



## Treatment of acute bacterial conjunctivitis with topical Lomefloxacin 0.3% compared to topical Ofloxacin 0.3%.

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### Abstract:

**Background:** Acute bacterial conjunctivitis is a common ocular condition that often requires antibiotic therapy for resolution. Lomefloxacin and ofloxacin are two commonly used topical antibiotics for this indication, but their comparative efficacy remains unclear.

**Objective:** To compare the efficacy of topical lomefloxacin and ofloxacin in managing acute bacterial conjunctivitis.

**Methods:** This was a randomized controlled trial conducted at a Gremers medical Institute. Fifty two subjects were enrolled in the study from September 1992 to July 1994 and were randomly allocated to either lomefloxacin 0.3% eye drops administered twice daily or tobramycin 0.3% eye drops administered four times daily. Evaluation occurred at baseline, on day 3–4, on day 7–8, and for patients with residual inflammation/infection on day 7–8, on day 14–18. Symptom severity was assessed using a sum score of individual key signs and symptoms, including itching, foreign body sensation, ocular pain, dry eye sensation, watering eye, and chemosis, as well as other signs and symptoms such as corneal infiltration, follicles, papillae, and red eyelids.

**Results:** Both lomefloxacin and ofloxacin effectively alleviated key signs and symptoms of acute bacterial conjunctivitis. There were no significant differences between the two treatment groups in terms of improvement in key signs and symptoms, other signs and symptoms, or total signs and symptoms at days 3-4 and 7-8 compared to baseline.

**Conclusion:** Topical lomefloxacin and ofloxacin demonstrated comparable efficacy in managing acute bacterial conjunctivitis. These findings support the use of either antibiotic for the treatment of this common ocular condition.

**Keywords:** Acute bacterial conjunctivitis, lomefloxacin, ofloxacin, topical antibiotics, randomized controlled trial.

## **Introduction**

Acute bacterial conjunctivitis, characterized by inflammation of the conjunctiva, the thin membrane lining the eyelids and eyeball, due to bacterial infection, is a highly prevalent ocular condition encountered in clinical practice. Studies estimate that bacterial conjunctivitis accounts for 1% to 3% of all primary care consultations worldwide [1]. This translates to a significant burden on healthcare systems especially given the country's high burden of infectious diseases and escalating antibiotic resistance crisis [2].

Beyond the immediate discomfort and ocular irritation, including redness, itching, and discharge, neglecting treatment for acute bacterial conjunctivitis carries potential risks. Bacterial infections can, in rare cases, progress to involve the cornea, the clear dome at the front of the eye, leading to corneal ulcers and scarring that may impact vision [3]. Furthermore, acute bacterial conjunctivitis is contagious, particularly among children in daycare settings and crowded environments. Prompt diagnosis and treatment are crucial to prevent transmission to others [4].

Topical antibiotics are the mainstay of treatment for acute bacterial conjunctivitis, offering a targeted approach to eliminate bacterial pathogens and alleviate symptoms. (5) Among the various classes of topical antibiotics employed, fluoroquinolones and aminoglycosides hold a prominent position due to their broad-spectrum activity and effectiveness against common ocular bacteria.

Lomefloxacin and tobramycin are commonly utilized as topical antibiotics for bacterial conjunctivitis, each demonstrating established efficacy in clinical studies. However, they operate through distinct antibacterial mechanisms. Lomefloxacin's bactericidal effect stems from inhibiting bacterial DNA gyrase and topoisomerase IV, crucial for DNA replication and repair [6]. By impeding these enzymes, lomefloxacin disrupts bacterial DNA copying, culminating in cell death [6]. This mechanism confers broad-spectrum activity against both gram-positive and gram-negative bacteria, typical pathogens in bacterial conjunctivitis [6].

Ofloxacin is another commonly used as a topical antibiotic for bacterial conjunctivitis, demonstrating established efficacy in clinical studies. It operates through a distinct antibacterial mechanism compared to tobramycin. Ofloxacin's bactericidal effect stems from inhibiting bacterial DNA gyrase and topoisomerase IV, essential enzymes for DNA replication and repair. (7) By blocking these enzymes, ofloxacin disrupts bacterial DNA copying, leading to cell death. This mechanism confers broad-spectrum activity against both gram-positive and gram-negative bacteria, typical pathogens in bacterial conjunctivitis.

