Original Article

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Effects of Systemic Steroid Treatment on Quality of Life and Computed Tomography Scoring in Patients of Chronic Rhinosinusitis: A Prospective Cohort Study

Ear, Nose and Throat Section

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ABSTRACT

Introduction: Chronic Rhinosinusitis (CRS) is a clinical condition characterised by mucosal inflammation of the nose and paranasal sinuses, with symptoms lasting for more than or equal to 12 weeks. Steroids can improve the symptoms and Computed Tomography (CT) scores in many patients.

Aim: To study the effects of systemic steroids on the quality of life and CT scoring in patients with CRS.

Materials and Methods: This prospective cohort study was conducted over 18 months (January 2020 to June 2021) in the Department of Otorhinolaryngology-Head and Neck Surgery at Government Medical College and Hospital, Chandigarh, India. It included 60 patients, all over the age of five, who were clinically diagnosed with CRS. The Quality-of-Life (QoL) assessment was performed using the Sinonasal Outcome Test (SNOT)-22 questionnaire, and Lund-Mackay (LM) CT scoring was performed for each CRS patient included in the study before and after a short course of Oral Corticosteroids (OCS). Tablet Deflazacort was given over a period of two weeks, starting initially at a dose of 0.8-0.9 mg per kg of body weight (60 mg) once per day and tapered every three days to 30 mg, 18 mg, 12 mg, and 6 mg, respectively. The patients were re-evaluated after two weeks, and the results were compared within each study group. Changes in outcome parameters were assessed by using the Wilcoxon signed rank test. The Chi-square test was used to assess the significance of associations between outcome parameters and patient characteristics. Data Analysis was carried out using Statistical Package for the Social Sciences (SPSS) version 25.0 software.

Results: The average age of the participants was 35.67±13.83 years with 44 (73.3%) participants being males and 16 (26.7%) females. Mean duration of symptoms was 6.5 months. Mean values of pre-steroid SNOT-22 score 52.60±20.51 improved to 15.40±13.24 after steroids (p-value <0.001). Mean values of pre-steroid LM CT Score was 16.02±6.07 which improved to 9.25±6.23 after steroids (p-value <0.001). Additionally, a statistically significant difference was observed in both categories when comparing pre-steroid and post-steroid SNOT-22 and LM CT scores (p-value <0.001 and p-value <0.001, respectively).

Conclusion: The use of systemic steroids has shown a significant improvement in terms of QoL and CT scoring in patients of CRS and hence they can be used effectively in the management of this condition.

Keywords: Lund-Mackay computed tomography score, Mucosal inflammation of the nose, Sinonasal outcome test 22

INTRODUCTION

Rhinosinusitis is a clinical condition characterised by the mucosal inflammation of nose and paranasal sinuses [1]. The European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) outlines the diagnostic criteria, which include primary symptoms (either or both), such as 'nasal blockage' or 'discharge (posterior or anterior).' If only one primary symptom is present, at least one additional symptom, such as facial pain/pressure or hyposmia/anosmia, must also be observed [2]. Rhinosinusitis is classified into acute and chronic forms depending on the duration of the symptoms. When symptoms last for more than 10 days but less than four weeks, it is classified as acute rhinosinusitis. If symptoms continue for 12 weeks or more, it is known as CRS [2].

The CRS treatments encompass both medical and surgical approaches. Medical management typically involves a combination of therapies, including topical Intranasal Corticosteroids (INCS) and/or OCS, antibiotics, nasal decongestants, and saline irrigation. These treatments aim to address underlying factors, manage infections, reduce mucosal oedema, and aid in sinus drainage [3]. INCS/OCS can help reduce mucosal swelling, shrink nasal polyps, alleviate sinonasal symptoms, and enhance patients' quality of life. However, OCS should be used with caution due to their potential for serious systemic side-effects [4].

The treatment effectiveness is assessed with the help of nasal endoscopy and sinonasal imaging and different Patient-Reported Outcome Measures (PROMs), which most commonly assess "Health-Related Quality of Life (HR-QoL)" [5].

