ISSN 2515-8260 Volume 10, Issue 1, 2023

"Comparative study between steroid nasal spray alone and steroid nasal spray with oral steroids in treatment of ethmoidal polyposis with chronic rhinosinusitis"

Dr. Parul Rathi, Resident, Dr. Rashmi P Rajashekhar, Professor,

Dr. G.D. Mahajan, Professor and HOD, Dr. Supriya Mathur, Resident, Department of ENT and head and neck surgery, Dr

DY Patil Medical College and research Hospital, Dr. D.Y. Patil Vidyapeeth, Pimpri, Pune (M.H.) INDIA

Corresponding address- Dr. Rashmi P Rajashekhar, Professor, Department of ENT and head and

neck surgery, Dr DY Patil Medical College and research Hospital, Dr. D.Y. Patil Vidyapeeth

Pimpri, Pune,9975082995, email id- parulrathi.96@gmail.com, rashmi.rajashekhar@dpu.edu.in

ABSTRACT

AIM: To study the efficacy of steroid nasal spray alone and steroid nasal spray with oral steroids in patients of ethmoidal polyposis with chronic rhinosinusitis.

MATERIALS AND METHODS: All the patients with presentation of chronic sinusitis with ethmoidal polyposis, fitting in the definition of the study and fulfilling the inclusion criteria had a detailed history taking of the concerned complaints. Steroid therapy was given to each patient in the study for 6 weeks. One group of patients were given topical steroid in form of mometasone nasal spray for 6 weeks (Group A) and the other group was given mometasone nasal spray along with 8 mg of methylprednisolone for 15 days in a tapering dose (Group B). Each patient underwent a thorough radiological examination of the nose following steroid therapy.

RESULTS: The symptoms were significantly reduced in both of our research groups, but the most improvement was shown in those who had both systemic and local steroid therapy. The odds of improvement with topical steroid treatment only is 0.1905 times that of the odds of improvement with topical and systemic steroid treatment based on

ISSN 2515-8260 Volume 10, Issue 1, 2023

CT PNS in all individuals. The symptom and polyp size reduction rate was significantly greater in Group B individuals than in Group A (p value-0.01209) as evidenced on CT PNS.

CONCLUSION: In conclusion the results of this study indicate that thrice daily administration of 8 mg oral preparation of methylprednisolone for 15 days and topical steroid in the form of nasal spray for 6 weeks is an efficacious treatment for chronic rhinosinusitis with ethmoidal polyposis. It also provides significant relief of symptoms, reduction in polyp size and overall control of mucosal inflammation and tissue remodeling (p value- 0.012)

KEYWORDS – Chronic rhinosinusitis, ethmoidal polyposis, steroid therapy

INTRODUCTION

Nasal polyps are one of the most commonly encountered conditions in the Otorhinolaryngology Out Patient Department (OPD). Nasal blockage, congestion, or discharge must be present as at least one symptom of rhinosinusitis, which includes nasal polyps. Other signs and symptoms include excessive nasal secretion, hyposmia or anosmia, postnasal drip with cough, headache, endoscopic evidence of polyps, discharge, edema, obstruction primarily in the middle meatus, &/or CT changes in the OMC &/or in the sinuses as well as sleep disturbance.[1] Chronic rhinosinusitis is defined as lasting longer than 8 to 12 weeks.[2] In this regard, it's critical to distinguish between acute recurrent rhinosinusitis and chronic rhinosinusitis. The latter is characterized by two to four discrete bouts of acute rhinosinusitis per year, with full recovery of symptoms in between. The anterior ethmoid sinus is most frequently affected.[3] Edematous connective tissue stroma herniating through the basement membrane causes polyps to develop.[4] They are often coated by pseudostratified ciliated columnar epithelium and histologically consist of loose connective tissue, inflammatory cells, and fluid. Gross nasal examination reveals stalked, mobile, smooth, grayish pear- shaped masses that are unresponsive to manipulation and do not bleed.[5] The preferred imaging technique for the paranasal sinuses is computed tomography which is the gold standard for identifying inflammatory sinus illness brought on by blockage for both adult and pediatric patients.[6] Determining the disease's extent, defining an anatomical

ISSN 2515-8260 Volume 10, Issue 1, 2023

variant, and establishing the relationship between the sinus and the nearby significant structures are some of the objectives of a CT scan.[7]

AIMS AND OBJECTIVES

AIM: To study the efficacy of steroid nasal spray alone and steroid nasal spray with oral steroids in patients of ethmoidal polyposis with chronic rhinosinusitis.

