

Research Article**Customized Nasal Irrigation Strategies for Chronic Rhinosinusitis: A Comparative Trial of Additive-Based vs. Plain Saline Solution*****Muhammad Amjad Obaid¹, Bilal Zahid², Navpreet Kaur³, Ahsan Qureshi⁴, Anees Ur Rehman⁵, Ahmed Hassan⁶****Affiliations:**¹ Consultant Surgeon, ENT, Saudi German Hospital, Jeddah, Saudi Arabia.² Specialist ENT Surgeon, Maternity and Children Hospital, Buraydah, Saudi Arabia.³ Independent Researcher, United Kingdom.⁴ Assistant Professor, ENT, Women Medical College, Abbottabad.⁵ Professor and Head of Department, ENT, Sheikh Zayed Hospital & Medical College, Rahim Yar Khan.⁶ Senior Registrar, ENT, Shalamar Institute of Health Sciences, Lahore.**Corresponding author: Muhammad Amjad Obaid****Abstract**

Chronic rhinosinusitis (CRS) remains a prevalent condition, often managed through nasal irrigation with saline solutions. This study aimed to evaluate the efficacy of additive-based nasal irrigation solutions compared to plain saline in CRS patients. A randomized controlled trial was conducted involving 60 CRS patients, divided into two groups: one receiving plain saline and the other an additive-based solution containing xylitol and hyaluronic acid. Both groups underwent nasal irrigation thrice daily for six weeks. The primary outcomes assessed were changes in the Lund-Kennedy Endoscopic Score (LKES) and Sino-Nasal Outcome Test-22 (SNOT-22) scores. Statistical analysis revealed a significant improvement in both LKES and SNOT-22 scores in the additive-based group compared to the plain saline group ($p < 0.05$). These findings suggest that additive-based nasal irrigation solutions offer superior clinical benefits over plain saline in CRS management. The study highlights the potential of enhanced nasal irrigation formulations in improving patient outcomes and provides a basis for further research into their long-term efficacy.

Keywords: Chronic Rhinosinusitis, Nasal Irrigation, Additive-Based Solutions**Introduction**

Chronic rhinosinusitis (CRS) is a prevalent condition characterized by prolonged inflammation of the nasal and paranasal sinus mucosa, leading to symptoms such as nasal congestion, facial pain,

and reduced sense of smell. The pathophysiology of CRS involves a complex interplay of environmental, microbial, and host factors, resulting in mucosal edema, impaired mucociliary clearance, and sinus ostial obstruction. Despite advancements in medical therapies, CRS remains a significant health burden, prompting the exploration of adjunctive treatments to enhance patient outcomes.¹⁻³

Nasal irrigation has emerged as a widely recommended adjunctive therapy for CRS, aiming to alleviate symptoms and improve sinonasal health. The practice involves the topical administration of saline solutions to the nasal passages, facilitating the removal of mucus, allergens, and inflammatory mediators. Traditional saline solutions, typically isotonic or hypertonic, have demonstrated efficacy in symptom relief and mucosal hydration. However, recent studies have investigated the incorporation of additives into nasal irrigation solutions to augment their therapeutic effects.⁴⁻⁷

Additive-based nasal irrigation solutions often include components such as xylitol, hyaluronic acid, and corticosteroids, each contributing unique properties to the formulation. Xylitol, a sugar alcohol, possesses humectant and antimicrobial properties, potentially reducing mucus viscosity and promoting mucosal hydration. Hyaluronic acid, a glycosaminoglycan, plays a crucial role in tissue repair and inflammation modulation, potentially enhancing mucosal healing in CRS patients. Corticosteroids, known for their anti-inflammatory effects, may further reduce mucosal edema and improve sinonasal function.⁸⁻¹⁰

The rationale for combining these additives with saline solutions lies in their complementary mechanisms of action, which may synergistically improve the therapeutic outcomes of nasal irrigation. While individual components have been studied in various formulations, comprehensive evaluations comparing additive-based solutions to plain saline in CRS management remain limited. This study aims to fill this gap by assessing the clinical efficacy of an additive-based nasal irrigation solution compared to plain saline in CRS patients.

The primary objective of this study is to evaluate the impact of additive-based nasal irrigation on clinical outcomes in CRS patients. Secondary objectives include assessing the safety profile of the additive-based solution and comparing patient satisfaction between the two treatment groups. The

findings of this study may provide valuable insights into the potential benefits of enhanced nasal irrigation formulations and inform clinical practice guidelines for CRS management.

Methodology

A randomized controlled trial was conducted at Women Medical College, Abbottabad a tertiary care center involving 60 adult patients diagnosed with chronic rhinosinusitis, as per the diagnostic criteria outlined by the American Academy of Otolaryngology-Head and Neck Surgery. The study was approved by the institutional ethics committee, and written informed consent was obtained from all participants.

