



Original Research Article

Comparative Study on Outcomes of Medical Management versus Combined Surgical and Medical Management of Chronic Rhinosinusitis with Polyps

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ABSTRACT

Introduction – In setting of severe scarcity of Indian literature on impact of disease and whether there should be any variation in treatment in view of tropical climate, with this prospective cohort study, we aim to bring some clarity on role of surgery, perioperative management, and its impact on Quality of Life of patients suffering from Chronic Rhinosinusitis with Nasal Polyps (CRSwNP).

Methods – 60 cases of CRSwNP were included as per the inclusion and exclusion criteria of this study. They were randomised into two groups after continued medical management with intranasal corticosteroid sprays (INCS) for 12 weeks. Group A was continued with INCS while Group B was scheduled for Endoscopic Sinus Surgery and postoperatively continued with same medical management. Visual Analogue Scores (VAS), Lund and Mackay endoscopic appearance scores were taken at baseline and on follow ups at 1, 3 and 6 months. Lund and Mackay radiological scores were recorded at baseline and at 6 months.

Results – Mean VAS scores at baseline and 6 months were 6.83 ± 1.12 and 3.83 ± 0.83 for Group A, and 7.27 ± 1.11 and 2.3 ± 0.79 for Group B. Mean Lund and Mackay Endoscopic appearance scores at same follow up period were 8.33 ± 1.03 and 4.73 ± 1.11 for Group A and 8.63 ± 1.13 for Group B. Mean Lund and Mackay Radiological scores at same follow up period were 15.43 ± 1.89 and 9.77 ± 2.56 for Group A and 18.37 ± 3.54 and 2.13 ± 1.28 for Group B. Statistical analysis revealed that there was significant improvement in Group B in terms of all three parameters as compared to Group A.

Conclusion – Carefully selected cases of Chronic Rhinosinusitis with Nasal polyps who have undergone Endoscopic Sinus Surgery with continued medical management with INCS has been proven to have significantly more benefited than those patients who were continued with medical management alone.

Key Words – Chronic Rhinosinusitis with Nasal Polyps, Endoscopic Sinus Surgery, VAS scores, Lund and Mackay scoring systems, Intranasal corticosteroid sprays

INTRODUCTION

Chronic Rhinosinusitis with nasal polyps (CRSwNP) is one of the subsets of Chronic Rhinosinusitis spectrum disorders and one of the most frequently occurring chronic disorders worldwide. [1] CRS is defined as a diagnosis made on clinical grounds based on the presence of

characteristic symptoms combined with objective evidence of mucosal inflammation. It is phenotypically divided into those cases with polyps (CRSwNP) and those without (CRSsNP) based on endoscopic findings. [2]

There is severe dearth of literature depicting prevalence of CRS in India, although few studies suggest it to affect 11% of worldwide population. [1,3]

A range of diagnostic tests and methods are available to aid in diagnosis of CRS with or without nasal polyps. Although, in majority of cases diagnosis is made in primary care on basis of symptoms alone but objective tests are available to corroborate and validate the diagnosis. [2] Visual analogue scale is a validated tool for subjective assessment of Quality of Life and has been reported in literature to be extensively used. [4] Rigid nasal endoscopy and CT scan have been established as “Gold Standard” tool for diagnosis of CRS [1,2] and validated, well established objective scoring methods are available for ease of quantification. Lund and Mackay staging system is such tool which takes in account the symptomatology, endoscopic findings and imaging findings and is invaluable tool in research in CRS. [5]

There is level I evidence present that strongly recommends use of Intranasal Corticosteroid sprays (INCS) in cases of CRSwNP. Although, there is also plenty of evidence suggesting that both subjective and objective improvement was significant in cases of CRSwNP who underwent Endoscopic Sinus Surgery first and then continued with INCS as compared to cases who did not undergo surgery. [2,6-9] However, high quality level I evidence in this regard is still lacking and ambiguity persists.

