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Comparative Study of the Effect of Steriods Preoperative And Postoperaitvely In Patients Under Going Functional Endoscopic Sinus Surgery For Sinonasal Polyposis

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Abstract:
Background*: Sinonasal polyposis is a chronic disorder with major effects on the quality of life of affected individual. Nasal polyp is a challenge to ENT surgeons because etiology is unknown and pathogenesis is poorly understood and reoccurence is common. The management options for sinonasal polyposis are medical treatment, surgery or combined medical and surgical treatment. Since there are no studies comparing both systemic and topical steroids we have selected this study to evaluate the effect of steriods preoperatively and postoperatively in patients undergoing Function Endoscopic Sinus Surgery for sinonasal polyposis. and we assess the patients using Lund –McKay visual analogue scoring system before and after surgery ,on each follow up and recurrence of polyp.*
Material and methods: *In this prospective study,45 patients of age groups 18- 60years with nasal polyposis undergoing functional endoscopic sinus surgery were randomly allocated into 3 groups of 15 patients each, Group A were given oral and topical(nasal) steroids, Group B with only topical steroids and Group C with no steroids. Effectiveness of topical and systemic steroids (preoperative and postoperatively), post operative outcome, advantage of using steroids in recovery and recurrence of polyps after surgery were compared between the groups.*
Results: *Efficiency of systemic and topical steroids were comparable and statistically significant difference were seen among the 3 groups with good surgical outcome. Recurrence of polyps were significantly less in Group A when compared to Group B and C.*
Conclusion: *Use of combination of oral and nasal steroids are effective in achieving good surgical outcome and reduce the incidence of recurrent nasal polyps.*
Keywords: *Nasal polyposis, oral steroids, intranasal steroids, Prednisolone, Fluticasone, recurrence.*

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I. Introduction

Nasal polyps are benign lesions arising from the mucosa of the nasal sinuses (commonly at the outflow tract of one or more of the sinuses) or from the mucosa of the nasal cavity. Having an uncertain etiology and a tendency to recur, they represent a challenging diagnosis for the otolaryngologist to treat. The management options for sinonasal polyposis are medical treatment, surgery or combined medical and surgical treatment. Endoscopic sinus surgery offers surgery tailored to the disease of each individual in order to restore sinus function through preservation of normal sinus anatomy. Good functional outcome is determined not just by surgical technique, but by medical measures in the immediate pre and post operative period. The introduction of multi angled telescope with rigid rod lenses allowed excellent visualization of the blind and intricte ethmoidal labyrinth. This was supplemented by CT scanner providing images in axial, coronal and saggital planes demonstrating what needs to be seen in the nose and sinus. Most theories consider polyps to be the ultimate manifestation of chronic inflammation, therefore, conditions leading to chronic inflammation in the nasal cavity can lead to nasal polyps Corticosteriods reduce inflamation by decreasing the infiltration of inflammatory cells, especially mast cells and eosinophils. They also play a role in diminishing the hyperreactivity and vascular permeability of nasal mucosa.

II. Material And Methods

Study Population

Study population include patients with sinonasal polyposis who underwent endoscopic sinus surgery in the department of ENT,OSMANIA MEDICAL COLLAGE,HYDERABAD from NOVEMBER 2019 - SEPTEMBER 2020.

Study Design : In this prospective interventional study, 45 patients with sinonasal polyposis who were failed to respond to the medical treatment were selected for the study. They were divided into three groups randomly. Group A were given oral and topical steroids, Group B with only topical steroids and Group C with no steroids. Patients and the responsible bystanders were counseled about the advantages and side effects of steroids, the expected surgical outcome, postoperative morbidity and complications. Before starting steroids, adequate control of infections, systemic illness, routine and relevant investigations were done. Specific investigations like AEC, Total IgE ,CT scan of nose and paranasal sinus was taken for all patients. Preoperative steroids given 1week before surgery and steroids were continued postoperatively. Steroids are given as Prednisolone (40mg for 3 days and tapered by reduction of 5 mg for every 3 days) for 4 weeks .Topical(intranasal) -Fluticasone 100mg 2 puffs twice daily for 4 weeks. Patient is admitted one day prior to surgery. Informed written consent is obtained from the patients. Preoperatively, patient is assessed by Lund -McKay (visual scoring system). Lund -McKay scoring system is a subjective scoring of various parameters such as facial pain, headache, nasal blockage, olfactory disturbances. All patients in the study were given antibiotics before surgery. Surgery done under general anesthesia. After endoscopic sinus surgery ,patient is discharged on third or fourth postoperative day and reviewed after 1 week, 3weeks, 3 months and 6 months when the patient is reassessed by the scoring system, anterior rhinoscopy and nasal endoscopy to know the improvement. Observations were tabulated as per standard scoring system and results were analysed using SPSS version 21.

