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Comparison of Outcomes of Management of Chronic Rhinosinusitis by Conservative Approach Vs Endoscopic Sinus Surgery with Review of Literature

Author
Dr Devendra M. Jain
-MS ENT (Pune)

Chronic rhinosinusitis (CRS) affects 1 in 8 people in India; about 5-15% of urban population. The prevalence of sinusitis (146/1000 population) has been reported to exceed that of any other chronic condition and is apparently on the increase. Sinusitis is a common health problem that leads to frequent visits to primary care physicians and to ear, nose and throat specialists in all over the world. It contributes to a significant amount of health care expenditure due to direct costs arising from physician visits and antibiotics, as well as indirect costs related to missed days at work and a general loss of productivity due to a decrease in life-quality of those affected.

Many medical & surgical therapies have been used to treat CRS. Medical therapy includes antimicrobials, corticosteroids, decongestants, antihistamines, mast cell stabilizers, antileukotr-ienes, nasal douching, immunotherapy, and reduction of environmental factors. The documentation of medical treatment of CRS is deficient in the literature, apart from a few randomized, controlled trials investigating the role of corticosteroids in CRS with nasal polyposis.

On the other hand, Endoscopic sinus surgery has yielded excellent subjective and objective outcomes, with a very low complication rate. The high success rate, the low incidence of complications and the technological advances in optical instrumentation and imaging techniques in the presence of poor documentation of outcomes of medical therapy has made endoscopic sinus surgery the primary therapy for CRS in the absence of a well performed, prospective, randomized, controlled trial that fulfills level I statement of evidence based medicine. To address this deficiency, the present study has been designed to evaluate and compare surgical and medical treatment of CRS.

Apart from the clinical parameters, concomitant radiologic evaluation of the subjects with CRS included in the trial, has helped in categorizing the patients in each cohort; so as to avoid any bias and to ensure that like are compared with like, thereby adding objective strength to the study.

Aim & Objectives

- To study the clinical features of cases of chronic rhinosinusitis.

- Clinico-radiologic study of chronic rhinosinusitis
- To conduct a prospective, randomized, controlled trial evaluating and comparing the medical and surgical treatment of chronic rhinosinusitis.

Diagnosis

As per European position paper on rhinosinusitis and nasal polyps, CRS is defined as inflammation of nose and paranasal sinuses with -presence of two or more symptoms one of which should be either nasal blockade/obstruction/congestion or nasal discharge (anterior /posterior nasal drip), facial pain and pressure, reduction or loss of smell for >12 weeks.

-Diagnosis of CRS requires in addition requires either: endoscopic signs of polyps; oedema or mucopurulent discharge; and / or

- CT PNS showing mucosal changes within osteomeatal complex and / or sinuses.

Plain CT PNS (3 mm coronal sections) correlates fairly well with the extent of disease. It approximates closest to the surgical field and best demonstrates the osteomeatal complex and the skull base . When pathology is present in posterior ethmoids and sphenoid, axial views are also required to optimally show optic nerve and carotid artery. Reconstructed sagittals are useful in evaluating the frontal recess. The timing of scan should take into account the effect of common cold which produces sinus opacification in 87 % of sinuses and persistence of changes on imaging many weeks after bacterial infection despite clinical resolution.

Staging of Rhinosinusitis

For valid assessment of results following various therapies for chronic rhinosinusitis, the Lund and Mackay staging system was devised. It is the system used in this study for outcome assessment of results after medical and/ or surgical treatment of CRS.

The Lund and Mackay staging system : symptom score (visual analogue method):

SYMPTOM (Score 1– 10)	Baseline (pre R)	3 months (post R1)	6 months (post R2)	1 year (postR3)	Avg. post R
Facial pain					
Nasal blockage					
Nasal discharge					
anosmia					
Overall discomfort					
Total points each visit					

(0, symptom not present; 0-10, degree of symptom severity, with 10 indicating greatest severity)

