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Original Article

Comparison of Conventional Alkaline Nasal Douching with Budesonide Nasal Irrigation on Post Endoscopic Sinus Surgery Patients

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Abstract

Background

Postoperative care after endoscopic sinus surgery for chronic rhinosinusitis plays a vital role in enhancing mucosal healing and preventing recurrence. This study aimed to compare the effectiveness of conventional alkaline nasal douching with budesonide nasal irrigation in patients undergone endoscopic sinus surgery.

Materials and Methods

This prospective comparative study was conducted at the Department of Ear, Nose and Throat and Head and Neck Surgery at the Manipal Teaching Hospital. A total of 80 patients with chronic rhinosinusitis with or without nasal polyps who underwent ESS were randomly assigned into two groups: Group A (alkaline nasal douche) and Group B (budesonide nasal irrigation) following same regimen of antibiotics, nasal steroids, analgesics and antihistamines. Data were collected from the outpatient department at the time of follow-up on 2, 6, and 10 weeks postoperatively as per the endoscopic Lund-Kennedy scoring system.

Results

Budesonide nasal irrigation was significantly more effective in reducing postoperative nasal polyps, edema and scarring as compared to the alkaline nasal irrigation group, particularly at 6 and 10 weeks ($p<0.0001$). While both groups showed improvements over time, budesonide nasal irrigation demonstrated superior overall outcomes in mucosal healing and endoscopic scores.

Conclusion

Budesonide nasal irrigation provides significantly better postoperative results in endoscopic sinus surgery patients with chronic rhinosinusitis compared to conventional alkaline nasal douching. It is more effective alternative for improving patient outcomes post-surgery.

Keywords: *Budesonide, Chronic Rhinosinusitis, Endoscopic Sinus Surgery, Nasal Irrigation*

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Introduction

Chronic Rhinosinusitis (CRS) is a persistent inflammatory condition of the nose, and the leading indication for Endoscopic sinus surgery (ESS) [1]. ESS is frequently performed on patients not improving with potential medication treatment [2]. In the United States, about 30% of endoscopic sinus surgeries in 2018 were due to CRS [3]. However, surgery alone is rarely curative, and rhinosinusitis remains uncontrolled despite surgery, steroids, and antibiotic use [4–7].

Budesonide nasal irrigation is a high-pressure system that improves steroid delivery to the postoperative nasal and sinus cavity [8-13]. Although not yet approved by the US Food and Drug Administration, it has shown satisfactory control in treating post-operative CRS symptoms [14,15].

Despite global advancements, there is a gap in understanding the comparative effectiveness of different postoperative interventions for CRS [16], particularly in low and middle-income countries such as Nepal. This study will compare the effectiveness of budesonide nasal saline irrigation with conventional alkaline nasal douchingusing Lund-Kennedy endoscope score.

Materials and Methods

This study followed a prospective comparative study conducted at the Department of Ear, Nose, and Throat (ENT) and Head and Neck (HNS) Manipal Teaching Hospital from April 2024 to April 2025 after clearance from institutional Review Committee (MCOMS/IRC/603/GA). Written informed consent was taken from the patients. Diagnosed with CRS as per task force criteria who have undergone endoscopic sinus surgery were included in this study. Meanwhile, patients with acute rhino sinusitis, fungal rhino sinusitis, revision surgery, and those who did not gave consent for the study were excluded.

Eighty patients undergoing endoscopic sinus surgery were registered for study and divided equally into two groups at time of planning for surgery, Group A (alkaline nasal irrigation) and Group B (budesonide nasal irrigation).Sample size was calculated using two independent means formula: $S_1^2 + S_2^2(Z_{1-\alpha/2} + Z_{1-\beta})^2 / (X_1 - X_2)^2$. Mean and Standard Deviation (SD) from a study was used to calculate the sample size resulting in 40 samples in each of the group [17]. Randomization was done by odd and even numbers on enrollment in serial order as patients with budesonide and patients with alkaline nasal irrigation. Both groups received the same protocol of Antibiotic, steroid nasal spray, Analgesic and antihistamine for the same duration of time. Alkaline nasal douching regime were at composition sodium bicarbonate 28.4 g, sodium biborate 28.4 g and sodium chloride 56.7 g mixed in 280 ml of warm water to make solution whereas budesonide of 400mcg powder were mixed on Luke warm water 280 ml. Then 20 ml plastic syringe with an 8 French long infant feeding cut on the appropriate length was used to irrigate the nasal cavity while the patient bends forward, twice a day on both groups, which was continued up to 10-week duration.

