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Original article

Comparison between Ciprofloxacin and Amoxycillin /Clavulanic Acid in Treatment of Mild to Moderate Cases of Acute Exacerbation of Chronic Suppurative Otitis Media

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ABSTRACT

Chronic Suppurative Otitis Media (CSOM) is a persistent middle ear infection associated with significant morbidity and hearing loss, particularly in low-resource settings. Its management commonly involves the use of topical or systemic antibiotics, among which ciprofloxacin and amoxicillin/clavulanic acid are widely prescribed. This study aimed to compare the clinical efficacy, follow-up behavior, and adverse effect profiles of ciprofloxacin versus amoxicillin/clavulanic acid in the treatment of CSOM. A comparative observational study was conducted on patients diagnosed with CSOM. Participants were assigned to two treatment groups: Group A received ciprofloxacin, and Group B received amoxicillin/clavulanic acid. Ciprofloxacin showed superior clinical efficacy with a higher complete cure rate (33.3%) and no treatment failures, compared to an 18.3% cure rate and 8.3% failure rate in the amoxicillin/clavulanic acid group (P = 0.030). Patients in the ciprofloxacin group also returned for follow-up significantly earlier, indicating faster symptomatic relief. Adverse effects were more frequent and severe in the amoxicillin/clavulanic acid group (P = 0.003); ciprofloxacin was better tolerated overall. At baseline, both groups had comparable symptom severity (p = 0.500). By day 14, ciprofloxacin demonstrated significantly greater clinical improvement, with 76.7% of patients achieving low symptom scores (0–2) compared to 43.3% in the amoxicillin/clavulanic acid group (p = 0.004). Ciprofloxacin demonstrated better clinical effectiveness, faster improvement, and fewer side effects compared to amoxicillin/clavulanic acid, making it a more favorable systemic treatment for CSOM.

Introduction

Chronic Suppurative Otitis Media (CSOM) is a persistent inflammatory condition of the middle ear characterized by recurrent ear discharge (otorrhea) through a tympanic membrane perforation lasting more than six weeks. It is a major cause of hearing impairment globally, particularly in low- and middle-income countries, where poor hygiene, inadequate access to healthcare, malnutrition, and repeated upper respiratory tract infections contribute to its high prevalence. Acute exacerbations of CSOM represent episodes of increased otorrhea and inflammatory activity, often triggered by secondary bacterial infections. These episodes not only worsen the patient's quality of life but can also accelerate the disease process and lead to complications if not promptly and effectively treated [1]. The global burden of CSOM is significant. The World Health Organization (WHO) estimates that CSOM affects over 65 to 330 million individuals worldwide, with more than half of these suffering from hearing loss. In many developing countries, including regions in Africa and Southeast Asia, the prevalence in children is reported to exceed 4%, which is considered a public health emergency by WHO standards. The socioeconomic consequences of CSOM are profound, including reduced academic performance in children, decreased productivity in adults, and increased financial strain due to healthcare costs [2].

One of the most important goals in managing CSOM, especially during episodes of acute exacerbation, is controlling infection and reducing inflammation to prevent complications and halt disease progression. Antimicrobial therapy plays a central role in this process. However, the increasing problem of antimicrobial resistance, combined with limited local data on comparative antibiotic effectiveness, underscores the need for rational antibiotic selection based on efficacy, safety, cost-effectiveness, and resistance patterns. [3] Two of the most commonly used antibiotics in the treatment of mild to moderate acute exacerbations of CSOM are ciprofloxacin and amoxicillin/clavulanic acid. Ciprofloxacin is a second-

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generation fluoroquinolone with broad-spectrum bactericidal activity, particularly effective against Gram-negative organisms, including Pseudomonas aeruginosa, which is frequently implicated in CSOM. It is available in both oral and topical forms, with the topical form 1 being particularly useful due to its ability to achieve high local concentrations with minimal systemic side effects [4].

Amoxicillin/clavulanic acid, on the other hand, is a combination of a beta-lactam antibiotic and a beta-lactamase inhibitor. It has broad-spectrum activity against both Gram-positive and Gram-negative bacteria and is often used in cases where beta-lactamase-producing organisms are suspected. This antibiotic combination is widely used in the treatment of otitis media and other upper respiratory infections due to its well-established safety profile and effectiveness. [4] Despite the common use of both agents, clinical consensus on which antibiotic is superior for mild to moderate exacerbations of CSOM remains unclear. Several studies have evaluated their efficacy individually, but head-to-head comparisons—particularly in resource-limited settings— are scarce. Moreover, most guidelines for CSOM treatment are based on expert opinion rather than robust comparative data. As a result, prescribing practices vary widely depending on clinician preference, drug availability, and patient affordability [5]. The pharmacological profiles of the two drugs also differ in important ways. Ciprofloxacin exhibits concentration-dependent killing, has a post-antibiotic effect, and offers excellent penetration into infected tissues. Its topical form minimizes systemic exposure and the risk of systemic side effects such as gastrointestinal upset or allergic reactions. However, concerns have been raised about ototoxicity and the emergence of resistant strains due to inappropriate use.