The SNOT-22 is an essential tool for evaluating the quality of life in patients with CRS. It has the advantage of comprehensive evaluation of sinonasal symptoms along with indicators of general wellbeing and quality of life. It can be used for both preoperative and postoperative assessment [6,7]. It is a validated, disease-specific, patient-reported measure that assesses symptoms affecting the nasal passages, paranasal regions, psychological wellbeing, and sleep disturbances.

Sinonasal imaging using a CT scan is a commonly used, non invasive technique for confirming the disease, evaluating the extent and severity of the condition in the paranasal sinuses and assisting in management decisions for patients with CRS. The Lund-Mackay System (LM) is the most commonly used method for assessing the severity of rhinosinusitis through CT scoring. It evaluates each sinus group (on cross-sectional images) as either completely 'clear', 'partially opaque', or 'fully opaque', yielding a straightforward number based score [8].

Since there were not much recent studies done to evaluate the effects of systemic steroid therapy in CRS in India, hence it was

deemed appropriate to conduct such study aimed to assess systemic steroids' impact on both the quality of life and disease progression in CRS patients. Radiological evaluation was performed using Computed Tomography of the Paranasal Sinuses (CT PNS), with Lund-Mackay scoring, comparing conditions before and after systemic steroid treatment.

MATERIALS AND METHODS

A prospective cohort study was conducted in the Department of Otorhinolaryngology, Head and Neck Surgery at the Government Medical College and Hospital, Chandigarh, India, from January 2020 to June 2021. Approval of the Institute's Ethics Committee (IEC) was obtained for conducting the study vide IEC no. GMC/IEC/2019/228 dated 27.12.19. Written consent was obtained from all patients or parents/guardians in case of patients under 16 years. Consecutive sampling was done.

Inclusion criteria: All clinically diagnosed cases of CRS in individuals aged 5 years or older were included in the study. The patients were diagnosed by widely accepted EPOS 2020 criteria [2] requiring the presence of at least one primary symptom (Nasal Obstruction or discharge), one additional symptom (Facial pain/pressure, reduction or loss of smell) along with objective evidence of mucosal inflammation either by nasal endoscopy or CT scan or both.

The patients included had received medical management in the form of antibiotics, antihistamines and decongestants but had not received systemic steroids.

Exclusion criteria: Patients who did not give consent for the treatment, patients who underwent previous management with steroids in the past three months, patients who have had any surgical procedure on nose or paranasal sinuses in the past, patients with absolute contraindication to steroids were excluded from the study.

Study Procedure

All patients with CRS who visited the ENT outpatient department and met the inclusion criteria underwent a thorough assessment, which included a detailed history, clinical examination, and endoscopic evaluation. Diagnostic nasal endoscopy was performed using a 0°, 4-mm nasal endoscope after nasal mucosal decongestion, and the findings were documented [9].

The patients underwent a non contrast CT scan of the nose and paranasal sinuses (including axial, coronal, and sagittal sections) using a 64-slice Multidetector CT scanner (Ingenuity CT, Philips) to evaluate disease extent using the Lund-Mackay CT scoring system [10]. The mild associated radiation risk was explained to them. For ease of evaluation and data analysis, the LM CT score was categorised into mild, moderate, and severe based on disease severity, with scores 0 to 8, 9 to 16, and 17 to 24, respectively. Additionally, their quality of life was assessed using the SNOT-22 [11]. For ease of evaluation and data analysis, the SNOT-22 score was categorised in mild, moderate, and severe depending on the severity of disease with scores <20, 20-50, and >50 scores, respectively.

The patients were then given a short course of steroids for two weeks. The oral steroid drug- Deflazacort was started initially at 0.8-0.9 mg per kg of body weight once per day after meal was given. Thus, the systemic steroids were given in an OD dose daily in a tapering manner starting from 60 mg and tapered to 6 mg and stopped in two weeks. Short-term course (<3 weeks) were given with the intent that there were minimal or practically no serious side-effects.