Data were collected from the outpatient department at time of follow-up on 2, 6, and 10 weeks postoperatively as per the Endoscopic Lund–Kennedy scoring system using a 30-degree rigid nasal scope under topical local anaesthesia. The Lund–Kennedy endoscopic score is applied for objective endoscopic assessment. It has five components, each with a score of 0–2, and the maximun score is 10 [2].

Data were collected and entered using SPSS version 26 software. For categorical variables, descriptive statistics such as frequency and percentage were displayed. The mean, standard deviation, minimum and maximum were used to represent numerical data following their distribution. The Friedman test was used to compare the means of the paired samples within the groups. The Independent Samples Test was applied to compare the means between two independent groups.

Results

Among 80 patients age ranged from 14 to 70 years, with a mean age of 35.9±13.7 years. The majority of the patients were between 21 to 30 years, accounting for 25(31.3%). (Table 1) The distribution of the patients based on gender was similar, with male patients 41(51.3%) and female patients 39(48.8%) respectively (Figure 1). majority of the patients 54(67.5%) were diagnosed with Chronic Rhinosinusitis (CRS) with a Polyp, followed by 26(32.5%) with only Chronic Rhinosinusitis (CRS). (figure 2)

Table 1: Age distribution of the study patients (n=80)

Age (In years)	Frequency	Percent (%)
Mean±SD	35.9±13.7	
Range (Min-Max)	14 to 70	
≤20	10	12.5
21 to 30	25	31.3
31 to 40	13	16.3
41 to 50	22	27.5
51 to 60	4	5.0
> 60	6	7.5

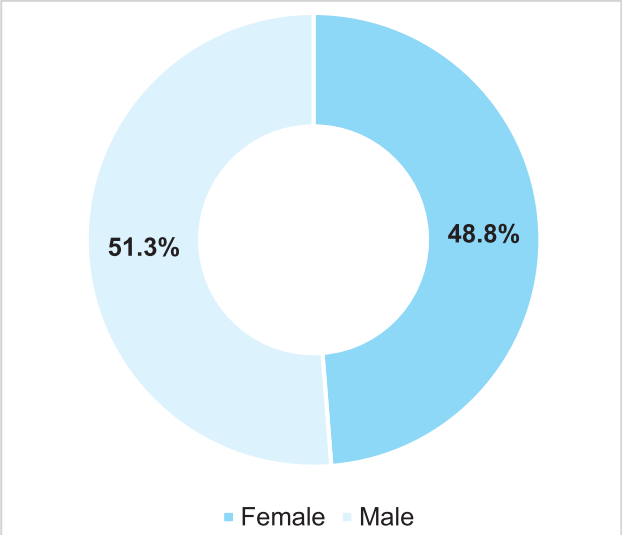

Figure 1: Gender distribution of the study patients Gender (n=80)

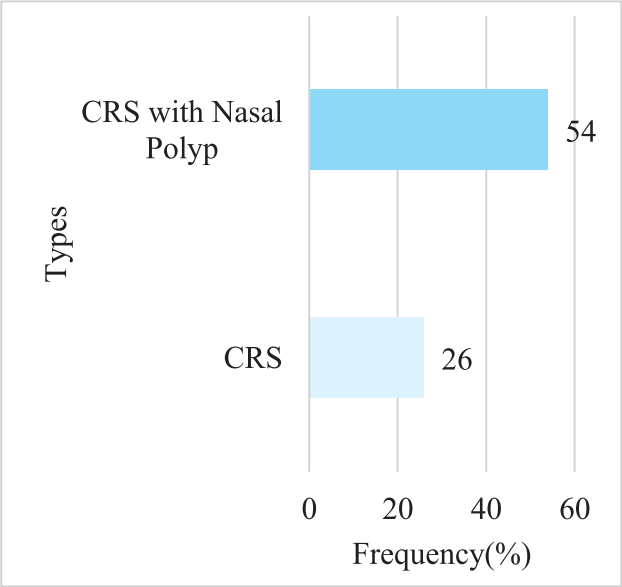

Figure 2: Diagnosis among study patients Diagnosis (n=80)

