



Original Research Article

A PROSPECTIVE STUDY ON THE EFFICACY AND SAFETY OF FLUTICASONE FUROATE VS. FLUTICASONE FUROATE-OXYMETAZOLINE COMBINATION FOR ALLERGIC RHINITIS

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ABSTRACT

Background: Objective: To compare the safety and efficacy of Fluticasone furoate (FFNS) nasal spray with a combination of Fluticasone furoate and Oxymetazoline (FFONS) in patients with allergic rhinitis.

Materials and Methods: A total of thirty patients, aged between 18 and 65, diagnosed with allergic rhinitis, were randomly assigned to two groups. Group I was administered FFNS (27.5 mcg), whereas Group II was given FFONS (27.5 mcg plus 50 mcg). Symptom severity was evaluated on a weekly basis throughout the six-week study period.

Results: The FFONS group demonstrated a quicker onset of action, particularly in alleviating nasal congestion, sneezing, and rhinorrhea. In contrast, FFNS proved to be more effective for long-term management, with gradual improvement observed throughout the study period.

Conclusion: Although FFNS is effective for managing mild to moderate symptoms, FFONS provides rapid relief, making it especially beneficial for patients with moderate to severe allergic rhinitis. Both treatments play important roles, with their use determined by the severity of symptoms.

Keywords: Allergic rhinitis, Fluticasone furoate, Oxymetazoline, Nasal spray, Intranasal corticosteroids.

INTRODUCTION

Allergic rhinitis (AR) is a persistent inflammatory condition characterized by symptoms such as sneezing, nasal discharge, congestion, and itching of the eyes and nose. It affects nearly 30% of people worldwide and, if inadequately managed, may contribute to complications like bronchial asthma or chronic rhinosinusitis.^[1,2] Treatment modalities for AR typically include oral antihistamines, corticosteroids, and immunotherapy. Among these, intranasal sprays are widely used due to their localized action and quick symptom relief. Fluticasone furoate, a potent synthetic corticosteroid, is recognized for its strong anti-inflammatory activity.^[3-6] Oxymetazoline, a

sympathomimetic agent, provides rapid decongestion by causing vasoconstriction.^[7-9] The use of combination therapies has shown greater efficacy and may overcome drawbacks like tachyphylaxis and rebound congestion linked with long-term monotherapy.^[8, 10-11] Recent clinical and observational studies have validated the safety and effectiveness of fixed-dose formulations containing both fluticasone furoate and oxymetazoline in real-world practice.^[9,12-13] Additionally, unmanaged nasal obstruction due to AR can significantly impair quality of life, especially by disrupting sleep.^[2,14] The present prospective and comparative study aimed at evaluating the efficacy and safety of Fluticasone Furoate Nasal Spray (FFNS) versus a combination of Fluticasone Furoate and

Oxymetazoline Nasal Spray (FFONS) in patients diagnosed with allergic rhinitis.

MATERIALS AND METHODS

Thirty patients, aged 18 to 65 years, with clinically diagnosed allergic rhinitis with symptoms including sneezing, rhinorrhea, nasal obstruction, and ocular symptoms were enrolled in the study. Patients with known history of bronchial asthma, any structural nasal abnormalities and those refusing to provide informed consent for participation in clinical testing were excluded from the study. Participants were randomly assigned to two groups: Group I (n = 15): Received Fluticasone Furoate Nasal Spray (FFNS) at a dosage of 27.5 mcg once daily. Group II (n = 15): Received Fluticasone Furoate and Oxymetazoline Nasal Spray (FFONS) at a dosage of 27.5 mcg plus 50 mcg once daily.

The demographic distribution showed that male participants were primarily engaged in outdoor occupations, whereas female participants had frequent exposure to indoor allergens such as dust and animal dander.

