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Original Research Article

"Clinical Outcomes of Combined Oral Prednisolone and Intranasal Fluticasone Therapy in Chronic Rhinosinusitis with Nasal Polyposis: A Prospective Observational Study"

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Abstract: ***Background***: Chronic rhinosinusitis with nasal polyposis (CRSwNP) is a common inflammatory condition that significantly affects quality of life. Topical corticosteroid nasal sprays alone are often inadequate due to poor penetration to deeper sites of inflammation. Aim: To evaluate the effectiveness of combination therapy with oral prednisolone and topical fluticasone propionate nasal spray in patients with CRSwNP, and to assess changes in symptom severity, endoscopic findings, and radiological scores before and after treatment. ***Materials and Methods***: This prospective observational study included 50 patients diagnosed with CRSwNP attending the Outpatient Department of Otorhinolaryngology, Government Medical College, Orai, Jalaun, Uttar Pradesh, India. Patients with symptoms persisting for more than 12 weeks underwent detailed clinical evaluation, nasal endoscopy, and computed tomography of the nose and paranasal sinuses (CT PNS). Pre-treatment assessment included Visual Analog Scale (VAS) symptom scores and Lund–Mackay scores for endoscopic and CT findings. Patients were treated with a combination of oral prednisolone and fluticasone propionate nasal spray. Post-treatment evaluations using the same scoring systems were performed during follow-up, and results were statistically analyzed. ***Results:*** The mean age of patients was 48.2 ± 17.6 years, with a male predominance (75%). At follow-up, significant improvement was observed in nasal discharge (95%), nasal obstruction (91.7%), facial pain (51.7%), and hyposmia (33.3%). Overall improvement was noted in VAS symptom scores in 78.3% of patients, nasal endoscopic (Lund–Mackay) scores in 80%, and CT PNS Lund–Mackay scores in 60% of patients. ***Conclusion***: Combination therapy with oral prednisolone and fluticasone propionate nasal spray is highly effective in reducing symptoms of CRSwNP, with significant improvement in clinical, endoscopic, and radiological parameters. This regimen leads to a marked reduction in nasal secretions, mucosal edema, and polyp size, supporting its role as an effective medical management strategy for CRSwNP.

Keywords: Chronic rhinosinusitis; Nasal polyposis; Oral prednisolone; Fluticasone propionate; Visual Analog Scale; Lund–Mackay score

INTRODUCTION

Chronic rhinosinusitis (CRS) is one of the most common chronic inflammatory disorders in adults, affecting approximately 10% of the population worldwide. It is defined as persistent inflammation of the nasal cavity and paranasal sinuses lasting for more than 12 weeks and is characterized by the presence of two or more of the following symptoms: nasal discharge, nasal congestion or obstruction, facial pain or pressure, and reduction or loss of smell [1]. Based on endoscopic findings or computed tomography (CT) imaging, CRS is broadly classified into two subtypes: CRS with nasal polyps (CRSwNP) and CRS without nasal polyps (CRSsNP).

Nasal polyps are benign inflammatory outgrowths of the sinonasal mucosa that typically develop

bilaterally within the nasal cavity and paranasal sinuses. Although histologically benign, they can cause significant nasal obstruction, impaired ventilation of the sinuses, and partial or complete loss of olfaction [2]. CRSwNP accounts for approximately 25–30% of all CRS cases and is associated with substantial morbidity and deterioration in quality of life. Given its chronic and recurrent nature, accurate diagnosis, assessment, and effective management of CRSwNP are of considerable clinical importance. Current medical treatment options are limited and are often used as adjuncts or preparatory measures prior to functional endoscopic sinus surgery (FESS) [3].

