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Topical Dudesonide Rnse for Postoperative Care in Chronic Rhino-Sinusitis with and without Polyp

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Abstract

Background and objectives: Chronic rhino sinusitis is a chronic inflammatory disease of the nasal mucosa and paranasal sinuses with no complete symptom resolution. The present study aimed to evaluate the efficacy of budesonide rinse on patients with chronic rhino sinusitis with and without a polyp. **Methods:** A total of 50 patients underwent operation for chronic rhino sinusitis, with or without nasal polyps were randomly assigned into experimental (25 patients) and control groups (25 patients). The patients in the experimental group received 2 cc of budesonide 0.5mg mixed with 240 cc of normal saline, used 2 times daily 50 cc (50 cc equals 0.2 mg budesonide) for each nostril for three months, whereas, the patients in control group received only normal saline. The efficacy of budesonide solution irrigation was assessed by SNOT 22. **Results:** The mean scores of SNOT-22 in both groups were significantly improved compared to baseline. Whereas, the improvement between experimental (26.0, 33.48, and 39.36 for 1, 2, and 3 months, respectively) and control groups (25.92, 29.88, and 34.32 for 1, 2, and 3 months, respectively) were not significant statistically. The patients with Chronic rhino sinusitis and without polyp in the experimental groups showed the significantly lower SNOT-22 scores for month 2 (27.13 vs. 36.47) and month 3 (33.25 vs. 42.24) compared to the patients with a polyp. **Conclusions:** The study showed that both methods of post-operative nasal irrigation with normal saline alone or budesonide mixed with normal saline had significant improvement in the scores of SNOT-22. However, the difference between the two methods was not statistically significant.

Keywords: Budesonide; Sinusitis; Rhino sinusitis.

Introduction

Chronic rhino sinusitis (CRS) is a chronic inflammatory disease of the nasal mucosa and paranasal sinuses with no complete symptom resolution for more than 12 weeks[1]. A growing body of perception thinks that CRS cannot be a single disease. This perception considers a broad spectrum of various diseases with similar clinical manifestations, which the common pathophysiological mechanism is a chronic inflammation. The term CRS is an umbrella that compromised various diseases presenting typically with nasal obstruction, rhinorrhea, olfactory changes and/or facial pain[2]. Chronic rhino sinusitis is not a life-threatening entity, while it is a potentially serious disease as its impact measured by the quality of life scales, such as SF-26[3] and Sino Nasal Outcomes Test (SNOT)-22 [4]. The medical and surgical management are the first and second choices of CRS treatment, respectively, and supplemented by postoperative topical treatment. The medical treatment is known as “maximal clinical treatment” compromise a combination of various kinds of drugs for therapy optimization and surgery avoidance. Currently, there is no consensus about the maximal clinical treatment in terms of composition and duration. CRS treatment has highly variable success rates[5]. In addition, long-term use of medications such as oral antibiotics and corticosteroids can result in considerable adverse impacts. There are some efforts in order to replace systemic therapy by topical nasal therapy for overall control of CRS[6]. The direct administration of the medications to inflamed tissue is recommended for an increased local concentration with a less systemic absorption and improvement in therapeutic efficacy[7]. Hence, the surgery is used as the essential step in the treatment of CRS by opening spaces to allow sufficient drug distribution through the nasal cavity[8-10].

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The objective of CRS treatment is to achieve and maintain control of the disease, which is defined as a state in which patients have no symptoms or do not bother by their symptoms. The nasal endoscopy must show the patients have healthy or almost healthy mucosa, and need only topical nasal medication[1]. The number of patients suffers from exacerbation of symptoms and insufficient clinical control despite clinical and surgical treatments owing to the large heterogeneity of the disease. The European Position Paper on Rhino sinusitis and Nasal Polyps (EPOS) 2012 considers the disease as difficult-to-treat because the patients do not reveal the suitable level of clinical control despite sinonasal surgery, intranasal corticosteroids and two cycles of antibiotics/systemic corticosteroids in the last year[1].