OBJECTIVES:

1.To compare CT Paranasal sinuses findings before and after steroid therapy.

MATERIALS AND METHODS

STUDY TYPE: Present study was a prospective study.

SOURCE OF DATA: Data for study was collected from all patients attending ENT OPD at tertiary care hospital with nasal obstruction, chronic sinusitis and clinically diagnosed nasal polyposis.

STUDY DURATION: The study was conducted from May 2021 to October 2022

SELECTION CRITERIA:

Patients were selected randomly as being admitted.

STUDY POPULATION:

The study population included patients diagnosed with chronic rhinosinusitis and nasal polyposis. The criteria for selection was as follows:

INCLUSION CRITERIA:

1) Patient age between 16 years-65 years

2) Patients with bilateral ethmoidal polyposis.

3) Patients with Chronic Rhinosinusitis with ethmoidal polyposis.

EXCLUSION CRITERIA:

1) Patients less than 16 years and above 65 years of age.

2) Comorbid conditions (diabetes mellitus and immunocompromised conditions)

ISSN 2515-8260 Volume 10, Issue 1, 2023

3) Past history of FESS

4) Recurrence

5) Malignant lesions of para nasal sinus.

SAMPLE SIZE:

The sample size calculation is based on an assumption. Assuming the medium effect size between 2 groups at 5% significance level and 80% power, the minimum sample size calculated is 68, 34 in each group.

The software used is G* Power version 3.1.9.7

METHOD OF STUDY:

Institute Ethics Committee clearance was obtained before the start of study. All the patients with presentation of chronic sinusitis with ethmoidal polyposis, fitting in the definition of the study and fulfilling the inclusion criteria had a detailed history taking of the concerned complaints. Prior to enrollment in the study, signed informed permission was obtained from each participant after they have been told of the study's purpose and specifics. A standard detailed examination of the nose which includes anterior rhinoscopy, posterior rhinoscopy, examination of paranasal sinuses along with this examination of ear and throat surgery was carried out in each patient in the Outpatient department of the hospital. Each patient underwent a computerized tomography of nose and paranasal sinuses with 0.5mm cuts in axial, coronal and sagittal views. A routine hemogram along with absolute eosinophil count was carried out. Steroid therapy was given to each patient in the study for 6 weeks. One group of patients were given topical steroid in form of mometasone nasal spray for 6 weeks (Group A) and the other group was given mometasone nasal spray along with 8 mg of methylprednisolone for 15 days in a tapering dose (Group B). Each patient underwent a thorough examination of the nose following steroid therapy, including an anterior rhinoscopy, posterior rhinoscopy and paranasal sinus examination. This was followed by a CT of the nose and paranasal sinuses to reassess the patient.

OBSERVATION AND RESULTS

Among the patients in our study, the age range of patients with the most prevalent age

ISSN 2515-8260 Volume 10, Issue 1, 2023

of presentation was 31-45 years followed by 46-65 years (table 1, graph 1). Among our patients with chronic rhinosinusitis and nasal polyposis, men made up the majority. 48 of the 68 cases were men, and 20 were women (table 2, graph 2). The nasal symptoms that our study participants experienced were sneezing, nasal discharge, blockage, and itching (table 3). The most typical ocular symptoms were wetness and itching of the eyes. Post nasal drip, throat irritability, coughing, chest congestion, and wheezing were among the other typical symptoms. The symptoms were significantly reduced in both of our research groups, but the most improvement was shown in those who had both systemic and local steroid therapy. The odds of improvement with topical steroid treatment only is 0.1905 times that of the odds of improvement with topical and systemic steroid treatment based on CT PNS in all individuals (table 5, graph 4). The symptom and polyp size reduction rate was significantly greater in Group B individuals than in Group A (p value-0.01209) as evidenced on CT PNS. In the topical group 20 patients had reduction in size of polyps while in topical plus systemic steroid group 30 patients had reduction in size of polyps (graph 4) In our study we also found that 52 patients had an associated raised absolute eosinophil count, 7 patients had bronchial asthma and 1 patient was a known case of aspirin intolerance (table 4, graph 3). Image 1 shows CT PNS of a patient before steroid therapy and image 2 shows CT PNS of a patient post getting 6 weeks of topical steroid in the form of nasal spray and 2 weeks of systemic oral steroids.

