Assessment of outcome of functional endoscopic sinus surgery in patients with chronic sinusitis with or without sinonasal polyposis

A dissertation submitted in partial fulfillment of MS Branch IV, ENT examination of the Tamil Nadu Dr.MGR Medical University, to be held in April 2013

DEPARTMENT OF OTORHINOLARYNGOLOGY
CHRISTIAN MEDICAL COLLEGE VELLORE

CERTIFICATE

This is to certify that the dissertation entitled —" **Assessment of outcome of functional endoscopic sinus surgery in patients with chronic sinusitis with or without sinonasal polyposis**'' is the bonafide original work of **Dr.ELIZEBETH SUNNY** submitted in fulfillment of the rules and regulations for the MS Branch IV, ENT examination of the Tamil Nadu Dr.MGR Medical University, to be held in April 2013.

Dr. Rupa Vedantam
Professor and Head of Unit 3
Dept of Otorhinolaryngology
Christian Medical College
Vellore- 632004.

DEPARTMENT OF OTORHINOLARYNGOLOGY
CHRISTIAN MEDICAL COLLEGE VELLORE

CERTIFICATE

This is to certify that the dissertation entitled **— Assessment of outcome of functional endoscopic sinus surgery in patients with chronic sinusitis with or without sinonasal polyposis** ’’ is the bonafide original work of **Dr.Elizebeth Sunny** submitted in fulfillment of the rules and regulations for the MS Branch IV, ENT examination of the Tamil Nadu Dr.MGR Medical University, to be held in April 2013.

Principal
Christian Medical College
Vellore – 632002
India

Dr.AchammaBalraj
Professor and Head
Dept of ENT
Christian Medical College
Vellore.

ACKNOWLEDGEMENTS

I wish to express my heartfelt thanks and deep sense of gratitude to my esteemed professor and guide Dr. Rupa Vedantam, Professor and Head of Department of ENT 3, CMC, Vellore for all her encouragement, constant support and guidance at every stage of this study and preparation of this dissertation.

I wish to thank Dr Suma Susan Mathews, Dr. Rajiv Michael, Associate professors, Dr Jareen, Dr Maheshwaran Asst.Professors, ENT unit 3 for their support and guidance throughout the study.

I wish to thank Dr. Achamma Balraj, Professor and Head of ENT, CMC, Vellore for facilitating this study.

I would like to thank Mrs. Grace Rebecca for her help and support in the planning of this study and analysis of the data.

My sincere thanks to Staff in the ENT scopy room for their cooperation.

I would like to thank all my patients who participated in the study and came for follow up without fail.

My sincere thanks to all my professors, seniors, colleagues and friends for all the encouragement and help in collecting the data. Special thanks to my colleagues in ENT 3 for pitching in and helping out in the routine works.

I wish to thank Mr.Sathiyamoorthy for his help regarding Epidata worksheet and statistical work.

A special thanks to my parents, husband and my little one,Ann, for the constant support and prayers.

I am grateful to God for his Grace which sustained me during the entire Course of this study.

Dr. Elizebeth Sunny

Table of contents

Sl No:	Title of contents	Page no:
1	Aims and objectives	1
2	Introduction	2
3	Present knowledge and review of literature	4
4	Materials and methods	38
5	Results	41
6	Discussion and conclusion	68
7	Bibliography	77
8	Annexures 1.Informed consent 2.Proforma 3.Excel data sheet 4.IRB approval 5Antiplagiarism certificate	84

Title of the study:

Assessment of outcome of functional endoscopic sinus surgery in patients with chronic sinusitis with or without sinonasal polyposis

Objectives and aims of study

To assess the outcome of functional endoscopic sinus surgery (FESS) in patients with chronic sinusitis with or without nasal polyposis using the quality of life assessment instrument SNOT 22 questionnaire and endoscopic scoring**.**

Method of study

This prospective study was conducted in the Department of ENT at Christian Medical College Vellore. Pre and postoperative data was collected from patients undergoing functional endoscopic sinus surgery for chronic rhinosinusitis with or without polyposis. We used a quality of life instrument (SNOT 22) along with Lund Kennedy endoscopic scoring and Lund Mackay CT scan scoring. Patients were followed up for a minimum of 3 to 6 months postoperatively and at the same scoring instruments re-administered. Descriptive data was analyzed and frequency distributions derived. Patients with and without sinonasal polyposis were compared in terms of demography as well as SNOT 22, endoscopic and CT scores using Student's t- test. Pearson's correlation was used to assess the correlation between endoscopic scores and CT scan scores. Changes in the SNOT 22 score, symptom specific frequency and endoscopic score after surgery were assessed using chi square test of proportions, to see if there was a significant difference in scores postoperatively. The frequency of complications following the procedures was also assessed.

Results:

Of a total of 90 patients who were included in the study, 50 patients came for the follow up. There were 37 patients with polyps and 13 patients without polyps. On comparing the pre and post operative results of SNOT 22 score, we observed that there was a mean improvement of 19.8 points in the score overall. Out of 37 patients in the group with polyps, 31 patients (83.8%) improved at least by 9 points postoperatively, while 84% (11/13 patients) improved by at least 9 points in the group without polyps. The mean improvement of total SNOT 22 score was 20.8 in the group with polyps and this was statistically significant (p=0.00). The mean improvement of total SNOT 22 score was 17.0 in the group without polyposis and this was also statistically significant (p=0.01). Symptoms- specific assessment showed a significant improvement for all the major symptoms. There was a significant improvement in Lund Kennedy endoscopic scores (p=0.03) as well in both the groups of the patients. The improvement in SNOT22 scores and endoscopic scores was seen in both patients who underwent primary surgery (p=0.00) as well as those who underwent revision surgery (p=0.00). The complication rate was only 2.2%.

Conclusions

Functional endoscopic sinus surgery provides a significant quality of life improvement as well as symptom specific improvement in patients with sinusitis with or without polyposis. The improvement in endoscopic appearances is also corroborated by improved endoscopic scores postoperatively. Functional endoscopic sinus surgery is equally effective in primary and revision cases. There are few complications and it is a safe procedure in experienced hands.

Key words: Chronic rhinosinusitis with polyps, Chronic rhinosinusitis without polyps SNOT22, Lund Kennedy score, Functional endoscopic sinus surgery outcome, Revision functional endoscopic sinus surgery

AIMS AND OBJECTIVES

To assess the outcome of functional endoscopic sinus surgery (FESS) in patients with chronic sinusitis with or without nasal polyposis using the quality of life assessment instrument SNOT 22 questionnaire as well as postoperative rigid nasal endoscopy.

INTRODUCTION

Chronic rhinosinusitis is a well recognised clinical syndrome, affecting patients of all ages and gender(1). It is a major health problem affecting with significant impact on the quality of life, productivity and finances(2). There is a wide geographical variation in the prevalence of chronic rhinosinusitis ranging from 1.01% to 16% (2,4)

As per the European Position Paper on Rhinosinusitis and Nasal Polyps 2012 guidelines(5), chronic rhino-sinusitis is characterized by inflammation of the mucous membranes of the nasal cavity and the paranasal sinuses, with typical symptoms that persist for more than 12 weeks and objective criteria using nasal endoscopic findings and or CT scan findings. Typical symptoms include more than or at least 2 symptoms, one of which should be nasal blockage/obstruction/congestion/nasal discharge (anterior/posterior), with or without facial pain/pressure, reduction/loss of smel1.

Inflammation of the nasal and paranasal mucosa, leads to ostial obstruction and retention of secretions, which further leads to secondary infection. Inflammation causes mucociliary dysfunction thereby perpetuating the condition. Various local and systemic factors can contribute to the pathogenesis of chronic rhino-sinusitis. Chronic sinusitis may be associated with nasal polyposis. Sinonasal allergy is often a coincidental finding.

Treatment of chronic sinusitis can be medical or surgical. Medical modalities of the therapy include topical steroid sprays, nasal douching with saline and long term antibiotic therapy. Historically established surgical techniques for the management of chronic rhinosinusitis

include antral lavage, Caldwell Luc procedure, intranasal polypectomy, external or transantral ethmoidectomy and external frontal sinus surgery depending on the sinuses involved.

However, with the advancement of endoscopic surgical procedures over the past two decades, the surgical management of sinusitis has completely changed. Functional endoscopic sinus surgery (FESS) is a minimally invasive technique in which the sinus ostia are opened under direct visualization, with an aim to restore sinus ventilation and normal function.

FESS has now become a well established surgical modality in the treatment of sinusitis refractory to medical treatment. However, there is a conspicuous lack of good surgical evidence on the efficacy of this intervention. Hence, we have undertaken this study on subjective and objective assessment of outcome of FESS in cases of chronic sinusitis, using the QOL instrument SNOT 22 questionnaire and Lund Kennedy endoscopic scoring system.

PRESENT KNOWLEDGE AND REVIEW OF LITERATURE

ANATOMY OF THE NOSE (6)

The nasal cavity consists of two irregular fossae on either side of the nasal septum, housed in a supporting framework of bone and fibroelastic cartilage. The larger bones in this framework contain air filled spaces collectively called as the paranasal sinuses.

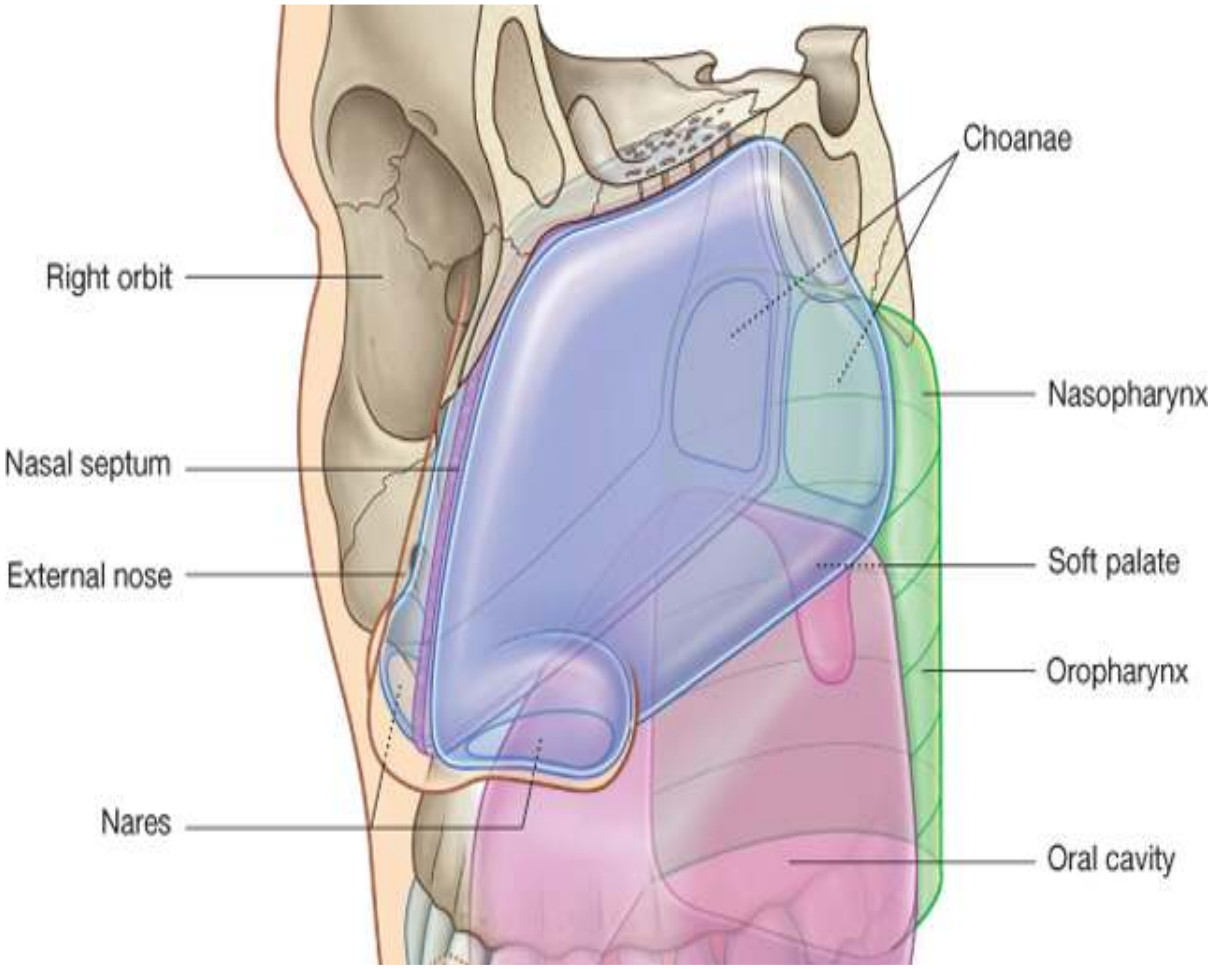
The Nasal Cavity

The nasal cavity extends from the anterior nares to the posterior choanae, where it becomes continuous with the nasopharynx (Fig.1). Vertically it extends from the superior border of the hard palate to the cribriform plate and can be divided into 3 regions – the nasal vestibule, the respiratory region and the olfactory region. Laterally it is related to the orbital cavity and the paranasal sinuses. The paranasal sinuses and the nasolacrimal duct drain into the nasal cavity through openings on the lateral wall.

Each nasal cavity has a roof, a floor, a medial wall and a lateral wall. The roof is narrow from side to side and is formed by the nasal bone, frontal bone, cribriform plate of the ethmoid bone and the body of the sphenoid (Fig.2). It is horizontal in the centre and slopes anteriorly and posteriorly.

The floor of the nose is flattened antero-posteriorly and is about 7cm length in adults. It is formed by the palatine process of the maxilla anteriorly and the horizontal process of the palatine bone posteriorly. The medial wall is formed by the nasal septum which has membranous, cartilaginous and posterior bony parts (Fig 2).

Fig. 1 Diagram showing the sagittal view of the nasal cavity and its relationship with the nasopharynx.



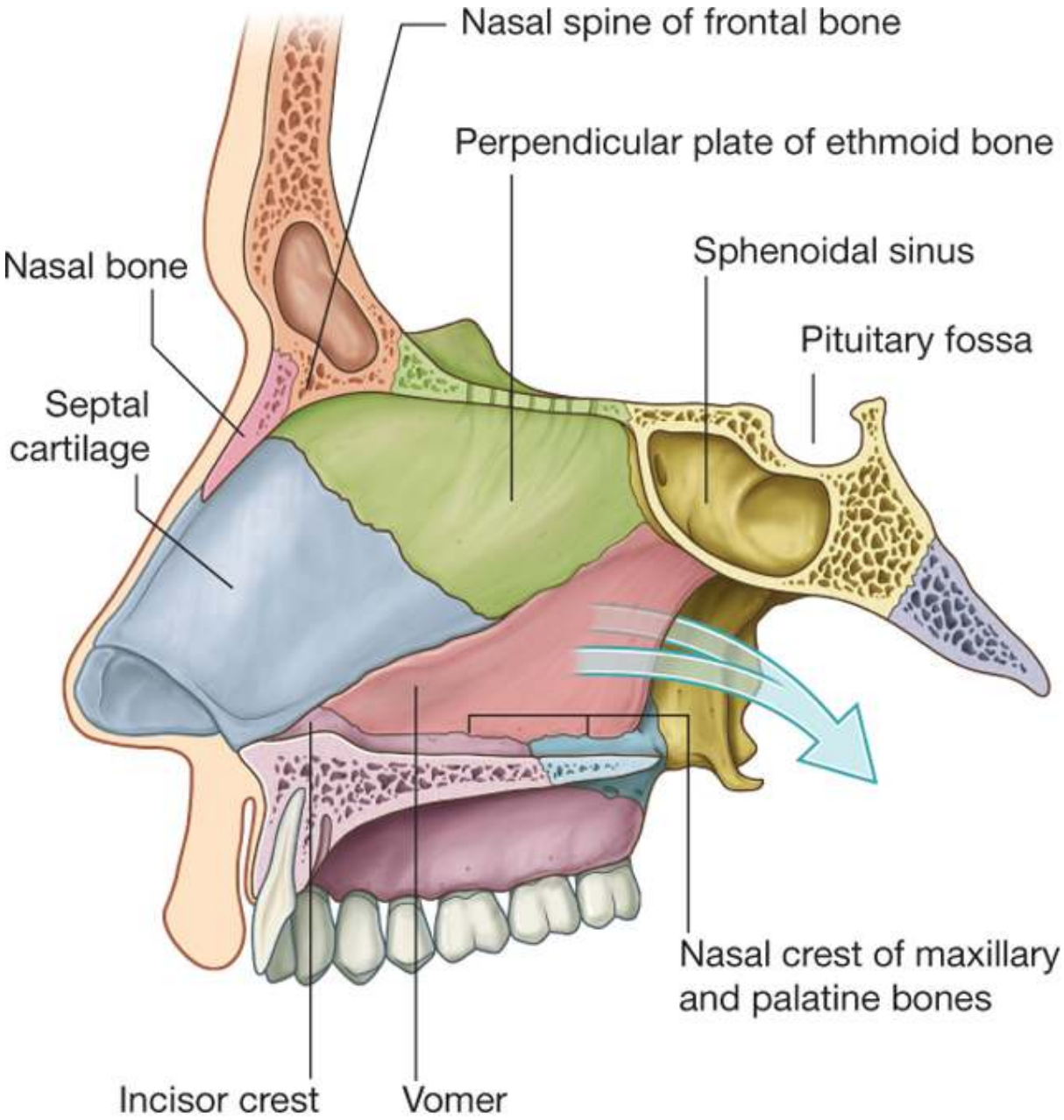


Fig.2 Diagram showing the roof of the nasal cavity and the bones constituting the same.

The lateral nasal wall is quadrangular in shape and is anatomically and functionally more complex. It is mostly bony and partly membranous. The bony part is constituted by parts of maxilla, ethmoid, lacrimal, nasal, palatine and sphenoid bones and the areas of deficiency in between is covered by the overlying nasal mucosa(Fig 3).

