Evaluation of OphthaCare Eye Drops – A Herbal Formulation in the Management of Various Ophthalmic Disorders

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SUMMARY

An open prospective multicentre clinical trial was conducted in patients suffering from various ophthalmic disorders namely, conjunctivitis, conjunctival xerosis (dry eye), acute dacryocystitis, degenerative conditions (pterygium or pinguecula) and postoperative cataract patients with a herbal eye drop preparation (OphthaCare) containing basic principles of different herbs which have been conventionally used in the Ayurvedic system of medicine since time immemorial. These include Carum copticum, Terminalia bellirica, Emblica officinalis, Curcuma longa, Ocimum sanctum, Cinnamomum camphora, Rosa damascena and Meldespumapum. These herbs reportedly possess anti-infective and anti-inflammatory properties. The present study was undertaken to elucidate the role of this herbal product in a variety of eye ailments. Side effects, if any, were noted during the study. An improvement was observed with the treatment of the herbal eye drop treatment in most cases.

There were no side effects observed during the course of the study and the eye drop was well tolerated by the patients. The herbal eye drop OphthaCare has a useful role in a variety of infective, inflammatory and degenerative ophthalmic disorders.

Keywords: OphthaCare; herbal drug; clinical evaluation; ocular disorders.

INTRODUCTION

The use of medicinal plants is based on the experience of many generations of physicians and traditional systems of medicine from different ethnic societies. The use of medicinal plants in modern medicine suffers from the fact that although hundreds of plants are used in the world to prevent or to cure diseases, scientific evidence in terms of modern medicine is lacking in most cases. However, today it is necessary to provide scientific proof as to whether or not it is justified to use a plant or its active principles. Ophthalmic problems afflict a substantial portion of the population. Some of these can be managed with antibiotics and steroids. However, the prolonged use of these drugs has its own drawbacks.

Various experimental studies have been conducted by different authors showing the activities of different ingredients/components of OphthaCare. OphthaCare is a combination of eight herbs. It is a colourless, odourless transparent aqueous extract of these eight plant: (1) Carum copticum (seeds) 0.60% w/v; (2) Terminalia belerica (fruits) 0.65% w/v; (3) Curcuma longa
(Rhizome) 1.30% w/v; (5) Ocimum sanctum (leaves) 1.30% w/v; (6) Rosa damascena (petals) 1.10% w/v; (7) Cinnamomum camphora (crystals) 0.5% w/v, and (8) Meldespumapum (Honey) 3.70% w/v. The formulation is standardized using fingerprint analysis by gas chromatography.

Each ingredient of the formulation is known to have different types of activities such as anti-inflammatory, antioxidant, antimicrobial and soothing. As it is desired that the final formulation should have all the above activities, each ingredient was screened for all these activities and then combined in various proportions. Carum coticum has been shown to possess antibacterial activity against Salmonella typhora, Micrococcus pyogenes and Escherichia coli. It is also recommended as a potential source of natural antioxidant (Mehta et al., 1994). Fruits of Terminalia belerica were found to be useful in many ocular diseases. Fully ripe or dried fruit, mixed with honey is used as an external application in ocular diseases (Nadakarni, 1976b). It also possesses significant antimicrobial activity against both gram-positive and gram-negative organisms (Valsaraj et al., 1994). The exudate obtained from the incisions of Emblica oficinalis fruits is used as an external application for ocular inflammation (Nadkarni, 1976a). An aqueous extract of Emblica oficinalis was found to be a potent inhibitor of lipid peroxide formation and as a scavenger of hydroxyl and superoxide radicals in vitro (Jose and Kuttan, 1995). Extracts of Curcuma longa exhibited anti-inflammatory, antioxidant and antimicrobial properties (Amon and Wahl, 1991; Arora et al., 1971). The volatile and fixed oils of Ocimum sanctum are known for their anti-inflammatory activity (Singh and Agrawal, 1991). The essential oil of Ocimum sanctum possesses bactericidal activity against gram-positive and gram-negative bacteria (Prasad and Rao, 1987). Rose water obtained from petals of Rosa damascena is known for its soothing effect and is also found to be beneficial in ophthalmopathy (Kirkkitikar and Basu, 1987). The extract of Cinnamomum camphora showed antibacterial activity against gram-positive and gram-negative organisms (Naqvi et al., 1985). Honey is generally recommended for sore eyes. It is also reported to prevent infection and promote healing, as it has ingredients similar to antibiotics (Mitra, 1985).

