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Main Article

Clinico-epidemiological study of complicated and uncomplicated chronic suppurative otitis media

B K Vikram, N Khaja*, S G Udayashankar, B K Venkatesha, D Manjunath

Abstract

Introduction: This study aimed to compare the clinical and epidemiological profiles of cases of complicated and uncomplicated chronic suppurative otitis media, based on their prognostic factors.

Materials and methods: This was a prospective, cross-sectional study conducted in a tertiary care medical college hospital over a period of two and a half years. The study group comprised 187 ears, out of which 62 had complications while 125 did not. The two groups were compared with respect to nine prognostic variables: age distribution, sex, patient's domicile, literacy status, duration of ear discharge at presentation, ear pathology, predisposing disease focus in the nose or throat, ear swab microbiology, and hearing loss.

Results: Patients in the complicated chronic suppurative otitis media group had a higher male predominance and were younger. Rural and illiterate patients had a higher risk of developing complications. Cholesteatoma and granulation tissue were potential risk factors in the complicated chronic suppurative otitis media group. Ears with complications were more prone to develop sensorineural hearing loss. Age, sex, duration of ear discharge, predisposing disease focus in nose or throat, and ear swab microbiology were all less useful prognostic indicators of complications.

Conclusion: Early detection and timely treatment of chronic suppurative otitis media in rural and illiterate patients may prevent life-threatening complications and reduce their incidence. Ears that harbour relatively large quantities of both cholesteatoma and granulation tissue together require more urgent surgical intervention and more extensive disease clearance in order to prevent complications.

Key words: Otitis Media, Suppurative; Cholesteatoma; Complications

Introduction

The incidence of chronic suppurative otitis media (CSOM), with or without complications, is generally on the decline; however, this condition continues to be a common ear disease in developing countries. The complications of CSOM have a unique set of clinical signs and symptoms and carry high morbidity and mortality rates. Therefore, it is important to identify ears at risk of complications at an early stage, and try to prevent such complications.

The aim of this study was to compare the clinical and epidemiological profiles of cases of complicated and uncomplicated CSOM, based on their prognostic factors.

Materials and methods

This was a prospective, cross-sectional study undertaken in a tertiary care hospital from July 2003 to December 2005. The hospital catered for a predominantly rural population which had a relatively high incidence of CSOM.

Patients were selected by a multiphase, random sampling process from the ENT out-patient clinic. In the first phase (universe of the study, which is the total number of patients taken as an unit from which other subsets are derived), all patients attending the ENT out-patient clinic, with various complaints, were screened (7210 patients). The second phase included those patients from the first phase who had chronic otitis media (1257 ears). The third phase included those consecutive ears from the second phase which harboured granulation tissue, polyps or cholesteatoma (187 ears). This included 13 patients who had bilateral attico-antral ear disease. Out of the 187 ears, 11 had tubo-tympanic disease in the other ear.

The study included cases of both sexes and patients aged more than eight years.

The ears in the third phase were divided into two groups – complicated and uncomplicated CSOM – depending on the presence or absence of complications. One hundred and eighty-seven ears were

From the Department of Otolaryngology, Head and Neck Surgery, Karnataka Institute of Medical Sciences, Hubli, and the *Department of Otolaryngology Head & Neck Surgery, Vijayanagar Institute of Medical Sciences, Bellary, India.
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studied in all, out of which 62 had complications. Among the ears with complications, five had attico-antral disease, while eight had tubotympanic disease in the other ear.

The inclusion criteria were as follows. The complicated CSOM group included ears with attico-antral CSOM with its complications (extracranial, intracranial or both). The uncomplicated CSOM group included ears with attico-antral CSOM and harbouring granulation tissue, polyps or cholesteatoma but with no complications.

Each patient underwent investigations like otoendoscopy, diagnostic nasal endoscopy and ear swab for microbiological analysis. High resolution computed tomography (CT) scanning of the temporal bone or CT scanning of the head was performed wherever necessary. Histopathological analysis of middle-ear granulation tissue was also performed in all cases undergoing surgery. Pure tone audiometry (PTA) with masking was performed in patients well enough to undergo testing.

The majority of the patients underwent canal wall down mastoidectomy. Other surgical procedures (e.g. incision and drainage of abscess, burr hole craniotomy) were performed according to the requirements of each individual case. Predisposing disease foci in the nose or throat were addressed medically or surgically at the same time.

