
Contemporary Use of Topical Decongestants: An Indian Perspective

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ABSTRACT

Background: Allergic rhinitis and sinusitis are commonly encountered in primary practice, and nasal congestion is a common symptom experienced by these patients. Thus, it is important to address nasal congestion when treating these conditions. Despite the availability of several treatment options, therapy is impacted by adverse effects and patient dissatisfaction. We conducted a survey to evaluate the prescribing practices of physicians treating allergic rhinitis and sinusitis, with a focus on the formulation of topical xylometazoline with moisturizers (hypromellose and sorbitol).

Methods: We surveyed the prescribing practices of 545 Indian ear, nose and throat (ENT) physicians for rhinitis and sinusitis to understand the place of the formulation containing xylometazoline and moisturizer (sorbitol, hypromellose) in clinical practice. Towards this, physicians provided their response to a 10-item questionnaire covering prescribing practice and patient satisfaction.

Results: Overall, 91% of doctors reported that a decongestant along with a moisturizer would be beneficial to patients with nasal congestion due to allergic rhinitis and sinusitis, and a majority of doctors (89.5%) preferred prescribing xylometazoline with sorbitol and hypromellose. A majority of doctors reported high patient satisfaction with this formulation. Additionally, 78.35% of doctors reported high ratings for the reduction of nasal dryness.

Conclusion: The overall satisfaction of doctors and patients is high, indicating that this formulation is an ideal choice for achieving relief from nasal congestion due to AR and sinusitis.

KEYWORDS: Allergic rhinitis; Rhino sinusitis; Xylometazoline; Hypromellose; Sorbitol.

Running title: Use of topical decongestants in India

1. INTRODUCTION

Allergic rhinitis (AR) is a common allergic condition that affects up to 25% of the global population and is a common cause of primary care consultation. In India, 20-30% of the population suffers from at least one allergic disease, and AR constitutes 55% of allergic conditions [1]. Sinusitis is another commonly encountered respiratory condition, with the prevalence of acute rhinosinusitis reported to be ~30%, and that of chronic rhinosinusitis reported to be 46.1% [2]. Nasal congestion is a common symptom of AR, affecting around 90% of patients [3]. The impact of nasal congestion on quality of life is well-known, with studies indicating that 59% of adults report an impact on their job performance, and 61% of caregivers report that nasal congestion affects their child's performance at school [4]. As a result, nasal congestion is one of the primary contributors to poor quality of life [3,5]. Among patients with sinusitis as well, nasal congestion is a common symptom, affecting 66-70% of patients [6]. Therefore, addressing nasal congestion is one of the primary objectives of treatment. However, despite the availability of several treatment options, adverse effects, patient dissatisfaction, and perceived ineffectiveness of various agents often hinder therapy [5]. Both oral and topical decongestants are available for the management of nasal congestion associated with upper respiratory conditions. Oral decongestants are associated with various side effects, including insomnia, palpitations, increased blood pressure, etc. Topical decongestants are considered more effective than oral decongestants [7]. Xylometazoline hydrochloride is a well-established topical nasal decongestant. This sympathomimetic drug acts selectively on α -adrenergic receptors (alpha-adrenergic agonist) [8]. Patients report relief from nasal congestion within 2 minutes of use of xylometazoline, and the increase in nasal conductance is five times higher than that noted with oral decongestants [9]. Topical formulations of nasal decongestants have the advantage of possible inclusion of moisturizers in the formulation. The inclusion of sorbitol and hypromellose restores moisture to the nasal mucosa due to the properties of high water-retention, thus counteracting dryness seen commonly in these patients [10,11]. Given the burden of nasal congestion related to AR and sinusitis in India and the need for better management of this bothersome symptom, understanding the prescribing practices of Indian physicians could guide treatment practices. Therefore, the aim of this study was to survey Indian ear, nose, and throat (ENT) physicians' prescribing practices for rhinitis and sinusitis and to understand the place of the formulation containing xylometazoline and moisturizer (sorbitol and hypromellose) in clinical practice.