The dosing schedule for the oral drug prescribed to an average adult patient was as follows:

T. Deflazacort 60 mg once daily for three days, followed by;

T. Deflazacort 30 mg once daily for three days, then;

T. Deflazacort 18 mg once daily for three days, followed by;

T. Deflazacort 12 mg once daily for three days, and finally;

T. Deflazacort 6 mg once daily for two days before stopping.

The patients did not receive any other treatment for CRS other than systemic steroids during the duration of two weeks. After two weeks on follow-up, the patient was then reassessed for the condition, status of the disease and quality of life of the patient using SNOT-22. Also, a repeat non-contrast CT scan was done to reassess the disease status.

Comparison of both the SNOT-22 scoring and CT Scoring by Lund Mackay Scoring System of both the scans i.e., scans before and after treatment with systemic steroids was done. The improvement in disease was quantified both clinically and radiographically.

STATISTICAL ANALYSIS

All data collected were evaluated and analysed to check for the outcome of the study and statistical analysis was applied. The statistical significance level was kept as p-value <0.05. Outcome parameters in terms of CT findings and quality of life at the baseline were described by using proportions and percentages for quantitative parameters. Changes in outcome parameters were assessed by using the Wilcoxon signed rank test. The Chi-square test was used for testing the significance of the association between outcome parameters with patient characteristics. Data analysis was carried out using SPSS-25.0 software.

RESULTS

The average age of participants was 35.67±13.83 years, 73.3% of participants were male, and 26.7% were female, indicating a male predominance with a male-to-female ratio of 2.75:1 [Table/Fig-1].

Demographic details	Mean±SD||Min-Max||Frequency (%)
Age (years)	35.67±13.83||8.00-68.00
Age group (years)	
≤10	1 (1.7)
11-20	9 (15.0)
21-30	12 (20.0)
31-40	15 (25.0)
41-50	15 (25.0)
51-60	6 (10.0)
61-70	2 (3.3)
Gender	
Male	44 (73.3)
Female	16 (26.7)
Geographical distribution	
Urban	32 (53.3)
Rural	28 (46.7)

[Table/Fig-1]: Demographic details summary.

1) Co-morbidities and addictions: In the present study, 11.7% (7) patients had bronchial asthma, 5.0% (3) had Type 2 Diabetes Mellitus (T2DM), history of epilepsy in 1.7% (1) of patients, 1.7% (1) had both T2DM and Hypertension (HTN) while 80.0% (48) had no co-morbidities. In 9 (15.0%) patients had an addiction to alcohol, smoking in 6 (10.0%) patients, both alcohol and smoking in 5 (8.3%) patients and Tobacco chewing in 2 (3.3%) patients. Rest 38 (63.3%) patients had no history of any addiction.

2) Diagnosis: Out of 60 patients, 32 (53.3%) were of CRS with nasal polyposis, 18 (30.0%) were of CRS without nasal polyposis and 10 (16.7%) had allergic fungal rhinosinusitis. The disease was Bilateral in 41 (68.3%) cases, right-sided in 7 (11.7%) cases and left-sided in 12 (20.0%) cases.

3) Symptoms: All 60 (100.0%) patients presented with nasal obstruction, anterior nasal discharge was present in 58 (96.7%) patients [Table/Fig-2]. Mean duration of symptoms was 6.5 months.

Symptoms	n (%)
Nasal obstruction	60 (100.0)
Anterior nasal discharge	58 (96.7)
Post nasal discharge	53 (88.3)
Hyposmia/anosmia	31 (51.7)
Facial pain/pressure	37 (61.7)
Headache	36 (60.0)
Cough	20 (33.3)
Dental pain	4 (6.7)
Ear fullness	28 (46.7)
Fever	4 (6.7)
Halitosis	17 (28.3)
Nasal bleed	9 (15.0)
Sneezing	9 (15.0)

[Table/Fig-2]: Summary of symptoms.

SNOT-22 symptom score distribution: The average SNOT-22 Symptom Score decreased from a high of 52.60 before steroid treatment to a low of 15.40 after treatment. This was a statistically significant change (Wilcoxon Test: Test Statistic W=1830.0), p-value <0.001) [Table/Fig-3].

