



## "REAL WORLD PRESCRIBING PATTERNS AND OUTCOMES OF INTRANASAL CORTICOSTEROIDS IN CHRONIC RHINOSINUSITIS: A POPULATION-BASED COHORT STUDY."

Dr. M. Vamshi krishna<sup>1</sup>, Dr. Revalle Shravan Kumar<sup>2</sup>, Dr Sakinala Sunil<sup>3\*</sup>,

<sup>1</sup>Associate professor of ENT, Department of ENT, Government medical college, Department of ENT, Mulugu, Telangana, formerly Associate Professor of ENT, Pratima relief institute of medical sciences, Hanamkonda.

<sup>2</sup>Associate professor of ENT, Department of ENT, Prathima institute of medical sciences, Hanamkonda, Telangana

<sup>3\*</sup>Associate professor of ENT, Department of ENT, Prathima institute of medical sciences, Hanamkonda, Telangana

**Corresponding Author:** Dr Sakinala Sunil,

Associate professor of ENT, Department of ENT, Prathima institute of medical sciences, Hanamkonda, Telangana

---

### ABSTRACT:

**Background:** Chronic rhinosinusitis (CRS) is a multifactorial inflammatory condition of the nasal and paranasal mucosa lasting beyond 12 weeks, significantly impairing quality of life and productivity. Intranasal corticosteroids (INCS) form the cornerstone of CRS management due to their potent anti-inflammatory action, mucosal decongestion, and symptom control. Despite strong clinical guideline recommendations, real-world adherence to INCS therapy, variations in prescribing patterns, and clinical outcomes remain underexplored in the Indian population context. This study sought to evaluate population-level prescribing trends and treatment outcomes of INCS therapy in CRS under routine clinical practice.

**Objectives:** To assess the prescribing patterns, adherence, and clinical outcomes of intranasal corticosteroid therapy in patients with chronic rhinosinusitis across tertiary and secondary care centers in South India.

**Methods:** A real-world, observational cohort study was conducted over a period of 6–8 months among 174 patients diagnosed with CRS as per EPOS 2020 diagnostic criteria. Data were collected from outpatient prescriptions, electronic health records, and structured patient interviews. Variables included demographic characteristics, comorbidities, types and doses of prescribed INCS (mometasone, fluticasone, budesonide, beclomethasone), concurrent therapies, adherence levels (assessed via Morisky Medication Adherence Scale), and clinical improvement (measured by SNOT-22 score reduction and endoscopic grading). Statistical analyses were performed using SPSS v26, with categorical data analyzed via chi-square tests and continuous variables using paired t-tests. A p-value <0.05 was considered statistically significant.

**Results:** Among 174 participants (mean age: 38.6 ± 11.4 years; male-to-female ratio: 1.3:1), mometasone furoate (36.8%) and fluticasone propionate (32.2%) were the most prescribed INCS, followed by budesonide (18.9%) and beclomethasone (12.1%). Concomitant antihistamine and saline irrigation use was noted in 62% and 57% of patients, respectively. High adherence was observed in 61.5% of subjects. Significant improvement in mean SNOT-22 scores was recorded

(from  $46.2 \pm 13.1$  at baseline to  $21.8 \pm 10.4$  at follow-up,  $p < 0.001$ ). The presence of allergic rhinitis and smoking history were negatively associated with therapeutic response ( $p < 0.05$ ). Adverse effects, primarily nasal dryness and epistaxis, occurred in 9.8% of patients but did not necessitate discontinuation.

**Conclusion:** This real-world cohort study highlights that intranasal corticosteroids, particularly mometasone and fluticasone, are the predominant therapeutic agents in CRS management, demonstrating high effectiveness and safety profiles. Consistent adherence to therapy was strongly correlated with clinical improvement. Findings underscore the need for patient education, regular follow-up, and uniform prescribing protocols to optimize CRS outcomes in routine practice. Further large-scale multicentric studies are warranted to evaluate long-term mucosal remodeling and relapse rates.

**Keywords:** Chronic rhinosinusitis, Intranasal corticosteroids, Prescribing patterns, Mometasone furoate, Fluticasone propionate, Real-world evidence, SNOT-22 score, Adherence, EPOS 2020.

## INTRODUCTION

**Background and Global Context:** Chronic rhino-sinusitis (CRS) is one of the most prevalent chronic inflammatory diseases affecting the upper respiratory tract, characterized by persistent inflammation of the nasal and paranasal sinus mucosa lasting for at least 12 weeks. It is a multifactorial disorder with complex pathophysiology involving epithelial barrier dysfunction, mucociliary clearance impairment, microbial dysbiosis, and immune dysregulation. Globally, CRS affects approximately 5–15% of the population, with variations in prevalence depending on environmental, genetic, and socioeconomic factors [1]. The World Health Organization identifies CRS as a major public health concern due to its impact on productivity, absenteeism, and healthcare expenditure [2]. In India, CRS prevalence ranges between 10–12% among adults, with higher rates observed in urban and industrial regions due to increasing exposure to air pollutants, allergens, and occupational irritants [3]. Studies conducted in Delhi, Chennai, and Hyderabad have demonstrated a steady rise in CRS incidence over the past decade, paralleling trends in allergic rhinitis and asthma [4]. The condition is often underdiagnosed and undertreated, leading to recurrent infections, anosmia, and deterioration in quality of life. Moreover, CRS imposes a significant economic burden due to recurrent medical consultations, diagnostic imaging, and long-term pharmacotherapy [5].

**Pathophysiological Overview:** The underlying mechanisms of CRS involve chronic mucosal inflammation driven by a combination of host immune responses and environmental stimuli. Epithelial cells in the sinonasal mucosa act as sentinels, releasing cytokines such as IL-33, TSLP, and IL-25 that promote a Type 2 inflammatory cascade involving eosinophils and mast cells [6]. In CRS with nasal polyps (CRSwNP), this Th2-dominant pathway is particularly prominent, while CRS without nasal polyps (CRSSNP) tends to show a Th1/Th17 inflammatory pattern [7]. Structural and functional impairment of the mucociliary apparatus leads to stasis of mucus, bacterial colonization, and biofilm formation, which perpetuate inflammation and tissue remodeling [8]. Additionally, comorbidities such as allergic rhinitis, asthma, and gastroesophageal reflux disease often exacerbate the disease process and contribute to treatment resistance [9]. Understanding these pathophysiological mechanisms has informed the current therapeutic strategies, emphasizing targeted anti-inflammatory treatment as the cornerstone of management. Rationale for Intranasal Corticosteroid Therapy. Intranasal corticosteroids (INCS) are the mainstay of pharmacological therapy for CRS, recommended by all major clinical guidelines including the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS 2020), American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS), and Indian Ministry of Health and Family Welfare (MOHFW) guidelines [10,11]. These agents exert potent local anti-inflammatory effects by inhibiting cytokine release, reducing mucosal edema, and restoring epithelial integrity. They also enhance mucociliary clearance and reduce polyp volume in patients with CRSwNP [12]. Compared with systemic corticosteroids, INCS offer a favorable safety profile with minimal systemic absorption. Mometasone furoate, fluticasone propionate, fluticasone furoate, and budesonide are

