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Expert perspectives on the prescription practice of artificial tears for the management of dry eye disease in Indian settings

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Abstract
Objective: The present survey-based study aims to gather expert opinion regarding the clinical use of artificial tears in managing dry eye disease (DED) in Indian settings, with a special focus on sodium hyaluronate.
Methodology: The study utilized a multiple-response questionnaire-based survey comprising 24 questions designed to collect feedback, clinical observations, and experiences from specialists regarding the treatment of DED using artificial tear compositions in routine settings. The questionnaire was structured to capture insights on the frequency of use, perceived efficacy, adverse effects, and preferences for specific tear compositions. Data analysis was conducted using descriptive statistics.
Results: The survey involved 194 participants. Approximately 39% indicated a preference for diagnosing DED using a slit lamp examination, while 38% favored the Schirmer score method. Around 36% of the experts identified sodium hyaluronate eye drops as the primary choice for treating moderate DED, with a substantial 72% recommending sodium hyaluronate for managing severe cases. Additionally, 37% of clinicians suggested switching to sodium hyaluronate for patients unresponsive to carboxymethylcellulose (0.5%) eye drops. Trehalose emerged as another preferred option for severe DED, endorsed by 51% of clinicians.
Conclusion: This study highlighted the preference for artificial tears, particularly sodium hyaluronate, in the treatment of moderate to severe DED. Sodium hyaluronate was identified as the first-line therapy for DED and was considered safe for patients who do not respond well to carboxymethylcellulose. Trehalose has been recommended as another preferred option for severe DED.

Keywords: Dry eyes disease, sodium hyaluronate, carboxymethylcellulose, Trehalose

Introduction

Dry eye disease (DED) is a widespread ocular condition impacting millions globally, with prevalence rates varying from 5% to 50% worldwide based on the geographic location [1]. DED is chronic, multifactorial, and often inflammatory, particularly affecting individuals over 50 years old, with a higher incidence among women. Tear Film and Ocular Surface (TFOS) Dry Eye Workshop (DEWS) II defined DED as: "a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles [2]." The propensity of the condition increases with age, affecting up to 30% of adults in this age group [3-5].

Studies have revealed significant variations in the prevalence rates of DED across different regions of India. For instance, a hospital-based study in North India reported a prevalence of around 32%, with individuals aged 21-40 being the most affected. In contrast, a study in South India documented a lower incidence rate of 1.46%. Other studies conducted in India have reported prevalence rates ranging from 15.4% to 18.4% [6-8]. Additionally, a 2019 study at the LV Prasad Eye Institute in Hyderabad projected that by 2030, approximately 45% of India's urban population-equivalent to a staggering 275 million people-will likely be affected by DED based on current incidence rates. Moreover, rural India was expected to witness the addition of 17 million new DED patients [9]. Effective management of DED requires a comprehensive approach. According to the management and therapy subcommittee of the TFOS DEWS II, tear substitutes are the first-line therapy for DED. Artificial tears are the primary choice for lubricating the eye surface and are often recommended initially due to their varied formulations and minimal risks. An ideal tear substitute should maintain the normal epithelial composition of the ocular Surface [10, 11].

Sodium hyaluronate, a water-soluble polymer, is a popular eye lubricant that effectively alleviates moderate to severe symptoms associated with DED. It benefits DED patients by retaining water, hydrating the ocular surface, increasing tear film thickness, and enhancing the ocular surface index [12, 13]. Over the past few decades, sodium hyaluronate has gained prominence as a viable option in artificial tear therapy. Its effectiveness was based on hyaluronic acid, a naturally occurring linear biopolymer composed of repeated disaccharide units of N-Acetyl-D-glucosamine and Sodium-D-glucuronate. Sodium hyaluronate has demonstrated both subjective and objective improvements in DED. Its natural origin and compatibility with ocular tissues make it a preferred choice in artificial tears and other eye care products [14, 15].

Trehalose is also a natural disaccharide with potential benefits for managing DED. It acts by stabilizing the lipid layer of the tear film, reducing tear-film osmolarity, and preventing ocular surface damage. Other artificial tear formulations include PEG-PG, hydroxypropyl methylcellulose, and carboxymethylcellulose [16-18]. Polyethylene glycol-propylene glycol (PEG-PG), hydroxypropyl methylcellulose, and carboxymethylcellulose are the other commonly used artificial tear formulations.