ISSN 2515-8260 Volume 10, Issue 1, 2023

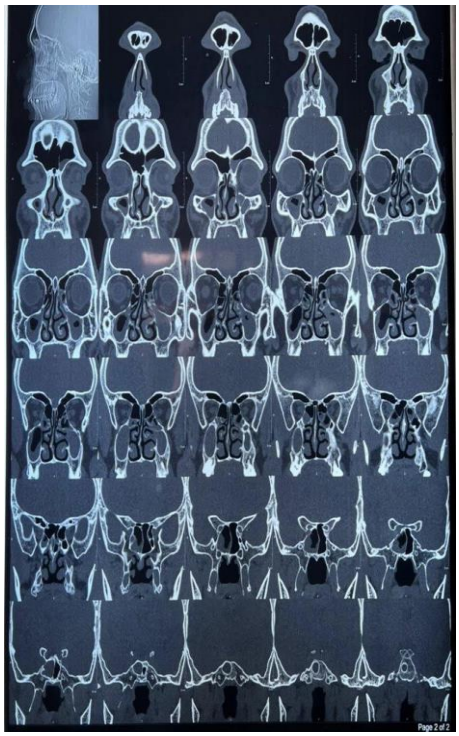


Image 1

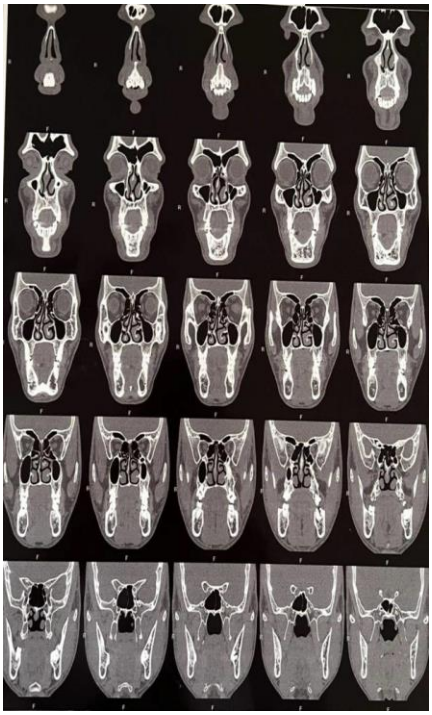


Image 2

Table 1: Age distribution

Age (in years)	N (%)	95% CI
16-30	14 (20.59)	12.23 – 31.41
31-45	33 (48.53)	36.84 – 60.35
46- 65	21 (30.88)	20.78 – 42.58

Graph 1: Age distribution

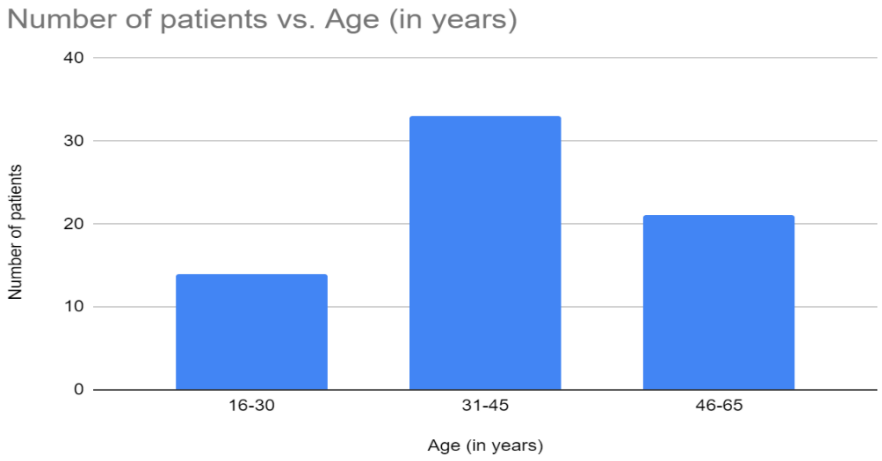


Table 2: Gender distribution

Gender	N (%)	95% CI
Male	48 (70.59)	58.98 – 80.48
Female	20 (29.41)	19.52 – 41.02

