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Original Research Article

Efficacy of Budesonide Nasal Irrigation as Adjunct Therapy in Moderate to Severe Allergic Rhinitis: A Prospective Randomized Controlled Study

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Conflict of interest: Nil

Abstract:

Background: Allergic rhinitis (AR) is a prevalent inflammatory disorder significantly impacting quality of life. While intranasal corticosteroid sprays remain the first-line treatment for moderate to severe AR, high-volume nasal irrigation with corticosteroids may offer enhanced mucosal drug delivery. This study aimed to evaluate the efficacy of budesonide nasal irrigation as adjunct therapy compared to standard oral medical treatment alone in patients with moderate to severe allergic rhinitis.

Materials and Methods: This prospective randomized controlled study was conducted at Government Medical College, Dungarpur, Rajasthan from July 2023 to August 2024. Sixty patients with moderate to severe allergic rhinitis (ARIA classification) were randomized into two groups: Group A (n=30) received oral medical therapy plus budesonide nasal irrigation (1.5 mg budesonide in 250 mL saline, thrice daily), while Group B (n=30) received oral medical therapy alone. Outcomes were assessed using the Sino-Nasal Outcome Test-22 (SNOT-22) and Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire (NRQLQ) at baseline, 1, 2, 3, and 6 months.

Results: Both groups demonstrated significant improvement in SNOT-22 scores over time ($p<0.001$). However, the budesonide irrigation group showed significantly greater reduction in SNOT-22 scores (mean reduction: 37.96 ± 8.2 vs 27.03 ± 6.8; $p=0.001$) and NRQLQ scores (mean reduction: 34.08 ± 7.6 vs 25.64 ± 5.9; $p=0.001$) at 6 months follow-up. The success rate (defined as ≥50% improvement in SNOT-22) was significantly higher in Group A (83.3%) compared to Group B (60.0%; $p=0.039$). No significant adverse effects were observed in either group.

Conclusion: Budesonide nasal irrigation as adjunct therapy provides significantly superior symptom relief and quality of life improvement compared to oral medical therapy alone in patients with moderate to severe allergic rhinitis. This cost-effective intervention should be considered as a valuable addition to the standard treatment protocol.

Keywords: Allergic rhinitis; Budesonide; Nasal irrigation; SNOT-22; Quality of life; ARIA classification.

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Introduction

Allergic rhinitis (AR) is a chronic inflammatory disorder of the nasal mucosa characterized by IgE-mediated hypersensitivity reactions to inhaled allergens. It is clinically defined by the presence of two or more symptoms including rhinorrhea, sneezing, nasal obstruction, and nasal itching occurring for more than one hour on most days. [1] The condition affects approximately 10-30% of the global population and represents a significant public health burden due to its impact on productivity, sleep quality, and overall quality of life. [2]

The Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines, first published in 2001 and subsequently updated, revolutionized the classification of AR by categorizing it based on symptom duration (intermittent vs persistent) and severity (mild vs moderate-severe).[3] This classification scheme has been adopted worldwide and provides a practical framework for treatment decision-making. According to ARIA, moderate-severe AR is characterized by the presence of troublesome symptoms affecting sleep, daily activities, or work/school performance.[4]

In India, the prevalence of AR ranges from 20-30%, with increasing trends observed in both adult and pediatric populations.[5] The International Study for Asthma and Allergies in Childhood (ISAAC) reported that approximately 14.6% of adolescents aged 13-14 years were affected in India.[6] The economic burden of AR is substantial, with studies indicating that 36% of affected individuals report reduced work productivity, and approximately 3.6% miss work days due to their symptoms.[7]

The pathophysiology of AR involves a complex interplay between allergen exposure, IgE-mediated mast cell activation, and subsequent release of inflammatory mediators including histamine, prostaglandins, and leukotrienes.[8] The inflammatory cascade results in early-phase symptoms (sneezing, rhinorrhea, itching) within minutes of allergen exposure, followed by late-phase reactions characterized by persistent nasal congestion occurring 4-8 hours later due to eosinophilic infiltration and tissue remodeling. [9]

Current treatment strategies for AR encompass allergen avoidance, pharmacotherapy, and immunotherapy. Pharmacological options include oral antihistamines, intranasal corticosteroids, leukotriene receptor antagonists, and decongestants. [10] Intranasal corticosteroids remain the most effective pharmacological treatment for moderate to severe AR, demonstrating superior efficacy compared to antihistamines in controlling nasal symptoms. [11] However, optimal drug delivery to the nasal mucosa remains challenging with conventional spray formulations.

