

Evaluation of Effectiveness of Fluoroquinolones in Treatment of Chronic Suppurative Otitis Media (CSOM)

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Abstract

Original Research Article

Background: Chronic Suppurative Otitis Media (CSOM) consider one of the most common otorhinolaryngologic sicknesses in ear, nose, and throat clinics. Swab is routinely done in patients with CSOM for culture and sensitivity. **Objectives:** Determining the efficacy of Fluoroquinolones in the treatment of chronic suppurative otitis media using two administration methods of Fluoroquinolones and providing a recommendation regarding the indiscriminate use of antibiotics. **Methods:** This retrospective study involved 70 patients with CSOM. Patients with renal and hepatic failure, pregnancy and lactation and children with CSOM under 12 years old are excluded. Swab taken and C&S done. **Results:** The distributions of CSOM in patients were highly trending with male gender. Also, more frequent in age category 13 – 20 y, 21 – 45 y, 46 – 70 y, respectively, with main complaint of Recurrent otitis media and Hearing loss. *Pseudomonas Aeruginosa* was high percentage of Microorganism isolated in swab (85.57%) with approximately (94%) sensitivity to Fluoroquinolones. **Conclusions:** Our study indicates that Topical Fluoroquinolones (with steroids) is the optimal treatment for chronic suppurative otitis media, so it must be started immediately after diagnosis. **Keywords:** CSOM, Fluoroquinolones, otorhinolaryngology outpatient clinic, Syria.

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INTRODUCTION

Chronic Suppurative Otitis Media (CSOM) is a frequent presentation in ear, nose, and throat clinics, Its define as persistent inflammation of the middle ear mucosa or mastoid cavity with persistent or recurring otitis media (otorrhea) for 6 weeks or more through perforation of the tympanic membrane [1]. Other clinical findings include granulomatosis of the middle ear mucosa, mucous polyps, and cholesteatoma in the middle ear, the chronic Suppurative otitis media (CSOM) must be distinguished from chronic otitis media associated with effusion (OME), where the tympanic membrane is intact in addition to the presence of fluid in the middle ear cavity without an active inflammatory condition, The World Health Organization defines CSOM as otorrhea lasting at least two weeks [1, 2]. It is estimated that there are 31 million new cases of CSOM per year worldwide, with nearly one-quarter occurring in children <5 years old [3]. It occurs more frequently in resource-limited settings, with prevalence ranging from 6 to 46 percent depending on the geographic area and population studied [4, 5].

Studies regarding the relative frequencies of different pathogens vary somewhat depending on the geographic area and population studied. Commonly isolated bacteria include *Staphylococcus aureus* (methicillin-resistant and methicillin-sensitive), *Pseudomonas*, *Proteus*, coagulase-negative staphylococci, *Enterococcus*, and anaerobes (including *Peptostreptococcus*, *Fusobacterium*, *Prevotella*, and *Porphyromonas*) [6-8].

The types of pathogens seen, and the likelihood of antimicrobial resistance may vary depending on the age of the patient (with greater risk of resistant organisms among older patients) [9-12].

Fluoroquinolones are highly effective antibiotics with many advantageous pharmacokinetic properties including high oral bioavailability, large volume of distribution, and broad-spectrum antimicrobial activity. Fluoroquinolones are not given during pregnancy, lactation and children under 12 years of age, as cartilage damage and deformities may occur. However, it is reasonable to use a systemic

fluoroquinolone in children when no safe or effective alternative exists or when parenteral therapy can be avoided by using an oral fluoroquinolone [13-16] in addition to that it cannot be used in patients with renal and hepatic failure.

MATERIALS AND METHODS

This retrospective study involved 70 patients who were visit the Ear, Nose, and Throat clinic of National Hospital, Latakia Governorate, Syria, with complaints of CSOM between January 2017 and December 2017. Patients with renal and hepatic failure, pregnancy and lactation and children with CSOM under 12 years old are excluded. Clinical history was taken with proper physical examination; all patients underwent to swab collection for culture and sensitivity. Fluoroquinolones were applied topically (ear drops), with steroids (35 patients) and without steroids (35 patient).

Informed consent was taken for the study and local ethical committee had no objection to do this study. Statistical analysis was done by simple manual analysis and chi square test. In this study we divided patients according of sex and categorized by age under 5 categories, main complains, Also, we study the relation between the CSOM and otoscopic finding,

results of culture (causative microorganism) and main routs of treatment (sensitivity for medication).

STATISTICAL RESULTS

Gender Distribution

Males represented by 68.5% of CSOM sample whereas females represented by 31.42%.