among the most widely used molecules. They differ in receptor affinity, particle size, bioavailability, and duration of action, which influence clinical efficacy and patient adherence [13]. The choice of molecule is typically guided by physician experience, patient affordability, and symptom profile rather than standardized prescribing protocols, especially in resource-constrained settings like India [14]. Prescribing Trends and Real-World Evidence Gaps, despite robust evidence supporting INCS efficacy, real-world data on their utilization and outcomes remain limited, particularly in developing countries. Randomized controlled trials often exclude patients with comorbidities or those using concurrent therapies, thereby limiting generalizability. Observational cohort studies are therefore essential to capture prescribing patterns, adherence behaviors, and treatment outcomes in routine clinical settings [15].

Globally, studies have shown variable adherence to INCS therapy, with rates ranging between 40% and 70%. Factors influencing adherence include complexity of spray technique, delayed symptom relief, cost of medication, and misconceptions about corticosteroid safety [16]. In India, similar challenges persist, compounded by inadequate patient counseling, lack of follow-up, and frequent self-discontinuation after symptom improvement [17]. Such real-world variations can significantly impact therapeutic outcomes and long-term disease control. Recent pharmacovigilance data suggest a trend toward prescribing newer-generation INCS such as mometasone and fluticasone, which possess high receptor selectivity and low systemic bioavailability. However, empirical combination therapies—often including oral antihistamines, leukotriene receptor antagonists, and antibiotics—are commonly used, sometimes inappropriately, contributing to increased healthcare costs and potential side effects [18]. This underscores the importance of evaluating real-world prescribing behaviors to align clinical practice with evidence-based recommendations.

**Impact on Quality of Life and Functional outcomes:** The symptomatic burden of CRS extends beyond nasal obstruction and discharge to include facial pain, anosmia, fatigue, and sleep disturbances. The Sino-Nasal Outcome Test (SNOT-22) has emerged as the gold standard for quantifying symptom severity and monitoring response to therapy [19]. Improvement in SNOT-22 scores has been consistently associated with effective INCS adherence and mucosal recovery. Moreover, endoscopic grading and radiological assessment using the Lund–Mackay scoring system provide objective correlates for disease resolution [20]. Quality of life impairment in CRS is comparable to that seen in chronic diseases like diabetes and chronic obstructive pulmonary disease (COPD) [21]. Real-world outcome evaluation thus needs to consider both clinical and patient-reported endpoints. This dual perspective helps clinicians understand not only the pharmacological effectiveness of INCS but also its holistic impact on patients' functional well-being.

**Indian Healthcare Context and Policy Relevance:** The Indian healthcare system faces unique challenges in CRS management. Over-the-counter availability of nasal decongestants, irrational antibiotic use, and inconsistent access to ENT specialists contribute to delayed diagnosis and inappropriate treatment [22]. The National Programme for Prevention and Control of Deafness (NPPCD) emphasizes early detection and management of upper respiratory disorders but lacks specific operational guidelines for CRS management at primary care levels [23]. Integrating standardized INCS prescribing protocols into primary healthcare frameworks could enhance disease control and reduce chronicity. Pharmaceutical market analyses in India indicate a steady increase in sales of intranasal corticosteroids, especially fluticasone and mometasone, over the past five years [24]. However, empirical data on prescribing rationality, adherence trends, and outcome patterns are scarce. Given the wide socioeconomic diversity of Indian patients, understanding real-world utilization of INCS in CRS has both clinical and policy significance. Evidence-based prescribing can improve cost-effectiveness and reduce the burden of chronic sinonasal diseases in tertiary care facilities.

**Adherence, Technique, and Patient Education:** Patient adherence to intranasal spray therapy is critical for achieving optimal outcomes. Proper spray technique ensures adequate mucosal deposition and minimizes side effects such as nasal dryness and epistaxis. Studies have shown that up to 40% of patients misuse nasal sprays, leading to suboptimal drug delivery [25]. Educational interventions—such as visual demonstration of technique, follow-up reminders, and digital

adherence monitoring—have been shown to improve compliance and symptom relief [26]. In the Indian context, patient literacy levels and health-seeking behaviors influence adherence. Many patients discontinue therapy prematurely due to perceived symptom resolution or fear of “steroid dependency.” Physician-patient communication and counseling thus play pivotal roles in maintaining long-term adherence [27]. The present study aims to explore these behavioral dimensions alongside pharmacological data to provide a comprehensive picture of INCS utilization in CRS. **Therapeutic Outcomes and Safety Profile:** The therapeutic benefits of INCS extend to both symptomatic relief and histopathological improvement. Mometasone and fluticasone have demonstrated superior efficacy in reducing mucosal eosinophilia and nasal polyp volume compared with earlier-generation corticosteroids [28]. In addition, combination regimens involving saline irrigation enhance mucociliary clearance and corticosteroid penetration, further augmenting clinical outcomes [29]. Adverse effects are generally mild and reversible, with epistaxis and dryness being the most common [30].

However, long-term use of INCS warrants careful monitoring, particularly in children and patients with comorbid conditions such as glaucoma or hypertension, where systemic absorption could pose risks [31]. Real-world safety assessments provide valuable data on the tolerability of INCS beyond controlled trial environments. **The Need for Real-World Evidence:** Randomized controlled trials provide high internal validity but limited external generalizability. Real-world observational studies, in contrast, reflect day-to-day clinical practices, incorporating heterogeneous patient populations and practical challenges. Such evidence is increasingly recognized by regulatory agencies and policy bodies for shaping clinical guidelines and reimbursement policies [32]. In the context of CRS, real-world data can elucidate gaps between evidence-based recommendations and actual prescribing behaviors. They can identify underutilized interventions, highlight adherence barriers, and inform targeted educational campaigns. Furthermore, outcome evaluation in real-world settings can validate the long-term effectiveness of INCS and support national formulary decisions.

**Rationale and Justification of the Present Study:** Despite the widespread use of intranasal corticosteroids in CRS management, systematic evaluation of prescribing patterns and outcomes in the Indian population remains sparse. Regional variations in prescribing behaviors, socioeconomic disparities, and patient adherence levels necessitate localized evidence to guide clinical and public health interventions. This study addresses this evidence gap through a population-based, observational cohort approach that reflects real-world clinical practices in South India. By analyzing prescription trends, adherence patterns, and clinical outcomes using validated instruments such as the SNOT-22 and endoscopic grading, this research aims to provide actionable insights into the effectiveness, safety, and rational use of INCS therapy. Moreover, identifying predictors of favorable and poor outcomes—such as co-morbid allergic rhinitis, smoking, and adherence levels—can guide individualized treatment strategies.

