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Comparison of Corticosteroids Effectiveness via High Volume Nasal Irrigation versus Conventional Nasal Spray after Endoscopic Sinus Surgery in Nasal Polyposis

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ABSTRACT

Objective: To compare the efficacy of two different methods of topical corticosteroid delivery techniques; conventional nasal spray versus high volume nasal irrigation with squeeze bottle, post-operatively in patients of nasal polyposis.

Study Design: Quasi-experimental study.

Place and Duration of Study: Department of Ear Nose Throat, Combined Military Hospital, Kohat Pakistan, from Sep 2021 to Aug 2022.

Methodology: A total of 80 patients diagnosed with nasal polyposis were recruited for this study. Selected patients were divided into two equal groups. Pre-operatively all patients were carefully assessed with the help of Sino-nasal outcome test 22 (SNOT 22) and Lund Kennedy Endoscopy score for severity of symptoms. Post-operatively, Group-A received Betamethasone via high volume irrigation by squeeze bottle whereas Group-B received the Beclomethasone via conventional nasal spray. This treatment plan continued for 3 months. Post-operatively, SNOT 22 and Lund Kennedy Endoscopy score assessment was carried out at 3 months.

Results: Both groups were comparable with respect to demographic data. In Group-A pre-op median and interquartile range for SNOT score was 68 and 10 respectively and it was reduced to 14 and 5 post-operatively, whereas in Group-B, it was 68 and 10; 27 and 5.5 pre and post-operatively. Post-operative difference was significant (p-value=0.001). Similarly, in Group-A, pre and post-operative median and interquartile range for LKE score 6 and 1 respectively and 2 and 0, whereas in Group-B it was 6.22 and 0.4 and 1.5 with statistically significant post-operative difference (p-value=0.001).

Conclusion: High volume irrigation with squeeze bottle is more effective method of delivering the drug to target tissue in comparison to conventional nasal spray after nasal polyposis surgery.

Keywords: Corticosteroids, Corticosteroid Irrigation, Endoscopic Sinus Surgery, FESS, Nasal Polyposis, Recurrent Nasal Polyposis.

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INTRODUCTION

Nasal polyposis is a very common condition affecting up to 10-14% of general population.[1] Nasal polyps are benign hyperplastic growths of sino-nasal mucosa. Patients usually present with symptoms of post-nasal drip, rhinorrhea and nasal obstruction, loss of smell, facial pain and headache.[2] If untreated may lead to reduced quality of life and long-term morbidity. Etiology remains unclear but most probably this condition is caused by environmental allergic triggers with some genetic predisposition.[3]

Mainstay of treatment has remained the oral or topical corticosteroids.[4] Once the medical therapies are exhausted and are unable to alleviate the symptoms, polyps can be surgically removed by Function Endoscopic Sinus Surgery (FESS). Despite various treatment options, recurrence is very common. It has a very high recurrence rate ranging from 4-60%,[5] which results in dissatisfaction not only for patients but also the cause of frustration in treating physicians. Use of various oral and topical corticosteroids or combination of both has been well documented for prevention of the recurrence of the disease.[6] Some of the commonly used corticosteroids include Mometasone furoate,[7] Budesonide,[8] Betamethasone,[9] and Beclomethasone. Betamethasone is a potent corticosteroid drug which is very economical and easily available. It has a long half-life of 10 to 12 hours with a wide therapeutic window. Beclomethasone dipropionate is a 2nd generation synthetic steroid drug. Its nasal spray

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formulation is commonly available in market and is one the most commonly prescribed drug after the polyposis surgery in this region.

These drugs are usually available as nasal sprays. Nasal sprays have been in use for quite some time. They are easily available and are user friendly and hence advised by majority of the clinicians. However, the delivery of the drug to target tissue via this technique is usually not adequate and treatment failure is quite common with this technique. To overcome this problem, a high volume nasal irrigation technique can be used. This can be done with the help of squeeze bottles.

The study aimed to compare the efficacy of two different techniques of topical corticosteroid delivery techniques i.e., conventional nasal spray versus high volume nasal irrigation, post-operatively in patients of nasal polyposis.

