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ORIGINAL RESEARCH

Comparative Efficacy Evaluation of Moxifloxacin 0.5% Eye Drops vs Tobramycin 0.3% Eye Drops vs Azithromycin 1.5% eye drops for Purulent Bacterial Conjunctivitis in Children at a Tertiary Care Hospital

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ABSTRACT

Background: Conjunctivitis is characterized by symptoms such as irritation, itching, a sensation of a foreign body in the eye, and excessive tearing or discharge. The primary pharmacotherapy options for the treatment of bacterial conjunctivitis are topical aminoglycosides, fluoroquinolones, and macrolides. Mostly empirical topical antibiotics are used to treat bacterial conjunctivitis without preliminary bacteriological identification. So first-line antibiotics should be more effective, cure at a higher rate, and have a favorable safety profile. Hence; the present study was conducted for comparative efficacy evaluation of moxifloxacin 0.5% eye drops vs tobramycin 0.3% eye drops vs azithromycin 1.5% eye drops for purulent bacterial conjunctivitis in children at a tertiary care hospital.**Materials & Methods:** A total of 60 children within the age range of 3 years to 15 years were enrolled. All the patients were randomized into three study groups as follows: Group 1- Patients receiving Moxifloxacin 0.5% Eye Drops, Group 2- Patients receiving Tobramycin 0.3% and Group 3- Patients receiving Azithromycin 1.5 %. All patients receive eyedrops according to their specific group, four times a day for moxifloxacin and tobramycin, and twice a day for azithromycin. The cardinal clinical indicators of bacterial conjunctivitis were evaluated for each eye using a slit lamp, and a grading system was applied. The main efficacy measure was defined as clinical resolution, characterized by the absence of bulbar conjunctival injection and purulent discharge in the most affected eye by the seventh day.**Results:** Mean age of the patients of group 1, group 2 and group 3 was 5.9 years, 4.9 years and 5.2 years respectively. 65 percent, 60 percent and 50 percent of the subjects of group 1, group 2 and group 3 were boys. Conjunctival purulent discharge was severe in majority of cases of all the three study groups at baseline. Clinical cure rate after 7 days was 85.5 percent, 60 percent and 85.5 percent among patients of group 1, group 2 and group 3 respectively. Hence;clinical cure rate was similar for group 1 and group 3 and was significantly lower for subjects of group 2.**Conclusion:** While managing Pediatric Population with Purulent Bacterial Conjunctivitis, the efficacy of moxifloxacin and Azithromycin was similar and was significantly better in comparison to Tobramycin.

Key words: Moxifloxacin, Tobramycin, Azithromycin, Conjunctivitis.

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INTRODUCTION

Conjunctivitis is characterized by symptoms such as irritation, itching, a sensation of a foreign body in the eye, and excessive tearing or discharge. In adults, viral infections are the predominant cause of conjunctivitis; however, children are more susceptible to bacterial conjunctivitis compared to viral forms. The primary bacterial agents responsible for conjunctivitis in adults include various species of Staphylococcus, while in children, the most common pathogens are Haemophilus influenzae, Streptococcus pneumoniae, and Moraxella catarrhalis.[1,2] The likelihood of a bacterial etiology increases if the eyelids are stuck together and there is an absence of itching. Individuals who wear contact lenses may have a heightened risk of developing infections caused by gram-negative bacteria. The incidence of bacterial keratitis among contact lens users is estimated to be as high as 30 per 100,000. Gonococcal ophthalmia neonatorum can affect up to 10% of infants who come into contact with gonorrheal exudate during childbirth, even with prophylactic measures in place, and may lead to serious complications such as bacteraemia and meningitis. Additionally, otitis media may occur in 25% of children diagnosed with H. influenzae conjunctivitis, while meningitis can arise in 18% of individuals suffering from meningococcal conjunctivitis.[3-5]

Mild cases are generally self-limiting in 2 to 5 days. Treatment options are largely restricted to topical aminoglycosides, fluoroquinolones, and macrolides.

Moxifloxacin is a new fluoroquinolone antibacterial agent with a broad spectrum of activity, encompassing gram-negative and gram-positive bacteria. It has improved activity against gram-positive species (including staphylococci, streptococci, enterococci) and anaerobes compared with ciprofloxacin. This is offset by slightly lower activity against pseudomonal species and Enterobacteriaceae. In common with other fluoroquinolones, moxifloxacin attains good penetration into respiratory tissues and fluids and its bioavailability is substantially reduced by coadministration with an antacid or iron preparation.[6]Tobramycin is a semisynthetic aminoglycoside that exhibits a spectrum of activity comparable to that of gentamicin. It is extensively utilized in the treatment of severe bacterial infections caused by susceptible organisms, particularly aerobic gram-negative bacteria. Similar to other aminoglycosides, tobramycin is believed to exert its effects by binding to bacterial ribosomes, thereby inhibiting protein synthesis. However, it is important to note that tobramycin is classified as both bactericidal and bacteriostatic.[7] Azithromycin is a broad-spectrum macrolide antibiotic with bacteriostatic activity against many Gram-positive and Gram-negative bacteria including Bordetella pertussis and Legionella species. It also has activity against Mycoplasma pneumoniae, Treponema pallidum, Chlamydia species and Mycobacterium avium complex.[8]