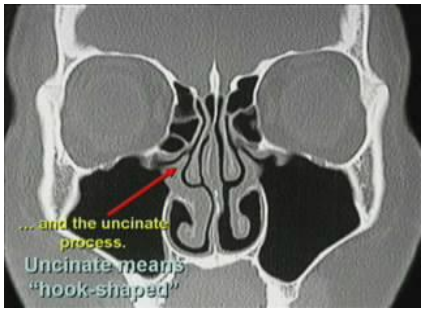
The Lund and Mackay radiologic staging system:

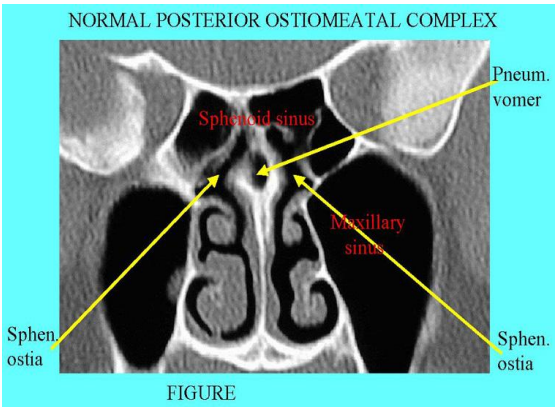
Sinus system	Left	Right
Maxillary (0 / 1 / 2)		
Anterior ethmoids (0 / 1 / 2)		
Posterior ethmoids (0 / 1 / 2)		
Sphenoid (0 / 1 / 2)		
Frontal (0 / 1 / 2)		
Osteomeatal complex (0 / 2)		
Total points		

(0, no abnormalities; 1, partial opacification; 2, total opacification)

Functional endoscopic sinus surgery (FESS) technique is based on the hypothesis that the osteomeatal complex (OMC) is the key area in the pathogenesis of chronic sinus disease. The removal of mechanical obstruction in the OMC area leads to proper ventilation, drainage and resolution of secondary mucosal changes in the frontal, maxillary and ethmoid sinuses without touching the mucosa in these sinuses. This helps in restoration of normal functional and anatomical situation with minimum destruction of nasal and paranasal anatomy. OMC is often referred to the area encompassed by: (a) The ostium of maxillary sinus, the ostia of anterior and middle ethmoidal air cells, the frontonasal duct (frontal recess), the ethmoidal infundibulum, and the middle meatus

NORMAL ANTERIOR OSTIOMEATAL COMPLEX





FIGURE

The sphenoethmoidal recess and the superior meatus, referred to as the posterior osteomeatal unit.

Along with the progress in surgical techniques for chronic sinusitis, sinonasal imaging has also progressed methodically to encroach on the domain of the former generation. While plain radiography was once the most common investigation to evaluate the sinonasal cavity, computed tomography (CT scan) has now supplanted the former because the endoscopic sinus surgery requires greater anatomic precision. The detailed anatomy of the osteomeatal complex as displayed by CT scan acts as a roadmap for surgeons prior to endoscopic sinus surgery .

Stammberger proposed that stenosis of the osteomeatal complex, from either the anatomical configuration or hypertrophied mucosa, can cause obstruction and stagnation of secretions that may become infected or perpetuate infection.

The posterior ethmoids were involved in 66%, maxillary antra in 50%, frontal sinuses in 32% and sphenoids in 18%. The extent of involvement reported by other authors was also in the same range.. Thus, this study has re-emphasized the concept that Osteomeatal complex is the key factor in the causation of chronic sinusitis. Removal of disease in Osteomeatal complex region is the basic principle of FESS which is best appreciated on CT Scan.

Material & Methods

The protocol of the study and the methods of consent had been approved by the institutional ethics committee of Tertiary care Hospital in Western Maharashtra.

CONSENT: Informed written consent was obtained from all patients included in the study.