Amoxicillin/clavulanic acid, while systemically administered and generally well tolerated, may not achieve sufficient local concentrations in the middle ear, especially when there is limited vascular access due to chronic inflammation. It may also be less effective against certain Gram-negative pathogens prevalent in CSOM, such as Pseudomonas species. [5] From a public health perspective, comparative evaluation of these antibiotics is essential to guide evidence-based treatment protocols, reduce antibiotic misuse, and address the growing threat of antimicrobial resistance. In resource-limited countries, where over-the-counter antibiotic use is common and access to culture and sensitivity testing is limited, empirical therapy must be grounded in local evidence. This is particularly important for a chronic and recurrent condition like CSOM, where repeated antibiotic exposure can select for resistant organisms and complicate future management. [1] 2 Furthermore, treatment outcomes in CSOM are influenced by patient-related factors such as age, nutritional status, compliance, and presence of comorbidities, as well as disease-related variables including the extent of tissue damage, pathogen virulence, and frequency of recurrence. A thorough comparison of ciprofloxacin and amoxicillin/clavulanic acid must take into account these factors to yield clinically meaningful conclusions. [6]. This study aimed to compare the clinical efficacy and safety of ciprofloxacin and amoxicillin/clavulanic acid in the treatment of mild to moderate cases of acute exacerbation of chronic suppurative otitis media.

Methods

Study design

This was a prospective, randomized, comparative clinical study conducted to evaluate the efficacy and safety of ciprofloxacin versus amoxicillin/clavulanic acid in the treatment of chronic suppurative otitis media (CSOM).

Study area

The study was conducted at Al-Kiesh Polyclinic, a secondary care center located in Benghazi, Libya. The facility provides outpatient otolaryngology services and is equipped with endoscopic examination tools, a clinical laboratory, and pharmacy support. The polyclinic serves a diverse population from all areas, making it a suitable setting for investigating common otologic infections such as chronic suppurative otitis media (CSOM).

Study population

The study population consisted of adult patients aged 18 to 60 years who presented to the ENT department of Al-Kiesh Polyclinic with clinical features suggestive of safe-type CSOM, including active ear discharge through a tympanic membrane perforation lasting more than three months. Patients were screened according to the inclusion and exclusion criteria outlined earlier. Eligible participants were those with safe-type CSOM without complications, who had not received antibiotic treatment within the previous week, and who provided informed consent.

Eligibility Criteria

Patients were enrolled based on the following criteria: Adults of either sex, aged between 18 and 60 years, patients presenting with active aural discharge and a visible tympanic membrane perforation, consistent with safe-type CSOM confirmed by clinical examination and endoscopic evaluation.

The following patients were excluded: Individuals with aural discharge from causes other than CSOM (e.g., otomycosis, foreign body, and furuncle); patients with a recent history of ear trauma; and pregnant or lactating women. ❖ Patients with

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severe or complicated CSOM requiring hospitalization or intravenous antibiotic therapy. And Known allergy or hypersensitivity to ciprofloxacin or amoxicillin/clavulanic acid.

Sample Size

A total of 60 patients meeting the eligibility criteria were enrolled and randomly assigned to one of the two treatment arms: Group A (n = 30): Received ciprofloxacin 500 mg twice daily for 7 days. Group B (n = 30): Received amoxicillin/clavulanic acid 1000 mg twice daily for 7 days. Patients were instructed to avoid any other systemic or topical otological medications during the study period. Effective parameters: Number of subjects achieving treatment success in each treatment group was considered an effectiveness parameter. Treatment success was based on changes in the Otolgical symptoms scores at the day 14 visit. It will be subdivided into two categories: [A] Clinical cure if the otological symptom score was between 3 and 5 on day 14. Treatment failure was declared if there is no change or increase in the baseline otological symptom score on day 14.

Study visits

The patients will be evaluated for two weeks. The first week will be the active treatment period. The following week will be treatment-free. Patients were evaluated clinically at baseline [day 0] and at subsequent follow-up visits on Days 7 and 14, Otological symptom score. Will be recorded at every visit.

Signs/symptoms	Score 0	Score 1	Score 2	Score 3
Tinnitus	Absent	Mild	Moderate	Severe
Amount of discharge	Absent	Mild	Moderate	Severe
Type of discharge	Absent	Mucoid	Muco-purulent	Purulent
Mucosal edema	Absent	Mild	Moderate	Severe

Data Collection Tool

Data were collected using a structured clinical assessment form, which included the following components: Demographic Information: Age, Gender, Occupation, Residence; Clinical History: Duration of symptoms, History of previous ear infections, Use of prior antibiotics, Associated symptoms (hearing loss, pain, fever, etc.) Otological Symptom Score: A validated numerical scoring system was used to evaluate the severity of otological symptoms (discharge, ear pain, fullness, hearing loss). Scores were recorded at Day 0 (baseline), Day 7, and Day 14. Examination Findings: Visual assessment using a 0-degree rigid otoendoscope to record the size and location of tympanic membrane perforation, presence of discharge, and condition of middle ear mucosa. Endoscopic images were stored and referenced during follow-up visits for comparison. Adverse Effects Monitoring: A section of the form was dedicated to tracking any side effects experienced by the patient during or after treatment, especially gastrointestinal symptoms or allergic reactions.

