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A Comparative Study of Intranasal Fluticasone Versus Intranasal Budesonide for Prevention of Nasal Polyposis after Polypectomy

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Abstract

Background: *Nasal polyposis is a common clinical condition it is histologically an inflammatory disease surgical removal is the preferred treatment. studies have demonstrated that topical corticosteroids are effective in reducing the size of the polyps, nasal symptoms after surgical treatment, and the recurrence rate of polyps after polypectomy. The aim of this study is the comparison of fluticasone propionate nasal spray with Budesonide in the prevention of nasal polyposis following surgery.* ***Method:*** *A total of n=90 cases were included. After the selection of cases, they were randomly allotted in three groups FPANS (n=30) (patients were advised to use fluticasone propionate nasal spray at a dose of 200 mcg/day). Group BUDNS used Budesonide nasal spray at a dose of 128 mcg/day (n=30). Group Control (n=30) was the control group that did not receive any intranasal spray.* ***Result:*** *In our study nasal obstruction seen in n=90 patients 100%, nasal discharge n=90 patients) 100%, sneezing n=90 patients 100%, altered smell in n=25 cases (27.77%) and headache in n=74 cases (82.22%). N=21 cases (23.33%) undergone conventional polypectomy, where n=69 cases (76.66%) undergone Functional Endoscopic sinus surgery guided polypectomy. In our study n=2 cases (7%) recurrence of nasal polyposis in fluticasone group, n=4 cases (14%) in budesonide group and n=9 cases (30%) in control group.* ***Conclusion****: comparison of fluticasone propionate nasal spray with budesonide in the prevention of nasal polyposis after surgery. No statistical significance was found in their efficacy which was assessed by their recurrent rate by proportion, which implies that topical intranasal spray (FPANS and BUDNS) having an equal role in preventing nasal polyposis.*

Keywords*: Nasal polyposis; Fluticasone nasal spray; Budesonide nasal spray*

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Introduction

Chronic rhinosinusitis with nasal polyps is a very common presentation. Although not a life-threatening disease but can disturb the quality of life. [1-4] The polyps appear grape-like structures in the upper nasal cavity usually originating from the ethmoid sinus. They consist of loose connective tissue edema inflammatory cells and some gland and capillaries. They are mostly covered with pseudostratified epithelium along with ciliated and goblet cells. Nasal polyposis due to differing theories of etiology remains a poorly understood disease. They are the nasal manifestation of an unstable respiratory mucosa which may be limited to the nose and sinuses or extend into the chest. Polyps are oedematous, hypertrophied prolapsed, mucous membrane. [5] Although numerous researches have dealt with the pathogenesis of nasal polyposis, the mechanism leading to the growth of nasal polyps remains unclear. Inflammatory responses within the nasal mucosa probably play certain

roles in the etiology and pathogenesis of nasal polyposis. [6] Although nasal polyposis is histologically an inflammatory disease, the preferred treatment is surgical, but the frequent recurrence of polyps after surgical treatment is a problem for many patients. Several studies have demonstrated that topical corticosteroids are effective in reducing the size of the polyps, nasal symptoms after surgical treatment, and the recurrence rate of polyps after polypectomy. [7] A review by Aouad et al; [8] found the advantage of topical medication in the prevention of polyp reformation and highlights their use as the mainstay of therapy. A variety of formulations are available for use and each having its safety and clinical efficacy. There is a paucity of data on which intranasal spray to be the most effective in managing the symptoms postoperatively in patients with nasal polyps. The most used are budesonide and fluticasone propionate and therefore we decided to conduct the study using these formulations in postoperative symptom control in nasal polyposis.

Materials and Methods

This prospective study was conducted in the Department of ENT, Prathima Institute of Medical Sciences, Karimnagar. Institutional Ethical Committee approval was obtained for the study after following the protocol for human research. Written consent was obtained from all the participants of the study after explaining the nature of the study in the local language. The patients included n=90 selected cases admitted in the ENT wards at Prathima Hospital, Karimnagar.

Inclusion criteria

1. Patients diagnosed with nasal polyposis who underwent polypectomy.
2. Those willing to participate voluntarily
3. Those available for follow-up

Exclusion criteria

1. Medical contraindication: TB, DM, HTN, Cardiovascular disorders, epistaxis.
2. Pregnant woman and lactating mother.
3. Those who have received sustained-release oral steroids within 2 months and topical steroids within 1 month.
4. Inability to attend all visits and follow up.
5. In cystic fibrosis.