SNOT-22 score	Mean±SD‖Min-Max‖Frequency (%)
SNOT-22 symptom scoring (Pre-steroid)	52.60±20.51‖14.00-96.00
SNOT-22 symptom scoring (Post-steroid)	15.40±13.24‖0.00-51.00
SNOT-22 symptom scoring category (Pre-steroid)	
Mild	2 (3.3)
Moderate	26 (43.3)
Severe	32 (53.3)
SNOT-22 symptom scoring category (Post-steroid)	
Mild	42 (70.0)
Moderate	17 (28.3)
Severe	1 (1.7)

[Table/Fig-3]: Summary of SNOT-22 score.

The overall change in SNOT-22 Symptom Scoring Category was statistically significant (Stuart-Maxwell test: χ^2=49.146, p-value <0.001) [Table/Fig-4].

SNOT-22 symptom scoring category		Pre-steroid				Stuart-Maxwell test	
		Mild	Moderate	Severe	Total	χ^2	p-value
Post-steroid	Mild	2 (3.3%)	24 (40.0%)	16 (26.7%)	42 (70.0%)	49.146	<0.001
	Moderate	0	2 (3.3%)	15 (25.0%)	17 (28.3%)		
	Severe	0	0	1 (1.7%)	1 (1.7%)		
	Total	2 (3.3%)	26 (43.3%)	32 (53.3%)	60 (100.0%)		

[Table/Fig-4]: Change in SNOT-22 Symptom Scoring Category over time (n=60). "The unshaded cells on the diagonal indicate patients whose category stayed the same. Cells shaded in red show patients who moved to a lower category, while green-shaded cells represent those who progressed to a higher category"

4) Lund-Mackay CT scoring distribution: The average LM CT Score decreased from 16.02 before steroid treatment to 9.25 after the treatment. This change was statistically significant (Wilcoxon Test: Test Statistic W=1711.0), p-value <0.001) [Table/Fig-5].

The overall change in Lund-Mackay CT Scoring Category was statistically significant (Stuart-Maxwell test: χ^2=32.693, p-value <0.001) [Table/Fig-6]. "The strength of the relationship between the two variables (Cramer's V) is 0.45, indicating a moderate association." "The strength of the relationship between the two variables (Bias Corrected Cramer's V) is 0.42, showing a moderate association."

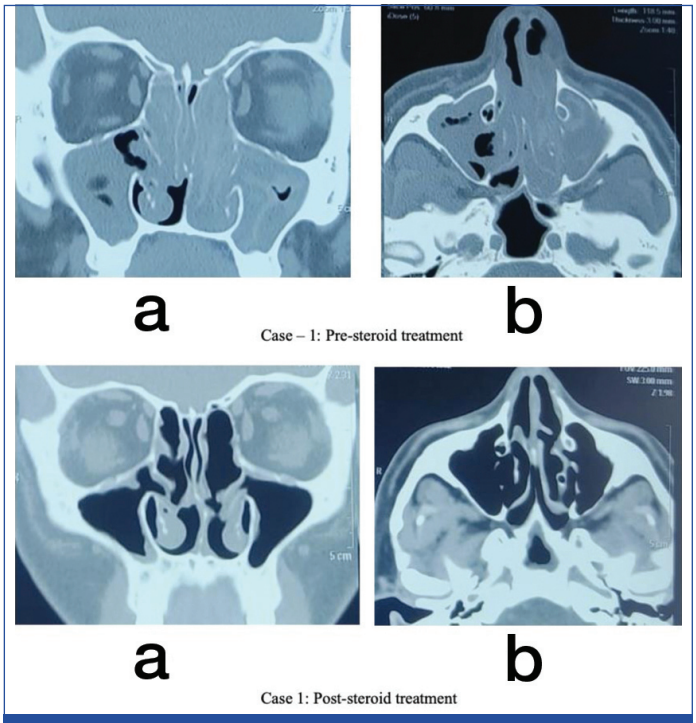
LM CT score	Mean±SD‖Median (IQR)‖RANGE‖
Lund-Mackay CT scoring (Pre-steroid)	16.02±6.07‖17.00 (12.00-21.00)‖3.00-24.00
Lund-Mackay CT scoring (Post-steroid)	9.25±6.23‖9.00 (4.00-12.00)‖0.00-24.00
Change in Lund-Mackay CT scoring (Post-steroid)	-6.77±4.25‖-6.00 (-9.00--4.00)‖-20.00-0.00
Lund-Mackay CT scoring category (Pre-steroid)	
0 to 8	9 (15.0)
9 to 16	20 (33.3)
17 to 24	31 (51.7)
Lund-Mackay CT scoring category (Post-steroid)	
0 to 8	28 (46.7)
9 to 16	24 (40.0)
17 to 24	8 (13.3)