The aim of this survey-based study was to gain insight into the clinician's perspectives on the use of artificial tear formulations for effective management of DED. Understanding the effectiveness of artificial tears prescribed in Indian settings may help improve patient management and develop consensus to optimize the treatment for DED.

Methodology

A cross sectional, multiple-response questionnaire based survey was carried out among ophthalmologists specialized in treating DED patients in the major Indian cities from June 2023 to December 2023.

Questionnaire

The questionnaire booklet titled TIDE (Trehalose in Dry Eye) study was sent to the ophthalmologists who were interested to participate. The TIDE study questionnaire comprised 24 questions designed to gather feedback, clinical observations, and experiences from specialists regarding the treatment of DED using artificial tear compositions in routine settings. It was structured to capture insights on the frequency of use, perceived efficacy, adverse effects, and preferences for specific tear compositions. The study was conducted after getting approval from Bangalore Ethics, an Independent Ethics Committee which was recognized by the Indian Regulatory Authority, Drug Controller General of India.

Participants

An invitation was sent to leading ophthalmologists in managing DED in the month of March 2023 for participation in this Indian survey. About 194 ophthalmologists from major cities of all Indian states representing the geographical distribution shared their willingness to participate and provide necessary data. Ophthalmologists were requested to complete the questionnaire without discussing with peers. A written informed consent was obtained from each clinicians before initiation of the study.

Statistical analysis

The data were analyzed using descriptive statistics. Categorical variables were presented as percentages to provide a clear insight into their distribution. The frequency of occurrence and the corresponding percentage were used to represent the distribution of each variable. To visualize the distribution of the categorical variables, graphs, and pie charts were created using Microsoft Excel 2013 (version 16.0.13901.20400).

Results

The present survey included 194 clinicians, of whom 29% responded that around 30 to 40 individuals on average are newly diagnosed with DED in a month in routine settings, while 25% reported it as 20-30. According to 60% of the clinicians, the urban population suffers mostly from the symptoms of DED. Around 73% of the clinicians responded that both males and females suffer equally from the symptoms of DED. Majority (60.82%) of the clinicians reported that the symptoms of DED were more prevalent in the age group between 25 to 40 years. About 56% of the respondents opined that individuals with digital screen exposure were more affected by DED, whereas 41% reported that professionals with computer exposure were more affected. About 39% of the clinicians responded that they normally diagnose DED by slit lamp examination while 38% of them reported using the Schirmer score to diagnose DED (Table 1).

Table 1: Distribution of response on the methods of diagnosing DED in patients

Diagnostic method	Response rate (n = 194)
Patient history and presented symptoms	14.43%
Schirmer score	38.14%
Slit lamp examination	38.66%
All of the above	6.7%
Others	2.08%

Over half of the participants (53.61%) reported rare use of the Ocular Surface Disease Index (OSDI) questionnaire for day-to-day examination of DED. Half of the participants reported that about 26 to 50% of individuals with DED were diagnosed with aqueous deficient DED. The common symptom found in patients diagnosed with both aqueous deficient dry eyes and evaporative dry eyes was a burning sensation in the eyes, as reported by 62% and 51% of the clinicians, respectively. As stated by 53% of the clinicians, about 26 to 50% of individuals with DED were diagnosed with evaporative dry eyes. Most of the respondents (87.63%) reported periodic screening and regular awareness as the methods to be considered for early diagnosis of DED. Approximately 53% of the experts recommended carboxymethylcellulose 0.5% as the first-line choice in managing patients diagnosed with mild DED. Nearly 36% preferred sodium hyaluronate eye drops as the first-line choice in managing moderate DED (Table 2).

