Efficacy of Budesonide Nasal Irrigation in Comparison to Normal Saline Irrigation in Post-Operative Management of Functional Endoscopic Sinus Surgery

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ABSTRACT

Background

Nasal irrigation with normal saline and topical steroid spray forms the mainstay of treatment in post endoscopic sinus surgery patients. However nasal sprays may not deliver optimum dosage of drug to the paranasal sinus mucosa. Budesonide nasal irrigation solves this problem by delivering drugs in a high-volume high-pressure system.

Objective

The main objectiveof this study will provide insight into the efficacy of budesonide nasal irrigation following functional endoscopic sinus surgery (FESS) surgery and will help to establish new protocols in future.

Method

Forty-four patients were included and divided into 2 groups of 22 each. One arm received normal saline nasal irrigation and the other arm received budesonide nasal irrigation (1 mg in 500 ml) twice daily. Patients were followed up at 1st post-operative week and 10th post-operative week and on each visit Sino-Nasal Outcome Test (SNOT) 22 and Lund Kennedy Endoscopic scores (LKES) were assessed.

Result

The mean scores in the first visit was SNOT 22 : 15.73 + 8.897 vs 12.73 + 16.110 ($p < 0.05$) and LKES : 2.82 + 1.097 vs 1.77 + 1.52 ($p > 0.05$) in the saline and budesonide groups respectively. The mean scores in the second visit was SNOT 22 : 7.09+3.87 vs 3.73 + 8.70 ($p < 0.05$) and LKES : 1.64 + 0.790 vs 0.18 + 0.501 ($p < 0.05$) in the saline and budesonide groups respectively. Thus the budesonide arm had statistically significantly better scores when compared to the normal saline group.

Conclusion

Budesonide nasal irrigation with a positive pressure high volume device was found to have better efficacy when compared to normal saline irrigation. Budesonide nasal irrigation may be used in the post-operative management of endoscopic sinus surgery patients.

KEY WORDS

Budesonide, Endoscopic surgical procedure, LKES, Nasal irrigation, SNOT 22

INTRODUCTION

Chronic rhinosinusitis (CRS) is a disorder of the immune response of the susceptible host and environmental factors causing chronic inflammatory response.[1] The symptoms of CRS include nasal blockage, loss of smell, facial pain, rhinorrhea, and symptoms derived from lower airway involvement which significantly affect the quality of life of patients and have negative effects on sleep, physical and mental health, social functioning leading to workplace absenteeism.[2]

Medical management includes a regimen of oral corticosteroids, topical steroid nasal spray and isotonic saline nasal douching. Those not responding to medical treatment need endoscopic sinus surgery which is a commonly used surgical procedure performed for many nasal pathologies.[3]

Post-operative complications like mucosal edema, crusting, secretion, synechiae formation can result following endoscopic sinus surgery.[4]

Budesonide application locally is useful for speeding up mucosal recovery, decreasing inflammation and the time of epithelization after functional Endoscopic sinus surgery, which have not been compared to the current use of normal saline alone, and no such studies have been conducted especially in Nepali population.

So, this study will provide insight into the efficacy of budesonide nasal irrigation following functional endoscopic sinus surgery (FESS) surgery and will help to establish new protocols in future.

METHODS

This was a prospective, cohort study conducted from 1st November 2021 to 1st May 2023 in the Department of Otorhinolaryngology, Dhulikhel Hospital, Kathmandu University Hospital, Kavre, Nepal. The ethical clearance was obtained from the Institutional Review Board. Informed consent was obtained from the patient before conducting the study.

All patients with or without polyps who underwent primary FESS for CRS, both gender and age of > 17 years were included in the study whereas patients with comorbid conditions like diabetes, hypertension, history of pituitary disease, morbidly obese, on oral contraception, pregnancy, chronic liver disease, chronic renal disease and patients undergoing revision surgery were excluded.

For sample size calculation, convenience sampling was done and the sample size was calculated using the formula,

$n=Z^2 X\ p\ X\ (1-p) / e^2$

$=(1.96)^2 \times 0.030 \times (1 - 0.030)/(0.05)^2$

$=3.8416 \times 0.030 \times 0.97/0.0025$

$=44$

Where,

Z= 1.96 at 95% Confidence Interval (CI)

n= sample size,

p= 0.030 (total number of FESS performed in the year 2019, who meet the inclusion criteria is 16 out of 526 surgeries)

q= 1-p,

e= margin of error.