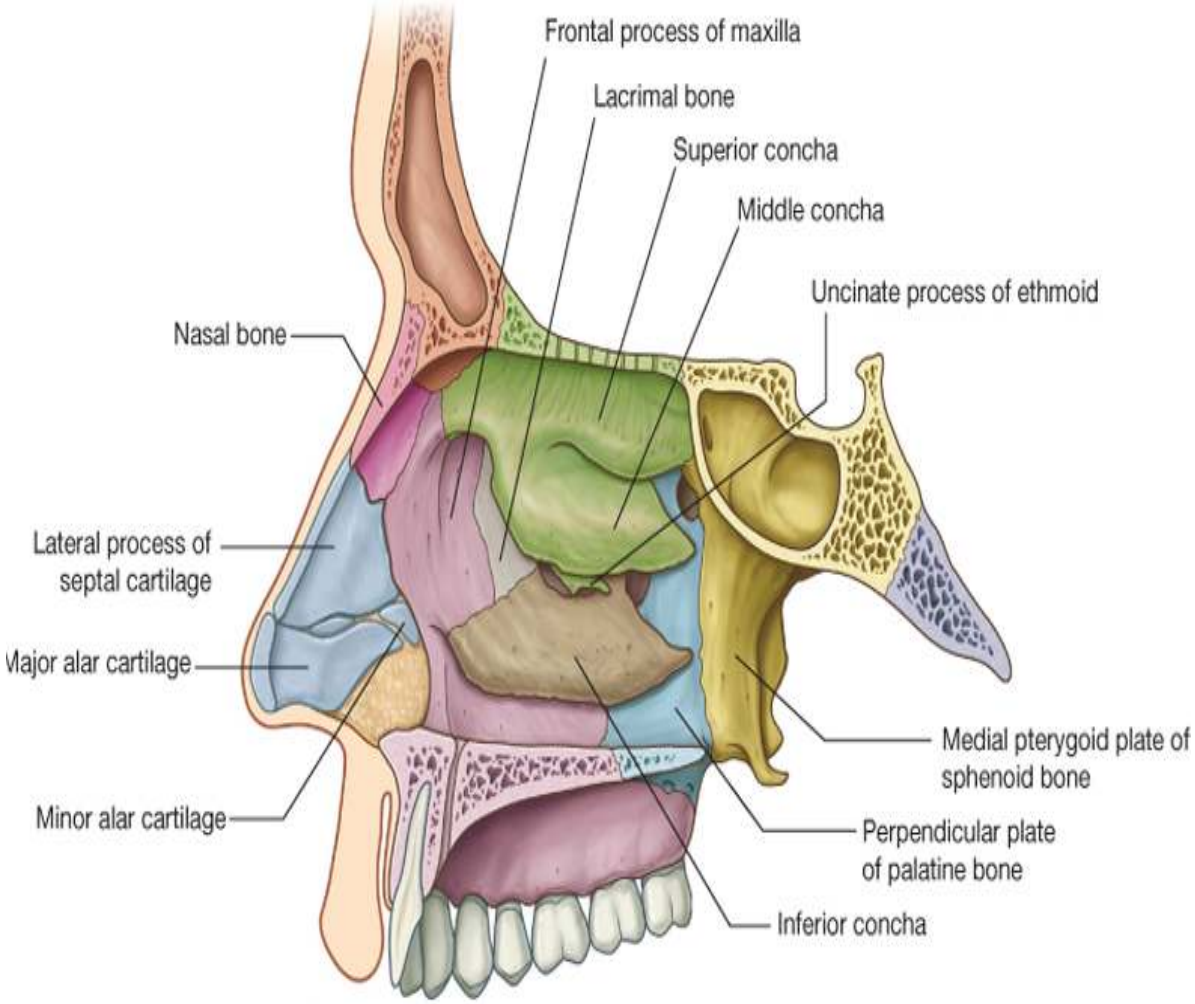


Fig. 3 Sagittal section of the skull showing the bones constituting the lateral nasal wall.

On the lateral wall are the three curved bony shelves called the conchae or the turbinates, one above the other projecting into the lumen, dividing it into four air channels (Fig 4).The middle and the superior conchae are parts of the ethmoidal labyrinth while the inferior concha is a separate bone. The inferior meatus lies between the inferior turbinate and the nasal floor while the middle meatus is between inferior and middle turbinate. Between the middle and superior turbinate is the superior meatus and spheno-ethmoidal recess lies between the superior turbinate and the roof. The inferior meatus has the opening of the nasolacrimal duct while the middle meatus has the opening for the maxillary sinus, anterior ethmoids and the frontal sinus. The turbinates increase the area of contact with the air and have rich blood supply and nerve supply, thereby helping in humidification and regulation of turbulence.

The superior concha is a medial process of the ethmoidal labyrinth above which the sphenoid sinus opens via the triangular sphenoethmoidal recess and below which the posterior ethmoidal sinuses open into the anterior part of the superior meatus via a variable number of apertures. Occasionally there can be a supreme turbinate on the wall of the sphenopalatine recess with a supreme meatus below it and can contain an opening of the posterior ethmoidal sinus.

The inferior meatus is the largest meatus lying along almost the whole length of the lateral wall. It admits the opening of the naso-lacrimal duct, at the junction of anterior one third and middle one third. The inferior turbinate articulates with the nasal surface of the maxilla and the perpendicular plate of the palatine bone.

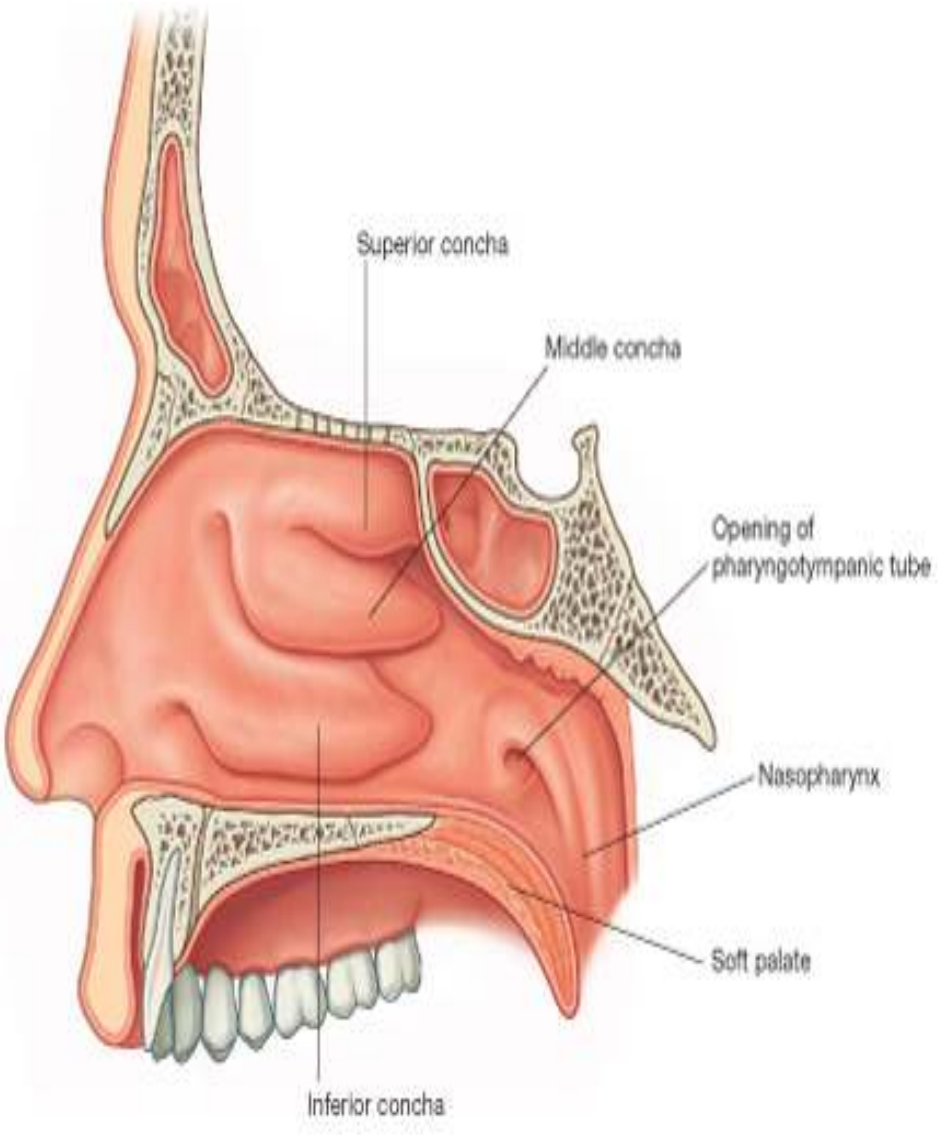


Fig.4 Sagittal section showing the configuration of superior, middle and inferior turbinates on the lateral wall of the nose.

The middle turbinate is also a part of the ethmoidal labyrinth and articulates posteriorly with the perpendicular plate of the palatine bone. Under the turbinate and lateral to it lies the middle meatus which is deeper anteriorly (Fig 5). The anterior end of the middle meatus forms a shallow fossa above the vestibule called the “atrium ‘’ of the middle meatus. Posterior to the middle meatus lies the sphenopalatine foramen which transmits the

sphenopalatine artery and, superior nasal and nasopalatine nerves from the pterygopalatine fossa. The anatomy of the lateral wall, especially that of the middle meatus is of particular significance in endoscopic sinus surgery.

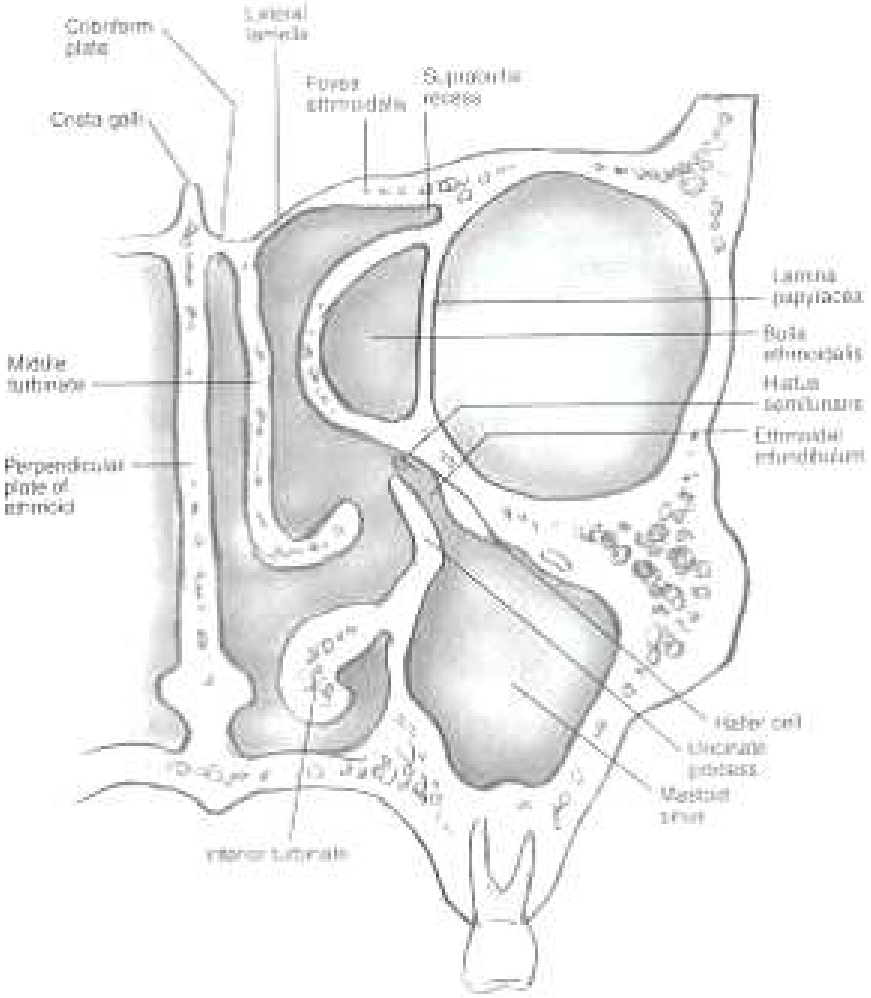


Fig.5 Coronal section showing the middle meatus and the structures within.

Osteomeatal complex (6,7)

The osteomeatal complex or osteomeatal unit (Fig 6) refers to a three dimensional area on the lateral wall of nose in the middle meatus which includes the maxillary sinus ostium, hiatus semilunaris and the ethmoidal infundibulum. It is best appreciated in a view in which the middle turbinate has been removed (Fig. 6). It forms the common pathway for drainage of secretions from the maxillary and the anterior group of ethmoidal sinuses, and, occasionally, the frontal sinus, depending on the insertion of uncinate process. Endoscopic finding of mucopus in this region is diagnostic of sinusitis and hence it is the functionality of this area which is the aim of functional endoscopic sinus surgery.

The rounded projection on the lateral wall in the middle meatus is the most constant and the largest ethmoidal air cell called the bulla ethmoidalis (Fig.6). Anterior to the bulla is the uncinate process, which is a thin sagitally oriented bony leaflet of the ethmoidal labyrinth (Fig7). It is a “boomerang” shaped bone extending from the lacrimal bone to the bulla. Between the free posterior concave margin of the uncinate and the bulla ethmoidalis is a 1 to 2mm wide, two dimensional, sagittally oriented cleft called the hiatus semilunaris (Figs. 6 & 7). The infundibulum is a slit like space extending from the hiatus and leading to the maxillary ostium. It may measure upto 4cm in length, with a height of 12mm and width of 5 to 6mm. Medially it is related to the uncinate process in its entire length while laterally it is related to the lamina papyracea, frontal process of the maxilla, the lacrimal bone and the posterior fontanelle. Posteriorly is the bulla ethmoidalis while the superior relationship largely depends on the attachment of the uncinate process.

The attachment of the middle turbinate to the lateral wall of nose is initially vertical, then oblique and, finally, horizontal. This attachment is best seen on a sagittal section of the skull with the middle turbinate excised (Fig. 6 and 7). This attachment has special significance in that the oblique attachment of the middle turbinate (also known as the ground lamella or

basal lamella) separates the anterior ethmoidal air cells from the posterior group. Posterosuperior to the bulla and anterior to the ground lamella of the middle turbinate is a cleft like space which is known as the lateral sinus or the sinus lateralis of Grunwald. This sinus can extend further upto the frontal recess. The cleft between the posterior wall of the bulla and the ground lamella, connecting the sinus lateralis to the middle meatus is called the hiatus semilunaris superior(10).

ANATOMY OF PARANASAL SINUSES (6)

Four paired paranasal sinuses - the frontal, ethmoidal, maxillary and sphenoid sinuses (Fig 5,6,7) are housed within the bones of nasal framework. Most sinuses are absent at birth and enlarge appreciably during the eruption of the permanent teeth and after puberty. All the sinuses drain into the nasal cavity via small apertures which helps in ventilation of the sinuses as well as clearance of the mucus. They add resonance to the voice and also allow the enlargement of local areas of the skull, sculpturing the facial features, while minimizing a corresponding increase in bony mass.

Frontal Sinus

The paired frontal sinuses lie between the outer and inner tables of the frontal bone below the triangular area on the forehead between the nasion, 3cm above the nasion and junction between the medial 1/3 and lateral 2/3 of the supraorbital margin on either side. The two sinuses are rarely symmetrical, with a septum in between. It is usually absent at birth and reaches full size only after puberty with an average adult dimensions of 2.6 cm x1.8 cm x 3.2 cm. The frontal sinus drains into the anterior part of the middle meatus either as a frontonasal recess (rather than a duct) (50 %) or medial to the hiatus semilunaris if the uncinate process is attached to the lateral nasal wall or an agger nasi cell (50%).

Ethmoidal Sinus

The ethmoid bone is a paired bony scaffold held together with a horizontal plate called the cribriform plate. The ethmoidal sinuses are formed of multiple thin-walled cavities in the ethmoidal labyrinth. The number and size of the cavities varies, from 3 large to 18 small sinuses on each side. They are separated from the orbit by the paper-thin lamina papyracea or orbital plate of the ethmoid and is usually the site of spread of infection to orbit especially in

children as these sinuses are well developed at birth. Pneumatization may extend into the middle concha (30 %), which is known as concha bullosa (Fig 8) or into the body and wings of the sphenoid bone lateral to the sphenoid sinus (Onodi cell) (Fig 9).

The ethmoidal sinuses are divided clinically into anterior and posterior groups on each side, distinguished by their sites of communication with the nasal cavity. The anterior and posterior groups are separated from each other by the basal lamella or the ground lamella of the middle concha (Fig 7).

a.**Anterior Group**

These can be further divided into anterior or peri-infundibular air cells and bullar sinuses or the middle ethmoidal cells .Anterior cells are about 11 in number and drain into either the ethmoidal infundibulum or the frontonasal duct by one or more orifices while the middle group, which are about 3 in number, drain on or above the bulla into the middle meatus. The most anterior group, the agger nasi cells, are related medially to the lacrimal sac and duct. Larger anterior and middle cells, Haller's cells, may develop medially beneath the orbital floor (Fig.10). The most anterior supraorbital ethmoidal sinus cells may encroach on the frontal sinus.

b. Posterior group

These are about 7 in number drain usually by a single orifice into the superior meatus but can also drain into the supreme meatus or into the sphenoid sinus. As they are separated from the anterior group by the basal lamella, each group can get infected independent of the other in patients with sinusitis.

The Maxillary Sinus:

The maxillary sinus (antrum of Highmore) is the largest of the paranasal sinuses and is pyramidal in shape (Fig.8). The base forms much of the lateral wall of the nasal cavity. The floor often lies below the nasal floor and is formed by the alveolar process and part of the palatine process of the maxilla. It is related to the roots of the teeth, especially the second premolar and first molar. The roof of the sinus forms the major part of the floor of the orbit and contains the infraorbital canal which may exhibit dehiscences. The lateral truncated apex of the pyramid extends into the zygomatic process of the maxilla and may reach the zygomatic bone, forming the zygomatic recess.

The facial surface of the maxilla forms its anterior wall and the infratemporal surface of the maxilla forms its posterior wall. The medial wall is deficient posterosuperiorly at the maxillary hiatus, which is a large opening partially closed in an articulated skull by portions of the perpendicular plate of the palatine bone, the uncinate process of the ethmoid bone, the inferior nasal concha, the lacrimal bone and the overlying nasal mucosa. The ostium usually opens into the inferior part of the ethmoidal infundibulum and thence into the middle meatus, via the hiatus semilunaris(Fig 6). It is usually found lateral to the anteroinferior part of the uncinate process. Posterior fontanelle lies posterior to the uncinate, inferoposterior to the hiatus, and frequently has an accessory ostium. All the openings are nearer the roof than the floor of the sinus that the natural drainage of the sinus is very much dependent on the ciliary action.

Sphenoid Sinus

The sphenoid sinuses are two large irregular cavities within the body of the sphenoid and therefore lie posterior to the upper part of the nasal cavity (Fig 6). At birth the sinuses are minute cavities and develop to adult dimensions of vertical height 2 cm; transverse breadth 1.8 cm; anteroposterior depth 2.1 cm by puberty. In 75% of cases the median septum is deviated, dividing the sinuses unequally and each sinus opens into the corresponding sphenoethmoidal recess via an aperture high on the anterior wall of the sinus. Pneumatisation of ethmoids on to the sphenoid bone can give rise to Onodi cell, which is situated postero lateral to the sphenoid sinus (Fig.9). The internal carotid artery, the pterygoid canal, the maxillary branch of the trigeminal and the optic nerve lie in close relation with the sinus and can project into the lumen of the sinus.