The recent reports claim that sprays and aerosols do not reach paranasal sinuses, and in most circumstances, these products even do not reach the middle meatus area. Therefore, such methods should be disregarded in favor of high-volume methods with a daily irrigation of at least 200 mL[7]. The current evidence shows the superiority of high volume solutions for sinus penetration and daily doses between 250 µg and 1 mg of budesonide have been used with encouraging outcomes[8].

Traditionally, treatment of CRS with polyps is difficult, but some preliminary evidence claim even better therapeutic response of CRS compared to other histopathologic subgroups[6]. Budesonide is a potent topical corticosteroid with an approximately 1,000-fold higher topical anti-inflammatory potency than cortisol. Budesonide binds the glucocorticoid receptor and exerts an anti-inflammatory effect through several mechanisms including altering the release of arachidonic acid metabolites, inhibiting the accumulation of leukocytes in affected tissue, decreasing vascular permeability, inhibiting neuro peptide-mediated responses, and altering the secretion of glycoproteins from sub-mucosal glands[11]. With promising outcomes of nasal irrigation with corticosteroids, particularly, in difficult cases, the present study aimed to evaluate the efficacy of budesonide rinse on patients operated for chronic rhinosinusitis with and without a polyp.

Patients and Methods

In the present prospective study, a total of 50 postoperative patients diagnosed with CRS, with or without nasal polyps that met the eligibility criteria were included. The patients were randomly assigned either into experimental group (Group A; n=25 patients) and control group (Group B; n=25 patients) through generating a random digit number by a computer. The patients in the experimental group received 2 cc of budesonide 0.5mg mixed with 240 cc of normal saline, used 2 times daily 50 cc (50 cc equals 0.2 mg budesonide) for each nostril for three months, whereas, the patients in control group received only normal saline. The efficacy of budesonide solution irrigation was assessed by SNOT 22 in both groups. The patients were selected from Rizgary Teaching Hospital-Erbil between August 2016 and February 2018.

The patients, regardless of their gender, that met eligibility criteria, were 18 years old and older, diagnosed with chronic rhinosinusitis and underwent surgery, irrespective of socio-demographic perspectives. The pregnant women and those using systemic steroid were excluded from the study. For each patient the following data were collected age, gender, and CRS type, use of antibiotics and/or systemic corticosteroids, and other drugs that interfere with the CRS treatment.

The diagnosis of CRS was established in accordance with the criteria of the American Academy of Otolaryngologists[10]. Those persons who have the following signs and symptoms for twelve weeks or longer of 2 or more: mucopurulent drainage (anterior, posterior, or both); nasal obstruction (congestion); facial pain/pressure/fullness, or decreased sense of smell. In addition, the patient has inflammation according to one or more of the following findings; endoscopic documentation of purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region; polyps in the nasal cavity or the middle meatus, and/or; inflammation of paranasal sinuses on the radiographic imaging[10]. The efficacy of budesonide solution rinse on the treatment of CRS was evaluated through Sino-Nasal Outcome Test SNOT 224. It is a subjective scoring form assessing the patients' symptoms and severity. It has 22 questions anchored on a 6-Likert scale level indicating from 0 (no problem), 1 (very mild problem),

2 (mild or slight problem), 3 (moderate problem), and 4 (severe problem), 5 (problem as bad as it can be). It is a scoring method designed to assess the patients' perception of the symptoms and their experiences of them. The numbers devoted to each item are added together indicating the higher score for the more severe symptom.

Data were analyzed using the Statistical Package for Social Sciences (SPSS, version 22). Chi-square test of association was used to compare the proportions. Fisher's exact test was used when the expected count of more than 20% of the cells of the table was less than 5. Student's t-test of two independent samples was used to compare two means. The paired t-test was used to compare readings before and after the operation. A p-value of ≤ 0.05 was considered statistically significant.