METHODOLOGY

This Quasi-experimental study was carried out in ENT department CMH Kohat from September 2020 August till 2022. Approval from Hospital Ethical Review board was sought before beginning the study (Certificate No. E-2005/A/04). A total of 90 patients diagnosed with nasal polyposis were recruited for this study after getting the written consent for participation in this study. Sample size was calculated with confidence level of 95%, margin of error 5% and population proportion (Population underwent FESS surgery for polyposis) of 4%.[10] Sample size came out to be 60, but was increased to 90 to increase the accuracy of results.

Inclusion criteria: Patients of either gender with age range from 18 to 65, diagnosed with nasal polyposis were included in this study.

Exclusion criteria: Patients with history of chronic renal failure, diabetes mellitus, morbid obesity and chronic liver disease were excluded from the study. Patients with contraindication to the betamethasone were also excluded from the study.

Selected patients were randomly divided into two equal groups. 45 patients were randomly placed in Group-A, while 45 patients were placed in Group-B (Figure). Pre-operatively all patients were carefully assessed with the help of Sino-nasal outcome test 22 (SNOT 22) (Table-I) and Lund Kennedy Endoscopy (LKE) (Table-II) score for severity of symptoms.

Post-operatively, Group-A received Betamethasone via nasal irrigation with the help of squeeze bottle. Irrigation fluid was prepared by instilling 5 drops of Betamethasone (0.25 mg) in 250 mL of normal saline, half used in each nasal cavity. Irrigation was done twice a day. Group-B patients received Beclomethasone via conventional nasal spray once a day. This treatment plan continued for the duration of 3 months. Post-operatively, SNOT 22 and LKE score assessment was carried out at 3 months.

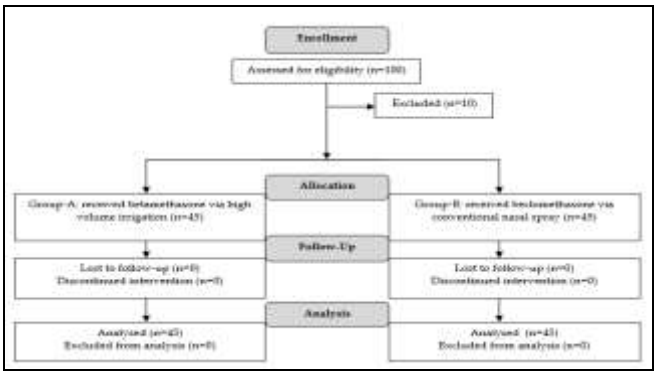

Figure: Patient Flow Diagram

All the data collected was computed with the help of Statistical Package for Social Sciences (SPSS) version 21. Continuous variables like age, SNOT 22 and LKE score were presented as median and interquartile range. Categorical variables like gender were presented as frequency and percentage. Two groups were compared using independent samples t-test (age, duration of symptoms), Chi-square test (gender) and Mann Whitney U test (SNOT 22 and LKE scores). A *p*-value of 0.05 or less was considered statistically significant.

RESULTS

Our primary outcome measure was improvement in the quality of life with the help of SNOT 22 and LKE scores. Age range of the selected cases was from 20 to 65 years, mean age for Group-A was 31.89±8.19 years and for Group-B it was 32.64±9.71 years. Difference between two groups in terms of age was statistically insignificant with *p*-value of 0.721. Both groups had predominantly male patients. In Group-A, 37(82.22%) patients were male and 8(17.78%) were female with male to female ration of 4.6:1. In Group-B, 33(73.33%) patients were male and 12(26.67%) patients were female with male to female ratio of 2.75:1. Gender difference between two groups was insignificant with *p*-value of 0.310. Mean duration of symptoms in Group-A was 2.44±1.35 years, whereas it was 2.67±1.47 years for Group-B. Difference was statistically insignificant with *p*-value of 0.436 (Table-III).

