International Journal of Medicine
pISSN 1468-3814 | eISSN 2667-7008
https://theinternationalmedicine.com/

Original Researcher Article *DOI: 10.61336/im/26-2-12*

Effectiveness of Steroid Nasal Irrigation Versus Normal Saline Nasal Irrigation in Postoperative Management of Endoscopic Sinus Surgery: A Prospective Randomized Comparative Study

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Received: **February 09, 2026**
Revised: **February24, 2026**
Accepted: **March 17, 2026**
Published: **March 30, 2026**

Abstract

Background: Chronic rhinosinusitis (CRS) is a prevalent inflammatory condition of the paranasal sinuses that significantly impairs quality of life. Endoscopic sinus surgery (ESS) is the standard surgical treatment for medically refractory CRS. Postoperative nasal irrigation is essential for mucosal healing, and the addition of topical corticosteroids to irrigation solutions has emerged as a promising adjunctive strategy. However, evidence regarding the superiority of steroid nasal irrigation over plain saline in the postoperative setting remains limited, particularly in resource-constrained settings. ***Objectives:*** To compare the effectiveness of budesonide nasal irrigation versus normal saline nasal irrigation in the postoperative management of patients undergoing ESS for CRS. ***Materials and Methods:*** This prospective, randomized, comparative study enrolled 80 adult patients with CRS who underwent ESS at a tertiary care center in rural Telangana, India. Patients were randomized into two groups of 40 each: Group A received budesonide (0.5 mg/2 ml) mixed with normal saline irrigation twice daily, while Group B received plain normal saline irrigation. Outcomes were assessed at 2 weeks and 2 months postoperatively using the Sino-Nasal Outcome Test-22 (SNOT-22), Lund-Kennedy Endoscopic Score (LKES), crust formation grading, compliance, and adverse effect profiles. ***Results:*** Both groups were comparable at baseline for age, gender, and symptom duration ($p>0.05$). The steroid group demonstrated significantly lower SNOT-22 scores at both 2 weeks (24.95 ± 8.38 vs. 37.90 ± 4.30; $t=7.812$, $p<0.001$) and 2 months (17.75 ± 6.39 vs. 28.53 ± 3.57; $t=8.534$, $p<0.001$). LKES improvement was significantly greater in the steroid group at 2 weeks ($\chi^2=56.000$, $p<0.001$) and 2 months ($\chi^2=52.571$, $p<0.001$), despite worse baseline endoscopic scores. Crust formation was significantly reduced in the steroid group at both time points ($p<0.05$). Adverse effects were comparable between groups ($\chi^2=0.394$, $p=0.821$). ***Conclusion:*** Budesonide nasal irrigation is significantly superior to plain normal saline irrigation in improving subjective symptoms, endoscopic healing, and crust reduction following ESS, with a comparable safety profile. It can be recommended as a routine adjunctive measure in postoperative ESS management.

Keywords: Chronic rhinosinusitis, Endoscopic sinus surgery, Budesonide, Nasal irrigation, SNOT-22, Lund-Kennedy score, Postoperative management.

INTRODUCTION

Chronic rhinosinusitis (CRS) is one of the most common chronic inflammatory conditions worldwide, affecting approximately 5–12% of the general population and imposing a substantial burden on healthcare systems and patient quality of life (Fokkens et al. (2012)[1]). The condition is characterized by persistent inflammation of the nasal and paranasal sinus mucosa lasting at least 12 weeks, manifesting as nasal obstruction, mucopurulent discharge, facial pain, and olfactory dysfunction. International consensus guidelines have established comprehensive frameworks for the diagnosis and management of CRS, emphasizing stepwise treatment approaches that progress from medical to surgical interventions (Orlandi et al. (2016)[18]).

Endoscopic sinus surgery (ESS) has become the gold standard surgical approach for medically refractory CRS since its introduction by Stammberger and Posawetz (1990)[19]. The procedure aims to restore sinus ventilation and mucociliary clearance by removing obstructive tissue and widening sinus ostia. Multiple studies have demonstrated significant improvements in patient-reported outcomes and quality of life following ESS (Soler and Smith (2010)[20]). However, the postoperative period is critical for optimal outcomes, as inadequate mucosal healing can lead to recurrence, adhesion formation, and persistent symptoms.

Nasal saline irrigation is universally recommended as a cornerstone of postoperative care after ESS. The mechanical action of high-volume irrigation facilitates removal of blood clots, crusts, and inflammatory debris, thereby promoting mucosal healing. Harvey et al. (2008)[2] demonstrated that post-surgical sinus cavities exhibit significantly improved penetration of irrigant solutions compared to unoperated sinuses. Grobler et al. (2008)[3] further confirmed that high-volume, low-pressure delivery devices achieve superior sinus penetration relative to nasal sprays, establishing the rationale for large-volume irrigation protocols.

