



Original Article

Comparison of Mean Change in SNOT-22 Score After Continued Medical Therapy Versus Endoscopic Sinus Surgery in Treating Refractory Chronic Rhinosinusitis: A Randomized Controlled Trial

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ABSTRACT

Background: Previous studies have indicated that patients whose medical therapy for chronic rhinosinusitis fails and subsequently undergo sinus surgery tend to exhibit improved outcomes compared to those who persist with medical therapy alone. However, these investigations typically present average outcomes for entire cohorts, thereby overlooking the possibility that specific subsets of patients may experience varying degrees of benefit from a particular treatment modality.

Objective: The objective of the study was to compare the mean change in SNOT-22 scores among patients with refractory chronic rhinosinusitis who were treated with either continued medical therapy or endoscopic sinus surgery (ESS).

Methods: A randomized controlled trial was conducted from the 25th of February 2019 to the 24th of August 2019 at the Department of ENT, Sir Ganga Ram Hospital, Lahore. Sixty patients aged between 15 and 55 years, regardless of gender, and diagnosed with refractory chronic rhinosinusitis were included in the study. Exclusion criteria comprised known psychiatric illness, recent upper respiratory tract infection, and the presence of massive nasal polyposis. Participants in Group A were administered medical therapy, including the antibiotic amoxycyclav, oral and nasal spray steroids, and decongestants, for a duration of three weeks. In contrast, participants in Group B underwent ESS performed by a consultant surgeon. All patients were regularly monitored post-treatment, and changes in their SNOT-22 scores were assessed after a three-month period.

Results: The mean ages of patients in Groups A and B were 29.44 ± 8.28 years and 30.12 ± 9.09 years, respectively. The mean duration of the disease was recorded at 3.31 ± 1.37 months. The sample comprised 41 males (68.33%) and 19 females (31.67%), resulting in a male-to-female ratio of 2.16:1. Post-treatment SNOT-22 scores and the observed changes in scores for Group A were 63.37 ± 5.80 and 2.17 ± 5.24 , respectively. In comparison, the corresponding values for Group B were 19.43 ± 4.58 and 43.90 ± 7.26 , respectively, with the difference being statistically significant (p -value < 0.0001).

Conclusion: The study concluded that endoscopic sinus surgery significantly improves SNOT-22 scores in patients with refractory chronic rhinosinusitis, in comparison to continued medical therapy.

Keywords: Refractory chronic rhinosinusitis, endoscopic sinus surgery, continued medical therapy, SNOT-22 score.

INTRODUCTION

"Chronic rhinosinusitis (CRS) is a pervasive and multifaceted chronic inflammatory condition with far-reaching implications on the health and quality of life of millions worldwide (1). Characterized by persistent inflammation of the sinus and nasal passages, the hallmark symptoms of CRS include nasal obstruction, facial pain, diminished olfactory function, and nasal discharge. According to the National Institute of Allergy and Infectious Diseases, CRS afflicts an estimated 134 million people globally, underscoring its significant prevalence (2).

The ramifications of CRS on individuals and society are profound. Clinically, CRS is synonymous with considerable morbidity, as afflicted individuals often experience significant impediments to their daily activities, social



engagements, and overall life enjoyment. Economically, the burden of CRS is substantial, encompassing direct medical costs, lost productivity, and missed workdays (3).

In terms of management, the therapeutic landscape for CRS is diverse yet frequently inadequate (4). Traditional treatment modalities, such as the use of nasal corticosteroids, saline irrigation, and antibiotics, have demonstrated benefits for a subset of patients (5). However, these interventions often fall short in adequately ameliorating the symptoms of CRS, especially in cases of severe or refractory disease. In such instances, more invasive measures, like endoscopic sinus surgery, may be necessitated. Albeit potentially efficacious, surgery is not uniformly successful and carries its own set of risks and complications (6).

Recent advancements in our comprehension of the intricate inflammatory pathways implicated in CRS have fueled the development of innovative therapeutic strategies aimed at ameliorating the disease process. Interleukin-4 (IL-4) and interleukin-13 (IL-13) are two cytokines implicated in the pathogenesis of CRS, functioning integral roles in the initiation and perpetuation of the inflammatory cascade characteristic of the condition (7). The novel monoclonal antibody Dupilumab, by selectively inhibiting the IL-4 and IL-13 signalling pathways, has emerged as a promising therapeutic avenue for patients with severe or refractory CRS (8).

Nevertheless, while Dupilumab represents a monumental stride in CRS management, its utilization is not without challenges (9). Notably, the cost of this medication may be prohibitive for some, and there is a pressing need for comprehensive long-term data to validate its safety and efficacy (10).

For a holistic and objective evaluation of CRS symptoms and the consequent impact on patients' quality of life, the Sino-Nasal Outcome Test-22 (SNOT-22) score is frequently employed. This metric, through its meticulous assessment of various disease facets, empowers clinicians and researchers to quantitatively gauge the disease's toll on individuals (11).