Selection of Cases:

A) Inclusion Criteria:

-Patient aged 18 to 75 years with

-atleast two of the following symptoms for atleast 12 consecutive weeks

(nasal obstruction, nasal discharge, facial pain, headache, olfactory disturbance, recurrent sneezing), with

-CT PNS demonstrating isolated or diffuse mucosal thickening, bone changes, air fluid levels, or nasal polyposis

B) Exclusion Criteria:

Age younger than 18 years and ages older than 75 years

Acute upper or lower respiratory tract infections within 2 weeks from the inclusion visit

Diagnosis of an established immunodeficiency, pregnancy, lactation, significant psychologic problems, inability to comply with study protocol,

Systemic diseases affecting nose (wegener granulomatosis, sarcoid, primary ciliary dyskinesia, cystic fibrosis, coagulation disorder, a diagnosis of AFS (allergic fungal sinusitis)

Nasal or sinus malignancy

Those with CRS with or without NP in whom systemic steroid therapy would be contraindicated

Those who are dependent on systemic steroid therapy for sinonasal disease or any other condition

Previous medical or surgical treatment influencing the study

Subjective assessment:

Patients were asked about their nasal symptoms before and at each post treatment visit. Nasal blockage or congestion, nasal discharge, olfactory disturbance, facial pain or pressure, headache and overall discomfort were used for the scoring criteria using a visual analogue scale of 0 to 10 cm., as per the Lund Mackay symptom scoring

Examination of the nose:

Full ENT examination of each patient was done before and at each post treatment visit; noting DNS, condition of nasal mucosa, middle meatal discharge, polyp, cold spatula test, paranasal sinus tenderness.

Investigations:

Hemogram, absolute eosinophil count

CT PNS (plain)

Initial medical treatment:

This was given to all patients with clinically suspected chronic rhinosinusitis. This included:

Tab amoxycillin clavulanate 625 mg BID for 7 days

Tab ebastine 10 mg HS for 7 days

Oxymetazoline nasal drops, 2 drops in each nostril TDS for 7 days

Steam inhalation before retiring to bed for 7 days

Radiological evaluation: This was followed by plain CT PNS (3 mm coronal sections).

Patients with radiologically confirmed CRS were categorized into 4 categories (A-D), as per Lund Mackay radiologic staging system .

Patients in each category were randomly allocated for medical or surgical line of treatment.

Follow up : was given at 3months and 6 months and 12 months after completion of treatment. At each follow-up, Lund Mackay symptom scores were obtained and average of each symptom score over the 3 post-treatment follow-ups calculated.

Medical line of management:

All patients received a 12 week course of :

a) Alkaline nasal douche: The alkaline nasal douche powder was prepared in a 1:1 mixture of sodium chloride and sodium bicarbonate. The douche was also used twice daily, followed after 15 minutes by steroid nasal spray.

b) Intranasal corticosteroid preparation: Mometasone furoate was delivered as two puffs in each nostril twice daily, with each metered dose containing 50 mcg.

After that, the medical treatment was tailored to the patient manifestations, which comprised a topical corticosteroid spray in most instances.

Medical treatment after surgery:

After FESS, all patients were prescribed one week course of the antibiotic and alkaline nasal douche. This was followed by a 3 month course of twice daily use of 100 mcg of mometasone furoate into each nostril and alkaline nasal douche. After that, the medical treatment was tailored to the patient manifestations, which comprised a topical corticosteroid spray in most instances.

Surgical treatment:

Functional Endoscopic Sinus Surgery was performed in all patients by Messerklinger technique by three senior surgeons. All cases were performed under general anaesthesia. The extent of the procedure was tailored to the extent of sinus disease as documented by CT Scan findings. A microdebrider was used in some cases of CRS with polyposis. At the end of the procedure, a piece of ivalon pack was inserted into the ethmoidal cavity on each side and soaked in Betadine Ointment. It was taken out after 48 hrs. Surgical steps, operative findings and complications were recorded in every case (ref 17).

Observations and analysis

Statistical methods:

Total 50 patients were randomly distributed into two groups receiving:

a) medical treatment b)surgical treatment

Patients in each group were categorized into 2 categories(A+ B) & (C+ D) based on Lund Mackay radiologic staging system (LMS)

LMS Score	3 - 6	7 - 12	13 - 18	19 - 24
Category	A	B	C	D

The primary end point was decided to be the visual analogue scale for CRS. The analysis was

performed using the SPSS for Windows, version 9statistics software package Chicago II.

