A prospective study comparing the efficacy of Budesonide nasal douching vs. Fluticasone nasal spray in Post FESS patients

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ABSTRACT

Introduction: The study assessed and compared the efficacy of Budesonide steroid nasal douching versus Fluticasone nasal spray in preventing recurrence of symptoms and nasal polyps post-FESS.

Materials And Methods: A prospective cohort study conducted in the Department of ENT, Saveetha Medical College and Hospital, Thandalam from June 2022 to June 2023 involving 60 patients diagnosed as Chronic sinusitis with polyposis were scheduled for FESS. Inclusion criteria included adults aged 18 and above with a confirmed diagnosis based on clinical symptoms, endoscopic findings, and radiological imaging. The severity of CRS was evaluated with SNOT22 score and Lund-Kennedy Endoscopic grading system. Patients were randomly assigned to two groups: Group A which was started on Budesonide nasal irrigation twice a day, and Group B, which received Fluticasone nasal spray.

Results: The average age of participants were 33.23 years, with an even distribution between females and males. Preoperative SNOT-22 and Lund-Kennedy scores were similar between both groups. One month postoperatively, both the groups had similar SNOT22 scores, but the Budesonide group had significantly lower Lund-Kennedy scores. At three months, no significant differences were observed. However, at six months, the Budesonide group had significantly lower SNOT22 and Lund-Kennedy scores when compared to the patients receiving Fluticasone.

Discussion: While Budesonide and Fluticasone are both effective post-FESS treatments, Budesonide nasal irrigation may offer better long-term symptom control and endoscopic outcomes. The broader nasal coverage achieved through nasal douching could contribute to its enhanced therapeutic effect.

KEYWORDS:
FESS, Budesonide, Sinusitis, Steroid nasal spray, Nasal Polyp

INTRODUCTION

Functional endoscopic sinus surgery is performed on patients diagnosed with chronic sinusitis and nasal polyps that are unresponsive to medical and conservative treatments to restore airflow and function of the paranasal sinuses.[1] Patients who undergo FESS have a good response in terms of their symptoms, with around 80-90% of them having a positive prognosis.[2,3] Postoperative therapy for FESS includes both topical and systemic medications. Topical treatments comprise antibiotics, steroids, and nasal irrigation, which can be saline or saline mixed with steroids such as budesonide, fluticasone, or mometasone. Topical antibiotics are also part of this category.[4-6]

The primary medications used in clinical therapy for sinusitis following FESS include normal saline, commercially available nasal douching solutions, and topical steroid nasal sprays. Studies have shown that budesonide, in different forms like powder form, in the aqueous form, or as respules of budesonide in normal saline, is more effective when used with high-volume, high-pressure irrigation devices.[7,8]

Combining the aqueous version of Budesonide with nasal saline is the standard procedure that is currently being used. A nasal irrigation is performed with the combination that was produced to assist in the reduction of local inflammation, to facilitate the early healing of wounds, and to improve the patient's overall outcomes in terms of symptom relief outcomes. The management of the patient after surgery is essential for maximising the results and minimising the likelihood of a recurrence. There is a dearth of direct comparative data evaluating the efficacy of Budesonide nasal douching and Fluticasone nasal spray in this patient population, even though both of these treatments are frequently used as post-FESS treatments to reduce inflammation and prevent recurrence. Both budesonide and fluticasone are classified as corticosteroids; but, because to differences in their pharmacokinetics, tissue penetration, and receptor affinities, they may have differing effects on the body.[9,10] To customise treatment regimens, it is crucial to have a solid understanding of how these variations translate into clinical results after FESS. The identification of the postoperative treatment option that appears to be the most effective can result in improved symptom control, enhanced quality of life, and decreased consumption of healthcare services for patients who have undergone FESS.

The aim of the study is to evaluate the efficacy of Budesonide nasal douching in enhancing post-operative outcomes following functional endoscopic sinus surgery (FESS), compare its effectiveness with Fluticasone nasal spray in reducing post-operative symptoms such as nasal obstruction,

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discharge, and inflammation, and assess the safety profile and incidence of side effects for both treatment modalities in post-FESS patients.

