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KEY WORDS:

EFFICACY OF TOPICAL HIGH VOLUME BUDESONIDE NASAL IRRIGATION IN POST FESS PATIENTS OF CHRONIC RHINOSINUSITIS WITH OR WITHOUT NASAL POLYPOSIS

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ABSTRACT

Chronic rhinosinusitis (CRS) is a chronic inflammatory process of nasal mucosa and paranasal sinuses, lasting more than 12 weeks, without complete resolution of symptoms. CRS is treated medically, followed by Endoscopic sinus surgery (ESS) if necessary, and supplemented by post-operative topical treatment with highly variable clinical outcomes. In this study we evaluate the efficacy of high volume Budesonide Nasal Irrigation in Post FESS Patients of Chronic Rhinosinusitis With or Without Nasal Polyposis **Methods:** Prospective uncontrolled intervention trial. Participants were assessed before- and 3 months after nasal irrigation with 1 mg of budesonide in 500 mL of saline solution daily for 3 times. Subjective (satisfactory clinical improvement) and objective (SNOT-22 questionnaire and Lund–Kennedy endoscopic scores) assessments were performed. **Results:** Sixteen patients were included, and 13 (81.3%) described satisfactory clinical improvement. SNOT-22 mean scores (50.2–29.6; p = 0.006) and Lund–Kennedy mean scores (8.8–5.1; p = 0.01) improved significantly. Individually, 75% of patients improved SNOT-22 scores, and 75% improved Lund–Kennedy scores after high volume budesonide nasal irrigations. **Conclusion:** High-volume corticosteroid nasal irrigations are a good option for Post FESS patients for control of disease and recurrence , reaching 81.3% success control and significant improvement of SNOT-22 and Lund–Kennedy scores.

Introduction

Chronic rhinosinusitis (CRS) is defined as a chronic inflammatory process of nasal mucosa and paranasal sinuses, lasting more than 12 weeks, without complete resolution of symptoms.1 There is a growing perception that CRS is not a single disease, but a spectrum of different diseases with similar clinical presentations, whose common pathophysiological mechanism is a chronic inflammation.2 In other words, the term CSR is nothing more than a large label or umbrella that hosts a number of different diseases featuring typically nasal obstruction, rhinorrhea, olfactory changes and/or facial pain.

Although not a life-threatening entity, CRS can be considered potentially serious, taking into account the impact produced in quality of life of affected patients, measured by generic quality of life questionnaires, such as SF-363 or questionnaires specific to the disease, such as Sino-Nasal Outcomes Test (SNOT)-22,4 even after treatment.5

In general, CRS is initially treated medically, followed by surgical treatment if necessary, and supplemented by post-operative topical treatment. The initial medical treatment is also known as "maximal clinical treatment", because it consists of a combination of different classes of drugs in order to optimize therapy and to avoid surgery. But there is no consensus on the composition and duration of maximal clinical treatment,7 with highly variable success rates.8, 9 In addition, the optimized and prolonged use of drugs such as oral antibiotics and corticosteroids can lead to significant adverse effects; thus, there is an effort for replacing systemic therapy by topical nasal therapy to achieve control of CRS.10 The direct administration of the drug to inflamed tissue allows an increased local concentration with less systemic absorption, enhancing therapeutic efficacy.11 For this reason, surgery has been considered an essential step in treating CRS, by opening spaces and allow for an adequate distribution of the drug through nasal cavities.10, 12,

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 their symptoms do not bother them), combined with nasal endoscopy showing healthy or almost healthy mucosa, and in need only of topical nasal medication.1 Due to the large heterogeneity of CRS, there exists a profile of patients who, despite clinical and surgical treatments, continue to experience exacerbation of symptoms and inadequate clinical control. The European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) 2012 defines difficult-to-treat rhinosinusitis as that entity in which patients do not show an appropriate clinical control level despite sinonasal surgery, intranasal corticosteroids and up to two cycles of antibiotics or systemic corticosteroids in the last year.1

Recently there has been a perception that sprays and aerosols are not able to reach paranasal sinuses, and that, in most cases, these products do not even reach the middle meatus area. If that is so, such methods should be disregarded in favor of high-volume methods, with a daily irrigation of at least 200 mL.11 In view of evidence of superiority of high volume/ pressure solutions with respect to sinus penetration, nasal irrigation with corticosteroids at daily doses ranging from 250 μg to 1 mg of budesonide have been used, with encouraging results.16 In this line, subgroups traditionally more difficult to control (e.g., CRS with polyps and increased tissue eosinophilia) had even better therapeutic response than the other subgroups.10

Taking into account the promising results of the use of nasal irrigation with corticosteroids, especially in those more difficult cases, the aim of this study was to evaluate the use of topical therapy with high-volume nasal irrigation with budesonide solution in patients with difficult-to-treat chronic rhinosinusitis.