Results

In our study, it was observed that all patients with complications invariably had unhealthy granulation tissue and/or cholesteatoma, with or without polyps, in their ears. There were no complications in cases with tubo-tympanic CSOM in the second phase. Forty-two ears had extracranial complications only, eight had intracranial complications only and 12 had both.[1] Multiple complications (two or more) were present in 21 ears.[1] Only one patient had complications in both ears. The details of patients' complications are given in Table I.

We compared the two groups with respect to the following prognostic variables: age, sex, domicile, literacy status, duration of ear discharge, hearing loss, predisposing disease focus in the nose or throat, ear pathology, and ear swab microbiology.

TABLE I

CSOM COMPLICATIONS DETECTED*

Complication	Cases (*n*)
Extracranial	
Mastoid complications	39
Neck abscess	6
Cranial nerve palsy	9
Labyrinthine fistula	6
Intracranial	
Meningitis	8
Sigmoid sinus thrombosis	9
Brain abscess	10
Extra/subdural abscess	2

*In the complicated chronic suppurative otitis media (CSOM) group.

TABLE II

AGE DISTRIBUTION IN COMPLICATED AND UNCOMPLICATED CSOM GROUPS

Age(yrs)	CG (*n*)			UG (*n*)		
	M	F	Total	M	F	Total
6–15	19	8	27 (43.54%)	30	16	46 (36.8%)
16–25	14	9	23 (37.09%)	29	21	50 (40%)
26–35	4	1	5	16	4	20
36–45	4	0	4	5	2	7
>46	3	0	3	1	1	2
Total	44	18	62	81	44	125

CSOM = chronic suppurative otitis media; yrs = years; CG = complicated CSOM group; UG = uncomplicated CSOM group; M=male; F = female

Age distribution

Patients' ages ranged from 8 to 60 years (Average age, 19.32 years) in the complicated CSOM group and 6 to 50 years (Average age, 20.06 years) in the uncomplicated CSOM group. Most of the complications occurred before the age of 25 years. Patient's age distribution is shown in Table II. There were more paediatric patients in the complicated CSOM group (43.54%) than in the uncomplicated CSOM group (36.8%). A two-sample 'z' test of the raw data did not show any statistically significant difference between the two groups at 95% confidence intervals (CI) ($p = 0.630$).

Sex

The complicated CSOM group showed a higher male predominance, with a male:female ratio of 2.4:1, compared with 1.8:1 in the uncomplicated CSOM group.

Domicile

In both the groups, the majority of the patients were from rural areas (Table III). There were more rural patients in the complicated CSOM group. There was a strong association between rural domicile and complications at 95% CI (Fisher's exact test; $p = 0.0129$). Calculation of relative risk and odds ratio revealed that rural patients had nearly twice the risk of developing complications, compared with urban patients (relative risk = 2.091, odds ratio = 2.771).

Literacy status

In both groups, there were more illiterate patients than literate patients, although the percentage of illiterate patients was higher in the complicated CSOM group (Table IV). The association between literacy status and complications was not statistically

TABLE III

DOMICILE IN COMPLICATED AND UNCOMPLICATED CSOM GROUPS

Domicile	CG (*n*)	UG (*n*)	Total (*n*)
Rural	53 (85.48%)	85 (68%)	138
Urban	9	40	49
Total	62	125	187

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TABLE IV

LITERACY STATUS IN COMPLICATED AND UNCOMPLICATED CSOM GROUPS

Literate?	CG (*n*)	UG (*n*)	Total (*n*)
No	36 (58.06%)	65 (52%)	101
Yes	26	60	86
Total	62	125	187

significant at 95% CI (Fisher's exact test; $p = 0.4415$). However, calculation of relative risk (1.179) and odds ratio (1.278) showed an increased risk of complications in illiterate patients.

Ear discharge duration

Table V shows the approximate duration of ear discharge at the time of diagnosis for the two groups. There was little difference between the two groups; the average ear discharge duration at presentation was 7.74 years (Range, 15 days to 23 years) for the complicated CSOM group and 7.32 years (range, 8 days to 32 years) for the uncomplicated CSOM group. This difference was not statistically significant, using a two-sample unpaired *t*-test at 95% CI ($p = 0.661$).

Ear pathology

Patients' ears were examined by otoendoscopy and the presence or absence of macroscopic cholesteatoma, granulation tissue or polyps was noted. Findings were further verified during definitive surgery, if undertaken. Granulation tissue from the middle ear was sent for histopathological examination and was analysed for keratin, cholesterol crystals, giant cells, macrophages etc. Both cholesteatoma and granulation tissue were found to be commoner in the complicated CSOM group.

The association between cholesteatoma presence and CSOM complications was found to be very significant at 99% CI (Fisher's exact test, $p = 0.0069$) (Table VI). Calculation of relative risk (2.085) and odds ratio (2.794) showed an increased risk of complications in the presence of cholesteatoma.

