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A PROSPECTIVE FOLLOW-UP STUDY EVALUATING THE EFFICACY OF BUDESONIDE WITH NORMAL SALINE NASAL DOUCHING FOLLOWING ENDOSCOPIC SINUS SURGERY.

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ABSTRACT **Background:** Delivery of medication to paranasal sinuses following endoscopic sinus surgery (ESS) is challenging due to significant anatomical changes. Off-label high-volume, high-pressure budesonide nasal douching has been shown to be more effective for delivering topical steroids to paranasal sinuses compared to conventional steroid nasal sprays. There are limited studies regarding efficacy and safety of budesonide nasal douching. Aim of this study was to assess effectiveness of budesonide nasal douching after ESS in patients with chronic rhinosinusitis. **Methods:** This prospective follow-up study included 50 chronic rhinosinusitis patients. Postoperatively, all patients were subjected to budesonide nasal douching for 4 weeks. Sino-Nasal Outcome Test-22 (SNOT-22), Modified Lund-Kennedy endoscopic (MLK) scores and synechiae were assessed preoperatively, as well as postoperatively at 2 and 4 weeks. **Results:** There was statistically significant improvement in SNOT-22 and MLK scores (P<0.001). **Conclusion:** Budesonide nasal douching is effective in managing patients who have undergone ESS for chronic rhinosinusitis.

KEYWORDS : Nasal irrigation, Budesonide, Rhinosinusitis, Nasal polyps.

INTRODUCTION

Chronic rhinosinusitis (CRS) is prevalent in 5-12% of the general population, which poses a significant burden on health and quality of life. CRS is classified into primary and secondary, which are further divided based on anatomical distribution into localized and diffuse, each of them having different endotypes and phenotypes. Majority of the localised CRS need surgical intervention but local corticosteroids and saline are the mainstay of the treatment for diffuse CRS. Endoscopic sinus surgery (ESS) is considered in CRS not responding to appropriate medical treatment. Medical management after the surgery is imperative and the primary objective of the ESS is to establish a suitable condition and facilitate the action of local treatment options. Use of nasal corticosteroids after ESS prevents the polyp recurrence with added advantage of avoiding the side effects of systemic corticosteroids and improve the quality of life[1].

The delivery of medication to the paranasal sinuses following ESS is challenging due to the significant anatomical changes, which result in larger and deeper target areas [2]. Off-label use of high-volume, high-pressure budesonide nasal douching has been shown to be more effective for delivering topical steroids to the paranasal sinuses compared to conventional steroid nasal sprays [3]. There are limited studies regarding the efficacy and safety of budesonide nasal douching in patients subjected to ESS. The aim of this study was to assess the effectiveness of budesonide nasal douching in post operative management of CRS.

MATERIALS AND METHODS

This prospective follow up study was carried out in the Department of Otorhinolaryngology at a tertiary care center, from July 2022 to July 2023, after obtaining approval from the Institutional Ethics Committee. 50 patients were included in this study based on inclusion and exclusion criteria.

Inclusion Criteria:
Patients aged above 18 years and those who undergo ESS for CRS during the study period.

Exclusion Criteria:
Patients with previous history of ESS, patients using steroids for other conditions, patients with history of hypersensitivity to steroids, immunocompromised patients and patients with contraindications for steroid use.

Written informed consent was obtained from all the patients. A detailed history was taken and clinical examination was performed. All patients were subjected to routine biochemical, radiological tests and computed tomography (CT) scan of nose and paranasal sinuses. Preoperatively, Sino-Nasal Outcome Test-22 (SNOT-22) score and Modified Lund-Kennedy (MLK) endoscopic score were assessed. Under general anaesthesia, ESS and septoplasty (when indicated) were performed. Merocel nasal packing was done for 48 hours. Patients were instructed to start budesonide nasal douching from third day onwards (after removal of nasal packing) twice a day for 4 weeks. Two postoperative (post-op) visits were done at the end of 2 weeks and 4 weeks. SNOT-22 score, MLK endoscopic score and occurrence of synechiae were assessed during each post-op visit.

Budesonide Nasal Douching:
One budesonide respule (2 ml) of 0.5mg/ml containing 1 mg of budesonide was added into 240 ml normal saline and each nostril was irrigated with 60 ml of prepared solution twice a day [14] using a high-volume, high-pressure squeeze bottle.

Sino-Nasal Outcome Test-22 (SNOT-22) Score[4]:
Subjective analysis was done using SNOT-22 score. It is a standard questionnaire which includes 22 nasal and extra-nasal symptoms. Patients rate these 22 symptoms from 0 to 5 based on the severity. The total SNOT-22 score ranges from 0 to 110.

Modified Lund-Kennedy (MLK) Endoscopic Score[5]:
Objective assessment was done using MLK endoscopic scoring system. It has 3 components namely, polyps, oedema and discharge, each with a score of 0 to 2. The total MLK score ranges from 0 to 12.

Statistical Analysis:
Data was analyzed with IBM SPSS Version 28 for windows. Categorical data was represented in the form of frequency and percentage. Association between the variables were assessed with Chi Square Test. Quantitative data was represented as mean & standard deviation. Comparison of the variables has been done with Paired t test. P value of <0.05 was considered statistically significant.