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2. METHODS

This cross-sectional survey was conducted in February 2022 among ear, nose, and throat specialists in India using a combination of web-based and in-person survey methods.

A. Respondents

This was a random sampling of physicians across India. A total of 600 physicians were invited to participate, of whom 545 completed the survey.

B. Survey instrument

The survey instrument consisted of a total of ten questions (and two sub-questions) related to prescribing practices for nasal decongestants in patients with AR and sinusitis. All questions were multiple-choice questions. All questions (whether physician-related or patient-related) were answered by the physicians. The questions examined: (i) the impact of nasal congestion on the quality of life (QoL) of patients with AR and sinusitis (rated on a scale of one to five, with five being the highest) (ii) the proportion of patients who report nasal congestion as a symptom to their doctor (iii) whether topical decongestants are routinely prescribed by the doctor (iv) the duration for which topical decongestants are prescribed (v) when improvement in symptoms is noted on use of topical decongestants (vi) the potential benefits of using topical decongestant formulations containing moisturizers (vii) whether the combination of xylometazoline with sorbitol and hypromellose is preferable (viii) when improvement in symptoms is noted on use of topical xylometazoline with sorbitol and hypromellose (ix) patient satisfaction with the use of xylometazoline with sorbitol and hypromellose (x) the proportion of patients for whom topical decongestants with moisturizers are prescribed (xi) the benefits of using topical decongestants with moisturizers (xii) how likely the physician is to prescribe nasal decongestants with moisturizers over nasal decongestants alone.

C. Data analysis

Data were anonymously entered in a Microsoft Excel database (Microsoft Corporation, Redmond, Washington, USA). Frequencies and proportions were calculated using Microsoft Excel.

D. Ethical considerations

The study was approved by the Institutional Ethics Committee of the HBT Medical College and Dr RN Cooper Hospital, Mumbai, India. All data were analyzed anonymously.

3. RESULTS

A total of 545 physicians completed the survey, of whom 99.4% (n=542) were ENT physicians.

Overall, 56.9% of doctors reported that over 50% of patients reported nasal congestion as a major symptom of AR and sinusitis. A majority of the doctors (60.2%, n=328) reported that nasal congestion had a severe impact (score of five) on QoL. In addition, the number of doctors reporting the impact on QoL was high or severe was 502 (92.1%; Figure 1).

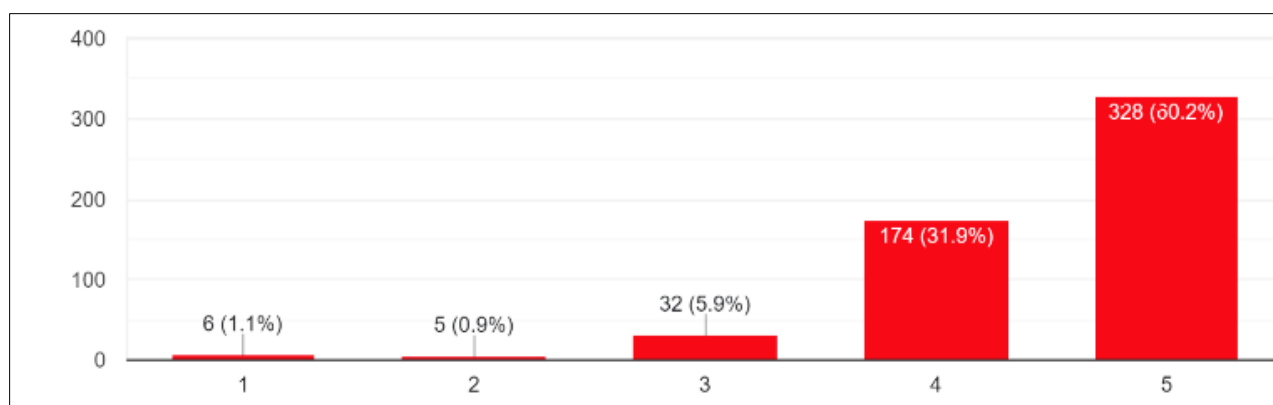


Figure 1. Responses of the doctors for the impact of nasal congestion on QoL of patients (1 – lowest impact on QoL; 5 – highest impact on QoL)