Among patients with endoscopic sinus surgery, the majority underwent surgery on both sides, 58(72.5%), followed by surgery performed on the left side in 12(15.0%) of the patients, and 10(12.5%) with surgery on the right side of the nose. (Table 2)

Postoperative Mean Lund-Kennedy Endoscopic scoring outcomes between Group A and Group B patients were compared over a 10-week follow-up period. At 2 weeks, neither group showed nasal polyps (0.0±0.0), p=1.000. At 6 weeks, Group A exhibited a higher mean nasal polyp score (0.2±0.4) compared to Group B (0.0± 0.00.2; p=0.014), and the difference further increased at 10 weeks (0.7±0.8 in Group A vs 0.2±0.4 in Group B; p<0.0001). The comparison over time showed statistically significant differences (p<0.0001 for Group A and p=0.009 for Group B). At two and six weeks, there were no statistically significant variations in nasal discharge between the groups. Group A's discharge scores (0.7 ± 0.7) were substantially higher than Group B's (0.2 ± 0.5; p = 0.001) at 10 weeks. There was no statistically significant change over time in either group (Group A: p = 0.122; Group B: p = 0.137). Group A showed a higher scores for edema at every time point. At two weeks, Group A's mean score was 0.6 ± 0.6, while Group B's was 0.2 ± 0.4 (p = 0.002). At 6 weeks (1.0 ± 0.5 vs. 0.6 ± 0.6; p < 0.0001) and 10 weeks (1.2 ± 0.7 vs. 0.4 ± 0.5; p < 0.0001). For both groups, the changes over time were statistically significant (Group B: p = 0.006; Group A: p < 0.0001). At two weeks, Group B's score was slightly higher (0.2 ± 0.4) than Group A's (0.1 ± 0.3; p = 0.041). Nonetheless, Group A's scarring scores were higher than Group B's at 6 and 10 weeks (0.9 ± 0.4 and 1.3 ± 0.6, respectively; p < 0.0001 for both time points). Over time, there were notable changes in both groups (p < 0.0001). (Table 3)

Both groups exhibited statistically significant changes over time (Group A and Group B: p < 0.0001) however, there was no significant differences between the groups undergoing crusting at any time point (p > 0.05). The mean postoperative scores of Group A was greater than Group B's overall scores for overall time points. Significant changes were seen after 6 weeks (3.0 ± 1.1 vs. 1.2 ± 1.0; p < 0.0001) and 10 weeks (3.8 ± 1.6 vs. 0.0 ± 0.0; p < 0.0001), while the difference was not statistically significant at 2 weeks (2.0 ± 0.9 vs. 1.6 ± 1.0; p = 0.077). In both groups, time-related changes in total scores were significant (Group B: p = 0.038; Group A: p < 0.0001) (Table 3).

Table 2: Site of Endoscopic Sinus Surgery (n=80)

Endoscopic Sinus Surgery	Frequency	Percent (%)
Both	58	72.5
Left	12	15.0
Right	10	12.5

Table 3: Mean Lund-Kennedy Endoscopic scoring at 2,6, and 10-weeks post-ESS (n=80)

Postoperative Parameters	Group A	Group B	P-Value
Nasal Polyp at 2 Weeks	0.0±0.0	0.0±0.0	1.000*
Nasal Polyp at 6 Weeks	0.2±0.4	0.0±0.2	0.014*
Nasal Polyp at 10 Weeks	0.7±0.8	0.2±0.4	<0.0001*
P-Value	<0.0001	0.009	
Discharge at 2 Weeks	0.5±0.6	0.4±0.5	0.671*
Discharge at 6 Weeks	0.7±0.7	0.4±0.5	0.059*
Discharge at 10 Weeks	0.7±0.7	0.2±0.5	0.001*
P-value	0.122	0.137	
Edema at 2 Weeks	0.6±0.6	0.2±0.4	0.002*
Edema at 6 Weeks	1.0±0.5	0.6±0.6	<0.0001*
Edema at 10 Weeks	1.2±0.7	0.4±0.5	<0.0001*
P-value	<0.0001	0.006	
Scarring at 2 Weeks	0.1±0.3	0.2±0.4	0.041*
Scarring at 6 Weeks	0.9±0.4	0.4±0.5	<0.0001*
Scarring at 10 Weeks	1.3±0.6	1.1±0.5	<0.0001*
P-value	<0.0001	<0.0001	
Crusting at 2 Weeks	1.1±0.5	0.4±0.5	0.490*
Crusting at 6 Weeks	0.2±0.6	0.1±0.2	0.234*
Crusting at 10 Weeks	0.2±0.6	1.7±0.9	0.311*
P-value	<0.0001	<0.0001	
Total score at 2 Weeks	2.0±0.9	1.6±1.0	0.077*
Total score at 6 Weeks	3.0±1.1	1.2±1.0	<0.0001*
Total score at 10 Weeks	3.8±1.6	0.0±0.0	<0.0001*
P-value	<0.0001	0.038	

