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The new ophthalmic formulation of bilastine: current state of knowledge

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Abstract

Background: Allergic conjunctivitis is a common ocular condition characterized by itching, redness and tearing, which significantly affect patient comfort and daily functioning. Recently, a preservative-free ophthalmic formulation designed for once-daily administration has been developed, containing the second-generation antihistamine bilastine at a concentration of 0.6%.

Aim: The aim of this review was to summarize the current state of knowledge on the new ophthalmic formulation of bilastine, evaluate the available clinical evidence on its efficacy and safety and identify major research gaps and directions for future investigation.

Materials and methods: A literature review was performed using PubMed, Google Scholar, ResearchGate, Embase, Scopus and Web of Science, applying the keywords: bilastine, ophthalmic, ocular, eye, conjunctivitis, eye drops, ophthalmic solution and formulation.

Results: Phase II and phase III studies demonstrated a rapid onset of action and sustained symptom control for up to 16 hours following single-dose administration. Bilastine was shown to be noninferior to ketotifen in relieving ocular pruritus. An 8-week placebo-controlled study confirmed clinically meaningful improvements in patient-reported symptoms, a favorable safety profile and good tolerability. Experimental pharmacokinetic studies demonstrated high concentrations in the conjunctival tissue with minimal systemic exposure, supporting a once-daily dosing regimen.

Conclusions: The 0.6% ophthalmic bilastine formulation represents an effective and well-tolerated treatment option for allergic conjunctivitis, offering the advantages of rapid onset of action, prolonged efficacy lasting up to 16 hours and a preservative-free formulation. However, scientific data remain limited regarding the safety of long-term use beyond 8 weeks, its use in pediatric populations and direct comparative studies with other commercially available ophthalmic second-generation antihistamines.

Keywords: bilastine; ophthalmic; conjunctivitis; eye drops; ophthalmic solution

Introduction

Allergic conjunctivitis is one of the most common eye conditions. Epidemiological data vary across studies, but some report that it affects up to 40% of the population. (1,2) It often occurs alongside other atopic disorders such as eczema, asthma and allergic rhinitis. The main symptoms of this condition include eye redness, swelling, itchiness and watering. These symptoms significantly reduce patients quality of life. (2,3)

The basic and widely used group of medications in allergic disorders are H1-receptor antagonists. Second-generation antihistamines are commonly used because they cause less sedation than the first-generation agents and they do not show anticholinergic activity. (4). Second generation antihistamines are available in both oral and topical formulations. In allergic conjunctivitis, topical antihistamines are preferred because they act faster than oral formulations, providing rapid relief from itching. Compared with topical ocular agents, oral antihistamines can also relieve other manifestations of allergy. (5)

Bilastine is a second-generation antihistamine widely used in the treatment of allergic disorders. Studies have shown that oral bilastine is more effective than placebo and at least as effective as other second-generation antihistamines such as cetirizine, levocetirizine or desloratadine in mitigating the symptoms of allergic rhinitis and urticaria. (6) The oral form of bilastine has also been shown to be effective in controlling ocular allergic symptoms associated with rhinoconjunctivitis. (7)

In the treatment of allergic conjunctivitis, many antihistamine agents are commercially available in topical formulations, including bepotastine, olopatadine, ketotifen, alcaftadine, cetirizine, emedastine, epinastine, levocabastine and azelastine. (8,9) These products vary in their inactive ingredient compositions, the presence or absence of preservatives and the required dosing frequency.

Recently, a new ophthalmic formulation of bilastine has been developed. Preclinical studies in animal models have shown that bilastine absorbed via the conjunctival route maintains significant concentrations in the conjunctiva for up to 24 hours after administration. (10) Preliminary clinical tests indicated that bilastine administered ocularly was safe in healthy

participants and that systemic absorption remained low. (11) Several clinical trials have been conducted, providing data on its effectiveness and safety.

The aim of this review was to synthesize the current state of knowledge on the ophthalmic formulation of bilastine, evaluate its safety and effectiveness and identify the main research gaps and recommendations for future studies.

Research materials and methods

A literature search was conducted using the following databases: PubMed, Google Scholar, ResearchGate, Embase, Scopus and Web of Science. To identify relevant publications, the databases were searched using the following keywords: “bilastine” AND (ophthalmic OR ocular OR eye OR conjunctivitis OR “eye drops” OR “ophthalmic solution” OR formulation). Studies published in languages other than English were excluded. Conference abstracts were also excluded from this review.