Nasal saline irrigation has emerged as a valuable adjunctive therapy in AR management. This technique, rooted in the ancient Ayurvedic practice of "Jala Neti," involves high-volume, low-pressure lavage of the nasal cavities with saline solution. [12] Nasal irrigation mechanically removes allergens, mucus, and inflammatory mediators while improving mucociliary clearance. [13] Systematic reviews have confirmed its efficacy in reducing symptoms and improving quality of life in AR patients. [14]

The addition of corticosteroids to nasal irrigation solutions represents an innovative approach to enhance topical drug delivery. Budesonide, a potent glucocorticoid with 1000-fold greater anti-inflammatory activity than cortisol, has been investigated as an additive to nasal irrigation. [15] High-volume irrigation delivers corticosteroids to areas not reached by conventional sprays, including the paranasal sinuses and posterior nasal cavity. [16] Studies in chronic rhinosinusitis have demonstrated superior outcomes with budesonide irrigation compared to sprays alone. [17]

The mechanism of action of budesonide involves binding to intracellular glucocorticoid receptors, leading to modulation of gene transcription and subsequent reduction in inflammatory mediator synthesis. Budesonide reduces vascular permeability, inhibits leukocyte chemotaxis, and decreases neuropeptide-mediated responses, thereby addressing multiple pathophysiological pathways in AR. [18] Its high first-pass hepatic metabolism results in minimal systemic bioavailability, making it suitable for topical nasal administration. [19]

Quality of life assessment has become increasingly important in AR research. Patient-reported outcome measures such as the Sino-Nasal Outcome Test-22 (SNOT-22) and Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) provide comprehensive evaluation of symptom burden and functional impairment. [20,21] The SNOT-22 is a validated 22-item questionnaire that assesses sino-nasal symptoms, with total scores ranging from 0 to 110, where higher scores indicate greater symptom severity. [22] The Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire (NRQLQ) specifically evaluates sleep-related symptoms and quality of life in patients with allergic rhinitis. [23]

Despite promising evidence from chronic rhinosinusitis literature, prospective randomized controlled trials specifically evaluating budesonide nasal irrigation in allergic rhinitis remain limited. [24] The present study was therefore designed to prospectively evaluate the efficacy of budesonide nasal irrigation as adjunct therapy to standard oral medical treatment in patients with moderate to severe allergic rhinitis.

Aim and Objectives

Aim: To evaluate the efficacy of budesonide nasal irrigation as adjunct therapy to oral medical treatment compared to oral medical treatment alone in patients with moderate to severe allergic rhinitis at Government Medical College, Dungarpur.

Objectives:

1. To compare the changes in SNOT-22 scores between the budesonide nasal irrigation group and oral medical therapy group at baseline, 1, 2, 3, and 6 months follow-up.
2. To compare the changes in Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire (NRQLQ) scores between the two groups.
3. To evaluate the treatment success rate (≥50% improvement in SNOT-22) in both groups.
4. To assess the impact of budesonide nasal irrigation on mucosal edema through diagnostic nasal endoscopy.
5. To evaluate the safety profile and adverse effects of budesonide nasal irrigation.
6. To identify prognostic factors associated with treatment response in both groups.

Materials and Methods

Study Design: This was a prospective randomized controlled study conducted at the Department of ENT and Head & Neck Surgery, Government Medical College, Dungarpur, Rajasthan, India, from July 2023 to August 2024. The study protocol was approved by the Institutional Ethics Committee and informed written consent was obtained from all participants prior to enrollment.

