

Clinical Evaluation of Ophthalmic Lomefloxacin 0.3% in Comparison with Fortified Cefazolin and Gentamicin Ophthalmic Solutions in the Treatment of Presumed Bacterial Keratitis

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Objective : To evaluate the efficacy and safety of 0.3% lomefloxacin single agent solution, by comparing to a combination of fortified ophthalmic solutions of cefazolin sodium 50 mg/ml and gentamicin sulfate 14 mg/ml, in the treatment of acute bacterial keratitis.

Design : Prospective, double-masked, randomized comparative trial.

Method : Forty patients with clinical diagnosis of any grade of severity of acute bacterial keratitis were randomized into 2 treatment groups: 20 to fortified cefazolin-gentamicin group, and 20 to lomefloxacin-normal saline group. The dosing of the drugs were scheduled for both treatment groups as follows: 1 drop of each solution was alternately instilled every 5 minutes for the first 30 minutes (as loading dose), then 1 drop with 5-minute interval between 2 bottles instilled hourly for day 1-3, tapering to every 2 hours on day 4-6, and every 4 hours on day 7-14. After day 14, dosing discretion was clinically adjusted, based on the clinical condition and finally discontinued after complete healing. Corneal scraping for cultures was obtained before starting the treatment. Ocular symptoms and signs, time to heal and adverse reactions were evaluated and compared between the 2 groups on day 2, 4, 7, 14, 21 and 28.

Results : No clinically or statistically significant difference were noted between two treatment groups, regarding demographic, symptoms and signs associated with bacterial keratitis. Positive results of bacterial corneal cultures were obtained in 27.5%. There was no statistically significant difference in time to complete re-epithelialization in all types of bacterial keratitis ($P=0.251$). By day 7, the keratitis was healed: 44% in lomefloxacin group, and 33% in fortified antibiotic group. Both study medications were well-tolerated, with no incidence of reported adverse event.

Conclusion : In this study, even though there is no statistically significant difference of symptoms and signs between the two study groups at any study visit, we found clinical improvement in all patients in lomefloxacin group. So, lomefloxacin may be used as an alternative to standard treatment in acute bacterial keratitis.

Keywords : Lomefloxacin, Cefazolin, Gentamicin, Bacterial Keratitis.

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Bacterial ulcerative keratitis is a common sight-threatening disease in the world and especially in developing countries, such as Thailand⁽¹⁻⁵⁾. Rapid onset of pain accompanied by conjunctival injection, photophobia, and decreased vision are clinical presentations in patients with bacterial corneal ulcer. Untreated, it often leads to tissue destruction with corneal perforation or extension of infection to adjacent tissues. Other

serious complications of bacterial keratitis include corneal scarring and opacification, with or without secondary glaucoma, leading to severe visual disability.

Because of the severity of bacterial keratitis and the potential disabling visual outcome, the ophthalmic standard practice of care has evolved towards an aggressive initial therapeutic approach with the use of broad spectrum antibiotics in fortified concentrations, administered topically⁽⁶⁾ at frequent intervals and modified according to clinical response and laboratory data concerning the susceptibility of the organisms⁽⁷⁻⁹⁾. Sometimes if the patient appears to be

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worsening in spite of using broad spectrum antibiotic, it is accepted as a fundamental principal to discontinue all antibiotics for 24-48 hours and then reculture the corneal specimen^(43,44).

Topical antibacterial agents which are used as initial therapy include a broad-spectrum combination of a first generation cephalosporin agent, active against gram-positive organisms, and an aminoglycoside agent, active against gram-negative organisms. These agents are compounded into fortified concentrations to achieve higher tissue concentrations⁽⁷⁻⁹⁾.