The ethical approval of the present study was obtained from the Kurdistan Board for Medical Specialties (KBMS). The written consent form was obtained from all patients prior to study recruitment. The patients were given a guarantee for the confidentiality of their personal information.

Results

Fifty patients with CRS have participated in the study. They were divided into two groups, 25 patients in each. Group A was given budesonide and Group B was given normal saline. The age range of the patients was 18 to 64 years. The mean age + SD were 40.4 + 11.4 years for group A and 36 + 12.2 years for group B as presented in Table 1 which shows that 30% of the patients aged less than 30 years, and 18% aged $\geq$ 50 years. No significant difference in age distribution was detected between the two groups (p-value = 0.775). The majority (88%) of group B were males compared with 52% of group A. The majority (72%) of the patients involved in this study had polyps, but no significant differences were detected between the two groups in the proportions of patients having polyps (p-value = 0.529).

Table (1): Basic characteristics of the two study groups.

	Budesonide (Group A)		Saline (Group B)		Total		
	No.	(%)	No.	(%)	No.	(%)	p-value
Age							
< 30	6	(24.0)	9	(36.0)	15	(30.0)	0.775*
30-39	6	(24.0)	7	(28.0)	13	(26.0)	
40-49	8	(32.0)	5	(20.0)	13	(26.0)	
≥ 50	5	(20.0)	4	(16.0)	9	(18.0)	
Mean (±SD)	40.4	(±11.4)	36	(±12.2)	38.2	(±11.9)	0.194†
Sex							
Female	12	(48.0)	3	(12.0)	15	(30.0)	0.005
Male	13	(52.0)	22	(88.0)	35	(70.0)	
Polyp							
Absent	8	(32.0)	6	(24.0)	14	(28.0)	0.529
Present	17	(68.0)	19	(76.0)	36	(72.0)	
Total	25	(100.0)	25	(100.0)	50	(100.0)	

*By Fisher's exact test. †By t-test for two independent sample.

In the budesonide group, the mean of the SNOT was 43.52 before the operation. Table 2 shows a significant (p-value < 0.001) decrease of this score one month after the operation to 17.52, and to 10.04 two months after the operation, and to 4.16 three months after the operation. The pre-operative SNOT score was 38.48 in the saline group. It decreased significantly to 12.56, 8.60, and 4.16 one, two, and three months after the operation respectively (p-value < 0.001).

Table (2): Means of scores of Sino-Nasal Outcome Test (SNOT-22) before the operation compared with the means of scores after the operation in each of the study groups.

	Budesonide (Group A)			Saline (Group B)		
Timing	Mean SNOT	(±SD)	p-value*	Mean SNOT	(±SD)	p-value*
Pre-op	43.52	(±10.65)		38.48	(13.60)	
1 Month Post-Op.	17.52	(±13.10)	< 0.001	12.56	(±5.20)	< 0.001
2 Months Post-Op.	10.04	(±9.44)	< 0.001	8.60	(±5.09)	< 0.001
3 Months Post-Op.	4.16	(±6.28)	< 0.001	4.16	(±3.46)	< 0.001

*Comparisons with the pre-operative readings by paired t-test.

The improvement (gain) in the SNOT scores was calculated by subtracting the one, two, and three months scores from the pre-operative scores. After one month postoperatively, the mean of gain was 26.00 in group A, and 25.92 in group B (p-value = 0.981). The means of gain, two months after the operation, were higher than the first month but still, the difference was not significant between the two groups (p-value = 0.264). After three months, the mean of gain was 39.36 in the budesonide group and 34.32 in the saline group (p-value = 0.126).

Table (3): Means of improvement (gain) in the SNOT scores of the two study groups.