Data were expressed as mean: SD. P values < 0.o5 were considered significant. Parametric tests such as unpaired t test was applied for data that followed normal distribution. Non parametric tests such as the Mann-Whitney U test, the Wilcoxon signed rank test, the chi square test were applied for data that did not follow a normal distribution.

The following tables & graphs depict the change in individual symptom score before and after treatment:

Facial pain:

Medical treatment: There was statistically significant improvement only in group (A+B)

Surgical treatment: There was no statistically significant improvement in either groups.

Table 2 : Change in facial pain visual analogue score (VAS) after medical and surgical treatment in group (A+B) & group (C+D)

FACIAL PAIN	N	Mean	Std. Deviation	Wilcoxon signed rank test Z	P
Group (A+B)					
Medical R					
Pre_ score	13	2.23	2.619	2.201	0.028 Sig
Post_ score	13	.62	1.044		
Surgical R					
Pre_ score	12	.33	1.155	1.0	0.317 NS
Post_ score	12	.00	.000		
Group (C+D)					
Medical R					
Pre_ score	12	.00	.000	0.0	1.0 NS
Post_ score	12	.00	.000		
Surgical R					
Pre_ score	13	1.15	2.824	1.342	0.180 NS
Post_ score	13	.00	.000		

(where, N –no. of patients; P- level of significance; R- treatment;

Med_Pre- VAS before medical treatment.

Med_Po-Average VAS over three post-treatment follow-ups at 3, 6, 12 months after medical treatment

Sur_Pre- VAS before surgical treatment

Sur_Po- Average VAS over three post-treatment follow-ups at 3, 6, 12 months after surgical treatment)

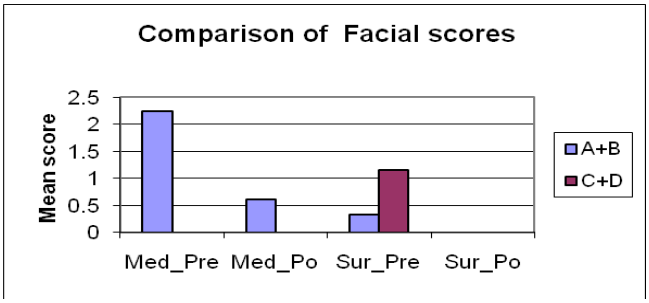


Figure 4: Change in facial pain visual analogue score (VAS) after medical and surgical treatment in group (A+B) & group (C+D)

Headache:

Medical treatment: There was statistically significant improvement in both groups.

Surgical treatment: There was statistically significant improvement in both groups.

Table 3: Change in Headache visual analogue score (VAS) after medical and surgical treatment in group (A+B) & group (C+D)

HEADACHE	N	Mean	Std. Deviation	Wilcoxon signed rank test Z	P
Group (A+B)					
Medical R					
Pre_ score	13	2.92	2.253	2.692	0.007Sig
Post_ score	13	.46	.660		
Surgery					
Pre_ score	12	1.50	2.195	2.041	0.041 Sig
Post_ score	12	.08	.289		
Group (C+D)					
Medical R	12	5.00	4.472	2.214	0.027 Sig
sPre_ score	12	2.75	3.745		
Post_ score					
Surgery					
Pre_ score	13	3.23	4.343	2.032	0.042 Sig
Post_ score	13	.77	1.878		

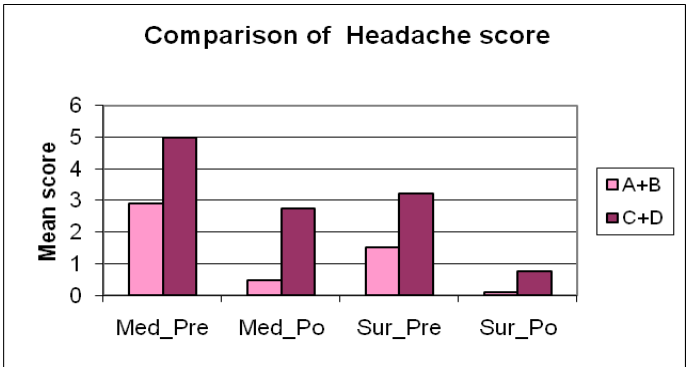


Figure 5: Change in Headache visual analogue score (VAS) after medical and surgical treatment in group (A+B) & group (C+D)

Nasal blockade:

Medical treatment: There was statistically significant improvement in both groups.