Research results:

The analysis presented in this review covers several studies, including a preclinical biodistribution study of bilastine after ophthalmic administration in a rabbit model, a phase I bioavailability clinical trial, a phase II dose-finding study and phase III efficacy study both evaluated separately and as a pooled analysis, a multicenter, randomized phase III safety and tolerability study and comparative in vitro studies of the new preservative-free formulation.

Biodistribution in ocular tissues after ophthalmic administration of bilastine

A preclinical study conducted in a rabbit model showed that bilastine administered directly to the ocular surface reaches significant concentrations in the conjunctiva and may be considered a promising route of administration for the drug. After administration, the highest concentration of bilastine was found in the conjunctiva, followed by the cornea, intermediate levels were observed in the iris/ciliary body, aqueous humor and retina/choroid. The lowest concentrations were detected in the crystalline lens and vitreous humor. Systemic absorption remained low, reaching plasma levels comparable to those in the vitreous humor. The highest plasma concentration occurred after 0.5 hours. The highest conjunctival concentration was observed after 6 hours and remained elevated 24 hours after administration. Due to the long concentration time in the conjunctiva and limited systemic exposure, the preclinical data indicate preferential distribution to the conjunctiva, supporting a local mechanism of action and a favourable safety

profile. The high conjunctival concentrations observed 24 hours after a single dose may indicate the possibility of once-daily administration of the preparation. (10)

Pharmacokinetics of bilastine after ophthalmic administration

A phase I study was conducted in a group of twelve healthy volunteers. Each participant received a single 35µl dose of a 6 mg/mL ophthalmic bilastine formulation in each eye once every 24 hours. Each volunteer received a total daily dose of 0.42 mg of bilastine. The parameters observed after a single dose showed that systemic absorption was low, with a maximum mean plasma concentration of 2793.79 ± 1384.40 pg/mL, reached at a median Tmax of 2.13 hours. The mean plasma half-life was 4.63 ± 1.75 hours. After once-daily administration to each eye for five consecutive days, the maximum mean plasma concentration at steady state was 2682.26 pg/mL, with a median Tmax of 2.50 hours and a mean calculated half-life of 7.88 ± 6.72 hours. (11) Participants did not report any serious or life-threatening adverse events during the study. Plasma concentrations remained low and were consistent with the results of the preclinical study in an animal model. (10) The study demonstrated good local tolerability and low systemic exposure in healthy volunteers after both single and multiple doses of ophthalmic bilastine. (11)

Efficacy of ophthalmic formulation of bilastine

In a phase II study, a total of 121 subjects were randomized into four groups that received an ophthalmic bilastine formulation at three different concentrations (0.2%, 0.4%, 0.6%) or a vehicle. Efficacy was assessed using the Ora-CAC model, a controlled system in which the allergen is applied to the eye until a clinical response is detected. The effectiveness of the intervention was measured as the mean reduction in ocular pruritus. Results were evaluated at three time points - 15 minutes, 8 hours and 16 hours after instillation. All three concentrations of bilastine proved to be better than the vehicle in reducing itching at all three assessed time points. Only the 0.6% concentration demonstrated statistically significant improvements over the vehicle in reducing conjunctival redness. In the group treated with bilastine 0.6%, no ocular adverse events were reported. The tolerability profile was favorable, with no significant adverse events related to the product. The 0.6% formulation provided fast symptom relief within 15 minutes and a long-lasting effect of over 16 hours, supporting the pharmacodynamic justification for a once-daily administration regimen. (12)