After the selection of cases, they were randomly allotted into three groups. Group FPANS (n=30) (patients were advised to use fluticasone propionate nasal spray at a dose of 200 mcg/day). Group BUDNS used Budesonide nasal spray at a dose of 128 mcg/day (n=30). Group Control (n=30) was the control group that did not receive any intranasal spray. A thorough history, regarding age, sex, socio-economic status, complaints, history of present illness, past history, family history, and associated history of allergy was taken, the previous history of any surgeries for ethmoidal polyposis. A thorough E.N.T. examination was done, and the data was recorded in the proforma. All necessary investigations like Hb%, TC, DC, ESR and absolute eosinophilic count, blood urea and serum creatinine, urine analysis, X-ray of paranasal sinuses, X-ray of nasopharynx were done. CT and other tests are done as and when required by the patient. Nasal smears for eosinophil count. After polypectomy, the tissue was sent for a histopathology examination. The antibiotic treatment was given to each patient. Anti-allergic treatment was instituted in those cases associated with allergic rhinitis and nasal discharge and put on oral prednisolone for few patients preoperatively. The surgeries performed were one of the following

1. FESS guided polypectomy
2. Simple polypectomy and intranasal antrostomy, Intranasal
3. ethmoidectomy

After surgery patient was put on an appropriate antibiotic, analgesics, decongestants nasal drops, and anti-histaminic and oral steroids such as prednisolone for 9 days in tapered dosage. Steroid nasal sprays after 1 week of surgery up to 3 months. All cases were followed up 3 months for the following parameters compared to preoperatively and postoperatively.

1. Nasal Obstruction: Unilateral or bilateral which is compared preoperatively and postoperative for 3 months in visual analog scale (<25%, >50%, <75%, and >75%) for the improvement of symptoms over the follow-up period.
2. Rhinorrhea: nasal discharge preoperatively and postoperatively in the quantity, decrease or not
3. Sneezing: frequency 5-10 or >10 per stretch.

4. Sense of Smell: improved or not
5. Headache
6. Recurrence: whether polyposis has recurred or not

Other factors such as granulation tissue synechiae, crusting are also considered during treatment as these can cause treatment failure and causes recurrence. Follow-up was done over 3 months (12 weeks).

Results

In our study majority being 31-50 years, that is n=64 cases (71.10%), followed by the patients >50 years n=16 patients (17.79%), and the least are 20 - 30 years n=8 (11.11%) cases. In our study, the majority of males n=65 cases (61.11%), and females were n=35 cases (38.88%). Their distribution was for males N=17, n=20, and n=18 respectively. For females n=13, n=10, n=12 in three groups respectively.

Table 1: Age wise distribution of cases in the study

Age group (years)	*FPANS (n=30)*	*BUDNS (n=30)*	*Control (n=30)*
20-30	3	5	2
31-40	15	14	14
41-50	6	8	7
>50	6	3	7

History of allergy was found in 63.33% cases in FPANS and 50% each in BUDNS and Control groups show in table 2. In our study nasal obstruction seen in n=90 patients 100%, nasal discharge n=90 patients) 100%, sneezing n=90 patients 100%, altered smell in n=25 cases (27.77%) and headache in n=74 cases (82.22%) given in table 3.

Table 2: History of allergy recorded in cases

	FPANS (n=30)		*BUDNS (n=30)*		*Controls (n=30)*	
	n	*%*	*n*	*%*	*n*	*%*
Allergy	16	53.33	12	40.00	12	40.00
Asthma	3	10.00	3	10.00	3	10.00

In our study n=21 cases (23.33%) undergone conventional polypectomy, where n=69 cases (76.66%) undergone Functional Endoscopic sinus surgery guided polypectomy details given in table 4.

Table 3: Clinical Symptoms recorded in patients

Symptoms	*FPANS (%)*	*BDNP (%)*	*Control (%)*
Nasal obstruction	100.00	100.00	100.00
Nasal discharge	100.00	100.00	100.00
Sneezing	100.00	100.00	100.00
Altered Smell	33.33	30.00	20.00
Headache	93.33	86.67	66.67

Table 4: Types of surgery performed in the cases of study

Surgery	*FPANS (n=30)*		*BUDNS (n=30)*		*Controls (n=30)*	
	n	*%*	*n*	*%*	*n*	*%*
Conventional	5	16.67	8	26.67	8	26.67
FESS	25	83.33	22	73.33	22	73.33
Total	30	100	30	100	30	100

Table 5: Comparison of symptom before and after treatment in groups

Symptom	*FPANS*		*BUDNS*		*Controls*	
	Before	*After*	*Before*	*After*	*Before*	*After*
Nasal Obstruction	30	3	30	3	30	10
Nasal Discharge	30	4	30	6	30	11
Sneezing	30	4	30	6	30	14
Smell	10	2	9	4	6	6
Headache	28	4	26	4	20	8