For selecting the patient in 2 groups, we performed lottery system with A as budesonide group and B as saline group. When A came we gave budesonide nasal douching and vice versa.

For the budesonide group:

The formulation recommended was 1 mg of budesonide mixed in 500 ml saline, irrigated twice a day for 2 days, continue same for 10 weeks. The patients were instructed to irrigate each nostril with a 62.5 ml solution twice a day using an irrigation bottle.[5]

For the saline group:

Patients used a total of 500 ml saline to irrigate each nostril with 62.5 ml twice a day for 2 days, and continue same for 10 weeks like they did in budesonide group.

The nasal douching was performed by the patient using a 20 ml syringe. The patient was advised to sit and hold the syringe parallel to the nasal floor and another patient relative was asked to completely empty the syringe in one go. Each nostril was flushed similarly 3 times in both morning and evening.

For the outcome measurement:

Efficacy of the two arms were compared by: SNOT 22 score (2 post-operative visits) and Lund - Kennedy Endoscopic score (2 post-operative visits).[6,7]

Forty-Four patients who underwent ESS had started nasal douching very next day after removal of nasal pack that is from the 4th post- operative day. Post- operative SNOT-22 and Lund Kennedy Endoscopic score were taken at 1st and 10th follow up weeks.

The statistical analyses were carried out by using the Statistical Package for Social Science software (IBM SPSS Statistics 21, Chicago, USA). Baseline data comparisons were made using descriptive statistical methods such as mean, standard deviation etc. Continuous variables were first evaluated using histogram, scattered data was analyzed using non- parametric tests (Mann Whitney Test). A p-value ≤ 0.05 was considered to be statistically significant.

The figure 1 shows the enrollment to data analysis of patients and n1 = first assessment; n2 = second assessment.

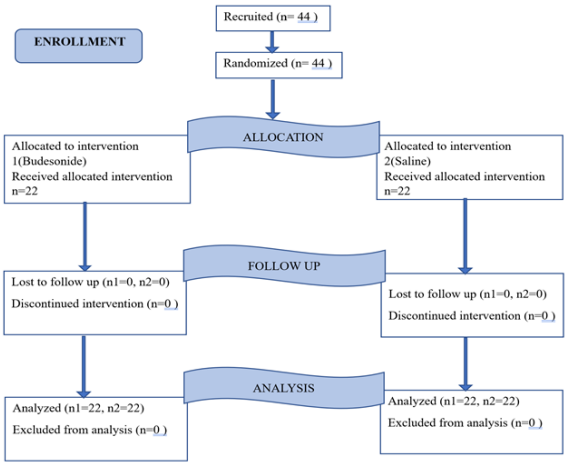

Figure 1. Patient flow chart from enrollment to analysis.

RESULTS

Of the total 44 patients, 17 (38.6%) were female and 27 (61.4%) were male. The mean ± SD of age was 33 ± 13.04 years. There was no statistically significant difference in SNOT -22 and Lund Kennedy score between the two groups (p-value > 0.05) at first pre-operative visit. The mean SNOT 22 score in the first post-operative visit (1st week) of Group 1 (Budesonide) was 12.73 ± 16.110, while that of Group 2 (Saline) was 15.73 ± 8.90. There was a statistically significant difference in SNOT -22 score between the two groups (p-value < 0.05). Similarly, the mean Lund Kennedy endoscopic score (LKES) in the first post-operative visit of Group 1 (Budesonide) was 1.77 ± 1.152, while that of Group 2 (Saline) was 2.82 ± 1.10. There was no statistically significant difference in LKES between the two groups (p-value > 0.05).

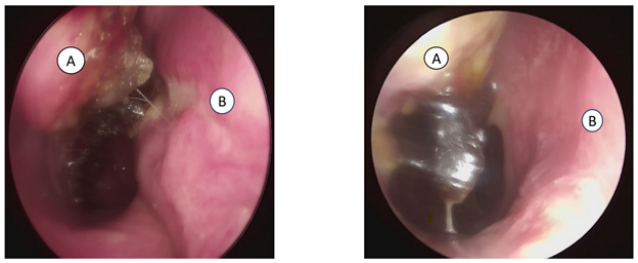

Fig : Endoscopic evaluation of Group 1 (Budesonide nasal irrigation) patient.

