

## Comparing Oral Moxifloxacin and Ciprofloxacin Ear Drops Versus Ciprofloxacin Ear Drops Only in Patients with Active Mucosal Chronic Otitis Media

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### ABSTRACT

**Objective:** To compare the effects of Oral Moxifloxacin and topical antibiotic ear drops in patients with active mucosal chronic otitis media.

**Study Design:** Comparative prospective study.

**Place and Duration of Study:** Combined Military Hospital Bahawalpur, from May 2018 to Apr 2020.

**Methodology:** A total of 100 patients with Active (mucosal) Chronic Otitis Media were included in the study. These patients were divided into two groups. The first group received oral Moxifloxacin and topical Ciprofloxacin ear drops, while the second group only received topical ciprofloxacin ear drops. Clinical success was compared in both groups regarding patients becoming asymptomatic and having a dry ear on examination.

**Results:** 45(90%) patients in combined treatment while 35 (70%) in the topical ciprofloxacin ear drops group became asymptomatic. The Chi-square test was applied (6.25). The *p*-value was .124. We found that oral Moxifloxacin, in addition to topical Ciprofloxacin ear drops, is a superior treatment option in decreasing the symptoms of tubotympanic chronic otitis media (COM) than the topical ciprofloxacin ear drops when used alone.

**Conclusion:** Moxifloxacin is an effective drug in controlling symptoms of tubotympanic chronic supportive otitis media, and its combination with topical ciprofloxacin ear drops is superior to the ciprofloxacin ear drops when used alone.

**Keywords:** Chronic otitis media (COM), Chronic supportive otitis media (CSOM), Ciprofloxacin, Moxifloxacin, Otorrhoea, *Pseudomonas aeruginosa*.

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### INTRODUCTION

The COM means permanent perforation of the tympanic membrane, resulting from an acute middle ear infection, effusion or negative pressure in the middle ear. Previously it was called CSOM, an obsolete term because chronic middle ear infection can occur without suppuration. The disease may be active when there is inflammation and formation of pus or inactive when the disease is dormant with chances to develop inflammation.<sup>1</sup> Formally, terminologies like 'safe' and 'unsafe' COM were used, but as complications can occur in both, these are now replaced with new terms, i.e., mucosal and squamous disease.<sup>2</sup> The recent classification of COM was given in the Table-I.

In active mucosal COM, there is increased vascularity, oedema of surrounding tissue, and granulations due to neovascularization.<sup>3</sup> Plasma cells, lymphocytes and histocytes are found scattered along with

fibroblasts. Copious mucopurulent discharge is pathognomonic of active mucosal COM. These inflammatory changes result in the formation of blebby and overhanging middle ear mucosa called 'aural polyps'. Inflammation may spread to the mastoid antrum. Resorptive of the ossicles is a part of the inflammatory process. Typically, the long process of the incus, crurae of stapes, and the body of incus and manubrium are eroded. Cholesterol granuloma may appear due to effusion or haemorrhage during the disease process.<sup>4</sup> Recent statistics revealed that COM has a prevalence of 4.1%; unilateral 3.1%, bilateral disease in 1.0%, no gender differentiation, double in people over forty years and more common in low socioeconomic groups and manual workers.<sup>5</sup>

The disease may persist, become inactive, or it may lead to complications. Patients usually present with ear discharge and decreased hearing. Otorrhoea mostly starts after an upper respiratory tract infection or due to ingress of unclean water. Hearing loss is usually conductive or mixed type. Examination of the tympanic membrane under the microscope is useful.

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Audiometry is to assess hearing loss. Culture and sensitivity of ear discharge are recommended in recurrent cases. *Pseudomonas aeruginosa* and *Staphylococcus aureus* are most commonly found along with gram-negative bacteria.<sup>6,7</sup> Management includes cleaning the ear, antibiotic drops, i.e., Ami-noglycosides or Quinolones drops.<sup>8,9</sup> Surgery is recommended once the ear is dry to curtail future infections and hearing improvement. If the infection persists and discharge continues, oral antibiotics are recommended, i.e. Moxifloxacin or Ciprofloxacin.<sup>10</sup> Oral Moxifloxacin gives promising results if given in a once-daily dose for 7 to

addition to topical Ciprofloxacin ear drops 0.3 % in thrice daily doses for ten days. Five patients in this group were lost to follow-up. While group "B" with the same number of patients (55 patients) were given only topical 0.3% Ciprofloxacin ear drops thrice daily for ten days. The number of patients lost to follow-up in this group was also.<sup>5</sup> Informed consent was taken from all patients. The patients were examined after ten days. Clinical success was compared in both groups regarding patients becoming asymptomatic/dry perforation. Patients were closely monitored and assessed for becoming free of infection in terms of no ear discharge,