The positive role of OphthaCare formulation has been proved by the above mentioned experimental and limited clinical studies (Kumari, 1998; Padmini, 1998; Reddy et al., 1998). However, further clinical evaluation of OphthaCare eye drops is necessary to estimate the clinical potency.

The present prospective study was conducted to evaluate the effectiveness of OphthaCare in various ocular disorders.

**MATERIALS AND METHODS**

In this multicentre prospective open uncontrolled clinical study in 100 patients having various ocular diseases attending the outpatient departments, the role of OphthaCare was evaluated. The various ocular diseases included were acute conjunctivitis (bacterial, viral or allergic), postoperative cataract patients, acute dacryocystitis, conjunctival xerosis (dry eye) and degenerative conditions such as pterygium/pinguecula. Of the 100 patients there were 67 males and 33 females and the age range varied from 20 to 67 years.
Before entering into the study protocol written consent was obtained from all patients after explaining the nature of the study. Before the treatment was started all the conjunctivitis, postoperative eyes operated for cataract, conjunctival xerosis cases were graded as mild, moderate or severe depending upon the severity of conjunctival reactions (Table 1).

In cases of dacryocystitis (inflammation of the lacrimal sac) the patients were clinically divided into acute and chronic depending upon their duration of symptoms and only acute cases with duration of symptoms less than 2 weeks were taken up for this study. In the conjunctival xerosis (dry eye) groups of patients with severe symptoms such as foreign body sensation, itching and redness were taken up. In the degenerative conjunctival group (pterygium and pinguecula) only symptomatic patients with redness, itching, etc. were included. In all the cases included in the study, none of the patients had taken local/systemic steroidal or antibiotic medications.

The inclusion and exclusion criteria for selecting the patients were evaluated by the ophthalmologists involved in the study (GKD, NK, PKM, SB). OphthaCare eye drops were instilled in the affected eye as two drops four times daily for 15 days. The patients were followed up every 3 days until the end of the study.

The conjunctival reactions (outcome measures) were measured as a categorical variable on ordinal scale (mild, moderate, severe). The criteria for labelling the reactions as mild or moderate or severe were adopted from the WHO criteria on trachoma, which is well validated (Dawson et al., 1981). However, there may be some interobserver variation (which we have not measured in this study) in counting the numbers of follicles. Further, since the reactions were labelled 1-5 as mild, 6-10 moderate and more than 10 as severe, the effect of subjective measurement, if any, would be insignificant.

**RESULTS**

Of the 100 cases enrolled in the study there were 35 of acute conjunctivitis, 20 dacryocystitis, 15 degenerative conditions (pterygium and pinguecula), 7 conjunctival xerosis (dry eye) and the rest were postoperative cataract patients. The total number of drop-outs were 12 and their distributions in various eye disorders are given in Table 2. Both subjective and objective responses were taken into

| Table 1: Grading of conjunctival reactions in acute conjunctivitis |
|-----------------------|----------|----------|----------|
| Objective parameter   | Mild     | Moderate | Severe   |
| Conjunctival discharge (watery/mucous/mucopurulent) | +         | ++        | +++       |
| Chemosis              | +         | ++        | +++       |
| Hyperaemia            | +         | ++        | +++       |
| Papillary hyperplasia | +         | ++        | +++       |
| Conjunctival follicles | + (1-5)   | ++ (6-10) | +++ (>10) |