MATERIALS AND METHODS

Study design: A prospective cohort study was performed in the Department of ENT, Saveetha Medical College and Hospital from June 2022 to June 2023, on 60 patients diagnosed as CRS with polyposis planned for Endoscopic Sinus Surgery.

The study included patients who were over 18 years of age with a confirmed diagnosis of chronic rhinosinusitis (CRS) with polyposis. The diagnosis was based on clinical symptoms, endoscopic findings, and radiological imaging. The severity of CRS in these patients was assessed using the SNOT-22 score and the Lund-Kennedy Endoscopic Grading System.

Exclusion criteria included the presence of other significant upper respiratory tract conditions, a diagnosis of chronic rhinosinusitis without polyposis, any known allergy to anaesthesia or contraindications to undergoing Functional Endoscopic Sinus Surgery (FESS), and uncontrolled systemic conditions that could potentially impact surgical outcomes.
Preoperative Assessment involved a detailed clinical history including the duration and severity of CRS, assessment of the symptoms using validated CRS scoring systems SNOT-22, comprehensive endoscopic evaluation of nasal anatomy, assessed by Lund Kennedy endoscopic scoring system and Imaging studies (computed-tomography (CT) scans) to determine the extension of the disease into the sinuses and identify potential anatomical variations.

Intervention (FESS)- All Patients underwent Functional Endoscopic Sinus Surgery performed by experienced otolaryngologists. The surgical procedure focussed on addressing sinus pathologies, optimising sinus ventilation, and alleviating any mechanical obstruction contributing to CRS. Pack removal was done for all patients on postoperative Day-1 or Day-2 depending on intraoperative bleeding, followed by nasal decongestants and saline nasal drops on the day of removal. Postoperatively, all patients were treated with oral antibiotics and proton pump inhibitors for five days, and analgesics as per requirement.

Sixty patients were divided into two groups: A and B, each group containing 30 post-FESS patients. Patients in the Group A received a solution of 1 mg Budesonide in 200 ml saline, administered as a nasal irrigation twice daily. This high-volume irrigation was designed to maximise mucosal coverage and drug distribution throughout the sinonasal cavity. In Group B patients received 50 µg of Fluticasone per puff, with two puffs applied to each nostril twice daily. These specific concentrations and volumes will facilitate replication in future studies and clinical practice, allowing for more consistent application of these treatment regimens.

Postoperative Follow-up included regular postoperative visits at specified frequencies (e.g., 1-month, 3-month, 6-month), assessment of symptom improvement using validated CRS scoring systems SNOT-22, endoscopic examinations to monitor sinus health postoperatively, which are assessed using the Lund-Kennedy scoring system. Patient-reported outcomes regarding quality of life, symptom resolution, and satisfaction with the intervention.

Ethical clearance for this study was obtained from the Institutional Ethics Committee of Saveetha Medical College and Hospital. The study was conducted in accordance with ethical guidelines for research involving human participants, ensuring patient confidentiality and informed consent. All participants provided written informed consent before enrolment in the study.

Statistics Analysis: Descriptive statistics were reported as mean (Standard Deviation, SD) for continuous variables and as frequencies (percentages) for categorical variables. An independent t-test was used to assess the relationship between the continuous variables of the two groups. A repeated measures ANOVA was employed to assess significance within the same group across time. The data analysis was conducted using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Chicago, IL).

RESULTS

SNOT-22: Sino-Nasal Outcome Test-22 LK score: Lund-Kennedy Endoscopic Grading System

The average age of the participants in the study was 33.23 years with a standard deviation of 7.96 years. The study included an approximately equal number of male and female participants. Prior to surgery, the mean SNOT-22 score was 74.97 (±10.84) in the budesonide nasal douching group and 75.07 (±9.85) in the fluticasone nasal spray group, with no statistically significant difference observed between the two groups (p=0.97). Similarly, the mean preoperative Lund-Kennedy (LK) score was 7.00 (±0.98) in the budesonide nasal douching group and 7.13 (±0.90) in the fluticasone nasal spray group, with no significant difference noted (p=0.59).