The addition of topical corticosteroids to nasal irrigation solutions represents a logical therapeutic extension, combining the mechanical benefits of saline lavage with the anti-inflammatory properties of corticosteroids delivered directly to the sinus mucosa. Rudmik (2014)[4] reviewed the safety and efficacy of high-volume budesonide irrigations for CRS, reporting favorable outcomes with minimal systemic absorption. A landmark systematic review and meta-analysis by Snidvongs et al. (2013)[5] demonstrated that corticosteroid irrigations delivered after sinus surgery significantly improved outcomes compared to non-steroid irrigations, particularly when administered via high-volume delivery systems.

Despite growing evidence supporting steroid nasal irrigation, most studies have been conducted in tertiary urban centers in developed countries, and data from resource-constrained rural settings remain scarce. This study was undertaken at a tertiary care institution in rural Telangana, India, where CRS is highly prevalent due to occupational dust exposure, environmental pollutants, and limited access to specialist care. The aim of this study was to compare the effectiveness of budesonide nasal irrigation versus plain normal saline nasal irrigation in the postoperative management of ESS, evaluating both subjective symptomatic relief and objective endoscopic outcomes, with attention to the affordability and accessibility implications for underserved populations.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomized, comparative study was conducted in the Department of Otorhinolaryngology, Rajiv Gandhi Institute of Medical Sciences (RIMS), Adilabad, Telangana, India, a tertiary care teaching hospital serving a predominantly rural population. The study was carried out over a period of 18 months.

Sample Size and Randomization

A total of 80 adult patients (aged ≥18 years) diagnosed with CRS who had failed maximal medical management and were scheduled for elective ESS were enrolled. Patients were randomized into two equal groups of 40 each using a computer-generated random number table. Group A (intervention) received budesonide respules (0.5 mg/2 ml) mixed with 240 ml of normal saline administered via a high-volume nasal irrigation bottle twice daily beginning on postoperative day one. Group B (control) received plain normal saline (240 ml) via the same irrigation device at the same frequency and duration.

Inclusion Criteria

Patients aged 18 years or older with a clinical and radiological diagnosis of CRS who had failed adequate medical management and were scheduled for elective ESS were included. Written informed consent was mandatory for enrollment.

Exclusion Criteria

Patients below 18 years of age, those unwilling to participate, those undergoing surgery for cerebrospinal fluid leak closure, patients with systemic comorbidities (diabetes mellitus, hypertension, immunocompromised states, or malignancy), those receiving concomitant oral corticosteroids, and patients with known hypersensitivity to corticosteroids were excluded from the study.

Outcome Measures

The primary outcome measures included the Sino-Nasal Outcome Test-22 (SNOT-22) for subjective symptom assessment and the Lund-Kennedy Endoscopic Score (LKES) for objective endoscopic evaluation. Secondary outcomes included the degree of crust formation (graded as absent, minimal, mild, moderate, or severe), patient compliance with the irrigation regimen (graded as excellent, good, or fair), and adverse effects (epistaxis, mild irritation, or none). All outcomes were assessed at 2 weeks and 2 months postoperatively. The clinician performing the LKES assessment was blinded to the group allocation.

Statistical Analysis

Data were analyzed using appropriate statistical methods. Continuous variables were expressed as mean ± standard deviation (SD) and compared using the paired t-test (within-group comparisons) and independent samples t-test (between-group comparisons). Categorical variables were expressed as frequencies and percentages and compared using the chi-square test. A p-value of less than 0.05 was considered statistically significant.

Ethical Statement

This study was approved by the Institutional Ethics Committee of Rajiv Gandhi Institute of Medical Sciences, Adilabad, Telangana, India. Written informed consent was obtained from all participants. The study was conducted in accordance with the Declaration of Helsinki

RESULTS

Demographic Profile and Baseline ComparabilityA total of 80 patients were enrolled and completed the study, with 40 patients in each group. The two groups were comparable with respect to baseline demographic and clinical characteristics. The mean age in the saline group was 35.57 ± 7.13 years and in the steroid group was 35.67 ± 7.34 years (t=0.061, p=0.951). Gender distribution was equal, with 50% males and 50% females in both groups (χ^2=0.000, p=1.000). The mean duration of symptoms was 13.38 ± 4.10 months in the saline group and 14.55 ± 4.96 months in the steroid group (t=1.412, p=0.162), confirming that there was no statistically significant difference between the groups at baseline.