Table 2: Distribution of response to the first-line choice of therapy for patients with moderate DED

Eye drops	Response rate (n = 194)
Carboxymethylcellulose 0.5%	3.09%
Carboxymethylcellulose 1.0%	28.87%
Polyethylene glycol + propylene glycol combination	32.47%
Sodium hyaluronate	35.57%

Approximately 72% of the clinicians stated that sodium hyaluronate was the first-line choice for managing patients diagnosed with severe DED (Table 3). About 77% of the clinicians opined that following the 20-20-20 rule, minimizing digital screen exposure, regular use of prescribed medication, and diet and exercise were the approaches that can result in good clinical outcomes (Table 4).

Table 3: Distribution of response to the first-line choice therapy for managing severe DED in patients

Eye drops	Response rate (n = 194)
Carboxymethylcellulose eye drops 0.5%	2.58%
Carboxymethylcellulose eye drops 1.0%	2.58%
Polyethylene glycol + propylene glycol combination	21.65%
Sodium hyaluronate	72.16%
All of the above	0.52%

Table 4: Distribution of response to the approaches leading to good clinical outcomes for DED management

Approaches	Response rate (n = 194)
Regular use of prescribed medication	1.55%
Minimizing digital screen exposure	4.12%
Following 20-20-20 rule	16.49%
Diet and exercise	0.52%
All the above	77.32%

As reported by 57% of clinicians, the recommended dose of carboxymethylcellulose for a mild DED patient was four times daily. Nearly 51% of the experts recommended one-to-one patient education as the model that will work for better patient education. Half of the clinicians (50.52%) reported that patient education sessions should be conducted once every three months to increase awareness regarding DED. As opined by 37% of the clinicians, the preferred strategy for patients who do not respond to carboxymethylcellulose 0.5% for managing DED was to switch to sodium hyaluronate (Fig. 1).

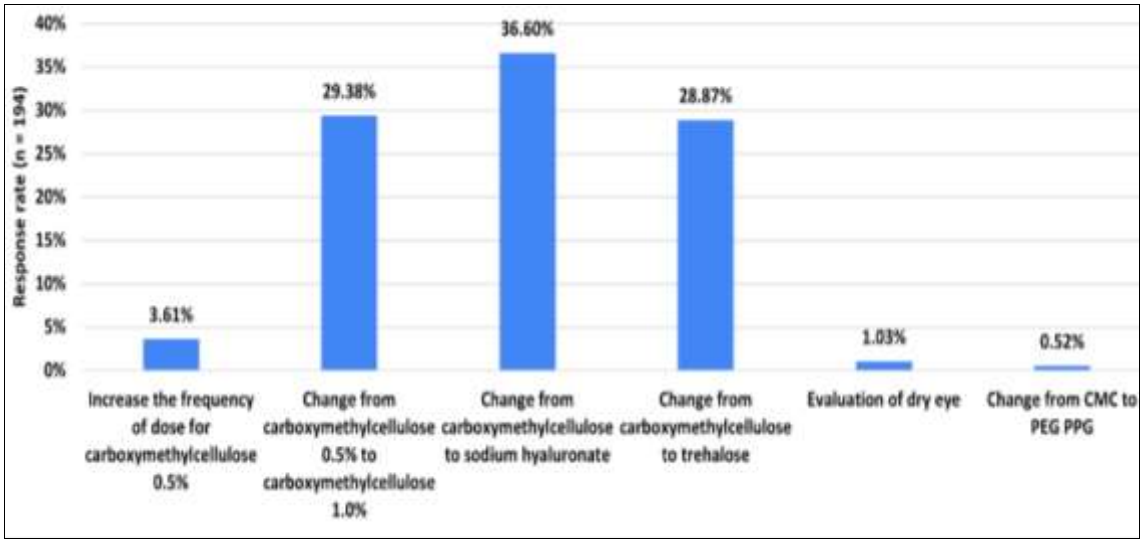

Fig 1: Distribution of response on the preferred strategies for managing DED in patients unresponsive to carboxymethylcellulose 0.5% eye drops

Majority of the experts (63%) indicated that patients with moderate DED conditions are normally recommended the polyethylene glycol + propylene glycol combination. According to 42% of clinicians, hydroxypropyl methylcellulose was typically recommended for patients with mild DED conditions. Nearly 61% of clinicians reported that patients with severe DED conditions were usually recommended sodium hyaluronate. As reported by 51% of the clinicians, trehalose was also a preferred choice in severe DED conditions (Fig. 2).