Study Population: A total of 60 patients with moderate to severe allergic rhinitis as per ARIA classification were enrolled in the study. Patients were randomized into two groups using computer-generated random numbers: Group A (Budesonide Irrigation Group, n=30) received oral medical therapy plus budesonide nasal irrigation, while Group B (Control Group, n=30) received oral medical therapy alone.

Inclusion Criteria

- Patients aged 18-60 years
- Moderate to severe intermittent or persistent allergic rhinitis as per ARIA guidelines
- Presence of at least one of: sleep disturbance, impairment of daily activities, or troublesome symptoms
- Willingness to comply with the treatment protocol and follow-up schedule

Exclusion Criteria

- Previous nasal surgery
- Nasal polyps, significant septal deviation, or other structural abnormalities
- Chronic rhinosinusitis or acute upper respiratory tract infection
- Known hypersensitivity to budesonide
- Pregnancy or lactation
- Severe systemic comorbidities or immunocompromised state

Treatment Protocol: Both groups received standard oral medical therapy consisting of: oral antihistamines (levocetirizine 5 mg or loratadine 10 mg once daily), leukotriene receptor antagonist (montelukast 10 mg once daily), intranasal corticosteroid spray (fluticasone furoate or mometasone furoate, 2 sprays per nostril once daily), and short-term topical decongestants (xylometazoline 0.1% for maximum 5 days) as needed.

In Group A, patients additionally received budesonide nasal irrigation. Three respules of budesonide (each containing 0.5 mg/2 mL, total 1.5 mg) were added to 250 mL of isotonic saline solution. Patients were instructed to perform nasal irrigation using a 20 mL syringe, irrigating each nasal cavity with 125 mL of the solution. Irrigation was performed three times daily at approximately 7:00 AM, 12:00 PM, and 8:00 PM.

Outcome Assessment: Patients were followed up at 1 month, 2 months, 3 months, and 6 months post-treatment initiation. The primary outcome measure was the Sino-Nasal Outcome Test-22 (SNOT-22), a validated 22-item questionnaire assessing nasal symptoms, sleep quality, and quality of life. [22] Each item is scored from 0 (no problem) to 5 (problem as bad as it can be), with total scores ranging from 0 to 110. The secondary outcome measure was the Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire (NRQLQ). [23]

Statistical Analysis: Statistical analysis was performed using SPSS version 26.0 (IBM Corporation, Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD) and compared using independent samples t-test. Categorical variables were expressed as frequencies and percentages and compared using Chi-square test or Fisher's exact test. Repeated measures ANOVA was used to analyze changes over time and between groups. Treatment success was defined as ≥50% reduction in SNOT-22 score. A p-value <0.05 was considered statistically significant.

Results

A total of 60 patients with moderate to severe allergic rhinitis were enrolled & completed the study.

Demographic and Clinical Characteristics: The baseline demographic and clinical characteristics of both groups are summarized in Table 1. There were no statistically significant differences between the groups in terms of age, sex distribution, symptom profile, or baseline scores, indicating adequate randomization.

Table 1: Demographic and Clinical Characteristics of Study Population

Parameter	Group A (Budesonide) n=30	Group B (Control) n=30	p-value
Age (years), Mean ± SD	35.8 ± 10.6	34.2 ± 11.2	0.572
Sex (Male:Female)	13:17	14:16	0.795
Abnormal Sleep	11 (36.7%)	13 (43.3%)	0.598
Impairment of Daily Activities	12 (40.0%)	14 (46.7%)	0.602
Troublesome Symptoms	9 (30.0%)	10 (33.3%)	0.781
Mucosal Edema on DNE	15 (50.0%)	14 (46.7%)	0.796
Baseline SNOT-22, Mean ± SD	79.8 ± 8.4	81.2 ± 7.9	0.508
Baseline NRQLQ, Mean ± SD	77.4 ± 5.2	78.1 ± 4.8	0.586

SD: Standard Deviation; DNE: Diagnostic Nasal Endoscopy; SNOT-22: Sino-Nasal Outcome Test-22; NRQLQ: Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire.

