# **Original Research Article**

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# Comparison of nasal douching with isotonic saline versus Ringer lactate in chronic rhinosinusitis: a randomized controlled trial

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## **ABSTRACT**

**Background:** Nasal douching is a best effective and simple treatment procedure for chronic rhinosinusitis. This study compares the efficacy of nasal douching with isotonic saline solution versus ringer lactate solution in patients suffering from chronic rhinosinusitis.

**Methods:** This randomized control trial was conducted among the patients with chronic rhinosinusitis who were attending the outpatient department of Otorhinolaryngology in Chettinad Hospital and Research Institute, Chennai, during the study period from June 2019 to December 2019. After randomization group A and B includes thirty cases of chronic rhinosinusitis each and they received nasal douching with saline and Ringer lactate two times a day for a period of three weeks and assessed using sino-nasal outcome test (SNOT) 20 during pre-treatment and post treatment. Data was entered in Microsoft excel and data analysis was done using SPSS version 17.

**Results:** On assessing the overall SNOT 20 mean score, in both group A and group B, there was statistically significant improvement post treatment score when compare to pre-treatment scores. But the differences in improvement between the two groups were not found to be significant.

**Conclusions:** Though isotonic saline and ringer lactate solution showed significant improvement after treatment both these are same with respect to efficacy in the treatment of douching for chronic rhinosinusitis with no difference in outcome.

Keywords: Chronic rhinosinusitis, SNOT 20, Isotonic saline, Ringer lactate

#### **INTRODUCTION**

Chronic rhinosinusitis (CRS) is a common disease which affects about five to fifteen percentage of the population. According to the rhinosinusitis task force CRS is defined as a form of rhinosinusitis lasting more than 12 weeks. 2

Its impact on health and quality of life of the individual is constantly increasing both in developing and developed contries.<sup>3,4</sup> But the best thing is that easy availability of treatment with intranasal steroids, nasal douching, and oral antibiotics result in great improvement of symptoms.<sup>4</sup>

Nasal douching is inexpensive and simple treatment procedure which relieves the symptoms of a variety of sinus and nasal conditions especially in allergic conditions.<sup>5</sup> Nasal douching or irrigation has been used for several decades in the treatment of sinonasal diseases.<sup>6,7</sup>

During the post-operative period nasal douching helps to clear the nasal secretions and infective debris from the nasal cavity, thereby reducing the chances of synechia formation and improving the mucosal healing.<sup>8,9</sup> Nasal douching is also found to improve the mucocilliary transport (MCT) function of the nasal mucosa.<sup>9</sup> In these procedures both isotonic and hypertonic solutions were

used. Douching has been tried in the past with different solutions like Ringer's lactate, normal saline, budesonide solution with individual advantages and disadvantages.<sup>9,10</sup> Isotonic saline and Ringer lactate has been used as the most preferred solution for nasal douching in the past.<sup>10</sup>

The objective of this study was to compare the efficacy of nasal douching with isotonic saline solution versus Ringer lactate solution in patients suffering from CRS.

#### **METHODS**

This randomized control trial was conducted among the patients with CRS who were attending the outpatient department of Otorhinolaryngology in Chettinad Hospital and Research Institute, Chennai, during the study period from June 2019 to December 2019. All cases between the ages of 18 to 60 years who were diagnosed to have CRS based on the sinus and allergy health partnership (SAHP) task force criteria for clinical research were included in the study. Patients with known head and neck malignancy, previous radiotherapy to head and neck, systemic granulomatous disease, past history of endoscopic sinus surgery and any mucociliary clearance disorders were excluded from the study. A total of sixty patients were included in the study.

The individual participants were explained about the study and they were also assured that, their identity would be kept strictly confidential and they have the option to refuse participation in the study. Written informed consent was obtained from the study participant's parents prior to the interview. Every effort was made, to be sure that all information collected from the participants, remain confidential.

The patients were randomized to group A and group B based on computer generated random numbers. All study participants were blinded for the treatment which they received. Group A includes thirty cases of CRS who received isotonic saline nasal douching two times a day over a period of three weeks. Group B includes thirty cases of CRS who received Ringer lactate nasal douching two times a day over a period of three weeks. The study was conducted using a proforma with the clinical history. examination and pre treatment sino nasal outcome test (SNOT) 20 score. Following which based on the allotted group, all the cases were treated and followed up for a period of three weeks. At the completion of three weeks of treatment with saline and Ringer lactate nasal douching post treatment SNOT 20 score was assessed and noted in the same proforma.

