

# COMPARISON OF EFFICACY OF TOPICAL WITH ORAL CIPROFLOXACIN IN PATIENTS OF TUBOTYMPANIC TYPE OF CHRONIC SUPPURATIVE OTITIS MEDIA TO OBTAIN DRY EAR

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## ABSTRACT

**Background:** Chronic suppurative otitis media (CSOM) is one of the common diseases in routine ENT practice. **Objective:** To compare the efficacy of topical ciprofloxacin with oral ciprofloxacin 500mg twice daily in achieving dry ear (Medical cure) in Tubo-tympanic type of Chronic suppurative otitis media. **Methodology:** Study Design: Quasi-experimental study. Place and Duration of Study: The study was carried out at ENT department of Bahawal Victoria Hospital Bahawalpur from 01<sup>st</sup> January to 30<sup>th</sup> September 2015. One hundred patients, 11 to 60 years of age of either gender having Tubo-tympanic type of chronic supportive otitis media were included. Patients with previous antibiotic treatment, pregnant or lactating women, history of hypersensitivity to Quinolones (ciprofloxacin), chronic suppurative otitis media of Attico-antral type, known case of DM and hypertension were excluded. Selected patients were divided into two groups (Group A & Group B) by using lottery method. Group A (n=50) was given Ciprofloxacin ear drops and Group B (n=50) was given Oral Ciprofloxacin 500mg twice daily. The patients were followed up to 08 weeks after treatment (at least two follow up visits) and examined otoscopically and under microscope to assess the efficacy. The efficacy of drugs was graded into four grades depending upon the decrease in discharge amount (Poor/no response, satisfactory, good and excellent). The data was entered and analyzed by using SPSS version 20. **Results:** The mean age of group A patients was  $27 \pm 5$  and in group B was  $30 \pm 5$  years. Males were 67 (67%) and females were 33 (33%) with ratio of 2:1. Bilateral CSOM in 27 (27%) and Unilateral was found in 73 patients (73%). Efficacy was excellent in 52%, good in 24%, satisfactory in 8% and poor/ no response in 11% patients of Group A while it was excellent in 36%, good in 24%, satisfactory in 1% and poor/no response in 30% patients of Group B. **Conclusion:** This study concluded that Topical ciprofloxacin is more effective than oral ciprofloxacin in the medical treatment of tubo-tympanic type of CSOM to obtain dry ear.

**Keywords:** Discharging ear, Quinolones, Eardrops, Systemic ciprofloxacin.

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## INTRODUCTION

Chronic Suppurative otitis media (CSOM) is a chronic infection of tympanic membrane perforation and variable degree of hearing loss.<sup>1</sup> Generally, patients with tympanic membrane perforations which continue to discharge mucoid material for periods of 6 weeks to 3 months,<sup>2</sup> despite medical treatment, are recognized as CSOM cases. The WHO definition requires only 2 weeks of otorrhoea, but otolaryngologists tend to adopt a longer duration, e.g. more than 3 months of active diseases.<sup>3,4</sup> In CSOM the bacteria may be aerobic or an-aerobic.<sup>5</sup>

The most frequently isolated organisms are *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Proteus mirabilis*.<sup>6</sup> The disease process can be aggressive and can lead to life threatening complications due to erosion of the adjacent bones. Several genetic and environmental factors along with anatomical and functional status of Eustachian Tubes can be

pathogenic elements.<sup>7</sup> The two principal aims of management are the eradication of infection and the closure of the tympanic membrane perforation. Medical management of CSOM is to control the otorrhoea and signs and symptoms of complication if any. The only curative treatment of the condition is however surgical intervention. Many clinicians prefer only topical antibiotic containing ear drops to solve the problem.<sup>7</sup>

Patients with chronic suppurative otitis media (CSOM) respond more frequently to topical therapy than to systemic therapy. Successful topical therapy consists of 3 important components. Selection of an appropriate antibiotic drop, regular aggressive aural toilet and control of granulation tissue.<sup>7,8,9</sup> The efficacy of topical ciprofloxacin in the treatment of CSOM and resolving otorrhoea was reported high,<sup>10</sup> whereas treating csom also showed good results.<sup>11</sup>

The objective of our study was to do comparative analysis regarding the efficacy in obtaining dry ear between topical Ciprofloxacin ear drops and oral

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Ciprofloxacin in local population. This study would be helpful to improve the condition of persistent ear discharge and would affect over all outcome of the disease management.