Nasal endoscopy is a readily available and reliable objective tool for the evaluation of patients presenting with symptoms of CRS. Endoscopic findings such as mucosal edema, purulent discharge, polyps, and anatomical variations involving the middle meatus and osteomeatal complex (OMC) show a strong correlation with CRS [4]. However, in cases where endoscopic visualization is limited due to extensive polyposis, deviated nasal septum, or obstruction of the OMC, computed tomography of the nose and paranasal sinuses (CT PNS) remains the gold standard for assessing the extent of disease, particularly in hidden areas such as the posterior ethmoid cells, ethmoid bulla, and sphenoid sinus [5]. Despite the high prevalence and significant morbidity associated with CRSwNP, clear evidence-based guidelines for initiating and maintaining medical therapy remain limited. Patients with CRSwNP often experience a high symptom burden and frequent disease recurrence following treatment [6]. While long-term monotherapy with intranasal corticosteroids is effective in reducing symptoms and has the advantage of minimal systemic side effects, its efficacy is often limited by poor penetration into the OMC and inadequate restoration of normal sinus drainage, leading to frequent relapses [7]. Although surgical intervention can temporarily relieve obstruction of the OMC, it is not curative and primarily serves to enhance the delivery and effectiveness of topical corticosteroid therapy. The concept of "medical polypectomy," involving a short course of systemic corticosteroids, has been shown to reduce polyp size and improve the long-term efficacy of topical treatments [8].

The present study is based on the hypothesis that combination therapy with oral prednisolone and fluticasone propionate nasal spray is effective not only in reducing nasal polyp size but also in improving nasal symptoms and objective disease parameters, without causing significant or sustained adverse effects.

MATERIALS AND METHODS

Study Design: This study was designed as a **prospective observational study**.

Study Setting and Sampling Design

The study was conducted among patients attending the Outpatient Department of Otorhinolaryngology at **Government Medical College (GMC), Orai, Jalaun, Uttar Pradesh, India**.

Inclusion Criteria

- Patients aged **≥18 years** who were willing to participate and provided **written informed consent**
- Patients presenting with symptoms of **nasal discharge, nasal obstruction, facial pain, and/or decreased sense of smell** persisting for more than **12 weeks**
- Presence of **bilateral moderate to large nasal polyps** confirmed on nasal endoscopy

Exclusion Criteria

- Patients unwilling to give informed consent
- Patients who had received **medical treatment for CRS in the preceding 4 months.**
- Patients who had undergone **surgical intervention within the last 6 months**
- Patients with known **hypersensitivity or contraindications to corticosteroids**
- **Pregnant, lactating, or planning pregnancy**
- Patients with significant co-morbidities such as **hypertension, diabetes mellitus, asthma, tuberculosis, epilepsy**, or other systemic illnesses

Methodology

Ethical clearance was obtained from the **Institutional Ethics Committee** prior to commencement of the study. A detailed clinical history was obtained from all eligible patients. Patients with symptoms suggestive of CRS persisting for more than 12 weeks underwent thorough clinical examination, **diagnostic nasal endoscopy**, and **computed tomography of the nose and paranasal sinuses (CT PNS)**. Diagnostic nasal endoscopy was performed under topical anesthesia using **4% lignocaine (xylocaine)** with a **Stryker 1188 HD camera**, **0° Karl Storz Hopkins II rigid endoscope**, **Wolf scope**, **Stryker X8000 light source**, and **Stryker Vision Pro LED display**. CT PNS was performed using a **128-slice CT scanner (Sceneria, Hitachi Medical Systems)** with **3-mm coronal section thickness**.

Pre-treatment assessment included:

- Symptom evaluation using the **Visual Analog Scale (VAS)**
- Endoscopic assessment using the **Lund–Mackay endoscopic scoring system**
- Radiological assessment using the **Lund–Mackay CT scoring system**

All confirmed cases were treated with **oral prednisolone at a dose of 1 mg/kg body weight in divided and tapering doses**, along with **fluticasone propionate nasal spray (200 mcg, two sprays in each nostril twice daily)** for a duration of **3 weeks**.

Post-treatment evaluations were carried out using the same scoring systems during follow-up visits at **3 weeks, 2 months, and 3 months** from baseline. The present study analyzed pre-treatment and post-treatment outcomes at baseline and at the end of **3 months**.

Statistical Analysis

Continuous variables were expressed as **mean ± standard deviation (SD)** and analyzed using the **Wilcoxon signed-rank test**. Categorical variables were expressed as **frequencies and percentages**. Data analysis was performed using **SPSS version 16.0**. Randomization was done using computer-generated random numbers. A **p-value <0.05** was considered statistically significant, and **p-value <0.01** was considered highly significant.