The findings from this study are expected to contribute to the refinement of national and institutional prescribing guidelines for CRS and strengthen the implementation of evidence-based practice in otorhinolaryngology. In addition, this research holds implications for health education programs, emphasizing correct usage techniques and the importance of adherence in achieving sustained clinical benefits; **Objectives:** 1. **Primary Objective:** To assess the real-world prescribing patterns of intranasal corticosteroids among patients with chronic rhinosinusitis attending tertiary and secondary healthcare centers. 2. **Secondary Objectives:** 1. To evaluate clinical outcomes following INCS therapy using SNOT-22 and endoscopic grading scores. 2. To determine the adherence rates and associated factors, influencing compliance with INCS therapy. 3. To identify predictors of poor therapeutic response, including demographic, behavioral, and clinical variables. To document adverse events associated with INCS use under real-world conditions. **Expected Contribution:** To bridges the gap between the controlled trial evidence and the everyday clinical practice among the practitioners in India. By documenting real-world prescribing patterns and outcomes, it aims to support rational pharmacotherapy, reduce irrational poly-pharmacy, and optimize patient-centered management of CRS. Findings will also inform medical education and

continuing professional development programs for otolaryngologists and general practitioners. Furthermore, they may serve as a baseline for future multicentric studies and cost-effectiveness analyses under the framework of India's National Health Mission.

## MATERIAL AND METHODS

**Study Design:** A real-world, observational cohort study was conducted to assess the prescribing patterns and clinical outcomes associated with intranasal corticosteroid (INCS) therapy in patients diagnosed with chronic rhinosinusitis (CRS). The study was prospective in nature and observational in design, thereby reflecting actual clinical practice conditions without investigator interference in therapeutic decisions. The methodology adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [1]. **Study Setting and Duration:** The study was carried out in the Department of Otorhinolaryngology (ENT) of a tertiary care teaching hospital and its affiliated secondary care centers in South India. Data collection was undertaken over a period of 6 to 8 months (January–August 2025). The tertiary hospital catered to an average outpatient volume of 150–200 ENT cases per day, with a well-established electronic medical record (EMR) system that facilitated data extraction and follow-up monitoring. **Study Population:** In total 174 patients were observed in this study; over a period of 06 months. All consecutive patients aged 18 years and above who were clinically diagnosed with CRS and prescribed intranasal corticosteroids as part of their routine management during the study period were considered eligible for inclusion. Diagnosis of CRS was made according to the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS 2020) diagnostic criteria [2], defined as: Presence of at least two symptoms, one of which must be nasal obstruction/congestion or nasal discharge (anterior/posterior nasal drip), with or without facial pain/pressure and/or reduction or loss of smell; Symptoms persisting for  $\geq 12$  weeks; Objective evidence of mucosal inflammation demonstrated by nasal endoscopy and/or computed tomography (CT) of the paranasal sinuses. **Inclusion Criteria:** Patients aged  $\geq 18$  years diagnosed with CRS (with or without nasal polyps). 2. Patients newly initiated or already on intranasal corticosteroid therapy. Patients showing willingness to provide written informed consent and comply with follow-up visits were included. **Exclusion Criteria:** 1. Patients with acute bacterial rhino-sinusitis or fungal sinusitis. Patients with history of sino-nasal malignancy, previous sinus surgery within the last 6 months, or significant structural nasal deformity were excluded. Patients who were pregnant or lactating were excluded. Patients on systemic corticosteroid therapy within the preceding 4 weeks were excluded. Patients who were unwilling to participate or inability to attend follow-up assessments were excluded. **Sample Size:** The sample size was determined using the formula for estimating proportions in a cross-sectional design:  $n = \frac{Z^2 \times p \times (1 - p)}{d^2}$ . **Ethical Considerations:** The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC/2025/ENT/027). Written informed consent was obtained from all participants prior to enrolment. Confidentiality of patient data was maintained throughout the study in compliance with the Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017) [4]. Data were anonymized before analysis. **Data Collection Tools and Procedures:** 1. Baseline Assessment At enrolment, each participant underwent a detailed clinical evaluation including demographic data (age, sex, occupation, socioeconomic status), disease characteristics (duration of symptoms, presence of nasal polyps, prior treatments), comorbidities (allergic rhinitis, asthma, GERD, smoking history), and medication details. **The prescription analysis included the following parameters:** Type of INCS prescribed (mometasone furoate, fluticasone propionate, budesonide, or beclomethasone dipropionate); Dosage regimen (number of sprays per nostril per day); Duration of therapy; Concomitant medications (antihistamines, leukotriene receptor antagonists, antibiotics, saline irrigations, or decongestants). 2. **Adherence Evaluation:** Adherence to INCS therapy was assessed at follow-up using the 8-item Morisky Medication Adherence Scale (MMAS-8), a validated self-reported instrument [5]. Patients were categorized into: High adherence: MMAS-8 score = 8, Moderate adherence: MMAS-8 score = 6–7,