One month postoperatively, the mean SNOT-22 score was 27.87 (±6.42) in the budesonide nasal douching group and 27.30 (±6.43) in the fluticasone nasal spray group, showing no significant difference (p=0.73). However, the postoperative LK score at one month was significantly reduced in the budesonide nasal douching group, mean 1.20(±0.93) compared to the fluticasone nasal spray group, mean 1.70(±0.65) with a p=0.01.

At three months postoperatively, the mean SNOT-22 scores were 31.77 (±8.56) and 32.30 (±8.28) in the budesonide nasal douching and fluticasone nasal spray groups, respectively, showing no significant difference (p=0.81). The mean LK scores at three months were 1.33 (±0.77) in the budesonide nasal douching group and 1.63 (±0.97) in the fluticasone nasal spray group, with no significant difference observed (p=0.18).

At six-months postoperatively, the mean SNOT-22 score was 30.23 (±7.38) in the budesonide nasal douching group and 41.27 (±8.62) in the fluticasone nasal spray group, showing a

Table I: At six months postoperatively, the Budesonide group had significantly lower SNOT22 and LK scores compared to the participants receiving Fluticasone. Black line with arrow indicates Budesonide nasal douching and the orange line indicates Fluticasone nasal spray

Sl. no	Variable	Budesonide nasal douching	Fluticasone nasal spray	p
1	Age	32.17±8.53	34.30 ± 7.33	0.31
2	Pre op SNOT 22	74.97±10.84	75.07±9.85	0.97
3	Pre op LK score	7.00±0.98	7.13±0.90	0.59
4	Post op SNOT 22 (1 month)	27.87±6.42	27.30±6.43	0.73
5	Post op LK score (1 month)	1.20±0.93	1.70±0.65	0.01
6	Post op SNOT 22 (3 months)	31.77±8.56	32.30±8.28	0.81
7	Post op LK score (3 months)	1.33±0.77	1.63±0.97	0.18
8	Post op SNOT 22 (6 months)	30.23±7.38	41.27±8.62	<0.001
9	Post op LK score (6 months)	1.36±1.01	2.70±0.92	<0.001