RESULTS

The highest incidence of CRSwNP was observed in the **51–60 years age group**, accounting for **36.7%** of the study population. The **youngest patient was 20 years** old, while the **oldest was 67 years**. Out of **60 patients**, **38 (63.3%) were males** and **22 (36.7%) were females**, with a **male-to-female ratio of 3.1:1**, indicating a clear male predominance.

Table 1: Age and gender distributions of cases

		Case (N=60)	
		N	%
Age	≤20	1	1.7
	21-30	8	13.3
	31-40	2	3.3
	41-50	16	26.7
	51-60	22	36.7
	≥61	11	18.3
Gender	Female	45	75
	Male	15	25

Nasal Symptoms

Nasal obstruction and nasal discharge were present in all patients (100%). This was followed by facial pain in 55% and hyposmia in 41.7% of patients. Other less common symptoms included headache in 46.7% of patients, fatigue in 3.3%, and earache in 1.7%. None of the patients reported fever, halitosis, dental pain, or cough. A statistically significant improvement was observed in nasal obstruction, nasal discharge, hyposmia, and facial pain when comparing baseline values with findings at 3 months post-treatment ($p < 0.001$), as shown in Table 2.

Table no.2: Pre-treatment & post-treatment difference between nasal symptom score ranks with wilcoxon signed ranks test

Symptom	Symptom before And after treatment	N	P-value
Nasal obstruction	Negative ranks	55	<0.001
	Positive rank	0	
	Ties	5	
Nasal discharge	Negative ranks	57	<0.001
	Positive rank	0	
	Ties	3	
Facial Pain	Nagative ranks	31	<0.001
	Positive rank	0	
	Ties	3	
Hyposmia	Negative ranks	20	<0.001
	Positive rank	0	
	Ties	3	

Post-treatment Symptom Improvement

Following treatment, improvement in nasal obstruction was observed in 55 patients (91.7%), while 3 patients (8.3%) showed no improvement. Nasal discharge improved in 57 patients (95%), with no improvement noted in 3 patients (5%). Facial pain showed improvement in 31 patients (51.7%), whereas 3 patients (5%) did not report any improvement. Improvement in hyposmia was noted in 20 patients (33.3%), with no improvement in 3 patients (5%).

Regarding minor symptoms, post-treatment improvement in headache was seen in 25 patients (41.7%), while fatigue and earache improved in 2 patients (3.3%) and 1 patient (1.7%), respectively. No improvement was observed in headache in 3 patients (5%), fatigue in 1 patient (1.7%), and earache in 1 patient (1.7%).

Table no.3: Distribution of polyp, edema and secretions on nasal endoscopy

Nasal endoscopy		**N**	**%**
Poly	Right	17	28.3
	Left	14	23.3
	Bileteral	29	48.3
Edema	Right	20	33.3
	Left	15	25
	Bileteral	25	41.7
secretions	Right	15	25
	Left	18	30
	Bileteral	27	45

Nasal Endoscopy

On pre-treatment nasal endoscopy, bilateral nasal polyps were observed in 29 patients (48.3%), while right-sided and left-sided polyps were seen in 17 patients (28.3%) and 14 patients (23.3%), respectively. Mucosal edema was bilateral in 25 patients (41.7%), right-sided in 20 patients (33.3%), and left-sided in 15 patients (25%). Nasal secretions were noted bilaterally in 27 patients (45%), on the right side in 15 patients (25%), and on the left side in 18 patients (30%).

Table no.4: Distribution of ppacities of sinuses on CT PNS and nose

Ppacities of sinuses		**N**	**%**
Maxillary	Right	11	18.3
	Left	9	15
	Bileteral	35	58.3
	No Opacity	5	8.3
Anterior ethmoids	Right	13	21.7
	Left	9	15
	Bileteral	33	55
	No Opacity	5	8.3
Posterior ethmoids	Right	9	15
	Left	12	20
	Bileteral	25	41.7
	No Opacity	14	23.3
Spenoids	Right	6	10
	Left	6	10
	Bileteral	6	10
	No Opacity	42	70
Frontal	Right	14	23.3
	Left	3	5
	Bileteral	15	25
	No Opacity	28	46.7
Osteometal Complex	Right	17	28.3
	Left	11	18.3
	Bileteral	18	30
	No Opacity	14	23.3

CT Scan of Paranasal Sinuses and Nose On pre-treatment CT evaluation, bilateral maxillary sinus involvement was the most common finding, seen in 58.3% of patients, followed by bilateral anterior ethmoid sinus involvement

in 55%, bilateral posterior ethmoids in 41.7%, bilateral frontal sinuses in 25%, and bilateral sphenoid sinuses in 10%. Bilateral osteo-meatal complex (OMC) blockage was observed in 30% of patients.