Graph 2: Gender distribution

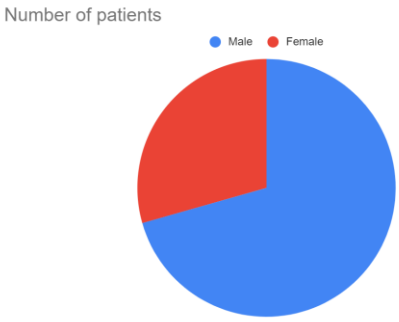


Table 3: Evaluation of symptoms

Symptoms of Allergic Rhinitis	N (%)	95% CI
Present	61 (89.71)	80.70 – 95.39
Absent	7 (10.29)	4.61 – 19.30

ISSN 2515-8260 Volume 10, Issue 1, 2023

*N (%)- percentage of Number of patients
CI (%)- Confidence Interval (percentage)

Table 4: Co-factors Associated in our study population

Co-factors Associated	N (%)	95% CI
Raised AEC	52 (76.47)	65.32 – 85.40
Bronchial Asthma	7 (10.29)	4.61 – 19.30
Aspirin Intolerance	1 (1.47)	0.07 – 7.04

Graph 3: Co-factors Associated in our study population

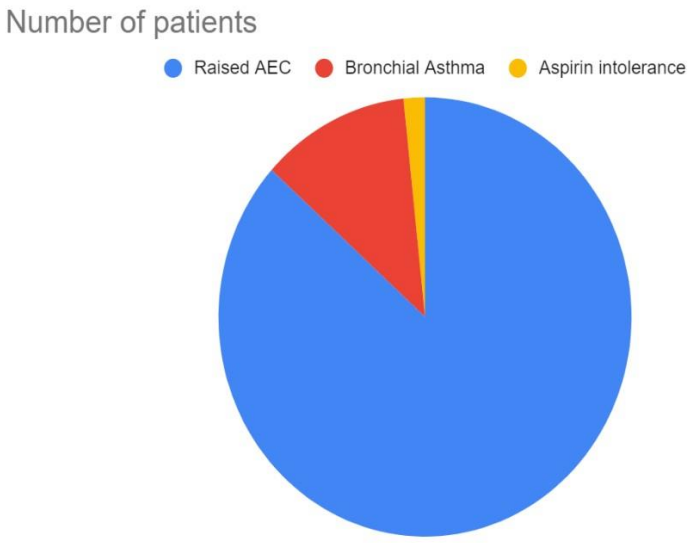


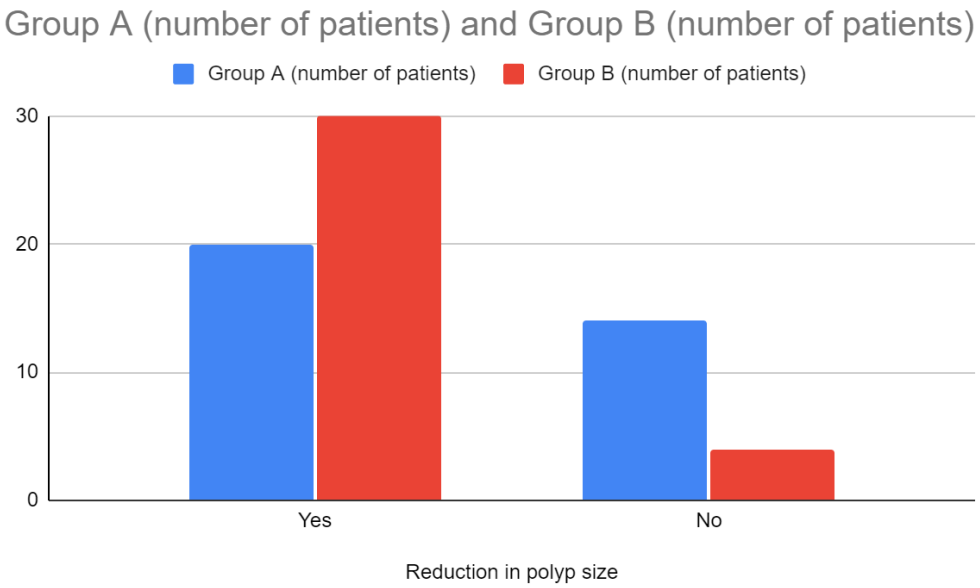
Table 5: Evaluation of CT PNS results post steroid therapy