A. Use of topical nasal decongestants for treating nasal congestion

The topical nasal decongestant was the preferred option for the management of AR or sinusitis among ENTs, and it was routinely prescribed by 80.3% of doctors. Most doctors (64.8%) prescribed topical nasal decongestants for a duration of over five days, while 29.9% prescribed them for three days, and 5.3% prescribed them for two days. Nearly 80% of doctors (Figure 2A) reported noticing an improvement in nasal congestion within two days of use of the topical nasal decongestant, while 18.7% noticed an improvement after two days. A majority of doctors (91%) reported that a decongestant along with a moisturizer would be beneficial to patients with nasal congestion due to AR and sinusitis, and 89.5% of doctors preferred prescribing xylometazoline with sorbitol and

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hypromellose to their patients. Analysis of responses indicated that 37.8% of doctors prescribed this formulation to over 50% of their patients, while 32.8% of doctors prescribed it to 20-50% of their patients, and 29.4% of doctors prescribed it to 10-20% of their patients.

B. Doctor's assessment of response to and satisfaction with treatment

Symptomatic relief within one day of using xylometazoline plus sorbitol and hypromellose was reported by 52.7% of doctors, while 28.1% of doctors reported relief within one to two days, and 19.3% reported relief after two days (Figure 2B). Statistical analysis of the duration to symptomatic relief revealed no significant difference between the findings for xylometazoline compared with xylometazoline plus hypromellose and sorbitol for the duration to symptomatic relief ($\chi^2 = 0.23$, $p = 0.891$).

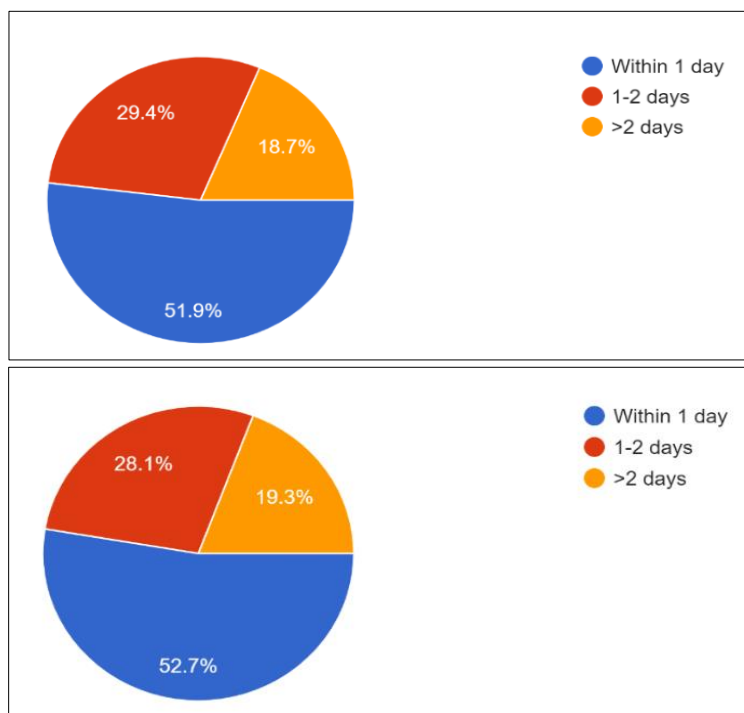


Figure 2. Responses of doctors for the duration after which improvement is noted with (A) Topical nasal decongestant with added moisturizers (B) Topical xylometazoline with sorbitol and hypromellose