On the right side, frontal sinus involvement was most frequent (23.3%), followed by anterior ethmoid sinuses (21.7%), maxillary sinus (18.3%), posterior ethmoid sinuses (15%), and sphenoid sinus (10%). Right-sided OMC blockage was noted in 28.3% of patients.

On the left side, posterior ethmoid sinus involvement was the most common (20%), followed by maxillary sinus (15%) and anterior ethmoid sinuses (15%), which showed equal involvement. Sphenoid sinus involvement was seen in 10% and frontal sinus involvement in 5% of patients. Left-sided OMC blockage was present in 18.3% of patients.

Regarding sinus opacification, absence of opacity was most frequently observed in the sphenoid sinus in 42 patients (70%), followed by the frontal sinus in 28 patients (46.7%), posterior ethmoid sinuses in 23.3%, and both anterior ethmoid and maxillary sinuses in 8.3% each. Absence of osteo-meatal complex opacification was noted in 23.3% of patients.

Table no.5: Efficacy of treatment in the overall improvement of visual analog symptom score, lund – mackay nasal endoscopy score and lund – mackay computed tomography score

Efficacy of treatment	n	%
VAS	47	78.3
Nasal endoscopy	48	80
CT PNS & nose	36	60

Overall Treatment Outcomes

Overall post-treatment assessment showed improvement in Visual Analog Scale (VAS) symptom scores in 47 patients (78.3%). Improvement on nasal endoscopy, assessed using the Lund–Kennedy scoring system, was observed in 48 patients (80%). Radiological evaluation using CT of the paranasal sinuses and nose, assessed by the Lund–Mackay scoring system, demonstrated improvement in 36 patients (60%).

Table no.6: Pre-treatment and post-treatment mean, standard deviation and Wilcoxon signed ranks test for lund-mackay nasal endoscopic scoring

Endoscopy	Mean Pre-post	SD Pre- post	Symptom beforeand after treatment	n	P-value
RT	3.94-1.92	0.86-0.5	Negative ranks	40	<0.001
			Positive ranks	0	
			Ties	5	
LT	3.98-1.83	0.9-0.39	Negative ranks	37	<0.001
			Positive ranks	0	
			Ties	7	

Post-treatment Nasal Endoscopy Outcomes

Post-treatment nasal endoscopy, assessed using the Lund–Mackay scoring system, demonstrated a statistically significant improvement. On the right side, improvement was observed in 40 patients (66.7%), with a mean score of 1.92 ± 0.50 ($p < 0.001$). On the left side, improvement was noted in 37 patients (61.7%), with a mean score of 1.83 ± 0.39 ($p < 0.001$), as shown in Table 6.

Table no.7: Pre-treatment and post-treatment mean, standard deviation and wilcoxon signed ranks test for lund – mackay ct paranasal sinus and nose scoring

CT PNS& NOSE	Mean Pre-post	SD Pre- post	Symptom beforeand after treatment	n	P-value
RT	5.53-3.96	1.12-0.87	Negative ranks	39	<0.001
			Positive ranks	0	
			Ties	14	
LT	5.33-3.65	1.37-0.93	Negative ranks	37	<0.001

			Positive ranks	**0**	
			Ties	**13**	

Post-treatment Radiological Outcomes (CT PNS & Nose)

Post-treatment radiological assessment using CT of the paranasal sinuses and nose, evaluated by the Lund–Mackay scoring system, showed statistically significant improvement. On the right side, improvement was observed in 39 patients (65%), with a mean score of 3.98 ± 0.87 ($p < 0.001$). On the left side, improvement was noted in 40 patients (66.7%), with a mean score of 3.65 ± 0.93 ($p < 0.001$), as presented in Table 7.