Surgical treatment: There was statistically significant improvement in both groups.

Table 4: Change in Nasal blockade visual analogue score (VAS) after medical and surgical treatment in group (A+B) & group (C+D)

NASAL BLOCKADE	N	Mean	Std. Deviation	Wilcoxon signed rank test Z	P
Group (A+B)					
Medical R					
Pre_ score	13	3.46	2.504	2.810	0.005 Sig
Post_ score	13	.92	1.188		
Surgery					
Pre_ score	12	4.17	2.791	2.810	0.005 Sig
Post_ score	12	.17	.389		
Group (C+D)					
Medical R					
Pre_ score	12	7.67	3.701	2.689	0.007 Sig
Post_ score	12	5.08	3.630		
Surgery					
Pre_ score	13	7.62	2.815	3.071	0.002 Sig
Post_ score	13	1.46	2.602		

Nasal discharge:

Medical treatment: There was statistically significant improvement in both groups.

Surgical treatment: There was statistically significant improvement in both groups.

Table 5: Change in Nasal discharge visual analogue score (VAS) after medical and surgical treatment in group (A+B) & group (C+D)

NASAL DISCHARGE	N	Mean	Std. Deviation	Wilcoxon signed rank test Z	P
Group (A+B)					
Medical R					
Pre_ score	13	4.23	2.204	3.070	0.002 Sig
Post_ score	13	.77	.832		
Surgery					
Pre_ score	12	3.25	2.261	2.831	0.005 Sig
Post_ score	12	.50	.674		
Group (C+D)					
Medical R					
Pre_ score	12	7.92	2.843	2.848	0.004 Sig
Post_ score	12	5.08	3.260		
Surgery					
Pre_ score	13	4.62	4.501	2.371	0.018 Sig
Post_ score	13	1.62	2.959		

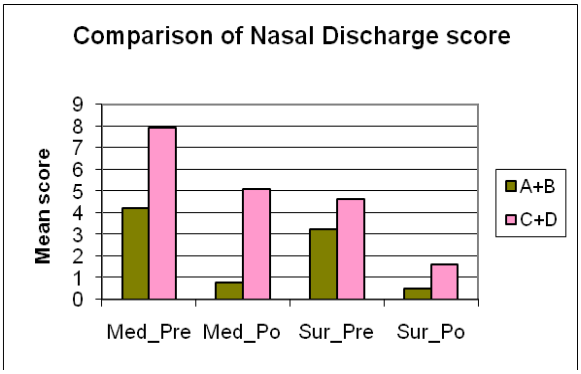


Figure 7: Change in Nasal discharge visual analogue score (VAS) after medical and surgical treatment in group (A+B) & group (C+D)

Anosmia:

Medical treatment: There was no statistically significant improvement in either group

Surgical treatment: There was no statistically significant improvement in either group

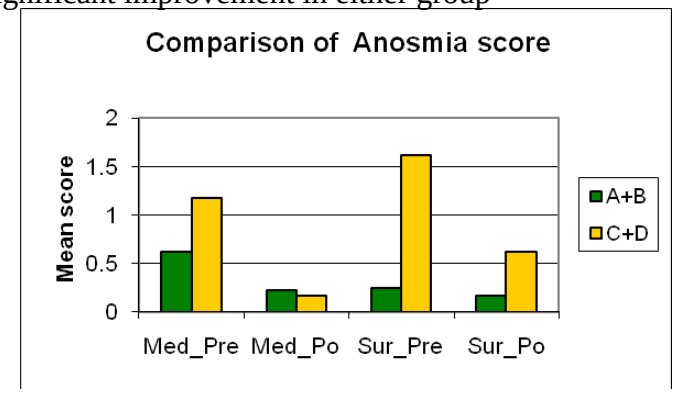


Figure 8: Change in Anosmia visual analogue score (VAS) after medical and surgical treatment in group (A+B) & group (C+D)