Place of study:

Department of ENT,OSMANIA MEDICAL COLLAGE, HYDERABAD

Study Subjects:

Inclusion criteria:

1) All patients undergoing functional endoscopic sinus surgery for sinonasal polyposis.
2) Age : 20 to 60 years.
3) Sex :Both Males and Females.

Exclusion criteria:

1) Patients who presents as sinonasal polyposis with underlying diseases like polyps secondary to Inverted papilloma, Sinonasal malignancy.
2) Patients with Diabetes mellitus, Hypertension, and other systemic diseases.
3) Revision endoscopic surgeries

According to current European guidelines,EP3OS 2007[1], the disease can be divided into mild ,moderate or severe based on total severity visual analogue scale (VAS) score (0-10).

Table-1

SYMPTOMS	GROUP A	GROUP B	GROUP C
Facial pain			
Nasal blockage			
Olfactory disturbances			
Headache			
Total score			

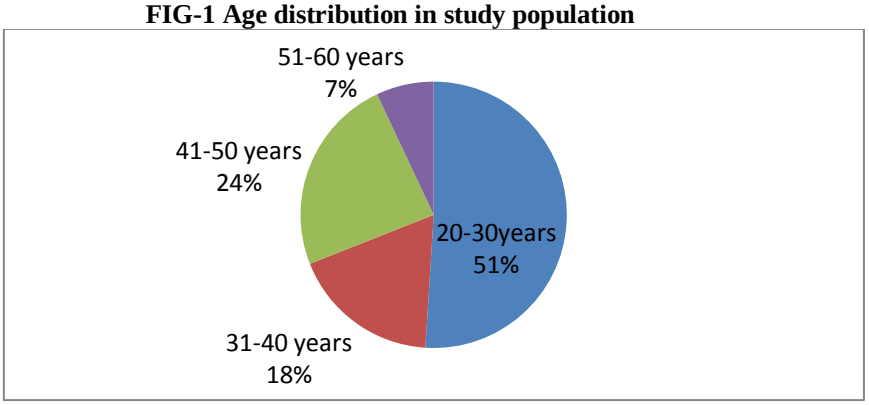
III. Results

45 patients with sinonasal polyposis, who underwent endoscopic sinus surgery were selected for the study. Initially these patients were put on medical treatment. Since there was no improvements, they were selected for surgical clearance.

Age distribution (n =45)

Age distribution of the population ranged from 20 to 60 years with mean age of 34.22 years. Maximum no. of patients are seen in age group of 20 to 30 years (51%).

FIG-1 Age distribution in study population

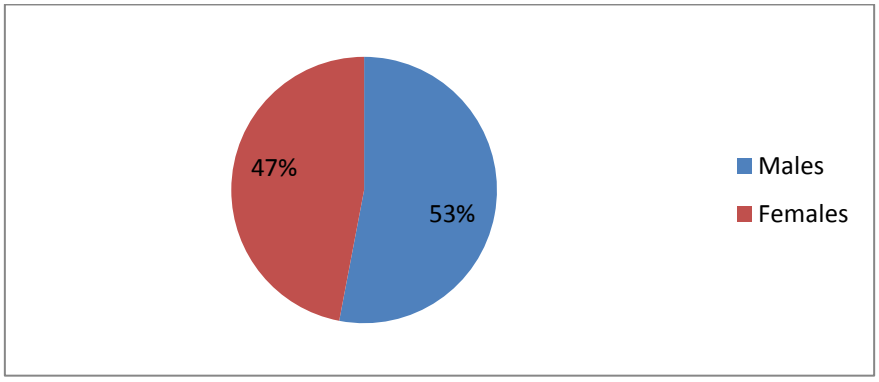


SEX DISTRIBUTION

Males are more affected than females. Male to female ratio 1.1 :1.Maximum number of males are present in Group A and C. females are more in Group B.

FIG2- Sex distribution in study population

Out of 45 study population, 24 were males and 21 were females. Male to female proportion is given below.



Distribution of patients with allergic rhinitis among the groups(n=45)

There were more number of patients suffering from allergic rhinitis in Group A (26.6%) and Group B(22.2%).

FIG-3 Allergic rhinitis in study population

Most association with allergic rhinitis. Out of total population ,31 patients (69%)were associated with allergic rhinitis.