Another study compared groups that received ophthalmic bilastine, ophthalmic ketotifen or a vehicle. In this multicenter, double-masked, randomized phase III trial, a total of 228 subjects were randomly divided into three treatment groups: 91 patients received ophthalmic bilastine 0.6%, 90 received multidose ketotifen ophthalmic solution 0.025% and 47 received the vehicle. Efficacy was assessed using the Ora-CAC model. The primary efficacy endpoint was the mitigation of ocular pruritus. Secondary outcomes included investigator-assessed effectiveness against conjunctival, ciliary and episcleral redness and chemosis. Eyelid swelling, nasal, ear and palate pruritus, rhinorrhea, tearing and nasal congestion were self-reported by the subjects. Results were compered at two time points: 15 minutes and 16 hours after instillation. Outcomes after 16 hours were evaluated only between the bilastine and vehicle groups because ketotifen requires twice-daily administration. Bilastine demonstrated significant efficacy in mitigating the itching at both time points compared with the vehicle. Ketotifen showed significant improvement in reducing itching 15 minutes after instillation compared with the vehicle group. Analysis of the bilastine versus ketotifen groups showed that bilastine was statistically noninferior to ketotifen 15 minutes after instillation. Summarising the secondary outcomes, bilastine showed statistically significant improvements at onset of action compared with the vehicle for conjunctival, ciliary and episcleral redness, eyelid swelling, tearing, eye and palate pruritus as well as nasal congestion. Bilastine was also noninferior to ketotifen for these secondary measures. No severe adverse events were observed during the study. Four adverse events occurred in the bilastine group, two in the ketotifen group and one in the vehicle group, all classified as mild in severity. No tolerability issues were observed. (13)

A pooled analysis of the phase II and phase III studies also assessed clinical significance using the 50% responder rate as an efficacy indicator. In the phase II study, 83.3% of patients treated with ophthalmic bilastine 0.6% formulation reported more than a 50% reduction in ocular itching 15 minutes after instillation, 76.7% reported this level of improvement after 8 hours and 58.1% after 16 hours. In the phase III study, the same efficacy indicator was applied, showing that 72.2% of patients achieved more than a 50% reduction in ocular itching 15 minutes after instillation of bilastine 0.6%. A significantly greater proportion of patients treated with bilastine 0.6% achieved more than a 50% reduction in itching compared with the vehicle group, confirming the drug's effectiveness in mitigating itching associated with allergic conjunctivitis. Together, both studies support a long-lasting effect of over 16 hours and demonstrate an overall good safety and efficacy profile. (14)

Safety and tolerability of ophthalmic formulation of bilastine

In the multicenter, international, randomized, double-blind, placebo-controlled phase III study, a total of 333 subjects were randomized into two groups. A total of 218 patients received ophthalmic bilastine 0.6% and 115 patients received placebo over an 8-week period. The primary objective of the study was to assess the safety of long-term use of ophthalmic bilastine, which was evaluated by summarizing the incidence of related treatment-emergent ocular adverse events (ocular r-TEAEs). The secondary objective was to assess long-term tolerability. Tolerability was evaluated 3 minutes after instillation in each eye separately using a numerical scale ranging from 0 to 10, where 0 indicated no manifestation and 10 indicated unbearable burning or stinging, excessive tearing, severe blurring or stickiness. (15)

Safety

A total of 12 ocular r-TEAEs were reported in 11 patients: 6 patients in the bilastine group (2.8%, 7 events) and 5 patients in the placebo group (4.3%, 5 events). One patient in the treatment group discontinued the trial due to reported ocular r-TEAEs. The most common ocular r-TEAEs were dry eye (4 patients, 1.2%), eye discharge (2 patients, 0.6%) and eye irritation (2 patients, 0.6%). Overall, the incidence of ocular r-TEAEs was low and fewer patients in the bilastine ophthalmic solution group experienced ocular r-TEAEs compared with the placebo group. All TEAEs were mild or moderate in severity and no severe events were recorded. (15)

Tolerability

Tolerability was assessed at two time points, at baseline and at 8 weeks, in both treatment groups. At baseline, more than 80% of patients in both groups experienced no discomfort or only slight discomfort. After 8 weeks, most patients in both groups continued to report no or only slight discomfort. In the group treated with bilastine, no patients reported very severe manifestations (scores of 9–10 on the numeric scale) at any point during the study. Overall, the study supports the safety and good tolerability of long-term treatment with 0.6% bilastine ophthalmic solution in adults with allergic conjunctivitis. (15)