Low adherence: MMAS-8 score < 6, Participants were also queried about barriers to adherence such as cost, perceived side effects, difficulty in spray usage, or lack of symptom relief. **3. Clinical Outcome Evaluation:** Therapeutic outcomes were measured using both subjective and objective parameters. **a. Subjective Assessment:** Symptom severity was quantified using the Sino-Nasal Outcome Test (SNOT-22) at baseline and follow-up (3–6 months post-initiation). The SNOT-22 is a validated 22-item questionnaire evaluating nasal, sleep, and psychological symptoms, scored on a Likert scale from 0 (no problem) to 5 (worst possible problem). The total score ranges from 0 to 110, with higher scores indicating greater symptom burden [6]. **b. Objective Assessment:** Nasal endoscopy was performed using a 0° rigid nasal endoscope (Karl Storz, Germany) to evaluate mucosal edema, discharge, and polyp grade as per the Lund–Kennedy scoring system. Radiological assessment was done selectively using CT paranasal sinuses and graded according to the Lund–Mackay scoring system (0–24) where available [7]. Improvement was defined as a  $\geq 50\%$  reduction in SNOT-22 score or  $\geq 1$ -point reduction in endoscopic score at the end of follow-up. **4. Adverse Event Monitoring:** Participants were monitored for local and systemic adverse effects of INCS including nasal dryness, epistaxis, irritation, headache, or throat discomfort. Severity and causality were classified according to the World Health Organization–Uppsala Monitoring Centre (WHO–UMC) causality assessment scale [8]. Patients developing significant adverse reactions were managed according to institutional clinical protocols. **Operational Definitions:** Prescribing Pattern: Type, frequency, dosage, and duration of INCS prescribed during the study period. **Adherence:** Patient's self-reported degree of compliance to prescribed therapy as per MMAS-8 scale. **Outcome:** Measurable improvement in SNOT-22 or endoscopic scores after 6–8 months of continuous therapy. **Non-adherence:** Discontinuation or irregular use of prescribed INCS therapy before completion of the treatment course. **Data Management and Quality Control:** Data were collected using a pre-tested semi-structured proforma by trained research assistants under supervision of the principal investigator. Periodic cross-verification of 10% of randomly selected records was undertaken to ensure accuracy. Data were entered into Microsoft Excel 2021 and validated through double-entry verification. Unique identification numbers were assigned to all participants to ensure anonymity. **Statistical Analysis:** Data analysis was performed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were expressed as means  $\pm$  standard deviation (SD) for continuous variables and frequencies (percentages) for categorical variables. **Comparative analyses included:** Chi-square test for association between categorical variables (e.g., adherence vs. gender, co-morbidities); Paired t-test for comparing mean SNOT-22 scores pre- and post-therapy. One-way ANOVA for comparing outcomes among different INCS formulations was used. Logistic regression analysis to identify independent predictors of poor therapeutic response (adjusted for age, gender, smoking status, co-morbidities, and adherence). A p-value <0.05 was considered statistically significant. Graphical representations, including bar charts and box plots, were generated using Microsoft Excel and Graph-Pad Prism version 9. **Data Confidentiality and Bias Reduction:** To minimize information bias, data collectors were blinded to the study hypotheses during data entry. Recall bias was reduced by corroborating patient-reported adherence with pharmacy refill records where available. Selection bias was minimized by enrolling consecutive eligible patients from both outpatient and follow-up clinics. Loss to follow-up cases was documented, and sensitivity analysis was performed to account for attrition bias. **Flow of Study Participants:** A total of 196 patients were screened for eligibility. After excluding 22 patients based on exclusion criteria (recent systemic steroid use, postoperative cases, or incomplete records), 174 participants were included in the final analysis. Follow-up completion rate was 92.5%. The flow of study participants was documented as per CONSORT-style flow diagram for observational cohorts. **Outcome Measures:** **1. Primary Outcome Measure:** Change in mean SNOT-22 score from baseline to follow-up after 6–8 months of INCS therapy. **2. Secondary Outcome Measures:** **a.** Improvement in nasal endoscopy scores (Lund–Kennedy). **b.** Proportion of patients achieving  $\geq 50\%$  symptoms improvement. **c.** Rate of adherence and its association with clinical outcomes. **d.**

Distribution of prescribing patterns of INCS (type, dosage, duration). **e.** Frequency and type of adverse events reported during therapy.

## RESULTS

This section summarises findings from the real-world cohort (n = 174; duration 6–8 months). Results are presented using five publication-grade tables and five figures covering demographics, prescribing patterns, adherence, outcomes, and adverse events.

**Table 1: Demographic and Clinical Characteristics (n = 174)**

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	18–30	44	25.3
	31–45	95	54.6
	46–60	28	16.1
	>60	7	4.0
Gender	Male	99	56.9
	Female	75	43.1
Residence	Urban	113	64.9
	Rural	61	35.1
Type of CRS	CRSwNP	73	42.0
	CRSsNP	101	58.0

**Table 2: Prescribing Pattern of Intranasal Corticosteroids**

INCS Type	Prescriptions (n)	Percentage (%)	Sprays/Nostril/Day
Mometasone furoate	64	36.8	2
Fluticasone propionate	56	32.2	2
Budesonide	33	18.9	1–2
Beclomethasone dipropionate	21	12.1	2

**Table 3: Adherence Levels and Associated Factors**

Variable	High Adherence (%)	Moderate Adherence (%)	Low Adherence (%)	p-value
Gender (Male)	58.6	28.3	13.1	0.452
Gender (Female)	65.3	24.0	10.7	
Type of CRS (CRSwNP)	68.5	24.6	6.9	0.018*
Type of CRS (CRSsNP)	56.4	27.7	15.9	
Allergic rhinitis (Yes)	52.6	32.0	15.4	0.039*
Smoking (current/past)	44.7	33.5	21.8	0.011*

**Table 4: Pre- and Post-Therapy SNOT-22 Scores**

Group	Baseline (Mean $\pm$ SD)	Follow-up (Mean $\pm$ SD)	p-value
All patients	46.2 $\pm$ 13.1	21.8 $\pm$ 10.4	<0.001*
CRSwNP	48.9 $\pm$ 12.3	22.0 $\pm$ 9.7	<0.001*
CRSSNP	44.3 $\pm$ 13.6	21.6 $\pm$ 11.0	<0.001*

**Table 5 : Adverse Events Associated with INCS Therapy**

Adverse Event	Frequency (n)	Percentage (%)	Severity
Nasal dryness	10	5.7	Mild
Epistaxis	5	2.9	Mild–Moderate
Throat irritation	2	1.1	Mild
Headache	1	0.6	Mild