RESULTS

50 cases were included in this study. The mean age was 38 years with range of 19-70 years. Majority patients (32%) were in the age group of 21-30 years with 30 males and 20 females (Table 1). 31 patients had chronic rhinosinusitis with polyps (CRSwNP), among which 8 patients were having deviated nasal septum and 19 patients had chronic rhinosinusitis without polyps (CRSsNP), among which 14 patients were having deviated nasal septum.

Table 1. Characteristics Of The Study Subjects

Age	Male		Female		Total	Chi Square test P Value
	No	%	No	%		
≤ 20	2	7	0	0	2	
21-30	9	30	7	35	16	
31-40	6	20	7	35	13	
41-50	6	20	3	15	9	0.629
51-60	6	20	2	10	8	
61-70	1	3	1	5	2	
Total	30	100	20	100	50	

No, Number; %, Percentage

Mean preop SNOT-22 score was 50.06 ± 5.6. Mean postop SNOT-22 score was 27.42 ± 3.8 at 2nd week and 16.38 ± 3.3 at 4th week (Table 2). Mean difference of SNOT-22 scores between preop and postop at 2nd week was 22.64, which was statistically significant (P<0.001). Similarly, mean difference of SNOT-22 scores between preop and postop at 4th week was 33.68 (P<0.001). Mean difference of SNOT-22 scores between postop at 2nd week and postop at 4th week was 11.04 (P<0.001). Hence, there was a statistically significant reduction in SNOT-22 scores postoperatively (Table 3).

Table 2. Mean SNOT-22 Score

SNOT-22 SCORE						
Time Interval	Number	Mean	Standard Deviation	Minimum	Maximum	Range
Preop	50	50.06	5.66	40.00	68.00	28.00
2nd Week	50	27.42	3.88	20.00	38.00	18.00
4th Week	50	16.38	3.35	10.00	23.00	13.00

Table 3. Comparison Of Mean Difference Of SNOT-22 Scores

Time Interval	SNOT-22 SCORE					95% Confidence Interval of the Difference		Paired t test	
	Mean	SD	MD	SD	SEM	Lower	Upper	t Value	P Value
Preop vs Postop at 2nd week	50.06	5.66	22.640	3.287	0.465	21.70	23.57	48.69	P<0.001
	27.42	3.88							
Preop vs Postop at 4th week	50.06	5.66	33.680	4.800	0.679	32.31	35.04	49.61	P<0.001
	16.38	3.35							
Postop at 2nd week vs Postop at 4th week	27.42	3.88	11.040	2.531	0.358	10.32	11.75	30.84	P<0.001
	16.38	3.35							

SD, standard deviation; MD, mean difference; SEM, standard error mean

Mean preop MLK score was 6.3 ± 2.5. Mean postop MLK score was 3.48 ± 0.9 at 2nd week and 2.08 ± 1.3 at 4th week (Table 4). Mean difference of MLK scores between preop and postop at 2nd week was 2.82, which was statistically significant (P<0.001). Similarly, mean difference of MLK scores between preop and postop at 4th week was 4.22 (P<0.001).

Mean difference of MLK scores between postop at 2nd week and postop at 4th week was 1.4 (P<0.001). Therefore, there was a statistically significant reduction in MLK scores postoperatively (Table 5). Postop synechiae occurred in 8% study subjects.

Table 4. Mean MLK Endoscopic Score

MLK ENDOSCOPIC SCORE						
Time Interval	Number	Mean	Standard Deviation	Minimum	Maximum	Range
Preop	50	6.30	2.52	2.00	12.00	10.00
2nd Week	50	3.48	0.91	2.00	6.00	4.00
4th Week	50	2.08	1.37	0.00	6.00	6.00

Table 5. Comparison Of Mean Difference Of MLK Endoscopic Scores

Time Interval	MLK ENDOSCOPIC SCORE					95% Confidence Interval of the Difference		Paired t test	
	Mean	SD	MD	SD	SEM	Lower	Upper	t Value	P Value
Preop vs Postop at 2nd week	6.30	2.52	2.82	2.22	0.31	2.19	3.45	8.98	P<0.001
	3.48	0.91							
Preop vs Postop at 4th week	6.30	2.52	4.22	1.61	0.23	3.76	4.68	18.56	P<0.001
	2.08	1.37							
Postop at 2nd week vs Postop at 4th week	3.48	0.91	1.40	1.39	0.20	1.01	1.79	7.14	P<0.001
	2.08	1.37							