Aim of this study was to compare the outcomes of combined Medical and surgical management of Chronic Rhinosinusitis with nasal polyps (CRSwNP) with medical management alone in terms of both subjective and objective parameters.

MATERIALS AND METHODS

A prospective cohort study was conducted in Department of ENT-HNS of a tertiary care centre in West Bengal during June 2016 to June 2018. In this study 60 patients of both genders, of 12-60 years of

age, diagnosed with Chronic Rhinosinusitis with nasal polyps were included. Patients suffering from Chronic Rhinosinusitis without nasal polyps, fungal rhinosinusitis, Allergic rhinitis, Diabetes mellitus, Hypertension, bleeding diathesis and malignancies; those with previous history of Endoscopic sinus surgery and pregnant females were excluded.

Objectives

1. Subjective assessment by correlating baseline quality of life scoring – Visual Analogue Scale (VAS) with that of follow up periods.
2. Objective assessment by correlating Lund and Mackay staging systems at baseline and follow up periods. Staging systems are used as per below –
 - a. Lund and Mackay endoscopic appearance scoring system - applied at baseline, 1, 3 and 6 months of treatment.
 - b. Lund and Mackay radiologic scoring system - applied at baseline and 6 months of treatment.

Methodology

Sample size is calculated to test the following hypothesis with 5% level of significance and 80% power. Sample size came out to be 64.

$H_0 = \pi_1 - \pi_2 = 0$ against $H_1 = \pi_1 - \pi_2 \neq 0$

Here π_1 and π_2 are improvement by combined (medical and surgical) management and medical management respectively.

After acquiring clearance from Institutional ethical committee, study was commenced, and subjects were included as per inclusion and exclusion criteria and their written informed consents were taken. All patients were given trial of Fluticasone nasal spray 200 µg per day 12 hourly for 12 weeks. Post 12 weeks assessment found 04 patients to be completely symptom free and were excluded from study.

Remaining 60 patients, after age and sex matching, were randomised into two groups - Group A and B using a Windows™

based random number generator software. Both groups were assessed and administered subjective Visual Analogue Scale and objective Lund and Mackay endoscopic and radiological (NCCT Nose and Paranasal sinuses) scoring systems as per study objectives. Taking this assessment as baseline evaluation, Group A was continued with Medical management, i.e., Fluticasone nasal spray 200 µg per day in two divided dosages; while patients in Group B were planned for Functional Endoscopic Sinus Surgery which was performed by same surgical team for the sake of uniformity of post-operative results. After 48 hours of surgery, patients of Group B were also started on Fluticasone nasal spray with same dosage. All patients were followed up after 1, 3 and 6 months and all subjective and objective parameters were assessed at each follow up.

Statistical methods

The data from each visit was charted in Microsoft Excel™ spreadsheet and analysed by SPSS 25.0 on a Windows™ based computer. Data was summarized as mean, median and standard deviation for numerical variables, and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. p -value ≤ 0.05 was considered as statistically significant.

RESULTS

Demographics -

There were 16 (53.3%) females and 14 (46.7%) male subjects in Group A with mean age distribution of 35.3 years and standard deviation of 6.25 years. Group B consisted of 11 (36.7%) females and 19 (63.3%) males with mean age distribution of 36.9 years and standard deviation of 6.45 years.

Visual Analogue Scale (VAS) Scores –

When mean VAS scores among both groups were compared at the end of follow up period, there was 43.92% reduction of symptoms in subjects of Group A, while subjects in Group B reported 61.48% reduction in symptoms (Figure 1 and Table 1).