METHOD

Study Population

The study included sixteen patients diagnosed with CRS, with or without nasal polyps (CRSwNP or CRSw/oNP, respectively) who were undergone FESS procedure with removal of all gross polyps and sufficiently widening the natural ostia of all

affected sinuses to allow access for topical medication.The FESS procedure was done in dept of ENT hitech medical college and hospital. The diagnosis of CRS was defined according to search criteria suggested by EPOS 2012.1

Patients younger than 18 years or who did not wish to participate in the study were excluded.

Study Design

This is a prospective, interventional, uncontrolled study in patients with CRS who were undergone FESS procedure. The study intervention was the high-volume topical therapy by nasal irrigation with budesonide solution.

Budesonide was prepared by a mixing 2 respules of budesonide(0.5mg) with 500ml normal saline. Patients were instructed to divide this 500 mL volume in half, i.e. instilling 250 mL each day for two days, irrigating his/her nostrils with a 20-mL syringe in pulses or jets, and to continue this regimen for 3 months. No previous recommendation was proposed as to frequency of irrigations; the patient should only apply the amount of 250 mL on a daily basis (corresponding to the use of 500 μg/day of budesonide).

Patients were evaluated before and after 3 months of topical irrigation therapy. The following epidemiological characteristics were evaluated: gender, age, type of CRS, presence of comorbidity and number of previous sinonasal surgeries. Moreover, the prescription and use of antibiotics and/or systemic corticosteroids, or of other medications that might interfere with the treatment of CRS during topical therapy by irrigation, was documented.

The subjective outcomes evaluated were subjective improvement and degree of satisfaction post-topical therapy by irrigation. When the topical therapy by irrigation came at an end, patients were asked if there was improvement of their clinical condition (total improvement, partial improvement, no improvement, worsening), and whether they were satisfied with the degree of this subjective improvement (satisfied or dissatisfied). "Therapeutic success" was defined as a satisfactory subjective improvement presented by the patient.

Objective outcomes evaluated were scores of the SNOT-22 questionnaire in Portuguese4 and endoscopic classification of Lund–Kennedy. These outcomes were quantitatively and qualitatively evaluated. Quantitative evaluation of objective outcomes involved statistical calculations comparing pre- and post-topical therapy by irrigation. For the qualitative evaluation, the following parameters were used: the minimally important difference of SNOT-22 = 14 points4; therefore, differences in post-pre scores between −7 and +7 were considered as "no improvement". When pre-post difference scores reached values < −7, they were considered as "improvement". In the other hand, pre-post differences > 7 were considered as "worsening."

Absolute scores of SNOT-22 (Portuguese version) between 0 and 8 are considered normal; thus, when the patient showed a difference value < −7 and scores for post-topical therapy by irrigation ≤ 8, were considered as "complete improvement". As to Lund–Kennedy scores, post-pre differences = zero were considered as "no improvement", any negative value in the post-pre difference was regarded as "improvement" and any positive value of the difference as "worsening". A post-topical therapy Lund–Kennedy score = zero was considered "complete improvement".

Epidemiological characteristics and outcomes were compared among patients with and without satisfactory improvement. Quantitative variables were compared by Student's t test or Mann–Whitney U test, depending on the homogeneity and normality of samples; and qualitative variables were evaluated by Fisher's chi-squared or Fisher's exact test. For all statistical tests, p-values < 0.05 were considered as significant.

RESULTS

The epidemiological characteristics of the study population are presented in Table 1.

Table1- Epidemiological Characteristics And Subjective Outcomes.