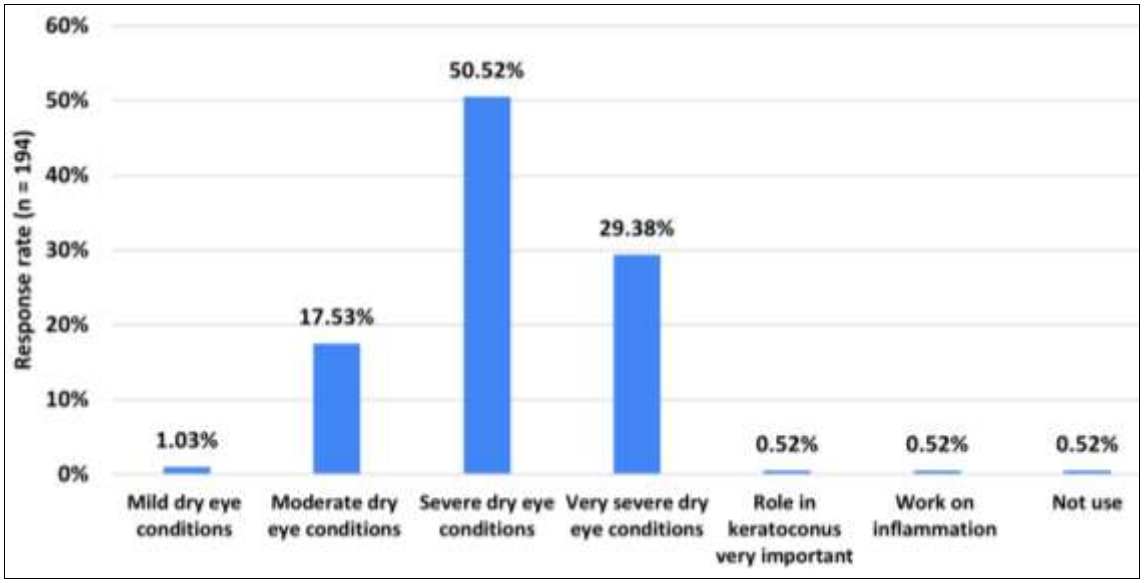

Fig 2: Distribution of response on the clinical recommendations for trehalose usage in DED patients

Discussion

The current survey findings offer valuable insights into the clinical landscape of DED, providing guidance for enhancing diagnosis, treatment, and patient care across diverse urban and rural settings. Timely diagnosis of DED was crucial for effective management of the condition. In this survey, clinicians predominantly favored diagnosing DED using slit lamp examination and the Schirmer score.

Schirmer's test, introduced as a diagnostic tool for DED in 1903, remains a commonly used method to evaluate tear volumes due to its straightforward procedure and minimal equipment needs [19]. Despite its widespread use, Schirmer's test was associated with several drawbacks, including poor repeatability, low sensitivity, low specificity, and discomfort for the patient [20].

According to Zeev *et al*., a comprehensive examination was essential for accurately diagnosing DED. To initiate the examination, an initial test called slit-lamp examination was performed. The patient's history can guide a more focused slit-lamp examination, which can aid in identifying certain ocular manifestations. Some of the DED signs identified during the slit-lamp examination include inadequate tear lake volume, early tear film break-up time, superficial corneal erosions, conjunctival hyperemia, conjunctival surface irregularities, and meibomian gland dysfunction [21]. Studies have also shown that moderate-to-severe cases of DED can be diagnosed based on subjective symptoms and slit-lamp findings [22]. Alves *et al*. compared the diagnostic accuracy of Schirmer Test I and II in DED. The researchers concluded that both tests were reliable methods for diagnosing DED, with Schirmer's score being particularly useful in assessing tear production [23].