Fig: Endoscopic evaluation of Group 2 (Normal saline irrigation) patient.

Figure 2. Endoscopic evaluation at first post-operative visit. (A: Inferior turbinate, B: Nasal septum)

The mean SNOT 22 score in the second post-operative visit of Group 1 (Budesonide) was 3.73 ± 8.71, while that of Group 2 (Saline) was 7.09 ± 3.87. There was statistically significant difference in SNOT 22 score between the two groups (p <0.05). Similarly, the mean Lund Kennedy endoscopic score (LKES) in the second post-operative visit of Group 1 (Budesonide) was 0.18 ± 0.501, while that of Group 2 (Saline) was 1.64 ± 0.80. There was a statistically significant difference in LKE score between the two groups (p-value < 0.05).

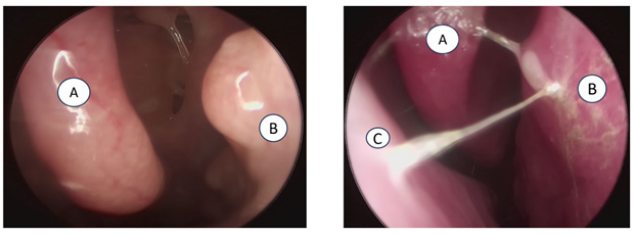

Fig : Endoscopic evaluation of Group 1 (Budesonide nasal irrigation) patient.

Fig: Endoscopic evaluation of Group 2 (Normal saline irrigation) patient.

Figure 3. Endoscopic evaluation at second post-operative visit. (A: Middle turbinate, B: Inferior turbinate, C: Nasal septum)

DISCUSSION

Topical therapy has become a cornerstone in the postoperative management of patients following endoscopic sinus surgery (ESS). The current gold standard comprises normal saline nasal irrigation and topical steroid nasal sprays. While normal saline nasal irrigation primarily provides mechanical cleansing of the postoperative sinus cavities, topical steroid sprays exert a pharmacological effect on the mucosa. However, due to their low-volume and low-pressure delivery, steroid sprays demonstrate limited distribution into the sinuses compared to high-volume positive-pressure devices. This limitation has led to increasing interest in budesonide nasal irrigation (BNI), which combines both the mechanical benefits of saline and the pharmacologic benefits of corticosteroids into a single, promising modality.

Despite its theoretical advantages, the widespread use of high-volume BNI is limited, largely due to the lack of robust evidence supporting its efficacy and safety in routine practice. Further research is essential before it can be recommended as a standard postoperative therapy.

Snidvongs et al. conducted a study involving 111 CRS patients post-ESS (mean age 50.1 ± 13.5 years; 40.5% female) who were treated with budesonide (1 mg in 240 ml saline).[8] After three months of BNI use, significant improvements (p < 0.05) were observed in symptom scores (2.6 ± 1.1 vs 1.2 ± 1.0), SNOT-22 scores (2.2 ± 1.1 vs 1.0 ± 0.8), and endoscopy scores (6.7 ± 3.0 vs 2.5 ± 2.0). Patients with high tissue eosinophilia (>10/HPF) demonstrated greater improvements. However, the absence of a control group precluded direct comparison with the current standard of care-normal saline irrigation with nasal sprays.

In contrast, our study included 44 CRS patients post-ESS, with a younger mean age of 33 ± 13.04 years and a female proportion of 38.6% (n=17). The relatively earlier onset of CRS in our cohort could be attributed to early allergen exposure prevalent in our region. A male predominance (61.4%) was also noted, consistent with previous findings, although no definitive genetic or environmental factors have been conclusively linked to CRS to date.[9] The cellular and molecular mechanisms underlying CRS symptoms remain incompletely understood.

As in the Snidvongs study, we included only patients who had undergone ESS. In our intervention group, 22 patients received BNI with 1 mg budesonide in 500 ml of saline twice daily. Statistically significant improvements ($p < 0.05$) were observed in both SNOT-22 scores (38.41 ± 17.380 vs 3.73 ± 8.708) and endoscopic scores (3.23 ± 1.602 vs 0.18 ± 0.501). Although our follow-up period was slightly shorter (10 weeks vs. 12 weeks), our study included a control arm, allowing a direct comparison between BNI and the standard treatment.

