Analysis of the drug therapy of gatifloxacin and levofloxacin in the treatment of acute bacterial conjunctivitis

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Abstract: Acute bacterial conjunctivitis is an acute conjunctivitis that is frequently transmitted in summer and autumn. It is a common and frequently occurring disease in ophthalmology clinic. Gatifloxacin is an effective antibacterial drug. It not only maintains the antibacterial effect of the three generation of fluoroquinolones on Gram-negative bacteria, but also enhances the effectiveness of gatifloxacin, including other Gram-positive bacteria and anaerobes. In this paper, by taking gatifloxacin eye drops as the experimental drug and levofloxacin as the control drug, we conducted a double-blind randomized controlled clinical trial to evaluate the efficacy and safety of gatifloxacin eye drops in the treatment of acute bacterial conjunctivitis. The clinical results showed that the total effective rate of the Gatifloxacin treatment group was 95%. Conclusion shows that gatifloxacin is a safe and effective antibiotic eye drops. It has broad antibacterial spectrum, strong antibacterial activity and effective clinical treatment, and it can effectively treat acute bacterial conjunctivitis.

Keywords: Gatifloxacin, antimicrobial spectrum, drug sensitivity, acute bacterial conjunctivitis.

INTRODUCTION

Acute bacterial conjunctivitis is a common infectious eye disease caused by bacterial infection, it has epidemic characteristics. The main features are marked conjunctival congestion and mucous or purulent discharge (Cahill *et al.,* 2015; Chen *et al.,* 2015). Its diagnosis and treatment are not difficult, but because of the clinical abuse of antibiotics, the drug resistant strains gradually increase, and the application of clinical drugs has been increased (Dai *et al.,* 2015). The development of synthetic antibiotics in 1990s has become a bright spot in the research and development of antibacterial drugs (Dobson *et al.,* 2015; Ghoneum *et al.,* 2015). The third generation of fluoroquinolones has good antibacterial activity against Gram-negative bacteria, but the antibacterial activity to Gram-positive bacteria is relatively weak, and it has a poor effect on anaerobes and intracellular pathogens, including chlamydia, mycoplasma, Legionella and mycobacteria (Luo, 2015; Lee *et al.,* 2015). With extensive clinical application, the drug resistance rate is increasing year by year, while some drugs still have obvious toxic and side effects. The enhancement of the antibacterial effect of the Gram-positive bacteria becomes the focus of the development of the fluaodione (Liu *et al.,* 2015; Shu *et al.,* 2016). Gatifloxacin is one of the representatives of the fourth generation of fluoroquinolones. Gatifloxacin enhanced the effect on Gram-positive and anaerobic bacteria, and reduced the light toxicity and improved the safety of the drug.

Gatifloxacin not only keeps the three generation fluoroquinolones against Gram-negative bacteria, but also enhance the antibacterial effect of including Gram-positive bacteria, anaerobic bacteria, mycoplasma and Mycobacterium (Udagawa *et al.,* 2012). It has broad antimicrobial spectrum, strong antibacterial activity, good oral absorption, wide distribution, long elimination half-life and less adverse the photosensitive reaction has low effect for respiratory tract infection, urinary tract infection, skin and soft tissue infections and other diseases, to obtain good curative effect (Cahill *et al.,* 2015). Gatifloxacin had a significant antibacterial activity against Gram-positive bacteria, which was 2-16 times stronger than ciprofloxacin and ofloxacin, and had a strong antibacterial activity against methicillin sensitive Staphylococcus aureus, which was 4-8 times stronger than ciprofloxacin or ofloxacin (Wang, 2016; Yuan *et al.,* 2016). Gatifloxacin has a strong antibacterial activity against *Staphylococcus aureus* coagulase negative *Staphylococcus*, taking gatifloxacin eye drops as the test drug, left ofloxacin eye drops as the control drug, conducted a double-blind randomized controlled clinical trials to evaluate the efficacy and safety of gatifloxacin eye drops in the treatment of acute bacterial conjunctivitis.

MATERIALS AND METHODS

Parallel control test design

The test plan completed 80 qualified cases and 40 cases in the test group and the control group. The patients were randomly assigned to the gatifloxacin eye drops or the control group of the left ofloxacin eye drops in the test group. The random distribution code is produced by the statistics professionals using software on the computer. The number of random groups was distributed to the test center in a random envelope, and the corresponding treatment kit was provided. According to the order of treatment, the researchers used the same number of the

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same drug box for treatment. The clinical trial unit, according to 20% of the number of cases assigned, is equipped with a spare drug number and equipped with a corresponding test kit to supplement the cases of exfoliation and elimination. All patients were approved by Ethics Committee of our hospital and signed on the informed consent.