Otoscopic Technique

Otoscopy is a diagnostic procedure used to examine the external auditory canal and tympanic membrane (eardrum). It is performed using an instrument called an otoscope, which provides a magnified and illuminated view of the ear canal. This examination helps clinicians detect signs of ear infections (e.g., otitis externa or otitis media), tympanic membrane perforations, wax impaction, foreign bodies, or structural abnormalities. Proper otoscopic technique involves gently pulling the auricle upward and backward in adults (downward and backward in children) to straighten the canal. Otoscopy is a routine and essential part of ENT examinations and is often the first step in evaluating complaints such as ear pain, hearing loss, discharge, or tinnitus.

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Figure 1. *Rigid endoscope 0 degrees*

Statistical Analysis

Data were analyzed using SPSS software version 25. Descriptive statistics summarized demographic and clinical characteristics. Comparative analyses between the two groups were conducted using chi-square and t-tests as appropriate. A p-value of <0.05 was considered statistically significant.

Ethical Approval

The study protocol received ethical clearance from the Ethics Committee of Al-Kiesh Polyclinic. Verbal informed consent was obtained from all participants prior to enrollment, following explanation of the study purpose, procedures, and potential risks.

Results

The age distribution (Table 1) showed that the majority of participants were young adults. The highest frequency was observed in the less than 25 years category (23.3%), followed by the 46–50 years category (18.3%).

Table 1: Distribution of Age Group among study population.

Age Group	Frequency	Percent
Less than 25 years	14	23.3
26–30 years	9	15.0
31–35 years	7	11.7
36–40 years	9	15.0
41–45 years	5	5 8.3
46–50 years	11	18.3
55–60 years	5	8.3
Total	60	100

Regarding gender distribution (Figure 2), females constituted a slight majority at 56.7%, while males accounted for 43.3% of the participants.

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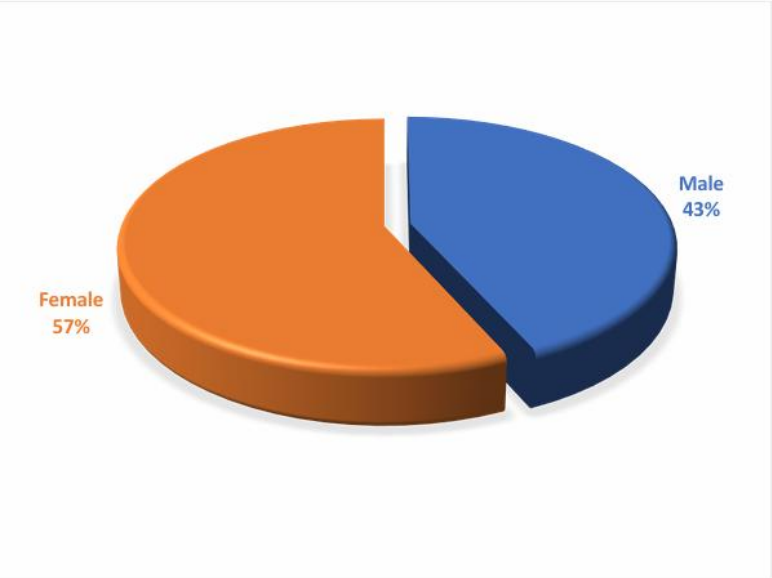

Figure 2. Distribution of gender among study population

Site distribution (Table 2) showed that the majority of the clinical involvement occurred on the right side (75%), with only 25% on the left. At day 0, the majority of participants (88.3%) had high otologic symptom scores (7–8), indicating severe symptoms at baseline.

Table 2. Distribution of site among study population

Site	Frequency	Percent
Right	45	75.0
Left	15	25.0
Total	60	100.0

Only 11.7% had moderate scores (5–6), and no participants had low scores as (Figure 3), By day 14, there was a marked improvement in symptoms: 60% of participants improved to low scores (0–2), 33.3% had moderate scores (3–5) & Only 6.7% remained in the high score category (6–8). (Table 3)

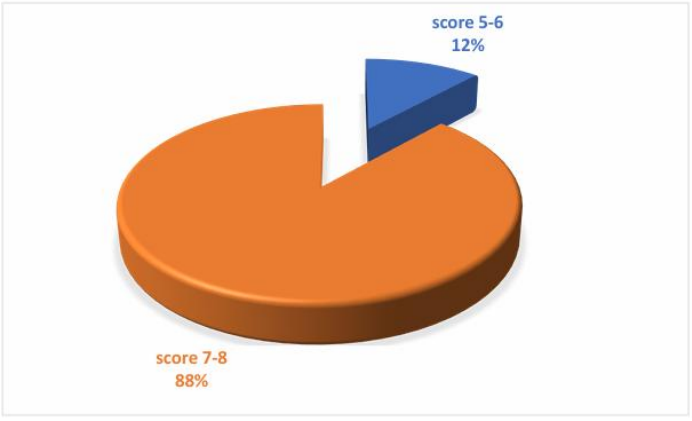

Figure 3. Distribution of Otological symptom score, visit (0) day among study population

Table 3. Distribution of Otological symptom score, visit day (14) among study population

Scores	Frequency	Percent
Score 0-2	36	60.0
Score 3-5	20	33.3
Score 6-8	4	6.7
Total 60	60	100.0

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In terms of overall treatment outcomes (Figure 4), the results were promising. A total of 51.7% of patients achieved complete cure, and an additional 33.3% showed clinical improvement. Only 8.3% experienced treatment failure, while 1.7% had a partial response and 5% were marked as absent.