Steinke et al. performed a prospective pilot study on 8 non-operated patients with chronic hyperplastic eosinophilic sinusitis and found significant improvements in CT scores (median 15 to 5; $p < 0.05$) and symptom scores (43.1 ± 5.4 to 20.1 ± 3.0; $p < 0.02$).[10] In contrast, our study involved post-ESS patients, and although CT scores were not evaluated, significant differences in SNOT-22 scores were found between the BNI and saline groups.

Nader et al. studied 71 CRS patients with refractory symptoms despite medical and surgical treatment and assessed the effects of high-volume BNI (dose and volume unspecified).[11] They reported symptom resolution in 61% of patients. However, unlike their study, our research focused on routine post-ESS patients and excluded revision or refractory cases. Moreover, we specified the budesonide dose and demonstrated a statistically significant improvement in subjective scores.

Jang et al. evaluated 60 post-ESS patients who discontinued BNI for at least a month during a 25-month follow-up.[12] Comparisons of SNOT-20 and Lund-Kennedy (LK) scores before and after BNI discontinuation revealed significantly better outcomes during BNI use. While similar in patient inclusion, our study was shorter-term (10 weeks), providing insights into the early postoperative phase.

Kang et al. studied 12 post-ESS patients with CRS and comorbid asthma, using high-volume BNI.[13] They found significant improvements in SNOT-22 and endoscopic scores, and importantly, a reduction in oral steroid use. Our study did not assess oral steroid dosage reduction and excluded patients with asthma, offering a more homogenous population.

Kosugi et al. performed a prospective study on 16 post-ESS patients unresponsive to steroid nasal sprays.[5] They used 0.5 mg/day of budesonide in high-volume irrigation and found 75% showed significant improvements in SNOT-22 and endoscopy scores. This is similar to our study in terms of patient population and budesonide dosage, although our study also included a control group for comparison.

The only Level I evidence available on BNI comes from Rotenberg et al., who conducted a randomized controlled trial on 60 ESS patients with Samter's triad.[14] Participants were assigned to three groups: BNI (1 mg in 240 ml/day), saline irrigation with budesonide spray, and saline irrigation alone. All groups showed improvement in SNOT-22 and LK scores at 6 months and 1 year; however, there were no statistically significant differences between groups. The unique focus on Samter's triad patients may account for discrepancies in outcomes compared to our study, which involved patients with classic CRS. Additionally, Rotenberg's study included a third intervention group, not used in our design.

Regarding safety, Bhalla et al. and Welch et al. studied daily budesonide doses of 1 mg and 2 mg, respectively, over 8 weeks and found no suppression of the hypothalamic-pituitary-adrenal (HPA) axis or adverse effects.[15,16] In our study, a lower dose of 0.5 mg/day was used over a 10-week period, and similarly, no adverse effects were reported.

Based on current evidence, it can be concluded that while high-volume budesonide nasal irrigations (BNI) have shown promising benefits, their efficacy has not yet been directly compared to the standard of care in a controlled clinical trial. Our study aimed to address this important gap in the existing literature.

However, there are some limitations to consider. The study was conducted over an 18-month period, which contributed to a relatively small sample size. Additionally, the follow-up duration was limited to 10 weeks, preventing the assessment of the long-term efficacy and safety of BNI. A longer follow-up period such as one year or more may provide deeper insights into sustained outcomes and potential adverse effects.

Another limitation was the heterogeneity of patient diagnoses included in the study. While this diversity enhances the generalizability of the findings to a broader patient population, it also limits the ability to determine the specific effectiveness of BNI within distinct pathological subgroups. Future research focusing on more homogenous patient groups may help to clarify the role of BNI in targeted CRS populations.

CONCLUSION

Budesonide nasal irrigation with a positive pressure high-volume device has been found to be more efficacious than normal saline nasal irrigation in post-endoscopic sinus surgery (ESS) patients. Therefore, budesonide may be included as a replacement for normal saline nasal irrigation in future management protocols and guidelines.

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