Friedman Test, Independent Samples Test*

The postoperative Mean Lund-Kennedy Endoscopic scoring among patients having Chronic Rhinosinusitis (CRS) with a Polyp showed increased scores at 2 weeks for Group A (1.9±0.9) compared to Group B (1.7±1.0), however, this was statistically not significant. At 6 weeks, the mean score for Group B significantly decreased compared with Group A's score (1.5±1.0 vs 3.0±1.1; p<0.0001). Similarly, the Group B score was significantly lower compared to Group A at 10 weeks (1.2±1.1 vs 4.1±1.6; p<0.0001). The scores over time within the groups was significant among Group A, p<0.0001, while in Group B there were no significant differences, p=0.437 (Table 4).

Table 4: Mean Lund-Kennedy Endoscopic scoring at 2,6, and 10 weeks post-ESS among patients having Chronic Rhinosinusitis (CRS) with a Polyp (n=54)

Postoperative Parameters	Group A	Group B	P-Value
Total score at 2 Weeks	1.9±0.9	1.7±1.0	0.470*
Total score at 6 Weeks	3.0±1.1	1.5±1.0	<0.0001*
Total score at 10 Weeks	4.1±1.6	1.2±1.1	<0.0001*
P-value	<0.0001	0.437	

Friedman Test, Independent Samples Test*

Discussion

This study evaluated the comparative efficacy of conventional alkaline nasal douching versus budesonide nasal irrigation in patients undergoing endoscopic sinus surgery (ESS) for chronic rhinosinusitis (CRS).

In the present study, the majority of the patients were between 21 to 30 years, accounting for 31.3%. Similarly, another study conducted in Nepal showed that two-thirds of the cases belonged to the age group below 30 years [18].This similar trend could be attributed to the increased environmental exposure, such as air pollution, and occupational factors in younger adults who work in outdoor work or education. On the other hand, the distribution of the patients based on gender was similar, with male patients 51.3% and female patients 48.8% respectively. Similar findings were observed in a study conducted in Nepal, which showed that 52.1% of patients were male and 47.8% were female. However, another study showed that females were more commonly affected as compared to males [18].These differences in terms of gender may have existed due to greater health-seeking behavior among men in this study.

Present study findings show that the majority of the patients, 67.5%, were diagnosed with Chronic Rhinosinusitis (CRS) with a Polyp, followed by 32.5% with only Chronic Rhinosinusitis (CRS). A similar study showed that 36.71% of CRS patients presented with polyps, and 63.8% presented without polyps [19].The higher prevalence of nasal polyps in the present study could be due the late presentation of patients with CRS

In the postoperative period, at 2 weeks, there was no recurrence of nasal polyps in both groups (0.0±0.0). However, by week 6, Group A had a higher mean of nasal polyp score of 0.2±0.4 while Group B scored 0.0 ±0. This was lower in Group B compared to Group A at week 2 (p=0.014), and became more significant at week 10, 0.7 ± 0.8 in Group A and 0.2 ± 0.4 in Group B (p < 0.0001). This implies that Group A has a higher recurrence rate than the others observed in this present study, demonstrating the effectiveness of Budesonide as compared to alkaline nasal irrigation. However, a similar study showed no significant difference between budesonide and nasal saline. Such difference may have existed due to a shorter follow-up period in later study [20].