Nasal Mucosa (5,6)

The lining of the anterior nasal cavity and the vestibule is by keratinised stratified squamous epithelium. Further posteriorly in the region of limen nasi it changes into non-stratified squamous epithelium and then to respiratory epithelium. Respiratory epithelium lines the rest of the nasal cavity and the paranasal sinuses, except in the region of olfactory cleft where the lining is by the olfactory epithelium.

The respiratory epithelium has pseudo-stratified ciliated columnar cells with numerous seromucinous glands in the lamina propria. The mucosa is thin in the sinuses and in the meati while it is thick and vascular over the conchae. The secretions make the surface sticky and trap the particles in the respired air. The secretions of the nasal mucosa contain lysozyme, beta densin, lactoferrin and immunoglobulin A.

Nerve supply

The nasal cavity and the paranasal sinuses are innervated by branches of olfactory nerve, trigeminal nerve and facial nerve. The olfactory nerve supplies the olfactory receptors while branches of the trigeminal nerve (ophthalmic branch V1 and maxillary branch V2) carry general sensation. Secretomotor fibres are supplied from the facial nerve through the pterygoplalatine ganglion while sympathetic supply is from the superior cervical sympathetic ganglion through the greater pertrosal nerve. Post ganglionic fibres are distributed via the branches of the maxillary nerve.

Blood supply:

The nasal cavity has rich blood supply.

The arterial supply of the nose arises from the external as well as internal carotid arteries. The external carotid artery branches include the sphenopalatine, greater palatine, superior labial, and lateral nasal arteries while the internal carotid branches are the anterior and posterior ethmoidal arteries.

The sphenopalatine artery is the terminal branch of the maxillary artery. It passes into the nasal cavity through the sphenoplatine foramen to divide into the posterior septal branches and posterior lateral nasal branches, supplying the septum and the lateral wall of the nasal cavity posteriorly.

The greater palatine artery is also a branch of the maxillary artery, enters the floor of the nose through the incisive canal to supply the anterior part of the septum and the floor of the nasal cavity.

The superior labial and lateral nasal arteries are branches of the facial artery. Both the anterior and posterior ethmoidal arteries are branches of the ophthalmic artery which inturn arises from the internal carotid artery. Both these vessels pass from the orbit into the nasal

cavity through the bony canals in between the ethmoidal labyrinth and the frontal bone to supply the adjacent paranasal sinuses and areas of the nasal cavity. The anterior ethmoidal artery is of particular importance in functional endoscopic sinus surgery as injury to this vessel can result in retraction of the vessel into the orbit and resultant orbital haematoma.

Veins draining the nose follow the arteries and drain into the maxillary vein, facial vein and via ophthalmic vein into the cavernous sinus. Lymphatic drainage from the anterior region of the nasal cavity is into the submandibular nodes while the posterior part of the nasal cavity as well as the paranasal sinuses drains into the upper deep cervical nodes either directly or via the retropharyngeal nodes. Some drainage from the posterior nasal floor goes to the parotid nodes also.

The Nasal Cycle (8)

The nasal cycle is a well recognised physiological phenomenon characterised by rhythmic alternating side to side fluctuation in nasal blood flow, resulting in phases of congestion and decongestion of the nasal mucosa. It is regulated by the autonomic nervous system and take about 40 minutes to several hours to complete one cycle. The sympathetic response causes vasoconstriction resulting in reduction in nasal airway resistance as well as a reduction in venous outflow from the sphenopalatine vein while the parasympathetic stimulation causes vasodilatation. The nasal cycle is believed to regulate the nasal secretions, the turbulence of the airflow as well as the mucociliary clearance, congested phase having more rapid clearance (9).

The Mucociliary Pathway:(7)

The mucous film in the nose and paranasal sinuses is continuosly moved into the oropharynx by the mucociliary escalator mechanism at the rate of 6mm per minute. The ciliary beat in the sinuses are towards its natural ostium (Fig.11) with a frequency of about 8 to 20 beats per second. Any obstruction at the sinus ostium causes retention of secretions, secondary infection and inflammation leading to further ciliary dysfunction and the vicious cycle sets in leading to chronic rhino sinusitis.

Drainage and ventilation of the sinuses is very important to maintain the normal physiology of the paranasal sinuses. Normal drainage of the sinuses is a complex function of both the secretion and the transport mechanism. It further depends on the amount of mucus produced, its composition, the effectiveness of the ciliary beat, mucosal resorption and the condition of the ostia through which it drains.

In health, there is a mucosal blanket which covers the nasal mucosa which has two layers – the inner serous layer called *the sol phase* and an outer more viscous layer called *the gel phase*. A proper balance is maintained between the gel phase and the sol phase at a pH of 7.5 to 7.6.The gel phase is transported over the sol phase as a mucosal carpet. Normally the secretions cover the mucosa of the sinuses homogenously, except at the ostia where the viscous layer appears to be thicker.

Movements of the nasal mucosa especially those of the fontanelles, the negative suction pressure created inside the sinues due to the flow of the inspired air, synchronized ciliary beat and the well balanced parasympathetic neuromediator secretions help in maintaining a smooth mucosal transport. It is not affected by the presence of small mucosal defects, bony crests, small mucosal lesions or by accessory ostia less than 4 mm diameter.

Normal ventilation, humidification, metabolism, osmotic pressure, pH and absence of any noxious stimuli are important for the optimal functioning of the mucociliary system.

CHRONIC RHINOSINUSITIS

Chronic rhino sinusitis (CRS) is a well-recognised clinical syndrome affecting patients of all ages and gender(1). It is a major health problem with significant impact on the quality of life, productivity and finances(3). There is a wide geographical variation in the prevalence of chronic rhino sinusitis ranging from 1.01% to 16% (2,4).

As per the European Position Paper on Rhinosinusitis and Nasal Polyps 2012 guidelines (5), chronic rhino sinusitis is characterized by inflammation of the mucous membranes of the nasal cavity and the paranasal sinuses, with typical symptoms that persist for more than 12 weeks, and objective criteria using nasal endoscopic findings with or without CT scan findings.

The diagnostic criteria for CRS in adults as per EPOS 2012 guidelines (5) can be summarized in table no. 1

Table.1 The EPOS 2012 guidelines for diagnosis of adult chronic rhino sinusitis summarized:

More than or atleast 2 symptoms of	**With / without**	**With Either Endoscopic findings of**	**Or CT scan findings of**
Nasal blockage	Facial pain or pressure	Nasal polyps	Mucosal changes within the OMC
Obstruction	Reduction / loss of smell	+/- mucopurulent discharge in middle meatus	+/- mucosal changes in the sinuses

Congestion		+/- mucosal obstruction or edema in middle meatus	
Anterior or posterior nasal discharge			

Chronic rhino sinusitis(CRS) can be broadly classified as chronic rhino-sinusitis with nasal polyps (CRSwNP) and without nasal polyps (CRSsNP) based on the endoscopic findings. Sinusitis without polyposis has more fibrosis, high levels of TGF and increased Treg activity (11,12).

The incidence of both subtypes of sinusitis is believed to increase with age, with a peak incidence in the age group of 50-59 years (13). The average age of onset of nasal polyps is around 42 years (14,15), and is more common in men than women (16).

Aetiopathogenesis of sinusitis:

The fundamental principle in the development of CRSsNP is the obstruction in the drainage pathways of the sinuses resulting in stasis of secretions while in CRSwNP there is diffuse mucosal response (17).

The osteomeatal complex obstruction may be anatomical, physiological or a combination of both. It leads to cessation of normal sinus drainage patterns and stagnation of secretions. The gas exchange becomes impaired, favouring the growth of anaerobic bacteria and promoting infection. Inflammation further worsens the ciliary dysfunction, leading to further stasis of secretions and thickening of the mucous membrane in the sinuses. This leads to repeated or chronic sino-nasal infection.

The aetio-pathogenesis of chronic rhino sinusitis is believed to be multifactorial (18). Etiological factors described include ciliary dysfunction, allergy, asthma, aspirin sensitivity,

immune status, genetic factors, iatrogenic factors, gastric reflux, local host factors, pregnancy and endocrine state, commensal flora, biofilms, pathogens and its characteristics and environmental factors (19).

There are several hypothesis proposed regarding the pathogenesis of sinusitis. The first hypothesis proposed was 'fungal hypothesis' which explained sinusitis as due to excessive host response to Alternaria fungi (20). Other proposed hypotheses include the immune barrier hypothesis, defects in the eicosanoid pathway, the staphylococcal super antigen hypothesis and genetic model in cystic fibrosis (11,21,22,24). Whatever be the mechanism, there is dysregulation of the local innate host defense mechanism leading to microbial colonization and site specific immunoglobulin production. Inappropriate or excessive immune response results in persistent mucosal inflammation, cellular influx, radiographic changes and clinical disease.

Diagnosis of chronic rhino sinusitis

Diagnosis of CRS in a primary care set up is mostly based on the symptomatology while a specialist relies on nasal endoscopy and radiological findings in addition. Additional tests like blood investigations and bacteriological cultures might help in defining the aetiopathogenesis.

The symptoms in sinusitis with or without polyps are mostly the same, but the pattern and intensity may vary. The most common symptom reported is nasal obstruction (84-92%) followed by post nasal drip (82- 87%) (25,26).

Assessment of symptoms and symptom severity:

The overall severity of symptoms in CRS can be recorded either by using visual analogue scale (VAS) or by using a validated symptom based health related quality of life (HRQOL) questionnaire. The visual analogue score is based on the severity of symptoms and is graded as mild, moderate, and severe. While the symptoms of sinusitis are well known, the disease

also affects several other aspects of the patient's life which are often not documented by the physician. Several studies have noted that the overall well –being of a patient should look at the quality of life changes that the disease produces. Chronic diseases often affect the social and emotional aspects of a patient's life. It is important, therefore, to assess these domains as well when reporting on the degree of the problem in a disease state as well as the response to treatment. The tools used to assess QOL in sinusitis should be validated and designed for a particular age group and to assess specific domains. There are several validated tools available currently for evaluation of chronic rhino sinusitis in the adult population. One of the most commonly used QOL instrument is the Sino Nasal Outcome Test (SNOT). Based on the number of questions asked, this questionnaire is available in 3 versions (SNOT 22,SNOT 20 and SNOT 16). Other QOL instruments include Rhinosinusitis Outcome Measure (RSOM-31), Rhinosinusitis Disability Index (RSDI), Rhino QOL, Chronic Sinusitis Survey (CSS) and Sino-Nasal Assessment Questionnaire (SNAQ-11)(18, 27-32).The various features and domains covered by the various QOL instruments are summarized in Table.2.

Table.2 QOL instruments used in adult chronic rhino sinusitis: a summary (EPOS 2012)

QOL instrument	Number of Questions	Domains covered	Completion time	Translations
RSOM-31	31	7	20min	Nil
SNOT 16	16	2	5 min	French
SNOT 20	20	3	5-10 min	Japanese,Chinese, Portuguese
SNOT 22	22	3	5-10 min	Danish, Czech, Swedish, Chinese

Rhino QOL	17	3	5-10 min	French
CSS	6	2	5 min	Norwegian Chinese
RSDI	20	1	5 min	Turkish
SNAQ-11	11	1	5 min	Nil

Sino nasal outcome test (SNOT22) is a validated, visual analogue scoring based questionnaire which was initially based on 16 criteria (SNOT 16) and later modified to SNOT 20 and, further, to SNOT 22 by adding two more items on smell disturbances and nasal obstruction(32). The SNOT 22 questionnaire (Table.3) covers various domains like the nasal symptoms, non- nasal symptoms (facial and ear symptoms), psychosocial aspects and sleep functions. The questionnaire has 22 symptoms, assessed in the order of increasing severity, each symptom graded 1 to 5, with a maximum score of 110.In a study done by Hopkins et al, it was established that a SNOT22 score of more than 7 may be an indication of sinusitis (23). This QOL instrument is a cross culturally adapted tool, with versions in other languages (33,34,35) and had been applied to study various surgeries on nose like septoplasty (36) and endoscopic surgery for sinusitis (37).

Table 3: SNOT 22 questionnaire

Below you will find a list of symptoms and social/emotional problems which affect patients with rhinosinusitis. We would like to know more about these problems and we would appreciate if you could answer the following questions about your symptoms. There is no right or wrong answer, and only you can provide us with this information. Please consider your problems in the past two weeks. Thank you for your participation. Should you have any doubt in filling out the questionnaire, please ask the physician for help.

Considering the severity of the problems, classify symptom intensity by circulating the corresponding number in the scale →	No problem	Very mild problem	Mild problem	Moderate problem	Severe problem	Worst possible problem
1. Need to "blow" your nose	0	1	2	3	4	5
2. Sneezes	0	1	2	3	4	5
3. "Running" nose	0	1	2	3	4	5
4. Cough	0	1	2	3	4	5
5. Nasal secretion going to your throat	0	1	2	3	4	5
6. Thick secretion from your nose	0	1	2	3	4	5
7. A feeling of full or stuffed ear	0	1	2	3	4	5
8. Dizziness or vertigo	0	1	2	3	4	5
9. Ear ache	0	1	2	3	4	5
10. Facial pain or pressure	0	1	2	3	4	5
11. Difficulty to sleep	0	1	2	3	4	5
12. Wake up in the middle of the night	0	1	2	3	4	5
13. Lack of a good night of sleep	0	1	2	3	4	5
14. Wake up tired	0	1	2	3	4	5
15. Fatigued or tired during the day	0	1	2	3	4	5
16. Low performance in doing your daily activities	0	1	2	3	4	5
17. Low concentration to do your daily activities	0	1	2	3	4	5
18. Frustrated, restless or irritated	0	1	2	3	4	5
19. Sadness	0	1	2	3	4	5
20. A feeling of shame	0	1	2	3	4	5
21. Difficulty to feel "smells" or "tastes"	0	1	2	3	4	5
22. Stuffed nose	0	1	2	3	4	5

TOTAL_____

Nasal Endoscopy

With the advent of endoscopes, nasal endoscopy has become a part of the routine examination of the nasal cavity. It serves as an objective, diagnostic tool in the evaluation of nasal mucosa, sinonasal anatomy and nasal pathology (Fig.12.a). Finding of mucopus in the middle meatus is diagnostic of sinusitis (Fig 12.b). The presence of nasal polyps and its characteristics can also be identified on endoscopy (Fig 12.c).

a) Procedure of diagnostic nasal endoscopy: (7)

After explaining the procedure and obtaining consent, the nasal mucosa is sprayed with a mixture of topical anesthetic and mild vasoconstrictor in equal parts. Alternatively, one can use a nasal pack with 4% lignocaine and xylometazoline which is left in the nose for about 2 to 5 minutes. The patient is made to lie supine with the head turned to the right, facing the examiner. A 4 mm 30^0 endoscope is used to examine the nasal cavity. The patient may also sit facing the examiner who is also seated. Classically, 3 "passes" are described. In the first pass, the endoscope is advanced along the floor inspecting the nasal vestibule, the inferior nasal meatus and the nasal cavity. In the second pass the scope is passed medial to the middle turbinate to examine the spheno-ethmoidal recess and the superior meatus. In the third pass, the scope is withdrawn and reintroduced into the middle meatus examining the structures within. The endoscope is held between the thumb and forefinger on the left hand, which rests lightly on the cheek and the nasal bridge. Care has to be taken not to injure the mucosa at any point of the examination.

b) Endoscopic scoring system

Many endoscopic scoring systems have been developed to record the endoscopic findings in a universally accepted way. The Lund –Kennedy endoscopic scoring system (LKES), the Kupferberg scoring system and the perioperative sinus endoscopic score (POSE) are the three well accepted scoring systems.

The Lund-Kennedy endoscopic scoring system (Table 4) is a widely accepted endoscopic scoring system which quantifies the pathologic states of the nose and paranasal sinuses. The scoring system is focused on the presence of polyps, discharge, edema, scarring, or adhesions and crusting. The scores range from 0 to 20 (38). Polyps are graded as absent (0), present in the middle meatus (1), or present beyond the middle meatus (2). Discharge is graded as not present (0), thin (1), or thick and purulent (2).Edema, Scarring, adhesions and crusting are used in postoperative assessment, each graded as absent (0), mild (1), or severe (2).

Table 4: Lund Kennedy Endoscopic Scoring summarized

Right/Left	Score 0	Score 1	Score 2
Polyps	absent	In the middle meatus	Beyond the MM
Discharge	absent	Thin	Thick / purulent
Edema	absent	mild	Blocking the OMC
Scarring	absent	mild	severe
Crusting	absent	mild	severe
Synechiae	absent	mild	severe

Endoscopic staging is performed bilaterally and typically takes place during the initial evaluation, preoperatively, and postoperatively at regular intervals. Kuhn emphasize that adding nasal endoscopy to the care of patients with CRS results in improved diagnostic accuracy (40). In combination with established symptom criteria, endoscopic findings

improve the specificity, positive predictive value and negative predictive value of assessment for chronic rhino sinusitis (41). This development suggests that the use of diagnostic endoscopy may help decrease the need for computed tomography (CT) and reduce costs and radiation exposure.

The Kupferberg postoperative scoring system described for allergic fungal rhino sinusitis (AFRS) has 4 stages (0-3) based on the `global` appearance of one side of the nose and is summarized in Table 5.

Table 5: Kupferberg postoperative endoscopic staging for allergic fungal sinusitis

Stage	Endoscopic finding
Stage 0	No mucosal edema or allergic mucin
Stage 1	Mucosal edema with or without allergic mucin
Stage 2	Polypoid edema with or without allergic mucin
Stage 3	Sinus polyps with fungal debris or allergic mucin

Imaging in sinusitis

The plain x-ray of the sinuses has limited usefulness for the diagnosis of chronic rhino sinusitis as compared with the CT scan. The negative predictive value of CT scan is high in sinusitis. However, in the absence of symptoms, diagnosis of CRS based on radiology alone is inappropriate, as incidental abnormalities are seen in up to a fifth of the normal population (43). The Lund Mackay system is a widely accepted, validated staging system based on CT scan findings (Fig 13). The maximum score is 12 per side and is summarized in table no: 6. Most of the studies have shown the mean Lund Mackay score in patients with CRSwNP is significantly higher than in those with CRSsNP (39)

Table: 6 The Lund Mackay Staging system for sinusitis based on CT scan findings

Sinus	Score = 0	Score= 1	Score=2
Maxillary sinus	Normal	Partial opacification	Total opacification
Anterior Ethmoids	Normal	Partial opacification	Total opacification
Posterior Ethmoids	Normal	Partial opacification	Total opacification
Sphenoid sinus	Normal	Partial opacification	Total opacification
Frontal sinus	Normal	Partial opacification	Total opacification
Osteo-meatal complex	Not occluded	_	Occluded

Management of Chronic Rhino sinusitis

The management of CRS varies with the underlying etiology as well as with the presence of sinonasal polyposis. There are few controlled studies that have looked at specific modalities of management.