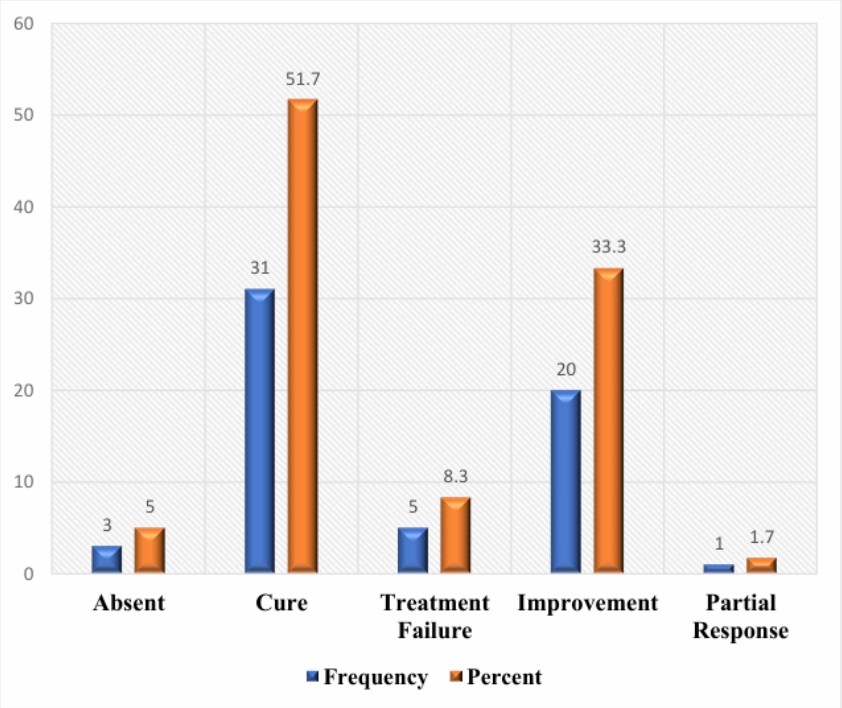

Figure 4. Distribution of Treatment Outcome among study population

Adverse effects (Table 4) were reported by 40% of participants, with the most common being epigastric pain (16.7%), diarrhea (8.3%), and nausea (8.3%). However, 60% of patients did not experience any side effects.

Table 4. Distribution of Adverse Effects among the study population

Adverse Effect	Frequency	Percent
Diarrhea	5	8.3
Epigastric Discomfort	1	1.7
Epigastric Pain	10	16.7
Nausea	5	8.3
Nausea & Vomiting	2	3.3
No Adverse Effect	36	60.0
Pain	1	1.7
Total	60	100.0

When the data were stratified by treatment group, additional insights emerged. As shown in Figure 5, there was no statistically significant association between age group and treatment group (P = 0.559). The age distribution between Group A (Ciprofloxacin) and Group B (Amoxicillin/Clavulanic acid) was balanced, ensuring fair comparison without demographic bias. Similarly

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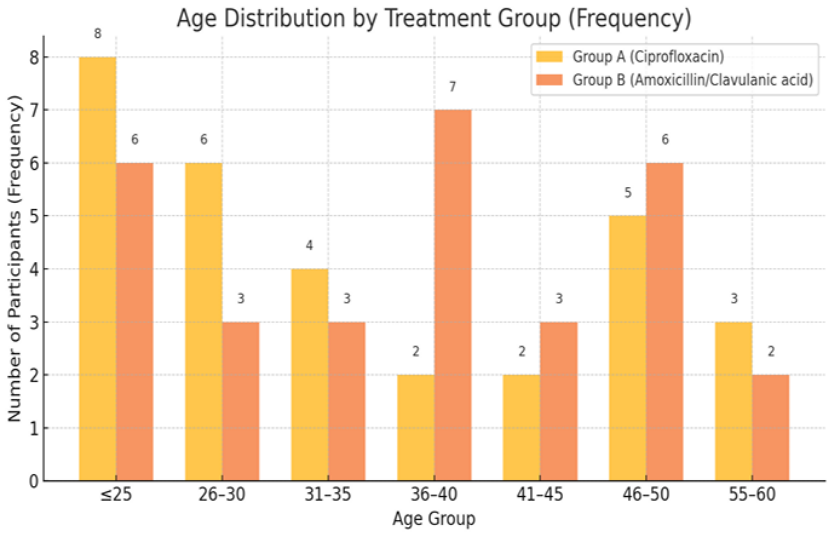

Figure 5. ***Association of Age Group among study group A (Receive Ciprofloxacin 500mg) and group B (Receive Amoxicillin / Clavulanic acid 1000mg.***

Table 5 showed no significant difference in site distribution between the groups (P = 0.276), confirming that anatomical location did not influence the treatment assignment.

