



## A RANDOMIZED CONTROL TRIAL ON COMPARATIVE STUDY OF MICRODEBRIDER ASSISTED ENDOSCOPIC SINUS SURGERY WITH CONVENTIONAL INSTRUMENTS AND ITS IMPACT ON THE PULMONARY FUNCTION TEST

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### ABSTRACT

#### INTRODUCTION

The nasal airways and their closely associated paranasal sinuses are an integral part of the respiratory tract. 1 -5. A close association has been suggested between sinusitis and lower respiratory disorders like bronchial asthma. It is known that chronic sinusitis coexists in as many as 40 –75 % of patients with asthma. Study done by Shaaban et al had shown that allergic rhinitis was associated with increased onset of bronchial hyper responsiveness, and less chance for remission except in those treated for rhinitis<sup>6</sup>.

#### AIMS AND OBJECTIVES

The Aim of this study is to assess the extent of improvement in chronic sinusitis following surgical treatment in the form of ESS (either with microdebrider or using conventional technique) and also if it can bring about a significant improvement in the pulmonary function tests of patients

#### CONCLUSION

1. In both methods after surgery, there was statistically considerable difference symptomatically in Microdebrider assisted endoscopic sinus surgery than the conventional method
2. In both the methods radiological score difference was good without any statistical difference. Hence both methods are equally good for clearing disease.
3. In both the methods endoscopic score difference was good without any statistical difference. Hence both methods are equally good for clearing disease.
4. There were no surgical complications in any of the method
5. In both methods after surgery, there was statistically considerable difference in FEV1 values in microdebrider assisted endoscopic sinus surgery than conventional method. Hence microdebrider assisted ESS is considered better in terms of addressing coexistence of lower

### KEYWORDS :

#### INTRODUCTION

Airborne particles and gases are continually exposed to the upper and lower respiratory tracts. It is very important to have a good host defence mechanism. Physical barriers, mucociliary clearance systems and cellular or humoral immune processes combine to protect the lung from damage. The patient may first present to the Otolaryngologist when there are abnormalities of these mechanisms even before serious bronchopulmonary involvement occurs.

Mucociliary clearance is the predominant clearance mechanism for both upper and lower airways. The cilia beat in a coordinated fashion with a ciliary beat frequency of 12–14 beats per second. Two layers of mucus are present over the ciliated cell; an outer thick, viscoelastic, semisolid mucus layer, which the cilia do not directly strike, and an inner layer of watery serous fluid. Because of the low viscosity of the layer of watery serous fluid, the cilia can beat normally and move the watery lower layer, affecting movement of the upper thick layer. Changes in these properties affect movement of the mucus blanket and play a major role in pulmonary and sinus disease. In the upper respiratory tract, cilia propel mucus, bacteria, and the particles trapped in mucus to the nasopharynx, where the mucus drops to the hypopharynx and is swallowed. In the lower respiratory tract, the cilia that line the trachea and bronchial tree similarly move the mucus blanket up the trachea and into the hypopharynx for swallowing.<sup>6</sup>

#### MATERIALS AND METHODS

##### STUDY DESIGN

This is a prospective randomised control study.

##### INCLUSION CRITERIA

- } Age: 10-75 years
- } Patients With Sinonasal Polyp
- } Patients with Chronic Rhino Sinusitis(CRS) not responding to Medical Treatment
- } Patients with Sinonasal Diseases Willing for Study

##### EXCLUSION CRITERIA

- } Sino Nasal Malignancies
- } Previous Sinus Surgeries
- } Pregnant Women
- } Bleeding disorders
- } Patience with pulmonary diseases

##### METHOD OF COLLECTION OF DATA

Sample size: 60

Group 1: 30

Group 2: 30

Patients who agreed to randomization were consented, included in the study and started on medical treatment with systemic steroids for 2 weeks and a topical nasal steroid one month. Patients in whom disease persisted after medical therapy were equally randomized into two groups - microdebrider and conventional endoscopic sinus surgery method with 30 patients in each group.

Subjective symptoms and findings of CRS were based on the CRS criteria<sup>27</sup> and were divided into major and minor factors. In consultation with other medical disciplines, the American Academy of Otolaryngology and Head and Neck Surgery established baseline parameters in 1996 for discerning the subtypes of rhinosinusitis (acute, recurrent acute, subacute and chronic). These parameters have since become widely adopted by researchers and by health maintenance organizations<sup>7,8</sup>. A CRS diagnosis requires presence of at least 2 major factors or one major factor with 2 or more minor factors or nasal purulence on examination. Facial pain is not considered to be a symptom of CRS without other nasal signs and symptoms. The signs and symptoms must persist for at least 12 weeks to qualify as CRS.

##### SYMPTOMS SCORE

Symptoms score is given with the help of LUND – MCKAY<sup>9</sup> symptoms scoring system both pre operatively 1 week before surgery as well as post operatively 2 months after surgery

## SYMPTOM SCORE BY VISUAL ANALOGUE METHOD

- Facial pain or pressure (0-10)
- Head ache (0-10)
- Nasal block/ nasal congestion (0-10)
- Nasal discharge (0-10)
- Olfactory disturbance (0-10)
- Overall discomfort (0-10)

The symptoms are scored out of 60 both pre operatively and post operatively after 2 months.