Severity of CRS

The EPOS 2012 guidelines have graded the severity of CRS based on visual analogue scale scores. A VAS score of 0-3 is considered as mild disease, while 3 – 7 is moderate and 7-10 is a severe disease. The following are the guidelines for treatment of CRS as per EPOS 12 guidelines.

a) CRSsNP. In CRS without polyposis, mild disease is treated with topical cortical steroids and nasal lavage. If the treatment fails at 3 months, the disease is treated as moderate / severe disease. Moderate / severe disease is treated with topical steroids / nasal lavage / and long term (4 weeks) of macrolide therapy or as per culture and sensitivity.

   Medical management of chronic sinusitis without polyposis in our practice does not follow all of the EPOS guidelines. Patients are administered at least 2 weeks of antibiotics, decongestants and saline drops and reviewed. If they have undergone at least 3 courses of antibiotic therapy and have significant symptoms with persistent endoscopic and radiological findings, they are recommended to undergo functional endoscopic sinus surgery.

b) In CRSwNP, mild and moderate disease are managed initially with topical corticosteroid sprays and reassessed at 3 months. If there is no improvement of symptoms, a short course of oral steroids can be added for 1 month. If the patient

continues to be symptomatic a surgical intervention can be considered. Severe disease warrants use of oral as well as topical corticosteroid for 1 month and if no improvement is noted, surgical intervention has to be considered. The medical management of CRS with polyposis is similar in our practice. However, we prefer to operate on these patients earlier rather than after a month long course of oral steroid in order to avoid missing coincident pathology (like fungal sinusitis or inverting papilloma) as well as to reduce costs for the patient.

Surgery in chronic rhino sinusitis

Historically established surgical techniques for the management of chronic rhino sinusitis include antral lavage, Caldwell Luc procedure, intranasal polypectomy, external or transantral ethmoidectomy or spheno-ethmoidectomy and external frontal sinus surgery depending on the sinuses involved. However, with the advancement of endoscopic surgical procedures over the past two decades, the surgical management of sinusitis has completely changed.

FUNCTIONAL ENDOSCOPIC SINUS SURGERY

Functional endoscopic sinus surgery (FESS) is a minimally invasive surgical technique in which the sinus ostia are opened under direct visualization, preserving as much as nasal mucosa as possible, with an aim to restore sinus ventilation and normal function.

a. Techniques of FESS

FESS can be performed either under general anesthesia or under local anesthesia, depending on the extent of the disease and the patient factors. The patient is positioned supine with the head turned to the right and a 15 degree tilt to the table in reverse Trendelenberg position. The surgeon stands on the right side of the patient facing the head, with the monitor in front. The endoscope is held in the left hand while the instruments are held on the right.

Traditionally, two techniques had been described in FESS – The Messerklinger technique and The Wigand technique. The Messerklinger technique addresses the sinuses from anterior to posterior while the Wigand technique is a posterior to anterior approach. However, it is believed that the complications and outcome depend more on the patient factors than the surgical technique. The National comparative audit reports perioperative bleeding as the most common complication. This study has reported major complications as 0.4% and minor complication as 6.6% (53).

Modification to the surgical instruments, better optics, advances in imaging and newer armamentarium like microdebrider have all added to better outcomes in endoscopic surgery in experienced hands.

b. Postoperative management following FESS

Following the surgery, the nasal cavity is packed either with BIPP or dehydrated gelatin sponge. The packing is removed on the following day and the patient is taught to periodically

wash and flush the nasal cavity with saline. Weekly endoscopic guided cleaning is performed in the outpatient clinics, to remove the debris and clean the cavities, till the surgeon is satisfied with the healing (Fig.14 a,b)

The patients are advised further follow up and medications depending on the etiology and extent of the disease.

c. Outcomes following FESS

FESS has now become a well established surgical modality in the treatment of sinusitis refractory to medical treatment. However, there is a conspicuous lack of good surgical evidence on the efficacy of this intervention comparing it to the various other modalities as it is difficult to standardize the surgery and to randomize and conduct blinded studies.

In the literature, there are several systematic reviews which have looked at the functional outcome of sinus surgery in children as well as adults (44, 45). However, most of these are of low evidence levels due to the difficulty in obtaining homogenous sample groups and the issues in randomization and standardization of the techniques.

Terris and Davidson conducted a meta-analysis, assessing the outcome of endoscopic sinus surgery, with a total of 1,713 patients, and found some subjective improvement in the symptoms in 91% of patients. They reported bleeding as the most common complication (1.5%) and the rate of revision surgery was 12%(57). In their prospective study on endoscopic sinus surgery in patients with chronic sinusitis with and without polyposis, Timothy et al assessed the outcome of endoscopic sinus surgery both subjectively and objectively by using the QOL instruments RSDI and CSS along with CT scan scoring and endoscopic scoring of the disease. The mean follow up was 1.4 years and they found significant improvement in QOL scores as well as in the endoscopic scores, following FESS, irrespective of the presence of polyps. Even patients who underwent revision FESS had

significant improvement in QOL scores though the endoscopic scores were comparatively worse(56).

Another prospective study by Tyson et al reported patients with polyps as having poorer outcome following FESS in comparison with those without polyps. They had included 201 patients in their study, of which 78 had polyps and 123 had no polyps. Pre operative and post operative QOL scores were obtained using SNOT 20 questionnaire and patients were followed up for a minimum of 1 year. The mean preoperative score in those with polyps was 32.2 with an improvement to 9.1 at 12 months follow up. The mean SNOT 20 score in those without polyps was 26.5 preoperatively which improved to 5 at 12 months postoperatively. Nine patients had required revision surgery of which 8 had polyps(54). In the National comparative audit of surgery using SNOT 22 score, on patients undergoing surgery for chronic sinusitis, Hopkins et al found that sinonasal surgery is safe and effective in reducing nasal symptoms over a 5 year period (37). Post operatively, patients reported a 14 point improvement over the base line score. Polyp patients reported a better SNOT 22 score at 5 years (mean 26.2,SD 21.6) than with CRS alone (mean :33.3 SD 23.7). The rate of revision surgery was 3.7% at the end of 1 year, and was higher in the group of sinusitis with polyps as compared to without polyps.

In a prospective study with 3 year follow up, Giger et al reported subjective satisfaction in 92% of the patients who underwent FESS in sinusitis without polyposis(58). The endoscopic scoring also had correlated well with the subjective outcome scores.

In another study by Khalid et al using SF-36 in post FESS patients with a follow up of 3 years, it was found that FESS resulted in significant improvement in quality of life(49).

Mace et al correlated endoscopic findings with the Rhino sinusitis Disability Index in patients with sinusitis and concluded that there was a statistically significant improvement in health related QOL as well as endoscopy scores after endoscopic sinus surgery in sinusitis. Also, the

changes in QOL were reflected on endoscopy (42).In their prospective study of patients undergoing FESS for chronic sinusitis, Chopra et al found that 82 % of the patients improved postoperatively (47).

The Cochrane review 2006, later updated in 2009 assesses FESS as a safe surgical procedure but could not demonstrate any additional benefit to that obtained by medical treatment in chronic rhino sinusitis (46).

As there is evidence that chronic rhinosinusitis with and without polyps are distinct subgroups of inflammatory disease of the upper airway, many studies had been conducted separately for these two groups. A systematic review by Dalziel et al compared outcome of FESS for nasal polyps with other procedures like Caldwell-Luc, intranasal ethmoidectomy and polypectomy(51). They reported a symptomatic improvement of 78-88 % following FESS as against 43-84% in other procedures. The recurrence rate was 8% in FESS and 28% in endoscopic ethmoidectomy, 14% for Caldwell-Luc and 35% for polypectomy. The rate of complication was 1.4% for FESS and 0.8% for conventional procedures(51).). In their systematic review comparing FESS to conventional techniques, Lund et al reported success rates ranging from 70% to 90%, while the complication rates were below 1%. The rate of revision surgery was 7 to 10 %(45)

The effects of primary and revision FESS were compared by Lee et al(52). The authors found significant improvement in SNOT 20 scores and endoscopic score in both the groups at the end of 12 months follow up. There was, however, no statistically significant difference.

Despite the widespread use of FESS techniques in ENT practice, we did not encounter many studies among Indian patients where a QOL instrument was used to determine benefit from sinus surgery. By using both the SNOT 22 questionnaire and the Lund Kennedy endoscopic scoring system, we have subjectively and objectively assessed the patients with CRS, to note

if the surgery was beneficial or not and whether symptom relief was greater for some symptoms compared to the others.

Materials and Methods

a) Study design

This prospective observational study was conducted in the Department of ENT at Christian Medical College Vellore, between July 2011 and August 2012.

b) Subjects

All patients aged 18 years and above who were diagnosed with chronic sinusitis with or without sinonasal polyposis, scheduled to undergo functional endoscopic sinus surgery, were included in the study.

c) Inclusion criteria

All patients who were 18 and above and had met the criteria of chronic sinusitis as per EP3OS 2007 guidelines.

d) Exclusion criteria

The exclusion criteria were as follows:

Age below 18 years

Septal deviation without sinusitis

Invasive fungal disease

Complications of sinusitis

Associated malignancy

Specific infections like TB and rhinosporodiosis

e) Informed consent

For all patients an informed consent was taken before including them in the study, after providing relevant details about the study in their language. The consent form and the patient information sheet are attached as Appendix A.

f) Sample size

Sample size for this study was calculated using the following formula

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 * 2 * PQ}{(p_1 - p_2)^2}$$

Where,

n = sample size

p_1 = mean SNOT 22 score preoperatively

p_2 = mean SNOT 22 score postoperatively

P = $(p_1 + p_2) / 2$

Q = 1 – P

Alfa = 5%

Beta = 80%

Using the data from The National Comparative Audit of Surgery for Nasal Polyposis and Chronic Rhinosinusitis (Ref), the average preoperative SNOT 22 score was taken as 41.5(SD 20.2) and post operative score was taken as 25.3 (SD 20.8) at 3 months post op and 28.5 (SD 22.7) at 1 year postop. Based on this, the sample size needed was at least 22 at the end of 1 year. Since we estimated that we may have only 20% follow up at the end of 1 st year, we calculated a sample size of 90, considering a 9 point improvement in SNOT 22 score postoperatively.

g) Method

After obtaining consent and a brief history, patients were asked to fill the SNOT 22 questionnaire themselves. Assistance was provided on demand.

Preoperatively rigid nasal endoscopy using a 4mm rigid scope was performed to assess the nasal cavity and Lund Kennedy scoring done.

Post operatively during the follow up visit at 3- 6 months, they were approached for filling the SNOT 22 questionnaire in the same manner along with a repeat office endoscopy. Postoperative scoring was done with the Lund Kennedy scoring system.

h) Statistical analysis

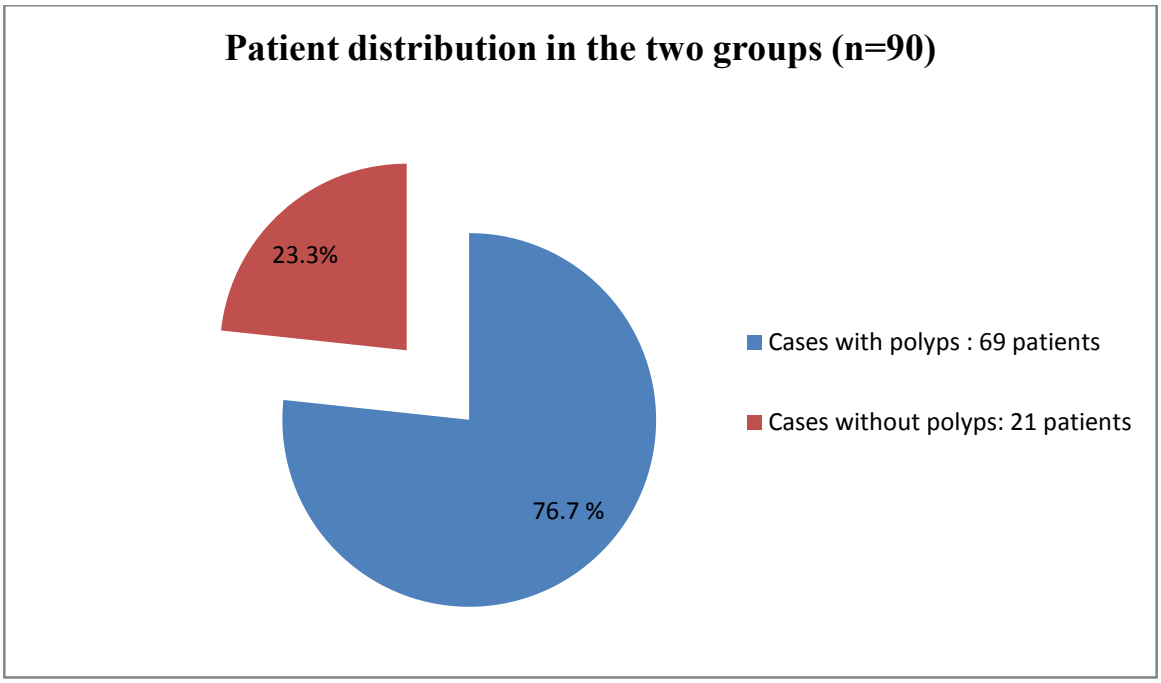
The patient details were entered in the MS excel sheet and analyzed. Descriptive data was analysed using frequency distribution for all the variables assessed. Descriptive data was analysed using frequency distribution. The data was analyzed in separate groups of chronic sinusitis with nasal polyps and chronic sinusitis without polyposis using SPSS tool. Pearson Chi-square test and Fisher's exact test was used for categorical data to check the association between preop and post operative scores.

The change in SNOT 22 score and comparison with the endoscopic scoring was done using independent and paired t test.

RESULTS

A total of 90 patients with chronic sinusitis were included in the study. Sinonasal polyposis was present in 69 patients (76.7%) and absent in 21 patients (23.3%).

Fig.15 Patient distribution in two groups of chronic rhino sinusitis



a) Age distribution

The ages of the patients ranged from 18 to 70 years with a mean of 41.17 (S.D = 14.8) years.

The age distribution of the study population is summarised in the following table:

Table 7: Age distribution of patients included in the study

Age group	Number of patients (%)
< 20 years	11(12.2%)
20-30 years	12 (13.3%)
30-40 years	20(22.2%)
40-50 years	21(23.3%)
50-60 years	23(25.5%)
➢ 60 years	3 (3.3%)
Total	90 (100 %)

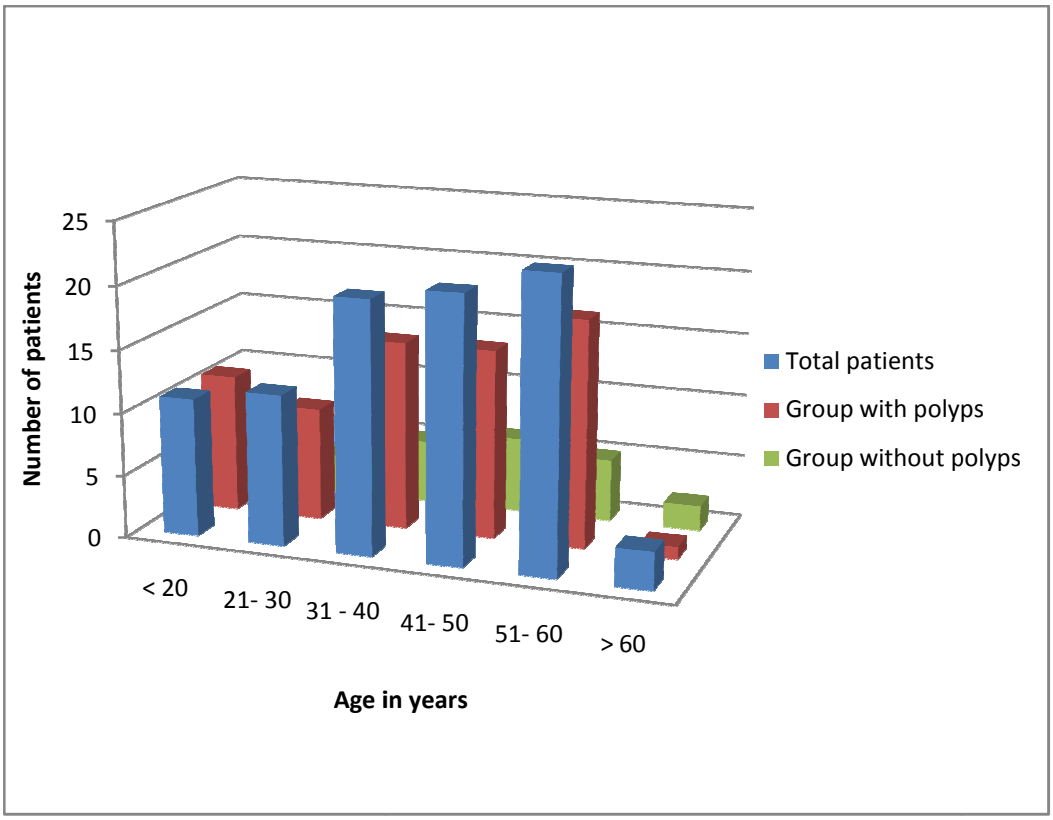
In the group of patients with polyps, the age ranged between 18- 70 years (mean 39.58 years) while in those without polyps the age range was between 25 to 70 years (mean of 46.38 years). This is well illustrated in Table 8 and Fig. 16.

Table 8: Age distribution of patients in patients with polyps and without polyps

Age (years)	Number of patients with polyps (%)	Number of patients without polyps(%)
< 20	11 (15.9%)	0
20-30	9 (13%)	3(14%)
30-40	15(21.7%)	5(24%)
40-50	15(21.7%)	6(28.5%)
50-60	18(26%)	5(24%)
>60	1(1.7%	2 (9.5%)
Total patients	69	21

It was observed from the data that patients with polyps were relatively younger than those without polyps. However, it was not statistically significant (p value .357). The prevalence of sinonasal polyps was greatest in the 5th decade. This is also illustrated in the figure below.