Table 6: Change in Anosmia visual analogue score (VAS) after Medical and surgical treatment in group (A+B) & group (C+D)

ANOSMIA	N	Mean	Std. Deviation	Wilcoxon signed rank test Z	P
Group (A+B)					
Medical R					
Pre_ score	13	.62	1.557	1.342	0.180 NS
Post_ score	13	.23	.599		
Surgery					
Pre_ score	12	.25	.866	1.0	0.317 NS
Post_ score	12	.17	.577		
Group (C+D)					
Medical R					
Pre_ score	12	1.17	2.758	1.414	0.157 NS
Post_ score	12	.17	.577		
Surgery					
Pre_ score	13	1.62	3.150	1.604	0.109 NS
Post_ score	13	.62	1.938		

Overall discomfort:

Medical treatment: There was statistically significant improvement in group (C+D)

Surgical treatment: There was statistically significant improvement in group (C+D)

Table 7: Change in Overall Discomfort visual analogue score (VAS) after Medical and surgical treatment in group (A+B) & group (C+D)

OVERALL DISCOMFORT	N	Mean	Std. Deviation	Wilcoxon signed rank test Z	P
Group (A+B)					
Medical R					
Pre_ score	13	1.38	2.219	1.633	0.102 NS
Post_ score	13	.46	1.127		
Surgery					
Pre_ score	12	.42	.996	1.342	0.180 NS
Post_ score	12	.17	.389		
Group (C+D)					
Medical R					
Pre_ score	12	5.83	3.664	2.694	0.007 Sig
Post_ score	12	3.83	3.215		
Surgery					
Pre_ score	13	2.77	3.700	2.032	0.042 Sig
Post_ score	13	1.15	1.864		

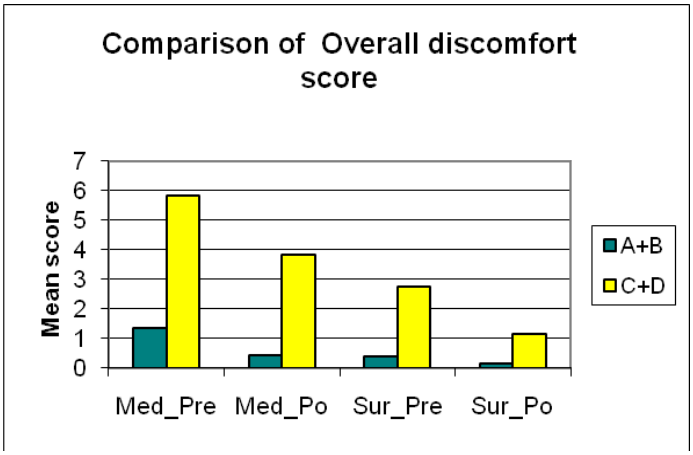


Figure 9: Change in Overall discomfort visual analogue score (VAS) after medical and surgical treatment in group (A+B) & group (C+D)

Total score:

Medical treatment: There was statistically significant improvement in both the groups

Surgical treatment: There was statistically significant improvement in both the groups

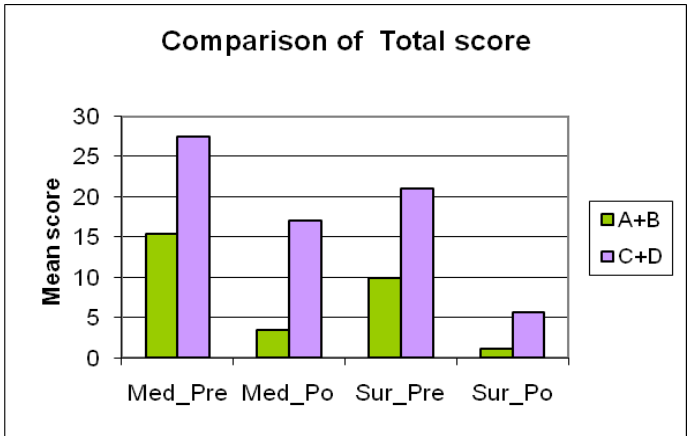


Figure 10: Change in Total visual analogue score (VAS) after medical and surgical treatment in group (A+B) & group (C+D)