SNOT-22 Outcomes: The changes in SNOT-22 scores over time are presented in Table 2. Both groups demonstrated significant improvement from baseline ($p<0.001$). However, Group A showed significantly greater improvement at all follow-up time points compared to Group B.

Table 2: SNOT-22 Scores at Different Time Points

Time Point	Group A Mean ± SD	Group B Mean ± SD	p-value
Pre-treatment	79.8 ± 8.4	81.2 ± 7.9	0.508
1 Month	66.4 ± 6.2	73.8 ± 7.4	0.001*
2 Months	57.2 ± 6.8	66.5 ± 7.2	<0.001*
3 Months	48.6 ± 8.2	59.8 ± 7.6	<0.001*
6 Months	41.8 ± 9.4	54.2 ± 8.2	<0.001*
Mean Reduction	37.96 ± 8.2	27.03 ± 6.8	0.001*

*Statistically significant ($p<0.05$); Repeated measures ANOVA: $F = 892.4$, $p<0.001$ (change with time); $F = 28.6$, $p<0.001$ (time × group interaction)

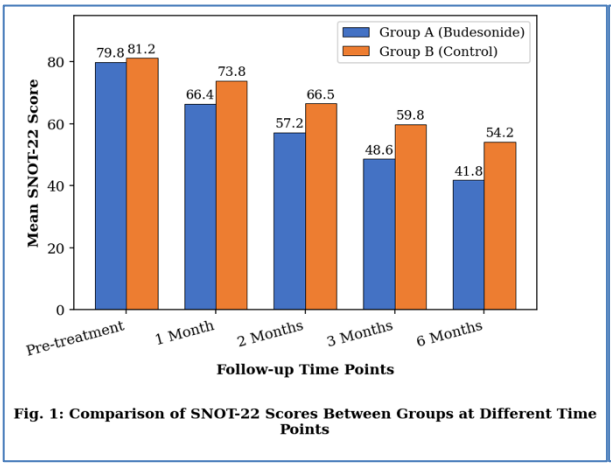

Fig. 1: Comparison of SNOT-22 Scores Between Groups at Different Time Points

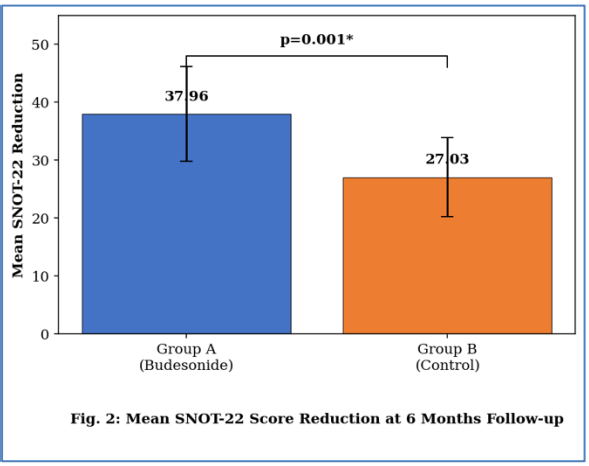

Fig. 2: Mean SNOT-22 Score Reduction at 6 Months Follow-up

Treatment success, defined as ≥50% reduction in SNOT-22, was achieved in 25 patients (83.3%) in Group A compared to 18 patients (60.0%) in Group B. This difference was statistically significant ($p=0.039$), demonstrating that budesonide nasal irrigation yields superior outcomes.

NRQLQ Outcomes: Similar patterns were observed for NRQLQ scores (Table 3). Group A demonstrated significantly greater improvement in quality of life measures compared to Group B at all follow-up visits.