Table .5 ***association of Site among study group A (Receive Ciprofloxacin 500mg) and group B (Receive Amoxicillin / Clavulanic acid 1000mg.***

Site	Group A (Total =30)	Group B (Total =30)	Total (Total =60)
Right	24 (40.0%)	21 (35.0%)	45 (75.0%)
Lift	6 (10.0%)	9 (15.0%)	15 (25.0%)
Total	30 (50.0%)	30 (50.0%)	60 (100.0%)

Gender distribution was also statistically comparable between the groups (Figure 6, P = 0.217), with both groups containing an equal number of male and female participants. Significant differences were observed in clinical course and outcomes.

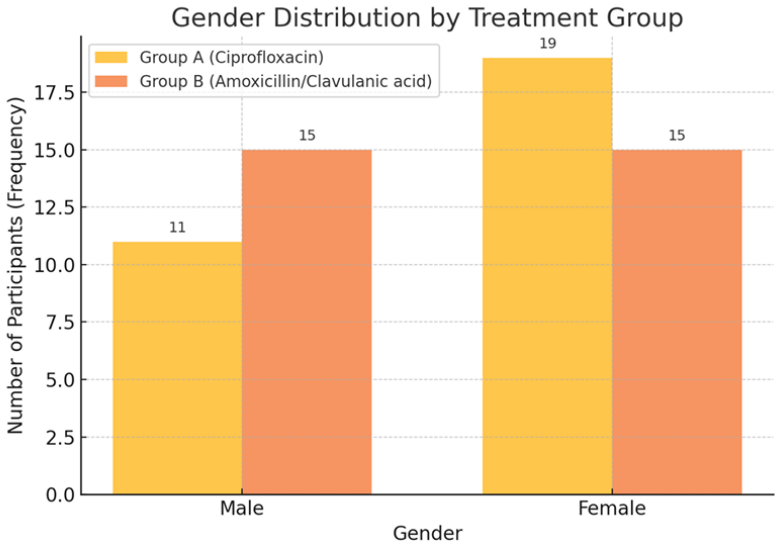

Figure 6. ***Association of gender among study group A (Receive Ciprofloxacin 500mg) and group B (Receive Amoxicillin / Clavulanic acid 1000mg.***

At baseline (day 0), there was no statistically significant difference in otological symptom scores between Group A (Ciprofloxacin 500 mg) and Group B (Amoxicillin/Clavulanic acid 1000 mg) (p = 0.500), as shown in (Table 6).

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Table 6. ***Association of Otological symptom score, visit day (0) among study group A (Receive Ciprofloxacin 500mg) and group B (Receive Amoxicillin / Clavulanic acid 1000mg.***

Score in Day Zero	Group A (n=30)	Group B (n=30)	Total (n=60)
Score 5–6	4 (13.3%)	3 (10.0%)	7 (11.7%)
Score 7–8	26 (86.7%)	27 (90.0%)	53 (88.3%)
Total	30 (100%)	30 (100%)	60 (100%)

By day 14, there was a significant association between otological symptom scores and treatment groups (p = 0.004). larger proportion of patients in the ciprofloxacin group (76.7%) achieved low scores (0–2) compared to 43.3% in the amoxicillin/clavulanic acid group. Meanwhile, 13.3% of patients in the amoxicillin/clavulanic acid group remained at high scores (6–8), as shown in Figure 7.

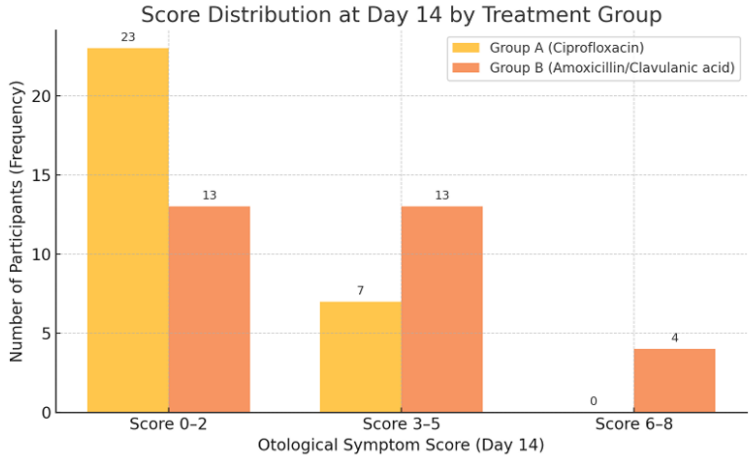

Figure 7. Association of Otolgical symptom score, visit day (14) among study group A (Receive Ciprofloxacin 500mg) and group B (Receive Amoxicillin / Clavulanic acid 1000mg.

There was a statistically significant difference in treatment outcomes between the two groups (p = 0.030). Cure rates were higher with ciprofloxacin (33.3%) compared to amoxicillin/clavulanic acid (18.3%), and no treatment failures occurred in the ciprofloxacin group, while the amoxicillin/clavulanic acid group showed an 8.3% failure rate, as shown in (Table 7).