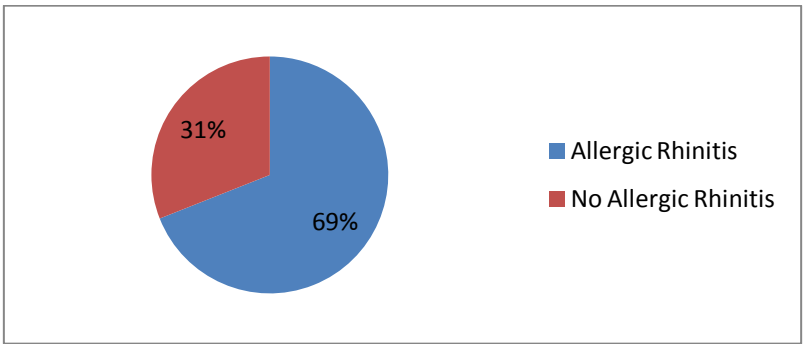


Table-2 Comparison of preoperative and postoperative symptom score among the 3 groups

	Groups	N	Mean Ranks	p-Value
Pre op score	Group-A	15	18.43	
	Group-B	15	24.60	0.243
	Group -C	15	25.97	

1st Follow up(1week)	Group-A Group-B Group -C	15 15 15	15.30 28.20 25.50	0.017*
2nd Follow up(3weeks)	Group-A Group-B Group -C	15 15 15	17.53 21.37 30.10	0.025*
3 rd Follow up(3months)	Group-A Group-B Group -C	15 15 15	10.87 25.80 32.33	<0.001*
4 th Follow up(6months	Group-A Group-B Group -C	15 15 15	11.63 26.97 30.40	<0.001*

***-significant.**

Kruskal Wallis test is used to analyse the data, p-value at 1st (1week), 2nd (3 weeks), 3rd (3months), 4th (6 months) follow up was 0.017*,0.025*, 0.000*, 0.000* accordingly. There is a statistically significant difference observed between the groups.

Table-3 Comparison of preoperative symptom score among the 3 groups.

Groups	N	Mean rank	Kruskal-Wallis Test	p- Value
Group-A Group-B Group -C	15 15 15	18.43 24.60 25.97	2.826	0.243

Kruskal Wallis test is used to analyse the data, which gave a statistic 2.826. and p- value 0.243.There is no significant difference statistically among the groups. This shows that test groups and control group are comparable to be taken up for the study.

Table-4 Comparison of symptom score among Group A and B at follow ups

	Mann-Whitney Test	p –Value
1 week	40.500	0.003*
3 weeks	91.500	0.373
3months	28.5	<0.01*
6 months	28.000	<0.01*

Mann- Whitney U Test was used to analyse the data, this gave a p- value which is significant at 1st week, 3months and 6months . Hence we conclude that Group A better than Group B.

Table-5 Comparison of symptom score among Group A and C at follow ups

	Mann-Whitney Test	p –Value
1 week	69.000	0.069
3 weeks	51.500	<0.01*
3months	14.500	<0.01*
6 months	26.500	<0.01*

Mann- Whitney U Test was used to analyse the data, this gave a p- value which is significant at 3rd week, 3months and 6months . Hence we conclude that Group A better than Group C (as corticosteroids take long time for their action).

Table-6 Comparison of symptom score among Group B and C at follow ups.

	Mann-Whitney Test	p –Value
1 week	106.500	0.802
3 weeks	67.000	<0.05*
3months	70.500	0.074
6 months	87.500	0.292

Mann- Whitney U Test was used to analyse the data,this gave a p-value which is not significant except at 3rd week. Hence we conclude that there is no significant difference between Group B and Group C.

Recurrence of polyp

Table -7 Percentage of number of recurrence and non recurrence among the groups(at 6 months)

GROUPS	REOCCURENCE (%)	NO REOCCURENCE (%)
GROUP A(n=15)	01(6.6%)	14(93.3%)
GROUP B(n=15)	02(13.3%)	13(86%)
GROUP C(n=15)	06(40%)	09(60%)

Recurrence is high in Group C out of 15, 6 had recurrence. Less recurrence in Group A and Group B only 1 cases out of 15 and 2 out of 15 respectively.

FIG-4 - Comparing the number of recurrence among the groups in the 6 months follow up period.

