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Original Article

# Functional Endoscopic Sinus Surgery Nasal Irrigation with Budesonide: Quality of Life Assessment in Chronic Rhinosinusitis Patients

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## Abstract

**Introduction:** Chronic rhinosinusitis (CRS) not responding to medical treatment is managed by functional endoscopic sinus surgery (FESS) followed by steroid nasal spray. CRS significantly affects the quality of life of patients. Saline nasal irrigation is recommended after sinus surgery. Off label addition of budesonide respules in saline irrigation solution is reported to beneficial for even distribution of steroid in opened sinuses.

**Materials and Methods:** The study was conducted in CRS patients who had undergone FESS. Normal saline with budesonide nasal irrigation was advised and the effect on the quality of life was determined using the Sino-nasal Outcome Test-22 (SNOT-22). Total 50 cases were studied. Pre-operative computed tomography scans were obtained and assessed by Lund-Mackay scoring. Rigid sinonasal endoscopy was performed and modified Lund-Kennedy endoscopy scale score calculated. Visual analog scoring and SNOT-22 questionnaire scoring were done preoperatively and at 3rd-and 6th-month postoperatively. These scores were compared and a value of $P < 0.05$ was considered statistical significant.

**Results:** Nasal blockage was the most common symptom followed by rhinorrhea. Maximum pre-operative SNOT-22 scores were of nasal blockage (4.24 ± 1.94), runny nose (3.74 ± 1.747), and facial pain (3.44 ± 1.567). The mean pre-operative SNOT-22 score was 43.56 ± 18.33. The average number of total nasal irrigation performed was 72.54 ± 10.73. After FESS, following patients reported improvement in visual analog scale and SNOT-22 scores.

**Conclusion:** In refractory CRS, patients' symptom score improved after FESS and steroid saline irrigation. Good compliance achieved for nasal irrigation after counseling, demonstration, and continuous motivation.

**Key words:** Budesonide nasal wash, Chronic rhinosinusitis, Functional endoscopic sinus surgery, Nasal douching, Sino nasal outcome test-22, SNOT-22

## INTRODUCTION

Chronic rhinosinusitis (CRS) is defined by European position paper on rhinosinusitis and nasal polyposis (EPOS) as inflammation of the nose and the paranasal sinuses characterized by two or more symptoms, one of which should be either nasal blockage or nasal discharge in addition to facial pain/pressure and/or reduction of smell, lasting for at least 12 weeks.[1] CRS is essentially a medical disease; however, in cases not responding to medical treatment surgery is indicated which includes functional endoscopic sinus surgery (FESS) which is performed to minimally remove the inflamed mucosa and restore the ciliary transport mechanism and mucous clearance pathway.[2]

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Saline nasal irrigation or nasal douche or lavage is a procedure that rinses the nasal cavity with isotonic or hypertonic saline solutions. Saline irrigation is highly recommended for medical and post-operative management of CRS without nasal polyposis in adults as well as children.

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Normal saline is also very commonly advised as an adjuvant for acute and chronic upper respiratory tract infections in infants and children. Normal saline is a physiological solution and it cleanses the nasal mucosa and improves mucociliary action by removing nasal crust and by thinning the mucous. There by saline irrigation helps in decreasing the infection and allergen load resulting in decreased inflammation and edema.[3,4]

Topical steroid is highly recommended as first line treatment for CRS with or without nasal polyposis for medical management and postoperatively in adults. Usually, topical nasal sprays are prescribed for variable period after surgery.[1] Transnasal nebulization has been proved more efficacious in comparison to nasal spray in the management of CRS.[5] Delivery of steroid by nasal irrigation with high pressure has been recommended as a better option for treating chronic sinus mucosal inflammation as it leads to better penetration of steroids in sinuses and has anti-inflammatory action.[6,7]

Budesonide is approved to be used in nasal spray form and respules form for nebulization. Early evidence outlined suggests that budesonide irrigations provide benefit to patients with CRS following FESS and short-term use of topical high volume budesonide sinonasal irrigations is likely to be safe.[7] The study was conducted with the aim of assessing clinical outcome and quality of life in patients with CRS after nasal irrigation using normal saline with budesonide after FESS.