SNOT 20 is a scale used to assess the severity of sinusitis among the patients. <sup>12</sup> It consist of 20 items and the scaling for each variables were from 0 to 5 where 0 refers to no problem, 1 refers to very mild problem, 2 refers to mild to slight problem, 3 refers to moderate problem, 4 refers to sever problem and and 5 refers to problem as bad as it can.

Data was entered in Microsoft excel and data analysis was done using Statistical Package for Social Sciences (SPSS) version 17. Data was presented using descriptive statistics and comparison of two means was done using independent sample t test and paired t test, appropriately. P value <0.05 was considered as statistically significant.

#### **RESULTS**

Among the sixty study participants, group A and group B consists of thirty participants each group. In both the groups, majority of the study participants were less than 30 years of age. Group A includes 46.7%, 33.3% and 20% of cases in less than 30 years, 31 to 45 years and more than 45 years of age, respectively. Similarly, group B includes 43.3%, 40% and 16.7% of cases in less than 30 years, 31 to 45 years and more than 45 years of age, respectively. Also, in group A 56.7% and in group B 53.3% were females and males, respectively (Table 1).

Table 1: Age and gender of the study participants.

Variables	Group A (n=30) N (%)	Group B (n=30) N (%)		
Age group (in years)				
<30	14 (46.7)	13 (43.3)		
31-45	10 (33.3)	12 (40)		
45-60	06 (20)	05 (16.7)		
Sex				
Female	17 (56.7)	14 (46.7)		
Male	13 (43.3)	16 (53.3)		

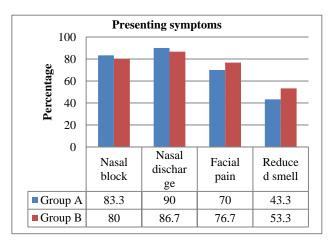


Figure 1: Proportion of cases with various presenting symptoms in both groups.

On assessing the presenting complaints of the study participants, nasal discharge (group A- 90%; group B-86.7%) was found to be more common in both the groups followed by nasal block (group A- 83.3%; group B-80%), facial pain (group A- 70%; group B- 76.7%) and reduced smell (group A- 43.3%; group B- 53.3%) (Figure 1).

In this study 10% and 16.7% of study participants in group A and group B had hypertension, respectively. Similarly, 13.3% and 10% of study participants in group A and group B had diabetes mellitus, respectively. Bronchial asthma was reported by 3.3% of participants in each group and migraine was reported among 3.3% of cases in group B and no case of migraine was reported in group A.

Table 2: Associated chronic illnesses and habits of the study participants.

Variables	Group A (n=30) N (%)	Group B (n=30) N (%)
Chronic illnesses		
Hypertension	3 (10)	5 (16.7)
Diabetes mellitus	4 (13.3)	3 (10)
Bronchial asthma	1 (3.3)	1 (3.3)
Migrain	0	1 (3.3)
Habits		
Smoking	2 (6.7)	4 (13.3)
Tobacco chewing	4 (13.3)	1 (3.3)
Alcohol	3 (10)	5 (16.7)

On assessing the habits of study participants, tobacco chewing (13.3%) was common in group A followed by alcohol consumption (10%) and smoking (6.7%) whereas in group B alcohol consumption (16.7%) was more common followed by smoking (13.3%) and tobacco chewing (3.3%) (Table 2).

Table 3: Comparison of mean SNOT 20 scores between groups.

Mean score	Group A (n=30) N (%)	Group B (n=30) N (%)	P value
Pretreatment SNOT 20	3.56±1.21	3.71±1.09	0.6158
Post treatment SNOT 20	1.67±0.72	1.80±0.9	0.5391
P value	< 0.0001*	<0.0001*	-
Change in SNOT 20 score	-1.89	-1.91	0.8306

<sup>\*</sup>Significant.