Table 3: NRQLQ Scores at Different Time Points

Time Point	Group A Mean ± SD	Group B Mean ± SD	p-value
Pre-treatment	77.4 ± 5.2	78.1 ± 4.8	0.586
1 Month	65.8 ± 4.9	71.2 ± 4.4	0.001*
2 Months	56.4 ± 5.8	64.6 ± 5.2	<0.001*
3 Months	47.2 ± 7.4	57.8 ± 5.6	<0.001*
6 Months	43.3 ± 9.2	52.5 ± 7.1	<0.001*
Mean Reduction	34.08 ± 7.6	25.64 ± 5.9	0.001*

*Statistically significant ($p<0.05$); Repeated measures ANOVA: $F = 786.2$, $p<0.001$ (change with time); $F = 24.8$, $p<0.001$ (time × group interaction)

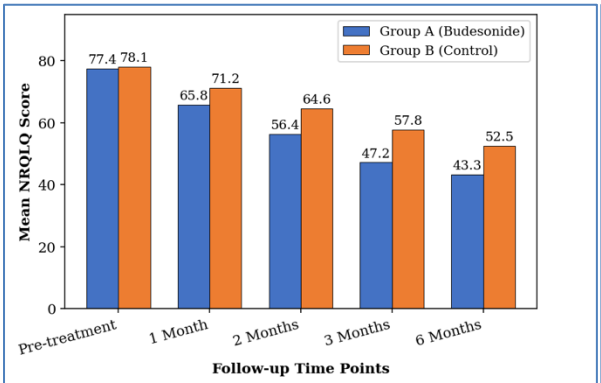

Fig. 3: Comparison of NRQLQ Scores Between Groups at Different Time Points

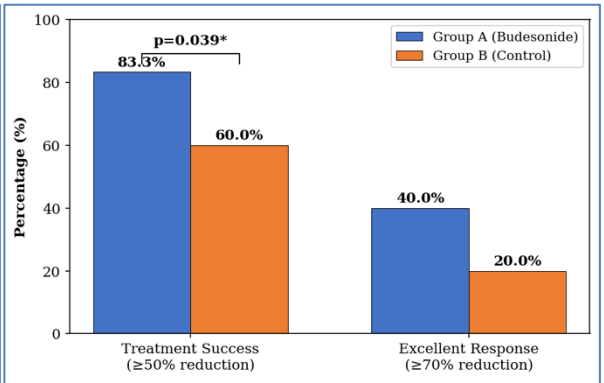

Fig. 4: Treatment Success Rates Between Groups

Treatment Success and Prognostic Factors: Treatment success, defined as ≥50% reduction in SNOT-22 score from baseline, was achieved in 25 patients (83.3%) in Group A compared to 18 patients (60.0%) in Group B. This difference was statistically significant (p=0.039). Univariate analysis identified budesonide irrigation (OR 3.33; 95% CI 1.02-10.89; p=0.046), younger age (OR 2.18; 95% CI 0.72-6.62; p=0.168), and absence of mucosal edema at baseline (OR 2.45; 95% CI 0.82-7.32; p=0.108) as factors associated with treatment success.

Table 4: Prognostic Factors for Successful Treatment Outcomes (Univariate Analysis)

Factor	Odds Ratio	95% CI	p-value
Budesonide vs Control	3.33	1.02-10.89	0.046*
Age <40 vs ≥40 years	2.18	0.72-6.62	0.168
No Mucosal Edema vs Edema	2.45	0.82-7.32	0.108
Male vs Female	1.28	0.44-3.72	0.648
No Sleep Disturbance vs Sleep Disturbance	1.86	0.62-5.58	0.268

CI: Confidence Interval; *Statistically significant (p<0.05)

Table 5: Adverse Effects

Adverse Effect	Group A (n=30)	Group B (n=30)	p-value
Nasal Dryness/Irritation	3 (10.0%)	2 (6.7%)	0.640
Epistaxis	2 (6.7%)	1 (3.3%)	0.554
Headache	1 (3.3%)	1 (3.3%)	1.000
Total Adverse Events	6 (20.0%)	4 (13.3%)	0.488

No cases of systemic corticosteroid effects or serious adverse events were observed in either group.

Discussion

The present prospective randomized controlled study demonstrates that budesonide nasal irrigation as adjunct therapy provides significantly superior symptom relief and quality of life improvement compared to oral medical therapy alone in patients with moderate to severe allergic rhinitis. The budesonide irrigation group achieved a treatment success rate of 83.3% compared to 60.0% in the control group (p=0.039), with significantly greater reductions in both SNOT-22 and NRQLQ scores at all follow-up time points.