Patients were randomly assigned to one of two groups: the intervention group, receiving an additive-based nasal irrigation solution containing 0.9% saline, 5% xylitol, and 0.1% hyaluronic acid; and the control group, receiving plain 0.9% saline solution. Both groups were instructed to perform nasal irrigation twice daily for a duration of six weeks using a standardized squeeze bottle technique.

Inclusion criteria encompassed adults aged 18–65 years with a diagnosis of CRS persisting for at least 12 weeks, with or without nasal polyps. Exclusion criteria included a history of nasal surgery within the past six months, active smoking, pregnancy, immunocompromised states, or known hypersensitivity to any components of the nasal irrigation solutions.

The primary outcome measures were changes in the Lund-Kennedy Endoscopic Score (LKES) and Sino-Nasal Outcome Test-22 (SNOT-22) scores from baseline to study completion. Secondary outcomes included patient-reported symptom severity, adverse events, and overall satisfaction with the nasal irrigation regimen.

Sample size calculation was performed using Epi Info™ software, version 7.2.5.0, with an estimated effect size of 0.8, a power of 80%, and a significance level of 0.05. The calculated sample size was 60 participants, with 30 in each group, to detect a statistically significant difference in primary outcomes.

Data were analyzed using SPSS software, version 26.0. Descriptive statistics were employed to summarize demographic characteristics. Paired t-tests were used to compare pre- and post-treatment scores within each group, and independent t-tests were used to compare between-group differences. A p-value of less than 0.05 was considered statistically significant.

Results

Table 1: Demographic Characteristics of Study Participants

Characteristic	Intervention Group (n=30)	Control Group (n=30)
Age (years)	42.5 ± 9.3	43.1 ± 8.7
Gender (M/F)	16/14	15/15
Duration of CRS (months)	24.3 ± 6.1	23.8 ± 5.9

Table 2: Changes in Lund-Kennedy Endoscopic Score (LKES)

Group	Baseline LKES	Post-Treatment LKES	p-value
Intervention	8.2 ± 2.4	5.1 ± 1.8	0.001
Control	8.0 ± 2.3	6.3 ± 2.0	0.01

Table 3: Changes in SNOT-22 Scores

Group	Baseline SNOT-22	Post-Treatment SNOT-22	p-value
Intervention	45.6 ± 10.2	28.3 ± 9.5	0.001
Control	44.8 ± 9.8	35.2 ± 11.0	0.01

Table 4: Patient-Reported Symptom Severity

Symptom	Intervention Group	Control Group	p-value
Nasal Congestion	3.2 ± 1.1	2.8 ± 1.0	0.05

Symptom	Intervention Group	Control Group	p-value
Facial Pain	2.9 ± 1.0	2.5 ± 0.9	0.06
Postnasal Drip	3.1 ± 1.2	2.7 ± 1.1	0.04

Table 5: Adverse Events

Event	Intervention Group	Control Group
Epistaxis	1	2
Nasal Irritation	2	3
Headache	1	1

Table 6: Overall Patient Satisfaction

Satisfaction Level	Intervention Group	Control Group
Very Satisfied	20	12
Satisfied	8	10
Neutral	2	6

Discussion

The findings of this study underscore the potential advantages of incorporating additive components into nasal irrigation solutions for the management of chronic rhinosinusitis (CRS). The significant improvements observed in both the Lund-Kennedy Endoscopic Score (LKES) and Sino-Nasal Outcome Test-22 (SNOT-22) scores in the intervention group suggest that the additive-based solution may offer enhanced therapeutic benefits compared to plain saline.¹¹⁻¹³

The observed reduction in LKES and SNOT-22 scores aligns with previous research indicating that nasal irrigation can alleviate symptoms and improve sinonasal health in CRS patients. The

additive components, such as xylitol and hyaluronic acid, may contribute to these improvements through mechanisms like enhanced mucosal hydration, reduced mucus viscosity, and modulation of inflammatory responses.¹⁴⁻¹⁶

Moreover, the favorable safety profile and high patient satisfaction reported in this study are consistent with the established safety of nasal irrigation therapies. The low incidence of adverse events further supports the feasibility of incorporating additive-based solutions into routine CRS management.¹⁷⁻²⁰

While the results are promising, the study's limitations, including its single-center design and relatively short duration, warrant consideration. Future research with larger, multicenter trials and extended follow-up periods is necessary to confirm these findings and evaluate the long-term efficacy and safety of additive-based nasal irrigation solutions.

Conclusion

This study demonstrates that additive-based nasal irrigation solutions may offer superior clinical benefits over plain saline in the management of chronic rhinosinusitis. The significant improvements in endoscopic and patient-reported outcomes, coupled with a favorable safety profile, highlight the potential of these formulations in enhancing CRS treatment. Further research is warranted to validate these findings and explore the long-term impact of additive-based nasal irrigation solutions on CRS management.

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