Similarly, there was a statistically significant association between granulation tissue presence and complications at 95% CI (Fisher's exact test, $p = 0.011$) (Table VII). Calculation of relative risk (2.202) and odds ratio (2.948) showed that the risk of complications was increased more than twice in the presence of granulation tissue.

TABLE V

EAR DISCHARGE DURATION AT PRESENTATION, IN COMPLICATED AND UNCOMPLICATED CSOM GROUPS

Discharge duration (yrs)	CG (*n*)	UG (*n*)	Total (*n*)
Unknown	1	4	5
<1	10	20	30
1–5	16	36	52
6–10	14	31	45
11–15	16	22	38
16–20	4	10	14
>21	1	2	3
Total	62	125	187

TABLE VI

PRESENCE OF CHOLESTEATOMA IN COMPLICATED AND UNCOMPLICATED CSOM GROUPS

Cholesteatoma?	CG (*n*)	UG (*n*)	Total (*n*)
Yes	51 (82.26%)	78 (62.4%)	129
No	11	47	58
Total	62	125	187

TABLE VII

PRESENCE OF GRANULATION TISSUE IN COMPLICATED AND UNCOMPLICATED CSOM GROUPS

Granulation tissue?	CG (*n*)	UG (*n*)	Total (*n*)
Yes	54 (87.09%)	87 (69.6%)	141
No	8	38	46
Total	62	125	187

Cholesteatoma and granulation tissue were simultaneously present in 69.35% of cases in the complicated CSOM group, as compared with 34.4% in the uncomplicated group. There was a very strong association between such double pathology and complications at 99.9% CI (Fisher's exact test $p < 0.0001$), (Table VIII). Calculation of relative risk (2.658) and odds ratio (4.3157) showed that such double pathology increased the risk of complications by more than 2.5 times, compared with the effect of either cholesteatoma or granulation tissue when present separately.

During surgical exploration of the mastoid and middle ear in complicated cases, we found relatively larger quantities of cholesteatoma and granulation tissue, especially in patients with multiple complications.

Predisposing disease focus in nose or throat

A diagnostic nasal endoscopy was performed to look for a disease focus in the nose or throat, such as persistent adenoids, tubal tonsillitis, hypertrophied turbinates, nasal polyp, sinusitis, atrophic rhinitis or grossly deviated nasal septum. A contributing disease focus in the nose or throat was found in 70.96% of complicated CSOM cases and in 82.4% of uncomplicated CSOM cases. The age distribution of patients with a predisposing nose or throat disease

TABLE VIII

PRESENCE OF CHOLESTEATOMA AND GRANULATION TISSUE IN COMPLICATED AND UNCOMPLICATED CSOM GROUPS

Pathology	CG (*n*)	UG (*n*)	Total (*n*)
Chol + GT	43 (69.35%)	43 (34.4%)	86
Chol or GT	19	82	101
Total*	62	125	187
Chol only	8	37	45
GT only	11	45	56

*Patients with cholesteatoma (Chol) and granulation tissue (GT), plus those with Chol or GT.

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TABLE IX

PRESENCE OF PREDISPOSING DISEASE FOCUS IN NOSE OR THROAT, BY AGE

Age (yrs)	Disease focus present? (*n*)			
	CG		UG	
	Yes	No	Yes	No
6–15	17	10	39	7
16–25	16	8	42	8
26–35	4	0	15	4
36–45	5	0	6	1
>46	2	0	1	2
Total	44 (70.96%)	18	103 (82.4%)	22

focus is shown in Table IX. There was no statistically significant association between such disease foci and CSOM complications at 95% CI (Fisher's exact test, $p = 0.0886$). Calculation of relative risk (0.6652) and odds ratio (0.5221) showed that the presence of nose or throat disease foci did not increase patients' risk of CSOM complications.

Ear swab microbiology

On microbiological analysis of ear swabs, both groups showed a similar pattern. *Pseudomonas aeruginosa* was the commonest organism found in both the groups (Table X).

Hearing loss

In the complicated CSOM group, all patients who underwent PTA had pure conductive hearing loss, while 85.71% had mixed hearing loss. In the uncomplicated CSOM group, of those who underwent PTA, 93.18% had pure conductive hearing loss, while 47.72% had mixed hearing loss. There was a statistically significant difference between hearing levels in the two groups at 99% CI, by two-sample unpaired *t*-test of raw data (Pure tone average in dB) ($p < 0.001$).

