Original Article

Report of a series of cases on the topical ophthalmic use of a pharmaceutical preparation of *Atropa belladonna* and *Euphrasia officinalis* for the treatment of dry eye: A multicenter observational study

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Abstract

Introduction: Dry eye syndrome is highly prevalent, and it is necessary to explore therapeutic alternatives for improving symptoms and lacrimal volume.

Objective: The objective of this study was to report a case series of patients with dry eye treated with an ophthalmic preparation of *Atropa belladonna* and *Euphrasia officinalis*.

Methods: Multicenter observational study of 33 patients with dry eye. Ocular surface disease index (OSDI) score and Schirmer test with anesthesia were analyzed before treatment and 1 and 3 months after starting treatment.

Results: Average age 52.38 years (29–76 years). The results showed significant improvement of OSDI score: pretreatment ($X = 38.46$, range: 15–89.5), 1 month ($X = 23.14$, range: 6.25–56.2; $P < 0.05$), and 3 months posttreatment ($X = 15.2$, range: 0–41.6; $P < 0.05$), and significant improvement of the Schirmer test with anesthesia: pretreatment $X = 8.62$ mm/5 min (range: 1–22), 1 month $X = 13.14$ mm/5 min (range: 0.5–38; $P < 0.05$) an at 3rd month $X = 17.15$ mm/5 min (range: 4–35; $P < 0.05$). Student's *t*-test was used for statistical analysis.

Conclusions: A preparation of *A. belladonna* and *Euphrasia* improved symptoms, OSDI scores, and Schirmer test results during a follow-up of three months.

Keywords: *Atropa belladonna*, dry eye, *Euphrasia*, ocular surface disease index, Shirmer test

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INTRODUCTION

Dry eye syndrome has a high incidence worldwide, and there is a likely additional association with the use of near-vision technology such as computers, cell phones, and electronic tablets.[1,2] Dry eye affects the patient's

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quality of life, and its diagnosis involves considering a wide range of symptoms and clinical ophthalmological findings. The severity and progression of dry eye can be assessed subjectively using the ocular surface disease index (OSDI) and objectively by determining the appearance and staining of the ocular surface, tear breakup time, and the classic Schirmer test.[3,4] Although there are several treatment options, it is common for patients to require chronic therapy. Furthermore, given the inflammatory component of the disease, it is not unlikely that treatment will need to include topical corticosteroids, with their recognized potential side effects.[5] It is therefore valid to investigate the efficacy and safety of treatment options with lubricating and anti-inflammatory potential that do not involve the use of steroids.

Using the OSDI score and the Schirmer test with anesthesia as comparison parameters, a multicenter, observational study was conducted in patients newly diagnosed with dry eye syndrome who received topical treatment with a mixture of *Atropa belladonna* and *Euphrasia*.

METHODS

An observational study was conducted at four ophthalmological centers corresponding to each author (Los Andes Medical Association-CJO, Barraquer Institute of America-EOL, Private Practice-AMA, Eye Clinic-MBC).

Thirty-five patients (70 eyes) were recruited, all adults (over 18 years of age) with a new clinical diagnosis of dry eye defined as a Schirmer test with anesthesia <10 mm in 5 min in at least one eye, dry eye symptoms, and a pretreatment OSDI score ≥15. The variables studied were the OSDI score, using the validated Spanish scale,[4] and the Schirmer test with standard anesthesia, using proparacaine as a topical anesthetic, one drop in each eye, and measurement with 35 mm × 5 mm Whatman 41 paper strips applied routinely for 5 min. The exclusion criteria were dry eye secondary to topical or systemic medications, any pathology of the ocular surface excluding dry eye, ocular disease of any type excluding ametropia, previous refractive and eye surgery of any kind, alterations in eyelid structure or function or blinking, and contact lens users. Patients were treated with a commercially available product in Colombia containing *A. belladonna* and *Euphrasia* (Optiseco®-Similasan AG, Jonen, Switzerland, INVIMA registration MH2015-0002377), for a period of 90 days, with a standardized dose of one drop every 8 h in both eyes throughout the study. Baseline assessments were conducted prior to treatment and 1 and 3 months after treatment started. All patients voluntarily agreed to participate in the study by signing an informed consent form, and the research protocol was approved by the Ethics and Research Committee of the Colombian Association of Integrative Ophthalmology (Asomint), an affiliate of the Colombian Society of Ophthalmology. The statistical analysis used was a Student's *t*-test for difference of means assuming independent distributions and another *t*-test, but analyzing the differences between each individual at different points in time. Stata 15 software (StataCorp LP, College Station, TX) was used to carry out this process. The baseline was presented as the initial measurement point, both in the Schirmer test with anesthesia and in the case of the OSDI, which were followed up after 1 month and 3 months. Both the tests were performed to compare the evolution from baseline with the evolution over 1 month and three months and also between the follow-up lines within the aforementioned periods. To this end, statistical significance ranging from 1 0% to 0.1% was considered, given the diversity of exercises performed.