Fluoroquinolone anti-infectives are bacterial DNA gyrase inhibitors that are bactericidal and have broad spectrum activity in vitro and in vivo against most gram-negative and many gram-positive bacteria⁽¹⁰⁻¹²⁾. Because of their broad spectrum bactericidal activity, low bacterial resistance rates, and relatively minimal toxicity, fluoroquinolones have great potentiality in the therapy of severe ocular infection⁽¹⁰⁻¹⁴⁾. Topical fluoroquinolone solutions have been approved for the treatment of conjunctivitis and keratitis and have been increasingly used as initial monotherapy in bacterial corneal ulcers.

Lomefloxacin is a difluorinated 4-quinolone antibacterial drug which is structurally related to nalidixic acid⁽¹²⁾. The drug has been shown to be active against both gram-positive and gram-negative bacteria, including *Pseudomonas aeruginosa*^(11,12). The antibacterial efficacy of oral lomefloxacin has been investigated in a wide variety of infections such as respiratory, uncomplicated and complicated urinary tract infections, obstetric, gynecological, joint, skin, oral, ear, nose, throat, as well as eye infections⁽¹²⁾. Lomefloxacin eye drops used with a loading dosage followed by a twice-daily regimen have been proven to be at least as effective, safe, and well tolerated as the various and currently well established treatments in patients with acute bacterial conjunctivitis⁽¹⁵⁻¹⁹⁾.

In spite of the increasing use of monotherapy with topical fluoroquinolone as initial therapy for bacterial keratitis, no published information is available about the efficacy and safety of lomefloxacin 0.3% in comparison with the use of the standard combination of topical fortified antibiotics.

The authors conducted a prospective, double-masked, randomized, and parallel-group trial to evaluate the ocular efficacy and safety of 0.3% lomefloxacin solution, used as monotherapy, in comparison with a combination of fortified ophthalmic solutions of 50 mg/ml cefazolin sodium and 14 mg/ml gentamicin sulfate, in the treatment of acute bacterial keratitis.

Subjects and Method

Study designs

Forty subjects were screened and recruited in the study at the Out-patient Unit of the Department of Ophthalmology, King Chulalongkorn Memorial Hospital, from February 2001 to November 2002, by using the convenient sampling technique.

Ophthalmologic eligible criteria included a clinical diagnosis of any type of acute (less than 2 weeks) bacterial corneal ulcer (mild, moderate, or severe according to Modified Jones' grading system) in one eye only, with or without a confirmed diagnosis of bacterial infection either by gram stain or culture from corneal scraping; best-corrected visual acuity of 20/200 or better in the uninvolved eye; no other active ocular infection; and if previous antibiotic treatment was documented from any patient, that patient would be asked to discontinue the present medication for 24 hours before reexamination by slit-lamp biomicroscopy, laboratory investigation and randomization for treatment. The purposes of discontinuing the present medications for 24 hours were to identify the correct organisms by increasing yield of its culture and sensitivity results and to study only the efficacy of medications that were used in the present study without effect from the previous medications.

General eligibility requirements included age higher than 1 year, absence of uncontrolled systemic disease, ability to complete up to 3 weeks of follow-up, absence of pregnancy and no history of allergy to any of the study medications or any of the components of the study medications. All participants gave their written informed consent.

Treatment Assignment

The patients were randomized into 2 groups according to a table of randomization. The lomefloxacin group received one bottle of 0.3% lomefloxacin solution and one bottle of placebo (0.9% normal saline) while the standard therapy group received one bottle of fortified cefazolin solution (50 mg/ml) and one bottle of fortified gentamicin solution (14 mg/ml). All patients and clinical personnel involved in the study were masked, on the account of the allocation of treatment.

Examination and treatment procedures

At baseline visit (day 1), a full medical and ophthalmic history and Snellen visual acuity were obtained. The lesion was examined using slit lamp biomicroscopy examination including the determination of the maximum dimension of the corneal epithelial

defect and infiltrate, maximum depth of stromal infiltration and corneal thinning. The affected cornea was scraped, under local anesthesia, with a surgical blade. The corneal scrapings were subjected to gram staining and KOH preparation, and were also inoculated in blood, chocolate, thioglycolate broth and Saboraud's agar plates. Ocular specimens from corneal scrapings were processed and analyzed at the Department of Microbiology, Faculty of Medicine, Chulalongkorn University.