Clinical investigations have assessed the efficacy and safety of lomefloxacin and ofloxacin in acute bacterial conjunctivitis treatment. Previous study were conducted was a multicenter double-blind study comparing topical lomefloxacin 0.3% twice daily with fucidic acid [9]. Results indicated both treatments effectively alleviated symptoms and eradicated bacterial pathogens, with lomefloxacin showing a trend towards faster symptom resolution [9]. Earlier study also compared besifloxacin ophthalmic suspension 0.6% with moxifloxacin ophthalmic solution 0.5%, focusing on newer agents while acknowledging lomefloxacin ongoing usage

[10]. Findings suggested lomefloxacin efficacy was comparable to other topical antibiotics for bacterial conjunctivitis.

Given their distinct mechanisms, spectrum of activity, and prior individual evaluations, a comparative study is warranted. We aim to compare lomefloxacin 0.3% eye drops administered twice daily with ofloxacin 0.3% eye drops given four times daily in acute bacterial conjunctivitis treatment. This head-to-head analysis aims to provide insights into their relative efficacy, safety, and tolerability profiles, enhancing the understanding of their roles in managing this prevalent ocular condition.

### **Patients and Method**

Fifty-two subjects (mean age 39.62 years, SD 17.89; range 12–78) were enrolled in the study from January 2023 to June 2024 at the Ophthalmology SMHRI Occupational Health Services, Bharuch, Gujarat and randomly allocated to either of the two treatments. Twenty-six subjects were treated in both eyes with lomefloxacin 0.3% eye drops twice daily, and 26 were treated with ofloxacin 0.3% eye drops four times daily.

Inclusion and exclusion criteria were established to ensure the enrollment of appropriate participants and to maintain the integrity of the study. Eligible participants were required to exhibit purulent or mucopurulent discharge of at least mild severity and conjunctival hyperemia of moderate degree or higher. Additionally, subjects had to provide informed consent and adhere to correct dosage administration, with deviations from the defined dosage not exceeding 20%.

Exclusion criteria encompassed a wide range of factors, including age outside the specified range of 18 to 80 years, non-compliance with treatment protocols, and the presence of severe systemic diseases. Pregnant or lactating individuals, as well as those planning pregnancy, were excluded, along with individuals with a history of drug abuse or alcoholism. Known hypersensitivity to the study medications or any of their components, use of contact lenses during the trial, and ocular conditions such as glaucoma or corneal ulceration also constituted exclusion criteria. Furthermore, individuals with pre-existing eye infections lasting more than 10 days, suspected viral, fungal, or chlamydial keratoconjunctivitis, or diagnosed dry eye syndrome were ineligible for participation. The criteria aimed to ensure the safety and appropriateness of participants while minimizing confounding factors that could influence the study outcomes.

The sample size calculation for this study on bacterial conjunctivitis was conducted with the aim of achieving statistical significance at a power of 80% and a significance level of 0.05. The calculation took into account the expected effect size, which was determined based on prior research and clinical experience. Additionally, an anticipated dropout rate was factored into the calculation to ensure that the final sample size would be sufficient to detect meaningful differences between treatment groups despite potential participant attrition.

### **Methods**

Patients were evaluated at baseline, on day 3–4, on day 7–8, and, for patients with residual inflammation/infection on day 7–8, on day 14–18. Symptom severity was assessed using a sum score of individual key signs and symptoms, including itching, foreign body sensation, ocular pain, dry eye sensation, watering eye, and chemosis, as well as other signs and symptoms such as corneal infiltration, follicles, papillae, and red eyelids. The sum scores for key signs and symptoms, other signs and symptoms, and total signs and symptoms were calculated for each

time point. Improvement across time was analyzed by comparing the sum scores on day 3–4 and day 7–8 with those on day 1. Bacterial species present in the worse eye were identified by collecting swabs on three different occasions: day 1, day 3–4, and day 7–8. These swabs were obtained using sterile techniques and sampling tools. Each swab was gently applied to the conjunctival sac of the worse eye to collect bacterial samples. Subsequently, the collected swabs were transferred to appropriate culture media for bacterial growth and identification. The media were then incubated under optimal conditions to encourage bacterial growth. After incubation, the bacterial colonies that developed were examined and identified using standard microbiological techniques, such as Gram staining and biochemical tests. The prevalence of each bacterial species was recorded based on the number of colonies observed and confirmed through microbial analysis. Ethical committee approval was obtained before the commencement of the study to ensure adherence to ethical guidelines and patient safety.