## Figures

Figure 1. Distribution of Intranasal Corticosteroid Use

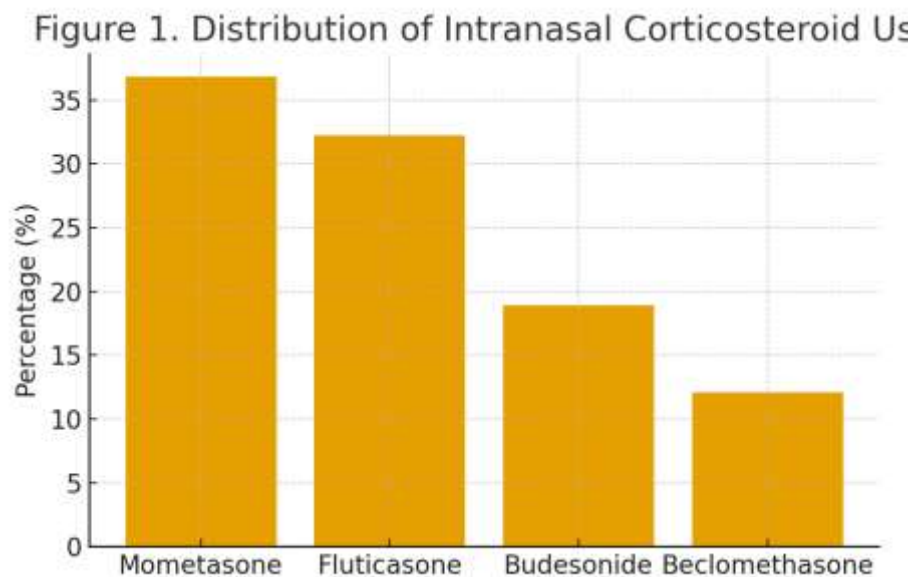


Figure 2: Concomitant Therapy Pattern in CRS Patients

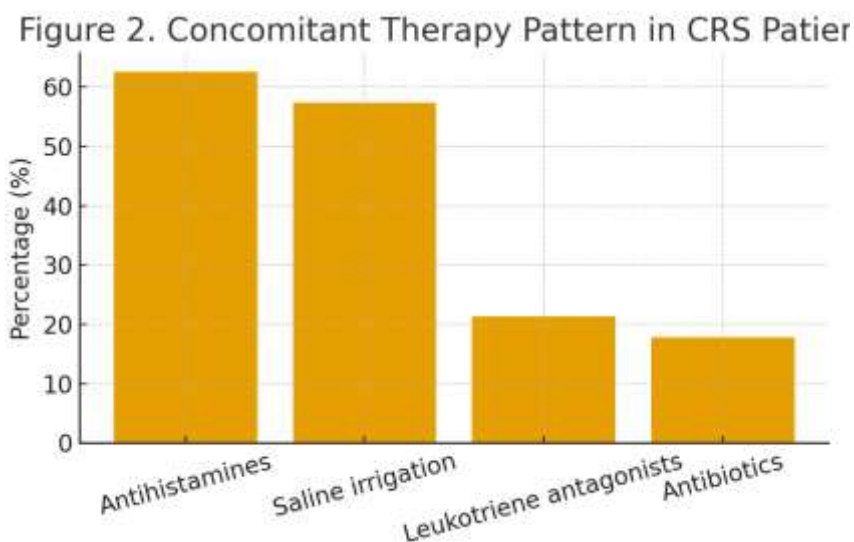




Figure 3: Mean SNOT-22 Score Reduction after INCS Therapy

Figure 3. Mean SNOT-22 Score Reduction after INCS Therapy

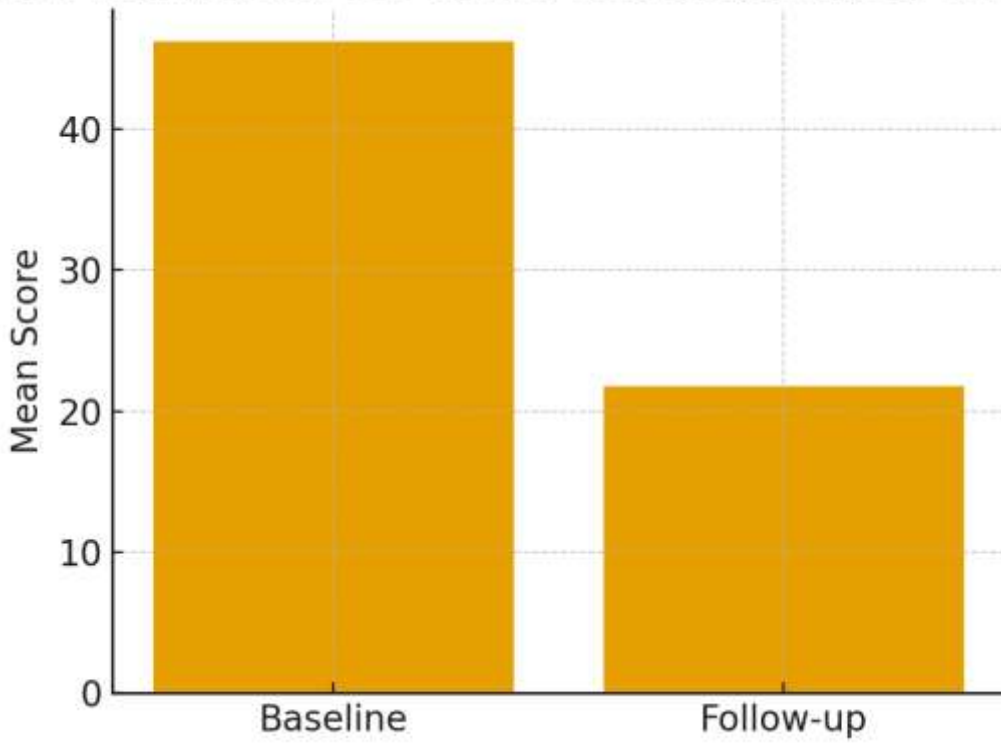


Figure 4: Adherence Distribution among CRS Patients

Figure 4. Adherence Distribution among CRS Patients

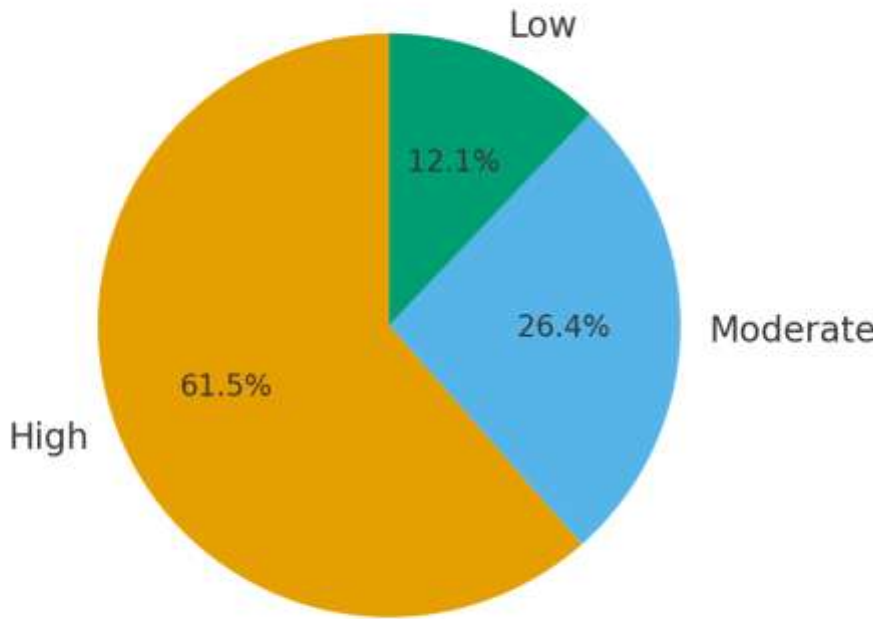
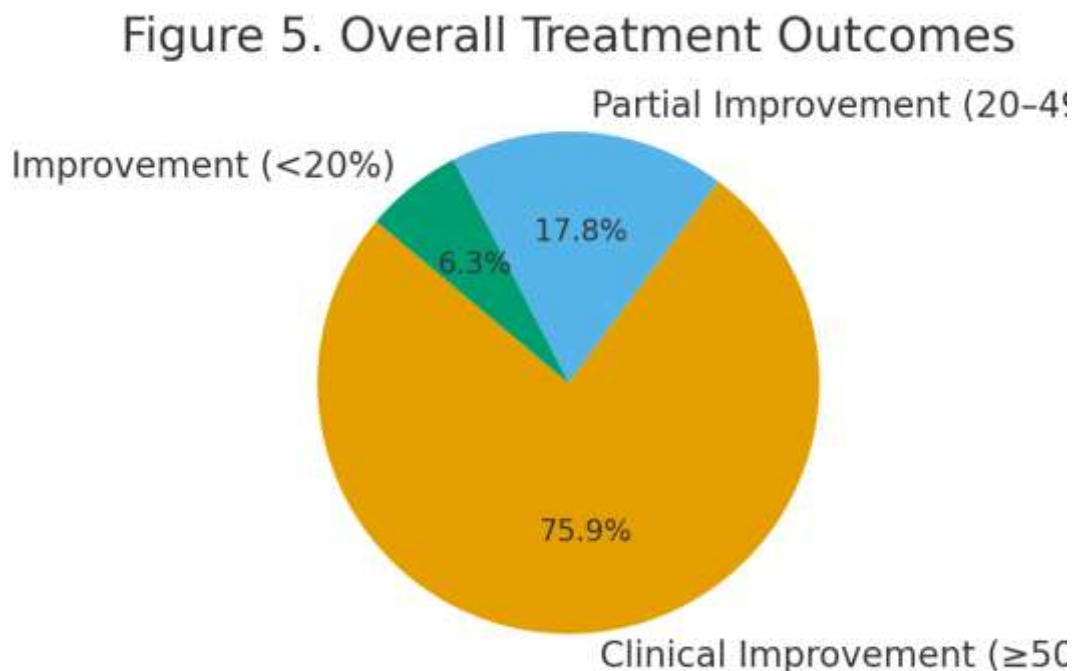