Data		Groups				
		With satisfactory improvement	Without satisfactory improvement	Total	Test	*p*-value
Patients, total	*n* (%)	13 (81.3)	3 (18.7)	16 (100)		
Female gender	*n* (%)	10 (76.9)	2 (66.6)	12 (75)	Fisher	1
Age (years)	Mean (SD)	48.9 (10.2)	59.3 (6.4)	50.9 (10.3)	T	0.11
Nasosinusal polyposis	*n* (%)	9 (69.2)	2 (66.6)	11 (68.8)	Fisher	1
Asthma	*n* (%)	6 (46.2)	1 (33.3)	7 (53.8)	Fisher	1
ASA intolerance	*n* (%)	2 (15.4)	0 (0.0)	2 (12.5)	Fisher	1
Rhinitis	*n* (%)	3 (18.8)	0 (0.0)	3 (18.8)	Fisher	1
Previous surgeries	Mean (SD)	1.5 (0.6)	2.7 (2.1)	1.8 (1.1)	T	0.09

n, number; %, percentage; SD, standard deviation; ASA, acetylsalicylic acid.

After topical therapy by irrigation, we asked questions on subjective outcomes to all 16 patients (detailed in Table 1). Of these, 6 reported overall subjective improvement; 9 informed partial subjective improvement; and only one patient felt no improvement, totaling 15 patients (93.8%) with clinical subjective improvement. In addition to the patient without improvement, two patients with partial subjective improvement were not satisfied with the outcome of their topical therapy by irrigation, totaling 13 patients (81.3%) with satisfactory subjective improvement. All patients who did not exhibit satisfactory subjective improvement received an indication for a new surgical procedure, with orientation to restart their topical therapy by irrigation postoperatively.

Quantitative evaluation of objective outcomes is presented in Table 2 . Globally, our quantitative evaluation showed significant improvement in SNOT-22 (mean of 50.2 in pre to 29.6 in post; p = 0.006) and in Lund–Kennedy (mean of 8.8 in pre- to 5.1 in post-; p = 0.01) scores in our study population. Corroborating subjective data, patients without satisfactory subjective improvement showed no significant improvement in SNOT-22 and Lund–Kennedy scores, unlike the rest of our study population.

Table 2- Quantitative Assessment Of Objective Outcomes.

Data		Groups			
		With satisfactory improvement	Without satisfactory improvement	Total	*t* test *p*-value With vs. without improvement
Patients, total	*n* (%)	13 (81.3)	3 (18.7)	16 (100)	
SNOT-22 pre	Mean (SD)	47.7 (19.6)	61.0 (16.4)	50.2 (19.3)	0.31
SNOT-22 post	Mean (SD)	25.3 (19.3)	48.0 (16.5)	29.6 (20.4)	0.13
Difference SNOT-22	Mean (SD)	22.4 (23.4)	13.0 (4.4)	20.6 (21.6)	0.19
Pre vs. post *t* test *p*-value		0.007a	0.39	0.006a	
Lund–Kennedy pre	Mean (SD)	8.5 (3.5)	10.3 (1.5)	8.8 (3.3)	0.19
Lund–Kennedy post	Mean (SD)	4.2 (4.3)	9.3 (1.2)	5.1 (4.4)	0.002a
Difference Lund–Kennedy	Mean (SD)	4.3 (4.0)	1.0 (1.0)	3.7 (3.8)	0.02a

N, number; %, percentage; SD, standard deviation.

Qualitative evaluation of objective outcomes is demonstrated in Table 3; this assessment showed that no patient exhibited poorer SNOT-22 scores, 4 (25%) showed no improvement, and 12 (75%) improved. Of the twelve patients with improvement, one of them was considered as achieving total improvement (6.3%). As to Lund–Kennedy scores, no patient suffered worsening, 4 (25%) showed no improvement, and 12 (75%) improved. Of these 12 patients, 5 (31.3%) achieved full recovery in their endoscopic score.