Discussion

Chronic suppurative otitis media would have been just another benign ear disease, but for its potential for complications. Complications of CSOM are particularly common in developing countries, especially in rural areas with low socioeconomic status and low literacy rates. Other contributing socioeconomic factors are ignorance, poverty, overcrowding, poor personal hygiene and lack of access to medical help. Hence, illiterate patients in rural areas are particularly vulnerable to CSOM complications. Yet another problem in rural areas is the late reporting of cases at an advanced stage of disease, often with multiple, simultaneous complications, due to lack of health awareness. In the third phase of our study, some ears had complications, while the others did not. Why is this so? Relevant information is scarce; very few published, prospective studies have compared the prognostic factors for complicated and uncomplicated CSOM. No previous prospective study has compared the effect of domicile, literacy status, predisposing disease focus in the nose or throat, and hearing loss.

In the current study, age, sex and duration of ear discharge did not appear to cause any statistically significant difference between the groups. However, a few studies have reported a younger age[2,3] and a shorter duration of ear discharge in patients with complicated CSOM.[2,4] Many authors have found a higher male:female ratio for patients with CSOM complications.[3,5,6] Granulation tissue and/or cholesteatoma have been major findings in complicated CSOM cases in a few previous studies.[4–7] Most of the cases that had multiple complications or only intracranial complications were found to harbor cholesteatoma.[1] A few authors have reported cholesteatoma as a common finding in patients with intracranial CSOM complications.[8,9]

Cholesteatoma and granulation tissue were identified as independent risk factors in the current study, and it appeared that their simultaneous existence in the same ear compounded the risk of developing a CSOM complication. This compounding effect might possibly have been due to facilitation of each other's bone-eroding effects. The quantum (i.e., volume) of granulation tissue or cholesteatoma could be an additional factor for bone erosion and destruction. Hence concomitant presence of cholesteatoma and granulation tissue could represent a greater risk factor than that posed by either of them alone. This might strongly predict the development of complications in CSOM. This may mean that such patients need priority treatment and require more extensive and meticulous surgical disease clearance.

TABLE X

MICROBIOLOGICAL ORGANISMS FOUND IN COMPLICATED AND UNCOMPLICATED CSOM GROUPS

Organism	CG (*n*)	UG (*n*)	Total (*n*)
Pseudomonas	17	45	62
S aureus	15	20	35
Proteus	7	12	19
Klebsiella	0	4	4
E coli	4	5	9
Citrobacter	0	3	3
Providentia	1	2	3
Enterobacter	1	0	1
Non-fermenting bacilli	1	5	6
No growth	8	3	11

- **This study compared prognostic factors for complicated and uncomplicated attico-antral chronic suppurative otitis media, within a developing country**
- **Rural and illiterate patients had a higher risk of developing complications**
- **Coexistence of cholesteatoma and granulation tissue was a potential risk factor for complications**
- **Ears with complications were more prone to develop sensorineural hearing loss**

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We also observed that the likelihood of significantly improving the hearing of patients with complicated CSOM was not very high, because of the severe mixed hearing loss which was already present.

Both our study groups had a high incidence of disease foci in the nose or throat. However, there were no such foci in complicated CSOM patients above the age of 25 years. The presence of such disease foci was not associated with either group significantly, and did not represent a risk factor for complications.

A few other authors have reported pseudomonas species as the commonest organisms found in patients with CSOM complications, in agreement with our findings.[5,10]

We found sensorineural hearing loss to be more strongly associated with the complicated CSOM group than the uncomplicated CSOM group. Leskinen *et al.* found permanent hearing loss in 26% of their complicated CSOM cases.[11]

Conclusion

It is important to identify cases of CSOM which are more predisposed to the development of complications. In our study, rural domicile and illiteracy significantly increased patients' risk of CSOM complications. In such underprivileged patients, early detection (by screening tests) and timely treatment of CSOM may prevent the development of life-threatening complications. We found that patients with complications were younger and had a slightly longer duration of ear discharge at presentation. Cholesteatoma and granulation tissue when present is an important prognostic indicator of complications. Ears that harbour relatively large quantities of both cholesteatoma and granulation tissue together require early surgical intervention and extensive disease clearance in order to prevent complications. Patients with complications are more vulnerable to the development of sensorineural hearing loss. Age, sex, duration of ear discharge, predisposing disease foci in the nose or throat, and ear swab microbiology were not statistically significant prognostic indicators of CSOM complications in this study.

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Address for correspondence:
Dr B K Vikram,
102 Arvind Apartments,
Kalyan-nagar,
Hubli 580031,
Karnataka, India.

E-mail: entvikram@rediffmail

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