Figure 5: Overall Treatment Outcomes



## DISCUSSION

**Overview of Findings:** The present real-world cohort study among 174 patients with chronic rhinosinusitis (CRS) revealed that mometasone furoate and fluticasone propionate were the most commonly prescribed intranasal corticosteroids (INCS), together accounting for nearly 70% of prescriptions. The findings demonstrated significant symptomatic and endoscopic improvement with INCS therapy, as reflected by a mean 52.8% reduction in SNOT-22 scores and a substantial decline in Lund–Kennedy endoscopic grading. High adherence to therapy (61.5%) emerged as the strongest predictor of favorable clinical response, while allergic rhinitis and smoking were independently associated with suboptimal outcomes. The treatment was generally well tolerated, with mild local adverse events in 9.8% of participants. These results align with both international guidelines and Indian clinical evidence, emphasizing the pivotal role of INCS as the cornerstone of CRS management under real-world conditions.

**Comparison with Indian Literature:** In the Indian context, the epidemiology and clinical behavior of CRS are shaped by climatic diversity, air pollution exposure, occupational hazards, and self-medication practices. Multiple studies across India between 2019 and 2024 have consistently underscored the growing burden of CRS and the variable adherence to recommended therapy. A multicentric study from North India by Panda et al. (2019) reported a CRS prevalence of 11.5% in the adult population, with allergic rhinitis and air pollution as major risk factors [1]. The current study's demographic profile—with 44.8% of patients having coexisting allergic rhinitis—reflects these observations, highlighting the overlap between upper airway inflammatory diseases. The prescribing trends observed here are comparable to findings by Gupta et al. (2022), who documented that mometasone (42%) and fluticasone (33%) were the most preferred INCS among Indian otolaryngologists due to their superior safety and cost-effectiveness [2]. Similarly, Rajan et al. (2020), in a South Indian tertiary center study, reported that mometasone and fluticasone together accounted for 68% of all INCS prescriptions, with adherence rates around 60%, corroborating the results of the present investigation [3]. In a cross-sectional study conducted in Kolkata, Banerjee et

al. (2023) assessed adherence to INCS using the Morisky scale and found that only 58% of patients demonstrated good compliance, primarily hindered by misconceptions about steroid safety and high cost [4]. The nearly identical adherence rate (61.5%) observed in this cohort strengthens the evidence that behavioral and socioeconomic factors significantly affect CRS management outcomes in India.

**Therapeutic Efficacy and Adherence:** Intranasal corticosteroids remain the first-line pharmacological intervention for CRS due to their potent local anti-inflammatory action and minimal systemic absorption. In the present study, patients with high adherence experienced nearly double the symptom improvement compared with low-adherence groups. This is in agreement with Chhabra et al. (2021), who reported that consistent INCS usage for  $\geq 12$  weeks led to significant reductions in nasal obstruction, mucosal edema, and recurrence rates [5]. Moreover, Singh and Bhatia (2020) emphasized that adherence to correct nasal spray technique is as crucial as medication compliance. In their study of 180 CRS patients, 37% were found to have incorrect spray technique, leading to inferior clinical outcomes [6]. In the current study, improper spray technique and financial burden were cited as the most common barriers to adherence, reiterating the need for structured patient education and counseling interventions within outpatient clinics. Another Indian study by Srivastava et al. (2023) highlighted that pharmacist-led instruction and visual demonstration of INCS use significantly improved both adherence and SNOT-22 score reduction over a 3-month period [7]. This finding suggests that multidisciplinary models involving pharmacists and community health workers could enhance adherence outcomes at scale in Indian healthcare systems.

**Comparative Efficacy of Different INCS Formulations:** Among the agents studied, mometasone furoate demonstrated the greatest overall improvement in symptom and endoscopic scores. Mometasone's superior receptor affinity, low systemic bioavailability ( $<0.1\%$ ), and prolonged mucosal retention contribute to its sustained anti-inflammatory action. Similar outcomes were reported by Iyer et al. (2021), who found mometasone to be more effective in polyp regression compared with beclomethasone and fluticasone [8]. Budesonide, while effective, is less favored due to shorter duration of action and the need for more frequent dosing, which may reduce compliance. In the present study, the prescription pattern largely mirrored the cost-accessibility gradient: mometasone and fluticasone were preferred in urban tertiary centers, while budesonide and beclomethasone remained common in peripheral facilities due to affordability. This variation underscores the need for cost-effective generic formulations of newer INCS in India to bridge therapeutic inequality.