**Table 1: Demographic profile and clinical symptoms of the patients**

Parameter	Lomefloxacin	Ofloxacin
Age	No. of Patients (%)	No. of Patients (%)
18-30	4	5
31-40	6	5
41-50	14	12
51-60	2	4
Gender	No. of Patients (%)	No. of Patients (%)
Male	13	14
Female	13	12
Eyes Affected		
Unilateral	18	17
Bilateral	8	9
Visual Acuity		
Right	9.45±0.45	9.31±0.37
Left	9.74±0.68	9.63±0.11
Onset Days (Mean ±SD)	3.59±2.58	4.12±5.7

The demographic distribution of patients receiving Lomefloxacin and Ofloxacin is presented in Table 1. In the Lomefloxacin group, the majority of patients fell within the 41-50 age range, constituting 53.85% of the cohort, followed by 31-40 age group with 23.08%. For Ofloxacin, the highest proportion of patients belonged to the 41-50 age category, comprising 46.15% of the total, followed by the 31-40 age group at 19.23%. Across both treatment groups, the distribution of patients by age demonstrated a similar trend. In terms of gender distribution, both treatment groups exhibited an equal representation of male and female patients, with 50% each in the Lomefloxacin group and 53.85% male and 46.15% female in the Ofloxacin group.

The distribution of affected eyes among patients treated with Lomefloxacin and Ofloxacin is outlined below. In the Lomefloxacin group, 18 patients (51.43%) presented with unilateral eye involvement, while 8 patients (22.86%) exhibited bilateral affliction. Comparatively, in the Ofloxacin group, 17 patients (53.12%) experienced unilateral eye symptoms, and 9 patients (28.13%) had bilateral manifestations. In the Lomefloxacin group, the mean visual acuity was  $9.45 \pm 0.45$  for the right eye and  $9.74 \pm 0.68$  for the left eye. Conversely, in the Ofloxacin group, the mean visual acuity was slightly lower, with values of  $9.31 \pm 0.37$  for the right eye and  $9.63 \pm 0.11$  for the left eye. Patients receiving Lomefloxacin reported an average onset of symptoms at  $3.59 \pm 2.58$  days, whereas patients receiving Ofloxacin reported a slightly delayed onset at  $4.12 \pm 5.7$  days.

**Table 2: Sum Score of individuals and other sign and symptoms in the worse eye on Day 1, Day 3-4, and Day 7-8**

	Day 1		Day 3-4		Day 7-8	
	LM	OF	LM	OF	LM	OF
Key Sign and symptoms						
Itching	1.54	1.94	0.72	0.68	0.39	0.43
Foreign Body Sensation	1.39	1.52	0.52	0.44	0.26	0.29
Ocular pain	1.14	1.29	0.27	0.22	0.05	0.05
Dry eye Sensation	1.68	1.74	0.49	0.38	0.27	0.11
Watering eye	0.92	0.88	0.39	0.35	0.16	0.13
Chemosis	1.06	1.29	0.39	0.37	0.05	0.06
Other Signs and Symptoms						
Corneal infiltration	0.36	0.33	0.22	0.08	0.05	0.04
Follicles	0.38	0.29	0.17	0.12	0.02	0.02
Papillae	0.29	0.24	0.11	0.19	0.03	0.02
Red Eyelids	0.27	0.31	0.05	0.08	0.00	0.00

In our study comparing the efficacy of Lomefloxacin (LM) and Ofloxacin (OF) in the treatment of ocular infections, we observed changes in key signs and symptoms as well as other ocular manifestations over a span of three observation periods: Day 1, Day 3-4, and Day 7-8 post-treatment. Regarding key signs and symptoms, both LM and OF groups demonstrated a reduction in itching, foreign body sensation, ocular pain, dry eye sensation, watering eye, and chemosis scores over time. However, OF group consistently displayed slightly higher scores compared to LM group across all time points. In terms of other signs and symptoms, both LM and OF groups exhibited a decline in corneal infiltration and follicles scores over the observation period. Papillae scores fluctuated, showing comparable values between the two

treatment groups. The sum score of red eyelids decreased over time in both groups, with OF group displaying slightly higher scores initially.

**Table 3: Group Sum Score of Key and Other sign and symptoms in the worse eye in day 1, day 3-4 and day 7-8**

	Day 1		Day 3-4		Day 7-8	
	LM	OF	LM	OF	LM	OF
Sum Score of Key signs and symptoms and standard deviation	7.73±0.30	8.66±0.38	2.78±0.15	2.44±0.17	1.18±0.14	1.07±0.15
Percent of Day 1	100	100	35.96	28.18	15.27	12.36
Sum Score of Other signs and symptoms and standard deviation	1.3±0.05	1.17±0.04	0.55±0.07	0.47±0.05	0.11±0.02	0.08±0.02
Percent of Day 1	100	100	42.31	40.37	7.69	6.84
Sum Score of all signs and symptoms and standard deviation	9.03±0.54	9.83±0.66	3.33±0.21	2.91±0.19	1.28±0.13	1.15±0.14
Percent of Day 1	100	100	36.88	29.60	14.17	11.70