New reports in in vitro studies

An in vitro study compared the preservative-free 0.6% ophthalmic bilastine formulation with eight other commercially available antiallergic formulations, both preservative-free and those

containing BAC (benzalkonium chloride). The physicochemical characteristics were evaluated and an in vitro biological assessment was performed using conjunctival and corneal epithelial cells. The study revealed clear differences in the physicochemical properties of the analyzed antiallergic formulations. The preservative-free 0.6% bilastine ophthalmic formulation most closely matched the physiological parameters of the tear film in terms of viscosity, pH, osmolarity and phosphate levels, suggesting good tolerability on the ocular surface. This formulation also demonstrated higher cell viability compared with the other tested formulations, likely due to the absence of preservatives, as it did not induce caspase-3/7–dependent apoptosis and caused only transient oxidative stress. These findings indicate that the presence of BAC in commercial eye drops may contribute to their cytotoxicity. Altogether, the results suggest that the 0.6% ophthalmic bilastine formulation may help support the maintenance of ocular surface integrity in patients with allergic conjunctivitis. (16)

In another in vitro study, the preservative-free 0.6% ophthalmic bilastine formulation containing sodium hyaluronate was compared with eight other commercially available antiallergic eye drops. Among the tested products, the bilastine formulation demonstrated favorable bioadhesive properties. Under in vitro conditions, the bilastine formulation also prevented dehydration and promoted re-epithelialization of corneal cells after scratch injury, indicating beneficial wound-healing effects. These findings suggest that the use of preservative-free 0.6% bilastine eye drops containing sodium hyaluronate is unlikely to adversely affect the ocular surface and may contribute to improving surface integrity in patients with allergic conjunctivitis. (17)

A new bilastine formulation was evaluated in an in vitro study. The physicochemical properties of bilastine in a mucoadhesive ophthalmic gel formulation were investigated. For this purpose, formulations were prepared using various concentrations of poloxamers 407 and 188 in combination with hydroxypropylmethylcellulose (HPMC), each containing bilastine at a concentration of 6 mg/mL. A composition with optimal physicochemical characteristics and prolonged drug release for more than 5 hours was identified, providing a basis for further research. (18)

Discussion

The preservative-free 0.6% ophthalmic bilastine formulation exhibits valuable properties that may be clinically beneficial for patients with allergic conjunctivitis. Preclinical studies have

demonstrated preferential distribution of bilastine to conjunctival tissue with minimal systemic absorption. (10) Data from randomized phase II and phase III clinical trials indicate that the formulation provides rapid relief of ocular pruritus, with onset of action observed within 15 minutes after instillation. Efficacy was maintained for more than 16 hours after a single dose, supporting a once-daily dosing regimen. (12–14) Results from an 8-week clinical study confirm sustained symptom relief with a favorable safety profile and good tolerability. (15) Findings from in vitro experimental studies suggest that an additional clinical advantage of the 0.6% ophthalmic bilastine formulation may be the absence of preservatives, as the presence of benzalkonium chloride (BAC) can irritate the conjunctiva due to its cytotoxic effects (16), while the inclusion of sodium hyaluronate may help improve ocular surface integrity in patients with allergic conjunctivitis. (17)

At the same time, the available literature highlights several areas that require further investigation. There is a lack of long-term data beyond 8 weeks evaluating ocular surface safety and tolerability during chronic use, as allergic conjunctivitis often necessitates prolonged treatment lasting several months due to sustained allergen exposure. Although oral bilastine administered at a dose of 10 mg has a well-established safety profile in the pediatric population (19,20), studies assessing the safety and tolerability of the ophthalmic formulation of bilastine in pediatric patients are still needed. To date, all available clinical studies of the ophthalmic formulation have been conducted exclusively in adult populations (≥18 years of age) and further research is required to determine the minimum effective dose in children. Data presented in review articles (8,9) show that there is a lack of studies directly comparing the efficacy of bilastine ophthalmic formulations with other commercially available antiallergic eye drops (such as bepotastine, olopatadine, azelastine, etc.). To date, only one study has compared the bilastine formulation with a ketotifen-containing product, demonstrating noninferiority of bilastine in relieving ocular pruritus 15 minutes after instillation.

Conclusions

The available data indicate that the 0.6% ophthalmic formulation of bilastine represents a promising and well-tolerated treatment option for allergic conjunctivitis. Of particular importance is the demonstrated rapid onset of action and the persistence of the therapeutic effect for up to 16 hours, which supports a once-daily dosing regimen. The favorable safety profile

and the absence of preservatives constitute additional clinical advantages. At the same time, the literature highlights several areas that require further investigation.

Disclosure

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