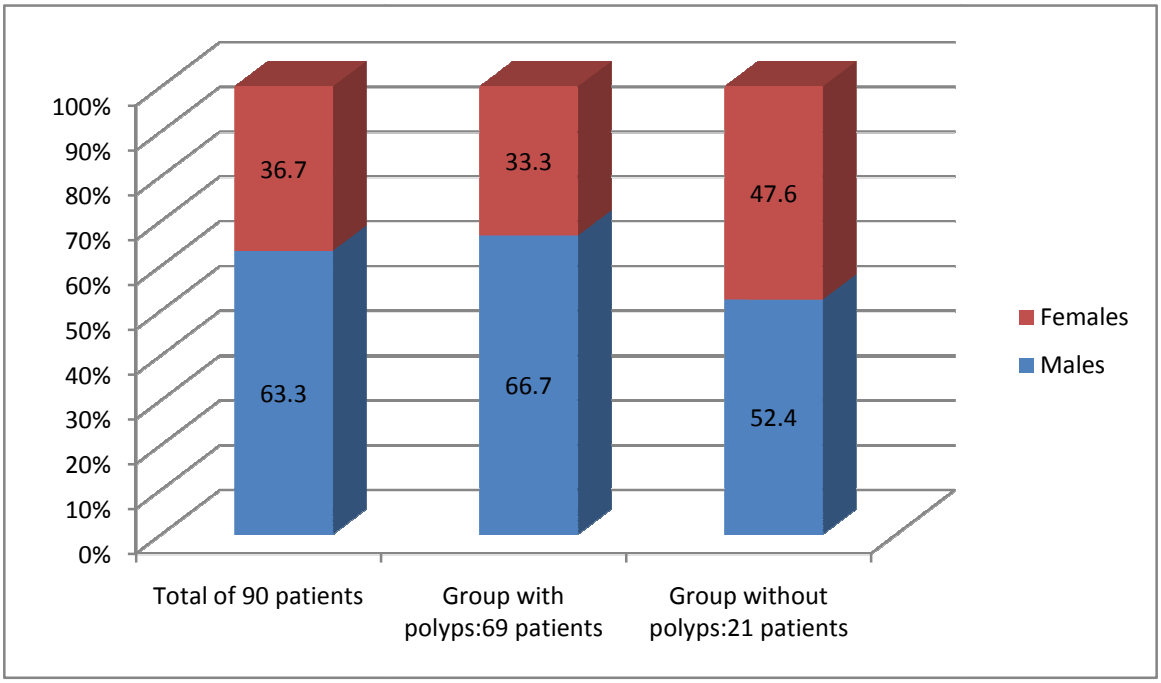
Fig 16 Comparative age distribution in both the groups of patients



b) Sex distribution (Fig. 17):

Out of 90 patients, 57 (63.3%) were male and 33 (36.7%) were female.

Fig 17 Sex distribution in both the groups of patients



In the group with polyps, there were 46 males (66.7 %) and 23 females (33.3%) while in the group without polyps, there were 11 males (52.4%) and 10 females (47.6%).Figure 17 illustrates the difference in sex distribution between the two groups. It is evident from the data that all the groups had more male than female patients.

c) Duration of complaints

The duration of complaints ranged from 2 weeks to 120 weeks with a mean of 34 weeks (S.D. =29.46). In the group with polyps, the average duration of the complaints was 33.7weeks (2 weeks to 120 weeks); while in the group without polyps the mean was 35.9 weeks (3 weeks to 80 weeks).

d) Presence of co morbidities

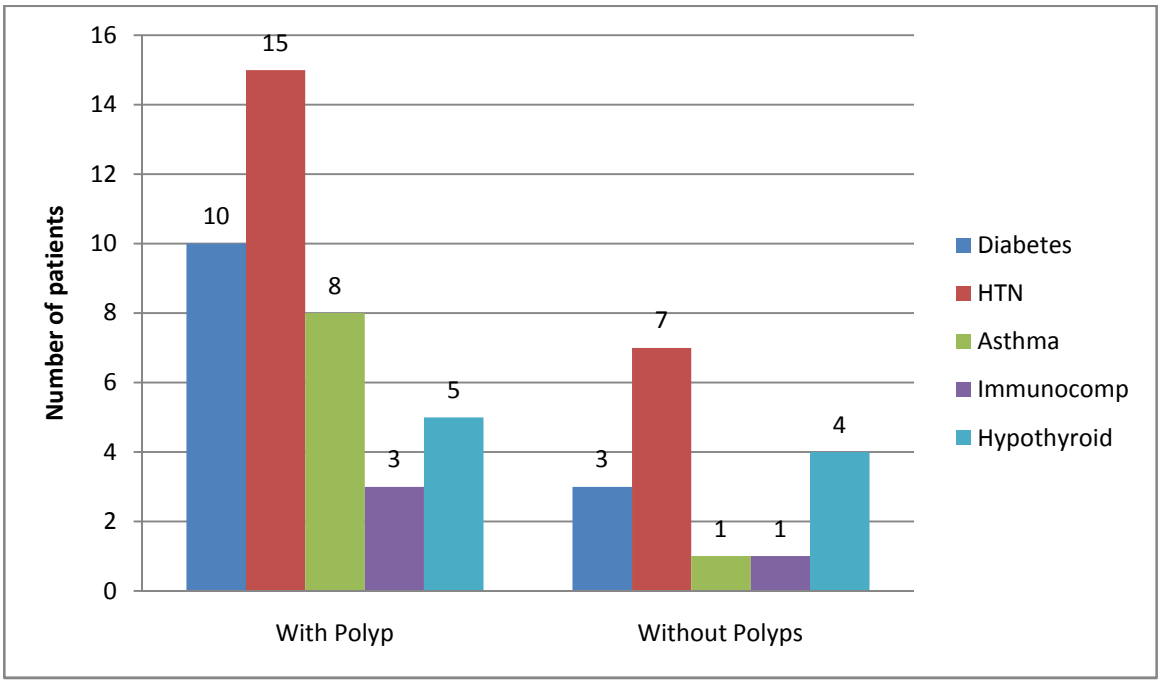
A total of 46(51%) patients had a co morbid illness while 11 of them had two co morbid illnesses. Hypertension (24.4%) was the most common co morbid illness. Out of 22 patients with hypertension, 15(68%) of them had polyps. The second commonest co morbidity was diabetes mellitus. The disease was present in 13 (14.4%) patients. Nine patients (10%) had bronchial asthma, out of which 8 of them had nasal polyps. It is observed from the data that co morbidities like diabetes mellitus, bronchial asthma and hypertension are more common in those patients with polyps. The co morbidities and its distribution in both the groups are summarized in Table 9.

Table 9: Pattern of distribution of co morbid illnesses

	Total number of patients (%)	Number with polyps (%)	Number without polyps (%)
Diabetes	13(14.4)	10(14.5)	3(14.3)
Hypertension	22(24.4)	15(21.7)	7(33.3)
Asthma	9 (10)	8(11.6)	1(4.8)
Immunocompromise	4 (4.4)	3(4.3)	1(4.8)
Hypothyroid	9 (10)	5(7.2)	4(19)
Total	57	41	16

The distribution of co morbidities is also illustrated in the figure below:

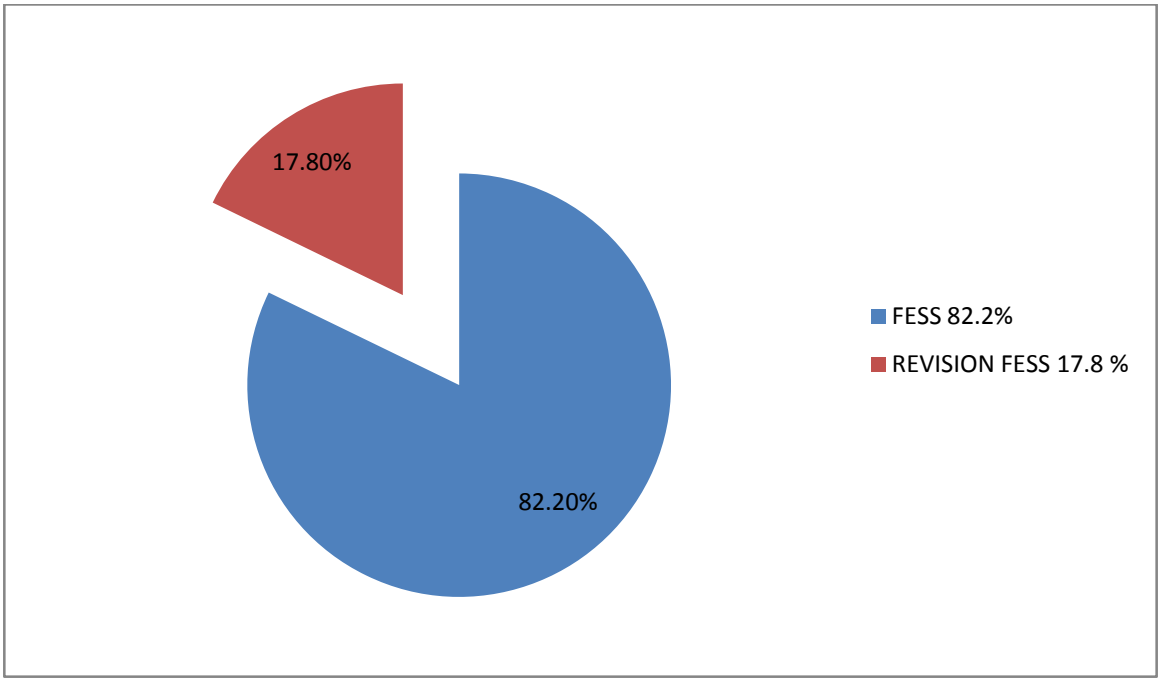
Fig 18.Distribution pattern of co morbid Illnesses in patients with and without polyps



e) Primary versus revision surgery (Fig. 19)

A total of 74 patients (82.2%) had FESS while 16 patients (17.8%) had revision FESS. Fourteen out of 16 (87.5%) patients who had revision FESS had polyposis. Clearly, patient with sinonasal polyposis had recurrent disease compared to those without.

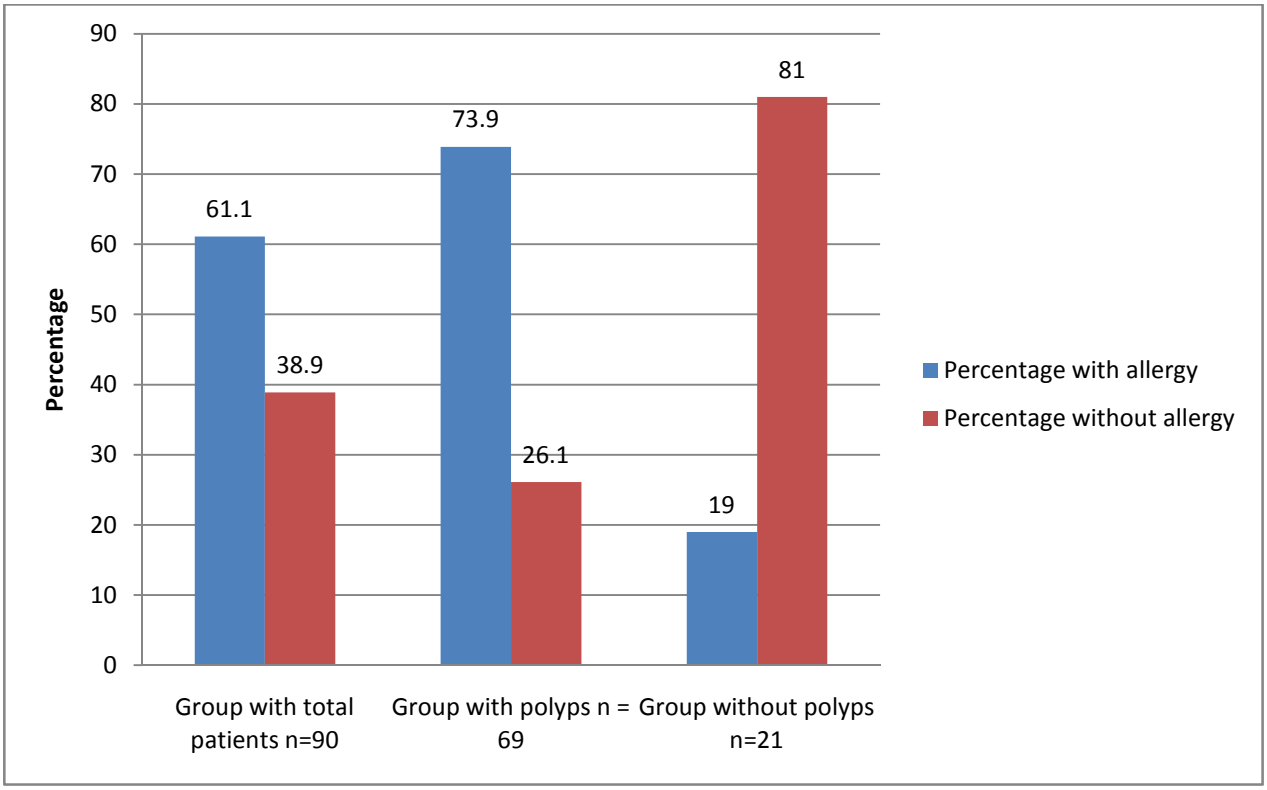
Fig 19: Percentage distribution of patients undergoing Primary / Revision FESS



f) Presence of allergy (Fig. 20)

A total of 55 patients (61.1%) had complaints suggestive of associated allergy, like sneezing or urticaria. It was more so in the group with polyps (73.9%) as against 19% in the group without polyps. Out of the 55 patients who had allergy, 25 of them had their Ig E levels tested. Nineteen out of 25 patients (76%) tested for Ig E levels in serum had raised levels.

Fig 20 Prevalence of allergic symptoms in patients with and without polyps



g) Use of prior antibiotics

A total of 65 patients (72.2%) out of 90 had received at least 1 course of antibiotics prior to the surgery. In the group of patients without polyps, 18 of them (85.7%) had received antibiotics while 47 patients (68.1%) in the polyp groups received antibiotics.

h) Use of steroids

A total of 54 patients (78.3%) in the group of cases with polyps had received either nasal steroid spray or a short course of perioperative oral steroids or both, while only 3 patients in the group without polyps had received steroids. The 3 in the group without polyps had received oral steroid because of their allergic complaints.

Postoperatively, 73 patients (81.1%) had received either a nasal corticosteroid spray or a spray combined with a short course of steroid to be continued for about 12 weeks. Only 17 patients were taken off all the drug therapy at 2 weeks postoperatively. All patients were advised to return for follow up after 3 months.

i) Histopathological examination

Out of 90 patients, 86 patients had histopathological evaluation at our institution.Out of the 86 patients,54(62.8%) were reported as chronic inflammatory polyps, while 32(37.2%) had feartures suggestive of allergic fungal sinusitis,as with allergic mucin or evident fungal hyphae. In the group of patients with polyps, 40 patients (58.8%) had histopathological features suggestive of chronic inflammatory polyps while 28 (41.2%) of them had features suggestive of allergic fungal sinusitis.In patients without polyps, 14(77.8%) of them had chronic inflammatory changes while 4(22.2%) of them had fungus: suggestive of a fungal ball. In 16 patients who underwent revision FESS, 10 patients (66.7%) had histopathological features of allergic fungal sinusitis while the rest had chronic inflammatory polyps.

j) Fungal culture results

In 33 patients, a fungal aetiology was suspected clinically and fungal culture of the tissue was obtained. Only 10 out of the 33 cultures grew fungus. Seven of the cultures reported Asperigillus flavus, while two reported Asperigillus fumigatus and one had mixed growth of Asperigillus flavus and fumigatus.

k) Preoperative SNOT 22 score

All the patients enrolled in the study were asked to fill the SNOT 22 questionnaire preoperatively. The preoperative score varied from 7 to 70, with a mean of 29.27 (S.D.= 13.5). Out of 90 patients, 89 of them (98.9%) had a score more than 7. In the group with polyps, the mean score was 30.52 (S.D = 12.9), and all patients except 1 had a score more than 7 (98.6%). In the group without polyps, the mean preoperative score was 25.14 (S.D.= 14.9). All patients in the group with sinusitis without polyposis had a score more than 7 preoperatively. It is evident from the data that if we are to consider a score more than 7 as indicative of having rhinosinusitis, all except one had met that criterion preoperatively. Also, the group with polyps was evidently more symptomatic with a higher SNOT score.

The SNOT 22 questionnaire scoring was sub-analysed in each group, dividing the questions into three domains: nasal complaints, non-nasal complaints and psychosocial complaints. The values are summarized in the table below.

Table 10: Sub analysis of the preoperative SNOT 22 score

	Complaints	Range of values	Mean score	Standard deviation
Rhinosinusitis with polyposis	Nasal	3-32	18.5	6.92
	Non-nasal	0-14	2.82	3.19
	Psychosocial	0-38	9.0	8.18
	Total score	7-70	30.52	12.9
Rhinosinusitis Without polyposis	Nasal	1-28	14.43	7.9
	Non-nasal	0-10	3.19	3.01
	Psychosocial	0-28	7.61	8.23
	Total score	9-66	25.14	14.9

It is obvious from the data that patients reported more of nasal complaints as compared to the non-nasal and psychosocial complaints in both the groups. But statistically there was no difference between both the groups.

The preoperative SNOT 22 questionnaire was also analysed aganist the various comorbid illnesses reported, to identify if there was any significant difference among these diseases on severity of symptoms. There was no statistical significance in the SNOT 22 scores between the groups, the inferences summarized in the following table.

Table 11.Preoperative SNOT 22 scoring aganist the various co morbid conditions

	Mean score in affected cases	Mean score in not affected cases	'p' value	Statistical significance
Diabetes	36.29	27.63	0.176	Not significant
Hypertension	32.42	27.71	0.368	Not significant
Bronchial asthma	34.50	28.35	0.456	Not significant
Immunocompromised	27.50	28.9	0.856	Not significant
Hypothyroidism	22.20	29.58	0.260	Not significant

l) Postoperative SNOT 22 score

Out of a total of 90 patients, 50 patients came for follow up between 3 to 6 months postoperatively. All of them were asked to fill the SNOT 22 questionnaire again during the follow up visit. The postoperative SNOT score ranged between 0-44, with a mean score of 9(S.D 9.7). Out of the 50 patients, 28 (56%) had a post operative score less than 7, while 22 (44%) of them continued to have a higher score than 7. In the group with polyps, 37 patients came for follow up. The mean postoperative score was 9.11 (S.D 10.5) with 22 patients (59.5%) reporting a score less than 7. In the group without polyps, 13 patients came for follow up and reported a mean score of 8.69(S.D 7.5). Out of 13 patients, 6 of them (46.2%) reported a score less than 7.

It is evident from the data that there is a significant improvement in the SNOT scores postoperatively. However, the majority of the patients continued to have a score higher than

7, which means that even after surgery they did not come to a score which was suggestive of a normal individual in the follow up period defined in the present study.

Post operative SNOT score was also sub analysed in the three domains of nasal, non-nasal and psychosocial complaints. The results are summarised in the table below.