## MATERIALS AND METHODS

The prospective study was carried out in the Department of Otorhinolaryngology, JLN Medical College and Hospital, Ajmer, from April 1, 2018 to March 31, 2019. Approval from the Institutional Ethics Committee was obtained. The study included cases fulfilling criteria of CRS diagnosed according to the European position paper on rhinosinusitis and nasal polyps EPOS 2012; characteristic changes in pre-operative computed tomography of paranasal sinuses assessed according to the EPOS 2012; CRS patients with bilateral nasal polyps and without nasal polyps who had not improved after medical treatment.[1] Other subgroups of CRS; secondary CRS; age <18 years; pregnant; immunodeficient; and patients undergoing revision FESS were excluded from our study group. The trial was registered with clinical trial registry of India CTRI/2019/02/017402. All procedures performed in the presented study involving human participants were in accordance with the ethical standards of the Institutional Ethical Committee of JLN Medical College Ajmer (Letter no. 2370/Acad-III/MCA/2016) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Target population for the study comprised of patients of CRS described as above not responding to medical management for a period of 3 months. Total 50 cases were included in our study group. Voluntary and informed consent was obtained from all study participants at the initial enrollment meeting. Written informed consent was obtained from all individual participants in native language. A detailed history was taken with special reference to age, sex, residence, occupation, family history, past history, allergic disorders, and any addictive habits. Detailed clinical examination local and general was made according to the proforma attached with special reference to nose and paranasal sinuses. Demographic data were recorded as well as associated medical comorbidities, including presence of nasal polyposis, asthma, allergies, prior sinus surgery, and treatment history. These cases were subjected to routine biochemical and hematological evaluation. Pre-operative computed tomography scans in the coronal plane were obtained and assessed by Lund-Mackay scoring (score range: 0–24).[8] Rigid sinonasal endoscopy was performed and graded according to the modified Lund-Kennedy endoscopy scale (LKES) (score range: 0–20) and Sino-nasal Outcome Test-22 (SNOT-22) was measured.[9] Endoscopic sinus surgery was then scheduled and performed in accordance with established functional principles. FESS was performed under general anesthesia, the surgical technique as described by Messerklinger.[10] The extent of surgery included at least a bilateral uncinectomy, middle meatal antrostomy with anterior ethmoidectomy. Septoplasty and/or inferior turbinoplasty were performed when indicated. Standard nasal packing (Merocel) was done for 48–72 h. Post-operative care was as follows: All patients received amoxicillin and clavulanic acid (875 mg/125 mg) twice a day for 10 days. After surgery, patients were instructed to begin nasal saline irrigations 48-72 h following surgery. Patients were instructed to irrigate with 240 ml normal saline, at least twice a day. Topical steroid irrigation was performed by adding one ampule having 0.5 mg/2 ml budesonide solution twice daily. Patients' noted the time, number, and amount of nasal irrigation in a proforma and submitted the proforma and empty respules every 15 day. Compliance to nasal saline irrigation instructions was defined as irrigation with 120 mL of normal saline per side, twice a day. Each patient was followed for four post-operative clinic visits at approximately 2 weeks, 4 weeks, 6 weeks, and 8 weeks after surgery.

Quality of life was assessed by SNOT-22 questionnaire and the symptom intensity was presented using visual analog score. Patients rate 22 questions from 0 (no problem) to 5 (problem is as bad as it can be). Lund Kennedy Endoscopic

scoring system (diagnostic nasal endoscopy) was used for signs of polyps, mucopurulent discharge primarily from middle meatus and/or edema/mucosal obstruction, scarring, and crusting preoperatively and postoperatively. The maximum score was 20 and the minimum score was 0.

The primary aim of the statistical analysis was to determine whether the changes of SNOT-22 scores, we had compared continuous variables using one-way analysis of variance tests and we used Pearson's $\chi^2$ test to compare categorical variables. We then summarized the means of SNOT-22 scores before FESS, 3 months, and 6 months after FESS in CRS patients and the changes of SNOT-22 scores from pre-FESS to, 3-month, and 6-month post-FESS visits in CRS patients.

## RESULTS

A total of 59 cases were recruited during the study period of which nine cases were excluded from the study. Demographic and clinical data of the study group are shown in Table 1.

