



Cross-sectional Study

Management evaluation of patients with chronic suppurative otitis media: A retrospective study

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ABSTRACT

Background: Chronic suppurative otitis media (CSOM) is a chronic infection of the middle ear with perforation of the tympanic membrane and secrete from the ear more for than two months, either continuously or intermittently. Chronic suppurative otitis media has a high prevalence and impact on the physical, social, and psychological of the patients. This disease may be fatal and even cause death.

Objective: Analyzing management evaluation of CSOM patients.

Methods: A retrospective study was conducted based on medical records of CSOM patients from January 2017–December 2019. The study used total sampling Chi-squared test with $p < 0.05$.

Results: There were 600 patients with CSOM in January 2017–December 2019. Most of them were male, aged 36–45 years old with normal body mass index. There were 431 patients on the follow-up post-treatment by either medical or surgical management. The recovery rate could be assessed from the evaluation of CSOM complaints 6 months after treatment, and the results were significant ($p < 0.001$). **Conclusions:** CSOM managements are in the form of operative and non-operative that shows improvement within 6-month evaluation.

1. Background

Chronic suppurative otitis media (CSOM) is a chronic infection of the middle ear with perforation of the tympanic membrane and secrete from the ear for more than two months, either continuously or intermittently [1]. According to WHO, the prevalence of CSOM in the world is 65–330 million people, with 60% of whom experiencing hearing loss. Meanwhile, the incidence rate is 9 cases out of 100,000 population [2]. The high incidence of CSOM is influenced by the etiology and the pathogenesis of the CSOM itself. There are several influencing factors, such as infection, anatomy or physiology dysfunction, environment, allergy, or patient's factor including immunity, gender, and others [3]. Clinically, CSOM is classified into two types, namely the tubotympanic and the atticointral. CSOM disease begins with inflammation of the middle ear that lasts a long time and does not receive adequate management [3,4].

Symptoms of CSOM may include thick and stink discharge from the ear canal (otorrhea), decreased hearing ability, ringing in ears, ear pain, ear fullness, headache, and dizziness. Diagnosis of CSOM can be confirmed by examination using an otoscope or a microscope, hearing examination, facial nerve topography examination, bacterial culture

examination, and antibiotics resistance test from the ear secretion, and also the ear and temporal bone imaging by *Computed Tomography-Scan* (CT-Scan) dan *Magnetic Resonance Imaging* (MRI) temporal [2,4].

CSOM management includes education, aural toilets, administration of antibiotics, and surgery. The initial therapy that can be given to patients with CSOM is aural toilet. Education should always be given to the patient to keep his/her ear dry, open his/her mouth while sneezing or coughing, consult a doctor immediately if there are any complaints of cough and colds. Ear canal cleaning (aural toilet) should be conducted using warm normal saline or hydrogen peroxide 3% solution. The administration of a broad-spectrum antibiotic to CSOM patients could be in form of topical and systemical (orally or intravenously) for a minimum of 5 days to 2 weeks to eliminate CSOM without complications [2,4]. Patient with treatment failure who presents with persistent otorrhea after three weeks of treatment can be additionally treated with topical antibiotics that are based on the culture in addition to the aural toilet. Oral treatment can be given if there is no selection of topical therapeutics based on the pathogen susceptibility pattern. If the patient fails topical or oral culture-based therapy, intravenous (IV) antibiotics may be administered. However, surgery is necessary if there is an infectious condition

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that requires evacuation or decompression to reduce infection, reconstruct, prevent, and treat infections and complications. Some researchers believe that middle ear and mastoid surgery should be performed on children who fail on maximal medical therapy including IV antibiotics, or recurrent in a relatively short time of about six to eight weeks [5]. The surgery can be performed based on the CSOM type, such as canal wall up and canal wall down, particularly on CSOM with cholesteatoma [4,6].

Evaluation of clinical conditions on the management given is carried out periodically to assess the possibility of recurrence. The evaluation should be conducted during hospitalization, one week after the procedure, within one to approximately six months, assessing the patient's complaints, ear and temporal state, and hearing function. Evaluation of the management both in the form of medical and operative measures must be carried out properly, so that patient management becomes more comprehensive. In the end, the evaluation of the management given can help reduce the morbidity and mortality rates of CSOM. This study aimed to evaluate the management that has been carried out on CSOM patients.

2. Methods

Participants in this study were CSOM patients who underwent treatment. Participant's inclusion criteria were patients diagnosed with CSOM [1,7,8]. Participant's exclusion criteria included incomplete participant medical records.