Table 3- Qualitative assessment of objective outcomes (SNOT-22 Score)

Patient	Gender	Age	Diagnosis	SNOT 22(Pre)	SNOT 22(Post)	Post-pre difference	Objective improvement
1	F	52	CRSwNP	79	64	-15	Improvement
2	F	61	CRSwNP	61	12	-49	Improvement
3	M	50	CRSwNP	75	0	-75	Total Improvement
4	M	60	CRSwNP	27	15	-12	Improvement
5	M	29	CRSwNP	67	17	-50	Improvement
6	F	56	CRSsNP	52	34	-18	Improvement
7	F	59	CRSwNP	6	8	2	Without Improvement
8	F	37	CRSsNP	65	40	-25	Improvement
9	F	47	CRSwNP	27	11	-16	Improvement
10	M	64	CRSwNP	47	31	-16	Improvement
11	F	58	CRSwNP	33	17	-16	Improvement
12	F	53	CRSwNP	54	61	7	Without Improvement
13	F	47	CRSsNP	51	39	-12	Improvement
14	F	62	CRSsNP	51	49	-2	Improvement
15	F	39	CRSwNP	58	58	0	Without Improvement
16	F	40	CRSsNP	44	17	-27	Improvement

SNOT-22, Sino-Nasal Outcome Test-22; F, female; M, male; CRSwNP, chronic rhinosinusitis with polyps; CRSsNP, chronic rhinosinusitis without polyps.

Table 4- Qualitative assessment of objective outcomes (Lund- kennedy Score)

Patient	Gender	Age	Diagnosis	Lund-kennedy (Pre)	Lund-kennedy (Post)	Post-pre difference	Objective improvement
1	F	52	CRSwNP	10	10	0	Without Improvement
2	F	61	CRSwNP	10	7	-3	Improvement
3	M	50	CRSwNP	9	0	-9	Total Improvement
4	M	60	CRSwNP	10	0	-10	Total Improvement
5	M	29	CRSwNP	10	9	-1	Improvement
6	F	56	CRSsNP	5	0	-5	Total Improvement
7	F	59	CRSwNP	5	0	-5	Total Improvement
8	F	37	CRSsNP	11	0	-11	Total Improvement
9	F	47	CRSwNP	6	6	0	Improvement
10	M	64	CRSwNP	12	10	-2	Improvement
11	F	58	CRSwNP	12	10	-2	Improvement
12	F	53	CRSwNP	10	10	0	Without Improvement
13	F	47	CRSsNP	5	0	-5	Improvement
14	F	62	CRSsNP	9	8	-1	Improvement
15	F	39	CRSwNP	10	8	-2	Improvement
16	F	40	CRSsNP	12	4	-8	Improvement

DISCUSSION

In the evaluation of Post FESS patient, that is, those who had already undergone endoscopic sinonasal surgery without adequate clinical control with topical nasal corticosteroids in the form of spray and up to two cycles of oral antibiotics and/or corticosteroids in the preceding year, the present study demonstrated efficacy of high-volume nasal irrigation with a solution of budesonide, with 81.3% of success in clinical management. Although this design does not allow for a high-level of evidence, we must consider that the study achieved a high success rate in patients who had previously failed treatment with topical nasal corticosteroids in the form of spray. Considering only objective criteria, topical therapy by irrigation was able to significantly reduce SNOT-22 and Lund–Kennedy scores, resulting in 75% improvement in objective parameters.

The corticosteroid dose is another variable that should be considered: the studies cited used 1 mg/day of budesonide or betamethasone, while in the present study our patients used budesonide 500 g/day. We choose a lower dose because this is closer to the usual dose of budesonide nasal spray for CRS, which is 400 g/day. But this option may have also contributed to a lower success rate of this study, when compared to that of Snidvongs et al.10 On the other hand, the dose we chose leads to another consideration: all patients included in this study did not achieve clinical control when using 400 g/day of budesonide nasal spray; however, with a small increase in the amount of corticosteroids (500 g/day) and a change in the form of administration (high-volume nasal irrigation), 81.3% of these patients did achieve clinical control. This finding can corroborate the concept that high-volume nasal irrigations with budesonide solution not only have the advantage of a drug distribution directly to paranasal sinuses, but also bring the benefit mechanical washings with saline.

CONCLUSION

High-volume irrigation with corticosteroids as topical therapy is a good option in the management of Post FESS patients of chronic rhinosinusitis, significantly improving their objective and subjective parameters. Both SNOT-22 and Lund–Kennedy scores improved in 75% of cases, with satisfactory subjective control in 81.3% of these patients.

Conflicts Of Interest

The authors declare no conflicts of interest.

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