**Table-I: Classification of chronic otitis media.**

Type	Characteristic	Appearance When Examined with Auriscope
Active Mucosal Chronic Otitis Media	Perforation in pars tensa and pus formation.	Perforation of tympanic membrane, inflammation of middle ear and discharge of pus
Active Squamous Chronic Otitis Media	Formation of Cholesteatoma	Retraction pocket in Pars flaccida/tensa with retention of epithelial debris, inflammation and scanty pus discharge.
Inactive Mucosal Chronic Otitis Media	Dry perforation	Permanent defect in pars tensa and no inflammation
Inactive Squamous Chronic Otitis Media	Retraction pocket	Attic/posterior marginal retraction pocket, retained debris with possibility to be active in future.
Healed Chronic Otitis Media	Scarring/Tympanosclerosis, thin healed perforation	Thin and opacified tympanic membrane

10 days in addition to topical antibiotic drops. This study employed this rationale to assess the patients becoming asymptomatic and having a dry ear.

## METHODOLOGY

This prospective comparative study was carried out at Combined Military Hospital Bahawalpur from May 2018 to April 2020. The sample size of 92 was calculated using the Raosoft sample size calculator. We took a sample of 110 patients to cater for follow-up loss. The prevalence of COM was 6.4%, as reported by Khan *et al.*<sup>11</sup> The confidence level was 95%, and the margin of error was 5%. The patients were selected by non-probability consecutive convenience sampled technique and purposive divided into Responsive and non-responsive groups depending on alleviation of ear discharge.

**Inclusion Criteria:** Patients of age 20 to 35 years, male gender, with more than three months of history of central perforation of their tympanic membrane along with active ear discharge were included in the study.

**Exclusion Criteria:** Patients with a marginal or posterior perforation of their tympanic membrane or cholesteatoma were excluded from the study.

Patients were divided into two groups. Group "A" comprised 55 patients who were given Tablet Moxifloxacin 400 mg once daily dose for ten days in

dry perforation and dry middle ear cavity when examined under the microscope. Statistical analysis was performed using Statistics Package for Social Science (SPSS) version 23.0. Participants were categorically marked as having an excellent response that showed no further ear discharge.

## RESULTS

A total of 110 patients were included in this study with a mean age of  $27.054 \pm 3.046$  years. Fifty-five patients in group "A" and fifty-five patients in group "B".<sup>10</sup> patients were lost to follow-up. The mean discharge duration was 102.54 days (SD  $\pm 10.32$ ) with a minimum of 90 days and a maximum of 120 days. At the end of our study, 85 (85 %) out of 100 patients showed an excellent response (improvement), while 15 (15%) showed no response to the treatment. In group "A", 45 (90%) showed excellent response. Their ear discharge was markedly reduced when reviewed after ten days, while 5 (5%) patients continued to have ear discharge (Table-II). In group "B", 35 (70%) showed good response with no ear discharge at the end of 10 days of treatment, while 15 (30%) patients continued to have ear discharge.

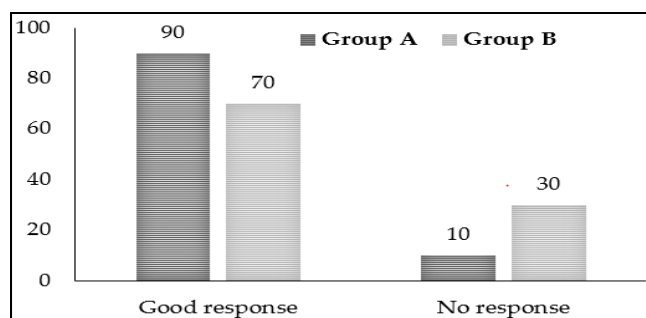
Symptoms were markedly reduced in both groups at the end of the study (Table-II). The results were 90% and 70%, respectively. Overall, 5 (10%)

patients of this group "A" and 15 (30%) patients of group "B" persisted with the disease. The chisquare test was applied (3.92). The *p*-value was 0.124.

**Table-II: Summary of Patients clinical response after 10 days.**

Parameters	Study Groups		<i>p</i> -value
	Group "A" (n= 55)	Group "B" (n= 55)	
Excellent response	45 (90%) [0.62]	35 (70%) [0.62]	0.12419
No Response	5 (10%) [2.5]	15 (30%) [2.5]	

Therefore it was concluded that the response of the patients in group "A" was better than group "B" (Figure). However, the patients non-responding to the treatment were advised further investigations, i.e., CT scan of the temporal bone to rule out any residual disease in the mastoid and cholesteatomas etc.



