

## **Nasal Saline Irrigation with vs. without Additives in Chronic Rhinosinusitis: A Trial of Symptom Relief and Mucociliary Clearance.**

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### **Abstract**

Chronic rhinosinusitis (CRS) significantly impairs quality of life due to persistent inflammation and impaired mucociliary function. Nasal saline irrigation is a standard adjunctive therapy, yet the benefit of adding agents such as sodium bicarbonate or xylitol remains controversial. This randomized controlled trial evaluates the impact of nasal saline irrigation with vs. without additives on symptom relief and mucociliary clearance. A total of 120 patients with CRS were randomized equally into two groups: Group A received isotonic saline only, while Group B received saline with additives (sodium bicarbonate and xylitol). Outcomes were measured using the Sino-Nasal Outcome Test (SNOT-22) and saccharin transit time at baseline and after four weeks. Group B showed a significantly greater reduction in mean SNOT-22 score (from  $51.3 \pm 8.6$  to  $21.4 \pm 6.1$ ) compared to Group A (from  $49.7 \pm 9.1$  to  $31.2 \pm 7.9$ ) ( $p < 0.001$ ). Mucociliary clearance improved more rapidly in Group B (saccharin time reduced from  $14.2 \pm 2.5$  to  $9.1 \pm 2.2$  minutes) than Group A (from  $13.9 \pm 2.3$  to  $10.8 \pm 2.4$  minutes) ( $p < 0.001$ ). No significant adverse effects were reported. These results suggest that saline with selected additives enhances both symptom resolution and mucociliary clearance in CRS more effectively than saline alone. This

study supports the incorporation of additive-based irrigation as a superior strategy for managing chronic rhinosinusitis.

**Keywords:** Chronic Rhinosinusitis, Nasal Irrigation, Mucociliary Clearance

## **Introduction**

Chronic rhinosinusitis (CRS) is a persistent inflammatory condition of the paranasal sinuses, characterized by nasal congestion, discharge, facial pressure, and olfactory dysfunction. Affecting a substantial proportion of the adult population globally, CRS has been associated with reduced quality of life, productivity loss, and high healthcare utilization. The pathophysiology of CRS involves a complex interplay between mucosal inflammation, impaired mucociliary clearance, microbial colonization, and structural anomalies. Central to effective management is the restoration of nasal mucosal function and clearance, as well as reduction of inflammatory burden.<sup>1-3</sup>

Among non-surgical therapeutic interventions, nasal saline irrigation is widely endorsed for its mechanical role in reducing mucosal edema, clearing mucus, and improving mucociliary transport. Saline irrigation not only helps in physically flushing allergens, crusts, and pathogens from the sinonasal cavity but also enhances ciliary beat frequency, promoting physiologic mucus transport. Despite these benefits, symptom control using saline alone often remains suboptimal, especially in patients with long-standing inflammation and thickened secretions.<sup>4-6</sup>

Emerging evidence suggests that the addition of buffering agents or antimicrobial substances to nasal irrigations may offer superior therapeutic outcomes. Sodium bicarbonate has been utilized to alkalinize nasal secretions and reduce mucosal viscosity, while xylitol exhibits anti-adhesive and antimicrobial properties. These additives potentially enhance epithelial repair and reduce biofilm formation. However, clinical studies evaluating their efficacy in routine CRS management remain limited and inconsistent, with some trials demonstrating benefits while others report negligible improvement over saline alone.<sup>8-10</sup>

Mucociliary clearance, a critical physiologic defense mechanism, is frequently impaired in CRS. Saccharin transit time, a non-invasive measure of nasal ciliary function, is delayed in affected

individuals, correlating with symptom severity. Improved clearance times following effective interventions often parallel symptomatic relief. Despite the utility of this biomarker, few randomized trials have comprehensively evaluated the effect of saline additives on mucociliary function using objective measures. Existing studies are often underpowered or limited by heterogeneous formulations.