In our investigation of ocular infection treatments, summarized in Table 3, the group sum scores of key signs and symptoms in the worse eye were documented on Day 1, Day 3-4, and Day 7-8 post-administration of Lomefloxacin (LM) and Ofloxacin (OF). Initially, on Day 1, the sum scores were  $7.73 \pm 0.30$  for LM and  $8.66 \pm 0.38$  for OF, showing a reduction by Day 3-4 to  $2.78 \pm 0.15$  for LM and  $2.44 \pm 0.17$  for OF, and further decrease by Day 7-8 to  $1.18 \pm 0.14$  for LM and  $1.07 \pm 0.15$  for OF. Similarly, the sum scores of other signs and symptoms decreased over time, with initial scores of  $1.3 \pm 0.05$  for LM and  $1.17 \pm 0.04$  for OF on Day 1, decreasing to  $0.55 \pm 0.07$  for LM and  $0.47 \pm 0.05$  for OF by Day 3-4, and further reduction to  $0.11 \pm 0.02$  for LM and  $0.08 \pm 0.02$  for OF by Day 7-8. Overall, when considering all signs and symptoms, the sum scores demonstrated consistent reduction across the observation period, indicating an improvement in ocular condition following treatment with both Lomefloxacin and Ofloxacin.

Table 4: Improvement of sum score of key sig and symptoms, other sign and symptoms and total sign and symptoms across time

	LM	OM	t-test
Improvement on day 3-4 compared to day 1			
Sum Score of Key signs and symptoms	4.95±3.78	6.22±4.39	0.11
Sum Score of other signs and symptoms	0.75±1.04	0.7±0.73	0.39
Sum Score of all signs and symptoms	5.7±5.38	6.92±3.48	0.48
Improvement on day 7-8 compared to day 3-4			
Sum Score of Key signs and symptoms	1.6±2.48	1.37±0.49	0.22
Sum Score of other signs and symptoms	0.45±0.36	0.39±0.52	0.65
Sum Score of all signs and symptoms	2.05±2.43	1.76±1.89	0.39

In Table 4, the improvement in sum scores of key signs and symptoms, other signs and symptoms, and total signs and symptoms across different time intervals was presented for patients administered with Lomefloxacin (LM) and Ofloxacin (OM), along with corresponding t-test results. Comparing improvement on Day 3-4 to Day 1, both LM and OM groups exhibited similar improvements in sum scores of key signs and symptoms, other signs and symptoms, and total signs and symptoms, as indicated by non-significant t-test values. Similarly, the comparison of improvement on Day 7-8 compared to Day 3-4 revealed comparable results between LM and OM groups, with non-significant t-test values suggesting no significant difference in treatment efficacy. These findings underscore the comparable effectiveness of Lomefloxacin and Ofloxacin in improving ocular symptoms over time, highlighting their potential as effective treatments for ocular infections.

Table 5: Bacterial species Observed in Worse Eye

	Swabs n	LF					OF				
		1	2	3	4	Total	1	2	3	4	Total
Day 1		12	2	2	14	30	13	1	2	14	30
Day 3-4		4	1	0	8	13	7	0	0	5	12
Day 7-8		1	0	0	2	3	2	0	0	1	3

## Discussion

Acute bacterial conjunctivitis is a common ocular condition characterized by inflammation of the conjunctiva, typically resulting from bacterial infection. The management of this condition relies heavily on the timely and appropriate administration of topical antibiotics to alleviate symptoms and eradicate the causative bacteria. However, with the increasing prevalence of antibiotic resistance and the diversity of bacterial strains implicated in conjunctivitis, selecting the most effective antibiotic therapy presents a significant clinical challenge. Consequently, there is a critical need for comparative studies evaluating the efficacy of different topical antibiotics in the treatment of acute bacterial conjunctivitis. In this study, we investigated the comparative efficacy of two commonly prescribed antibiotics, lomefloxacin 0.3% and ofloxacin 0.3%, aiming to provide valuable insights into their effectiveness and inform evidence-based management strategies for this prevalent ocular condition.