Table 12: Sub analysis of postoperative SNOT 22 scores

	Complaints	Range of values	Mean score	Standard deviation
Rhinosinusitis with polyposis	Nasal	0-29	7.21	6.67
	Non-nasal	0-4	0.37	1.00
	Psychosocial	0-4	0.37	1.00
	Total score	0-44	9.11	10.4
Rhinosinusitis Without polyposis	Nasal	0-10	5.07	2.87
	Non-nasal	0-3	0.92	1.03
	Psychosocial	0-3	0.31	0.85
	Total score	1-28	8.69	7.52

There appeared to be a significant reduction in the non-nasal and psychosocial symptoms postoperatively in both groups of patients (Table 12). However there was no statistically significant difference between both the groups, in all the three domains.

m) Preoperative LKES score

All the patients included in the study had a preoperative endoscopy and Lund Kennedy scoring of the findings. In the group with nasal polyps the preoperative LKES average score was 7.7 (S.D.= 2.65).In the group without polyps, the preoperative average score was about 6.14 with a range from 2 to 14 (S.D.= 2.97).The data suggests that the patients with polyps have a higher pre operative Lund Kennedy score as compared to those without polyps.

n) Postoperative LKES score

Post operatively at 3 to 6 months, in the group with polyps the mean LKE score was 1.94 (S.D = 2.6) and in the group without polyposis the mean LKE score was 2.04 (S.D = 2.08).Though both the groups of patient with polyps and without polyps showed improvement in the score, it was less pronounced in the group without polyps , as evident from the values.

0) Preoperative Lund Mackay score

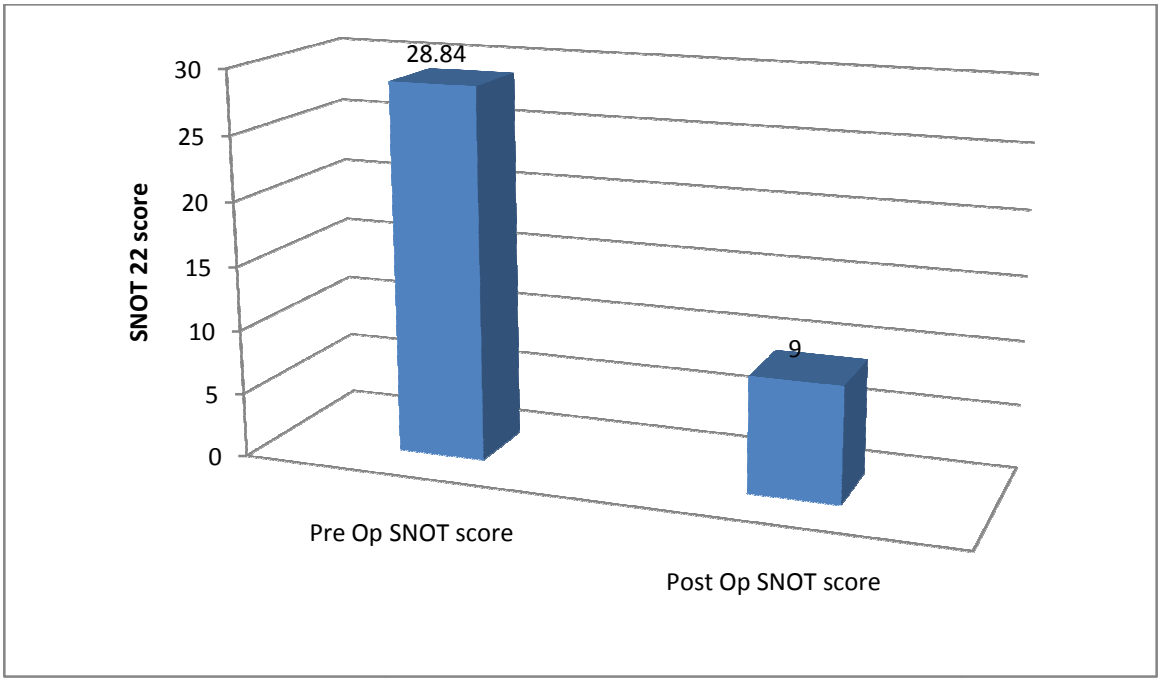
The Lund Mackay scoring was done on the CT scan images of 75 patients preoperatively. The mean score was 13.44(S.D =7.46).In the group with polyps, there were 57 patients. The mean score in this group was 15 and all of them had atleast one side osteomeatal complex occluded. In the group without polyps 18 scans were analysed and the mean score was 8.5 with 72.3% of patients with at least one osteomeatal complex occluded. Overall, 93.3% of patients (70/75) had at least one osteomeatal complex blocked.

p) Comparison of preoperative and postoperative SNOT 22 scores

The preoperative and post operative SNOT 22 questionnaire scores of the 50 patients who came for the follow up were compared and analyzed separately. Also, the scores were sub analysed in two groups of those with polyps and those without polyps. There were 37 patients in the group with polyps and 13 patients in the group without polyps.

The mean total SNOT 22 score preoperatively was 28.84(S.D.= 15.6), while the mean postoperative score was 9.0 (S.D.= 9.7).Out of the 50 patients with follow up, 49 of them(98%) had a preoperative score more than 7 and 28 of them improved after the surgery to have a score less than 7.The mean improvement in the total score was 19.8 (p=0.00), which was statistically significant. The preoperative and post operative SNOT 22 score comparison is illustrated in the figure (Fig. 21) below.

Fig 21 Comparison of SNOT 22 score preoperatively and post operatively



In the group of patients with polyps, a total of 37 patients returned for follow up, and the mean preoperative score was 29.95(S.D.= 15.47) and mean post operative score was 9.11(S.D = 10.45). In the group of patients without polyps, the mean preoperative score was

25.69(S.D = 16.23) and mean postoperative score was 8.69(S.D = 7.52). Out of 37 patients in the group with polyps, 31 patients (83.8%) improved at least by 9 points postoperatively, while 84% (11/13 patients) improved by at least 9 points in the group without polyps. The mean improvement of total score was 20.8 in the group with polyps (p=0.00) and 17.0 in the group without polyposis (p=0.01). Hence, there was statistically significant improvement in SNOT 22 score in both the groups postoperatively. The mean improvement in the score was comparable in both the groups with no statistical difference (p=.338). The comparison of scores in both the groups is illustrated in the figure (Fig. 22) and the calculations summarized in the table given below.

Fig 22 Comparison of SNOT 22 score in both the groups pre operatively and post operatively

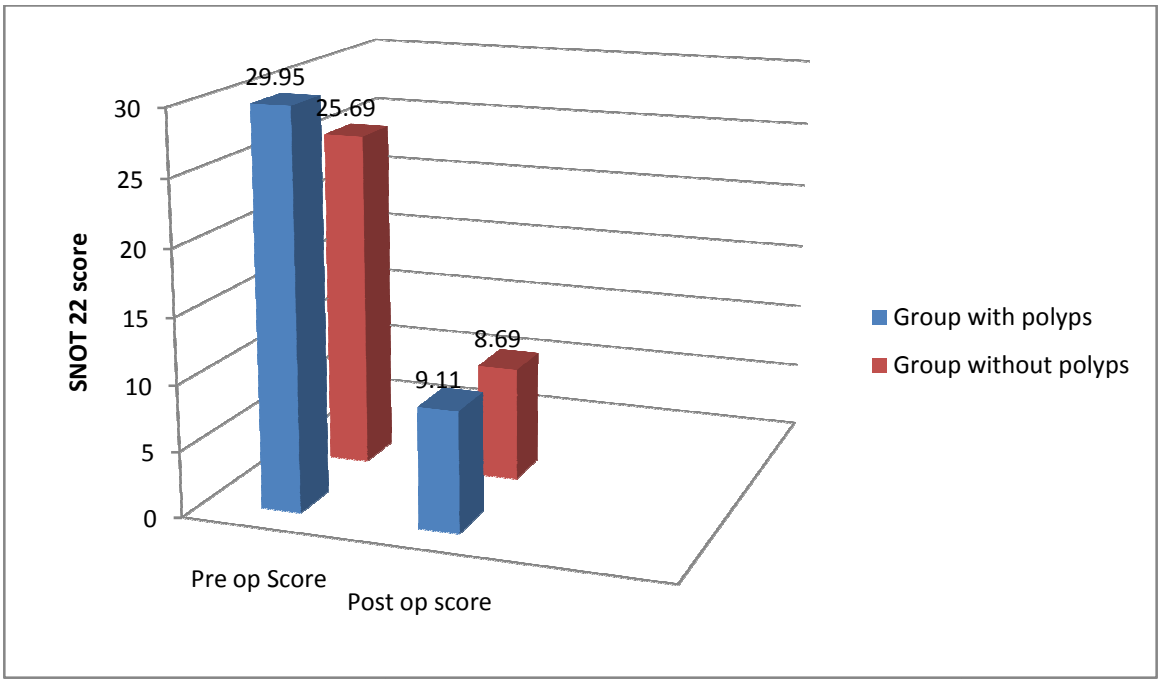


Table 13: Comparison of SNOT 22 score in both the groups pre operatively and post operatively

	Mean preop SNOT 22 score	Mean post op SNOT22 score	Mean improvement	P value
Group with polyps (n=37)	29.95	9.11	19.8	0.00
Group without polyps (n=13)	25.69	8.69	20.8	0.00
Total score (n=50)	28.84	9.0	17.0	0.01

Also a comparative analysis of the SNOT 22 scores were done between the groups of primary FESS and revision FESS. There were 40 patients in the group of primary FESS and 10 patients in the group of revision FESS. All the patients except one (39/40) in the group of primary surgery had a preoperative score more than 7, with a mean score of 25.62(S.D= 14.2).Post operatively, 32 patients (80%) improved at least by 9 points and the mean post operative score was 8.78(S.D 10.47).The mean improvement in the score was 16.8 points(p=0.00),which was statistically significant.

In the group of revision FESS, the mean preoperative score was 41.70(S.D = 14.99), all of them with a score more than 7. All the patents improved postoperatively by at least 9 points to reach a mean post operative score of 9.90(S.D= 5.97).The mean improvement in score was 31.8, (p=0.00) which was also statistically significant. When we compared the mean improvement in SNOT 22 score, between the groups of primary surgery and revision surgery, there was no statistically significant difference (p value .143) .The comparative analysis of

the SNOT22 score in both the groups are summarized in Figure 23 and Table 14 given below.

Fig 23 Comparison of SNOT 22 score between groups of primary FESS and revision fess

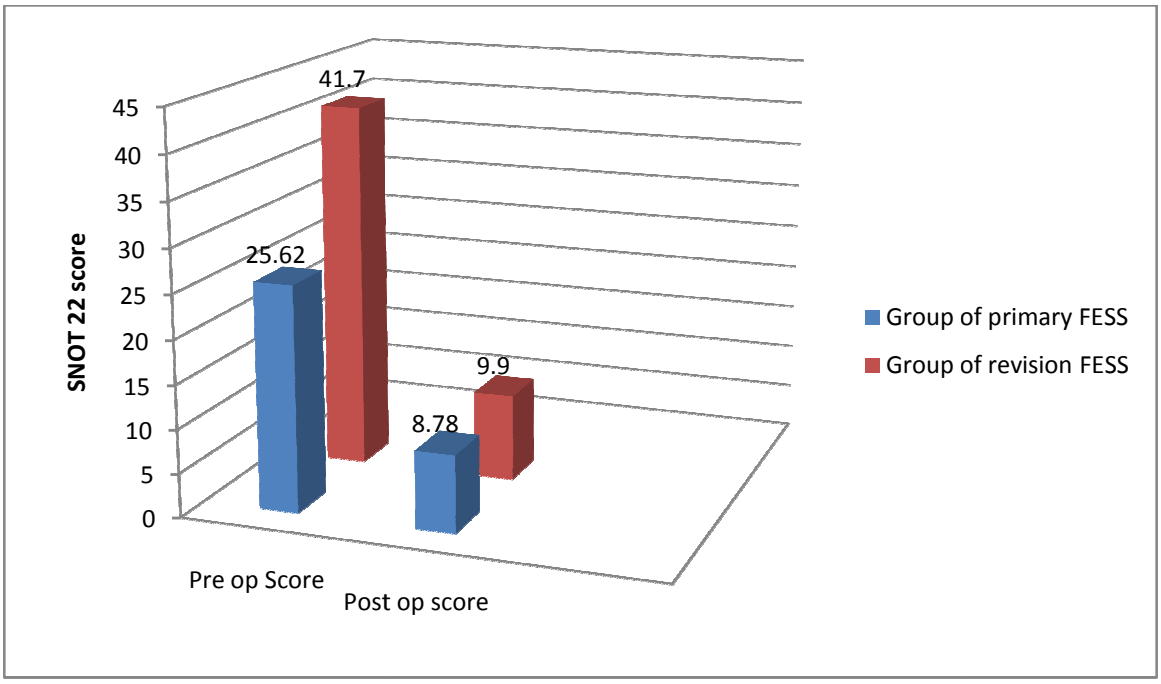


Table 14: Comparison of SNOT 22 score between groups of primary FESS and revision fess

	Mean preop SNOT 22 score	Mean post op SNOT22 score	Mean improvement	P value
Group of primary FESS (n=40)	25.62	8.78	16.8	.00
Group of revision FESS (n=10)	41.70	9.90	31.8	.00
Total score (n=50)	28.84	9.0	17.0	.01

The SNOT22 questionnaire was also analysed separately in all the three domains of nasal, non-nasal and psychosocial domains, in both the groups of with polyps and without polyps, comparing the preoperative and postoperative scores. All the comparisons were statistically significant and are summarized in the table below.

Table 15: Comparison of preoperative and postoperative SNOT 22 score in various domains

	Domain of complaints	Mean preoperative score	Mean postoperative score	p value
Rhino sinusitis with polyposis	Nasal	18.5	7.21	.00
	Non-nasal	2.82	0.37	.00
	Psychosocial	9.0	0.37	.00
	Total score	29.95	9.11	.00
Rhino sinusitis Without polyposis	Nasal	14.43	5.07	.00
	Non-nasal	3.19	0.92	.01
	Psychosocial	7.61	0.31	.00
	Total score	25.69	8.69	.01

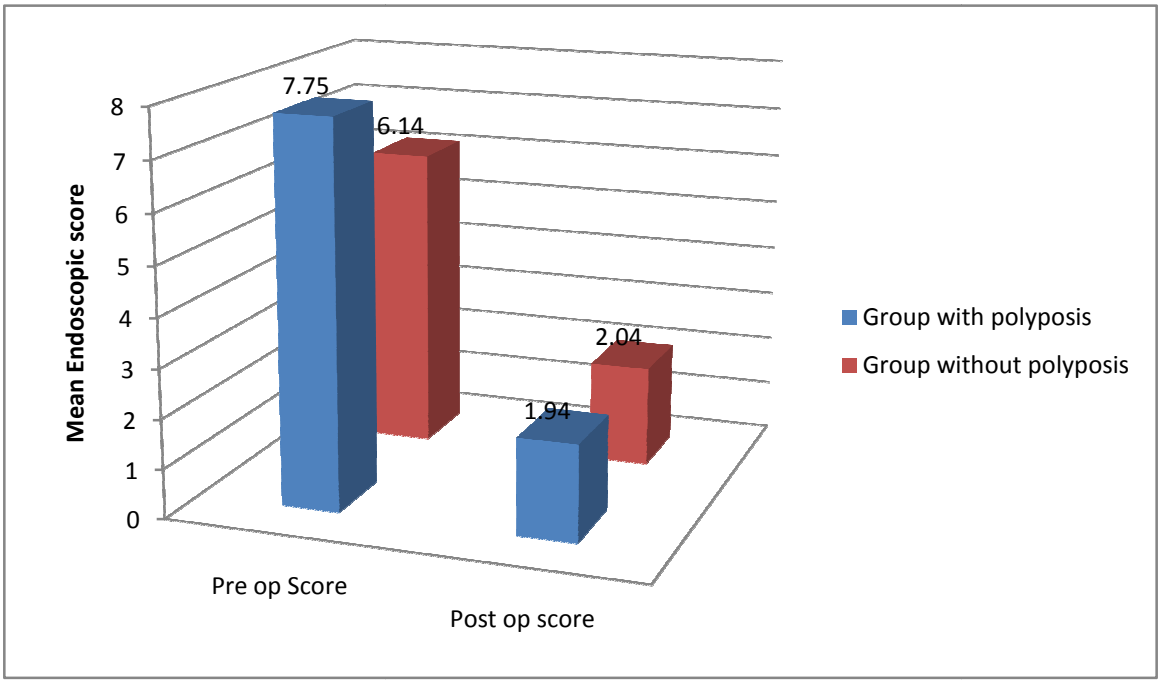
q) Comparison of preoperative and postoperative LKES scores

Lund Kennedy endoscopic scoring done preoperatively and post-operatively at 3-6months follow up visit was compared. The data was analyzed and compared between the group with polyps and without polyps. In the group with polyps the mean preoperative score of 7.75 improved to a mean score of 1.94. In the group without polyps also, there was a comparable improvement of the mean LK score from 6.14 to 2.04 postoperatively. The details of the analysis are summarized in the table and the figure given below. Both the groups showed statistically significant improvement postoperatively.

Table 16: Comparison of improvement in LK score in both groups of sinusitis

	Preop mean LK score	Postop mean LKscore	
Group with Polyposis n=37	7.75	1.94	Chi square value 6.58
Group without polyposis n=13	6.14	2.04	P value = 0.037

Fig 21 Pattern of improvement in Endoscopic scoring in both groups of sinusitis



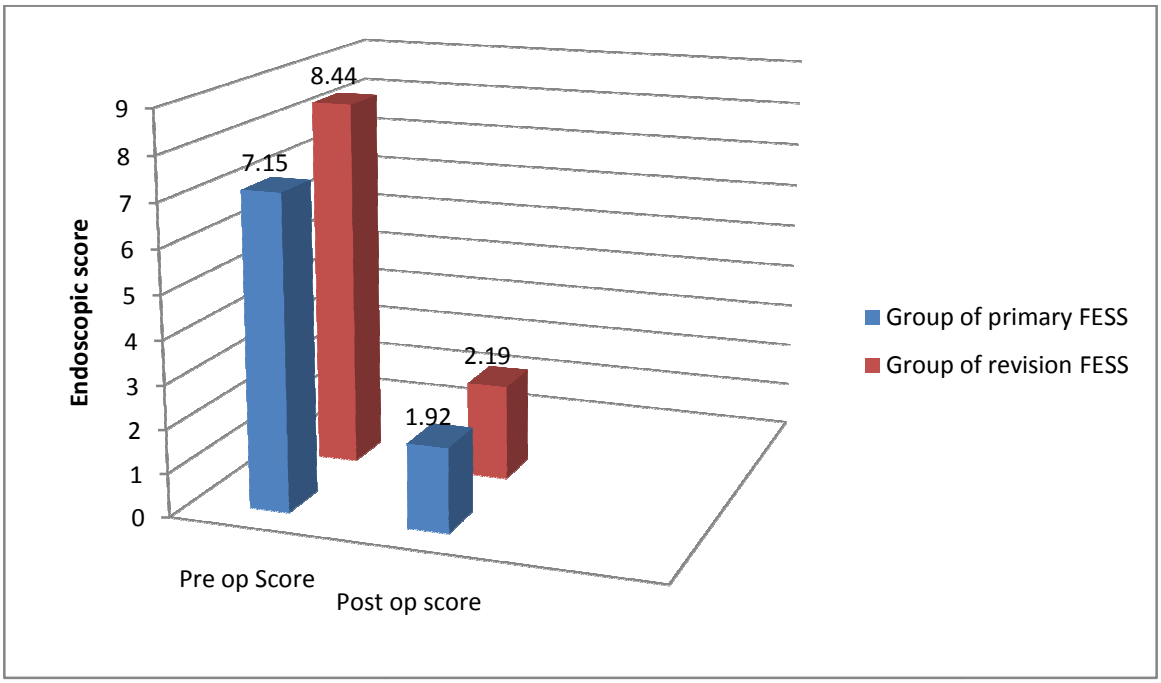
Also, the Lund Kennedy endoscopic score was analysed to compare between the two groups of surgery, FESS done the first time and in cases of revision surgery. In the group of first time surgery, the mean preoperative score was 7.15 (S.D = 2.62) which improved to 1.92 (S.D = 2.44) postoperatively. In revision FESS, the mean preoperative score was 8.44 (S.D = 3.38) which improved to a mean score of 2.19 (S.D = 2.7) post operatively.