Mostly empirical topical antibiotics are used for the treatment of bacterial conjunctivitis without previous bacteriological identification. So, first-line antibiotics should be more efficacious, have a better cure rate, and be compliant with a good safety profile. Hence; the present study was conducted for comparative efficacy evaluation of moxifloxacin 0.5% eye drops vs tobramycin 0.3% eye drops vs azithromycin 1.5% eye drops for purulent bacterial conjunctivitis in children at a tertiary care hospital.

MATERIALS & METHODS

This study was conducted at Maharishi Markandeshwar Institute of Medical Science & Research, Ambala, Haryana, India from October 2023 to March 2024. A total of 60 children, within the age range of 3 years to 15 years were enrolled.Complete demographic and clinical details of all the patients were obtained. Inclusion criteria for the present study included pediatric patients with purulent bacterial conjunctivitis defined by mild-to-severe bulbar conjunctival injection and purulent discharge in at least one eye. Exclusion criteria include bacterial infection due to trauma, corneal ulceration, viral infection, and allergy to fluoroquinolones, macrolides, and aminoglycosides. All the patients were randomized into three study groups as follows:
Group 1: Patients receiving Moxifloxacin 0.5% Eye Drops,
Group 2: Patients receiving Tobramycin 0.3% and
Group 3: Patients receiving Azithromycin 1.5 %.

The eyedrops are administered to each patient in accordance with their particular group, with moxifloxacin and tobramycin being administered four times per day and azithromycin being administered twice each day. The cardinal clinical indicators of bacterial conjunctivitis were evaluated for each eye using a slit lamp, and a grading system was applied. The main efficacy measure was defined as clinical resolution, characterized by the absence of bulbar conjunctival injection and purulent discharge in the most affected eye by the seventh day.

All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software. Chi-square test and student t test were used for evaluation of level of significance.

RESULTS

Mean age of the patients of group 1, group 2 and group 3 was 5.9 years, 4.9 years and 5.2 years respectively. 65 percent, 60 percent and 50 percent of the subjects of group 1, group 2 and group 3 were boys. Conjunctival purulent discharge was severe in majority of cases of all the three study groups at baseline. Clinical cure rate after 7 days was 85.5 percent, 60 percent and 85.5 percent among patients of group 1, group 2 and group 3 respectively.

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Hence;clinical cure rate was similar for group 1 and group 3 and was significantly lower for subjects of group 2.No death or significant treatment related adverse effects were reported in this study. Mild adverse effects were reported in 4 patients. These include slight blurring of vision with tobramycin in 2 patients, mild irritation with moxifloxacin in 1 patient, and mild itching with azithromycin in 1 patient.

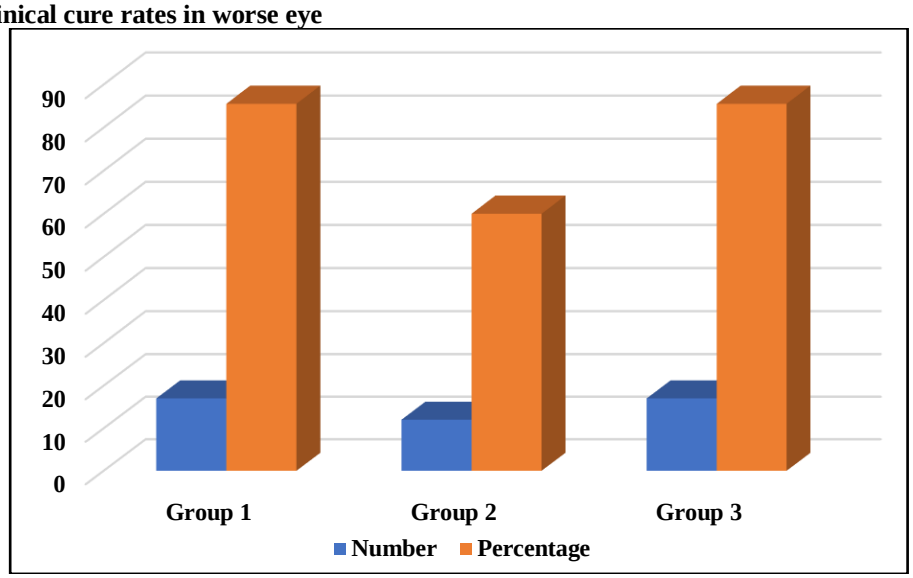
Table 1: Baseline characteristics

Variable		Group 1	Group 2	Group 3	p-value
Mean age		5.9	4.9	5.2	0.746
Gender	Boys	13	12	10	0.810
	Girls	7	8	10	
Conjunctival purulent discharge in worst eye	Absent	0	0	0	0.338
	Mild	4	3	3	
	Moderate	7	8	7	
	Severe	9	9	10	