## METHODOLOGY

**Study Design:** Quasi –experimental study. This study was carried out at ENT department of Bahawal Victoria Hospital Bahawalpur from 1<sup>st</sup> January to 30<sup>th</sup> September 2015. After approval from local ethical committee, 100 patients with Tubo-tympanic type of Chronic suppurative otitis media fulfilling the inclusion criteria were selected. Informed written consent was taken from every patient.

### Inclusion Criteria:

- Age: 11-60 years
- Both males and females
- Tubo- tympanic type of CSOM

### Exclusion Criteria

- Attico-antral type of CSOM
- Age below 10 years
- Hypersensitivity to Ciprofloxacin
- Known case of Diabettes mellitus and hypertension
- Pregnant and Lactating females

Chronic suppurative otitis media was labeled after otoscopic and microscopic examination, having presence of chronic inflammation of the middle ear cleft with ear discharge and permanent perforation of tympanic membrane.

Patients were divided into two groups (A & B) by lottery method. Group A was given Topical ciprofloxacin ear drops and instructed to do proper aural toilet and put a 3 drops thrice daily in supine position with the affected ear facing upward followed by the tragal rub for 5 minute. Group B was given Ciprofloxacin (500 mg tablet BD), for two weeks. After two weeks each patient underwent otoscopic & microscopic examination to assess the efficacy of treatment regimen. Efficacy was divided into four grades (Poor/ no efficacy (<25%), satisfactory (26% to 50%), good (51% - 76%) and excellent) (>76%) depending upon the decrease in discharge amount as stated by the patients.

All the data were entered in SPSS version 20 and analyzed. Mean and standard deviation were calculated for numerical data. Frequencies and percentages were calculated for categorical variables. Chi Square test was applied to compare

two groups. P value less than 0.05 was taken as significant.

## RESULTS

Age range in this study was from 11 to 60 years with mean age in Group A,  $27 \pm 5.72$  and in group B,  $30.94 \pm 5.72$  years. Males were 67 (67%) and females were 33 (33%) with ratio of 2:1. Bilateral CSOM was found in 17 (34%) patients of Group A and 15 (30%) patients of Group B while Unilateral was found in 33(66%) patients of Group A and 35 (70%) patients of Group B (Table I).

**Table I: Frequency of patients according to side affected.**

Side affected	Group A(n=50)		Group B(n=50)		Total (n=100)	
	Frequency	%age	Frequency	%age	Frequency	%age
Bilateral CSOM	17	34	15	30	32	32
Unilateral CSOM (Right side)	18	36	21	42	39	39
Unilateral CSOM (left side)	15	30	14	28	29	29

**Table II: Age and Gender Distribution of Patients of Tubo-tympanic type of CSOM.**

Age (In years)	No. (%)	Male No (%)	Female No (%)
11-20	39 (39%)	24 (24%)	15 (15%)
21-30	32 (32%)	20 (20%)	12 (12%)
31-40	17 (17%)	12 (12%)	05 (05%)
41-50	07(07%)	04 (04%)	03(03%)
51-60	05 (05%)	02(04)	03 (03%)

Duration of disease was from 3 months to 6 years. The mean duration of disease in group A was  $1.65 \pm 0.82$  years and in group B was  $1.83 \pm 0.94$  years. Majority of the patients 75 (75%) were < 3 years of duration of disease. (Table II)

**Table III: Frequency of patients according to Efficacy in both groups.**

Grade of Efficacy	Group A (Topical Ciprofloxacin)		Group B (Oral Ciprofloxacin)	
	No	%age	No	%age
No /poor	08	16%	15	30%
Satisfactory	04	08%	05	10%
Good	12	24%	12	24%
Excellent	26	52%	18	36%

Efficacy was excellent in 52%, good in 24%, satisfactory in 8% and poor/ no response in 16% patients of Group A while it was excellent in 36%, good in 24%, satisfactory in 10% and poor/no response in 30% patients of Group B (Table III).