The search for an optimized irrigation solution that combines safety, cost-effectiveness, and superior mucosal response is therefore of clinical interest. While saline remains the foundational component, enhancing its efficacy through evidence-based additives may offer a simple yet impactful strategy to improve treatment outcomes in CRS patients. Moreover, the potential to reduce reliance on systemic corticosteroids or antibiotics through enhanced local therapy has implications for reducing adverse events and antimicrobial resistance.

This study was designed to evaluate the comparative effectiveness of nasal irrigation with saline versus saline plus additives in patients with CRS, focusing on two primary outcomes: symptom relief measured by the validated SNOT-22 score, and mucociliary function measured by saccharin transit time. By integrating patient-reported outcomes and objective physiologic data, this trial aims to provide clinically relevant guidance for optimizing nasal irrigation protocols in chronic rhinosinusitis management.

## **Methodology**

This prospective, randomized, parallel-arm trial was conducted at DG Khan Medical College over a four-month period in a tertiary otolaryngology clinic. A total of 120 adult patients aged 18–65 years diagnosed with chronic rhinosinusitis according to EPOS 2020 criteria were enrolled after obtaining verbal informed consent. Sample size was calculated using Epi Info software with 95% confidence level, 80% power, and an expected mean difference of 7 points in SNOT-22 scores between groups. Patients were randomly assigned to two groups using block randomization: Group A (n=60) received isotonic saline irrigation alone, and Group B (n=60) received saline with 5% sodium bicarbonate and 5% xylitol mixed per 100 mL. Irrigation was performed twice daily for four weeks using standardized squeeze bottles. Exclusion criteria included nasal polyposis, recent nasal surgery, active allergic rhinitis, systemic immunosuppression, or concurrent

antibiotic/steroid use. SNOT-22 questionnaires and saccharin transit tests were conducted at baseline and post-treatment. Mucociliary clearance was assessed by placing a 1 mm saccharin particle on the anterior inferior turbinate and recording the time to perceived sweetness. Data were analyzed using SPSS v26. Paired and unpaired t-tests were used for intra- and intergroup comparisons. A p-value <0.05 was considered statistically significant. The study protocol was approved by the institutional ethics committee.

## Results

**Table 1: Baseline Demographics and Clinical Characteristics (n = 120)**

Variable	Saline Only (n=60)	Saline + Additives (n=60)	p-value
Age (years)	41.8 ± 10.7	42.3 ± 11.1	0.77
Male (%)	31 (51.7%)	30 (50.0%)	0.85
Duration of CRS (months)	18.5 ± 6.9	19.1 ± 7.4	0.63
Baseline SNOT-22 score	49.7 ± 9.1	51.3 ± 8.6	0.28
Saccharin transit time (min)	13.9 ± 2.3	14.2 ± 2.5	0.42

Both groups were comparable at baseline, with no significant differences in demographics or symptom severity.

**Table 2: Changes in SNOT-22 Scores After 4 Weeks**

Time Point	Saline Only	Saline + Additives	p-value (between groups)
Baseline	49.7 ± 9.1	51.3 ± 8.6	0.28
Post-Treatment	31.2 ± 7.9	21.4 ± 6.1	<0.001*
Mean Reduction	18.5 ± 5.3	29.9 ± 5.2	<0.001*

Group B (saline + additives) experienced significantly greater symptom improvement.

**Table 3: Changes in Saccharin Transit Time (STT)**

Time Point	Saline Only	Saline + Additives	p-value
Baseline STT (min)	13.9 ± 2.3	14.2 ± 2.5	0.42
Post-Treatment STT	10.8 ± 2.4	9.1 ± 2.2	<0.001*
Mean Change	-3.1 ± 1.5	-5.1 ± 1.6	<0.001*

Significant improvement in mucociliary clearance was noted with additive-based irrigation.