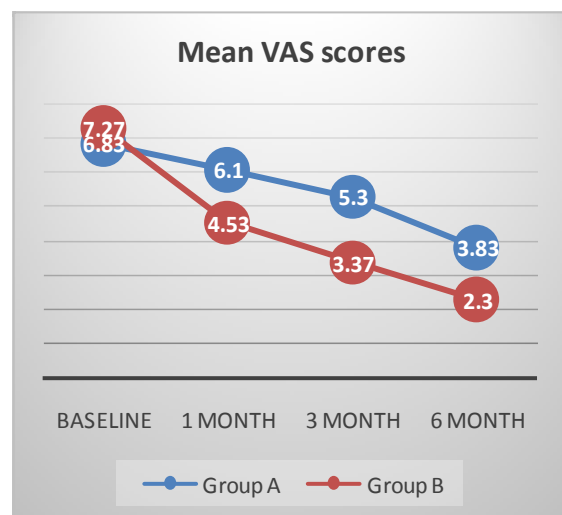


Figure 1: Trends of Mean VAS Scores along the follow up period among both groups

Table 1: Correlation of VAS scores among both groups along the follow up period

Group A n = 30	Follow up period	Mean	Standard deviation	Median	Minimum	Maximum
	Baseline	6.83	1.12	7.0	5	9
	1 month	6.10	0.88	6.0	5	8
	3 months	5.30	0.88	5.0	4	7
	6 months	3.83	0.83	4.0	3	6
	p - value	<0.0001				
Group B n = 30	Follow up period	Mean	Standard deviation	Median	Minimum	Maximum
	Baseline	7.27	1.11	7.0	5	9
	1 month	4.53	1.07	4.5	3	6
	3 months	3.37	1.03	3.0	2	5
	6 months	2.3	0.79	2.0	1	4
	p - value	<0.0001				

Statistical analysis of VAS scores of Group A was done using Student's paired t test, with 95% confidence of interval, degrees of

freedom = 29 and standard error of difference = 0.198, two tailed p value came out to be <0.0001, which was statistically

significant. When VAS scores of Group B was analysed keeping the same statistical method and analysis, two tailed *p* value was found to be statistically significant. When end of follow up VAS scores (6 months) of both groups were compared and analysed using Student's unpaired t test, *p* value came out to be extremely statistically significant (<0.0001) proving that end of 6 months' VAS scores of Group B were better than Group A.

Lund and Mackay endoscopic appearance scoring system –

On comparison of endoscopic appearance scores of Group A, there was 12% reduction of scores after 1 month and 43.2% reduction at the end of follow up (6 months). Group B reported 83% reduction

in scores after 1 month and 87% reduction after 6 months (Figure 2 and Table 2).

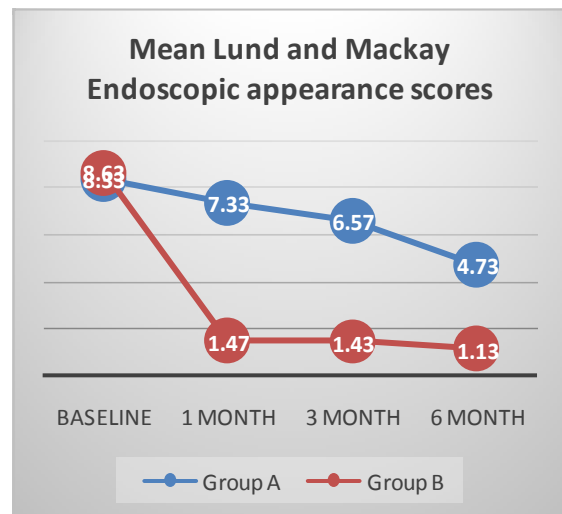


Figure 2: Trends of Mean Lund and Mackay Endoscopic appearance Scores along the follow up period among both groups

Table 2: Correlation of Lund and Mackay Endoscopic appearance scores among both groups along the follow up period

