Evaluation of the Efficacy of Ophthacare eye drops in Inflammatory and Infectious Ophthalmic Conditions

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ABSTRACT
Two hundred and thirty eight patients with ocular symptoms of conjunctivitis, conjunctival xerosis, pterygium and pinguecula were selected for this clinical trial. All the patients were administered Ophthacare eye drops topically as a single medication at the dose of 2 drops every 2 hours for 15 days. Ophthacare eye drops showed excellent results in relieving symptoms of viral conjunctivitis in 93.87% of the patients and 77.77% of the patients with acute allergic conjunctivitis. The response to treatment in bacterial conjunctivitis was slower. Ophthacare also relieved the inflammatory symptoms of pterygium and pinguecula. There were no side effects reported by patients during the course of the study. The open clinical trial conducted at BRD Medical College, Gorakhpur, confirmed the efficacy and safety of Ophthacare eye drops.

Key words: conjunctivitis; xerosis; pterygium; ocular disorders; Ophthacare

INTRODUCTION
Conjunctivitis is one of the most common inflammatory conditions of the eye. It broadly manifests as acute or chronic conjunctivitis and may be primarily viral, allergic or bacterial in origin. Viral conjunctivitis usually has an acute onset, unilaterally at first, with involvement of the second eye within 1 week. It is manifested by watery discharge and conjunctival hyperemia, and is usually accompanied by preauricular lymphadenopathy on the affected side. The diagnosis of viral conjunctivitis can be made clinically, thus viral culture and laboratory investigations are rarely undertaken. Bacterial conjunctivitis is characterized by a rapid onset of unilateral conjunctival hyperemia, lid edema, and mucopurulent discharge. The second eye typically becomes involved 1-2 days later. The pathogenesis of bacterial conjunctivitis usually involves a disruption of the host defense mechanisms. Examples are abnormalities of the ocular surface secondary to eyelid abnormalities, surface trauma, tear-film abnormalities, or a preceding infection such as Herpes simplex. The ocular surface may exhibit a wide variety of immunologic responses that may result in conjunctival and corneal inflammation resulting in allergic conjunctivitis. Diagnosis of allergic conjunctivitis is generally made by thorough history taking and careful clinical observation. The important features of history include a personal or family history of atopic disease, such as allergic rhinitis, bronchial asthma, and/or atopic dermatitis.

Another condition, which is commonly encountered in ophthalmic practice is pterygium, which is an inflammation of the conjunctiva aggravated with exposure to environmental extremes, pollution, dust, etc. It is a degenerative and hyperplasmic process in which the
conjunctiva becomes adherent to the underlined tissue. Pterygium contains all types of inflammatory cells such as lymphocytes, plasma cells and immunoglobulins. On many occasions, it is associated with infection.

Pingueculae are areas of bulbar conjunctival thickening that adjoin the limbus in the palpebral fissure area. They are elevated, white-to-yellow in color, and horizontally oriented. They are less transparent than normal conjunctiva, often have a fatty appearance, are usually bilateral, and more often located nasally than temporally. When a pinguecula crosses the limbus onto the cornea, it is called a pterygium. Current information, however, suggests that pinguecula does not progress to pterygium, and that the two are distinct disorders. The causes of pingueculae are not known with certainty. Good evidence exists, however, of an association with increasing age and ultraviolet light exposure. Pingueculae are seen in most eyes by 70 years of age, and in almost all by 80 years of age.

The present clinical trial was undertaken to evaluate the clinical efficacy of Ophthacare eye drops in patients with allergic, viral, and bacterial conjunctivitis and other disorders of the conjunctiva such as pterygium, xerosis and pinguecula.

MATERIAL AND METHODS
Two hundred and thirty eight patients with various ocular symptoms were included in the study. Among them, 162 patients had conjunctivitis, 16 had conjunctival xerosis, 42 had pterygium and 18 patients had been diagnosed for pinguecula.

The study was conducted according to the protocol provided by The Himalaya Drug Company, Bangalore, India.

Each of the 238 cases with varied symptoms, were administered Ophthacare eye drops as a single medication at the dosage of two drops, every 2 hours for 15 days in the affected eyes.

The bacteriological study involved isolation of pathogens from the eyes under study (before the start of Ophthacare drug treatment and after the treatment) and testing the susceptibility of the isolates to the drug in vitro. The isolation of bacteria was done on fresh sheep blood Agar/MacConkey's agar and the inoculated media incubated at 37°C in an aerobic atmosphere. The cultured bacteria were identified using standard techniques. The drug sensitivity of the isolates in Ophthacare eye drops was tested by the Kirby-Bauer disc diffusion method using Muller-Hinton agar medium.