## Discussion

This trial demonstrates that nasal saline irrigation with additives significantly improves both subjective symptoms and objective mucociliary function in patients with chronic rhinosinusitis. Patients receiving the combination of sodium bicarbonate and xylitol exhibited superior reductions in symptom burden and faster mucociliary clearance compared to those irrigating with saline alone. These findings support the therapeutic advantage of additive-enhanced irrigation in CRS.<sup>11-13</sup>

The observed reduction in SNOT-22 scores among patients in the additive group suggests that symptom resolution is not merely a function of mechanical lavage, but also of biochemical modulation. Sodium bicarbonate likely contributed by altering mucus pH and viscosity, facilitating easier drainage and ciliary activity. Meanwhile, xylitol may have disrupted bacterial adhesion and reduced local inflammation, improving the mucosal environment for ciliary function.<sup>14-17</sup>

Mucociliary clearance, measured via saccharin transit time, showed a statistically significant acceleration in the additive group. These findings are consistent with previous reports suggesting enhanced ciliary beat frequency and epithelial recovery in response to xylitol and buffered solutions. Importantly, no participants reported adverse effects, underscoring the safety of these compounds when used at controlled concentrations.<sup>18-20</sup>

This study highlights the importance of using both subjective and objective outcomes to evaluate nasal irrigation therapies. While symptom relief is critical to patients, mucociliary improvement reflects underlying physiologic recovery and may reduce long-term disease recurrence. Additive-based irrigation may therefore represent a more comprehensive management strategy.

The findings also contribute to addressing a clinical gap: the absence of standardized irrigation protocols in CRS. By demonstrating reproducible benefits with specific additives, this study supports the development of evidence-based recommendations. Future research may focus on identifying optimal concentrations, frequency of use, and long-term outcomes.

Despite the strengths of this randomized trial, limitations include the short follow-up period and absence of endoscopic or radiologic outcomes. Further multicenter studies with longer observation periods are warranted to evaluate durability and potential effects on revision surgery rates.

Potential effects

## **Conclusion**

Nasal irrigation using saline with sodium bicarbonate and xylitol additives significantly improves symptoms and mucociliary clearance in chronic rhinosinusitis compared to saline alone. This study fills a clinical gap by offering a superior, safe, and accessible modification to standard care. Future trials should explore long-term benefits and cost-effectiveness.

## **References**

1. Kablak-Ziembicka A, Przewlocki T. Clinical significance of carotid intima-media complex and carotid plaque assessment by ultrasound for the prediction of adverse cardiovascular events in primary and secondary care patients. *J Clin Med*. 2021;10(20):4628. DOI: <https://doi.org/10.3390/jcm10204628>
2. Jiramongkolchai P, Frasnelli J, Bojanowski C. The efficacy of xylitol-based nasal irrigations on sinonasal symptoms: A meta-analysis. *Am J Rhinol Allergy*. 2022;36(1):69–75. DOI: <https://doi.org/10.1177/19458924211018592>
3. Krajewska J, Krajewski W, Zub K, Zatoński T. Additive-enhanced nasal irrigation in CRS: A prospective, randomized trial. *Eur Arch Otorhinolaryngol*. 2023;280(2):785–793. DOI: <https://doi.org/10.1007/s00405-022-07645-9>
4. Snidvongs K, Kalish LH, Sacks R, Craig JC, Harvey RJ. The efficacy of sodium bicarbonate in nasal irrigation for CRS: A randomized controlled trial. *Laryngoscope*. 2022;132(3):620–627. DOI: <https://doi.org/10.1002/lary.29567>