In the investigation of treatment efficacy for refractory chronic rhinosinusitis (CRS), researchers embarked on a meticulous comparison of the mean change in SNOT-22 scores following continued medical therapy versus endoscopic sinus surgery (12). The SNOT-22 score, a critical index for assessing CRS symptomatology, served as the primary outcome measure to determine the impact of these treatment modalities on patients' quality of life (13).

The comparative analysis drew from a cohort of patients with refractory CRS, each diagnosed by an ENT specialist. Refractory CRS was characterized by the persistence of specific symptoms and physical findings despite the application of standard medical therapies. The persistence of such symptoms necessitates an examination of the therapeutic trajectory for CRS—whether ongoing medical therapy offers sufficient relief or if surgical intervention presents a more effective alternative (14).

The study's findings are poised to fill a crucial void in otolaryngology literature by providing robust data on the relative efficacy of the two treatment approaches. Through rigorous statistical analysis, the investigation yielded a detailed account of the mean changes in SNOT-22 scores for each treatment group (15). These insights are invaluable for clinicians who regularly face challenging decisions in managing refractory CRS. With a clearer understanding of the potential outcomes of continued medical therapy compared to endoscopic sinus surgery, clinicians can make more informed decisions, tailoring treatments to optimize patient outcomes. The research thus not only contributes to the body of medical literature but also stands to influence clinical practices significantly, enhancing the decision-making process for treatments of refractory CRS (3).

MATERIAL AND METHODS

The study was designed as a randomized controlled trial conducted at the Department of ENT, Sir Ganga Ram Hospital, Lahore, from February 25th, 2019, to August 24th, 2019. A total of 60 participants were enrolled in the study, with 30 individuals allocated to each group. The sample size was calculated based on a 5% level of significance, an 80% power of the study, and the mean change in SNOT-22 scores for medical therapy and endoscopic sinus surgery (ESS) as 8.5 ± 15.9 and -50.1 ± 20.0 , respectively (16).

Participants were selected using a non-probability consecutive sampling technique. Inclusion criteria comprised patients aged 15 to 55 years, of both genders, and diagnosed with refractory chronic rhinosinusitis according to the operational definition. Pregnant women, as determined by ultrasound, individuals with known psychiatric



illnesses, those with a recent upper respiratory tract infection in the last month, and patients with massive nasal polyposis were excluded from the study (17).

Upon obtaining informed consent, participants were randomly assigned to one of the two groups by selecting a slip from a mixture of slips labeled 'A' or 'B.' Group A underwent medical treatment for three weeks, receiving antibiotic amoxycylav, oral and nasal spray steroids, and decongestants. Group B participants underwent ESS performed by a consultant surgeon with a minimum of three years of post-fellowship experience. Prior to surgery, these patients received seven days of prednisone (30 mg once daily) and seven days of antibiotics (either amoxicillin-clavulanic acid 1 g twice daily or trimethoprim sulfamethoxazole DS twice daily). Postoperative care included high-volume isotonic saline sinonasal irrigations starting one day after surgery, seven days of systemic antibiotics, and in-office sinonasal debridement at one and three weeks post-surgery. All participants were monitored regularly, with changes in SNOTT scores recorded three months post-treatment (18). Data, including age, gender, duration of refractory chronic rhinosinusitis, living area (rural/urban), occupation, and pre- and postoperative SNOTT scores, were meticulously recorded on a specifically designed proforma (19).

For the statistical analysis, SPSS version 22.0 was utilized. Quantitative variables such as age, duration of refractory chronic rhinosinusitis, and SNOTT scores were expressed as means and standard deviations. Qualitative variables like gender, living area, and occupation were presented as frequencies and percentages. An independent 't' test was employed to compare the mean change in SNOTT scores between the two groups, with a p-value of ≤ 0.05 considered significant. The effects of modifiers such as age, gender, duration of refractory chronic rhinosinusitis, living area, occupation, and preoperative SNOTT score were controlled through stratification, followed by post-stratification independent 't' tests to ascertain their impact on the mean change in SNOTT scores. A p-value of ≤ 0.05 was deemed significant for these analyses.

RESULTS

Table 1 Demographic Characteristics

Characteristic	Group A (n=30)	Group B (n=30)	P-value
Age (years)	29.44 ± 8.28	30.12 ± 9.09	0.75
Age Category (15-35)	21 (70.0%)	19 (63.33%)	0.57
Age Category (36-45)	9 (30.0%)	11 (36.67%)	0.57
Place of living (Rural)	12 (40.0%)	11 (36.67%)	0.79
Place of living (Urban)	18 (60.0%)	19 (63.33%)	0.79
Occupation (Office)	13 (43.33%)	15 (50.0%)	0.53
Occupation (Field)	14 (46.67%)	12 (40.0%)	0.53
Occupation (Other)	3 (10.0%)	3 (10.0%)	1.00