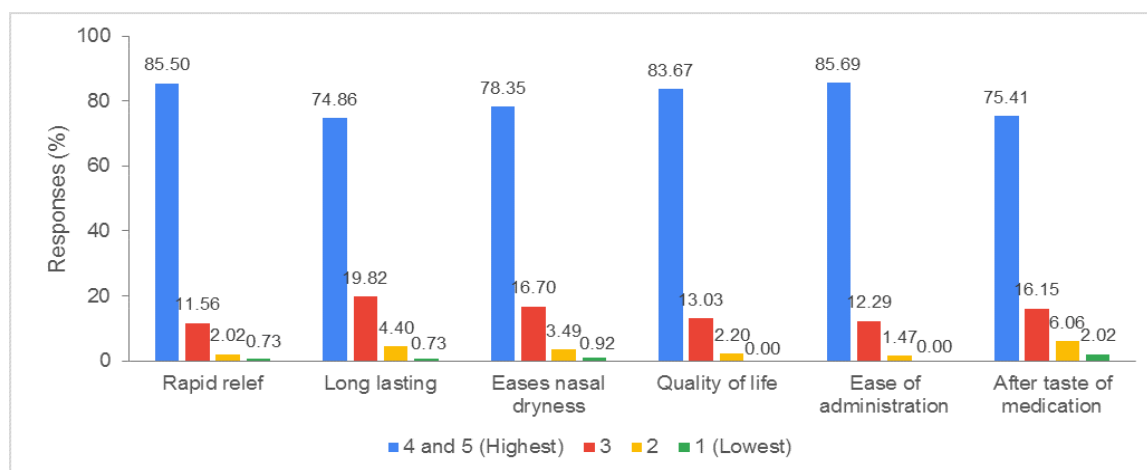


Figure 3. Responses of doctors for the various parameters of patient satisfaction with the combination of xylometazoline with sorbitol and hypromellose

The findings of patient satisfaction with the formulation of xylometazoline with sorbitol and hypromellose are presented in Figure 3. A majority of doctors reported high patient satisfaction (score of four and five) for all parameters assessed, i.e.,

- Rapid relief
- Long-lasting effect
- Eases nasal dryness

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- QoL
- Ease of administration
- Aftertaste of the medication

C. Perception of doctors on benefits of medication and future prescription

Two-thirds of doctors opined that topical nasal decongestants with moisturizers provided benefit from nasal congestion and dryness simultaneously, were more beneficial across congestion states, and were long-acting compared to traditional decongestants (Figure 4). Approximately 70% of doctors would be more likely to prescribe topical nasal decongestants with moisturizing benefits over traditional nasal decongestants in the future.

Table I describes the key finding of prescribing practices of nasal decongestants for rhinitis and sinusitis.

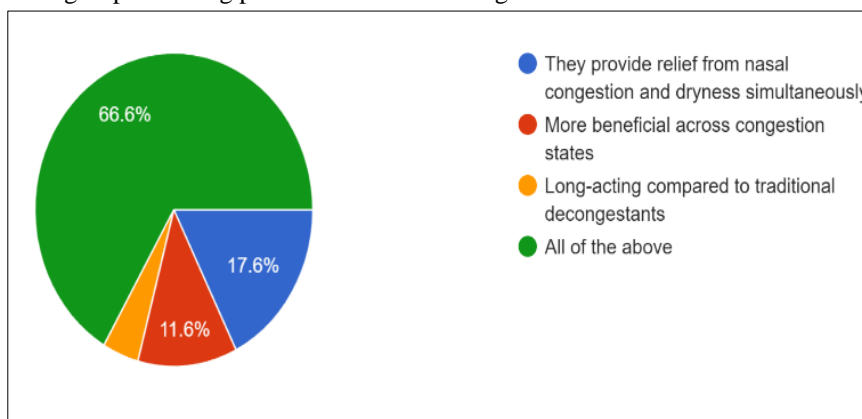


Figure 4. Responses of doctors for the benefits of nasal decongestants that have moisturizing properties

Table I. Key findings of the survey of prescribing practices for rhinitis and sinusitis