5. Lechien JR, Saussez S, Hans S. Chronic rhinosinusitis: Clinical features, pathophysiology, and implications for treatment. *Front Allergy*. 2021;2:703584. DOI: <https://doi.org/10.3389/falgy.2021.703584>
6. Wu D, Ye L, Shen Y, et al. The impact of xylitol on nasal mucociliary clearance in CRS patients: A prospective study. *Int Forum Allergy Rhinol*. 2022;12(5):640–646. DOI: <https://doi.org/10.1002/alr.22967>
7. Tan BK, Chandra RK, Conley DB, et al. Advances in understanding mucociliary clearance and its role in CRS. *Otolaryngol Clin North Am*. 2021;54(3):515–528. DOI: <https://doi.org/10.1016/j.otc.2021.01.004>
8. Singh A, Garg A, Sharma N. Effectiveness of nasal saline irrigation with and without sodium bicarbonate: A comparative study. *Indian J Otolaryngol Head Neck Surg*. 2022;74(Suppl 1):110–115. DOI: <https://doi.org/10.1007/s12070-021-02786-z>
9. Workman AD, Kohanski MA, Cohen NA. Mucociliary clearance and sinonasal disease: What's new? *Curr Allergy Asthma Rep*. 2023;23(2):47–55. DOI: <https://doi.org/10.1007/s11882-023-01017-9>
10. Hopkins C, Rudmik L, Lund VJ. The role of nasal irrigation additives in CRS: Review and recommendations. *Clin Otolaryngol*. 2021;46(2):236–244. DOI: <https://doi.org/10.1111/coa.13622>
11. Mullol J, Alobid I, Marino-Sanchez F, et al. Update on CRS diagnosis and treatment: Endotyping and personalized approaches. *J Allergy Clin Immunol Pract*. 2021;9(3):1130–1142. DOI: <https://doi.org/10.1016/j.jaip.2020.11.032>
12. Park Y, Cho HJ, Kim JW. Long-term outcomes of nasal irrigation therapy in CRS: A prospective study. *Rhinology*. 2022;60(2):132–139. DOI: <https://doi.org/10.4193/Rhin21.111>
13. Keojampa BK, Cohen NA. The role of pH in sinonasal mucus rheology and implications for therapy. *Curr Opin Otolaryngol Head Neck Surg*. 2023;31(1):25–31. DOI: <https://doi.org/10.1097/MOO.0000000000000854>
14. Lee JC, Kim DH, Park HY. Xylitol nasal irrigation: A new approach to managing CRS symptoms. *Clin Exp Otorhinolaryngol*. 2023;16(3):245–252. DOI: <https://doi.org/10.21053/ceo.2022.01832>

15. Alshaikh NA, Alzahrani A, Almuntashri A. A prospective comparison of hypertonic and isotonic nasal irrigation in CRS patients. *Ear Nose Throat J.* 2021;100(9):724–729. DOI: <https://doi.org/10.1177/0145561320954384>
16. Ryu G, Jung JH, Jang W. The use of xylitol in chronic sinusitis: Mechanistic insights and outcomes. *Int J Mol Sci.* 2022;23(4):2035. DOI: <https://doi.org/10.3390/ijms23042035>
17. Cho SH, Kim KR, Jang JY. Impact of buffered saline nasal irrigation on epithelial integrity in chronic rhinosinusitis. *Am J Rhinol Allergy.* 2021;35(4):468–474. DOI: <https://doi.org/10.1177/1945892420984850>
18. Grayson JW, Cavada M, Harvey RJ. The evolving role of non-surgical management in CRS. *Curr Opin Otolaryngol Head Neck Surg.* 2023;31(2):109–115. DOI: <https://doi.org/10.1097/MOO.0000000000000875>
19. Yoon JH, Kim CH, Kim DW. Modulating mucociliary function in CRS: Experimental approaches and clinical trials. *Allergy Asthma Immunol Res.* 2022;14(1):49–57. DOI: <https://doi.org/10.4168/aair.2022.14.1.49>
20. Peters AT, Hsu J, Chandra R, Tan BK. Evidence-based application of nasal irrigation in chronic rhinosinusitis. *Curr Opin Allergy Clin Immunol.* 2021;21(1):12–17. DOI: <https://doi.org/10.1097/ACI.0000000000000710>.