(Tab-1)

Gender	Male	Female
Number (70)	48	22
Percentage	68.5 %	31.42 %

Age Distribution was as below

The greatest representation in the sample is in the 13-20 years old age group, nearest percentage seen in age group 21- 45 year.

(Tab-2)

Age	13 – 20 y	21 – 45 y	46 – 70 y
No of Pts	33	28	9
Percentage	47.14 %	12.85 %	24.28%

Distribution of Most & Main Complaint

As we noticed below the main complaint was recurrent otitis media with nearest percentage for hearing impairment.

(Tab-3)

Patients number	Main complaint
69 (98.57%)	Recurrent otitis media
65 (92.85%)	Hearing loss
56 (80%)	Ear blockage
39 (55.71%)	Auricular fullness or ear discomfort
21 (30%)	Itching of ear
8 (11.42%)	Tinnitus
1 (1.42%)	Dizziness and imbalance

Distribution According to the Most Common (non-auricular)

Almost 17% of the sample reported Headache, with high percentage of URTI.

(Tab-4)

Symptoms	Fever	Recurrent nasal blockage	URTI	Headache
Patients number	3 (4.28%)	5 (7.14%)	14 (20%)	17 (24.28%)

Distribution According to the Otoloscopic Findings

All patients present with Perforated Tympanic Membrane, followed by Eczema of External Ear Canal.

(Tab-5)

Otosopic findings	Patients number
Perforated Tympanic membrane	70 (100%)
Eczema of ear canal	23 (32.85%)
Signs of AOM	22 (31.42%)
Otitis externa	4 (5.71%)

Distribution According to the Culture and Sensitivity

High percentage for Pseudomonas Aeruginosa, it was 58%.

(Table 6)

Samples number	Microorganisms
Pseudomonas Aeruginosa	41 (58.57%)
Staphylococcus aureus	15 (21.42%)
Proteus	10 (14.28%)
E coli	6 (8.57%)
Klebsiella	4 (5.71%)
Aspergillus	2 (2.85%)
Candida	1 (1.42%)

- Distribution According to the Pattern of Microbial Culture**

Most pattern of growth was unimicrobial culture with sensitivity to fluoroquinolone was 80%.

(Table 7)

Pattern of microbial culture	Unimicrobial cultures with sensitivity to Fluoroquinolones	Polymicrobial cultures with sensitivity to Fluoroquinolones
Samples number	56 (80%)	14 (20%)

- Distribution According to the Pattern of Microbial Culture**

High percentage of sensitivity to fluoroquinolone was for Pseudomonas (94%), Proteus (82%), and E coli (80%) then (67%) Staphylococcus aureus lastly for Klebsiella (33.33%).

(Table 8)

Microorganisms	Sensitivity to Fluoroquinolones
Pseudomonas Aeruginosa	94%
Staphylococcus aureus	67%
Proteus	82%
E coli	80%
Klebsiella	33.33%

Results after Treatment

After taking ear swabs and send it for the laboratory study, an aural toilet was done and ears were completely cleaned, in addition to the patient's full explanation of the treatment plan and the need to follow up weekly for aural toilet, or in case of any deterioration in the condition or the lack of improvement in clinical symptoms. The Fluoroquinolone used is (Ciprofloxacin 0.3 g/100 ml) topically in the form of an ear drop (2 drops in the affected ear) used 4 times daily, and the topical steroid

used is Dexamethasone (Dexamethasone 1mg/1ml) in combination with a drop of the antibiotic, or an ear drop that contains both the antibiotic and the steroid. (Ciprofloxacin 0.3% and dexamethasone 0.1%) **CIPRODEX®**. In addition to the symptomatic treatment in case of accompanying symptoms.

The clinical results and data were studied after 2 weeks and 4 weeks of treatment.

* Clinical results after 2 weeks of treatment, as shown below:

(Table 9)

	Dry ear	Regression of ear discomfort	Regression of hearing loss	Regression of ear blockage	Improvement of other symptoms	Improvement of otoscopic findings
Fluoroquinolone with steroid	28 patients (80%)	25 patients (71.42%)	20 patients (57.14%)	30 patients (85.71%)	23 patients (65.71%)	28 patients (80%)
Fluoroquinolone without steroid	25 patients (71.42%)	23 patients (65.71%)	18 patients (51.42%)	20 patients (57.14%)	19 patients (54.28%)	25 patients (71.42%)
Total	53 patients (75.71%)	48 patients (68.57%)	38 patients (54.28%)	50 patients (71.42%)	42 patients (60%)	53 patients (75.71%)

* Clinical results after 4 weeks of treatment, as shown below:

(Table 10)