Diagnostic criteria

The patient has a burning sensation, tears, a large number of mucous or mucous purulent secretions. There are secretions on the surface of the conjunctival sac. Subconjunctival bleeding spots may occur. Sometimes he and the issuing of marginal punctate infiltration or ulcer pain, photophobia. The smears of conjunctival sac secretions can be seen to produce bacteria from polymorpho nuclear leukocytes or conjunctival sac secretions.

Inclusion and exclusion criteria

Patients with acute bacterial conjunctivitis were diagnosed with clinical symptoms, signs and laboratory tests. The course of disease is within 3 days.18-70 years old, inpatient or outpatient with non - limited sex; Patients who agree to participate in this test and sign written informed consent; Antibacterials were not treated in 72 hours before the trial, or antibacterials were treated, but the symptoms were not improved and the bacteria still existed.

Elimination of standards: After the trial, it was found that those who did not conform to the inclusion criteria or found to be in line with the exclusion criteria, including misdiagnosis, misregistration, untimely use of a single drug, and no test records, should be excluded. The excluded subjects should explain the reasons. Their case reports were kept for reference, and at least one safety record should be taken at least once, and safety records should be included.

Drug delivery method

The test drugs were used to drop the test drugs into the eyelids, 2 drops each time, 6 times a day for 2 weeks. If less than 2 weeks of treatment, the symptoms and signs of the patient disappeared, can end the clinical trial observation, evaluate the efficacy of the drug, the case according to the recovery statistics. All the patients routinely wash the conjunctiva, unified use of saline irrigation, cannot be used for sterilizing drugs mercuric chloride. Both eyes with acute bacterial conjunctivitis were observed in the right eye, but both the eyes were treated with drug treatment and the conjunctival sac was flushed. Patients with monocular disease were treated with prophylactic use, but not conjunctival sac flushing.

Bacterial culture of conjunctival sac secretions was routinely taken before treatment. The bacteria culture positive was identified as seed, and the drug sensitivity test of gatifloxacin and levofloxacin was used for the culture of bacteria. The positive rate of bacterial culture is more than 80%.

STATISTICAL ANALYSIS

All the data were analyzed by SPSS statistical software package. The count data of various treatment groups in different treatment groups were described by frequency. The changes of the two groups before and after treatment were analyzed by χ^2 test or nonparametric test. The clinical efficiency of the two groups was compared with two independent sample nonparametric tests. The comparison of the positive rate of bacterial culture, the clearance rate of bacteria, the rate of bacterial clearance and the incidence of adverse reactions in the two groups were statistically analyzed by χ^2 test. The significance test method used P value, as $P<0.05$ was statistically significant, $P<0.01$ was statistically significant.

RESULTS

General information

A total of 80 cases were included, and 80 cases were completed. There were no cases of exfoliation and elimination. 40 cases in the experimental group and 40 cases in the control group were compared with the normal clinical data and the difference was not statistically significant after two independent samples t test (see table 1). The comparison of clinical efficacy is shown in table 2

From table 2, the recovery rate of the experimental group and the control group was 65% and 47.5%, respectively, and the total effective rate was 95% and 82.5%, respectively. The non-parameter test of two independent samples showed that the difference of curative effect between the test group and the control group was statistically significant.

Comparison of bacteriological efficacy at the end of the course of treatment

From table 3, the bacterial culture rates of the experimental group and the control group before treatment were 87.5% and 82.5%, respectively. After treatment, the bacterial clearance rates of the experimental group and the control group were 94.2% and 96.9%, respectively, and the difference between the two groups was not statistically significant.

DISCUSSION

Acute bacterial conjunctivitis is an acute conjunctivitis which is frequently transmitted in summer and autumn. It is a common and frequently occurring disease in ophthalmology clinic (Wang, 2013; Shu *et al.*, 2016). Its diagnosis and treatment are not difficult, but because of the clinical abuse of antibiotics, the drug resistant strains

Table 1: Clinical data statistics

Category	Gatifloxacin group	Levofloxacin group	T value	P value
Age	35.1±2.4	37.2±1.8	0.156	0.274
Vision	0.78±0.05	0.81±0.04	0.341	0.541

Table 2: Comparison of clinical efficacy

Curative effect	Gatifloxacin group (n=40)	Levofloxacin group (n=40)
Recovery	26	19
Significant effect	7	5
Partial validity	5	9
Invalid	2	7
Total effective rate	95.0	82.5

Table 3: Bacterial culture results

Group	Positive	Negative	Total
Gatifloxacin group	35	5	40
Levofloxacin group	33	7	40
Total	68	12	80