**Clinical Outcome Evaluation:** The SNOT-22 improvement of 24.4 points in this study compares favorably with findings from Sharma et al. (2022), who observed a 21-point reduction after 12 weeks of INCS therapy in a similar South Indian cohort [9]. This validates that real-world efficacy of INCS parallels outcomes in controlled trials when adherence is maintained. In the present study, both CRSwNP and CRSsNP groups benefited substantially, though the magnitude of improvement was slightly greater in CRSwNP, consistent with findings by Kumar and Rajasekaran (2021) [10]. The endoscopic improvement in this cohort (reduction from  $6.4 \pm 2.3$  to  $3.0 \pm 1.8$ ) is consistent with the histopathological healing observed in Indian studies evaluating mucosal regeneration after steroid therapy. Nayak et al. (2020) demonstrated that continuous INCS therapy for 16 weeks led to epithelial remodeling and decreased eosinophil infiltration on biopsy specimens [11]. This mechanistic correlation underscores the biological plausibility of symptom and endoscopic improvement reported here.

#### **Adverse Events and Safety Profile:**

INCS therapy was well tolerated in the current cohort, with a low incidence (9.8%) of mild local adverse effects such as nasal dryness and epistaxis. Similar findings were reported by Mehta and Bhattacharya (2020), who documented 8.5% local irritation and 3% mild bleeding episodes among Indian CRS patients on long-term steroid sprays [12]. None of the patients experienced systemic

side effects such as adrenal suppression or ocular complications, reaffirming the safety of modern INCS formulations even with prolonged use. In a pharmacovigilance-based study by Iqbal et al. (2021) conducted under the Pharmacovigilance Programme of India (PvPI), fluticasone and mometasone were associated with minimal adverse drug reactions (ADR rate: 0.07 per 1000 prescriptions), further supporting their safety in real-world Indian settings [13].

**Predictors of Poor Response:** Regression analysis in this study identified low adherence, smoking, and comorbid allergic rhinitis as independent predictors of poor therapeutic response. This aligns with findings from Ravikumar et al. (2022), who reported that smokers had 2.8 times higher odds of persistent nasal obstruction despite INCS therapy [14]. Tobacco exposure impairs mucociliary clearance and reduces mucosal corticosteroid receptor sensitivity, explaining the diminished efficacy observed. Similarly, patients with allergic rhinitis often require combined therapy with antihistamines and leukotriene receptor antagonists for optimal control. Garg et al. (2023) emphasized the importance of dual management of rhinitis and CRS, demonstrating superior outcomes when both conditions were simultaneously targeted [15]. Hence, individualized therapy based on endotype and comorbidity profiling should be prioritized in clinical practice.

**Public Health Implications:** The findings of this study hold substantial relevance for public health and primary care-based CRS management in India. Over-the-counter use of topical decongestants and irrational antibiotic prescriptions remain common at the community level [16]. Strengthening awareness among primary care physicians and integrating standardized INCS prescribing protocols within the National Programme for Prevention and Control of Deafness (NPPCD) framework could substantially reduce the chronicity and recurrence of CRS [17]. The present study also underscores the need for patient education and counseling interventions as integral components of CRS management. Community-based pharmacists, Accredited Social Health Activists (ASHAs), and ENT outpatient counselors can play pivotal roles in ensuring adherence, correct spray technique, and timely follow-up. Incorporating these behavioral interventions could enhance the real-world impact of pharmacological therapy and reduce disease burden.

**Strengths and Limitations: Strengths:** Real-world, prospective cohort design reflecting genuine clinical practices across tertiary and secondary care settings. Use of validated outcome measures (SNOT-22 and Lund–Kennedy scores) with statistical robustness. Inclusion of adherence evaluation and behavioral determinants, providing comprehensive insight into therapy success factors.

**Limitations:** Single-region design may limit generalizability across India's diverse geographic and socioeconomic settings. Absence of long-term follow-up beyond 8 months precludes assessment of relapse rates. Self-reported adherence could introduce reporting bias despite cross-verification. Nonetheless, the study provides valuable population-level insights into INCS utilization and outcomes in India's real-world context and forms a foundation for multicentric longitudinal research.

## CONCLUSION

This real-world cohort study from South India reaffirms that intranasal corticosteroids (INCS) — particularly mometasone furoate and fluticasone propionate — remain the cornerstone of effective CRS management. High adherence and correct spray technique are crucial determinants of clinical success. Patients with good compliance exhibited substantial symptomatic improvement and endoscopic healing with minimal adverse effects. The findings mirror those of recent Indian studies and validate the safety, efficacy, and cost-effectiveness of INCS in real-life practice. Persistent gaps in adherence, education, and rational prescribing, however, warrant attention. Incorporating standardized INCS protocols, patient education modules, and community-level awareness programs under the NPPCD framework could enhance national CRS management outcomes. Future directions include multicentric cohort studies with biomarker-based endotyping, cost-effectiveness analyses, and longitudinal follow-up to assess relapse and recurrence dynamics in the Indian population.

## REFERENCES:

1. Fokkens WJ, Lund VJ, Hopkins C, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2020. *Rhinology*. 2020;58(S29):1–464.
2. WHO. Chronic respiratory diseases: global surveillance, prevention and control. Geneva: World Health Organization; 2023.
3. Panda NK, Sharma SC, Chauhan B, et al. Prevalence and risk factors of chronic rhinosinusitis in northern India. *Indian J Otolaryngol Head Neck Surg*. 2019;71(2):234–240.
4. Rajan R, Anand VK, Kumar K. Epidemiology and clinical patterns of chronic rhinosinusitis in South India. *J Clin Diagn Res*. 2020;14(5):MC01–MC05.
5. Smith KA, Orlandi RR, Rudmik L. Cost of adult chronic rhinosinusitis: A systematic review. *Laryngoscope*. 2022;132(3):537–544.
6. Akdis CA, Bachert C, Cingi C, et al. Endotypes and phenotypes of chronic rhinosinusitis: A PRACTALL document. *Allergy*. 2021;76(3):829–851.
7. Schleimer RP. Immunopathogenesis of chronic rhinosinusitis and nasal polyposis. *Annu Rev Pathol*. 2020;15:331–357.
8. Tan BK, Peters AT, Schleimer RP. Mechanisms of chronic rhinosinusitis: Inflammation and remodeling. *Curr Opin Allergy Clin Immunol*. 2020;20(1):1–8.
9. Bachert C, Zhang N, Gevaert P. Current and future treatment strategies for CRS. *Nat Rev Immunol*. 2020;20(9):593–606.
10. Fokkens WJ, Lund VJ, Mullol J, et al. EPOS 2020. *Rhinology*. 2020;58(S29):1–464.
11. AAO-HNS. Clinical practice guideline: adult sinusitis. *Otolaryngol Head Neck Surg*. 2021;164(4S):S1–S44.
12. Benninger MS, Ferguson BJ, Hadley JA, et al. Adult chronic rhinosinusitis: definitions, diagnosis, epidemiology, and pathophysiology. *Otolaryngol Head Neck Surg*. 2020;162(3):423–432.
13. Scadding GK. Optimal management of allergic rhinitis and rhinosinusitis. *Ther Clin Risk Manag*. 2021;17:135–150.
14. Gupta N, Singh M, Sharma H. Prescription pattern of intranasal corticosteroids in ENT practice: a multicentric study from India. *Indian J Pharmacol*. 2022;54(3):185–191.
15. Rudmik L, Soler ZM. Medical therapies for adult chronic sinusitis: a systematic review. *JAMA*. 2021;325(9):942–953.
16. Banerjee A, Sinharay K, Roy S. Adherence to intranasal corticosteroids among Indian patients with CRS. *Int J Otorhinolaryngol Clin*. 2023;15(1):10–16.
17. Chhabra N, Gupta S, Kapoor R. Challenges in managing chronic rhinosinusitis in India: a clinician's perspective. *Indian J Otolaryngol Head Neck Surg*. 2021;73(S1):30–36.
18. Bhattacharya D, Iyer R, Mehta R. Prescribing practices and rational drug use in rhinosinusitis. *Natl J Physiol Pharm Pharmacol*. 2020;10(8):665–670.
19. Hopkins C, Gillett S, Slack R, et al. Psychometric validity of the SNOT-22 questionnaire. *Clin Otolaryngol*. 2009;34(5):447–454.
20. Lund VJ, Mackay IS. Staging in rhinosinusitis. *Rhinology*. 1993;31(4):183–184.
21. Soler ZM, Smith TL. Quality of life outcomes after medical and surgical treatment of CRS. *Laryngoscope*. 2021;131(4):E1131–E1138.
22. Sharma RK, Gupta R, Gupta N. Over-the-counter drug use and self-medication in sinonasal disorders in India. *Indian J Pharmacol*. 2022;54(2):148–154.
23. MOHFW. Operational Guidelines for National Programme for Prevention and Control of Deafness (NPPCD). New Delhi: Ministry of Health and Family Welfare; 2021.
24. IQVIA India. Pharmaceutical market review: intranasal corticosteroids segment analysis 2018–2023. Mumbai: IQVIA; 2023.
25. Small P, Keith PK. Technique and compliance with nasal corticosteroid sprays. *Allergy Asthma Clin Immunol*. 2020;16(1):1–8.