Reduction in polyp size	Group A N (%)	Group B N (%)	Odds Ratio (95% CI)	p-value

ISSN 2515-8260 Volume 10, Issue 1, 2023

Yes	20 (58.82)	30 (88.24)	0.1905 (0.0547 – 0.6628)	0.01209
No	14 (41.18)	4 (11.76)		

Graph 4: Evaluation of CT PNS results post steroid therapy



DISCUSSION

This study was performed to evaluate the efficacy of topical steroids in the form of nasal spray and systemic oral steroids in treatment of ethmoidal polyposis with chronic rhinosinusitis.

We decided on an oral tablet methylprednisolone dosage of 8mg/d TDS in tapering dose as it has a good systemic anti-inflammatory impact. In our clinical practice, this regimen is routinely used to promote adherence and lessen the risk of adverse effects from greater doses, like sleep disturbance. We did not observe any serious complications after giving systemic steroids. Systemic oral steroids were given for 2 weeks and steroid nasal spray therapy was administered for 6 weeks because we expected that adequate clearing of the osteomeatal complex would enhance the outcomes of CRS with nasal polyposis illness. Nasal sprays have a lesser systemic absorption and offer superior osteomeatal

ISSN 2515-8260 Volume 10, Issue 1, 2023

complex deposition. Topical steroids have been found in controlled studies to delay the return of polyps following surgery and, consequently, the necessity for additional surgery. However, the impact is very temporary, especially in situations when there is considerable inflammatory activity.[8] Evidently, topical steroids do not work for all patients. This can be because the spray wasn't distributed properly in the nasal passages of a very congested nose. Intranasal steroids may not provide instant relief; however, some relief may be seen within 3–4 hours. These drugs only effectively control symptoms when used continuously over extended periods of time.[9] Afterward, responsiveness can be attained following a brief course of systemic steroids. Prednisolone tablets and depot injections of systemic steroids are also options that likely have comparable therapeutic indices. When receiving medication orally, a greater overall dose is likely required, for instance, 8 mg of prednisolone thrice daily for 10- 14 days in tapering doses. All nasal symptoms, including anosmia, can be significantly alleviated within a few days of application. A brief course of systemic steroids can be used as a "medical polypectomy" and is just as effective as a straightforward snare-based polypectomy. Preoperative administration of a systemic steroid will significantly speed up surgery in cases of severe or recurrent disease necessitating endoscopic surgery. The hypothalamic-pituitary-adrenal axis can be disturbed by oral steroids and they can also cause high blood sugar and diabetes mellitus, GI ulcers, heartburn, glaucoma, cataract, water retention, and gain in weight.[10,11] With a brief treatment, these adverse effects might not be anticipated and in patients with advanced disease, a better quality of life might outweigh them. Blomqvist and colleagues recently came to the conclusion that the majority of cases of nasal polyposis can be treated with medical care.[12] Numerous other trial including those by Bonfils, Krunichuno Rino, Cassano, Kowalski and their colleagues , have demonstrated that the most efficient treatment for shrinking polyps and delaying the need for surgical intervention is a combination of oral and topical steroids. This is due to the fact that when used before or after surgery, topical and oral steroid’s effects complement one another.

SUMMARY

ISSN 2515-8260 Volume 10, Issue 1, 2023

Nasal polyposis may present as a distinct clinical condition or it may coexist with (and aggravate) other disease states such as cystic fibrosis, asthma and aspirin intolerance.