Table 7. ***Association of Treatment Outcome among study group A (Receive Ciprofloxacin 500mg) and group B (Receive Amoxicillin / Clavulanic acid 1000mg.***

Treatment	Outcome Group A (n = 30)	Group B (n = 30)	Total (N = 60)
Absent	2 (3.3%)	1 (1.7%)	3 (5.0%)
Cure	20 (33.3%)	11 (18.3%)	31 (51.7%)
Failure of Treatment	0 (0.0%)	5 (8.3%)	5 (8.3%)
Improvement	7 (11.7%)	13 (21.7%)	20 (33.3%)
Response (partial)	1 (1.7%)	0 (0.0%)	1 (1.7%)
Total	30 (50.0%)	30 (50.0%)	60 (100.0%)

Adverse effects were significantly more frequent and severe in the amoxicillin/clavulanic acid group compared to ciprofloxacin (p = 0.003). Gastrointestinal symptoms, particularly epigastric pain (15%), were more common with amoxicillin/clavulanic acid, while ciprofloxacin adverse events were milder and less frequent (mainly mild nausea and diarrhea). Notably, no severe adverse events occurred with ciprofloxacin, and 33.3% of patients in this group reported no adverse effects at all, compared to 26.7% in the amoxicillin/clavulanic acid group as shown in (Figure 8).

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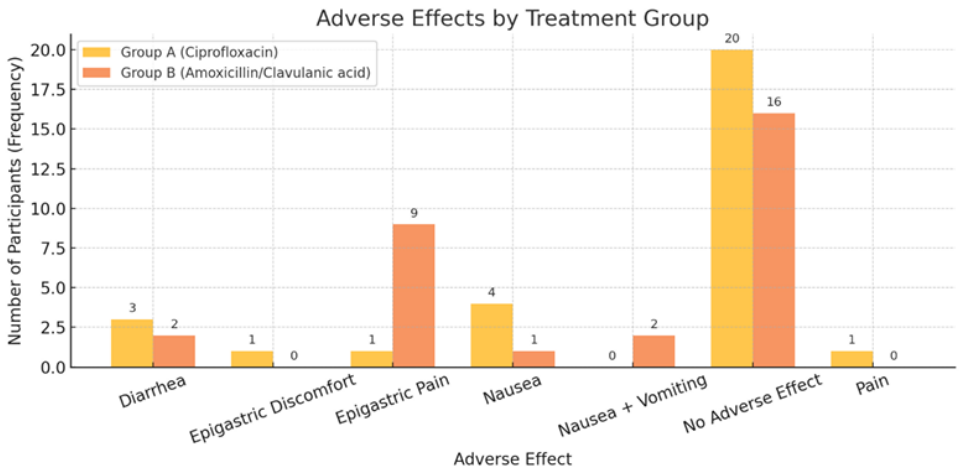

Figure 8. Association of Adverse Effect among study group A (Receive Ciprofloxacin 500mg) and group B (Receive Amoxicillin / Culvacine acid 1000mg.

Discussion

Chronic suppurative otitis media (CSOM) is one of the most common diseases, affecting between 65 to 330 million people worldwide, mainly in poor socio- economic developing countries [7]. The prevalence of CSOM in sub-Saharan African countries ranges from 0.4% to 4.2% (8). It is a major cause of acquired hearing loss and morbidity in these countries (9). CSOM is an infection characterized clinically by recurrent middle ear discharge through a persistent perforation of the tympanic membrane more than three months (10). If not treated early and appropriately, the size of the tympanic perforation may increase over time and destruction of the ossicular chain ensues with a change in the tympanic mucosa. The evolution of such a situation leads to worsening deafness and often fatal intracranial complications. In the literature, there are many causative agents' foursome, but Pseudomonas aeruginosa and Staphylococcus aureus are the most common (11).

The medical management of CSOM is usually empirical, based on topical antibiotics such as ciprofloxacin, ofloxacin, or rifampicin in combination with systemic antibiotics (ciprofloxacin, levofloxacin, amoxicillin/clavulanic acid, ceftazidime) (12). Antibiotics can be used alone or in addition to other treatments for CSOM such as antiseptics or ear cleaning. Excessive and inappropriate use of antibiotics is a source of increased antibiotic resistance of pathogens causing CSOM (13). In our study, the majority of participants were under 25 years old (23.3%), consistent with global patterns showing higher prevalence of CSOM among young individuals, particularly in regions with limited access to early healthcare, as found by (14) who found 40% of their study population presented among age 21-30 years. The gender distribution showed a slight female predominance (56.7%), though not statistically significant between the treatment groups, ensuring balanced baseline characteristics. Another study (14) found 60% of participant were female. The site distribution also demonstrated a dominance of right-sided ear involvement (75%), but this anatomical variation had no effect on treatment outcomes or group allocation.