Group	Follow up period	Mean	Standard deviation	Median	Minimum	Maximum
Group A n = 30	Baseline	8.33	1.03	8.0	6	10
	1 month	7.33	1.09	7.0	5	9
	3 months	6.57	1.10	7.0	4	8
	6 months	4.73	1.11	5.0	3	7
	<i>p</i> - value	<0.0001				
Group B n = 30	Baseline	8.63	1.25	9.0	4	10
	1 month	1.47	1.55	1.0	0	5
	3 months	1.43	1.55	1.0	0	5
	6 months	1.13	1.22	1.0	0	4
	<i>p</i> - value	<0.0001				

Same statistical methods were applied for correlation of Lund and Mackay endoscopic appearance scores for both groups, i.e., Student's paired t test for correlation between baseline and end of follow up scores within each group and Student's unpaired t test for comparison of end of 6 months data between the groups. Statistical analysis of Group A revealed that with 95% confidence interval, degrees of freedom = 29 and standard error of difference = 0.212, two tailed *p* value was <0.0001 which was statistically significant. For Group B, with 95% confidence interval, *t* = 31.4426, degrees of freedom = 29 and standard error of difference = 0.239, two tailed *p* value was <0.0001 which was statistically significant. Inter group comparison of end of follow up period

revealed that taking same confidence interval, *t* = 11.9216, *df* = 58 and standard error of difference = 0.302, two tailed *p* value was <0.0001, which by conventional statistical criteria, was extremely statistically significant, revealing that end of follow up Lund and Mackay Endoscopic scores of Group B were way better than that of Group A.

Lund and Mackay radiological scoring system –

As per the methodology of the study, non-contrast CT scan was performed at baseline and end of follow up period for all subjects. Overview of data showed that there was 36% reduction in Lund and Mackay radiological scores in Group A and

88.4% reduction in Group B (Figure 3 and Table 3).

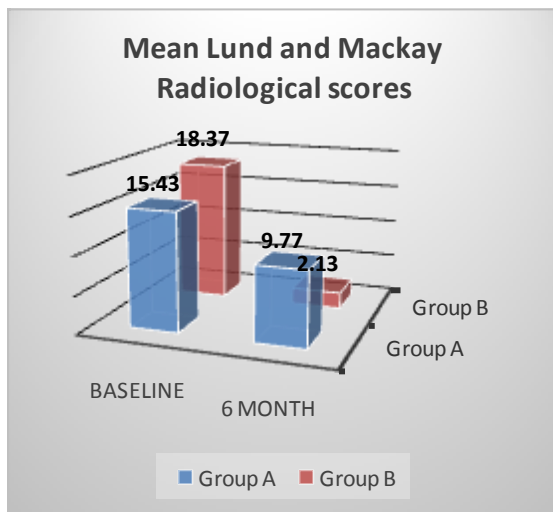


Figure 3: Trends of Mean Lund and Mackay Radiological Scores along the follow up period among both groups

By applying the same statistical methods, it was found that for Group A, when confidence interval was taken as 95%, $t = 16.8268$, $df = 29$ and standard error of difference = 0.337, two tailed p value was statistically significant. Statistical analysis of Group B revealed that with same confidence interval and degrees of freedom, $t = 31.2101$ and standard error of difference = 0.520 the two tailed p value was again statistically significant. But when end of follow up scores among two group were calculated with Student's unpaired t test, with 95% confidence interval, $df = 58$, $t = 14.6303$ and standard error of difference = 0.522 the two tailed p value was <0.0001 which was statistically extremely significant proving that Lund and Mackay radiological scores at the end of follow up of Group B were better than that of Group A.