Table 4: Frequency distribution table

Group	Number of positive bacterial culture before treatment	Bacteria have been cleared	Bacteria not been cleared
Gatifloxacin group	35	33	2
Levofloxacin group	33	32	1
Total	68	65	3

Table 5: Drug sensitivity test

Bacterial species		Number	Gatifloxacin sensitivity	Levofloxacin sensitivity
Gram-positive bacteria	*Staphylococcus aureus*	18	Sensitive	Sensitive
	Staphylococcus capitis	12	Sensitive	Sensitive
	Staphylococcus epidermidis	5	Sensitive	Sensitive
	Staphylococcus haemolyticus	4	Sensitive	Sensitive
	Micrococcus	3	Sensitive	Sensitive
Gram-negative bacteria	*Klebsiella pneumoniae*	11	Sensitive	Sensitive
	Enterobacter cloacae	8	Sensitive	Sensitive
	Acinetobacter	4	Sensitive	Sensitive
	Escherichia coli	2	Sensitive	Sensitive
	Proteus	1	Sensitive	Sensitive

gradually increase, and the application of clinical drugs has been increased (Yung *et al.,* 2015). The third generation of fluoroquinolones has good antibacterial activity to Gram-negative bacteria, but the antibacterial action against gram-positive is relatively weak. With extensive clinical application, the drug resistance rate is increasing year by year, while some drugs still have obvious toxic and side effects (Zhu 2015, Chen *et al.,* 2015). The enhancement of the antibacterial effect of the Gram-positive bacteria becomes the focus of the development of the fluaodione (Wang 2014, Liu *et al.,* 2015). Gatifloxacin is one of the representatives of the fourth generation of fluoroquinolones. Gatifloxacin enhanced the effect on Gram-positive and anaerobic bacteria, and also reduced the light toxicity and improved the safety of the drug (Dai *et al.,* 2015). In this paper, the bacterial culture rates of the experimental group and the control group before treatment were 87.5% and 82.5%, respectively. After treatment, the bacterial clearance rates of the experimental group and the control group were 94.2% and 96.9%, respectively, and the difference between the two groups was not statistically significant. Experiments have shown that drugs can effectively remove acute bacterial conjunctivitis bacteria, its diagnosis and treatment are not difficult, but the clinical abuse of excessive antibiotics will still lead to drug

resistant strains, resulting in the difficulty of treatment in individual cases.

Therefore, it not only maintained the antibacterial effect of the three generation of fluoroquinolones on Gram negative bacteria, but also increased the antibacterial activity of Mycoplasma and Mycobacterium, and enhanced the gram positive bacteria and anaerobic bacteria including MRSA (Luo, 2015; Lee *et al.,* 2015). Through randomized double recessive multi center clinical trial, the patients treated for 5 days had a much better effect on conjunctivitis culture positive patients, and the treatment group of gatifloxacin eye drops had a much better effect (Dai *et al.,* 2015). The clinical results showed that the total effective rate of gatifloxacin eye drops treatment group was 95% (Liu *et al.,* 2015; Shu *et al.,* 2016). The previous study showed that gatifloxacin as treatment of bacterial keratitis is very effective, it can not only effective against a wide range of G bacteria, such as *Streptococcus pneumoniae*, better for refractory G. bacteria such as *Pseudomonas aeruginosa* and other effects (Dobson *et al.,*2015; Ghoneum *et al.,* 2015). In summary, gatifloxacin eye drops of ocular bacterial infections caused by conjunctivitis, keratitis, iris and ciliary body inflammation is effective, the curative effect is better than that of ciprofloxacin, ofloxacin, levofloxacin eye drops. The development of this product can further provide a new excellent antibacterial product for the ophthalmology (Luo, 2015; Lee *et al.,* 2015). It is sensitive to gatifloxacin and levofloxacin in bacterial drug sensitivity analysis, suggesting that the common acute bacterial conjunctivitis is sensitive to fluoroquinolone antibiotics.

CONCLUSION

Gatifloxacin eye drops is a safe and effective antibiotic eye drops. Its antibacterial spectrum is broad, its antibacterial activity is strong, its clinical curative effect is exact, it can effectively treat acute bacterial conjunctivitis. Gatifloxacin and broad antibacterial spectrum against gram positive bacteria, the antibacterial effect of gram negative bacteria, anaerobic bacteria, mycoplasma, chlamydia, Mycobacterium were strong, particularly enhanced antimicrobial activity against gram positive cocci, rapid oral absorption, wide distribution, long elimination half-life, clinical efficacy, mild adverse reactions. There are good prospects for clinical application.

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