Table-I: Sino-nasal Outcome Test (SNOT) 22 Score[11]

S. No	SNOT 22 Parameter	No Problem	Very Mild Problem	Mild Problem	Moderate Problem	Severe Problem	Problem as bad as it can be
1	Need to blow nose						
2	Sneezing						
3	Runny Nose						
4	Congestion or Blockade of nose						
5	Loss of smell/taste						
6	Cough						
7	Post-nasal discharge						
8	Thick nasal discharge						
9	Ear fullness						
10	Dizziness						
11	Ear Pain/ Pressure						
12	Facial Pain/ Pressure						
13	Difficulty Falling asleep						
14	Waking up at night						
15	Lack of a good night sleep						
16	Waking up tired						
17	Fatigue during day						
18	Reduced Productivity						
19	Reduced Concentration						
20	Frustrated/ Restless/ Irritable						
21	Sad						
22	Embarrassed						

Pre-operative SNOT 22 and LKE scores were comparable in both groups with p-value of 0.882 and 0.164 respectively. Significant difference in post-operative SNOT 22 and LKE scores post-operatively with *p*-values of 0.001 for both scores. Detailed comparison is shown in Table-IV below.

Table-II: Lund Kennedy Endoscopy (LKE) Score[12]

Assessment Criteria/ Endoscopic Observation	Score		
	0	1	2
Polyps in middle meatus	Absent	Restricted to middle meatus	Beyond middle meauts
Discharge in middle meatus	Absent	Thin and clear discharge	Thick and purulent
Edema of middle meatus	Absent	Mild to moderate	Moderate to severe
Crusting in middle meatus	Absent	Mild to moderate	Moderate to severe

Table-III: Comparison of Demographic Characteristics among groups (n=90)

Parameters	Study Groups		*p*-value
	Group-A (n=45)	Group-B (n=45)	
Age in years (mean±SD)	31.89±8.19	32.64±9.71	0.721
Gender Male Female	 37(82.22%) 8(17.78%)	 33(73.33%) 12(26.67%)	0.310
Duration of symptoms(years) (mean±SD)	2.44±1.35	2.67±1.47	0.436

Table-IV: Pre-Operative and Post-Operative SNOT 22 And LKE Scores (n=90)

Parameters		Study Groups		*p*-value
		Group-A (n=45)	Group-B (n=45)	
SNOT 22 (0-110)	Pre-op	68.0(10.0)	68.0(10.0)	0.882
	Post-op	14.0(5.0)	27.0(5.5)	0.001
LKE (0-8)	Pre-op	6.0(1.0)	6.0(0.0)	0.164
	Post-op	2.0(0.0)	4.0(1.5)	0.001

Mann Whitney U test

DISCUSSION

In this study, we compared the efficacy of high-volume nasal irrigation of Betamethasone versus conventional Beclomethasone nasal spray and we found out that high volume nasal irrigation is highly effective as compared to the nasal spray. Difference was huge and almost magical. In a study conducted by Thanneru *et al.,* the outcome was similar to our study. They compared the standard post-op care which includes nasal spray and oral corticosteroids on requirement base versus high-volume highpressure irrigation.[13] Another study by Jiramongkolchai *et al.,* showed the consistent results.[14] Piromchai *et al.,* conducted a multicenter survey on effectiveness of different nasal irrigation devices. Results were quite similar to our study. They concluded that high volume irrigation devices are far better than the other nasal drug delivery devices.[15] In our study, we observed great improvement in SNOT 22 and LKE scores. Huang *et al.,* and in their study observed the similar findings.[16,17]

In another study conducted by Kothiwala *et al.,* researchers from India observed the difference of efficacy of corticosteroid nasal irrigation with saline irrigation. They reached out the conclusion that corticosteroid nasal irrigation has better efficacy than saline irrigation.[18]

Adappa *et al.,* conducted a study in which they used various nasal irrigation solutions and observed their effect on chronic rhinosinusitis and nasal polyposis. They concluded that there is no sufficient evidence that topical steroids provide any clear benefit in cases of chronic rhinosinusitis without polyposis.[19]

One possible limitation of our study is that we could not carry out the follow up beyond 3 months and could not observe the effects of discontinuation of corticosteroid irrigation. It is recommended that a similar study should be conducted with a follow up till one year post-operatively to observe for recurrence of symptoms and polyps.

CONCLUSION

High volume steroid nasal irrigation via squeeze bottle is far more effective method of delivering the drug to target tissue than conventional nasal spray after nasal polyposis surgery and helps improve quality of life.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

CMBA & AH: Data acquisition, data analysis, critical review, approval of the final version to be published.

AH & MZK: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MK & KAAB: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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