This study employed a retrospective design using data from January 2017–December 2019. The number of participants in this study was 600 participants based on total sampling method. This study reported the data based on the Strengthening the Reporting of Cohort Studies in Surgery (STROCSS) 2019 guideline [9]. The study data collection included patient's characteristics, physical examination records, supportive examination records, complications, management, and complaints within 6 months after treatment were recorded for further evaluation based on medical records. Management of CSOM and diagnosis uses guidelines adopted from WHO [1,7,8,10].

The data collected were analysed using SPSS assistance and presented based on the analysis. Univariate data were presented in the form of tables and frequency distributions. Meanwhile, bivariate analysis used the Chi-squared test with $p < 0.05$, where the results of the analysis were significant if $p < 0.05$.

3. Results

3.1. Characteristics of participants

Most participants were male as much as 53.7%. Most participants aged between 36 and 45 years as much as 28%, followed by the age group of 46–65 years as much as 23.3%. The youngest participant was 3 years old and the oldest was 82 years old. Most of the identified participants had BMI in the normal category as much as 43.2% (Table 1).

3.2. Diagnosis

History of otorrhea was the most common symptom as much as 86.3%, followed by hearing loss of 38%. The examination on tympanic membrane showed that 37.3% were perforated >50%. Inaccessible tympanic membrane on 21.5% of patients was due to cholesteatoma or granulation tissue blockage. There were 33.9% of patients who suffered facial nerve paralysis House Brackmann IV. Moderate conductive type hearing loss was found in 40.5% of patients. Mastoid plain radiographs were examined in all patients, and a sclerotic image was obtained in 65% of patients. A mastoid CT scan was carried out to 358 patients, with temporal bone destruction being found in 35.3% of patients, followed by mass or fluid in the middle ear in 23% of patients. The most common confirmed diagnosis was complicated CSOM, with the most

Table 1
General characteristics.

Characteristics	n (%)
Gender	
Male	322 (53.7)
Female	278 (46.3)
Age	
<5 years	20 (3.3)
5–15 years	26 (4.3)
16–25 years	45 (7.5)
26–35 years	125 (20.8)
36–45 years	168 (28)
46–55 years	140 (23.3)
56–65 years	48 (8)
>65 years	28 (4.7)
BMI	
Underweight	129 (21.5)
Normal	259 (43.2)
Overweight	95 (15.8)
Obesity class 1	89 (14.8)
Obesity class 2	28 (4.7)

Note: BMI, Body Mass Index.

Table 2
Examination's results and diagnosis.

Examination	n (%)
Tympanic Membrane	
Adhesive Tympanic Membrane	21 (3.5)
<25% Perforated	33 (5.5)
25–50% Perforated	143 (23.8)
>50% Perforated	224 (37.3)
Cannot be evaluated	129 (21.5)
Total	46 (7.7)
Attic perforation	4 (0.7)
Facial Nerve	
House Brackmann II	18 (14.5)
House Brackmann III	33 (26.6)
House Brackmann IV	42 (33.9)
House Brackmann V	31 (25.0)
House Brackmann VI	0 (0.0)
Audiogram	
Normal	44 (7.3)
Conductive type hearing loss	
Mild	112 (18.7)
Moderate	243 (40.5)
Severe	48 (8.0)
Sensorineural type hearing loss	
Mild	31 (5.2)
Moderate	42 (7.0)
Severe	13 (2.1)
Mixed type hearing loss	
Mild	16 (2.7)
Moderate	51 (8.5)
Mastoid CT Scan	
Temporal bone destruction	212 (35.3)
Mass or fluid in the middle ear	138 (23.0)
Ossicles destruction	5 (0.8)
Cochlear abnormalities	3 (0.5)
Diagnosis	
Uncomplicated CSOM	125 (20.8)
Complicated CSOM	475 (79.2)
Complications	
Extracranial	
Mastoiditis	308 (51.3)
Labyrinthitis	1 (0.2)
Facial nerve paralysis	124 (20.7)
Retro-auricular fistula	38 (6.3)
Subperiosteal abscess	3 (0.5)
Intracranial	
Cerebral abscess	1 (0.2)

complication being mastoiditis (51.3%). Moreover, there were 0.2% intracranial complications in the form of cerebral abscesses (Table 2).