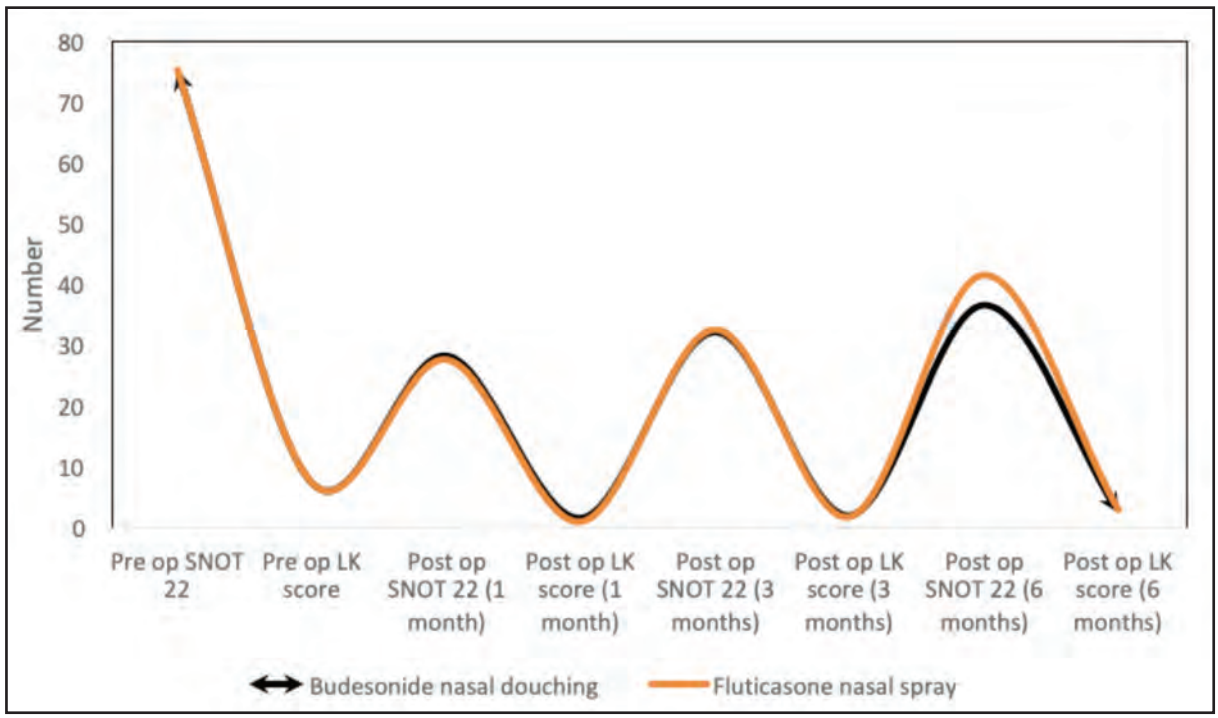

Fig. 1: At six months postoperatively, the Budesonide group had significantly lower SNOT22 and LK scores compared to the participants receiving Fluticasone. Black line with arrow indicates Budesonide nasal douching and the orange line indicates Fluticasone nasal spray

significant difference (p<0.001). Likewise, the mean LK scores at six months were significantly different between the two groups, with values of 1.36 (±1.01) and 2.70 (±0.92) in the budesonide nasal douching and fluticasone nasal spray groups, respectively (p<0.001). (As per Figure 1)

SNOT-22: Sino-Nasal Outcome Test-22 LK score: Lund-Kennedy Endoscopic Grading System

In the Budesonide nasal douching group, the mean preoperative SNOT-22 score was 74.97, which significantly decreased to 27.87 at one month postoperatively (p<0.001). This reduction remained statistically significant at three months (mean=31.77) and six months (mean=30.23), demonstrating a progressive increase in the score over time, with each interval showing statistical significance (p<0.001). Similarly, the mean preoperative Lund-Kennedy (LK) score in this group was 7.00, significantly decreasing to 1.20 at one month postoperatively (p<0.001). This reduction was maintained at three months (mean=1.33) and six months (mean=1.36), with each interval exhibiting statistical significance (p<0.001).

In the group receiving fluticasone nasal spray, the mean preoperative SNOT-22 score was 75.07, which significantly decreased to 27.30 at one month postoperatively (p<0.001). This reduction remained statistically significant at three months (mean = 32.30) and six months (mean=41.27), with each time point showing a progressive increase in the score and statistical significance (p<0.001). Similarly, the mean preoperative Lund-Kennedy (LK) score in this group was 7.13, significantly decreasing to 1.70 at one month postoperatively (p<0.001). This reduction was maintained at three months (mean=1.63) and six months (mean=2.70), with each interval exhibiting statistical significance (p<0.001).

DISCUSSION

The demographic characteristics of the study participants indicates an average age of 33.23 years with a standard deviation of 7.96 years. The study included a balanced representation of both male and female participants, ensuring a diverse sample. Prior to surgery, comparable baseline scores were observed between the Budesonide nasal douching and Fluticasone nasal spray groups for both the SNOT22 and Lund-Kennedy (LK) scores, indicating similarity in the severity of symptoms and endoscopic findings.

One month postoperatively, both treatment groups exhibited significant improvements in their SNOT-22 scores compared to baseline, with no significant difference noted between both groups. However, the Fluticasone nasal spray group showed a significantly lower LK score at one month compared to the Budesonide nasal douching group, suggesting a more favourable endoscopic outcome with Fluticasone nasal spray during the early postoperative period.