The otological symptom score used in this study served as a quantitative measure to assess the severity of otological symptoms, including ear pain, discharge, hearing loss, and tinnitus. Scores ranging from 7–8 indicated severe symptoms, 5–6 moderate symptoms, and 0–2 mild or resolved symptoms. This scoring system is widely utilized in clinical research for otitis media and other middle-ear pathologies because it allows objective tracking of symptom progression and treatment response over time (15). At baseline (day 0), the majority of patients (88.3%) presented with high symptom scores (7–8), confirming that participants entered the study with severe symptoms. Both treatment groups — ciprofloxacin (Group A) and amoxicillin/clavulanate (Group B) — had comparable scores at this stage ($p = 0.500$), ensuring that subsequent improvements could be attributed to the therapeutic effects rather than baseline differences. By day 14, the symptom score distribution shifted markedly toward improvement: 60% of patients achieved scores of 0–2, 33.3% had scores of 3–5, and only 6.7% remained at severe levels (6–8). When analyzed by treatment group, patients receiving ciprofloxacin demonstrated significantly better outcomes, with a greater proportion achieving low scores (0–2) compared to those treated with amoxicillin/clavulanate ($p = 0.004$).

These findings are consistent with other studies reporting rapid score improvement with fluoroquinolone therapy. For instance, (16) found that topical ciprofloxacin /dexamethasone significantly reduced symptom scores within 3–5 days in children with acute otitis media with tympanostomy tubes, compared to oral amoxicillin/clavulanate. Similarly, a study demonstrated significant reductions in symptom scores by day 10 when ciprofloxacin was used either topically or systemically in chronic suppurative otitis media [17]. The rapid decline in symptom scores observed in this study reflects

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both effective bacterial eradication and reduced local inflammation. Ciprofloxacin's superior penetration into middle ear tissue and activity against Gram-negative organisms, particularly Pseudomonas aeruginosa, likely contributed to the observed faster resolution. Conversely, the slower improvement with amoxicillin/clavulanate may be linked to emerging resistance patterns among otopathogens, including β-lactamase–producing H. influenzae and Moraxella catarrhalis (18).
Clinically, the symptom score provides a practical bedside tool for monitoring treatment progress and determining the need for antibiotic change or additional interventions. A drop from high (7 8) to low (0–2) scores within two weeks indicates successful therapy and resolution of infection, as observed predominantly in the ciprofloxacin group. The accelerated return in the ciprofloxacin group may be interpreted in several ways. Most notably, it likely reflects the superior pharmacokinetics and broader antibacterial coverage of ciprofloxacin, particularly against gram-negative organisms like Pseudomonas aeruginosa, which are frequently implicated in CSOM.
Ciprofloxacin's high tissue penetration and bactericidal activity enable faster resolution of infection-related symptoms such as otorrhea, ear pain, and fullness factors that influence a patient's decision to return early for reassessment. (Khatun et al., 2021) [18] & (Brennan Jones et al.,2020) [7] These findings are consistent with (George.2014), in a clinical comparison of ciprofloxacin and combination therapy for CSOM, observed that patients treated with ciprofloxacin alone showed quicker symptomatic relief, with noticeable reduction in ear discharge and inflammation within the first few days of therapy [19]. Similarly, Chong et al. (2021) conducted a systematic review and concluded that fluoroquinolones, especially ciprofloxacin, were associated with faster cessation of otorrhea, lower recurrence rates, and improved patient compliance compared to beta-lactam-based therapies [20]. Additionally, the early follow-up pattern in the ciprofloxacin group may also reflect a lower incidence of side effects, which may increase patients' willingness to complete follow-up visits. Patients who tolerate their medication well are more likely to adhere to follow-up schedules and actively participate in clinical monitoring, unlike those experiencing gastrointestinal distress or discomfort—as observed more frequently in the amoxicillin/clavulanic acid group in this study. From a clinical standpoint, early follow-up is highly desirable. It not only allows for timely assessment of treatment response and potential complications, but also provides an opportunity for early intervention in cases of partial or poor response. Thus, the earlier return observed in Group A supports the role of ciprofloxacin not only as an effective bactericidal agent but also as a patient centered therapeutic option with favorable clinical progression and follow-up patterns. The clinical outcomes observed in this study demonstrated a distinct and statistically significant advantage in favor of ciprofloxacin over amoxicillin/clavulanic acid in the treatment of chronic suppurative otitis media (CSOM). Specifically, 33.3% of patients in Group A (ciprofloxacin) achieved complete clinical cure, with no cases of treatment failure recorded. In contrast, Group B (amoxicillin/clavulanic acid) exhibited a markedly lower cure rate of 18.3%, and a considerable 8.3 % of patients experienced treatment failure. This difference was statistically significant (P = 0.030), confirming the superiority of ciprofloxacin in this patient population. These findings are consistent with prior clinical investigations.
Legent et al. reported that ciprofloxacin was significantly more effective than amoxicillin/clavulanic acid in treating non-CSOM. In their study, ciprofloxacin achieved a higher rate of bacterial eradication and clinical resolution, particularly in cases involving Pseudomonas aeruginosa and Staphylococcus aureus— the two most commonly implicated pathogens in CSOM. These organisms often display resistance to beta-lactam agents, further supporting the rationale for using fluoroquinolones as first-line therapy in such contexts. Similarly, Siddique et al. emphasized the efficacy of ciprofloxacin, both topical and systemic, in managing CSOM, citing its rapid bactericidal action and effective penetration into middle ear tissues. The drug's broad-spectrum coverage and ability to eliminate biofilm-forming organisms make it especially suitable for treating persistent or recurrent infections where conventional beta-lactam therapies may fall short. While both ciprofloxacin and amoxicillin/clavulanic acid were generally well-tolerated by the patients in this study, a closer look at the reported side effects showed a clear difference between the two treatments. Around 40% of participants overall experienced at least one adverse effect during their treatment. However, the frequency and severity of these effects were notably higher in Group B, the group that received amoxicillin/clavulanic acid. The most common complaints among Group B patients were gastrointestinal issues, including epigastric pain (15.0%), nausea (1.7%), and vomiting (3.3%). these side effects were significantly more common in this group compared to those receiving ciprofloxacin (P = 0.003). This is consistent with what is already known about this antibiotic combination—it often causes irritation of the digestive tract due to its impact on gut flora and mucosal lining.
Similar findings were reported by (Saeed et al.2020) in a study conducted, reported that where patients treated with amoxicillin/clavulanic acid for CSOM frequently reported digestive discomfort, which in many cases affected their ability to stick with the full course of treatment. The authors highlighted that such side effects can lead to non-compliance or early discontinuation, ultimately affecting the success of the therapy. In contrast, Group A, which received ciprofloxacin, showed a much better safety profile. Most patients in this group either had no side effects at all or only experienced mild symptoms that resolved on their own. This more comfortable experience likely contributed to better adherence to the treatment plan and a higher likelihood of completing the full course as prescribed. These findings align with (Chong et al.,) who reported that fluoroquinolones, whether taken orally or used as ear drops, are better tolerated than beta-lactam antibiotics, causing fewer gastrointestinal side effects and leading to greater patient satisfaction due to their broad-spectrum efficacy and rapid