In various symptoms, the drug response for symptomatic as well as clinical relief was evaluated at regular intervals in each individual case and the response was graded as 0 for poor response, 1 for equivocal, 2 for good and 3 for excellent response.

Among the 162 patients with conjunctivitis, 98 were diagnosed as viral conjunctivitis, 36 as allergic conjunctivitis and 28 as bacterial conjunctivitis.

Acute allergic conjunctivitis was diagnosed on the basis of its sudden onset and severe presenting symptoms, while bacterial infection was confirmed with positive bacterial culture.
reports. The absence of bacterial growth in culture and acute symptoms suggested the probability of viral infection.

The allergy manifested with watering, discharge, itching, foreign body sensation and photophobia.

Patients with viral conjunctivitis had complaints of moderate degree of itching and foreign body sensation with evidence of excessive lacrimation, eyestrain and photophobia. Patients with allergic conjunctivitis had symptoms of severe redness, watery discharge and photophobia. The 28 patients diagnosed for bacterial conjunctivitis presented with severe redness and discharge along with foreign body sensation in their eyes.

RESULTS

Viral Conjunctivitis

Ophthacare eye drops showed good symptomatic relief in 59 (60.20%) cases within 8-10 days. There was excellent relief in 19 (19.38%) cases (9 patients did not report for follow up). After two weeks’ (15-18 days) use of Ophthacare eye drops, 24 (24.48%) manifested excellent relief in symptoms, 68 (69.38%) cases manifested good relief. Thus, overall a good to excellent response was seen in 92 (93.87%) cases of viral (non-specific) conjunctivitis after 15-18 days’ use of Ophthacare eye drops (Table 1).

| Table 1: Response to Ophthacare in viral conjunctivitis |
| Follow-up day | Response grade |
| 0 | 1 | 2 | 3 |
| 3 – 5 days | – | 34 | 23 | – |
| 8 – 10 days | – | 11 | 59 (60.20%) | 19 (19.38%) |
| 15 – 18 days | – | 06 | 68 (69.38%) | 24 (24.48%) |

Response grade: 0 = Poor, 1 = Equivocal, 2 = Good and 3 = Excellent

Acute Allergic Conjunctivitis

In 36 cases of acute allergic conjunctivitis, 20 (55.55%) had good relief within 3-5 days, while the response was equivocal in 11 (30.55%) cases. In 8–10 days, there was excellent improvement both in signs and symptoms in 21 (58.33%) cases, though in a few cases a mild conjunctival flush persisted. The overall response was good to excellent in 77.77% of the cases (Table 2). Ophthacare eye drops were very effective in providing faster symptomatic relief in acute allergic conjunctivitis.

| Table 2: Response to Ophthacare in allergic conjunctivitis |
| Follow-up day | Response grade |
| 0 | 1 | 2 | 3 |
| 3 – 5 days | 05 | 11 (30.55%) | 20 (55.55%) | – |
| 8 – 10 days | – | 03 | 07 | 21 (58.33%) |
| 15 – 18 days | – | 01 | 04 | 29 |

Response grade: 0 = Poor, 1 = Equivocal, 2 = Good and 3 = Excellent

Bacterial conjunctivitis

In 28 cases of bacterial conjunctivitis, the response to Ophthacare in the first 3–5 days was poor in 18 (64.28%) cases, and equivocal (more towards poor) in 6 (21.42%) cases. Four patients did not report for follow up. In 15–18 days, only 3 (10.71%) patients had good response, where the initial cultures were very weakly positive (Table 3). The response to treatment was slower in patients with bacterial conjunctivitis. In
this group the bacterial isolates encountered were either *S. aureus* or *E. coli*. Ophthacare eye drops did not show any antibacterial activity *in vitro* against these isolates.

**Conjunctival xerosis**

Sixteen cases of conjunctival xerosis were taken for the trial. The common presenting symptom was vague discomfort or presence of white spots (Bitots spots) in the eyes. Local examination revealed definite xerotic conjunctiva in all the cases.

With the use of Ophthacare eye drops, there was no significant improvement of signs or symptoms in 15-18 days (Table 4).

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<th>Table 4: An overview of the efficacy of Ophthacare in ophthalmic conditions</th>
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**Pterygium**

In 42 cases of pterygium, where Ophthacare eye drops were administered for 3 weeks, there was no resolution of pterygium.

