sup>[3-6,8]</sup> Greater severity of COM in people from lower social classes may be multifactorial, related to lack of education, health awareness, increased number of children, homes with poor sanitation & hygiene, overcrowding, malnutrition, impaired immunity, increased risks of infections & presence of cross infection among family members. In our present study we found overcrowding to have statistically significant association with development of COM. However we found no significant difference in COM prevalence among rural & urban population, which may be related to increased health awareness among rural people attending health care facility.

Poor personal habits like bathing in pond/river, pouring oil in ear & unhygienic ear picking habits were found to be widely prevalent among our study population, which are associated with progression of COM. Lack of knowledge about the disease & misconceptions were also found to be high among our study population. This resulted in negligence, delayed & irregular attendance to medical facility, lower perception of chances of life threatening complications among the patients. Similar observations were made by various authors.<sup>[10,11]</sup> This gap in public awareness can be overcome by imparting proper IEC (i.e. information, education & communication) activities which needs to be initiated from general practitioners, ancillary health care personnel as

well as specialist Otorhinolaryngology practitioners.

In the present study, aural discharge was found to be the commonest presenting symptom followed by deafness. Duration of COM was found to be longer than 5 years in majority of the cases followed by duration between 2-5 years. Similar presentation & duration have been reported from various studies.<sup>[12-14]</sup>

Unilateral disease was more common in the present study and similar result was reported in various studies.<sup>[14,15]</sup> Majority of the patients in our study had central perforation (47.5%) followed by 15.6% cases with subtotal perforation. The result closely resembles to that of studies reported by Memon et al.<sup>[14]</sup> & Nagle SK et al.<sup>[16]</sup> It was also noted from our observation that central perforation commonly caused mild hearing loss (41.9% cases) whereas subtotal & postero-superior marginal perforation resulted in moderate hearing loss and attic perforation in squamous COM is associated with severe hearing loss. Studies by various authors have reported that air bone gap is positively correlated with the size of the perforation.<sup>[17]</sup> Mucosal COM was more common type of disease in the present study although we encountered a good number of squamous COM cases (23.7%) as well and this is slightly in contrary to some other studies with a lower percentage of squamous COM cases.<sup>[3,14]</sup> This can be accounted by the fact that being a tertiary care Govt. hospital in eastern India, cases are referred to us from all over our state as well as from eastern & north-eastern part of India & most of the referred cases are complicated case with extensive involvement by cholesteatoma. For the same reason we also encountered a higher number of cases with COM complications (11.9% cases) even in this era of improved antibiotic therapy.

In the present study normal middle ear mucosa was noted in 59.4% cases whereas congested, persistently discharging & polypoidal middle ear mucosa were found to be significantly associated with cholesteatoma statistically. Nearly similar rates of normal middle ear mucosa were reported

in the studies.<sup>[18,19]</sup> The present study corroborated the fact that middle ear pathology reflects the antral pathology, as similar observation was reported in the study by Veeranjanyulu P et al.<sup>[18]</sup> The pattern of ossicular necrosis has been similar with long process of incus was the commonest ossicles to be eroded followed by stapes superstructure, as also reported by Rout MR et al.<sup>[20]</sup> In our study granulation tissue was associated with ossicular erosion in most of the cases, which has been supported in literature.<sup>[19,20]</sup> Complications encountered in the present study were mostly associated with squamous disease with prolonged untreated, partially treated & neglected disease. Similar complications were also documented in various studies.<sup>[3,14]</sup> Occurrence of these complications indicates need of early & definitive management of COM in order to prevent life threatening complications.

### Conclusion

The present study indicates that prevalence of COM can be reduced by avoiding unhealthy habits, improving health status & knowledge about the disease,. The need of combining mastoid exploration based on high risk middle ear pathology reasserted as it reflects mastoid antrum pathology. Thorough clinical examination & early & definitive management of COM helps to give the patients better outcome & reduces the chances of complications.

**Conflict of Interest:** None declared

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