The patients were asked about the following symptoms: discomfort, pain, tearing, photophobia and itching. The following signs were evaluated by the investigator: watering, discharge, lid edema, conjunctival chemosis and limbal hyperemia. The scoring of ocular signs and symptoms (absent = 0, mild = 1, moderate = 2, severe = 3) was reflective of the clinical condition of the bacterial corneal ulcer and not of the transient symptomatologic analysis related to the instillation of the study medications.

After corneal specimens were obtained, the study patients were assigned to receive the appropriate study medications. The clinical investigator was responsible for the initial administration of the assigned medications into the patient's affected eye as follows: One drop of each solution was alternately instilled every 5 minutes for the first 30 minutes as loading dose. The patients were then instructed to continue with the drops, from each of the two bottles (5 minutes apart), once every hour during all waking hours. The patients were also instructed to record the actual time when the study medications were instilled.

Follow-up examinations were scheduled on days 2, 4, 7, 14, 21, and 28, following the start of the treatment. A final follow-up examination was to be performed after the ulcer had completely healed and the study medication could be discontinued. If the keratitis was not healed by day 28 visit, but showed clinical improvement, treatment and follow-up could continue until healed. If the keratitis became worse, or if the patients experienced an adverse reaction during follow-up, the patient would be terminated from the study.

Each follow-up examination included visual acuity testing, biomicroscopy to evaluate the extent of changes from baseline in fluorescein staining and infiltration in relation to the corneal ulcer, clinical evaluation by the investigators of the progress of ocular infection, and evaluation of the symptoms of discomfort and the adverse events. At every post-treatment visit, the patient's compliance with the instillation of the study medications and the need, if any, for the replacement

of the bottles of the study medications were also checked.

The frequency of dosing of the study medications was reduced after the first follow-up visit. At day 4, the dose was reduced to one drop from each of the two bottles (5 minutes apart), every 2 hours during waking hours. At day 7, the dose was tapered to one drop every 4 hours during waking hours. At the day 14 visit, the frequency of dosing of the study medications was at the discretion of the investigator, based on the clinical condition of the ulcer; the dosing was to be terminated as soon as the corneal ulcer was completely healed.

Concomitant medications such as cycloplegic drugs, oral analgesics and appropriate antiglaucoma drugs in cases of secondary ocular hypertension were permitted. All related data were recorded in the case report form.

Data Analysis and Statistical Methods

The authors used descriptive analysis for patient demographic variables, unpaired t-test for comparing the efficacy (time to healing) between the two study groups, Mann whitney-U test for comparing signs and symptoms between the two study group and Wilcoxon signed rank test for comparing signs and symptoms before and after treatment within each study group.

Results

Of the 40 patients who were recruited into the study, 20 were randomized to receive 0.3% lomefloxacin and placebo (lomefloxacin group). The other 20 patients were randomly assigned to receive fortified cefazolin and fortified gentamicin (standard group).

Patient Demographics

The mean age (\pm standard deviation) of lomefloxacin and standard therapy treated patients were 25.95 (\pm 6.98) years and 28.0 (\pm 13.9) years, respectively. The ages of the lomefloxacin patients ranged from 17 to 42 years, compared with 9 to 64 years in the standard group. There were 13 females and 7 males on lomefloxacin while there were 12 females and 8 males in the standard therapy group (Table 1).