At three months postoperatively, no significant differences were found between the two treatment groups in terms of SNOT-22 and LK scores, indicating similar levels of symptom improvement and endoscopic outcomes. However, at six months postoperatively, significant differences emerged between the two groups in both SNOT-22 and LK scores. The Budesonide nasal douching group maintained lower scores compared to the Fluticasone nasal spray group, indicating better long-term symptom control and endoscopic outcomes with Budesonide nasal douching.

Steinke et al. in 2009 observed that Budesonide nasal douching showed a better response to symptoms and patient's CT imaging and endoscopic scores. However, the study did not specify the volume, dosage, or frequency of the irrigation.[11] Similarly, a retrospective study by Nader et al., from 2010, advocated for Budesonide douching thrice daily post-FESS, reporting a 61% resolution rate of symptoms. This study also did not provide details on the volume or dosage of Budesonide used.[12]

Snidvongs et al., in 2012 published a study where patients post FESS received Budesonide steroid irrigation (1 mg in 240ml, four time daily). The study found that 95% of patients showed improvement, with those having high tissue eosinophilia experiencing greater benefits when compared to those with decreased eosinophils. Participants with ASA sensitivity, polyps, and asthma showed a good response to those without these conditions.[13]

Our findings align with prior studies that emphasise the benefits of corticosteroid nasal douching post-FESS. Bourhis et al., demonstrated that Budesonide nasal douching after surgery led to enhanced distribution across the sinonasal mucosa, resulting in better symptom control and reduced recurrence of polyps.[14] Shipman et al., quantified the retention of Budesonide in the sinonasal cavity following high-volume saline irrigation, highlighting the increased sinonasal coverage achievable with douching. This improved coverage and retention may underlie the observed long-term benefits of Budesonide in our study, as enhanced mucosal exposure likely facilitates a more robust and sustained anti-inflammatory response.[15]

Calvo-Henriquez et al., supported these findings in a systematic review, concluding that corticosteroid irrigations are highly effective in chronic rhinosinusitis management, especially in post-FESS patients. The review noted that corticosteroid douching enhances mucociliary clearance, contributing to improved long-term symptom control. These mechanisms are consistent with our observation that Budesonide nasal douching provided better symptom control than Fluticasone spray at six months, suggesting that the broader nasal surface coverage achieved by douching plays a significant role in its sustained efficacy.[16]

Senior et al., investigated the exhalation delivery system with Fluticasone, finding it effective in patients unresponsive to standard sprays. Although beneficial, their study noted that the spray's distribution was limited compared to irrigations, which may partially explain the lesser long-term efficacy of Fluticasone spray observed in our study.[17]

The study's design minimised bias by blinding evaluators to treatment groups, although patient blinding was not feasible due to the differences between nasal douching and spray application. This lack of blinding among patients may introduce subjective bias, particularly in patient-reported outcomes such as symptom severity. Future studies could consider a double-blind design with a placebo control to further mitigate potential bias. The specific concentrations and volumes used in this study will facilitate replication in future studies and clinical practice, allowing for more consistent application of these treatment regimens.

In summary, although both Budesonide and Fluticasone showed comparable effectiveness, our findings imply a potential benefit for steroid nasal irrigation. The broader coverage of nasal surfaces achieved through nasal douching might contribute to a more thorough therapeutic impact in individuals post-FESS. These findings suggest in our study that while both Budesonide nasal douching, and Fluticasone nasal spray are effective in improving symptoms and endoscopic outcomes post-FESS, Budesonide nasal douching may offer superior long-term benefits in terms of symptom control and endoscopic outcomes. Further research, including larger randomised controlled trials, is warranted to confirm these findings and elucidate the underlying mechanisms contributing to the observed differences in efficacy among the two treatments given.

CONCLUSION

Budesonide steroid douching versus Fluticasone nasal spray in patients post FESS suggest that while both treatments are effective in the short term, Budesonide nasal douching may offer superior long-term benefits, potentially reducing recurrence in CRS with polyposis patients post-FESS. Further research, including larger randomised controlled trials, is necessary to validate these findings and elucidate the underlying mechanisms driving the observed differences in efficacy between the two treatment modalities.

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