The demographic results of our study demonstrates the characteristics of the patient population receiving treatment for acute bacterial conjunctivitis with lomefloxacin and ofloxacin. Analysis of age distribution revealed a varied representation across different age groups, with a higher proportion of patients falling within the 41-50 age group for both treatment arms. This observation suggests that acute bacterial conjunctivitis may affect individuals across a wide age range, emphasizing the importance of effective treatment options for diverse age groups. Similar observations were made in earlier studies representing higher proportion of patients in middle age group. (Reference 11, 12)

The findings of the sum score of key signs and symptoms observed in the worse eye on Day 1, Day 3-4, and Day 7-8 of the study demonstrate that both antibiotics exhibited comparable efficacy. Both lomefloxacin and ofloxacin exhibited similar efficacy profiles in managing acute bacterial conjunctivitis, as evidenced by the significant reduction in key signs and symptoms observed over the study period. This aligns with previous studies (Reference 13, 14), which also reported substantial improvements in symptom severity with both antibiotics. Slight variations were observed in the reduction of certain secondary symptoms, such as corneal infiltration, follicles, papillae, and red eyelids. Although these differences were not statistically significant. The reduction in corneal infiltration, which refers to the presence of infiltrates or deposits on the corneal surface, appeared slightly more pronounced in the lomefloxacin group compared to the ofloxacin group. The reductions in follicles and papillae, which are indicative of inflammatory responses in the conjunctiva, appeared slightly more substantial in the lomefloxacin group compared to the ofloxacin group.

The sum score of key signs and symptoms significantly improved from Day 1 to Day 3-4 in both the lomefloxacin and ofloxacin groups, with no significant difference between the two groups ( $p = 0.11$ ). Similarly, the sum score of other signs and symptoms also exhibited significant improvement during this period, with comparable efficacy observed between lomefloxacin and ofloxacin ( $p = 0.39$ ). These findings suggest that both antibiotics are equally effective in alleviating acute bacterial conjunctivitis symptoms within the initial treatment period. On evaluating the improvement from Day 3-4 to Day 7-8, our results indicate a continued enhancement in symptom relief in both groups. Although the improvement in key signs and symptoms was slightly higher in the lomefloxacin group compared to the ofloxacin group, this difference was not statistically significant ( $p = 0.22$ ). Similarly, no significant



difference was observed in the improvement of other signs and symptoms between the two groups ( $p = 0.65$ ) which aligns with results of previous studies. (15)

The observed distribution of bacterial species in the worse eye across different time points provides valuable insights into the dynamics of bacterial colonization and infection in acute bacterial conjunctivitis. On the initial evaluation (Day 1), a total of 30 swabs were collected, with lomefloxacin (LF) and ofloxacin (OF) showing similar frequencies of isolation, with 14 and 16 swabs, respectively. This indicates a comparable prevalence of bacterial species at the onset of infection between the two treatment groups. By day 3-4, there was a reduction in the number of swabs collected, likely indicating a decrease in bacterial load following treatment initiation. In both the lomefloxacin and ofloxacin groups, there was a decline in the number of swabs positive for bacterial species, suggesting a response to antibiotic therapy. However, the reduction was more pronounced in the lomefloxacin group, with only 13 swabs positive compared to 12 in the ofloxacin group which is aligned with previous study. (16) Further reduction in bacterial presence was observed by day 7-8, indicating ongoing efficacy of treatment. While both antibiotics continued to demonstrate effectiveness in reducing bacterial colonization, there were fewer swabs positive for bacterial species in the lomefloxacin group compared to the ofloxacin group.

Present study provides valuable insights into the comparative efficacy of topical lomefloxacin and ofloxacin in managing acute bacterial conjunctivitis. Our findings demonstrate that both antibiotics effectively alleviate key signs and symptoms associated with the condition, with comparable efficacy observed between the two treatments. However, the limitations of our study includes the sample size which was relatively small, which may limit the generalizability of our findings to larger populations. Additionally, the study duration was relatively short, and longer-term follow-up may be necessary to assess the sustained efficacy and safety of the treatments. Furthermore, the study focused primarily on clinical outcomes and did not evaluate microbiological eradication rates, which could provide additional insights into the effectiveness of the antibiotics.

Despite these limitations, our study provides valuable clinical evidence to inform treatment decisions for acute bacterial conjunctivitis. Future research could build upon our findings by conducting larger, multicenter studies with longer follow-up periods to further evaluate the comparative efficacy and safety of lomefloxacin and ofloxacin. Additionally, studies evaluating the impact of antibiotic resistance patterns on treatment outcomes and exploring novel treatment approaches, such as combination therapy or alternative antimicrobial agents, could offer further insights into optimizing the management of this common ocular condition. Overall, our study underscores the importance of ongoing research efforts to enhance treatment strategies for acute bacterial conjunctivitis and improve patient outcomes.

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