In our study nasal obstruction complained after surgery and intranasal steroid in n=3 (10%) cases in fluticasone group, in budesonide group, and n=10 (33%) cases in the control group. Nasal discharge: Seen in n=4 cases (13%) in fluticasone group, n=6 cases (20%) in budesonide group, and n=11 (37%) cases in control group. Sneezing was seen in n=4 cases (13%) in the fluticasone group 6 cases (20%) in the budesonide group and n=14 cases (47%) in the control group. Smell: Sense of smell is not altered (improved) in 2 cases (20%) in fluticasone group, n=4 (44%) in budesonide group and control group all n=6 cases (100%) no improvement of smell. Headache is seen in n=4 (14%) cases in the fluticasone group, n=4 (15%) in the budesonide group, and n=8 (40%) in the control group.

Table 6: Fisher's Exact test for significance between groups

Symptom	*Fisher's exact test*		
	FPASP vs Control	*BUDNS vs Control*	*FPASP vs BUDNS*
Nasal Obstruction	0.023 *	0.044 *	0.258
Nasal Discharge	0.032 *	0.16	0.863
Sneezing	0.042 *	0.021 *	0.547
Smell	0.033 *	0.033 *	0.244
Headache	0.021 *	0.031 *	0.558

* significant

Recurrence rate: In our study n=2 cases (7%) recurrence of nasal polyposis in the fluticasone group, n=4 cases (14%) in the budesonide group, and n=9 cases (30%) in the control group. Recurrence between treatment group and control group. In our study, FPANS V/s control shown (Z-value 2.40) statistical significance $P<0.05$.

Discussion

Nasal polyposis is a nasal manifestation of an unstable respiratory mucosa that may be limited to the nose and sinuses. In our study the comparison of fluticasone propionate nasal spray with budesonide nasal spray in the prevention of nasal polyposis following surgery. The treatment of nasal polyposis and the prevention of relapses of this common disorder is a subject of much debate among clinicians and researchers. In allergy-related nasal polyposis such as ethmoidal polyposis, medical treatment in most cases are not enough, and surgical treatment for nasal polyposis is only partially successful. [9-11] In the current study most of the patients belong to the age group 31-40 years (47.77%) and least were in the age group of 20-30 years (11.11%). it is diagnosed frequently during the 3rd and 4th decade of life. Drake et al; [5] in their study found the maximum number of cases 43% from the 21- 40 years age group. Enlargement of nasal polyps may lead to broadening of the nasal bridge, rarely can encroach into the orbit, cavity compression of ocular structures, resulting in unilateral proptosis. [11, 12] In this study 23.33% of patients underwent Intranasal ethmoidectomy and 76.66% also underwent FESS guided polypectomy under general anesthesia. Often only surgical treatment of nasal polyposis produces unsatisfactory Intranasal ethmoidectomy results and brings temporary relief of nasal obstruction symptoms but is often followed by recurrence. [13-16] The use of topical intranasal corticosteroids is considered by some to the best treatment for the prevention of recurrence of nasal polyposis. [11, 13] In our study FPANS group patients were advised to use fluticasone propionate nasal spray at a dose of 200 mcg/day. Group BUDNS used Budesonide nasal spray at a dose of 128 mcg/day. Group Control (n=30) was the control group that did not receive any intranasal spray. A comparison was done between the fluticasone group and control group, budesonide group and control group, fluticasone group versus budesonide group. In this study, we found FPASP versus controls showed all the symptoms of nasal obstruction, nasal discharge, sneezing, smell, and headache were significantly improved in the FPASP group as compared to controls. Similarly, in BUDNS versus controls, we found all symptoms except nasal discharge were significantly improved in BUDNS when compared to controls. Interestingly the comparison of FPASP versus BUDNS did not show any significant change in improvement. S Shankar et al; [17] in a similar study found both intranasal budesonide and fluticasone propionate effective in controlling symptoms after endoscopic surgery. However, fluticasone was found to be superior to budesonide in control of postoperative symptoms. These results are like the findings of the current study. Valerie JL et al; [18] comparing the effect of fluticasone in severe polyposis found fluticasone and beclomethasone nasal sprays were effective in treating symptoms of severe nasal polyps and patients with FPANS responded quickly to intervention with better magnitude compared to beclomethasone.

Conclusion

In our study the comparison of fluticasone propionate nasal spray with budesonide in the prevention of nasal polyposis after surgery. No statistical significance was found in their efficacy which was assessed by their recurrent rate by proportion, which implies that topical

intranasal spray (FPANS and BUDNS) having an equal role in preventing nasal polyposis.

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