## CT ASSESSMENT

LUND-MCKAY CT SCORING SYSTEM<sup>9</sup> separately assesses the extent opacification of the individual sinuses and osteomeatal complex and a score of 2, 1 or 0 is respectively allotted based on if there is complete, partial or no opacification. During the study, CT scans of paranasal sinuses were done and assessed on the basis of 33 Lund and McKay criteria for each sinus with a maximum score of 24 pre operatively 1 week before surgery and post operatively 2 months after surgery.

## RADIOLOGICAL STRUCTURES LEFT RIGHT

MAXILLARY (0/1/2)

ANTERIOR ETHMOIDS (0/1/2)

POSTERIOR ETHMOIDS (0/1/2)

FRONTAL (0/1/2)

SPHENOID (0/1/2)

OMC (0/2)

0 - No Abnormalities 1- partial opacification 2- complete opacification

0-OMC not occluded 2- occluded

## DIAGNOSTIC NASAL ENDOSCOPY & ENDOCOPIC GRADING

Nasal examination including Diagnostic nasal endoscopy is done and endoscopic grading is given by LUND- MCKAY scoring system<sup>54</sup> PRE- OPERATIVE GRADING

## CHARACTERISTIC LEFT RIGHT

Polyp (0, 1, 2, 3)

Oedema (0, 1, 2,)

Discharge (0, 1, 2)

## Polyp

0- Absence

1- Polyp in MM only

2- Polyp in MM, but not completely obstructing the nose

3- Polyps completely obstructing the nose 34

## Oedema

0- Absent

1- Mild

2- Severe

## Discharge

0- Absent

1- Clear thin discharge

2- Thick purulent discharge

Done preoperatively 1 week before surgery and 2 months after surgery post operatively.

## PULMONARY FUNCTION TESTS

PFT was assessed using Spirometer (KOKO Legend) 1 week prior to surgery. In a Normal case, FVC and FEV1 should be greater than or equal to 80% of predicted, and the FEV1 to FVC ratio should be no more than 8-9 absolute percentage points below the predicted ratio. The PFT values were considered to indicate significant airway obstruction when FEV1/FVC < 0.7 and FEV1 < 80 % of the predicted value for a patient's age, height and weight. In this study FEV1 value is alone taken and compared. PFT is also assessed 2 months post-surgery.

## DISCUSSION

### Symptoms score:

The mean difference of symptom score for group 1 was found to be 28.0 and group 2 found to be 22.53. Therefore all the patients had a improvement in their symptoms irrespective of the group to which they have been randomized. But the difference between the improvements of symptoms found to be statistically significant implying Microdebrider assisted ESS gives more relief in patient symptoms.

### Endoscopic scores

The mean of endoscopic score postoperatively for both the groups post op were 1.90 and 2.87 respectively for group 1 and 2 which shows significant improvement indicating the clearance of disease without any sequel.

### CT Findings:

The mean of preoperative CT score of group 1 and 2 were 16.63 and 15.3 respectively in this study. According to modified Lund scoring system, in the present study patients had the score in the range of 7-24 and 8-24 for group 1 and group 2 respectively.

Contrary findings were noted by Bhat tacharya et al<sup>10</sup>. Whereas, in a study conducted by Wang et al, 118 (51.3%) cases had the score in the range of 0-4<sup>11</sup>. These findings suggest that majority of the patients have presented to the hospital at a relatively early stage of the disease. Whereas the patients in rural population of Kanchipuram did not seek medical attention early.

### PFT findings:

In the present study, it is noted that there is increase in mean postoperative FEV1 for both the groups 3.318 and 2.87 from the preoperative value of 2.94 and 2.80. The difference between the FEV1 values pre operatively and post operatively were measured and compared between two groups.

The mean difference were 0.376 and 0.065 for group 1 and 2 respectively. The independent student t test showed statistically significant difference.

Both the group showed increase whereas the group 1 showed statistically significant increase compared to group 2. Hence we can conclude microdebrider assisted ESS better in terms of improving pulmonary function test.

In general this improvement can be attributed mainly to the surgery followed by steroid sprays. In a study done by Ragab et al<sup>12</sup>. it was found that the 6- and 12-month postoperative FEV1 percent (% of predicted) showed significant increase. Only a few patients demonstrated statistically significant improvement after FESS in asthma symptom 60 scores (1 patient), medication use scores (1 patient), or pulmonary function test results (2 patients).

In another study by Ikeda et al<sup>13</sup> which evaluated the clinical efficacy of endo nasal ESS in patients with asthma associated with chronic sinusitis, the average peak expiratory flow 6 months following surgery improved in the ESS patients significantly ( $p < 0.05$ ). In a similar study conducted on asthmatic patients by Dhong et al. there was no significant change in pulmonary function<sup>14</sup>.

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