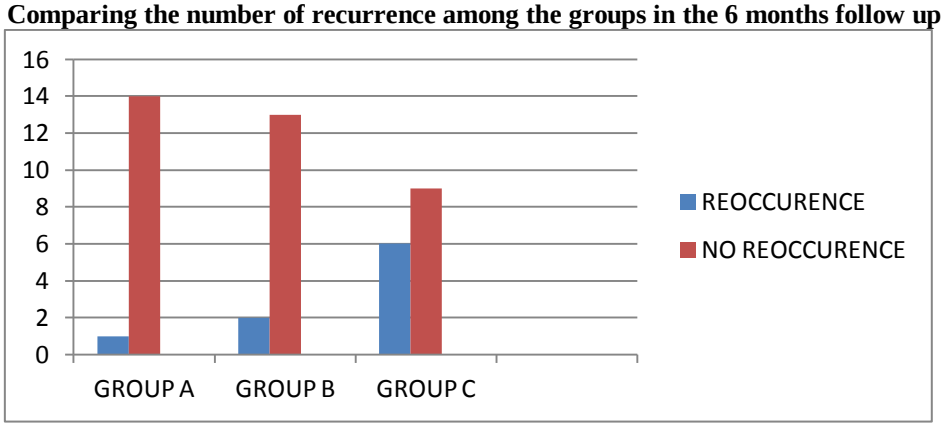


Table -8 Comparison between post-operative recurrence among the groups

Groups	Chi square test	p- value
Group A Group B Group C	5.83	0.05*

Statistically there is significant difference seen in recurrence among the 3 groups(less recurrence in Group A)

IV. Discussion

Age Distribution

In this present study, the most commonly affected age group was between 20-30 years (51.1%) and mean age of 34.2 years. However, most of the literature state that nasal polyps affect an older age group reaching a peak in those aged 50 years and older. Interestingly, a study on 240 patients conducted in our country by Zafar et al[2]. have also found nasal polyps affecting younger age group ranging from first decade onwards, with the peak seen in second and third decade of life. The difference in slightly younger age of presentation among the patients could be due to better diagnostic facilities, better access to medical facilities or could be attributed to hereditary and ethnic variations. In study conducted by Himanshu V et.al[3] in 2016 mean was 33.41 years, Satish nair et.al[4] in 2011 mean age was 37.5 years, Zafar et al.in 2008 mean age was 22.7 years Dijkstra in 2004, patients Mean age: 41 years. All these studies were comparable with our study.

SEX DISTRIBUTION

In the present study 53% (24) cases were male while 47% (21) cases were females. In study conducted by Himanshu V et al.[3] majority of pateints were males 54% and females 45% In a study conducted by Ecevit et al.[5] there were male 78% and 22% are female. The study of Stevens et al.[6] there are male 62% and female 38%. In study conducted by G. Berkiten et al[7]. males 73% were more commonly affected than females 27%. All of the above studies including present study had a male predominance.

EFFECT OF ORAL AND NASAL STEROIDS

In this present study both systemic and topical steroids therapy treated patients (Group A) showed significant difference in symptoms relief (Lund Mac Kay Score) in comparison to Group B(only topical steroids) and Group C (no steroids therapy). In this study in comparison between the patients who were given oral and nasal steroids(Group A) and control group (Group C) there is a significant difference clinically and statistically.

In a study conducted by Ecevit et al[5]. in 2015, 60 mg oral prednisolone was started 2 weeks before surgery. And there visual analog scale (VAS) was evaluated for smell, nasal obstruction, facial pressure, headache, before and after the use of study drug. There results were smell p(<0.41), nasal obstruction(p<0.005), facial pain p(<0.018), headache p(<0.011).In study conducted by Vaidyanathan et al. in 2011[8] used 25 mg prednisolone for 2 weeks followed by topical steroids, and there was improvement in the steroid group(p<0.05.)

Systemic corticosteroids can reach all parts of the nose and sinuses, including the olfactory cleft and middle meatus, and improve the sense of smell better than topical steroids. Additionally, short courses of systemic steroids can be used for nasal polyposis to open up nasal obstruction before therapy with intranasal steroids, which results in improvement of the intranasal spray distribution.

In the study conducted by Ecevit et al[5](2015), the duration of steroid administration is 17 days, beginning with 60 mg prednisolone and attenuated after day 7. The dosage and duration of prednisolone were found to have a statistically significant impact on each variable. Short course of oral steroids is reported to improve subjective symptoms and objective findings in sinonasal polyposis. However, persistently symptomatic patients and those with advanced diffuse polyposis often require surgical therapy. Meanwhile, several studies have reported that intranasal steroids are effective for preventing polyp recurrence after endoscopic sinus surgery

(ESS).Preoperative steroids have been reported to help in stabilizing the inflammation of the disease state, resulting in easier surgery compared to the non-steroid administration group[9] It has been noted, also, that preoperative steroids decrease the oedema of nasal mucosa and shrink the size of nasal polyps which greatly facilitates the access and makes the operation easier without increasing the risk of postoperative bleeding as expected.