RESULTS

Two patients were excluded from the study – one for not completing the OSDI score measurement in the 3rd month, and the other one for having a Schirmer test result >10 mm/5 min in both eyes. A total of 66 eyes from 33 patients were finally evaluated. The expected predominance of females (n = 28) over males (n = 5) was confirmed. The average age was 52.38 years (range: 29–76 years). The results show a significant improvement in the OSDI score, consistent with the overall subjective assessment of patients who reported a significant improvement in their symptoms. The average pretreatment OSDI score was 38.46 (range: 6.25-93,1). The average OSDI score at the 1st month of treatment was 23.1 4 (range: 6.25–56.2), and at the 3rd month, it was 1 5.2 (range: 0–41.6). The difference between the OSDI baseline pretreatment and the observation after 1 month was 15.32, which is significant at 5% (P = 0.01) with the independent test and at 0.1% (P = 4.75e−05) with the paired test. When comparing the OSDI baseline with the observation after 3 months, the difference is 23.25, and the significance improves to 0.1% in both cases (independent P = 4.17e−05 and paired P = 6.49e−07). The change observed between the observation after 1 month and that presented 3 months posttreatment is 7.93 and is significant at 1 0% with the independent test (P = 0.06) and at 0.1% in the paired test (P = 0.0003) [Figure 1]. The results of the Schirmer test with anesthesia also showed statistically significant changes that were evident from the 1st month of treatment and persisted into the 3rd month. The average Schirmer test result prior to treatment in the 66 eyes was 8.62 mm/5 min.

One month after starting treatment, the average Schirmer test result was 13.1 4 mm/5 min (range: 0.5–38). At the end of the follow-up after 3 months of treatment, the average Schirmer test result was 17.1 5 mm/5 min (range: 4–35). A statistically significant difference of 0.1% was found in both tests when comparing the pretreatment baseline with the 1-month follow-up, showing an improvement of 4.52 mm/5 min (independent $P = 0.0001$ and paired $P = 2.80e{-}06$). Similarly, when comparing the pretreatment baseline with the Schirmer test result under anesthesia at 3 months of treatment, the improvement was 8.53 mm/5 min, which was significant at 0.1% in both tests (independent $P = 7.40e{-}08$ and paired $P = 1.23e{-}08$). The difference between the 1-month and 3-month treatment evaluations was 4.01 mm/5 min, with a significance of 5% for the independent test ($P = 0.01$) and 1% for the paired test ($P = 0.002$) [Figure 2]. As an incidental note, no adverse events associated with the medication were reported.[4]

DISCUSSION

The discovery of the lacrimal gland by Nicolaus Steno in 1662 changed the concept of lacrimal secretion and allowed the development of some pathophysiological considerations in ophthalmology[6] However, a more specific classification of inflammatory eye disease, known globally and until then as ophthalmia, came almost 150 years later, when James Wardrop first used the term keratitis to describe ocular inflammation according to the tissue affected.[7] Finally, there were the German Otto Schirmer and the Swede Henrik Sjögren, who laid the foundations for understanding the local and systemic impact of tear hyposecretion and the existence of an important component in tear composition originating in the glands and conjunctival cells.[8]

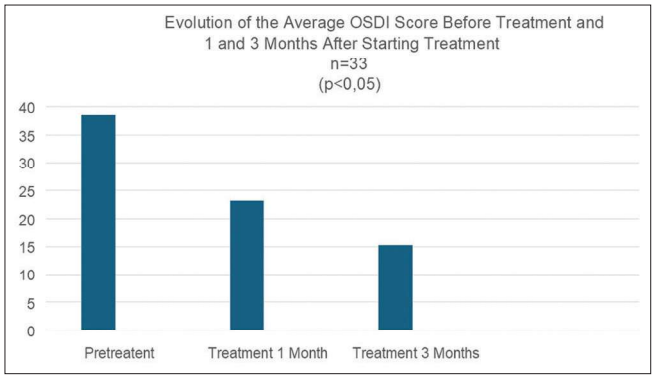

Figure 1: Ocular surface disease index (OSDI) score pretreatment and 1 and 3 months after: A significant and progressive improvement in the OSDI score is evident from the 1st month of treatment. The OSDI is a scale with a score directly proportional to the severity of symptoms: the lower the score, the fewer the symptoms. OSDI: Ocular surface disease index