Majority patients were <30 years. There were more males than females in the study group. Nasal blockage was the most common symptom followed by rhinorrhea. The symptoms of patients were scored based on visual analog score where 46 patients reported their symptoms as annoying or uncomfortable, while four patients as dreadful. Out of 50 patients, 32 were associated with allergy and nasal polyps and four patients had asthma. Twenty-one patients had deviated nasal symptom. Scores of SNOT-22 were given 0–5 for each symptom depending on the severity. Maximum SNOT-22 scores were of nasal blockage (4.24 ± 1.94), runny nose (3.74 ± 1.747), and facial pain (3.44 ± 1.567). The mean total TEC was 456.2 ± 181.23 per cubic mm and mean serum IgE was 151.97 ± 151.6.

**Table 1: Demographic characteristics of study population**

| variables | Frequency (*n*=50) | Percent |
|---|---|---|
| Gender | | |
| Female | 19 | 38 |
| Male | 31 | 62 |
| Age distribution | | |
| <30 years | 18 | 36 |
| 30–40 years | 10 | 20 |
| 40–50 years | 12 | 24 |
| >50 years | 10 | 20 |
| Mean±SD | 39.92±15.08 | |
| Rural/Urban | | |
| Rural | 24 | 48 |
| Urban | 26 | 52 |

Average visual analog scale (VAS) scores for nasal obstruction, discharge, reduction of smell, and facial pain showed significant and sustainable post-operative improvement at 6 months after surgery ($P < 0.01$) [Table 2].

Mean pre-operative total SNOT-22 was 43.56 ± 18.33. Five patients showed nasal polyps at follow-up at 5–7-month postoperatively. The pre-operative mean total score on diagnostic nasal endoscopy was 8.26 ± 3.65 [Table 3].

Maximum patients ($n$ = 41) performed nasal irrigation between 21 and 30 times at 2 weeks follow-up. The mean of total nasal irrigation performed was 72.54 ± 10.73.

**Table 2: Pre-operative and post-operative mean total visual analogue scale scorer**

| Parameters | Baseline (Mean±SD) | At 6 months (Mean±SD) | *P*-value |
|---|---|---|---|
| Nasal obstruction | 4.28±1.294 | 2.98±0.742 | <0.01 |
| Nasal discharge | 2.12±1.92 | 0.00±0.00 | <0.01 |
| Reduction or loss of smell | 2.34±1.507 | 1.78±0.764 | <0.01 |
| Facial pain/Pressure | 3.44±1.56 | 2.84±1.434 | <0.01 |

**Table 3: Comparison of pre-operative and 3rd- and 6th-month post-operative mean diagnostic nasal endoscopy scoring**

| Parameter | DNE score | Mean | Std. Deviation | Significance of change with preoperative (*P*-value) |
|---|---|---|---|---|
| Polyp | Pre-operative | 2.06 | 1.284 | |
| | Post-operative 3rd month | 0.12 | 0.328 | <0.01 |
| | Post-operative 6th month | 0.10 | 0.303 | <0.01 |
| Discharge | Pre-operative | 3.38 | 1.028 | |
| | Post-operative 3rd month | 0.38 | 0.567 | <0.01 |
| | Post-operative 6th month | 0.16 | 0.370 | <0.01 |
| Scarring | Pre-operative | 0.00 | 0.00 | |
| | Post-operative 3rd month | 0.84 | 0.866 | <0.01 |
| | Post-operative 6th month | 0.70 | 0.909 | <0.01 |
| Crusting | Pre-operative | 0.00 | 0.00 | |
| | Post-operative 3rd month | 1.56 | 0.675 | <0.01 |
| | Post-operative 6th month | 1.72 | 0.536 | <0.01 |
| Edema | Pre-operative | 0.00 | 0.00 | |
| | Post-operative 3rd month | 1.56 | 0.675 | <0.01 |
| | Post-operative 6th month | 1.72 | 0.536 | <0.01 |
| Total | Pre-operative | 8.26 | 3.658 | |
| | Post-operative 3rd month | 2.80 | 1.678 | <0.01 |
| | Post-operative 6th month | 2.76 | 1.623 | <0.01 |

DNE: stands for Diagnostic nasal endoscopy

Post-operative significant improvement of headache and all the symptoms of CRS was seen in those undergoing higher number of budesonide nasal irrigation and less crusting and synechiae formation was seen. Mean post-operative total SNOT-22 score after 3 months 14.42 ± 4.717 ($P < 0.01$) and after 6 months was 21.82 ± 7.819 ($P < 0.01$) [Figure 1].