All the patients were followed up for a period of six weeks on a weekly basis using a standardized response scale, where scores ranged from 0 (no relief) to 6 (excellent relief). The following symptoms were evaluated: Sneezing, Rhinorrhea, Nasal obstruction, and Ocular symptoms (itching, redness, watering of the eyes).

Throughout the study, both groups were closely monitored for any adverse effects, and their progress was recorded to evaluate the efficacy of each treatment regimen over time.

Symptom response over 6 weeks:

- 0-1: No response or negligible response**
- 1-2: Minimal response**
- 2-4: Mild to moderate response**
- 4-6: Good to excellent response**

RESULTS

Table 1: Demographic Summary

Total Patients	Age Range	Males	Females
30	18–65 years	17	13

Table 2: Group I-Results with Fluticasone furoate (FFNS) nasal spray

Duration in weeks	Sneezing	Itching	Rhinorrhea	Nasal congestion	Ophthalmic symptoms
1	0-1	0-1	0-1	1-2	1-2
2	2-3	2-3	2-3	2-3	2-3
3	3-4	3-4	3-4	2-3	4-5
4	3-4	4-5	4-5	4-5	5-6
5	4-5	4-5	4-5	4-5	5-6
6	4-5	4-5	4-5	4-5	5-6

Table 3: Group II- Results with Fluticasone furoate with oxymetazoline (FFONS) combination

Duration in weeks	Sneezing	Itching	Rhinorrhea	Nasal congestion	Ophthalmic symptoms
1	2-3	2-3	2-3	3-4	2-3
2	3-4	3-4	3-4	4-5	4-5
3	4-5	4-5	4-5	5-6	5-6
4	5-6	5-6	5-6	5-6	5-6
5	5-6	5-6	5-6	5-6	5-6
6	5-6	5-6	5-6	5-6	5-6

Group I – FFNS: The patients in Group I, who received Fluticasone Furoate Nasal Spray (FFNS), demonstrated a gradual yet noticeable improvement in symptoms over the study period. By the end of the second week, patients reported significant relief from symptoms of allergic rhinitis, particularly in nasal obstruction and rhinorrhea. The most remarkable improvement was observed in ophthalmic symptoms, which showed the most substantial response by the sixth week, indicating that FFNS is effective in addressing both nasal and ocular manifestations of allergic rhinitis, though the therapeutic effects took a longer period to become fully evident.

Group II – FFONS: In contrast, patients in Group II, who received the combination of Fluticasone Furoate and Oxymetazoline Nasal Spray (FFONS), experienced a significantly quicker onset of symptom relief, with noticeable improvements occurring within minutes of application. By the end of the first week, patients in this group had achieved significant control over their symptoms, especially nasal congestion and sneezing. This rapid onset of relief was sustained throughout the study period, indicating the effectiveness of FFONS for quick and continuous symptom control, particularly beneficial for acute flare-ups and severe nasal congestion. Although both treatments showed comparable overall efficacy by the end of the sixth week,

FFONS demonstrated superior control during the early phase of treatment, offering quicker relief for patients suffering from moderate to severe allergic rhinitis symptoms. This highlights the potential advantages of FFONS for patients seeking rapid and sustained symptom relief during allergic rhinitis episodes.