[Table/Fig-5]: Summary of LM CT score.

Lund-Mackay CT scoring category		Pre-steroid				Stuart-Maxwell test	
		0 to 8	9 to 16	17 to 24	Total	χ^2	p-value
Post-steroid	0 to 8	9 (15.0%)	13 (21.7%)	6 (10.0%)	28 (46.7%)	32.693	<0.001
	9 to 16	0	7 (11.7%)	17 (28.3%)	24 (40.0%)		
	17 to 24	0	0	8 (13.3%)	8 (13.3%)		
	Total	9 (15.0%)	20 (33.3%)	31 (51.7%)	60 (100.0%)		

[Table/Fig-6]: Change in Lund-Mackay CT scoring category over time (n=60). The uncolored cells on the diagonal represent patients whose category did not change. The red shaded cells represent patients who moved to a lower category. The green shaded cells represent patients who moved to a higher category

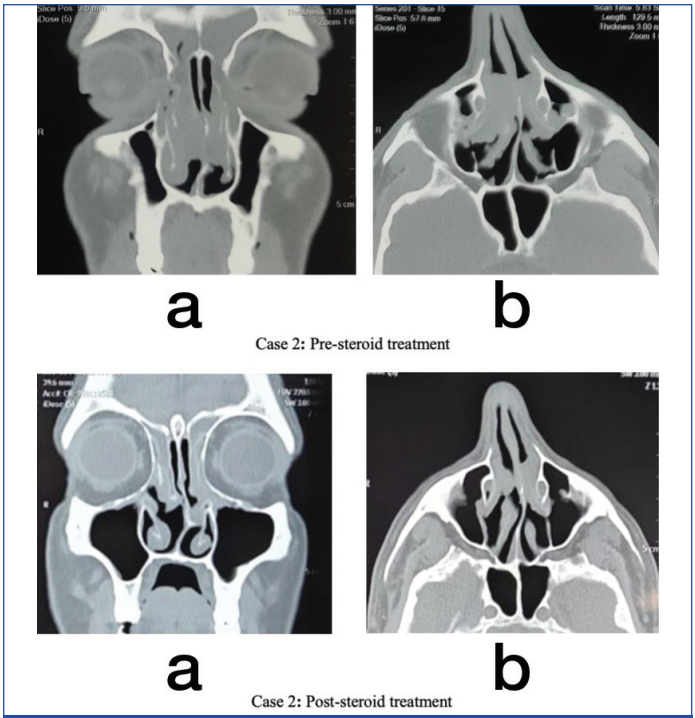
Representative cases are shown in [Table/Fig-7,8].



[Table/Fig-7]: Pre-steroid coronal and axial sections of NCCT PNS of case 1 showing LM severe category of CRS (Above) and post-steroid coronal and axial sections of NCCT PNS of patient I transforming to LM mild category of CRS (Below).

DISCUSSION

Out of the total 60 patients, the ages in the present study ranged from 8 to 68 years, with a mean±SD of 35.67±13.83 years, which was in concordance with Mainasara MG et al., and Ogunleye AOA and Fasunla AJ in which the mean age was 36.19±12.23 years and 34 years, respectively [12,13].