In our study for the treatment of CRS with ethmoidal nasal polyposis, we discovered that a 2-week initial course of oral steroid therapy along with topical steroid therapy for 6 weeks is more beneficial than topical therapy alone for 6 weeks in reducing polyp size. Consequently, it aids in alleviating symptoms without long-term negative effects. This is especially true when used for a brief period of time. When compared to each therapy alone, a combination of the two has been found to be the most successful. Intranasal steroids may be preferred prior to surgery due to the potential side effects associated with oral steroids, but systemic oral steroids may be preferable due to their superior ability to reduce symptomatology and enhance the results of surgery.

Therefore,

1. Systemic and topical steroids used in combination are far more successful at treating nasal polyps than topical steroids used alone.
2. Although intranasal steroids do not completely remove polyps, they do significantly shrink the polyp. On the other hand, a change in the middle meatus polyps cannot be anticipated because just a small portion of the spray reaches the middle meatus.

CONCLUSION

In conclusion the results of this study indicate that thrice daily administration of 8 mg oral preparation of methylprednisolone for 15 days and topical steroid in the form of nasal spray for 6 weeks is an efficacious treatment for chronic rhinosinusitis with ethmoidal polyposis. It also provides significant relief of symptoms, reduction in polyp size and overall control of mucosal inflammation and tissue remodeling (p value- 0.012) (table 9).

BIBLIOGRAPHY

[1] Fokkens WJ, Lund VJ Mullol J, et al. European position paper on rhinosinusitis and nasal polyps 2012. Rhinology 2012;23:1-299

[2] Rosenfeld RM, Andes D, Bhattacharyya N, et al. Clinical practice guideline: adult sinusitis. Otolaryngol Head Neck Surg. 2007;137(3, suppl):S1-S31

ISSN 2515-8260 Volume 10, Issue 1, 2023

[3] Chaaban MR,Walsh EM,Woodworth BA.Epidemiology and differential diagnosis of nasal polyps,Am J Rhinol Allergy 2013;27:478-8

[4] Berger G, Kattan A,Bernheim J,Ophir D. Polypoid mucosa with Eosinophilia and glandular hyperplasia chronic sinusitis:a histopathological and immunohistochemical study. Laryngoscope 2002;112(4):738-45

[5] Scott-Brown's, Nasal Polyposis, otorhinolaryngology Head and Neck Surgery Volume 1 Basic Sciences Endocrine Surgery,Rhinology, 8th Edition,John Watkinson, Ray Clarke, CRC Press,Taylor and Francis Group, Boca Ratan.2018 Pages-1037-44

[6] Kronemer KA, McAlister WH. Sinusitis and its imaging in the pediatric population. Pediatr Radiol.1997 Nov;27(11):837-46.

[7] Duvoisin B, Landry M, Chapuis L, Krayenbuhl M, Schnyder P. Low-dose CT and inflammatory disease of the paranasal sinuses. Neuroradiology. 1991;33(5):403-6.

[8] Seidman MD, Gurgel RK, Lin SY. Guideline Otolaryngology Development Group. AAO-HNSF. Clinical practice guideline: allergic rhinitis. Otolaryngol Head Neck Surg. 2015;152(1 Suppl):S1- S43.

[9] Mygind N, Lund V. Intranasal Corticosteroids for Nasal Polyposis. Treat Respir Med. 2006;5:93-102.

[10] Hardy JG, Lee SW, Wilson CG. Intranasal drug delivery by spray and drops. J Pharm Pharmacol. 1985;37:294-7.

[11] Kang G, Yoon BK, Jung JH, Cha HE, Kim ST. The Effect of High-dose Topical Corticosteroid Therapy on Prevention of Recurrent Nasal Polyps after Revision Endoscopic Sinus Surgery. American Journal of Rhinology. 2008;22(5):497-501.

[12] Bridgeman MB. Overcoming barriers to intranasal corticosteroid use in patients with uncontrolled allergic rhinitis. Integr Pharm Res Pract. 2017;6:109- 19

ABBREVIATIONS

CRS- Chronic RhinoSinusitis ESS- Endoscopic Sinus Surgery

ISSN 2515-8260 Volume 10, Issue 1, 2023

CRSwP- Chronic Rhinosinusitis with Sinonasal Polyposis

FESS- Functional Endoscopic Sinus Surgery

CT- Computed Tomography

OMC- Osteomeatal Complex

PNS- Paranasal Sinus

AEC- Absolute Eosinophil Count