Effect of Nasal steroids

In this present study there was no significant difference between Group B (only topical steroids) and Group C (no steroids).The results of present study is in accordance with studies conducted by Dijkstra in 2004, Ehnhage[10] in 2009 and Rowe-Jones in 2005.

In study conducted by Dijkstra[11] found no significant difference between the effect of fluticasone nasal spary compared with placebo on individual symptoms or on the total symptom score. In study conducted by Ehnhage[10] in 2009 also found no significant difference between subjects treated with fluticasone versus placebo at 3 months follow-up.Rowe-Jones[12] also found similar scores between fluticasone and placebo at 1 year of follow-up. The distribution of topical drugs within the nose is very limited. The preoperative use of a topical steroid can be helpful only for patients with stage 1 nasal polyps.

Effect of steroids on recurrence

There are various evidences regarding the prevalence of the recurrent nasal polyposis in patients who had been under endoscopic sinus surgery due to unilateral or bilateral polyposis. It has been estimated that the recurrence rate of sinonasal polyposis varied from 15% to 25%[13]

In this present study the recurrence rate in 6 months follow up is significantly less in Group A in comparison to Group B and Group C.

Table- 9 COMARISION OF RECURRENCE BETWEEN VARIOUS STUDIES USING ORAL AND NASAL STEROIDS with Group A

STUDY	Percentage(%)of Recurrence in oral and nasal steroid group	Percentage(%)of Recurrence in no steroid group
Arsalan et al	16%	40%
Khaled et al	8.3%	25%
Present study	6.6%	40%

In study conducted by Arsalan Shaikh[14] consisted of 25 patients who received preoperatively 60mg prednisolone tablets daily for one week and postoperatively topical nasal steroid spray for three months. All patients were followed up for at least one year. Recurrence of nasal polyps was assessed endoscopically. After one year of follow-up the total number of recurrences in the control group was 12 patients (40%) compared with only 4 patients (16%) in the group of patients treated with oral steroids. Khaled et al[15](2011) in his study divided the sample into two groups. Group I constituted 24 patients treated by endoscopic nasal polypectomy without oral and local steroid therapy. Group II consisted of 24 patients also treated by endoscopic nasal polypectomy but received preoperatively 60mg prednisolone tablets daily for one week and topical nasal steroid spray (Mometasone furoate suspension) for three months. After six months of surgery the total recurrence was detected in 6 patients (25%) in the first group and in 2 patents (8.3%) in the second group of patients. After one year of follow-up the total number of recurrences in the first group was 10 patients (41.6%) compared with only 3 patients (12.5%) in the second group of patients.

Table- 10 Comparison of recurrence in Group B and Group C with various studies

In this present study, recurrence rate is less in Group B (with topical steroids) compared to Group C (without steriods) the following studies supports our study. Postoperative treatment with intranasal steroids is required because it helps to slow the rate of recurrence of polyps.

	Percentage (%)of recurrence in Topical steroid group	Percentage (%)of recurrence in non steroid group
Bross-Soriano et al. 2004	14%	44%

Gulati 2001	25%	80%
Present study	13%	40%

Bross-Soriano et al. in their study on 162 patients concluded that the use of topical intranasal steroid (fluticasone propionate) after resection of sinonasal polyps is not only effective in reducing recurrence (14% compared to 44.4% in control group), but also it is a safe and reliable and does not increase the prevalence of infection[16].

Kang et al. reported that high-dose topical corticosteroid therapy is more effective than low dose topical therapy in preventing recurrent nasal polyps (7.1% opposed to 44%)[17] Gulati et al[18]. found that only patients who stopped using postoperative nasal sprays (10%) developed recurrence three months after surgery. The results of the previous studies strongly support the results of our study and emphasize the importance of corticosteroid use to decrease the recurrence. Overall, according to many studies, postoperative steroids, both topical and systemic, have been shown to improve endoscopy scores and symptom scores and decrease polyp recurrence and, therefore, should be considered as an adjunct in certain post-surgical patient populations.[19, 20, 21]

V. Conclusion

Nasal polyps are more common in age group 20-30 in our study. There is a significant difference in the surgical outcome of patients who were given preoperative and post operative steroids (Group A-oral and topical steriods).Recurrences among Group A and Group B (only topical steriods) were less as compared to Group C (no steriod) and this was statistically significant especially in 3rd and 4th follow up. Hence the present study conclude that use of combination of oral and nasal steroids are effective in achieving good surgical outcome and reduce the incidence of recurrent nasal polyps. The results of previous studies strongly support the results of our study and emphasize the importance of corticosteroids either orally or topically to the surgical outcome and to reduce the incidence of recurrent nasal polyps.

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