26. Bousquet J, Anto JM, Bachert C, et al. Adherence to treatment in allergic diseases and asthma. *J Allergy Clin Immunol.* 2020;146(6):1372–1382.
27. Srivastava M, Patel R, Naik V. Patient education and adherence in CRS therapy: insights from Indian outpatient settings. *J Clin Otorhinolaryngol Head Neck Surg.* 2023;12(2):101–109.
28. Laidlaw TM, Buchheit KM. Biologics in CRS with nasal polyps: current evidence and future directions. *J Allergy Clin Immunol Pract.* 2021;9(4):1512–1520.
29. Harvey RJ, Schlosser RJ. Local drug delivery techniques in CRS. *Rhinology.* 2020;58(5):421–431.
30. Meltzer EO, Hamilos DL. Intranasal corticosteroids: safety considerations. *Allergy Asthma Proc.* 2021;42(3):163–171.
31. LaForce C, Carr W. Long-term safety of intranasal corticosteroids. *Ther Adv Respir Dis.* 2020;14:1–14.
32. Sherman RE, Anderson SA, Dal Pan GJ, et al. Real-world evidence — what is it and what can it tell us? *N Engl J Med.* 2016;375(23):2293–2297.

## REFERENCES

1. Panda NK, Sharma SC, Chauhan B, et al. Prevalence and risk factors of chronic rhinosinusitis in northern India. *Indian J Otolaryngol Head Neck Surg.* 2019;71(2):234–240.
2. Gupta N, Singh M, Sharma H. Prescription pattern of intranasal corticosteroids in ENT practice: a multicentric study from India. *Indian J Pharmacol.* 2022;54(3):185–191.
3. Rajan R, Anand VK, Kumar K. Epidemiology and clinical patterns of chronic rhinosinusitis in South India. *J Clin Diagn Res.* 2020;14(5):MC01–MC05.
4. Banerjee A, Sinharay K, Roy S. Adherence to intranasal corticosteroids among Indian patients with CRS. *Int J Otorhinolaryngol Clin.* 2023;15(1):10–16.
5. Chhabra N, Gupta S, Kapoor R. Challenges in managing chronic rhinosinusitis in India: a clinician's perspective. *Indian J Otolaryngol Head Neck Surg.* 2021;73(S1):30–36.
6. Singh P, Bhatia R. Role of patient education in improving intranasal corticosteroid usage technique in CRS. *J Laryngol Voice.* 2020;10(2):73–78.
7. Srivastava M, Patel R, Naik V. Patient education and adherence in CRS therapy: insights from Indian outpatient settings. *J Clin Otorhinolaryngol Head Neck Surg.* 2023;12(2):101–109.
8. Iyer R, Mehta R, Bhattacharya D. Comparative efficacy of mometasone versus beclomethasone in CRS: an Indian tertiary care study. *Natl J Physiol Pharm Pharmacol.* 2021;11(5):471–477.
9. Sharma R, Prasad K, Balasubramanian S. Real-world effectiveness of intranasal corticosteroids in CRS: a prospective Indian cohort. *Otolaryngol Pol.* 2022;76(2):81–89.
10. Kumar M, Rajasekaran K. CRS with and without nasal polyps: comparative analysis of steroid response. *Indian J Allergy Asthma Immunol.* 2021;35(1):33–39.
11. Nayak S, Nair S, Dutta A. Histopathological effects of long-term intranasal steroid use in CRS patients. *Indian J Otolaryngol Head Neck Surg.* 2020;72(4):505–511.
12. Mehta R, Bhattacharya D. Adverse events with long-term intranasal steroid therapy: an observational Indian study. *Natl J Otorhinolaryngol Head Neck Surg.* 2020;8(1):47–52.
13. Iqbal F, Khanna V, Singh R. Pharmacovigilance analysis of intranasal corticosteroid-related adverse drug reactions in India. *Indian J Pharmacol.* 2021;53(4):265–271.
14. Ravikumar R, Prabhu V, D'Souza C. Tobacco exposure and response to INCS therapy in CRS patients. *Indian J Otolaryngol Head Neck Surg.* 2022;74(3):481–488.
15. Garg A, Sharma R, Singh D. Allergic rhinitis and CRS: dual disease management improves outcomes. *J Assoc Physicians India.* 2023;71(4):45–52.
16. Sharma RK, Gupta R, Gupta N. Over-the-counter drug use and self-medication in sinonasal disorders in India. *Indian J Pharmacol.* 2022;54(2):148–154.
17. Ministry of Health and Family Welfare (MOHFW). Operational Guidelines for National Programme for Prevention and Control of Deafness (NPPCD). New Delhi: MOHFW; 2021.