## DISCUSSION

Chronic Suppurative otitis media (CSOM) is one of the most common chronic infectious Diseases worldwide, and it affects all racial and cultural groups both in developing and industrialized countries. It involves considerable morbidity and can cause extra – and intracranial complication.<sup>12</sup>

History of acute and recurrent otitis media, parental history of chronic otitis media, and crowded conditions (i.e large families with several siblings, large day care centers ) are found as significant risk factors for CSOM. Management of CSOM with ototopical agents is common practice among otolaryngologists. Several combinations of ear drops preparations are available to treat external and middle ear infections. They remain the cornerstone of treatment, despite the fact that some of them are recognized as ototoxic drugs, and convincing evidence of sensori-neural hearing loss in animals has been found.<sup>13</sup>

The mean age of patients in group A (with topical ciprofloxacin) was  $27 \pm 5$  and in group B  $30 \pm 5$  years. Majority of the patients 71 (71%) were between 11 to 30 Years of age. CSOM usually manifests in children and is more common in patients younger than 15 Years.<sup>14</sup>

In our study, the results were different compared to published literature because the age range was from 11 to 60 years. In our study, out of these 100 patients, 67 ( 67%) were male and 33 (33%) were females with ratio of 2:1. These results coincide with results of many previous studies which have shown the two times greater prevalence of CSOM amongst men than amongst women.<sup>8-10</sup>

In our study, efficacy (excellent & good efficacy) on otoscopic examination after two weeks of treatment of Group A was 38 (76%) while in Group B was 30 (60%) (P-value = 0.0166) which is slightly different as compared to other studies. Macfadyen CA et al<sup>15</sup> in his review of systemic ciprofloxacin versus topical ciprofloxacin for treating CSOM has assessed nine randomized controlled trails and concluded that topical quinolone antibiotics were better than systemic

antibiotics at clearing discharge at 1-2 weeks. In a study, micro N<sup>16</sup> with cooperation from the Spanish ENT study group found the efficacy to topical ciprofloxacin in treating CSOM as 93%. Similarly, Agro AS et al<sup>29</sup> in his study has found the efficacy of topical ciprofloxacin in treating CSOM as 100%.

KirisM et al<sup>17</sup> reported the 88 % efficacy of ciprofloxacin eardrops in 80 patients with otorrhoea due to chronic suppurative otitis media in two treatment settings. Supiyaphun P et al<sup>18</sup> reported the 92% efficacy of ciprofloxacin eardrops in patients with chronic supportive otitis media. Efficacy of topical ciprofloxacin in patients with chronic suppurative otitis media.

Efficacy of topical ciprofloxacin in patients with recurrent otorrhoea which were unresponsive to other antibiotics was evaluated by Wintermeyer SM et al<sup>19</sup> and found to be 70%. In 1999, De Miguel Martinez I et al<sup>20</sup> performed a study by including five treatment regimens for CSOM. In another study from Acuin Jet al<sup>21</sup> in 2000 published a meta-analysis of 24 trails that concluded that topical antibiotics were superior to systemic agents and that combining the two was no more effective than topical therapy alone.

In another study where treatment of CSOM with oral ciprofloxacin was done in adults, the otorrhea disappeared in 67% of the evaluated patients.<sup>24</sup> Fombour JP et al<sup>22</sup> showed the efficacy of oral ciprofloxacin in CSOM patients as 59% while Legent F et al<sup>16</sup> has shown this efficacy as 58% which is comparable to our study.

The topical ciprofloxacin was found to be more effective than oral ciprofloxacin, As higher concentration of antibiotic solution can be delivered to the site of infection by topical administration.<sup>23</sup>

## CONCLUSION

This study concluded that Topical Ciprofloxacin is more effective than oral ciprofloxacin in achieving dry ear in chronic suppurative otitis media. So, we recommend that ciprofloxacin eardrops should be used as a primary treatment in every patient of CSOM (Tubotympanic type) for achieving dry ear in order to reduce the morbidity of these particular patients from persistent discharge and its complications.

## Conflict of interest:

The authors have declared no conflict of interest.

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