Our findings are consistent with the growing body of evidence supporting the use of high-volume corticosteroid irrigation in inflammatory sinonasal disease. Ishak et al. [25] in their randomized controlled trial of 99 patients with allergic rhinitis demonstrated significant improvements in SNOT-22 scores and nasal endoscopy findings with budesonide nasal irrigation compared to saline irrigation alone. The mean SNOT-22 improvement in their budesonide group (13.93 points) was substantially lower than our observed reduction (37.96 points), possibly reflecting differences in baseline severity, treatment duration, and irrigation protocols.

Periasamy et al. [26] conducted a similar prospective study comparing budesonide in buffered hypertonic saline versus hypertonic saline alone in 52 AR patients. They reported a 71.86% improvement in SNOT-22 scores in the budesonide group compared to 55.23% in the saline group (p=0.012). Our results align with their findings, with the budesonide group demonstrating approximately 47.6% mean reduction in SNOT-22 scores

compared to 33.3% in the control group at 6 months follow-up.

The mechanism underlying the superior efficacy of budesonide irrigation compared to conventional treatment likely relates to enhanced drug delivery to the nasal mucosa and paranasal sinuses. Harvey et al. [17] demonstrated that high-volume irrigation delivers significantly more corticosteroid to the sinuses than spray formulations in post-surgical patients. The irrigation technique provides mechanical clearance of allergens, mucus, and inflammatory mediators while simultaneously depositing topical corticosteroid across a larger mucosal surface area.

The improvements in NRQLQ scores observed in our study highlight the impact of budesonide irrigation on sleep-related symptoms and quality of life. Sleep disturbance is a significant contributor to AR morbidity, affecting cognitive function, daytime performance, and overall well-being. [27] Abdelhafeez et al. [28] similarly reported significant improvements in NRQLQ domains with intranasal corticosteroid therapy, supporting the importance of effective symptom control for sleep quality.

The safety profile of budesonide nasal irrigation in our study was excellent, with no significant difference in adverse event rates between groups. This finding is reassuring given concerns about systemic corticosteroid absorption from high-volume irrigation. Thanneru et al. [29] reported similar safety in their evaluation of budesonide irrigation in post-FESS patients with allergic rhinosinusitis. Budesonide's high first-pass metabolism results in minimal systemic bioavailability (<10%), making it particularly suitable for topical nasal administration. [19]

Our univariate analysis identified budesonide irrigation as a significant predictor of treatment success (OR 3.33; p=0.046). While younger age and absence of baseline mucosal edema showed trends toward better outcomes, these did not reach statistical significance. The clinical implications of our findings are substantial. Budesonide nasal irrigation offers a cost-effective addition to standard AR treatment that can be performed by patients at home with minimal training.

This study has several limitations. First, the sample size of 60 patients may limit generalizability and subgroup analyses. Second, the 6-month follow-up period may not capture long-term outcomes. Third, objective measures such as nasal airflow assessment or inflammatory biomarkers were not included. Fourth, the open-label design introduces potential performance bias. Future research should focus on longer-term follow-up studies to assess durability of treatment effects and comparative studies evaluating different budesonide concentrations and irrigation frequencies.

Conclusion

Budesonide nasal irrigation as adjunct therapy demonstrates significantly superior efficacy compared to oral medical therapy alone in patients with moderate to severe allergic rhinitis. The treatment success rate was 83.3% in the budesonide irrigation group versus 60.0% in the control group. Both SNOT-22 and NRQLQ scores showed significantly greater improvement with budesonide irrigation at all follow-up time points. The intervention is safe, cost-effective, and can be easily performed by patients at home. Based on these findings, budesonide nasal irrigation should be considered as a valuable adjunctive therapy in the management of moderate to severe allergic rhinitis, particularly in patients with inadequate response to conventional pharmacotherapy.

Conflict of Interest

The authors declare that they have no conflicts of interest. No financial or personal relationships exist that could have influenced the work reported in this paper.

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