	Dry ear	Regression of ear discomfort	Regression of hearing loss	Regression of ear blockage	Improvement of other symptoms	Improvement of otoscopic findings
Fluoroquinolone with steroid	34 patients (97.14%)	33 patients (94.28%)	32 patients (91.42%)	34 patients (97.14%)	33 patients (94.28%)	34 patients (97.14%)
Fluoroquinolone without steroid	32 patients (91.42%)	32 patients (91.42%)	29 patients (82.85%)	33 patients (94.28%)	32 patients (91.42%)	30 patients (85.71%)
Total	66 patients (94.28%)	65 patients (92.85%)	61 patients (87.14%)	67 patients (95.71%)	65 patients (92.85%)	64 patients (91.42%)

DISCUSSION

Chronic Suppurative Otitis Media (CSOM) is a frequent presentation in ear, nose, and throat clinics, it defines as persistent inflammation of the middle ear mucosa or mastoid cavity with persistent or recurring otitis media (otorrhea) for 6 weeks or more through perforation of the tympanic membrane. Dry ear was considered the main indicator in evaluating the cure, without neglecting other factors such as regression of clinical symptoms and improvement of otoscopic findings.

Topical Fluoroquinolones with steroid (ear drops) is better than topical Fluoroquinolones without steroid in obtaining satisfactory clinical results. Addition of dexamethasone to ciprofloxacin decreased the recovery period [20].

The use of topical steroid with topical Fluoroquinolones clearly relieves the associated itching of ear, in addition to the regression of eczema of the ear canal. The topical steroid also relieves inflammatory signs and mucosal oedema of the middle ear, associated hearing loss regressed in 61 patients (87.14%) out of 70 patients.

All cases studied were without association of cholesteatoma as these kinds of cases need surgical intervention and other different treatment methods than the methods used in our study.

The recurrence cases were 10 patients (14.28%), 50% of recurrence cases (5 patients) were within two weeks of the end of the specified treatment period, 20% (2 patients) within a month, 20% (2 patients) within two months, and 10% (one patient) within 6 months.

Numerous studies have investigated the relationship between ototopical apply of Ofloxacin for treatment of CSOM and evaluation and assessment of efficacy of this method. Angelo S; Agro MD, *et al*, [17] entitled: Clinical trial of ototopical ofloxacin for treatment of chronic suppurative otitis media - at 27 centers in the United States and Central America - USA in 1998, the study showed the effectiveness of topical Fluoroquinolones in the treatment of chronic

suppurative otitis media, where dry ears were obtained in 91% of patients (148 cases out of 162 studied cases), which is similar to the result of our study of 32 patients out of 35 patients, or 91.42%, and dry ear in the previous study was the clinical indicator of recovery as in our study. Nuria Miro [18], entitled Controlled multicentre study on chronic suppurative otitis media treated with topical applications of ciprofloxacin, Department of Otolaryngology, University Hospital, Barcelona, Spain, 2000. Where the effect of ciprofloxacin given topically without steroids in the treatment of chronic suppurative otitis media in adults was studied, and the results showed a cure of 91% of cases, while in our study the cure rate was 91.42%.

Although L Podoshin 1, A Brodzki, *et al*, [19], entitled Local treatment of purulent chronic otitis media with ciprofloxacin, which showed the efficacy of ciprofloxacin eardrops in the treatment of chronic suppurative otitis media for 3 weeks, the clinical responses were 78.9%, while in our study the cure rate was 91.42%.

Also, according to Irfan Kaygusuz 1, Turgut Karlidağ, *et al*, [20], entitled Efficacy of topical ciprofloxacin and tobramycin in combination with dexamethasone in the treatment of chronic suppurative otitis media, which showed that the clinical response for ciprofloxacin increased from 80% to 90% with dexamethasone, while in our study increased from 91.42% to 97.14%.

CONCLUSIONS

The primary goal of treatment of CSOM is eradicating infection and preventing complications, which is achieved by producing a dry ear, starting by aural toilet plus empiric topical antibiotics for initial therapy. Longer term goals include healing/repair of the tympanic membrane (TM) and improvement in hearing [21]. So, ear discharge must be aspirated for all patients of CSOM, after taking swabs and send it for ear cultures study and bacterial sensitivity for antibiotics.

Topical Fluoroquinolones (with steroids) is the optimal treatment for chronic suppurative otitis media, so it must be started immediately after diagnosis.

Educating caregivers on the proper administration of topical antibiotics and other measures that reduce recurrence is an important aspect of initial management. So, it is very important to focus on the issue of health awareness, especially personal hygiene, and topical care of affected ear, in addition to a detailed explanation of the method of using ear drops and making sure that the drop reaches the place of infection.

Finally, emphasizing not to take antibiotics randomly, because this would increase the stubborn bacterial groups on antibiotics (antimicrobial resistance) and increase the incidence of recurrence.

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