The pattern of improvement is summarized in the table and figure given below. Both the group of primary FESS and revision FESS showed statistically significant improvement.

Table 17 .Pattern of improvement in Endoscopic Scoring in cases of Primary Vs Revision FESS

	Mean preop LK score	Mean postop LK score	
Primary FESS n=40	7.15	1.92	Chi square value 7.519 P value 0.023
Revision FESS n=10	8.44	2.19	

Fig 22: Pattern of improvement in Endoscopic Scoring in cases of Primary Vs Revision FESS



r) Improvement in individual symptoms in SNOT 22

Each individual question in the SNOT22 questionnaire was analysed separately, comparing the preoperative and postoperative data of the 50 patients who came for follow up. Most common preoperative complaint was nasal block (92%), followed by sneezing (72%), runny nose (70%) and post nasal discharge (70%). It was observed that complaints pertaining to question 2 (Sneezing), question 5 (Post nasal discharge), question 21 (Sense of taste / smell) and question 22(Blockage / Congestion of the nose) persisted in more than 50% of the patients, though statistically there was significant improvement in the scores. The change in the preoperative and post operative complaints of each individual question is summarized in the table below. (Table 18)

Table 18: SNOT 22 Individual Symptom : Improvement in percentage

Qn.No		Preop:Score 0.No complaint(%)	Preop: Score 5. As bad as it can be (%)	Postop:Score 0.No such complaint (%)	Postop: Score 5.As bad as it can be (%)
1	Need to blow nose	21 (42%)	3 (6%)	38 (76%	1 (2%)
2	Sneezing	14 (28%)	7 (14%)	22 (44%)	1 (2%)
3	Runny nose	15 (30%)	7 (14%)	31 (62%)	1(2%)
4	Cough	28 (56%)	1 (2%)	44 (88%)	1 (2%)
5	Postnasal discharge	15 (30%)	4 (8%)	25 (50%)	1 (2%)
6	Thick nasal discharge	17 (34%)	5 (10%)	40 (80%)	1 (2%)
7	Ear fullness	37 (74%)	1 (2%)	48 (96%)	0
8	Dizziness	44 (88%)	0	48 (96%)	0
9	Ear pain / pressure	40 (80%)	0	49 (98%)	0
10	Facial pain/ pressure	26 (52%)	0	42 (84%)	0
11	Difficulty falling asleep	28 (56%)	2 (4%)	43 (86%)	0
12	Waking up at night	27 (54%)	1 (2%)	46 (92%)	0
13	Lack of good night sleep	33 (66%)	0	44 (88%)	0
14	Waking up tired	37 (74%)	0	48(96%)	0
15	Fatigue during the day	30 (60%)	1 (2%)	44(88%)	0
16	Reduced productivity	38 (76%)	1 (2%)	44(88%)	0
17	Reduced concentration	38 (76%)	0	45 (90%)	0
18	Frustrated/restless/irritable	27 (54%)	2 (4%)	42 (84%)	1(2%)
19	Sad	35 (70%)	4 (8%)	43 (86%)	0
20	Embarrassed	33 (66%)	2 (4%)	48 (96%)	0
21	Sense of taste or smell	16 (32%)	13 (26%)	20 (40%)	2 (4%)
22	Nasal block/Congestion	4 (8%)	23 (46%)	5 (10%)	1 (2%)

s) Other observations

We had also noted that few of the patients had some extra complaints other than those included in the SNOT22 questionnaire. The observations are summarized in the table below.

Table 19: Other preoperative complaints summarized

Serial No:	Complaint	Number of patients
1	Bleeding / blood stained nasal discharge	11
2	Breathing difficulty	4
3	Recurrent fever	2
4	Halitosis	12
5	Headache	8
6	Epiphora	3
7	Proptosis	2
8	Snoring	8
9	Ear discharge	3
10	Dry mouth (mouth breathing)	3
11	Parosmia	1

As all the 90 patients did not come for follow up a comparative analysis of these symptoms could not be made. However, ear discharge had stopped in all the three patients following FESS. Two of the patients had developed the complaint of blood stained discharge postoperatively. Snoring had persisted in two of the patients, both with high BMI.

t) Complications and failures

Of all the 90 patients who underwent FESS two patients had postoperative complications. First patient with extensive polyposis had right orbital haematoma, which was recognised on table and orbital decompression was done immediately. There were no visual complaints postoperatively. The second patient had postoperative bleeding following nasal pack removal the next day and nose had to be repacked. He was also managed conservatively and recovery was uneventful. The blood loss in all the patients were within permissible limits and none needed any transfusion.

Three of the patients had recurrence of the disease and had to be planned for revision surgery within a year. Two of these patients had polyps and the third one was a diabetic with sphenoidal sinusitis in whom the mucopurulent discharge and post nasal drip persisted. Overall, the complication rate was low and patients were symptomatically better during the follow up visits.

Discussion and conclusions:

CRS is an apparently common condition whose diagnosis is largely symptom based with corroboration of diagnosis based on endoscopic and radiological findings. The exact prevalence of the disease is unknown and most estimates are based on hospital –based figures. The demographic pattern of this disease has been poorly studied in the Indian population. Much less is known about the outcome following FESS among adult Indian patients.

The present study revealed that most patients with CRS were males (63.3%). This is in contrast to the findings of Chen Y et al, Bhattacharya et al and Chambers et al, who found that CRS was more prevalent in females. Our finding that CRS was commonest in the 4th to 5th decades among adult patients has been substantiated by other authors [Table 20]. Analysing the group of patients with CRSwNP, we found that polyps were more common in men with a peak incidence in the age group of 50-59 years. This was similar to the findings of Larsen and Tos (16). We also found that the average age of patients with polyps was 39.6 years, which was also quite comparable to that reported in the literature (14-16)

Table 20 :Comparison of demographic parameters

Author/ year	Number of patients			Sex Distribution		Mean Age(yrs)
	Total	CRSwNP	CRSsNP	Male	Female	
Bhattacharya / 2007	251	86	165	111	140	42.9
Deal et al /2004	201	78	123	104	97	49
Timothy et al/ 2005	119	43	76	45	74	47.1
Giger et al / 2004	77	NM*	77	37	36	42.7
Khalid et al / 2004	150	NM*	NM*	61	89	NM*
Our study	90	69	21	57	33	41.17

*= Not mentioned

Patients with sinusitis are known to have comorbidities. In the present study we found that hypertension was the commonest comorbidity (24.4%). Patients with diabetes mellitus (14.4%) were less frequently seen. Only 10% of our patients had bronchial asthma. Chandra et al found a higher prevalence of CRS among asthmatics (18%) compared to those with hypertension (4.4%). The authors found that CRSwNP was more common in bronchial asthma and certain autoimmune diseases like atopic dermatitis and inflammatory bowel disease, suggesting that a similar immunological mechanism was involved in the etiopathogenesis of these diseases. The immunological mechanisms in CRS have been shown to be Th2 mediated with tissue eosinophilia in CRSwNP and Th1 mediated with neutrophilia in CRSsNP(59).In the present study, we found that 8 of 9 patients with bronchial asthma had CRSwNP while only 1 of these 9 patients had CRS s NP. This finding further reaffirms the fact that there is a higher proportion of CRSwNP phenotype among CRS patients who have bronchial asthma. Other authors have also commented on this phenomenon(48). The unified airway concept where different parts of the upper and lower airways are affected (CRS and bronchial asthma) does lend credence to such an association.

The application of a QOL instrument like SNOT 22 in the preoperative evaluation of patients with CRS enabled us to make valid, objective comparisons of preoperative and postoperative status of these patients using the derived scores. Chambers et al used a visual analogue scale ranging from 1 to 5, dividing those who had “moderate to major benefit” (scores of 4 or 5) into one group and those with lower scores into another group(61). As specific nasal, non-nasal and functional benefit is not assessed in this form of evaluation, comparison of results is made difficult. Giger et al used symptom specific evaluation to assess severity of symptoms pre and postoperatively(58). Here again, the lack of inclusion of data on functional impairment does not allow assessment of the impact of CRS on the patient’s QOL.

As QOL instruments assess some non-disease specific symptoms in addition to disease specific symptoms, it is essential to acquire normative data. In this connection, the SNOT 20 QOL has been administered to adult individuals with no sinonasal diseases to ascertain cutoffs for patients with CRS (23). The authors noted that the scores ranged from 0 to 50 with a median score of 7. They suggested that a score of 7 be used to separate normal from diseased patients. In the present study, 98.9% of our patients had SNOT 22 scores exceeding 7, making it evident that the underlying disease process had significantly affected these patients necessitating surgery. The mean preoperative SNOT 22 score of patients with CRS in our study was 29.27 (S.D=13.5), which was lower than the preoperative SNOT22 score reported in the National comparative audit by Hopkins et al, of 40.9 (S.D.=19.9)(37). Further, in contrast to the observation made by Hopkins et al, we had a higher preoperative mean score in the group with polyps in comparison to that of the group without polyps, though the difference was not statistically significant. When comparing patient with CRSwNP and CRSsNP who underwent FESS, Deal et al (54) also found higher SNOT-20 scores (mean =32.2+/-1.2) in patients with CRSwNP compared to those with CRSsNP whose mean SNOT 20 scores were 26.5 (SD=1.0). Using the CSS QOL instrument, Smith et al also described a higher QOL score preoperatively in patients with CRSwNP compared to those with CRSsNP(56). These findings were also noted in the present study.

The greater endoscopic (Lund Kennedy) and CT scan (Lund Mackay) scores in patients with CRSwNP than in those with CRSsNP that was seen in our study has also been described by other authors (43,56,62). The edema and bulk of the polyps filling the nasal cavities and paranasal sinuses in patients with CRSwNP are responsible for the higher endoscopic and CT scan scores in thses patients.

Postoperative improvement in QOL and endoscopic scores following FESS have been described by several authors (37,43,51,54,56,61-63). In the present study, there was significant improvement in SNOT 22 scores, with a mean improvement of 19.8 points. The mean improvement in scores was higher in the groups with polyps and the results were comparable to the Hopkins study (37). Sub analysis of SNOT 22 in its three domains also reflected comparable results in both the groups. The efficacy of FESS is related to both the benefit of removing inflammatory tissue and reduction in antigen load as well as improved sinus ventilation and mucociliary clearance.

Most authors report symptomatic improvement in patients who have undergone FESS. Using symptom specific improvement as a criterion, Chester et al pooled data from 21 studies most of which used a visual analogue score for assessment(63). Their analysis revealed that while all symptoms improved postoperatively, nasal obstruction was the symptom that showed the greatest change, followed by headache and postnasal drip. In the present study, we found a similar significant improvement in nasal obstruction, although symptoms of sneezing and nasal discharge often persisted in patients with nasal allergy. An interesting finding in the present study was the improvement in many non-nasal symptoms after FESS. This included ear discharge and epistaxis. Ehnage et al showed a reduction in asthma symptom severity postoperatively(64). Giger et al, however, found that non-asthmatics had a better outcome after FESS than asthmatics(58).

In the present study we noted that with the improved SNOT 22 scores in all patients with CRS, a corresponding improvement in the postoperative endoscopic Lund Kennedy scores occurred. Giger et al also found a strong correlation between postoperative endoscopic scores and symptom scores (58). However, they noted that some patients with lower symptom

scores had residual/recurrent polyps in the ethmoid cavities at follow up. In contrast, Kennedy found no correlation between symptoms and endoscopic scores (60).

Revision surgery is occasionally required in patients with CRS, although the rate of revision surgery varies widely from centre to centre (Table 21). In the present study, while 40 patients with follow up had primary FESS, 10 had revision FESS. The patients with revision FESS appeared to have higher preoperative SNOT 22 scores and greater postoperative improvement. Similar findings were noted by others (55,52).

Lund et al showed a sustained improvement in SNOT 22 scores upto 5 years after surgery in revision cases. Most studies have shown that in patients undergoing revision FESS, CRSwNP is more common than CRSsNP (5,37). This was the case in our study too where out of the 16 revision FESS cases which we had included in our study, 14 of them (87.5%) had polyps. The reason for this is that the underlying mechanisms that predispose to polyposis like allergic rhinitis and allergic fungal sinusitis or cystic fibrosis are operative and unless simultaneous measures to treat these conditions are in place, polyposis will inevitably recur.

Table 21: Comparative analysis of revision FESS for CRS

Author/year	Number of patients			Revision rate
		CRSwNP	CRSsNP	at 12 months
Deal et al/2004	201	78	123	4.5%
Hopkins/ 2006	3128			3.7%
Bhattacharya/2007	251	86	165	4.3%
Giger et al/2004			77	15%
Our study	90	69	21	6%

Intraoperative and postoperative complications of FESS are largely dependent on the surgical skills of the surgeon. Table 22 compares complication rates in a few studies that have addressed this issue. Our complication rate of 2.2% compares favourably with the studies listed. Clearly, where a large number of surgeons of varing experience and calibre are

involved in performing FESS, a higher complication rate may be observed that in situations where one or a few specialised surgeons alone operate on all the cases.

Table 22 : Comparative analysis of complication rates following FESS

Author/year	Number of patients	Complication rate
Nair et al/2011	90	11.2%
Hopkins/2006	3128	6.9%
Lee et al/2007	125	1.4%
Lund/1994	650	0.3%
Our study	90	2.2%

In conclusion, FESS is an effective procedure for the management of CRSwNP and CRSsNP. The subjective as well as objective outcomes are good in cases of revision surgery as well as in those with polyps. It is also a safe procedure in experienced hands. However, there is still a need for more randomised controlled studies with long term follow up comparing different surgical techniques in FESS as well as comparison of FESS with medical therapy to clearly outline a recommendation for the management of both cases of CRSwNP and CRSsNP.

Bibliography

1. McCormick A, Fleming D, Charlton J. Morbidity statistics from general practice : fourth national study 1991-1992.London. HMSO; 1995.199.

2. Blackwell DL, Collins JG, Coles R. Summary health statistics for U.S. adults: National Health Interview Survey, 1997. Vital Health Stat 10. 2002 ;(205):1-109.

3. Gliklich RE, Metson R. The health impact of chronic sinusitis in patients seeking otolaryngologic care. Otolaryngol Head Neck Surg. 1995;113(1):104–9.

4. Greisner WA, 3rd, Settipane GA. Hereditary factor for nasal polyps. Allergy and asthma proceedings: the official journal of regional and state allergy societies. 1996 ;17(5):283-6.

5. Fokkens WJ, Lund VJ, Mullol J, Bachert C, Alobid I, Baroody F, et al. EPOS 2012: European position paper on rhino sinusitis and nasal polyps 2012. A summary for otorhinolaryngologists. Rhinology. 2012 ;50(1):1–12.

6. Stranding S et al. Gray's Anatomy. 40th edition. Edinburgh.Elsevier.2008.547-559 .

7. Stammberger H. Functional Endoscopic Sinus Surgery: The Messerklinger Technique.Philadelphia. Mosby-Year Book; 1991.17-200

8. Cole P. Physiology of the nose and paranasal sinuses. Clin Rev Allergy Immunol. 1998 Spring-Summer;16(1-2):25–54.

9. Littlejohn MC, Stiernberg CM, Hokanson JA, Quinn FB Jr, Bailey BJ. The relationship between the nasal cycle and mucociliary clearance. Laryngoscope. 1992 ;102(2):117–20.

10. Kennedy DW, Bolger WE, Zinreich SJ. Diseases of the Sinuses: Diagnosis and Management. PMPH-USA; 2001.

11. Van Crombruggen K, Zhang N, Gevaert P, Tomassen P, Bachert C. Pathogenesis of chronic rhinosinusitis: Inflammation. The Journal of allergy and clinical immunology. 2011.

12. Van Bruaene N, Bacher t C. Tissue remodeling in chronic rhinosinusitis. Curr Opin Allergy Clin Immunol. 2011 ;11(1):8-11.

13. Chen Y, Dales R, Lin M. The epidemiology of chronic rhinosinusitis in Canadians. The Laryngoscope. 2003 ;113(7):1199-205.

14. Drake-Lee AB, Lowe D, Swanston A,Grace A. Clinical profile and recurrence of nasal polyps. J Laryngol Otol. 1984 Aug;98(8):783-93.

15. Moloney JR. Nasal polyps, nasal polypectomy, asthma, and aspirin sensitivity. Their association in 445 cases of nasal polyps. J Laryngol Otol. 1977 ;91(10):837-46.

16. Larsen K, Tos M. The estimated incidence of symptomatic nasal polyps. Acta Otolaryngol. 2002 ;122(2):179-82.

17. Leung R, Conley D, Kern R, Chandra R. OMC Obstruction is Not Associated with Adjacent Sinus Disease in Chronic Rhinosinusitis with Polyps. AJRA. 2011

18. DeMarcantonio MA, Han JK. Nasal polyps:pathogenesis and treatment implications. Otolaryngologic clinics of North America.2011 ;44(3):685-95, ix.

19. Littman DR, Pamer EG. Role of the commensal microbiota in normal and pathogenic host immune responses. Cell Host Microbe. 2011 ;10(4):311-23.

20. Ponikau JU, Sherris DA, Kern EB, Homburger HA, Frigas E, Gaffey TA, et al. The diagnosis and incidence of allergic fungal sinusitis. Mayo Clinic proceedings Mayo Clinic. 1999; 74(9):877-84.

21. Bachert C, Gevaert P, Holtappels G, Johansson SG, van Cauwenberge P. Total and specific IgE in nasal polyps is related to local eosinophilic inflammation. The Journal of allergy and clinical immunology. 2001 ;107(4):607-14.

22. Kern RC, Conley DB, Walsh W, Chandra R,Kato A, Tripathi-Peters A, et al. Perspectives on the etiology of chronic rhinosinusitis:an immune barrier hypothesis. American journal of rhinology.2008 ;22(6):54959.

23. Gillett S, Hopkins C, Slack R, Browne JP. A pilot study of the SNOT 22 score in adults with no sinonasal disease. Clin Otolaryngol. 2009 ;34(5):467–9.