Fifteen (75%) patients in the lomefloxacin group and 11 (52%) in the standard group had corneal ulcers in which contact lens wear was noted as the predisposing cause while one patient in the lomefloxacin group and 5 patients in the standard group had a history of ocular trauma. Eighteen patients (11

Table 1. Patient demographic data

Age (mean±SD)	Lomefloxacin Group		Cefazolin+ Gentamicin	
	N = 20 17-42		N = 20 9-64	
	(25.95±6.98)		(28.00±13.91)	
	N	%	N	%
Gender				
• Female	13	65.0	12	60.0
• Male	7	35.0	8	40.0
Eye				
• OD	9	45.0	11	55.0
• OS	11	55.0	9	45.0
Trauma				
• Yes	1	5.0	5	25.0
• No	19	95.0	15	75.0
Contact lens Wearer				
• Yes	15	75.0	11	55.0
• No	5	25.0	9	45.0
Previous treatment				
• Yes	11	55.0	7	35.0
• No	9	45.0	13	65.0
Classification of corneal ulcer				
• Mild	7	35.0	13	65.0
• Moderate	7	35.0	6	30.0
• Severe	6	30.0	1	5.0

patients in the lomefloxacin group and 7 patients in the standard group) had prior antibiotic treatment. All patients stopped their antibiotic medication 24-48 hours before enrolling in the study.

Pre-study evaluation

No clinically significant difference between the two treatment groups were noted for any of the baseline symptoms and signs. Using the Modified Jones' grading system, the authors observed that 20 patients (7 in the lomefloxacin group, 13 in the standard group) had mild corneal ulcers; 13 (7 patients in the lomefloxacin group and 6 patients in the standard group) had moderate corneal ulcers; and 7 (6 patients

in the lomefloxacin group and 1 patient in the standard group) had severe corneal ulcers.

Clinical efficacy

There was no difference in patient compliance between both groups by checking the patients' check list of instillation of medication and volume of the medication in the bottle at each follow-up visit.

Clinical symptoms and signs

When comparing the symptoms and signs between day 2, 4, 7, 14, 21 and 28 to baseline at day 1, all the signs (watering, discharge, limbal hyperemia, lid edema and conjunctival chemosis) and symptoms (discomfort, pain, tearing and photophobia) except itching were statistically significantly decreased by 4 days ($p < 0.05$), 7 and 14 days ($p < 0.01$) after treatment in both the study groups. However, the authors did not find any statistically significant difference of symptoms and signs between the two study groups at any study visit.

Time to heal (Table 2)

The mean time to heal for corneal ulcers was not statistically significant between the study groups, either overall ($p = 0.251$) or for the various grades of severity of the corneal ulcers. Mean time to heal in the mild group was $9.57 (\pm 4.39)$ days in the lomefloxacin group compared to $7.46 (\pm 4.94)$ days in the standard group ($P = 0.358$); in the moderate group, it was $10.00 (\pm 5.51)$ days in the lomefloxacin group and $12.67 (\pm 8.64)$ days in the standard group ($P = 0.514$); and in the severe group, it accounted for $16.50 (\pm 9.65)$ days in the lomefloxacin group compared to 13.00 days in the standard group ($P = 0.751$).

Microbiologic evaluation

Positive bacterial corneal culture results were obtained in 11 study patients (28 %). The bacterial organism most commonly identified was *Pseudomonas*

Table 2. Mean time to cure in each classification of ulcer in both study groups

Classification	Drug	Number of patients	Mean day to heal	P-value
Mild	Lomefloxacin	7	9.57 ± 4.39	0.358
	Fortified Cefazolin-gentamicin	13	7.46 ± 4.94	
Moderate	Lomefloxacin	7	10.00 ± 5.51	0.514
	Fortified Cefazolin-gentamicin	6	12.67 ± 8.64	
Severe	Lomefloxacin	6	16.50 ± 9.65	0.751
	Fortified Cefazolin-gentamicin	1	13.00	
Total	Lomefloxacin	20	11.80 ± 7.08	0.251
	Fortified Cefazolin-gentamicin	20	9.30 ± 6.46	

aeruginosa (10 patients of whom 7 were in the lomefloxacin group and 3 in the standard group). The other organism was reported as *Enterobacter* and occurred in the lomefloxacin group. All the culture-positive patients were contact lens wearers.

Safety

Lomefloxacin was safe and well tolerated for the treatment of bacterial corneal ulcers. No adverse event related to therapy (burning, stinging, toxic conjunctivitis) was reported during the study.