Parameter	Responses
Nasal congestion as a symptom of allergic rhinitis and sinusitis in over 50% of patients	56.9%
Severe impact of nasal congestion of quality of life	60.2%
High or severe impact of nasal congestion on quality of life	92.1%
Improvement in nasal congestion within two days of using topical nasal decongestant	80%
Improvement in nasal congestion within two days of using topical xylometazoline with hypromellose and sorbitol	80.8%
Doctors likely to prescribe topical nasal decongestants with moisturizing benefits over traditional nasal decongestants in the future	70%

4. DISCUSSION

Nasal congestion is a bothersome symptom of upper respiratory illnesses such as AR and sinusitis. While oral decongestants are often used, the drawbacks of systemic adverse effects limit their use. Furthermore, topical decongestants have proven efficacy in relieving nasal congestion [3-5, 7]. The findings of this study overwhelmingly indicated that the formulation of topical xylometazoline with added moisturization is preferred by doctors across the country due to the multiple treatment benefits and patient satisfaction with the formulation. Increasing industrialization and the resulting rise in air pollution have become a factor in the development of acute and chronic sinusitis, with typical features of inflammation and congestion [12]. In fact, a study in India reported that nearly 25% of children experience an upper respiratory syndrome (URS) in the preceding 3 months, and that URS was more prevalent in the months when pollution was higher [13]. In this study, over half of the doctors reported that over 50% of patients consider nasal congestion a major symptom of AR and sinusitis, and ~92% of doctors reported that nasal congestion had a high or severe impact on QoL. Therefore, there is a need to address nasal congestion with a rapid, effective, and safe treatment to relieve symptoms and restore QoL. Xylometazoline has been proven to be an effective treatment for nasal congestion. Clinical studies have shown that xylometazoline provides a greater benefit than placebo in improving the total common cold symptom score on day 1 of treatment (28.2% greater benefit than placebo) [9,14]. The majority of doctors in this study reported that the use of xylometazoline with sorbitol and hypromellose also eases nasal dryness. This property of the formulation is beneficial because dryness of the nasal mucosa can lead to pain and nosebleeds, increasing the burden on patients [8]. Therefore, it can be concluded that xylometazoline with sorbitol and hypromellose is an effective treatment for nasal congestion that also relieves nasal dryness. Sorbitol and hypromellose together exhibit hygroscopic properties, and the formulation of xylometazoline with sorbitol and hypromellose remains on the epidermal surface for a longer duration, with a lower rate of water loss. The sustained water-holding effect has significant moisturizing properties on the epidermis and increases epidermal water content. The findings of the study

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indicated that the formulation may behave in a similar manner in the nasal mucosa, thus counteracting nasal dryness [11]. Among the other benefits of the formulation reported by doctors in this study were the ease of administration, long-lasting effect, and lack of aftertaste. These properties, along with the aforementioned benefits of rapid relief, improved QoL, and relief from nasal dryness, make the formulation of xylometazoline with sorbitol and hypromellose an ideal choice for the treatment of nasal congestion due to AR and sinusitis [15]. This is evidenced by the fact that 89.5% of doctors who participated in this study preferred prescribing xylometazoline with sorbitol and hypromellose to their patients. The scores of patient satisfaction add weight to these findings and support the use of this formulation. This study has certain limitations. Firstly, patient satisfaction was evaluated based on the doctor's perception rather than a direct evaluation of patients. Secondly, nasal congestion was not evaluated using commonly used tools (total nasal symptoms score, visual analog scale) and tests (acoustic rhinomanometry).

5. CONCLUSION

In conclusion, topical nasal decongestants such as xylometazoline, when combined with moisturizers such as sorbitol and hypromellose, provide rapid and effective relief from nasal congestion and relieve nasal dryness. The overall satisfaction of doctors and patients is high, indicating that this formulation is an ideal choice for achieving relief from nasal congestion due to AR and sinusitis.

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CONFLICT OF INTEREST

Dr. Atul Sharma is on the payrolls of Haleon/GlaxoSmithKline Asia Private Limited, India.

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