24. Ooi EH, Psaltis AJ, Witterick IJ, Wormald PJ. Innate immunity. Otolaryngologic clinicsof North America. 2010 ;43(3):473-87, vii

25. Damm M, Quante G, Jungehuelsing M, Stennert E. Impact of functional endoscopic sinus surgery on symptoms and quality of life in chronic rhinosinusitis. The Laryngoscope. 2002 ; 112(2):310-5.

26. Ling FT, Kountakis SE. Important clinical symptoms in patients undergoing functional endoscopic sinus surgery for chronic rhinosinusitis. The Laryngoscope. 2000 ;117(6):1090-3.

27. Anderson ER, Murphy MP, Weymuller EA, Jr. Clinimetric evaluation of the Sinonasal Outcome Test-16. Student Research Award 1998. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery. 1999 ; 121(6):702-7.

28. Piccirillo J. Psychometric and clinimetric validity of the 31-item rhinosinusitis outcome measure. American journal of rhinology. 1995(9):297-306.

29. Benninge r MS , S enior BA. The development of the Rhinosinusitis Disability index. Archives o f otolaryngology--head & neck surgery.1997 ;123(11):1175-9.

30. Atlas SJ, Gallagher PM, Wu YA, Singer DE, Gliklich RE, Metson RB, et al. Development and validation of a new health-related quality of life instrument for patients with sinusitis. Quality of Life Research. [Review].2005;14(5):1375-86.

31. Fahmy FF, McCombe A, McKiernan DC. Sino nasal assessment questionnaire, a patient focused, rhinosinusitis specific outcome measure. Rhinology. 2002 ;40(4):195-7

32**.** Hopkins C, Gillett S, Slack R, Lund VJ, Browne JP. Psychometric validity of the 22-item Sinonasal Outcome Test. *Clin Otolaryngol*. 2009;34(5):447-454.

33. Bezerra TFP, Piccirillo JF, Fornazieri MA, et al. Cross-Cultural Adaptation and Validation of SNOT-20 in Portuguese. *Int J Otolaryngol*. 2011;2011:306529.

34. Lange B, Thilsing T, Al-kalemji A, et al. The Sino-Nasal Outcome Test 22 validated for Danish patients. *Dan Med Bull*. 2011;58(2):A-4235.

35. Baumann I, Blumenstock G, DeMaddalena H, Piccirillo JF, Plinkert PK. [Quality of life in patients with chronic rhinosinusitis: validation of the Sino-Nasal Outcome Test-20 German Adapted Version]. *HNO*. 2007;55(1):42-47.

36. Pannu KK, Chadha S, Kaur I preet. Evaluation of benefits of nasal septal surgery on nasal symptoms and general health.*Indian J of Otolaryngol and Head & Neck Surg*.2009;61:59-65.

37. Hopkins C, Slack R, Lund V, Brown P, Copley L, Browne J. Long-term outcomes from the English national comparative audit of surgery for nasal polyposis and chronic rhinosinusitis. Laryngoscope. 2009 ;119(12):2459–65.

38. Lund VJ, Kennedy DW. Quantification for staging sinusitis. The Staging and Therapy Group. *Ann Otol Rhinol Laryngol Suppl*. 1995;167:17-21.

39. Bhattacharyya N. Influence of polyps on outcomes after endoscopic sinus surgery. Laryngoscope. 2007 ;117(10):1834–8.

40. Kuhn FA. Role of endoscopy in the management of chronic rhinosinusitis. *Ann Otol Rhinol Laryngol Suppl*. 2004;193:15-18.

41. Bhattacharyya N, Lee LN. Evaluating the diagnosis of chronic rhinosinusitis based on clinical guidelines and endoscopy. *Otolaryngol Head Neck Surg*. 2010;143(1):147-151.

42.Mace J C,Michael Y.L, Carlson N.E, Jamie R. L, and Timothy L.S. Correlations Between Endoscopy Score and Quality-of-Life Changes After Sinus Surgery.Arch Otolaryngol Head Neck Surg.2010 ; 136(4):340-346

43. Fokkens W, Lund V, Mullol J,et al. EP3OS 2007: European position paper on rhinosinusitis and nasal polyps 2007. A summary for otorhinolaryngologists. *Rhinology*. 2007;45(2):97-101.

44. Hebert RL 2nd, Bent JP 3rd. Meta-analysis of outcomes of pediatric functional endoscopic sinus surgery. Laryngoscope. 1998;108(6):796-799.

45. Lanza DC, Kennedy DW. Adult rhinosinusitis defined. *Otolaryngol Head Neck Surg*. 1997;117(3 Pt 2):S1-7.

46. Khalil HS, Nunez DA. Functional endoscopic sinus surgery for chronic rhinosinusitis. *Cochrane Database Syst Rev*. 2006;3:CD004458.

47. Chopra H,Khurana A.S,Munjal M,Due K. Role of F.E.S.S. in Chronic Sinusitis. Indian J of Otorhinolaryngol & Head and Neck surg 2006 ;58(2):137-140

48. Chandra RK, Lin D, Tan B, Tudor RS, Conley DB, Peters AT, et al. Chronic rhinosinusitis in the setting of other chronic inflammatory diseases. Am J Otolaryngol. 2011 ;32(5):388–91.

49. Khalid AN, Quraishi SA, Kennedy DW. Long-term quality of life measures after functional endoscopic sinus surgery. Am J Rhinol. 2004 ;18(3):131–6.

50. Musy PY, Kountakis SE. Anatomic findings in patients undergoing revision endoscopic sinus surgery. Am J Otolaryngol. 2004 ;25(6):418–22.

51. Dalziel K, Stein K, Round A, Garside R, Royle P. Systematic review of endoscopic sinus surgery for nasal polyps. Health Technol Assess. 2003;7(17):iii, 1–159.

52. Lee JY, Lee SW, Lee JD. Comparison of the surgical outcome between primary and revision endoscopic sinus surgery for chronic rhinosinusitis with nasal polyposis. Am J Otolaryngol. 2008 ;29(6):379–84.

53. Hopkins C, Browne JP, Slack R, Lund VJ, Topham J, Reeves BC, et al. Complications of surgery for nasal polyposis and chronic rhinosinusitis: the results of a national audit in England and Wales. Laryngoscope. 2006 ;116(8):1494–9.

54. Deal RT, Kountakis SE. Significance of nasal polyps in chronic rhinosinusitis: Symptoms and surgical outcomes. Laryngoscope.2004;114(11 I):1932-5.

55.Lund VJ, MacKay IS. Outcome assessment of endoscopic sinus surgery. J R Soc Med. 1994;87(2):70-2.

56.Smith TL, Mendolia-Loffredo S, Loehrl TA, Sparapani R, Laud PW, Nattinger AB. Predictive factors and outcomes in endoscopic sinus surgery for chronic rhinosinusitis. Laryngoscope. 2005;115(12):2199.

57.Terris MH, Davidson TM. Review of published results for endoscopic sinus surgery. Ear Nose Throat J. 1994;73(8):574-80.

58. Giger R, Dulguerov P, Quinodoz D, Leuba D, Landis BN, Lacroix JS, et al. Chronic panrhinosinusitis without nasal polyps:Long-term outcome after functional endoscopic sinus surgery.Otolaryngol Head Neck Surg. 2004;131(4):534-41.

59. Van Zele T, Claeys S, Gevaert P, et al. Differentiation of chronic sinus diseases by measurement of inflammatory mediators. Allergy. 2006; 61:1280–9.

60. Kennedy DW. Prognostic factors, outcomes and staging in ethmoid sinus surgery. Laryngoscope 1992;102:1-18.)

61. Chambers DW, Davis WE, Cook PR, Nishioka GJ, Rudman DT. Long-term outcome analysis of functional endoscopic sinus surgery: correlation of symptoms with endoscopic examination findings and potential prognostic variables. Laryngoscope. 1997;107(4):504–10.

62. Nair S, Dutta A, Rajagopalan R, Nambiar S. Endoscopic sinus surgery in chronic rhinosinusitis and nasal polyposis: a comparative study. Indian J Otolaryngol Head Neck Surg. 2011;63(1):50–5.

63. Chester AC, Antisdel JL, Sindwani R. Symptom-specific outcomes of endoscopic sinus surgery: a systematic review. Otolaryngol Head Neck Surg. 2009;140(5):633–9.

64. Ehnhage A, Olsson P, Kölbeck K-G, Skedinger M, Stjärne P. One year after endoscopic sinus surgery in polyposis: asthma, olfaction, and quality-of-life outcomes. Otolaryngol Head Neck Surg. 2012 ;146(5):834–41.

Annexures:

a. Informed consent form

Study Title: Outcome of FESS in chronic sinusitis with or without polyposis

Subject's Name: Study no:
Father's / Husband's name:
Date of Birth / Age : Hospital no.

Consent given by:

I. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions [ ]
II. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]
III. I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial, I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

IV. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]
V. I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/ :
Legally Acceptable Representative

Signatory's Name: _____ Date: _____/_____/_____

Signature of the Investigator: _____ Date: _____/_____/_____
Study Investigator's Name: _____

Signature of the Witness: _____ Date:_____/_____/_____
Name of the Witness: _____

b. **PROFORMA FOR STUDY ON OUTCOME OF FESS IN CHRONIC SINUSITIS**

Date: Study number:

Patient name : Age : Sex :

Hospital number Admitting Unit :

Present Address:

Telephone number : Cell number:Email ID :

Complaints: Nasal blockage / obstruction /congestion /nasal discharge (ant / post)

Facial pain / pressure. Reduction / loss of smell

Total duration of complaints: Allergic complaints:

Preop Antibiotic: Steroids:Oral /Nasal spray

Comorbid illnesses: IgE:

DIAGNOSIS : CHRONIC RHINOSINUSITIS WITH POLYPOSIS /WITHOUT POLYPOSIS

SURGERY: Biopsy: Fungal culture:

Follow up dates:

LUND KENNEDY ENDOSCOPIC SCORING

Left:	***0***	***1***	***2***
Polyps	***absent***	***In MM***	***Beyond MM***
Discharge	***absent***	***thin***	***Thick/purulent***
Edema	***absent***	***Mild***	***Severe***
Scarring	***absent***	***Mild***	***Severe***
Crusting	***absent***	***Mild***	***Severe***

Right	***0***	***1***	***2***
Polyps	***absent***	***In MM***	***Beyond MM***
Discharge	***absent***	***thin***	***Thick/purulent***
Edema	***absent***	***Mild***	***Severe***
Scarring	***absent***	***Mild***	***Severe***
Crusting	***absent***	***Mild***	***Severe***

Total score: right left

4: Name and No: Date Study no:
Preop/post op

: Sino-Nasal Outcome Test-22 Questionnaire

Please rate complaints given below on how 'bad' it is by circling the number that corresponds with how you feel using this scale .**No problem 0 Very mild problem 1 Mild or slight problem 2 Moderate problem 3 Severe problem 4 Problem as bad as it can be 5)** *Kindly tick and mark 3 worst complaints*

Below you will find a list of symptoms and social/emotional problems which affect patients with rhinosinusitis. We would like to know more about these problems and we would appreciate if you could answer the following questions about your symptoms. There is no right or wrong answer, and only you can provide us with this information. Please consider your problems in the past two weeks. Thank you for your participation. Should you have any doubt in filling out the questionnaire, please ask the physician for help.

Considering the severity of the problems, classify symptom intensity by circulating the corresponding number in the scale →	No problem	Very mild problem	Mild problem	Moderate problem	Severe problem	Worst possible problem
1. Need to "blow" your nose	0	1	2	3	4	5
2. Sneeze	0	1	2	3	4	5
3. "Running" nose	0	1	2	3	4	5
4. Cough	0	1	2	3	4	5
5. Nasal secretion going to your throat	0	1	2	3	4	5
6. Thick secretion from your nose	0	1	2	3	4	5
7. A feeling of full or stuffed ear	0	1	2	3	4	5
8. Dizziness or vertigo	0	1	2	3	4	5
9. Ear ache	0	1	2	3	4	5
10. Facial pain or pressure	0	1	2	3	4	5
11. Difficulty to sleep	0	1	2	3	4	5
12. Wake up in the middle of the night	0	1	2	3	4	5
13. Lack of a good night of sleep	0	1	2	3	4	5
14. Wake up tired	0	1	2	3	4	5
15. Fatigued or tired during the day	0	1	2	3	4	5
16. Low performance in doing your daily activities	0	1	2	3	4	5
17. Low concentration to do your daily activities	0	1	2	3	4	5
18. Frustrated, restless or irritated	0	1	2	3	4	5
19. Sadness	0	1	2	3	4	5
20. A feeling of shame	0	1	2	3	4	5
21. Difficulty to feel "smells" or "tastes"	0	1	2	3	4	5
22. Stuffed nose	0	1	2	3	4	5

TOTAL:_____

Extra complaints if any:
Post op steroids:oral/ spray: *Duration*
Complication

Proforma for post.op patients

Study:OUTCOME OF FESS IN CHRONIC SINUSITIS Study no:

Name: Hosp.No: Date:

Post op ------ months Date of surgery:

Diagnosis:

LUND KENNEDY ENDOSCOPIC SCORING

Right	***0***	***1***	***2***
Polyps	***absent***	***In MM***	***Beyond MM***
Discharge	***absent***	***thin***	***Thick/purulent***
Edema	***absent***	***Mild***	***Severe***
Scarring	***absent***	***Mild***	***Severe***
Crusting	***absent***	***Mild***	***Severe***
Left:	***0***	***1***	***2***
Polyps	***absent***	***In MM***	***Beyond MM***
Discharge	***absent***	***thin***	***Thick/purulent***
Edema	***absent***	***Mild***	***Severe***
Scarring	***absent***	***Mild***	***Severe***
Crusting	***absent***	***Mild***	***Severe***

Total score: **Right** **Left**

Name and number: Study number :

Sino-Nasal Outcome Test-22 Questionnaire

Please rate complaints given below on how 'bad' it is by circling the number that corresponds with how you feel using this scale .**No problem 0 Very mild problem 1 Mild or slight problem 2 Moderate problem 3 Severe problem 4 Problem as bad as it can be 5)** *Kindly tick and mark 3 worst complaints*

1. Need to blow nose	-------	0	1	2	3	4	5	
2. Sneezing	-------	0	1	2	3	4	5	
3. Runny nose	-------	0	1	2	3	4	5	
4. Cough	-------	0	1	2	3	4	5	
5. Post nasal discharge	-------	0	1	2	3	4	5	
6. Thick nasal discharge	-------	0	1	2	3	4	5	
7. Ear fullness	-------	0	1	2	3	4	5	
8. Dizziness	-------	0	1	2	3	4	5	
9. Ear pain/pressure	-------	0	1	2	3	4	5	
10. Facial pain/pressure	-------	0	1	2	3	4	5	
11. Difficulty falling asleep	-------	0	1	2	3	4	5	
12. Waking up at night	-------	0	1	2	3	4	5	
13. Lack of a good night's sleep	-------	0	1	2	3	4	5	
14. Waking up tired	-------	0	1	2	3	4	5	
15. Fatigue during the day	-------	0	1	2	3	4	5	
16. Reduced productivity	-------	0	1	2	3	4	5	
17. Reduced concentration	-------	0	1	2	3	4	5	
18. Frustrated/restless/irritable	-------	0	1	2	3	4	5	
19. Sad	-------	0	1	2	3	4	5	
20. Embarrassed	-------	0	1	2	3	4	5	
21. Sense of taste/smell	-------	0	1	2	3	4	5	
22. Blockage/congestion of nose	-------	0	1	2	3	4	5	
Total:								Grand total

Any other complaint:
Any new complaint:

c.IRB Approval

INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE
VELLORE 632 002, INDIA

Dr.B.J.Prashantham, M.A.,M.A.,Dr.Min(Clinical)
Director, Christian Counseling Centre
Editor, Indian Journal of Psychological Counseling
Chairperson, Ethics Committee, IRB

Dr. Alfred Job Daniel, MS Ortho
Chairperson, Research Committee &
Principal

Dr.Gagandeep Kang, MD, Ph.D, FRCPath
Secretary, Research Committee, IRB
Additional Vice Principal(Research)

November 22, 2011

Dr. Elizebeth Sunny
PG Registrar
Department of ENT
Christian Medical College
Vellore 632 002

Sub: **FLUID Research grant project NEW PROPOSAL:**
Assessment of outcome of functional endoscopic sinus surgery in patients with chronic sinusitis with or without sinonasal polyposis
Dr. Elizebeth Sunny, PG Registrar, ENT, Dr Rupa Vedantam., ENT

Ref: IRB Min. No. 7660 dated 18.11.2011

Dear Dr. Sunny,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Assessment of outcome of functional endoscopic sinus surgery in patients with chronic sinusitis with or without sinonasal polyposis" on November 18, 2011.

The Committees reviewed the following documents:

1. Format for application to IRB submission
2. Information Sheet and Informed Consent Form(English, Tamil, Bengali and Hindi)
3. Proforma
4. Cv of Dr. Elizabeth Sunny
5. A CD containing document 1 – 5

The following Institutional Review Board (Ethics Committee) members were present at the meeting held on November 18, 2011 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore- 632002.

INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE
VELLORE 632 002, INDIA

Dr.B.J.Prashantham, M.A.,M.A.,Dr.Min(Clinical)
Director, Christian Counseling Centre
Editor, Indian Journal of Psychological Counseling
Chairperson, Ethics Committee, IRB

Dr. Alfred Job Daniel, MS Ortho
Chairperson, Research Committee &
Principal

Dr.Gagandeep Kang, MD, Ph.D, FRCPath
Secretary, Research Committee, IRB
Additional Vice Principal(Research)

Name	Qualification	Designation	Other Affiliations
Dr. B.J.Prashantham	MA (Counseling), MA (Theology), Dr Min(Clinical)	Chairperson(IRB)& Director, Christian Counselling Centre	Non-CMC
Mr. Harikrishnan	BL	Lawyer	Non-CMC
Mrs. S. Pattabiraman	BSc, DSSA	Social Worker, Vellore	Non-CMC
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M.Phil, BL.	Legal Advisor, CMC.	
Dr. Gagandeep Kang	MD, PhD, FRCPath.	Secretary IRB (EC)& Dy. Chairperson (IRB), Professor of Microbiology & Addl. Vice Principal (Research), CMC.	

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any serious adverse events occurring in the course of the project, any changes in the protocol and the patient information/informed consent and requires a copy of the final report.

A sum of ₹ 49400/- (Rupees Forty nine thousand four hundred only) is sanctioned for 1 year ½ months.

Yours sincerely,

Gagandeep Kang, MD, PhD, FRCPath
Secretary (Ethics Committee)
Institutional Review Board

Secretary
Institutional Review Board
(Ethics Committee)
Christian Medical College
Vellore - 632 002, Tamil Nadu, India

d.Antiplagiarism Certificate