| Table 2: Showing the results of treatment with herbal eye drop preparation OphthaCare in different ocular ailments |
|------------------------|----------|----------|----------|
| Disease                 | Cases starting | Cases dropping out | Response |
|                        |            |            | Improved | Not improved |
| Acute conjunctivitis   | 35         | 3          | 28 (87.5%) | 4 |
| Dacryocystitis         | 20         | 3          | 15 (88.2%) | 2 |
| Degenerative conditions | 15        | 2          | 10 (76.9%) | 3 |
| Conjunctival xerosis   | 7          | 1          | 4 (66.7%)  | 2 |
| Post cataract operative eyes | 23     | 3          | 19 (95%)   | 1 |
| Total                  | 100        | 12         | 76 (86.4%) | 12 |
consideration to evaluate the outcome of the OphthaCare response. The responses obtained are mentioned in Table 2. It shows that in most of the patients positive therapeutic responses were obtained with the use of OphthaCare, the maximum benefit was seen in postoperative cataract patients (95%). No side effects of drug were noted during the course of the study and the eye drops were well tolerated by the patients.

DISCUSSION

Acute conjunctivitis is one of the most frequently occurring ocular diseases. Therapy of acute bacterial conjunctivitis includes agents effective against causative gram-positive and gram-negative organisms. While many antibacterial agents have similar spectra of activity, they are not equally potent against several organisms and vary in pharmacokinetic properties (Neu 1991). OphthaCare revealed marked antimicrobial and antifungal activity in this study. The effects of OphthaCare eye drops against both gram-positive and gram-negative bacteria make it a promising drug in the treatment of ocular diseases originating from infections (Valsaraj et al., 1994).

Following cataract surgery some trauma-induced inflammation is expected in almost all patients. Usually this type of inflammation is treated with steroidal anti-inflammatory drugs. However, the prolonged use of steroid drugs can lead to glaucoma and cataract (Black et al., 1960; Becker and Hahn, 1964). In this study of postoperative cataract patients OphthaCare acted as a good anti-inflammatory agent. Secondly, complications caused by steroid eye drops were not seen following topical OphthaCare use.

Acute dacryocystitis an acute infective condition of the lacrimal sac is usually caused by bacteria and also sometimes by fungi. The usual treatment of acute dacryocystitis is antibiotic agents. In our study OphthaCare demonstrated a good beneficial effect in the treatment of acute dacryocystitis. Padmini (1998) demonstrated broad spectrum antimicrobial activity of OphthaCare. Reddy et al. (1998) also demonstrated the usefulness of OphthaCare in acute dacryocystitis patients. Each ingredient of this formulation is known to have different types of activity. Emblica officinalis is antioxidant (Jose and Kuttan, 1995), Curcuma longa is predominantly anti-inflammatory (Arora et al., 1971) whereas Cinnamomum camphora is predominantly antibacterial (Naqvi et al., 1985). So it is desirable that their combination will have antimicrobial, anti-inflammatory and antioxidant properties.

Surgical excision is the mainstay of therapy for degenerative conditions of the conjunctiva such as pinguecula and pterygium. However, the recurrence rate following surgery may be as high as 50%. However, in the present study as well as in a previous study (Reddy et al., 1998) OphthaCare showed a good response in the treatment of degenerative conditions. Conjunctival xerosis (dry eyes) is also a common ophthalmic problem particularly in the elderly. The presently available therapy is by the frequent topical administration of tear substitutes with highly unpredictable outcome. In this prospective study the herbal preparation OphthaCare provided symptomatic relief in various dry eye patients.

One limitation of the study was that there was no control group. But with OphthaCare treatment, the positive outcome seen in various ophthalmic conditions were highly encouraging. However, the outcome for various ocular conditions were variable showing that
OphthaCare may have more beneficial effect for one condition or another (Table 2). As already discussed, the various ingredients of OphthaCare have anti-infective, anti-inflammatory and antioxidant properties. So various clinical conditions were tried to determine the efficacy of OphthaCare.

CONCLUSION
The findings of the present study suggest that OphthaCare can be safely prescribed in different infective and inflammatory ophthalmic diseases. However, its efficacy remains to be evaluated in a double-blind active drug controlled clinical trial.

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REFERENCES