Discussion

Bacterial keratitis is a sight-threatening infection. Currently, fortified topical antibiotic eye drops have been well established as the standard therapy for the treatment of bacterial keratitis since the 1970s⁽⁷⁻⁹⁾. The lack of a single broad-spectrum antibiotic, capable of killing all pathogenic gram-positive and gram-negative bacteria made it necessary to treat bacterial keratitis initially with two and sometimes even three antibacterial agents⁽²⁰⁾. A single, commercially available, non-fortified, broad-spectrum antibiotic with proven efficacy against most gram-positive and gram-negative bacteria would greatly simplify and improve the treatment of patients with bacterial corneal ulcers.

Fluoroquinolones are potent bactericidals having a broad spectrum of activity in vitro and in vivo against most gram-negative and many gram-positive bacteria. They have good ocular penetration, low resistance and high patient acceptance with few adverse effects⁽¹³⁾. However, fluoroquinolones are generally less active against gram-positive bacteria than gram-negative bacteria⁽²¹⁻²³⁾. Topical fluoroquinolone solutions have been approved for the therapy of conjunctivitis and keratitis and have been increasingly used as initial single-agent therapy. Leibowitz found an overall clinical success of 91.9% in 148 corneal ulcers treated with ciprofloxacin^(24,25). Insler et al reviewed two cases of methicillin-resistant *S.aureus* keratitis that were managed successfully with ciprofloxacin⁽²⁶⁾. Since then, there have been worldwide reports about the success in the treatment of bacterial keratitis with topical fluoroquinolone.

Many fluoroquinolones have been investigated in the management of bacterial keratitis. Previous comparative studies by Leibowitz HM⁽²⁵⁾ and Park DJ⁽²⁷⁾ reported that in patients with bacterial keratitis the efficacy of monotherapy with topical ciprofloxacin hydrochloride was similar to that of a combination of topical fortified cefazolin and gentamicin solutions. Also,

a report from the Bacterial Keratitis Study Research group showed that the efficacy of ofloxacin 0.3% solution in the treatment of bacterial keratitis was equivalent to that of a combination of fortified cefazolin and tobramycin solutions⁽²⁸⁾. However, it should be pointed out that there have been several recent reports⁽²⁹⁻³²⁾ about a significant increase in the occurrence of ciprofloxacin-resistant and ofloxacin-resistance bacterial keratitis from 5% to 35% since 1992.

In the present study, comparing topical 0.3% lomefloxacin solution with topical fortified cefazolin (50 mg/ml) and gentamicin (14 mg/ml), the authors found that lomefloxacin was not clinically and statistically different from the standard therapy in the resolution of all symptoms and signs associated with corneal bacterial ulcers. There was no statistically significant difference between the two study groups in the time to complete re-epithelialization of the corneal ulcer in spite of more patients with severe corneal ulcers in the lomefloxacin group. Interestingly, even in cases of severe bacterial corneal ulcers, the lesions healed within 14 days, similar to that observed for mild to moderate corneal ulcers.

The results of the present study are consistent with the results of a study in a *Pseudomonas aeruginosa* - induced keratitis model in guinea pigs⁽³³⁾. It was found that 0.3% lomefloxacin eye drops significantly reduced the bacterial colony count as well as the signs and symptoms of keratitis in comparison with the groups receiving no treatment or vehicle treatment.

Lomefloxacin is a difluorinated 4-quinolone antibiotic drug against gram negative bacteria, including *Pseudomonas aeruginosa*, and also has some activity against gram-positive bacteria^(12,41). In ocular kinetic studies, lomefloxacin showed a better kinetic profile compared to ciprofloxacin in corneal ulcer studies, the efficacy of four-times-a-day application of ciprofloxacin is equivalent to twice-a-day application of lomefloxacin. Lomefloxacin also showed nearly 10 times more ocular bioavailability in aqueous humor compared to ciprofloxacin. Lomefloxacin was found to have significant efficacy in the healing of *Staphylococcus aureus*-induced corneal ulcer and associated lesions. Moreover, aqueous formulation of lomefloxacin showed a good compatibility at neutral pH⁽⁴²⁾. Excellent corneal penetration of lomefloxacin has also been reported by Kodama T⁽³⁹⁾ and Ooishi M⁽³⁷⁾. Lomefloxacin therapy in experimental bacterial keratitis induced by *Pseudomonas* in guinea pigs with an initial high dose followed by low dose was reported by Malet P et al⁽³³⁾. Twice daily application of lomefloxacin was found to be