In Table 1, the demographic characteristics of the two groups were compared. The mean age of patients in Group A was 29.44±8.28 years, while in Group B, it was 30.12±9.09 years, with no significant difference between the two groups (p=0.75). When looking at age categories, 70.0% of Group A and 63.33% of Group B were aged between 15 to 35 years (p=0.57), and 30.0% of Group A and 36.67% of Group B were aged between 36 to 45 years (p=0.57). In terms of place of living, 40.0% of Group A and 36.67% of Group B lived in rural areas (p=0.79), while 60.0% of Group A and 63.33% of Group B lived in urban areas (p=0.79). The occupation distribution was also similar between the two groups, with 43.33% of Group A and 50.0% of Group B working in an office, 46.67% of Group A and 40.0% of Group B working in the field, and 10.0% of both groups working in other occupations (p=0.53 for office and field, and p=1.00 for other occupations).

Table 2 Clinical Characteristics

Characteristic	Group A (n=30)	Group B (n=30)	P-value
Duration of ileostomy	3.13 ± 1.43	3.45 ± 1.21	0.48
≤3 months	14 (46.67%)	13 (43.33%)	0.79
>3 months	16 (53.33%)	17 (56.67%)	0.79

In Table 2, the clinical characteristics of the two groups were analyzed. The mean duration of ileostomy was 3.13±1.43 months in Group A and 3.45±1.21 months in Group B, with no significant difference



between the two groups ($p=0.48$). When looking at the duration of ileostomy in categories, 46.67% of Group A and 43.33% of Group B had an ileostomy for 3 months or less ($p=0.79$), and 53.33% of Group A and 56.67% of Group B had an ileostomy for more than 3 months ($p=0.79$).

Table 3 Outcome Measures

Outcome	Group A (n=30)	Group B (n=30)	P-value
Pre-operative SNOTT	63.37 ± 5.80	63.40 ± 5.66	0.984
Post-operative SNOTT	61.20 ± 3.85	19.43 ± 4.58	0.0001
Change in SNOTT	2.17 ± 5.24	43.90 ± 7.26	0.0001

In Table 3, the outcome measures were assessed. The mean pre-operative SNOTT score was 63.37 ± 5.80 in Group A and 63.40 ± 5.66 in Group B, showing no significant difference between the two groups ($p=0.984$). However, there was a significant difference in the post-operative SNOTT scores, with Group B having a much lower mean score of 19.43 ± 4.58 compared to 61.20 ± 3.85 in Group A ($p < 0.0001$). The change in SNOTT scores also showed a significant difference between the two groups, with Group B having a much larger mean change of 43.90 ± 7.26 compared to 2.17 ± 5.24 in Group A ($p < 0.0001$).

DISCUSSION

Chronic rhinosinusitis (CRS) represents a significant medical and socio-economic burden, profoundly impacting patients' quality of life (QoL). The clinical decision between continued medical therapy or endoscopic sinus surgery (ESS) for refractory CRS is predominantly influenced by the individual's baseline disease specific QoL.

Studies conducted by Smith et al. and Smith and Rudmik provide an extensive analysis of this decision-making process (20). In the research conducted by Smith et al., patients with relatively preserved baseline QoL typically opted for continued medical therapy, and this was substantiated with marked improvements post-treatment. In contrast, those with markedly reduced QoL often gravitated towards ESS (20, 21).

The investigation by Xu et al., in 2022 further expands on this dichotomy by highlighting the ramifications of protracted medical therapy in refractory CRS patients with substantially compromised baseline QoL (22, 23). The study meticulously documented that extended medical therapy spanning seven months culminated in a decline in QoL, aggravated endoscopy scores, and an escalation in the number of workdays lost. This finding is pivotal as it underscores the inadequacy of prolonged medical therapy for patients with significantly diminished QoL, thereby spotlighting ESS as a potentially more efficacious alternative (17).

Nevertheless, it is crucial to delve into the limitations and constraints of the current evidence base. Another study, which was subsequently updated in 2009, made a concerted effort to appraise the relative effectiveness of surgical versus medical interventions in CRS (24, 25). However, the review was constrained by the inclusion of merely three level 1 studies, each delving into different aspects of CRS treatment. This inherent heterogeneity in study designs and objectives considerably muddles our capacity to draw unequivocal conclusions about the superiority of one treatment approach over the other (26).

CONCLUSION

The prevailing evidence inculcates a pivotal message: the choice between medical therapy and ESS for CRS is inextricably linked to the patient's baseline disease specific QoL. ESS emerges as a vital option for those with significantly compromised QoL, where extended medical therapy may prove futile. Nonetheless, the paucity of comprehensive, high-caliber studies directly juxtaposing the efficacy of medical and surgical interventions in CRS poses a formidable barrier to reaching a consensus. Future research endeavours should be meticulously designed to plug these gaps in the literature, thereby paving the way for clearer, more robust clinical guidelines that can aid clinicians and patients in making informed treatment decisions.

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