The post-operative mean total score of diagnostic nasal endoscopy after 3 months and 6 months postoperatively was 2.80 ± 1.68 ($P < 0.01$) and 2.76 ± 1.62 ($P < 0.01$) [Table 3].

## DISCUSSION

The present study was designed to evaluate and compare the quality of life in patients of CRS before and after FESS by SNOT-22. The study was conducted on the patients of CRS with or without nasal polyposis. The diagnosis of CRS was based on the definition of the EPOS 2012.[1]

In presented study, we enrolled 59 patients aged between 15 and 60 years of age. Out of 59 patients, nine patients were excluded from the study. Ling *et al.* reported average age of 49.4 (range 18–80) with a male-female ratio of 1:1.1.[11] Out of 50 patients, 9 (18%) were smokers. In the study of Gray *et al.*, 25.7% were smokers.[12]

Nasal obstruction was the most commonly reported disabling condition, reported in 42 (84%) patients, followed by rhinorrhea in 40 patients (80%), headache in 39 patients (78%), facial pain in 39 patients (78%), sneezing in 38 patients (76%), and hyposmia in 15 patients (30%). The study by Shivakumar *et al.* showed the most common symptom as nasal block (86.66%), followed by anosmia (77.14%), facial pressure (73.33%), postnasal drip (70.47%), headache (62.85%), nasal discharge (58.09%), fatigue (30.47%), halitosis (26.66%), dry cough (11.42%), dental pain (10.4%), and earache/fullness (6.66%).[2]

The mean of nasal irrigations (2-week, 4-week, 6-week, and 8-week follow-up) was 72.54 ± 10.73. Total ($n = 41$) patients had done nasal irrigation between 21 and 30 times at 2 weeks follow-up. Significant improvement in CRS symptoms was seen postoperatively in patients with higher compliance of budesonide nasal irrigation. Average VAS scores for nasal obstruction, nasal discharge, sneezing, and facial pain/pressure showed significant and sustainable post-operative improvement at 6 months after surgery ($P < 0.001$). Similar results have been reported by Soler *et al.* and Mace *et al.*[13,14]

The mean diagnostic nasal endoscopy Lund-Kennedy score postoperatively was 2.76 ± 1.62 at 6th months. In the study conducted by Smith *et al.,* postoperatively mean of Lund-Kennedy score was 4.5 ± 3.7 with a significant mean change of 3.5 ± 4.5 ($P < 0.01$).[15] In the analysis of subgroups by patient factor, all patients irrespective of subgroup showed significant improvement on endoscopy with the exception of smokers. There was no significant difference between smokers ($n = 10$) and non-smokers in change in endoscopy scores.