Table 2: Clinical cure rates in worse eye

Clinical cure after 7 days	Group 1	Group 2	Group 3
Number	17	12	17
Percentage	85.5	60	85.5
Group 1 Vs Group 2	p-value = 0.001 (Significant)		
Group 1 Vs Group 3	p-value = 1		
Group 2 Vs Group 3	p-value = 0.001 (Significant)		

Graph 1: Clinical cure rates in worse eye



DISCUSSION

Conjunctivitis refers to the inflammation of the conjunctiva, typically marked by symptoms such as irritation, itching, a sensation of a foreign body, and excessive tearing or discharge. The management of this condition often relies on clinical judgment regarding the likelihood of a bacterial origin, without awaiting microbiological test results. This review aims to differentiate the outcomes of empirical treatment from those observed in patients with confirmed bacterial conjunctivitis through culture. Bacterial conjunctivitis is particularly concerning among contact lens users due to the heightened risk of developing bacterial keratitis, an infection of the cornea that can arise from acute or subacute trauma and poses a greater challenge in treatment, potentially jeopardizing vision. Additionally, conjunctivitis caused by Neisseria gonorrhoeae, known as ophthalmia neonatorum, predominantly affects neonates, resulting from exposure to the cervicovaginal secretions of infected mothers during childbirth. Historically, the distinguishing features of bacterial conjunctivitis compared to other forms have included the presence of a yellow-white mucopurulent discharge, a papillary reaction characterized by small bumps with fibrovascular cores on the palpebral conjunctiva, which appear as a fine velvety surface, and the occurrence of bilateral infection.[9- 11]

Hence; the present study was conducted for comparative efficacy evaluation of moxifloxacin 0.5% eye drops vs tobramycin 0.3% eye drops vs

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azithromycin 1.5% eye drops for purulent bacterial conjunctivitis in children at a tertiary care hospital.

The mean age of the patients of group 1, group 2 and group 3 was 5.9 years, 4.9 years and 5.2 years respectively. 65 percent, 60 percent and 50 percent of the subjects of group 1, group 2 and group 3 were boys. Conjunctival purulent discharge was severe in majority of cases of all the three study groups at baseline. Clinical cure rate after 7 days was 85.5 percent, 60 percent and 85.5 percent among patients of group 1, group 2 and group 3 respectively. Hence;clinical cure rate was similar for group 1 and group 3 and was significantly lower for subjects of group 2. Bremond-Gignac D et al determined the efficacy and safety of azithromycin 1.5% eye drops in a paediatric population with purulent bacterial conjunctivitis. Patients received either azithromycin 1.5% eye drops (twice daily for 3 days) or tobramycin 0.3% eye drops (every 2 h for 2 days, then four times daily for 5 days). 286 patients (mean age 3.2 years; range 1 day–17 years) were included; 203 had positive cultures on D0. Azithromycin was superior to tobramycin in clinical cure rate on D3 (47.1% vs 28.7%, p=0.013) and was non-inferior to tobramycin on D7 (89.2% vs 78.2%, respectively). Azithromycin treatment eradicated causative pathogens, including resistant species, with a similar resolution rate to tobramycin (89.8% vs 87.2%, respectively). These results were confirmed in a subgroup of patients younger than 24 months old. Azithromycin 1.5% eye drops provided a more rapid clinical cure than tobramycin 0.3% eye drops in the treatment of purulent bacterial conjunctivitis in children, with a more convenient twice-a-day dosing regimen.[11]

Cochereau I et al. conducted a comparative study assessing the efficacy and safety of Azyter, which contains azithromycin 1.5% eye drops administered over a three-day period, against tobramycin 0.3% used for seven days in the treatment of purulent bacterial conjunctivitis. Participants were assigned to receive either azithromycin 1.5% twice daily for three days or tobramycin 0.3%, with one drop every two hours for the first two days, followed by four times daily for the subsequent five days. In a per-protocol analysis involving 471 patients who tested positive for D0, the clinical cure rates were 87.8% for the azithromycin group and 89.4% for the tobramycin group at the time of the test of cure (TOC) visit. The results indicated that azithromycin was non-inferior to tobramycin in terms of both clinical and bacteriological outcomes. Notably, the clinical cure rate was significantly higher in the azithromycin group at Day 3. The safety profile of azithromycin was found to be satisfactory, with favorable acceptability reported by both patients and investigators. Overall, azithromycin 1.5% administered over three days demonstrated comparable efficacy and safety to tobramycin over seven days, with a greater proportion of patients in the azithromycin group achieving early clinical cure by Day 3. [12]

CONCLUSION

While managing Pediatric Population with Purulent Bacterial Conjunctivitis, efficacy of moxifloxacin and Azithromycin was similar and was significantly better in comparison to Tobramycin.

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