SNOT-22 Scores Both groups showed significant within-group improvement in SNOT-22 scores from 2 weeks to 2 months (p<0.001 for both). However, the steroid group demonstrated significantly lower (better) SNOT-22 scores compared to the saline group at both time points. At 2 weeks, the mean SNOT-22 score in the steroid group was 24.95 ± 8.38 compared to 37.90 ± 4.30 in the saline group (t=7.812, p<0.001). At 2 months, the steroid group scored 17.75 ± 6.39 versus 28.53 ± 3.57 in the saline group (t=8.534, p<0.001). The between-group differences are presented in Table 1.

Table 1: Between-group Comparison of SNOT-22 Scores

Time Point	Saline Group (Mean ± SD)	Steroid Group (Mean ± SD)	t-value	p-value
2 Weeks	37.90 ± 4.30	24.95 ± 8.38	7.812	<0.001*
2 Months	28.53 ± 3.57	17.75 ± 6.39	8.534	<0.001*

*Statistically significant (p<0.05); SD = Standard Deviation

Lund-Kennedy Endoscopic Scores

Notably, baseline LKES were significantly worse in the steroid group, with 20% of patients scoring >16 compared to none in the saline group (χ^2=6.929, p=0.031). Despite this baseline disadvantage, the steroid group demonstrated markedly superior endoscopic improvement at both follow-up points. At 2 weeks, 50% of the steroid group achieved scores ≤5 compared to only 2.5% in the saline group, while 50% of the saline group still had scores ≥10 compared to 20% in the steroid group (χ^2=23.914, p<0.001). The magnitude of improvement was significantly greater in the steroid group: all saline patients improved by 3–4 points, whereas 90% of steroid patients achieved ≥5 points of improvement at 2 weeks (χ^2=56.000, p<0.001). By 2 months, 80% of steroid patients had achieved ≥7 points of improvement compared to all saline patients remaining at 5–6 points of improvement (χ^2=52.571, p<0.001), as shown in Table 2.

Table 2: Lund-Kennedy Improvement Scores at 2 Weeks and 2 Months

Time Point	Improvement	Saline n (%)	Steroid n (%)	χ^2	p-value
2 Weeks	3–4 points	40 (100%)	4 (10%)	56.000	<0.001*
	≥5 points	0 (0%)	36 (90%)		
2 Months	5–6 points	40 (100%)	8 (20%)	52.571	<0.001*
	≥7 points	0 (0%)	32 (80%)		

*Statistically significant (p<0.05)

Crust Formation

Crust formation was significantly less severe in the steroid group at both time points. At 2 weeks, moderate crusting was observed in 55% of saline patients versus 32.5% in the steroid group, while minimal crusting was seen in 17.5% of the steroid group and none in the saline group (χ^2=4.109, p=0.043). By 2 months, 27.5% of steroid patients had absent crusting compared to none in the saline group, while 27.5% of saline patients still had moderate crusting versus none in the steroid group (χ^2=18.602, p<0.001). The detailed comparison is presented in Table 3.

Table 3: Crust Formation Comparison Between Groups

Time Point	Crust Grade	Saline n (%)	Steroid n (%)	χ^2	p-value
2 Weeks	Minimal	0 (0%)	7 (17.5%)	4.109	0.043*
	Mild	18 (45%)	20 (50%)		
	Moderate	22 (55%)	13 (32.5%)		
2 Months	Absent	0 (0%)	11 (27.5%)	18.602	<0.001*
	Minimal	29 (72.5%)	29 (72.5%)		
	Moderate	11 (27.5%)	0 (0%)		

*Statistically significant (p<0.05)