**Figure: Comparison of the results between Group 'A' and Group 'B'.**

## DISCUSSION

Formerly chronic otitis media was classified into two types, i.e., atticofurcular and tubotympanic.<sup>1</sup> Tubotympanic chronic otitis media is a long-standing infection of a part or whole of the middle ear space, characterized by aural discharge and permanent defect in the tympanic membrane.<sup>11</sup> Although complications are scanty in tubotympanic type compared to atticofurcular type of chronic otitis media, persistent ear discharge and associated problems like decreased hearing and inflammation of the external auditory canal warrant treatment.<sup>12</sup>

Sattar *et al*, declared pseudomonas aeruginosa and staph aureus to be the most frequently found pathogens in patients with chronic otitis media, followed by Proteus Vulgaris and Klebsiella pneumonia.<sup>13</sup> Aural toilet and topical antibiotic ear drops have been suggested for the disease. These include Gentamycin, Neomycin, Ofloxacin and Ciprofloxacin ear drops with or without steroid combination and is considered the first-line treatment modality for active mucosal chronic otitis media.<sup>14</sup> In clinical practice, most of the time, oral

antibiotics are deemed important to control the symptoms and are necessary for early recovery from the disease. In this regard, Moxifloxacin, when given in combination with the topical Ciprofloxacin ear drops, gives excellent results compared to the topical antibiotic ear drops alone. Moxifloxacin is now considered an effective drug in treating chronic otitis media, especially in patients with persistent symptoms, i.e., ear discharge. A once-daily oral dose of Moxifloxacin for seven days is helpful in cases not responding to the topical ear drops.

Moxifloxacin is 8 Methoxy Quinolone and belongs to a class of drugs called fluoroquinolones. Other commercially available Fluoroquinolones include Ciprofloxacin, Ofloxacin, Levofloxacin, Gatifloxacin, Norfloxacin, Gemifloxacin, Lomefloxacin and Sparfloxacin.<sup>15</sup> As a class, the Fluoroquinolone antibiotics, especially Moxifloxacin, have many beneficial properties like broad-spectrum coverage for different bacterial strains, easy intake and good absorption. Fluoroquinolones are very effective drugs against many gram-negative, gram-positive, atypical bacteria and anaerobes. Moxifloxacin is an excellent anti pseudomonas aeruginosa drug, i.e., the main pathogen in Chronic Otitis media. Many studies suggested that it is a potent agent in controlling pathogens involved in acute otitis media.<sup>16</sup> Adverse effects of Moxifloxacin are minimal, i.e., Q-T interval prolongation, but cardiac toxicity is quite less.

Mohammed *et al*, in their cross-sectional study on 125 patients received in ENT department as outdoor patients. The culture sensitivity result of their ear discharge revealed strains of staph aureus and pseudomonas aeruginosa, showing high sensitivity to Moxifloxacin (93.6%).<sup>17</sup>

Madana *et al*, concluded their research by saying that continuous and periodic evaluation of microbiological patterns and antibiotic sensitivity of chronic otitis media is necessary to decrease the potential risk of complications early institution of systemic and topical antibiotic therapy is always advised.<sup>18</sup>

Zhu *et al*, revealed that Moxifloxacin as an oral drug is a very effective first-line agent in controlling the pathogens like staphylococcus aureus and pseudomonas aeruginosa, thus reducing the risk of complications of chronic ear infection.<sup>19</sup>

Yagupsky *et al*, study confirmed that novel Fluoroquinolones, including Moxifloxacin, are of potential value in treating otitis media caused by pathogens resistant to traditional antibiotics and resistance to the

Fluoroquinolones noted in their study was only 0.25%.<sup>20</sup>

Formally, COM treatment included cleaning the ear and prescribing the antibiotic ear drops for weeks. However, according to our research, if oral antibiotics are added to the treatment, the results are quick and better than the traditional treatment.<sup>21</sup> In addition, the ear drops are painful when used in active disease, thus affecting compliance with the treatment. Our research showed that oral Moxifloxacin is an excellent drug and is very useful in controlling aural discharge when given in addition to topical drops, especially in cases not responding to the topical drops alone. In addition, the drug is safe and cost-effective.

### CONCLUSION

Moxifloxacin is a Fluoroquinolones when given orally in active mucosal chronic otitis media. It is more effective than ear drops alone in blocking the inflammatory process. It is safe, cost-effective and can be utilized to manage prolonged cases of chronic otitis media where ear drops are not efficient in controlling the infection.

**Conflict of Interest:** None.

### Authors' Contribution

AAK: Main author, MUA.; STR: Data collection, article writing, references checking, SFN.; MAK: Data analysis, review of article, UR: Data collection, review of article.

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