The current survey finding showed that sodium hyaluronate eye drops were the first line of choice of clinicians in managing moderate to severe DED in patients for the majority of the participants. Similarly, Zhao *et al*. concluded that in patients with DED, conventional artificial tears, such as sodium hyaluronate, were the first-line therapy to alleviate DED due to their ability to retain water [24]. Aragona *et al*. also supported the efficacy of sodium hyaluronate in severe DED [25]. Cheema *et al*. highlighted the beneficial effects of sodium hyaluronate on the conjunctival epithelium in a well-defined population of DED patients, suggesting its utility in DED treatment.[26] Multiple studies have demonstrated the effectiveness of sodium hyaluronate in managing moderate to severe DED and promoting a healthy corneal epithelium. Sodium hyaluronate treatment has been shown to enhance tear film stability, alleviate DED discomfort and ocular pain, and effectively mitigate ocular inflammation [27, 24, 14].

The current survey highlighted that following the 20-20-20 rule, minimizing digital screen exposure, regular use of prescribed medication, and diet and exercise were the approaches that can result in good clinical outcomes for DED. In line with these findings, Estarelles *et al*. demonstrated that implementing the 20-20-20 rule was effective in reducing DED and dry eye symptoms [28]. Several studies have also emphasized the relationship between digital screen exposure and DED, advocating for measures such as limiting screen time, adjusting screen settings, and adopting ergonomic practices to alleviate symptoms [29, 30, 2]. Moreover, various medications including artificial tears, anti-inflammatory agents, and immunomodulators have been shown to be beneficial in managing DED [31, 32]. While diet and exercise may not directly treat DED, they can positively impact overall ocular and systemic health, indirectly improving DED symptoms. Studies have demonstrated associations between nutrition, lifestyle factors, and ocular health, highlighting the importance of holistic approaches to managing DED [33, 34].

As highlighted in the current survey, the recommended approach for patients who do not respond to carboxymethylcellulose 0.5% for managing DED was to switch to sodium hyaluronate. According to a comparative study by Salim *et al*., both sodium hyaluronate and carboxymethylcellulose groups showed significant improvement in patient symptoms, tear film breakup time, and Schirmer's test from baseline at 8 weeks' post-treatment. Both carboxymethylcellulose and sodium hyaluronate demonstrated equal efficacy in treating mild to moderate DED [35]. Another study compared the effectiveness of hyaluronic acid, carboxymethylcellulose, and artificial tears in treating dry eye syndrome. The findings suggested that hyaluronic acid outperformed carboxymethylcellulose in enhancing tear film stability and alleviating dry eye symptoms [36]. These studies underscore the importance of considering alternative treatments like sodium hyaluronate for patients who do not respond adequately to carboxymethylcellulose, based on their demonstrated efficacy and potential benefits in managing

DED.

Majority of the current survey respondents emphasized that trehalose was also a preferred choice in severe DED. Consistent with this, Matsuo *et al*. reported that trehalose solution was an effective and safe treatment option for individuals with moderate to severe DED [16]. Trehalose-based tear substitute treatments demonstrated superior outcomes compared to traditional tear substitutes, resulting in high patient satisfaction and no adverse events [4]. Trehalose/sodium hyaluronate eye drops were found to be efficient in alleviating dry eye symptoms and enhancing tear film stability [13]. These findings support the efficacy and safety of trehalose-based treatments for managing severe DED.

The current survey results may assist clinicians in enhancing treatment strategies and patient care by considering the preferences and prescription practices of artificial tears, especially sodium hyaluronate in Indian settings. The major strength of the current survey was the utilization of a well-designed and validated questionnaire to collect data from clinicians. However, it was important to acknowledge certain limitations of the survey. The results may be subject to bias due to reliance on expert opinion, which can be influenced by diverse perspectives and preferences among clinicians. It was essential to keep these limitations in mind when interpreting the findings. Additionally, the survey may not fully account for emerging evidence or evolving trends in infection management. To address these limitations, it was recommended to conduct prospective trials or real-world observational studies to validate the survey results and provide a more comprehensive understanding of optimal treatment approaches.

Conclusion

The survey highlighted the clinicians' preference for sodium hyaluronate as the first-line therapy for moderate to severe DED. Both slit lamp examination and Schirmer score have been recommended as the preferred tests for the diagnosis of DED. Sodium hyaluronate was also used in patients who do not respond to carboxymethylcellulose 0.5%. Trehalose has been recommended as another preferred option for severe DED.

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Conflict of Interest

Nothing to disclose.

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