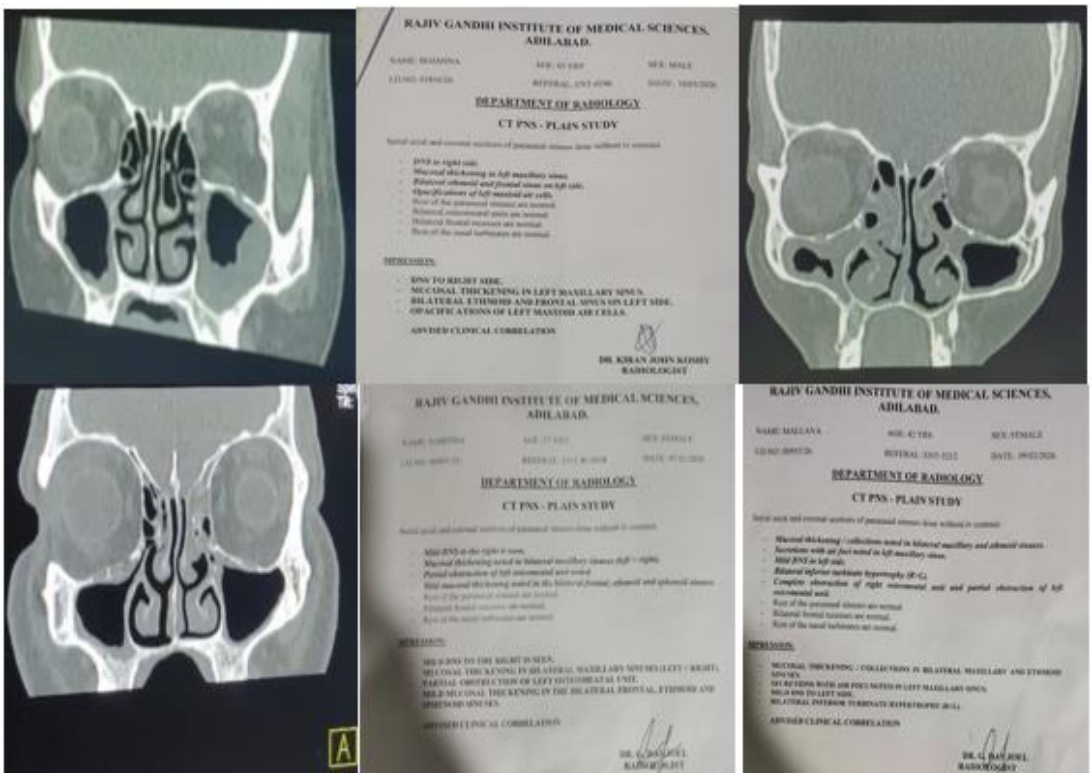
Compliance and Adverse Effects

Compliance was significantly better in the steroid group, with 17.5% reporting excellent compliance compared to 5% in the saline group (χ^2=6.207, p=0.045). Good compliance was comparable at 65% in both groups, while fair compliance was higher in the saline group (30% vs. 17.5%). Adverse effects were comparable between the groups (χ^2=0.394, p=0.821): epistaxis occurred in 7.5% of both groups, mild irritation in 2.5% of the saline group and 7.5% of the steroid group, and 90% of saline patients and 85% of steroid patients reported no adverse effects. The compliance and adverse effect data are summarized in Table 4.

Table 4: Compliance and Adverse Effects

Parameter	Category	Saline n (%)	Steroid n (%)	χ^2	p-value
Compliance	Excellent	2 (5%)	7 (17.5%)	6.207	0.045*
	Good	26 (65%)	26 (65%)		
	Fair	12 (30%)	7 (17.5%)		
Adverse Effects	Scanty blood tinged discharge	3 (7.5%)	3 (7.5%)	0.394	0.821
	Mild Irritation	1 (2.5%)	3 (7.5%)		
	None	36 (90%)	34 (85%)		

*Statistically significant (p<0.05)



DISCUSSION

The present study demonstrates that budesonide nasal irrigation is significantly superior to plain normal saline irrigation in improving both subjective symptoms and objective endoscopic outcomes following ESS for CRS. These findings contribute to the growing body of evidence supporting the incorporation of topical corticosteroid irrigations into routine postoperative management protocols.

The significant improvement in SNOT-22 scores observed in the steroid group is consistent with several published studies. Grover et al. (2022)[7] reported significant SNOT-22 improvement with high-volume budesonide irrigation in post-ESS patients with CRS, with and without nasal polyposis. Similarly, Thanneru et al. (2020)[8] demonstrated the superiority of

budesonide irrigations in patients with chronic allergic rhinosinusitis with polyps after ESS. Deva (2023)[9] compared conventional nasal douching with corticosteroid nasal douching in post-surgical CRS patients and reported significant symptomatic improvement in the steroid group. Most recently, Balasubramanya et al. (2024)[10] conducted a double-blinded randomized controlled trial comparing budesonide and saline nasal rinses and confirmed the superiority of budesonide in postoperative symptom control. A meta-analysis by Mattos et al. (2018)[16] comprehensively evaluated SNOT-22 outcomes after ESS and established the clinically meaningful improvement thresholds that provide context for interpreting our results.

The endoscopic outcomes in our study, as measured by the Lund-Kennedy score, align with findings from prior investigations. Li et al. (2021)[11] evaluated corticosteroid irrigation after surgical cavity formation in diffuse eosinophilic CRS and reported significant endoscopic improvement. Piccirillo et al. (2018)[6] conducted a randomized clinical trial assessing the effect of budesonide added to large-volume saline sinus irrigation and demonstrated improved endoscopic outcomes in the steroid arm. A notable finding in our study is that the steroid group had significantly worse baseline LKES (χ^2=6.929, p=0.031), with 20% of patients scoring above 16 compared to none in the saline group. Despite this initial disadvantage, the steroid group achieved markedly superior endoscopic improvement at both 2 weeks and 2 months, underscoring the potent anti-inflammatory effect of topical budesonide irrigation on mucosal healing.