effective when compared with fucidic acid in the management of acute bacterial conjunctivitis⁽¹⁵⁾.

Lomefloxacin 0.3% eye drops are ideally suited for the treatment of bacterial corneal ulcers since lomefloxacin exhibits a broad-spectrum of activity against a wide variety of gram-positive and gram-negative bacteria^(11,12) while bacterial resistance rates are lower vis-à-vis conventional antibiotics⁽³⁴⁾. Furthermore, lomefloxacin has a rapid onset of bactericidal activity⁽³⁵⁾, sustained and high concentrations in the tear film^(36,37) and excellent corneal penetration⁽³⁶⁻⁴⁰⁾.

Lomefloxacin was found to be well tolerated in the treatment of patients with bacterial corneal ulcers. No adverse events related to lomefloxacin were reported during the course of the present study. This is consistent with the observations in several clinical studies on acute bacterial conjunctivitis where there were none or very few occurrences of adverse events.⁽¹⁵⁻¹⁸⁾ Moreover, lomefloxacin offers several other advantages over conventional antibiotics, namely: convenience of commercial availability, superior stability at room temperature, and absence of proper concentration or sterility concerns that relate to extratemporaneous fortified preparations.

This controlled study demonstrated that there is no statistically significant difference in the efficacy between the lomefloxacin group and the standard group which may be because of too small sample size. But all patients in the lomefloxacin group showed clinical improvement, so the authors plan to increase the sample size in the future study. To the authors' knowledge, this pilot study presents for the first time, clinical evidence that topical lomefloxacin is effective in the treatment of severe corneal ulcers in humans (central or peripheral diameter > 6 mm, extending to inner-one-third, hypopyon > 2 mm, and associated with significant thinning).

The rate of positive culture in the present study is 28%. The authors found that all cases of positive culture are associated with contact-lens wearing. Since most of our candidates were contact-lens wearers, so the most common organism that could be isolated was *Pseudomonas aeruginosa* which was found 91%. Limitation of this study is the small number of candidates and low positive rate of culture that cause the uneven distribution of bacteria among the gram-positive and gram-negative organisms.

In conclusion, ophthalmic lomefloxacin 0.3% may be recommended as initial monotherapy in the treatment of all grades of severity of acute bacterial keratitis at a dose of one drop, once every hour, in order

to maximize the therapeutic effect until the corneal ulcer starts to improve.

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การศึกษาการใช้ยาหยอดตา 0.3% lomefloxacin เปรียบเทียบกับยาหยอดตา fortified cefazolin ร่วมกับ gentamicin ในการรักษาผู้ป่วยติดเชื้อแบคทีเรียที่กระจกตา

สุภาวดี เอื้อจงมานี, งามจิตต์ เกษตรสุวรรณ, ณัฐรินทร์ ภูษิตไทยโคย, วิลาวัณย์ พวงศรีเจริญ, ลลิตา ปริญนก

วัตถุประสงค์ : เพื่อศึกษาประสิทธิภาพและความปลอดภัยของการใช้ยาหยอดตา 0.3% lomefloxacin เปรียบเทียบกับยาหยอดตา fortified cefazolin (50 มิลลิกรัม/มิลลิลิตร) ร่วมกับ gentamicin (14 มิลลิกรัม/มิลลิลิตร) ในการรักษาผู้ป่วยติดเชื้อแบคทีเรียที่กระจกตา