[Table/Fig-8]: Pre-steroid coronal and axial sections of NCCT PNS of case 2 showing LM moderate category of CRS (Above) and post-steroid coronal and axial sections of NCCT PNS showing transformation to LM mild category of CRS (Below).

In the present study, the majority of patients were male (44, 73.3%), and 16 (26.7%) were female. These results were in concordance with the study of Ogunleye AOA and Fasunla AJ who reported a higher incidence in the male population in their studies i.e., around 60% were males [13].

This condition was found more frequently in the urban population (53.3%) than the rural population (46.7%) in the present study. A study by Kaur R et al., in India reported similar findings, with 82% of the patients coming from urban areas [14].

The present study results were in agreement with those of Lind H et al., in which 97 CRS patients who underwent ESS over an 18-month trial period were evaluated preoperatively using the SNOT-22 score, Sniffin' Sticks score, modified Lund-Kennedy endoscopic score, and Lund-Mackay CT score. Patient outcomes were re-evaluated at clinical follow-up one and six months postoperative. ESS efficiently and immediately improved quality of life for both CRSwNP and CRSsNP patients, with over 50% reduction in SNOT-22 score one month after surgery, which sustained six months postoperative [15].

A similar trend was seen in a randomised control study by Xu Z et al., which compared 127 patients of CRS with nasal polyposis divided in three groups of treatment with nasal sprays alone and add on with nasal drops and oral steroids, which showed a significant difference in the percentage of improvement in all the three groups out of which a maximum sensitivity of 52.5% was seen in the oral steroid group [16].

The findings of the present study were similar to those of De Silva AP et al., who observed significant improvements in all three clinical measures, i.e., SNOT-22, nasal endoscopy (Lund-Kennedy), and sinus CT scan scores (Lund-Mackay), in CRSsNP patients treated with short-term oral prednisolone. Surgical intervention was avoided in 52.5% patients in the first 12 months. The mean symptom duration was less than 11 months in patients who had maximum benefit [17].

In the present study, the mean pre-steroid LM CT score was 16.02±6.07, and it decreased to 9.25±6.23 after completion of the steroid course. Similar results were found in a randomised controlled study by Ozturk F et al., which compared 45 CRS patients assigned to either an antibiotic and oral steroid treatment group or a placebo group. The study showed a significant improvement in both groups, with the oral steroid group experiencing a reduction in the average LM CT score from 12.8±5.3 to 1.2±2.8, reflecting a mean change of approximately 90% (11.6 points), which was statistically significant (p-value <0.001). Although their study consisted mostly of paediatric patients, as compared to the present study, which included both paediatric and adult age groups. Methylprednisolone as an adjunct was significantly more effective than placebo in reducing CT scores (p-value=0.004), total rhinosinusitis symptoms (p-value=0.001), and individual symptoms of nasal obstruction (p-value=0.001), postnasal discharge (p-value=0.007), and cough (p-value=0.009). At the end of treatment, 48% of the children in the placebo group still had abnormal findings on CT scans versus 14% in the methylprednisolone group (p-value=0.013). Additionally, by the end of treatment, 19 patients (86%) in the oral steroid group had no residual disease, defined as an LM CT score of 2 or less, a difference that was statistically significant [18]. Future research may incorporate a double-blind, placebo-controlled design to confirm that the observed improvements are directly attributable to systemic steroids. The strength of the study was that it used a prospective cohort design, allowing direct assessment of changes in patients following a specific intervention (systemic steroids).

Limitation(s)

The study did not include a placebo or a control group receiving alternative treatments (e.g., topical steroids alone), making it difficult to definitively isolate the effects of systemic steroids from other factors. The study was conducted at a single tertiary healthcare facility in Chandigarh, India, which may limit the generalisability of the findings to different healthcare settings or populations. Co-morbidities were reported, but their potential impact on steroid response or LM CT score was not analysed as a confounder.

CONCLUSION(S)

It was concluded that the use of systemic steroids in patients with CRS is effective in improving quality of life and in achieving disease clearance on radiological imaging.

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