The safety profile of budesonide nasal irrigation observed in our study is reassuring and consistent with previously published data. Soudry et al. (2016)[14] conducted a long-term safety analysis of budesonide nasal irrigations in post-ESS patients and found no significant adverse effects on hypothalamic-pituitary-adrenal axis function, intraocular pressure, or bone mineral density. Welch et al. (2010)[15] specifically measured serum and urinary cortisol levels in patients receiving topical budesonide irrigations and confirmed the absence of significant systemic steroid absorption. In our study, adverse effects were comparable between the two groups (χ^2=0.394, p=0.821), with no serious adverse events reported, supporting the safety of this intervention.

Our findings are further supported by several systematic reviews and meta-analyses. Maniaci et al. (2023)[12] conducted a state-of-the-art systematic review on the role of corticosteroid nasal irrigations in CRS management and reported moderate-level evidence supporting their efficacy in improving both symptomatic and endoscopic outcomes. Snidvongs et al. (2013)[5] published a comprehensive meta-analysis demonstrating that sinus surgery and high-volume delivery systems significantly enhance the effectiveness of topical corticosteroids, providing strong-level evidence for post-surgical corticosteroid irrigation. Conti et al. (2024)[13] performed a systematic review of high-volume nasal irrigations with steroids for CRS and allergic rhinitis, further corroborating the benefits observed in our study. Lee et al. (2013)[17] conducted a meta-analysis specifically examining postoperative topical corticosteroids in CRS with nasal polyps, reporting significant improvements in endoscopic scores and symptom reduction.

An important consideration of the present study is its setting in rural Telangana, India, where access to specialist ENT care and advanced medications is often limited. The use of commercially available budesonide respules mixed with normal saline represents a practical, affordable, and easily implementable intervention that does not require specialized equipment beyond a standard nasal irrigation bottle. The improved compliance observed in the steroid group (17.5% excellent vs. 5% excellent in the saline group; p=0.045) may reflect the greater symptomatic relief experienced by these patients, which in turn motivates continued adherence to the irrigation regimen. These findings have important implications for resource-constrained settings where cost-effective postoperative interventions are essential.

This study has several limitations that warrant acknowledgment. First, it is a single-center study conducted at a tertiary care institution in a specific geographic region, which may limit the generalizability of the findings. Second, the sample size of 80 patients, while adequate for detecting statistically significant differences, is relatively modest. Third, the follow-up period of 2 months may be insufficient to evaluate long-term outcomes, recurrence rates, and sustained treatment effects. Fourth, while the clinician performing LKES assessment was blinded, complete double-blinding was not achieved, as patients were aware of their irrigation solution composition. Fifth, there was no stratification by disease severity or polyp status, which may confound outcome interpretation. Finally, objective measures such as imaging or mucociliary clearance assessment and monitoring of systemic steroid effects (e.g., cortisol levels) were not included. Future multicenter studies with larger sample sizes, longer follow-up, complete blinding, polyp stratification, and objective safety monitoring are recommended to confirm and extend these findings.

CONCLUSION

Budesonide nasal irrigation is significantly superior to plain normal saline nasal irrigation in the postoperative management of patients undergoing endoscopic sinus surgery for chronic rhinosinusitis. The steroid irrigation group demonstrated significantly better symptomatic relief as measured by SNOT-22 scores, superior endoscopic healing as assessed by Lund-Kennedy scores, and reduced crust formation at both 2 weeks and 2 months postoperatively. Notably, the steroid group

achieved these superior outcomes despite having worse baseline endoscopic scores, further highlighting the therapeutic potency of topical budesonide irrigation. The adverse effect profile was comparable between the groups, confirming the safety and tolerability of this intervention. Based on these findings, budesonide nasal irrigation can be recommended as a routine adjunctive measure in the postoperative management of ESS, particularly in settings where cost-effective and easily implementable interventions are needed to optimize surgical outcomes.

ETHICAL STATEMENT

This study was approved by the Institutional Ethics Committee of Rajiv Gandhi Institute of Medical Sciences, Adilabad, Telangana, India. Written informed consent was obtained from all participants. The study was conducted in accordance with the Declaration of Helsinki.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

FUNDING

This research received no specific grant from any funding agency.

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