Time of gain after the operation	Budesonide (Group A)		Saline (Group B)		p-value
	Mean	(±SD)	Mean	(±SD)	
1 Month	26.00	(±12.03)	25.92	(±11.88)	0.981
2 Months	33.48	(±10.52)	29.88	(±11.96)	0.264
3 Months	39.36	(±9.85)	34.32	(±12.82)	0.126

In the budesonide group, the mean of gain in the SNOT score among those with polyp was 36.47 two months after the operation compared with 27.13 among those without polyp (p-value = 0.010). The mean of gain was 42.24 three months after the operation among those with polyp which was significantly higher than the mean of gain (33.25) among those withoutpolyp(p-value=0.030). In the saline group, the differences (between those with and without polyp) in the means of gain were not significant one month (p-value = 0.307), two months (p-value = 0.475), and three months (p-value = 0.315) after the operation.

Table (4): Means of gain in SNOT scores of those with and without polyp in each of the study groups.

	Polyp		No polyp		p-value
	Mean of gain	(±SD)	Mean of gain	(±SD)	
Budesonide group only					
1 Month Post-Op.	27.94	(±14.12)	21.88	(±3.44)	0.111
2 Months Post-Op.	36.47	(±11.10)	27.13	(±5.46)	0.010
3 Months Post-Op.	42.24	(±9.55)	33.25	(±7.85)	0.030
Saline group only					
1 Month Post-Op.	24.53	(±11.28)	30.33	(±13.74)	0.307
2 Months Post-Op.	28.89	(±11.54)	33.00	(±13.84)	0.475
3 Months Post-Op.	32.84	(±12.08)	39.00	(±15.11)	0.315

Discussion

This study showed that receiving 2 cc of budesonide 0.5mg mixed with 240 cc of normal saline was effective in symptom improvement in postoperative patients with difficult-to-treat chronic rhino sinusitis.

Rotenberg and Zhang et al[12] compared three different medication regimens among three randomized groups diagnosed with chronic rhino sinusitis with polyposis underwent endoscopic sinus surgery. The groups were saline irrigation (control group), normal saline with separate budesonide nasal spray (group B), and saline irrigation with budesonide nasal spray (control C). The outcomes were improved statistically and clinically in all three groups in comparison with baseline status, while the outcomes were not different statistically and clinically following one-year follow-up. These results are completely congruent with our study in the current investigation. The only difference is that they included the patients with polyps in three groups. However, our findings showed that the patients without polyp did reach significantly and clinically lower SNOT scores compared to the polyposis patients[12].

Jang and Lanchans et al[13] tested the efficacy of budesonide nasal irrigation (BNI) delivered by concentrated steroid solution through a high-pressure, high-volume system in 60 patients postoperatively. The patients included in the study were: 30 patients with eosinophilic chronic rhinosinusitis (eCRS) with polyps, 13 patients with allergic fungal sinusitis (AFS), 13 patients with Samter's triad (ST), and 4 cases with eosinophilic chronic rhinosinusitis without polyps. They were followed up for 25 months between 2 and 89 months. Prospectively, the SNOT-20 scores were substantially improved with BNI in patients with eCRS and ST; p-value=0.04 and p-value=0.03, respectively. Whereas, endoscopy findings were substantially improved only in patients with eCRS (p-value=0.02). In similarity with the previous studies, the main issue of this was that the study had not the control group, hence, the results could not be

attributed to the BNI[13].

Rowe-Jones and Medcalf et al14 showed that patients used twice-daily fluticasone had better symptom outcome and endoscopic findings after 5-year follow-up compared with placebo. The study shows that the patients may need a longer time period for overall different improvement compared to the control group[14].

The string point of the present study is including the control group that made the strength compared to one-single group studies. But the findings reported in the current study must be interpreted in the inherence of study design and setting, because the patients were recruited from one geographic area. This may face us with difficulties to generalize the findings to other settings across the country. The difference between the findings of the present study with those reported in other published studies may be related to the differences in the study design or eligibility criteria. In addition, the investigators used different solution concentrations for their patients.

Conclusions

The study showed that both methods of post-operative nasal irrigation with normal saline alone or budesonide mixed with normal saline had significant improvement in the scores of SNOT-22. However, the difference between the two methods was not statistically significant.

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