3.3. Treatment and prognosis

Operative management was carried out to 82.5% of patients, with canal wall up surgery being the majority. During surgery, cholesteatoma and granulation tissue were found in 7.2% of patients, cholesteatoma in 3% of patients, and pus in 1.8% of patients. The medication given after surgery was topical and systemic antibiotic, with cephalosporine being the most common drug given to the patients (69.7%). The results of patient's examination after six months of treatment showed that 426 patients (71.00%) had no complaints of any symptoms. In this study, there were no patients who died nor experienced iatrogenic complications (Table 3).

The correlation between the patient's management with recovery rate could be seen in Table 4. Patient's recovery rate could be evaluated from the patient's complaints, physical examination using microscope or endoscope, and audiometry 6 months after treatment both operative and non-operative. This study found a statistically significant relationship between operative and non-operative management and patient recovery rate ($p = 0.001$).

4. Discussion

The ratio between male and female participants in this study was almost equal, with a greater percentage in males. This finding is consistent with a study in India which stated that the incidence ratio of CSOM in male and female was almost equal with the percentage of male 53.7% and female 46.5% [3]. Another study also stated that CSOM is more common in men than women [11].

This study was a retrospective study evaluating the success of CSOM management. Based on several studies, it was found that CSOM causes hearing impairment on a unilateral or bilateral basis depending on the

Table 4

Correlation between CSOM management with outcome after 6-month treatment.

Post 6-month evaluation	Operative n (%)	Non-Operative n (%)	p
No complaints	337 (56.1)	89 (14.8)	0.001*
Persistent complaints	158 (26.3)	16 (2.7)	
Intact tympanic membrane	396 (66.0)	27 (4.5)	0.000**
Other disorders	99 (16.5)	78 (13)	
Increased hearing level	353 (58.8)	58 (9.7)	0.000**
Same hearing level	133 (22.2)	26 (4.3)	
Decreased hearing level	9 (1.5)	21 (3.5)	

Note: *Significance $p < 0.05$; **Significance $p < 0.001$.

involvement of the affected ear [3,11]. In addition, one of the CSOM management is tympanoplasty, which has been shown to improve the patient's hearing function by 57–97% [12]. This study aimed to evaluate whether the CSOM management performed quantitatively can be measured and improve CSOM procedures in the future. Studies similar to ours suggested that retrospective studies can be used to consider making a safe CSOM surgery procedure [13]. Some studies suggest that this retrospective study can be used to compare the results of several CSOM surgery techniques before and after surgery [12,14].

A study conducted by Metri Basavaraj in India reported that the age range of most CSOM patients was 1–20 years old (52.8%), followed by 21–60 years old (45.9%) [15]. Based on a study conducted in 2016, ages of 40–60 years have a higher incidence rate due to the high incidence of comorbid diseases such as diabetes mellitus [16]. BMI examination from research conducted in China in 2016 showed that the average BMI was 22.18 (normal), which is consistent with the results of this study [17].

The number of participants in this study is similar to that of Indorwala et al., which is 789 CSOM patients [12]. In addition, a study conducted by Hunt et al. had a total of 281 pediatric CSOM patients [3]. Avnstrop et al. used participants as many as 223 pediatric patients with CSOM [18]. The majority of patients in this study complained of otorrhea symptoms. The complaint is in accordance with the definition of CSOM, namely a recurrent or persistent otorrhea for 2–6 weeks through a perforation in the tympanic membrane [19]. A study in the UK in 2015, which was followed by 51 patients, also reported otorrhea as a main complaint (58.8%) [2]. Apart from otorrhea, the second most common symptom was hearing loss, which is consistent with an Australian study that found 60% of patients with CSOM experienced hearing loss. This occurs due to the reduced difference in sound pressure that transmits vibrations to the middle ear due to the perforation [19, 20].

From the results of the examination, the majority of patients did not show any symptoms of complications (85.8%). This is consistent with the WHO report in South Korea that there were only 10.4% of patients with complicated CSOM. A retrospective study in Thailand for 8 years found that intracranial complications only occur in 0.24% of patients. The results are consistent with this study that shows intracranial complications in only 0.24% of patients. In the same study, one of the most reported extracranial complications was facial nerve paralysis (27.9%). These results resemble the findings which obtained facial nerve paralysis as the second-most complications [8]. These results are also supported by research in 2012, which stated that the incidence of facial nerve paralysis had decreased to 0.16–5.1% since the administration of antibiotics. Facial nerve paralysis in CSOM patients with cholesteatoma can be caused by one of these four factors, such as facial nerve compression, edema and hyperemic on a certain segment, fibrosis segment, and disconnected segments. Some experts stated that paralysis on cholesteatoma patients may be caused by the cholesteatoma itself through neurotoxic substances that are secreted and cause bone damage through enzymatic reactions [21]. In this case, the most common complication was retroauricular fistula, which was formed as a result of the opening of the insulating bone and the thinness of the overlying skin [22].