Table 3: Correlation of Lund and Mackay Radiological scores among both groups along the follow up period

Group	Follow up period	Mean	Standard deviation	Median	Minimum	Maximum
Group A n = 30	Baseline	15.43	1.89	15.0	13	19
	6 months	9.77	2.56	9.0	6	15
	p - value	<0.0001				
Group B n = 30	Baseline	18.37	3.54	19.0	13	24
	6 months	2.13	1.28	2.0	0	4
	p - value	<0.0001				

DISCUSSION

Chronic Rhinosinusitis has always been an enigma for Otorhinolaryngologists since the entity was explained way back in late 90s. [10-12] After more than two decades since the disease is known, we are still theorising about its etiopathogenesis, definitive treatment and follow up. Among many meta-analyses in the plethora of literature, European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) remains the one the pioneer publication which has tried to readdress the issue and tried to offer some clarifications on diagnosis, [1,2] but still, lacunas in treatment protocols and follow up schedule are overwhelming. Moreover, there is a serious lack of Indian perspective over such collation of multicentric trials and meta-analyses in setting of having tropical climate and thus abundance of allergic etiopathology of Chronic Rhinosinusitis

further widening the grey areas. This study has tried to clarify one glaring issue on whether to operate or not, in what cases, when, and whether the subjective and objective criteria explained and evaluated in European settings are valid in Indian scenario. We have tried to address Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) which somewhat has lesser grey areas that Chronic Rhinosinusitis without Nasal Polyps (CRSsNP) in terms of, at least, whether to do surgery or not. [2] Functional Endoscopic Sinus Surgery with Messerklinger technique is very well valid in cases of CRSwNP as has been proven and thoroughly discussed in EPOS 2012 article and offers much better post-operative results than other limited procedures. [2,13,14]

There are various objective and subjective parameters which have been developed for assessment of patients suffering from CRSwNP who have been

managed medically as well as surgically. One of the valid criteria used worldwide is Lund and Mackay scoring systems which address not only the quality of life but also offers objectivity in terms of endoscopic examination and imaging assessment. [4,5] It includes a quality of life assessment scores in terms of Visual Analogue Scale scoring system [2,5] whose much simplified, modified version being used worldwide has been utilised in this study [2,4] as well as objective (though not without observer bias) endoscopic and radiological scoring.

Visual Analogue Scale utilised in this study, which is measured by patients on a line giving a measurable continuum (0 – 10 cm), states ‘mild disease’ to be defined as a VAS score of 0-3 inclusive, ‘moderate’ as >3-7 inclusive, and ‘severe’ as ≥ 7 . [2,4] It is a simplified and validated version of Lund and Mackay Symptom Scoring System [5,10] which does not complicate the issue with taking each symptom as separate entity, which further has to be correlated post treatment whether medical or surgical. Among the subjective scoring systems, we have taken into consideration the Lund and Mackay Endoscopic Scoring system [5,15] which takes into account the presence of oedema, polyps and discharge in various defined regions of nasal cavity. Other subjective criteria which have been studied well and considered in this study was Lund and Mackay Radiological scoring system which considers the presence of opacification and occlusion of various paranasal sinuses and osteomeatal complex. [2,5,10]

Results of this prospective cohort study are in sync with concept of “Evidence based surgery” for CRSwNP brought in light by EPOS 2012 article. [2,16,17] It has been reiterated time and again in literature that CRS is a medical disease and should be treated by intranasal corticosteroid sprays (only medication with backed up plenty of evidence of being useful in CRS). However, as the natural history of disease goes, there is development of mucosal oedema and later polyps which block osteomeatal complex

and hinders entry of corticosteroid sprays rendering this management useless. Here comes the role of surgery, where, with conservative Messerklinger approach, polyps are removed, and ostia of paranasal sinuses are widened enough to facilitate entry of steroid sprays.

With this study, we aim to provide objective evidence regarding role of conservative surgery in CRSwNP with continued medical management.

CONCLUSIONS

1. Mainstay treatment of both variants of Chronic Rhinosinusitis remains intranasal corticosteroid sprays (INCS).
2. In cases of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP), treatment with INCS alone is insufficient and role of combined medical and surgical management, though debated, starts.
3. Conservative surgery in carefully selected cases of CRSwNP provides significant improvement in quality of life of patients.
4. However, perioperative management with INCS holds more importance as long term post-surgical results depends on it.

Conflicts of interests: None declared.

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