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action. Moreover, the better tolerability of ciprofloxacin may explain the earlier symptom relief and higher rate of follow-up attendance seen in Group A. When patients feel better and aren't bothered by side effects, they're more likely to attend check-ups and stick with their treatment key factors in achieving a full recovery. From a clinical perspective, the lower risk of side effects with ciprofloxacin gives it a clear advantage, especially in patients with sensitive digestive systems, the elderly, children, or those with a history of antibiotic intolerance (Hasan .2019) Although this study focused solely on systemic antibiotic treatment, it's important to consider the role of topical therapy in managing CSOM, especially in light of recent evidence supporting the use of topical ciprofloxacin [21].

Topical antibiotics offer a number of advantages, such as delivering high concentrations directly to the infection site, minimizing systemic absorption, and reducing the risk of side effects—making them particularly appealing in children and more vulnerable patients. Study by (Brennan-Jones et al. 2020) which found that topical fluoroquinolones, especially ciprofloxacin and ofloxacin, were just as effective as systemic antibiotics in drying the ear and stopping discharge in CSOM patients. The review also pointed out that topical treatments had a better safety profile, which is a big plus in settings where managing side effects may be more challenging. In another study conducted by (Khalifa et al. 2020) compared topical ciprofloxacin drops with oral amoxicillin/clavulanic acid in cases of acute otitis media [22]. Their findings showed no major difference in how well the two treatments worked, but patients using the ear drops had fewer side effects, quicker relief, and higher satisfaction overall. These results support the growing view that topical therapy can be a safe and effective alternative, particularly in uncomplicated or localized infections. In moderate to severe infections, or when there are systemic symptoms like fever or swollen lymph nodes, topical therapy on its own might not provide sufficient coverage. In such cases, systemic antibiotics are necessary to ensure the medication reaches infected tissues and prevents the condition from spreading or worsening. Ciprofloxacin's pharmacological properties including its strong tissue penetration, long half-life, and broad-spectrum activity make it an ideal choice for systemic use in more serious cases. Its effectiveness against common and sometimes resistant organisms like Pseudomonas aeruginosa and Staphylococcus aureus further reinforces its value in treating chronic or recurrent infections. Our study results support this clinical approach: patients treated with systemic ciprofloxacin showed higher cure rates, faster improvement, and fewer side effects than those treated with amoxicillin/clavulanic acid. These outcomes underline ciprofloxacin's role as a preferred systemic therapy for CSOM, especially when quick and reliable results are needed.

Conclusion

This study found the clear clinical advantage of ciprofloxacin over amoxicillin/clavulanic acid in the systemic treatment of chronic suppurative otitis media. Ciprofloxacin not only resulted in higher cure rates and faster symptom resolution but also showed significantly fewer side effects, particularly gastrointestinal discomfort. These factors contributed to earlier follow-up attendance and greater patient compliance. The pharmacological strengths of ciprofloxacin, including broad antimicrobial coverage and excellent tissue penetration, reinforce its value in the management of CSOM, especially in moderate to severe or resistant cases. The study showed a significant reduction in otological symptom scores after 14 days. Ciprofloxacin produced greater improvement than amoxicillin/clavulanate, with both groups starting at similar baseline severity. Both treatments were well tolerated, suggesting ciprofloxacin is more effective for moderate-to severe or resistant cases, while amoxicillin/clavulanate remains suitable for less severe infections.

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Conflicts of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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