Administration of broad-spectrum antibiotics for a minimum of 5 days to 2 weeks may eradicate uncomplicated CSOM. However, in some

Table 3

Treatment and prognosis of CSOM.

Treatment	n (%)
Management	
Operative	495 (82.5)
Non-operative	105 (17.5)
Type of surgery	
Myringoplasty	4 (0.7)
Type 2 tympanoplasty	53 (8.8)
Canal wall up	206 (34.3)
Canal wall down	118 (19.7)
Facial nerve decompression	113 (18.8)
CAE Stenosis Reconstruction	1 (0.2)
Post-6 month evaluation	
No complaints	426 (71.0)
Otalgia	12 (2.0)
Otorrhea	87 (14.5)
Tinnitus	27 (4.5)
Hearing impairment	58 (9.7)
Crooked face	21 (3.5)
Balance impairment	4 (0.7)
Clinical Finding	
Intact tympanic membrane	423 (70.5)
Ear canal stenosis	13 (2.2)
Tympanic membrane perforation	73 (12.2)
Otorrhea	38 (6.3)
Cholesteatoma	6 (1.0)
Granulation tissue	21 (3.5)
Retro-auricular fistula	5 (0.8)
Facial nerve paralysis	21 (3.5)
Subperiosteal abscess	0 (0.0)
Audiogram	
Increased hearing level	411 (68.5)
Same hearing level	159 (26.5)
Decreased hearing level	30 (5.0)

cases, it may take more time for the ears to dry, so a follow-up of at least 1 month after treatment is recommended to assess the likelihood of recurrence [23]. At the 1-month postoperative examination, 71.8% of patients had no complaints. This finding is consistent with a study conducted in Pakistan in 2011, which stated that as many as 143 out of 160 patients (89.4%) who attended the study had a good status due to the development of the antibiotic administration protocol and the management they were given [24].

Post-treatment monitoring is important to assess the therapy success in the patient, and periodic evaluation should also be carried out to assess recurrence. Evaluation is carried out during hospitalization, one week after the procedure, within one month to approximately six months, assessing the patient's complaints, ear and temporal condition, and hearing function. In a 2017 study in India that assessed the final success rate after CSOM treatment, 2 years of dry ears was found in 100% of cases. The optimal final success rate obtained was dry ears for 2 years without re-operation and retraction/perforation in 100% of cases [25].

The operative and medical management given in accordance with proper diagnosis will result in good management. In this study, the management conformed with the needs of patients according to his/her diagnosis. This study found a correlation between CSOM management with the successful treatment of the patient ($p < 0.05$). This finding is consistent with an Israeli study in 2020, which stated a significant relationship between the management or operative and non-operative with reduced patient complaints of otorrhea in CSOM [26]. Based on previous research, CSOM improvement can begin to be evaluated >14 days, which supports the results of our study [27,28]. Patients who underwent canal wall down surgery on CSOM with cholesteatoma with or without obliteration require longer observation to see the healing cavity. Several studies have stated that complete healing can be seen starting in 3 months and post-surgery CSOM evaluation can be carried out in 1–6 months [29,30].

5. Conclusion

In this study, most CSOM cases occur in the age range of 36–45 years. The most frequent complaint is otorrhea, with most complications being in the form of mastoiditis. Management of CSOM is in the form of operative and non-operative measures. The recovery rate can be assessed from the evaluation of CSOM complaints and physical examination, with increased hearing level 6 months after treatment.

Declaration of competing interest

The authors declare that they have no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.amsu.2021.102492>.

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Ethical approval

We have conducted an ethical approval base on Declaration of Helsinki at Ethical Committee in Dr. Hasan Sadikin General Hospital, Bandung, Indonesia.

Consent

Written informed consent was obtained from the patient.

Author's contributor

All authors contributed toward data analysis, drafting and revising the paper, gave final approval of the version to be published and agree to be accountable for all aspects of the work.

Registration of research studies

1. Name of the registry: -
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Guarantor

Sally Mahdiani is the person in charge for the publication of our manuscript.

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