At all the periods, Group A showed significantly higher oedema scores than Group B. The scores were 0.6±0.6 at 2 weeks, 1.0±0.5 at 6 weeks, and 1.2±0.7 at 10weeks in group A, whereas it was 0.2±0.4, 0.6±0.6, and 0.4±0.5 in group B, respectively (at 6 and 10 weeks, p<0.0001). In a study by Ishak et al., there was a significant improvement (P < 0.001) of nasal mucosal oedema in

patients treated with budesonide nasal irrigation compared with those treated with saline nasal irrigation [21] In a similar study, this finding was not significantly associated with either of the groups at the 7th day post-operation. However, in the second visit, i.e. 30th postoperative day, oedema was significantly reduced in the budesonide groups as compared to the normal saline group [20]. Inflammation of the mucous membrane persists after the operation, and this may be an indicator that the polyps are still recurrent. Postoperative mucosal oedema as well as endoscopic scores have also been found to be reduced by budesonide nasal irrigation. Consequently, the higher oedema in Group A may indicate inadequate postoperative anti-inflammatory response.

At 2 and 6 weeks, there were no differences in nasal discharge noted in either group, but at 10 weeks, Group A had a higher mean score (0.7± 0.7) of nasal discharge than Group B (0.2±0.5, p=0.001). Similarly, nasal secretions in patients treated with budesonide nasal irrigation and saline nasal irrigation, there was a significant improvement found (P < 0.001). In the budesonide nasal irrigation group. Similarly, the nasal discharge score was better in the budesonide group at 7th day [20]. The similarity in results across these studies could be due to the effectiveness of budesonide in alleviation of glandular secretions and mucosal irritation as compared to alkaline nasal irrigation.

The scarring scores were moderately higher in Group B (0.2±0.4) as compared to Group A at 2 weeks of follow up (0.1±0.3, p=0.041). However, at 6 and 10 weeks, scarring scores of Group A increased significantly as compared to Group B (p<0.0001). The findings were consistent in a study where scaring was significantly improved in the budesonide group at the 30th postoperative day [20]. Presence of scarring post ESS can result in the formation of synechiae and obstruct sinus drainage pathways, contributing to disease recurrence.

In terms of crusting, there was no significant difference observed in the present study. However, another study showed significant improvement in crusting in the budesonide groups as compared to nasal irrigation groups [21].Lack of significant difference in the present study could be because both groups may have maintained good nasal hygiene or received similar postoperative care.

In the present study, among patients with endoscopic sinus surgery, the majority underwent surgery on both sides, 72.5%, followed by surgery performed on the left side in 15.0% of the patients, and 12.5% with surgery on the right side of the nose. The high rate of bilateral surgeries is likely due to the nature of ethmoidal polyps, which commonly affect both sides of the nose due to their central location and diffuse inflammatory origin. This aligns with a previous study in Nepal where patients undergoing endoscopic sinus surgery for nasal polyps had bilateral involvement in terms of ethmoidal polyps, followed by 3.75% in the left side of the nose, and 2.5% on the right. In antrochoanal polyp, the left side was 23.75% and 20% on the right [22].

As per the findings, budesonide nasal irrigation significantly improved postoperative outcomes, particularly in reducing nasal polyps, mucosal oedema, discharge, and scarring as measured by the Lund-Kennedy Endoscopic Score (LKES) as compared to alkaline nasal douching. These results aligned with previous research findings indicating the benefits of budesonide nasal irrigation post-ESS. Similarly, the results from the present study align with previous research indicating the benefits of budesonide nasal irrigation post-ESS [23]. Similarly, another study reported that budesonide nasal irrigation was better option when compared to saline irrigation at 1, 4, and 12-weeks post-surgery [24]. In addition, Huang et al also found that budesonide nasal irrigation had a better effect than normal saline nasal irrigation [25].Similarity across these studies can be attributed to the anti-inflammatory properties of budesonide, which effectively reduces mucosal inflammation, oedema, and polyp re growth following endoscopic sinus surgery.

The current study findings reinforce growing concerns that budesonide nasal irrigation provides superior postoperative benefits in ESS patients with CRS. However, this study was limited by its single-centre design and small sample which may affect the generalizability of the results. This short follow-up period did not capture long-term outcomes or recurrence rates. In addition, potential confounding factors such as comorbidities and environmental exposures were not assessed.

Conclusion

This study demonstrated that budesonide nasal irrigation is significantly more effective than conventional alkaline nasal douching to enhance postoperative outcomes in patients undergone ESS for chronic rhinosinusitis. Budesonide irrigation led to lower endoscopic scores for nasal polyps, mucosal oedema, discharge, and scarring.

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Conflict of interest: None

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