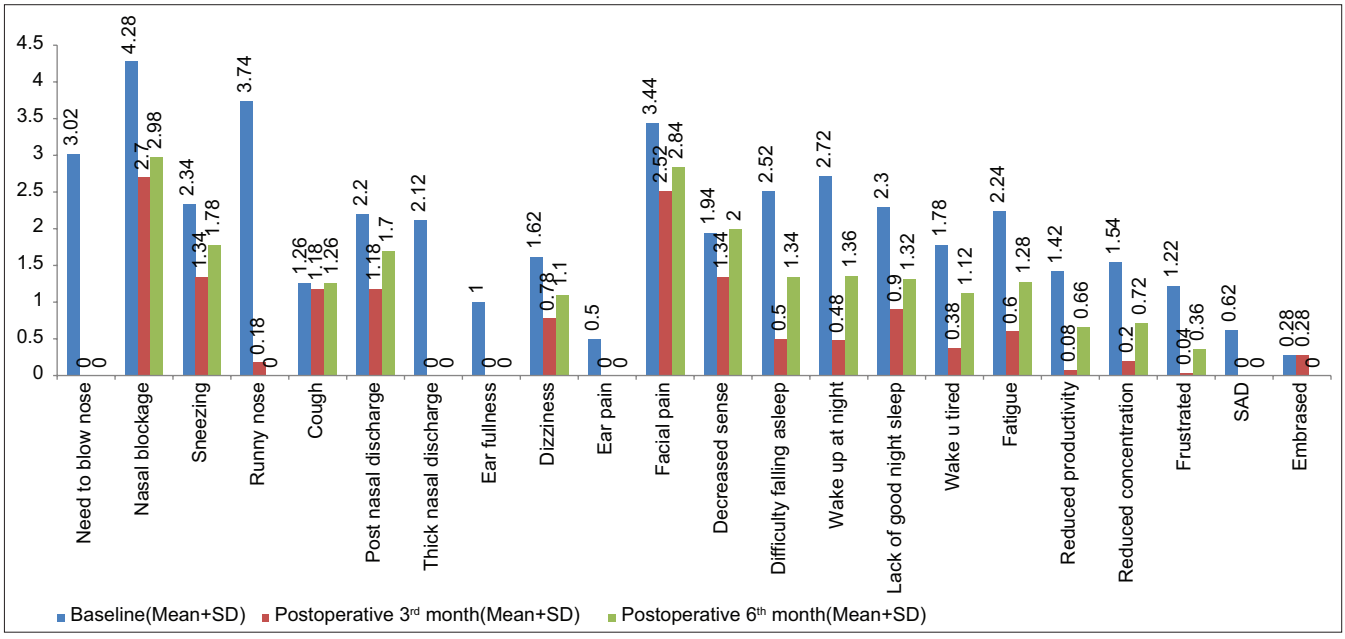


**Figure 1: Bar diagram comparing Pre-operative SNOT-22 score with Post-operative SNOT-22 score after 3rd and 6th month of functional endoscopic sinus surgery**

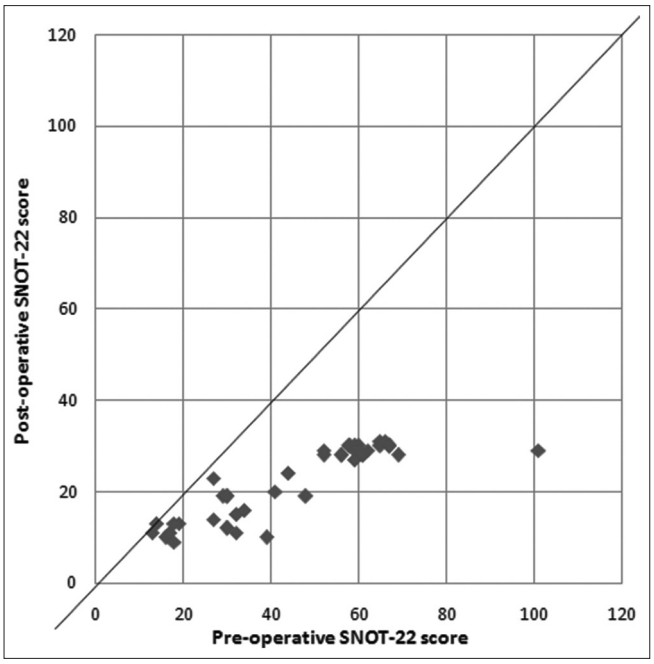


**Figure 2: Scatter plot of pre-operative and post-operative SNOT-22 scoring of individual patients**

The mean post-operative SNOT-22 score was 14.42 ± 4.78 at 3rd month and 21.82 ± 7.81 at 6th month. There was a statistically significant ($P < 0.01$) decrease in patient reported SNOT-22 scores at 6 months. In Figure 2, scatter plot is shown using individual patients' pre-operative and post-operative (6-month) SNOT-22 mean score. It clearly indicates that all patients were benefitted by the intervention as post-operative symptom score improved in all. Here, we can clearly notice that the patients having higher pre-operative SNOT-22 score have shown greater benefit. Hopkins *et al*. reported mean post-operative SNOT-22 score as 25.5 ± 20.8 at 6 months.[16]

Statistically significant reductions in major and minor symptom scores were achieved for all symptoms. Large effect sizes were noted for reductions in facial pressure, nasal obstruction, congestion, and rhinorrhea. Similar large effect sizes were noted for reductions in headache and fatigue. Moderate effect sizes were noted for hyposmia, fever, halitosis, cough, and ear pain.

## CONCLUSION

- SNOT-22 is a self-administered easy to use tool for CRS patients to self-assess improvement in symptom score and it helps in motivation of patient for continuing medical management and nasal irrigation
- Quality of life improves after FESS and nasal steroid irrigation in refractory CRS patients
- Patients with higher pre-operative SNOT-22 score showed relatively better post-interventional SNOT-22 scores.

## COMPLIANCE WITH ETHICAL STANDARDS

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