Based on the pretreatment and post treatment SNOT 20 scale, items like need to blow nose, runny nose, sneezing, facial pain, post nasal discharge, wake up tired and frustration were significantly improved in both the groups. In group A, items like thick nasal discharge, fatigue, dizziness, reduced concentration and embarrassment were improved during the post treatment when compared to pretreatment. Whereas in group B, items like ear fullness, difficulty falling asleep, lack of good night's sleep, reduced productivity and sad were found to be improved during post treatment when compared to pretreatment scores.

On assessing the overall SNOT 20 mean score, in both group A (isotonic saline) and group B (Ringer lactate solution), there was statistically significant improvement post treatment score when compare to pretreatment scores. But the differences in improvement between the two groups were not found to be significant. Thus, both isotonic saline and Ringer lactate solution are same with respect to efficacy in the treatment of douching for chronic rhinosinusistis.

#### DISCUSSION

Among the various methods of treatment for CRS, high volume and low pressure nasal douching has been considered most effective. <sup>13</sup> Nasal irrigation has shown to clear nasal secretions and infective debris, minimizes crusting, reduces the probability of synechia formation and accelerates mucosal healing. <sup>14</sup> In addition, it has been observed that nasal irrigation appears to improve mucociliary transport function of the nasal mucosa. <sup>15</sup> Nasal douching is considered to improve mucocilary function, decrease mucosal edema, dilute inflammatory mediators and mechanically clear inspissated mucous. <sup>16</sup>

According to Boek et al, isotonic saline solution has a negative effect on ciliary beat frequency which is one of the most important parameters of mucociliary clearance in an in vitro situation, but Ringer-lactate solution does not affect ciliary beat frequency.<sup>17</sup>

Low et al in their study proposed that douching with lactated Ringer's solution resulted in better resolution of the severity of symptoms from CRS, compared with the other solutions, in particular, for symptoms of nasal blockage or congestion, headache, facial pain and nasal discharge.<sup>18</sup>

Many studies have been done using different topical nasal solutions with varying results. 19,20 This study was conducted to compare the efficacy of nasal douching with isotonic saline solution versus Ringer lactate solution in patients suffering from CRS.

In this study, based on SNOT 20 items scoring scale, both isotonic saline and Ringer lactate, there was statistically significant improvement post treatment score when compare to pretreatment scores. But the differences in improvement between the two groups were not found to be significant. Thus, both isotonic saline and Ringer lactate solution are same with respect to efficacy in the treatment of douching for CRS. These reports were consistent with the findings of Friedman et al.<sup>21</sup> They reported that both isotonic saline and Ringer lactate groups showed significant improvement in mean SNOT 20 scores following treatment but the degree of improvement was not significantly different between groups.

Kumar et al reported that there was no significant difference found in the mucocilliary transport scores in

hypertonic saline and isotonic saline groups.<sup>8</sup> Whereas they found irrigation with hypertonic saline resulted in better symptom score in SNOT 20 and visual analogue scale as compared to isotonic saline.

Low et al conducted a study with normal saline, Ringer lactate and hypertonic saline. <sup>18</sup> They reported that all groups showed an improvement with treatment in SNOT 20 scores and VAS scores, as well as endoscopic evaluation of mucosa appearance over time. But there was no improvement of mucociliary clearance during the treatment period. Irrigation with lactated Ringer's solution resulted in better symptom scores in SNOT 20 and VAS, compared with irrigation with normal saline or hypertonic saline solutions.

Smruti et al conducted a study in Uttar Pradesh and reported that hypertonic saline for nasal douching had a better symptom score as compared with isotonic saline for nasal douching.<sup>22</sup> They also reported that there was not much significant difference in the mucociliary clearance test scores of both the group patients. Hanifi et al conducted a study to assess the effects of tap water, buffered isotonic saline, saline with xylitol, and hypertonic sea water following septoplasty.<sup>23</sup> They reported that there was no significant difference found in the preoperative and postoperative findings with respect to mucociliary clearance times among the four groups.

## **CONCLUSION**

In our study, among the cases with CRS, treatment with isotonic saline and Ringer lactate both showed significant improvement in symptoms on comparing the pretreatment and post treatment SNOT 20 scores. But the differences in improvement between the two groups were not found to be significant. Hence both isotonic saline and Ringer lactate solution are same with respect to efficacy in the treatment of douching for CRS.

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