Inappropriate tear secretion, whether due to insufficient volume, changes in quality, or both, causes uncomfortable symptoms and clinical signs in the conjunctiva and cornea. Although dry eye may be associated with systemic processes, medication use, or a history of eye surgery, most patients currently diagnosed with dry eye have a localized condition with no additional associations.[1-5,9-11] It is believed that the indiscriminate use of nearby technology screens may contribute to an increase in the typical symptoms of dry eye in adults and children.[2,12]

An accurate diagnosis of dry eye can only be made with clinical evidence of associated structural or functional changes (inflammation of the ocular surface, low tear volume, poor tear film quality, etc.).[5,13-15] On the other hand, the impact of the disease on the patient's quality of life can be assessed quantitatively by applying the validated OSDI questionnaire, making it possible to determine the severity of the disease as perceived by the patient and the benefits of treatment.[3,5] Knowledge about the pathophysiology of dry eye has advanced considerably. Microstructural, cytological, molecular, and osmolar analysis of the tear film has provided a better understanding of the inflammatory nature of the disease and has led to the proposal of numerous treatment schemes and alternatives.[16-21] Despite progress in research related to dry eye syndrome, frequent lubrication with artificial tears and temporary or permanent blockade of the tear duct remain the most common therapeutic options in clinical practice.[5,22-24] However, the inconvenience of frequent administration, necessary when using topical lubricants, and the permanent search for more effective strategies that not only restore the volume and osmolarity of the tear film, but also have an effect on the associated inflammatory component without producing significant adverse effects, has led to the use of unconventional strategies in western

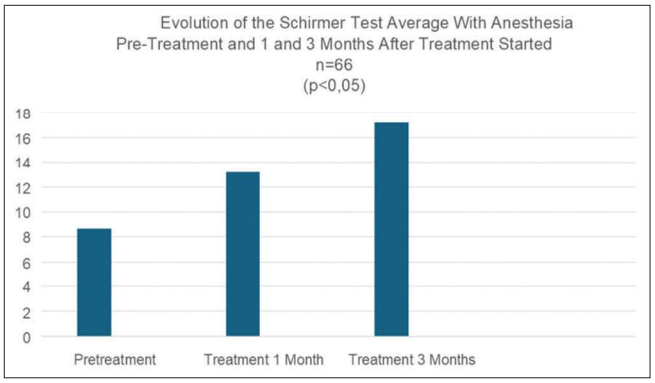

Figure 2: Evolution of the average Schirmer test with anesthesia before treatment and 1 and 3 months after treatment. An improvement in tear volume measured with the Schirmer test with anesthesia was observed, which is progressive and evident from the 1st month

medicine. Electroacupuncture has shown to improve objective clinical findings and symptoms (OSDI) in patients with dry eye syndrome, while significantly modifying the cytokine profile of the tear film.[25] A similar favorable impact on the concentration of lacrimal cytokines in dry eye has been achieved with the use of diferuloylmethane, commonly known as curcumin, the active ingredient in the natural product *Curcuma longa*.[7] Previous studies have shown that curcumin could prevent the resulting tear hyperosmolarity.[26,27]

Regarding the combination used in this study, *Euphrasia* (*Euphrasia officinalis*), a botanical product traditionally used in diseases of the ocular surface, has been used successfully in the treatment of various types of conjunctivitis.[28] On the other hand, modulation of the cholinergic system, particularly in ocular muscarinic receptors, could have focal functions independent of autonomic innervation, in the form of nonneuronal activity, which could explain the effect of *A. belladonna*.[29] The results of this study are clinically and statistically significant. Although this is a small sample, patients reported significant improvement in the impact of the disease on their quality of life (OSDI), and objective evaluation with the Schirmer test confirmed a significant increase in tear volume. It is important to note that none of the patients reported adverse events associated with the administration of the medication, and the clinical evaluation did not reveal any undesirable changes in the ocular surface, a significant advantage when compared to the application of topical steroids. The lack of an optimal treatment that can be considered the gold standard in the management of dry eye, and reports from basic and clinical research support the use of the combination of *A. belladonna* and *Euphrasia* evaluated in this study.

CONCLUSIONS

A combination of *A. belladonna* and *Euphrasia*, applied three times a day in both eyes, showed improved symptoms, better quality of life associated with the parameters evaluated with the OSDI form, and improved the objective evaluation of tear volume in patients with a clinical diagnosis of isolated dry eye syndrome, as early as the 1st month of treatment and with a progressive positive impact throughout the entire study period. This observational study of a series of cases shows favorable results and serves as a basis for the design of future randomized studies with a significantly larger sample size.

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Conflicts of interest
There are no conflicts of interest.

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