DISCUSSION

Chronic rhinosinusitis with nasal polyposis (CRSwNP) is a common disorder responsible for frequent hospital visits. It is diagnosed and managed by multiple medical specialties, including otorhinolaryngology, internal medicine, and allergy, resulting in considerable variability in clinical practice. Early diagnosis and timely intervention are essential to reduce disease-related morbidity and healthcare burden. Although several studies have evaluated the etiology, surgical management, diagnostic accuracy of nasal endoscopy and CT, or symptom profiles of CRSwNP, there is a paucity of prospective studies in the Indian population correlating the effects of combination therapy with oral prednisolone and topical fluticasone nasal spray.

CRSwNP affects a wide range of age groups. In the present study, the mean age of patients was 48.2 years (range: 20–67 years), with a male predominance (45 males, 15 females). These findings are comparable to those reported by Wabnitz et al., who observed a mean age of 44.5 years [9]. Ling FT and Kountakis reported a mean age of 49.4 years with a male-to-female ratio of 1.1:1 [10]. In contrast, Nayak et al. reported the highest incidence in the third decade of life (78%), whereas in our study the majority of patients (38%) were in the fifth decade [11].

In our cohort, the most common symptoms were nasal discharge (100%) and nasal obstruction (100%), followed by facial pain (55%), headache (46.7%), hyposmia/anosmia (41.7%), fatigue (3.3%), and earache (1.7%). These findings are similar to those reported by Lilly Tariah, where nasal discharge (100%), nasal obstruction (97.4%), headache (54.8%), and anosmia (54.8%) were predominant symptoms [12]. However, Pokharel et al. reported differing symptom frequencies, with nasal obstruction (85.1%) and headache (80.5%) being more common, while nasal discharge and facial pain were less frequent [13]. Other studies by Lohiya et al. and Rathor and Bhattacharjee have demonstrated variable symptom prevalence, reflecting differences in study populations and disease severity [14,15].

Following combined therapy with oral and topical corticosteroids, significant symptomatic improvement was observed. Nasal obstruction improved in 91.7% of patients, nasal discharge in 95%, facial pain in 51.7%, and hyposmia in 33.3%, with an overall improvement in visual analogue scale (VAS) scores in 78.3% of patients. These results are consistent with those reported by Rino K et al., who demonstrated marked improvement in nasal obstruction (98.5%), nasal discharge (83.6%), hyposmia (89.6%), and facial pain (68.7%) following treatment [9]. Vaidyanathan et al. also reported improvement in hyposmia in 83% of patients treated with a short course of oral steroids followed by prolonged topical therapy [8]. Multiple studies have supported the efficacy of combined oral and topical corticosteroids in improving symptoms, reducing polyp size, and decreasing recurrence rates [16–19].

Radiological evaluation in our study revealed that the bilateral maxillary sinuses were most commonly involved (58.3%), followed by bilateral anterior ethmoids (55%), posterior ethmoids (41.7%), frontal sinuses (25%), and sphenoid sinuses (10%). Bilateral osteomeatal complex (OMC) blockage was noted in 30% of patients. These findings are comparable to those reported by Baruah et al., Lloyd et al., and Zojaji et al., who also identified the maxillary sinus as the most frequently involved sinus and the frontal and sphenoid sinuses as the least affected [20–22]. OMC blockage was observed in 76% of our patients, which is similar to frequencies reported by Neto et al. and Bolger et al. [23,24].

Post-treatment evaluation demonstrated improvement in nasal endoscopy (Lund–Mackay scoring) in 78.3% of patients and improvement in CT PNS scores in 60% of patients. Lal et al. reported resolution of symptoms and endoscopic improvement in 51% of patients following combination steroid therapy [25]. Subramanian et al. and Alobid et al. similarly demonstrated significant improvement in symptoms, endoscopic findings, and radiological scores following combined oral and topical steroid therapy [26,27].

Conclusion

Combined treatment with oral prednisolone and topical fluticasone propionate nasal spray for three weeks is effective in improving nasal symptoms and reducing polyp size in patients with chronic rhinosinusitis with nasal polyposis, without sustained adverse effects. Nasal endoscopy is a convenient, reliable, and readily available tool for evaluating patients with CRSwNP. Computed tomography of the paranasal sinuses and nose remains the gold standard for assessing disease extent, particularly in patients with limited or poor endoscopic

visualization due to polyps, deviated nasal septum, or osteomeatal complex obstruction.

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