However, in 8 patients having inflamed pterygium who presented with complaints of redness and discomfort in the eye, there was improvement in the inflammatory symptoms after 8-10 days’ use of Ophthacare eye drops. Congestion was relieved marginally (Table 4). Ophthacare helped to relieve symptoms of inflammatory pterygium.

**Pinguecula**

Of the 18 cases of pinguecula included in the study, 5 (27.77%) cases presented with cosmetic symptoms, while 9 (49.99%) cases did not have any symptoms related to pinguecula and were diagnosed on examination for other varied symptoms. Four (22.22%) patients complained of localized redness and pain in the eye. These were the cases of inflamed pinguecula.

In cases of inflamed pinguecula, the inflammation was significantly relieved within 14-18 days, but there was no change or improvement in size/resolution of pinguecula (Table 4).

Ophthacare eye drops, though helpful in relieving the symptoms of inflammation associated with pinguecula, had directly no role in resolving pinguecula.
DISCUSSION

Ophthacare eye drops contain herb extracts like *Carum copticum*, *Terminalia belerica*, *Emblica officinalis*, *Curcuma longa*, *Ocimum sanctum*, *Rosa damascene*, *Cinnamomum camphora* in a *Mel despumatum* base. The herbs in the formulation act synergistically to produce anti-inflammatory, anti-infective and cooling effect in various inflammatory conditions of the eye.

*Curcuma longa* (Yawani) has anti-inflammatory property comparable to hydrocortisone, helpful in reducing inflammation, congestion and irritation in conjunctivitis. It possesses antibiotic activity against *Salmonella typhi*, *Micrococcus pyogenes* var. *aureus* and *Escherichia coli*. *Terminalia belerica* produces antibacterial and antifungal effects in patients with acute and chronic bacterial conjunctivitis. *Terminalia belerica* is used in various eye disorders and when combined with honey, it displays antibacterial properties against *Micrococcus pyogenes* var. *aureus* and *Escherichia coli*. *Emblica officinalis* (Amalaki) is effective in treating inflammation of the eyes; its flowers are known to have a cooling effect on the eyes. The aqueous extract of *Emblica officinalis* is a potent inhibitor of lipid peroxide formation and a scavenger of hydroxyl and superoxide radicals. This property is beneficial in relieving strain and stress in the eye occurring as a result of industrial and automobile pollution as it produces soothing and cooling effects on the eye. *Curcuma longa* (Haridra) possesses anti-inflammatory properties, which is comparable to hydrocortisone acetate and phenyl butazone and also has antibacterial activities, comparable to the action of penicillin and streptomycin on gram-positive and gram-negative organisms. *Ocimum sanctum* influences the healing process. It possesses antimicrobial and anti-inflammatory activities, which help in healing inflammation. The ethanolic extract (50%) of the fruits of *Cinnamomum camphora* (Karpoor) possesses antibacterial activity against several gram-positive and gram-negative bacteria. *Mel despumatum* (Honey) is recommended as an effective remedy in conjunctivitis. Honey prevents infection and promotes healing; its effect can be compared with antibiotics. It is easily absorbed into the tissues and is helpful in preserving healthy cornea, enucleated within 6 hours after death. It has bactericidal as well as bacteriostatic properties. It inhibits the growth of *Escherichia coli*, *Hemophilus influenzae*, *Proteus*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Streptococcus pyogenes*, *Salmonella species* and *Vibrio cholerae*.

Ophthacare eye drops produced symptomatic relief in a significant number of patients with non-specific viral conjunctivitis. In patients with inflamed pterygium, Ophthacare reduced redness and inflammation. Ophthacare helps arrest the progress of the pterygium and is a useful drug in patients who are contraindicated for surgery. Many times pterygium is accompanied by mild conjunctivitis.

CONCLUSION

The open clinical trial confirmed the efficacy and safety of Ophthacare eye drops. Ophthacare eye drops were very well tolerated and accepted by all types of patients irrespective of age, sex and ocular ailment. It was found to be very effective in the management of viral conjunctivitis by providing excellent symptomatic relief and is effective demonstrating a quick response in cases of acute allergic conjunctivitis (not associated with secondary infection). Ophthacare has excellent soothing/astringent effect on the eyes. It has no
adverse/toxic effects even after prolonged use. Hence, Ophthacare can be safely and effectively used as a general soothing eye lotion for relief from eye strain/irritations caused by day-to-day atmospheric pollution.

Ophthacare has no direct effective role in the treatment of bacterial conjunctivitis, conjunctival xerosis and degenerative conditions of the conjunctiva (i.e. pterygium and pinguecula). Ophthacare has good anti-inflammatory effect on the surface inflammation of the eye.

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REFERENCES