รูปแบบการวิจัย : การศึกษาไปข้างหน้าแบบ randomized comparative trial

วิธีการศึกษา : ผู้ป่วย 40 รายที่ได้รับการวินิจฉัยว่ามีการติดเชื้อที่กระจกตาที่ลักษณะทางคลินิกเข้าได้กับเชื้อแบคทีเรียได้รับการสุ่มและแบ่งออกเป็น 2 กลุ่มโดยกลุ่มแรกจำนวน 20 รายจะได้รับการรักษาด้วยยาหยอดตา fortified cefazolin ร่วมกับ gentamicin ในขณะที่ผู้ป่วยอีก 20 รายจะได้รับการรักษาด้วยยาหยอดตา 0.3% lomefloxacin ร่วมกับน้ำเกลือ (placebo) โดยทั้งสองกลุ่มมีวิธีการหยอดยาดังนี้ หยอดยา 1 หยดสลับกัน 2 ขวดทุก 5 นาทีในช่วง 30 นาทีแรกเพื่อเพิ่มปริมาณยาให้สูงขึ้นในช่วงแรก หลังจากนั้นหยอดยาหยอดตาทั้ง 2 ขวด ๆ ละ 1 หยดห่างกัน 5 นาที ทุก 1 ชั่วโมงในวันที่ 1-3 และลดความถี่ของการหยอดยาเป็นทุก 2 ชั่วโมงในวันที่ 4-5 และหยอดยาทุก 4 ชั่วโมง ในวันที่ 6-14 และหลังจากวันที่ 14 ความถี่ของการให้ยาจะขึ้นกับอาการทางคลินิกและจะหยุดยาเมื่อแผลติดเชื้อที่กระจกตาทาย ก่อนทำการรักษา ผู้ป่วยทุกรายจะได้รับการขูดเชื้อจากแผลบริเวณกระจกตาเพื่อนำไปเพาะเชื้อ การศึกษาครั้งนี้ทำการประเมินอาการ อาการแสดงของผู้ป่วยระยะเวลาตั้งแต่เริ่มการรักษาจนแผลหายและผลข้างเคียงจากการใช้ยา ในผู้ป่วยทั้งสองกลุ่มและทำการศึกษาเปรียบเทียบในวันที่ 2, 4, 7, 14, 21 และ 28

ผลการศึกษา : ไม่พบความแตกต่างในแง่ของเพศ อายุ ลักษณะ อาการ อาการแสดงระหว่างผู้ป่วยทั้งสองกลุ่ม ผลการเพาะเชื้อแบคทีเรียได้ผลบวก 27.5% ไม่พบความแตกต่างทางสถิติของระยะเวลาตั้งแต่เริ่มการรักษาจนแผลหายในทุกระดับความรุนแรงของแผลติดเชื้อที่กระจกตา ($P = 0.251$) โดย 44% ของแผลติดเชื้อที่กระจกตาในกลุ่มที่ใช้ยาหยอดตา 0.3% lomefloxacin เปรียบเทียบกับ 33% ของแผลติดเชื้อในกลุ่มที่ใช้ยาหยอดตา fortified cefazolin ร่วมกับ gentamicin หายในวันที่ 7 นอกจากนี้ยังไม่พบผู้ป่วยที่มีผลข้างเคียงจากการใช้ยาทั้งสองกลุ่ม

สรุปผล : การศึกษานี้ถึงแม้ว่าไม่พบความแตกต่างของอาการและอาการแสดงภายหลังการรักษาอย่างมีนัยสำคัญทางสถิติแต่อย่างไรก็ตามพบว่าผู้ป่วยทุกรายที่ได้รับยาหยอดตา 0.3% lomefloxacin ในการรักษาแผลติดเชื้อแบคทีเรียที่กระจกตาทายทุกราย ดังนั้น lomefloxacin อาจจะเป็นอีกทางเลือกหนึ่งในการรักษาผู้ป่วยแผลติดเชื้อแบคทีเรียที่กระจกตา