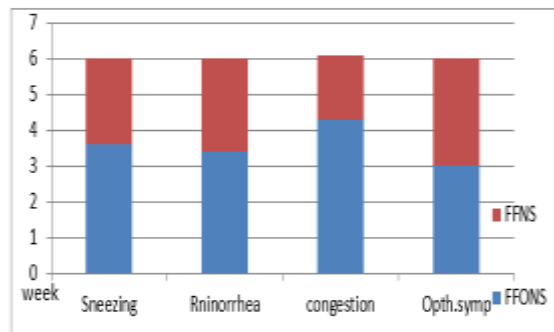


Chart 1: Comparative statistical analysis showing efficacy of FFNS and FFONS

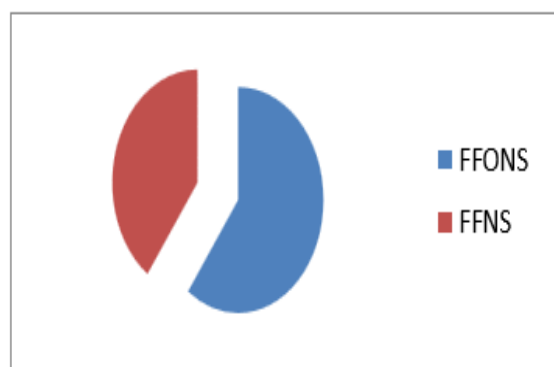


Chart 2: Overall efficacy of FFNS and FFONS in relieving the symptoms

DISCUSSION

This research underscores the therapeutic advantage of using a combination of fluticasone furoate and oxymetazoline for treating allergic rhinitis (AR), particularly in comparison to intranasal corticosteroid monotherapy. AR, a condition marked by nasal congestion, sneezing, and rhinorrhea, is known to negatively affect quality of life across a significant portion of the population [13,14]. Intranasal corticosteroids such as fluticasone furoate have long been established as effective and safe for managing inflammation in AR. [1,3,11,14] However, adding oxymetazoline—a nasal decongestant—can provide faster symptom relief through its vasoconstrictive action. [6,7,10] Clinical studies support the enhanced benefits of this combination approach. Baroody and Naclerio, [7] demonstrated that oxymetazoline enhances the decongestant effect of fluticasone in patients with perennial AR. Similarly, Thongngarm et al. [10] found that patients experienced quicker and more complete relief when treated with both medications. These observations are echoed in a randomized

controlled trial by Kumar et al, [9] which confirmed the superior efficacy of combination therapy in managing acute congestion.

A notable issue with extended oxymetazoline usage is the potential for diminishing drug effectiveness over time, known as tachyphylaxis, as well as the development of rebound nasal congestion upon withdrawal. However, research by Williamson and Myers, [8] suggests that co-administration with fluticasone can prevent these effects, making the combination safer for extended use. Kumar et al, [9] and Juvekar et al, [12] also emphasized the safety and efficacy of this combination in both clinical and real-world environments.

The practical value of this treatment strategy is further highlighted by real-world data. In an observational study, Juvekar et al, [12] reported significant improvements in nasal symptoms and overall patient well-being with the fixed-dose combination, while maintaining a strong safety profile. Neighbors et al, [13] in a comprehensive review, supported these findings and concluded that dual therapy is a viable, well-tolerated option for chronic rhinitis.

Additionally, untreated AR—particularly nasal congestion—can impair daily activities and disrupt sleep, which significantly reduces quality of life [10,14]. The fast action of oxymetazoline and the sustained anti-inflammatory effects of fluticasone address both immediate and chronic symptoms, offering comprehensive relief.

Taken together, these findings demonstrate that the fixed-dose combination of fluticasone furoate and oxymetazoline offers multiple benefits, including rapid symptom control, prolonged efficacy, and reduced side effects associated with prolonged decongestant use. This aligns well with guideline-based, individualized treatment approaches as advocated by ARIA. [1] Further large-scale studies are encouraged to confirm these results and refine treatment protocols for broader clinical use.

CONCLUSION

Both FFNS and FFONS are effective treatments for allergic rhinitis, but they serve different purposes depending on symptom severity. FFNS is ideal for long-term management, offering consistent relief for mild to moderate cases and preventing symptom recurrence. It is suitable for long-term use without significant risk of adverse effects. In contrast, FFONS provides rapid relief, especially for severe congestion or acute episodes, making it suitable for immediate symptom relief. Healthcare providers must consider the patient's specific needs, including medical history and any underlying conditions like hypertension, when selecting the appropriate therapy. Further long-term research is necessary to assess the sustained benefits and effects of both treatments.

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