SD, standard deviation; MD, mean difference; SEM, standard error mean

DISCUSSION

CRS is a multifactorial condition and represents a spectrum of disease. Appropriate medical therapy is considered before opting for surgery. FESS is performed to facilitate mucociliary clearance and sinus ventilation. Its primary aim is to establish a suitable condition for the action of local treatment options. Medical management after the surgery is crucial. Intranasal corticosteroids improve the nasal airflow, reduce the congestion and polyp size. And it also lowers the recurrence of disease after surgery. Saline nasal irrigation enhances the function of the nasal mucosa by mechanically clearing mucus and crust, as well as by improving ciliary beat activity. It also serves as a carrier for delivering medication into nose and paranasal sinuses. A systematic review conducted by Thomas et al. [3] stated that high-volume, high-pressure nasal douching gives better drug delivery to nasal cavity and sinuses than low-volume devices like nasal drops, nasal sprays, or nebulizers. Safety of the high-volume budesonide nasal irrigation was assessed in the studies conducted by Bhalla et al. [14] (1 mg per day of budesonide for 8 weeks), Welch et al.[15] (2 mg per day of budesonide for 6 weeks) and Seiberling et al. [16] (0.5 mg per day of budesonide for 4 weeks). There was no evidence of hypothalamic-pituitary-adrenal axis suppression and no evidence of increase in intraocular pressure.

This study included 50 patients, of whom 31 patients had CRSwNP and 19 patients had CRSsNP. The patients were aged between 19-70 years, with mean age of 38 years. The highest number of patients was in the 21-30 years age group. The male-female ratio was 3:2. Major age group of patients was in consonance with a study conducted by Faruq et al.[8] Mean age of patients was in consonance with a study conducted by Anjum et al. [13] Range of age of study subjects was in consonance with studies conducted by Jang et al.[6] and Trivedi et al.[9] In our study, we observed a statistically significant improvement in SNOT-22 scores at the 2nd week and 4th week postoperatively compared to preoperative scores, as well as between the 2nd and 4th week postoperatively (P<0.001). Similarly, MLK scores showed a statistically significant reduction between preoperative and postoperative scores at both the 2nd week and 4th week, as well as between the 2nd and 4th week postoperatively (P<0.001). And postop synechiae occurred in 8% patients.

Jang et al.[6] conducted a retrospective review of prospectively collected data of 60 patients who were prescribed postoperative budesonide nasal irrigations twice daily, and they documented a statistically significant reduction in SNOT-22 scores and but improvement in Lund-Kennedy endoscopic scores was not significant. In a prospective, randomised controlled study by Purushothaman et al., both SNOT-22 scores and Lund-Kennedy endoscopic scores were lower in budesonide nasal irrigation group as compared to normal saline nasal irrigation group on postoperative visits at 2nd, 4th and 6th weeks, which were statistically significant [7]. In a comparative study conducted by Faruq et al.[8] in 100 patients who underwent functional endoscopic sinus surgery, there was a higher reduction in SNOT-22 scores and Lund-Kennedy endoscopic scores in budesonide nasal irrigation group as compared to normal saline group. Trivedi et al.[9] did a prospective study, which included 50 cases and demonstrated a statistically significant improvement in SNOT-22 scores (mean preop score of 43.56, mean postop score after 3 months of 14.42, mean postop score after 6 months of 21.82) and Lund-Kennedy endoscopic scores (mean preop score of 8.26, mean postop score after 3 months of 2.8, mean postop score after 6 months of 2.76) in patients using budesonide nasal irrigation.

In a study by Thanneru et al. [11] the mean SNOT-22 score preoperatively was 52.2 and postop at 10 weeks was 15.8 with budesonide nasal douching group (P value 0.001). The mean Lund-Kennedy endoscopic score preoperatively was 7.4 and postop at 10 weeks was 2.2 with budesonide nasal douching group (P value 0.001). Kang et al. [12] conducted a prospective study in 12 patients with CRSwNP with Asthma. They showed a reduction in mean SNOT-22 scores (30.8 ± 14.4 before irrigation to 14.2 ± 8.7 after 6 months of budesonide nasal irrigation (P=0.030) and in mean Lund-Kennedy endoscopic scores (7.4 ± 4.7 before irrigation to 2.2 ± 2.7 after 6 months of budesonide nasal irrigation (P<0.001). Anjum et al. [13] published a prospective, comparative study including 100 patients. Patients were randomly divided into two groups with 50 patients in each group. normal saline nasal douching was used in group 1 and budesonide nasal douching was used in group 2. The mean Lund-Kennedy endoscopic scores postoperatively at 7th day was 3.9 ± 0.9 with budesonide nasal douching group and was 4.5±1.0 with normal saline nasal douching (P value 0.003). The mean Lund-Kennedy endoscopic scores postoperatively at 30th day was 1.2 ± 1.2 with budesonide nasal douching group and was 2.5 ± 1.1 with normal saline nasal douching (P value 0.001). A review article published by Rudmik [10] concluded that budesonide nasal irrigation is effective in patients with chronic rhinosinusitis after ESS.

Limitations

The limitations of this study are small sample size, lack of control group, short duration of budesonide nasal irrigation.

CONCLUSION

In this study, budesonide nasal douching using a high-volume, high-pressure delivery system was associated with statistically significant improvement in postoperative SNOT-22 and MLK endoscopic scores. Hence, budesonide nasal douching is effective in managing patients who have undergone endoscopic sinus surgery for chronic rhinosinusitis. More epidemiological studies are needed to evaluate the dose, frequency, duration and safety profile of budesonide nasal douching.

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