Table 8: Change in Total visual analogue score (VAS) after Medical and surgical treatment in group (A+B) & group (C+D)

TOTAL POINTS	N	Mean	Std. Deviation	Wilcoxon signed rank test Z	P
Group (A+B)					
Medical R					
Pre_ score	13	15.38	6.199	3.183	0.001 Sig
Post_ score	13	3.46	4.684		
Surgery					
Pre_ score	12	9.92	3.118	3.065	0.002 Sig
Post_ score	12	1.08	1.165		
Group (C+D)					
Medical R					
Pre_ score	12	27.58	7.971	2.938	0.003 Sig
Post_ score	12	17.08	9.249		
Surgery					
Pre_ score	13	21.00	7.906	3.181	0.001 Sig
Post_ score	13	5.62	9.042		

Overall efficacy:

If a therapy giving >50% relief is considered as significant, the following results are obtained:

Table 9: Table depicting no. of patients with less than 50% Vs more than 50% reduction in symptom scores with medical treatment in group (A+B); their association with mean absolute eosinophil count (AEC);

Applying the Chi Square test, Std deviation > 24 is significant.

(A+B) Medical R

Reduction in total score	N	Mean AEC	Sd. (std. deviation)
<50%	1	750.00	-.
≥50%	12	157.50	52.592

Table 10: Table depicting no. of patients with less than 50% Vs more than 50% reduction in symptom scores with surgical treatment in group (A+B)

(A+B) Surgical R

Reduction in total score	N	Mean AEC	Sd.
<50%	-	-	-
≥50%	12	110.83	48.703

Table 11: Table depicting no. of patients with less than 50% Vs more than 50% reduction in symptom scores with medical treatment in group (C+D)

(C+D) Medical R

Reduction in total score	N	Mean AEC	Sd.
<50%	9	352.22	291.967
≥50%	3	100.00	10.000

Table 12: Table depicting no. of patients with less than 50% Vs more than 50% reduction in symptom scores with surgical treatment in group (C+D)

(C+D) Surgical R

Reduction in total score	N	Mean AEC	Sd.
<50%	3	493.33	318.800
≥50%	10	176.00	67.198

If a therapy giving >50% relief is considered as significant, the following results are obtained:

In group (A+B), both medical and surgical treatment are equally effective. In group (C+D), medical treatment is much less effective than surgical treatment. Patients with higher Absolute eosinophil count, had poor response to therapy, as assessed on Visual analogue scale.

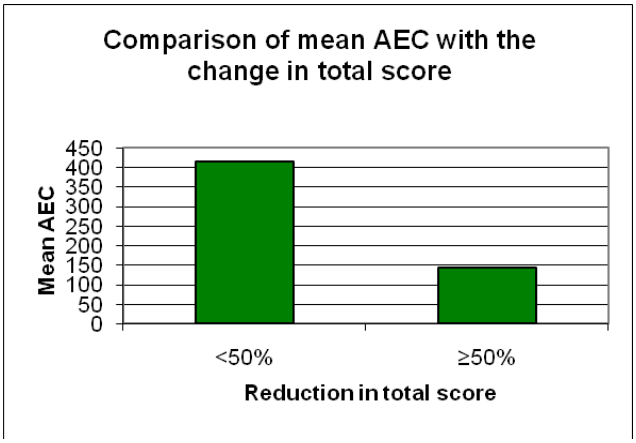


Figure 11: Association of mean Absolute Eosinophil Count with reduction in symptom score

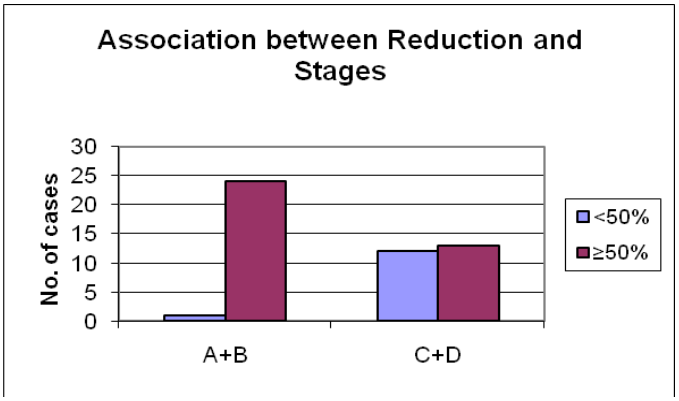


Figure 12: Association between Lund Mackay group and response to therapy:

Patients with higher LMS score (13-24), i.e.,group (C+D), had higher probability of <50% response to therapy

Discussion

Majority (84%) of patients were of the age between 20 – 40 years, comprising the productive sector of society. Hence, the cost bearing of CRS in terms of loss of work days and, in turn, loss of productivity to the society is large.

Majority (62%) of patients with CRS were males (31 males; 19 females). Hence, again the loss of productivity in a male dominated society is large.

Patients with higher Absolute eosinophil count, had poor response to therapy, as assessed on Visual analogue scale. This factor helps to prevent recurrence after FESS for CRS by keeping the patient on medical line of treatment for longer duration.

Maxillary sinus was most commonly involved in CRS (90%), followed by osteomeatal complex blockade and involvement of anterior ethmoid air cells. Hence, messerklinger technique of clearing & widening the sinus ostia from anterior to posterior seems more rational than Wigand.

In the present study, the medical regimen:- 12 week course of alkaline nasal douche and topical corticosteroids (after 1 week course of antibiotic and nasal decongestant), appears to be an effective, well tolerated therapy for CRS in group (A+B), i.e., in patients with LMS score 3-12 (mild to moderate CRS).

If a therapy giving >50% relief is considered as index of its efficacy, the following results are obtained

:i) In group (A+B), both medical and surgical treatment are equally effective.

ii) In group (C+D), medical treatment is much less effective than surgical treatment.

Previous studies on CRS with polyposis reported no significant difference between snare polypectomy and a depot injection of 14 mg betamethasone

Blomqvist et al (ref 22) studied the additive effect of endoscopic sinus surgery for CRS with polyposis over topical steroids after treating all patients with oral prednisolone for 10 days. They claimed an additional effect of surgery on nasal obstruction but not on sense of smell, although a significant worsening in nasal obstruction scores was experienced between the third and six months post operatively. Twenty-five percent patients were willing to undergo endoscopic sinus surgery on the unoperated side at the end of the study.

In this study, it was observed that the improvement in anosmia after either medical or surgical treatment was not statistically significant.

Endoscopic sinus surgery significantly improved the subjective symptoms in both the groups (mild to severe CRS). The present trial also confirms the low complications profile of endoscopic sinus surgery reported in previous studies.

In patients with severe changes of CRS (LMS 13-24), the medical treatment is much less effective than surgical treatment in improving the subjective symptoms consistently over a follow up period of 12 months. Hence, surgery should be considered in such cases along with medical line of treatment

Summary and Conclusions

This study provides evidence that the preferred therapy for CRS varies with the extent of involvement of various sinuses.

As per Lund Mackay radiologic staging system,

i) Individuals with LMS score from 3 to 12 should be initially targeted with maximal medical therapy including an oral amoxicillin-clavulanate antibiotic & an antihistaminic with decongestant nasal drops for 7 days;

followed by steroid nasal spray and alkaline nasal douching for 3 months.

After this, patients should be assessed and surgery considered in those cases refractory to medical therapy.

ii) Individuals with LMS score from 13 to 24 should be considered for Functional Endoscopic Sinus Surgery followed by medical therapy for 3 months.

iii) In both the groups, medical therapy can be tailored as per patients response to the therapy. Usage of steroid nasal spray (mometasone furoate) can be extended upto 1 year without significant side effects.

iv) Functional Endoscopic Sinus Surgery is effective in all cases of CRS (mild to severe). However, to avoid the cost, potential complications, and psychologic burden of surgery, FESS should be opted for only in cases with LMS score > 12, or in cases refractory to medical therapy, or in cases with poor compliance to medical therapy.

v) The presence of nasal polyps does not serve as a poor prognostic factor for the efficacy of CRS therapy.

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