ASSESSMENT OF POST OPERATIVE OLFACTORY DYSFUNCTION, NASAL MORBIDITY AND QUALITY OF LIFE IN PATIENTS UNDERGOING EXPANDED ENDOSCOPIC APPROACH

A dissertation submitted to the Tamil Nadu Dr. M. G. R. Medical University, Chennai in partial fulfilment of the requirement for the MS Otorhinolaryngology (Branch IV) degree examination to be held in May 2020

ASSESSMENT OF POST OPERATIVE OLFACTORY DYSFUNCTION, NASAL MORBIDITY AND QUALITY OF LIFE IN PATIENTS UNDERGOING EXPANDED ENDOSCOPIC APPROACH

Dissertation submitted to the

THE TAMIL NADU DR. MGR MEDICAL UNIVERSITY, CHENNAI

In partial fulfilment of the requirements for the degree of

MASTER OF SURGERY

IN

OTORHINOLARYNGOLOGY

By

LIDIA DENNIS CHIRAMAL

Register number: 221714353

DEPARTMENT OF OTORHINOLARYNGOLOGY

CHRISTIAN MEDICAL COLLEGE

VELLORE

MAY 2020

CERTIFICATE

This is to certify that "**Assessment of post-operative olfactory dysfunction, nasal morbidity and quality of life in patients undergoing expanded endoscopic approach**" is the bona-fide work of Dr. Lidia Dennis Chiramal under my supervision in the Department of Otorhinolaryngology, Christian Medical College Vellore in partial fulfilment of the requirements for the M.S ENT Examination Branch IV of the Tamil Nadu Dr. M.G.R Medial University to be held in May 2020 and no part thereof has been submitted for any other degree.

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Dr. Rita Ruby Anbuselvi

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CERTIFICATE BY THE PRINCIPAL

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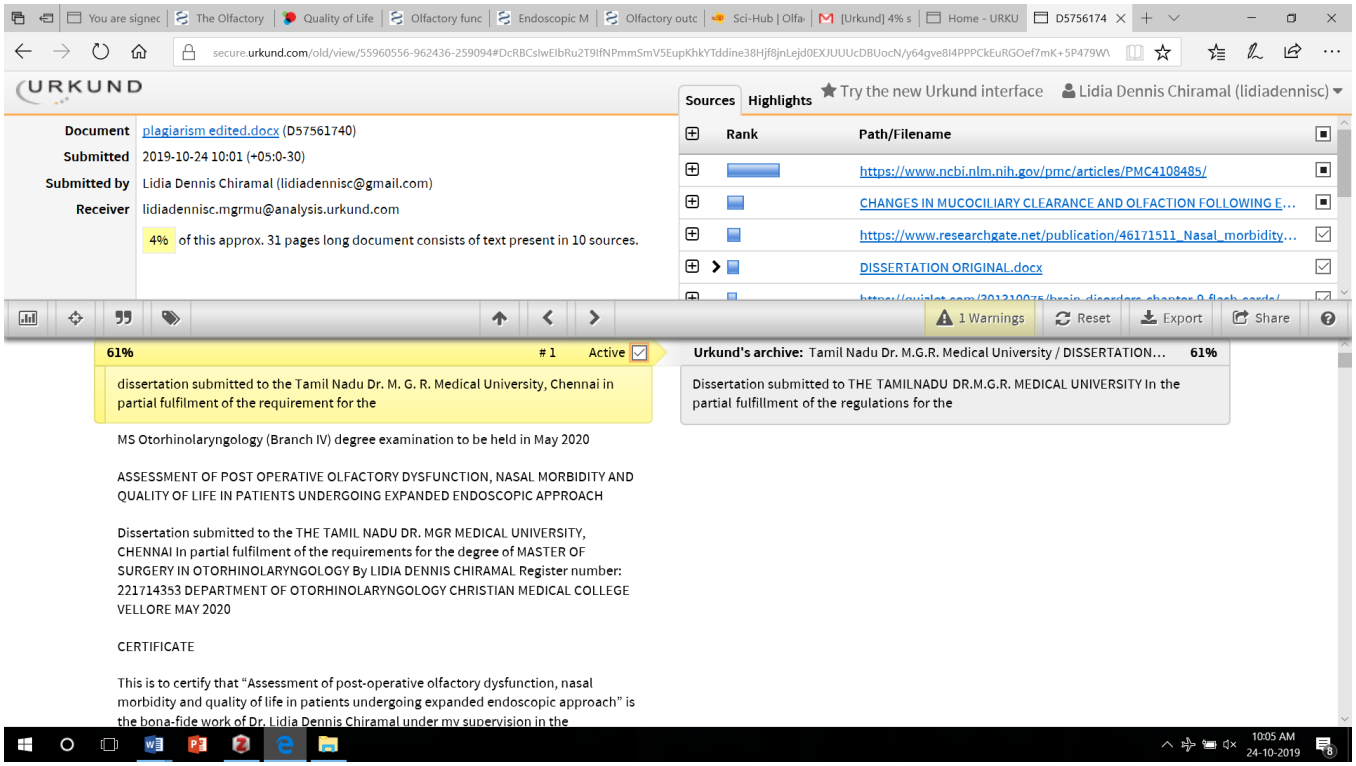
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CONTENTS

INTRODUCTION

The human body interacts with the outside world with the help of a wide array of sensory inputs.

Olfaction, the sensation of smell is an important aspect of the sensory system. Smell and taste both come under the term “Chemo-sensation” which is the ability to transduce chemical stimuli into electrical stimuli which translate as sensations in the brain.

Potential harms like smoke, toxic chemicals and spoiled food can be detected with the sense of smell. (1)

Human beings rely on their sense of smell for the detection of potential harms such as fire, smoke, toxic chemicals, and also spoiled food. Olfaction also affects the general mood, may be associated with memories or feelings of pleasure. Any dysfunction of the sense of smell can hence cause distress to the patient.

In humans, the olfactory epithelium is found high in the nasal vault. It measures around 1 square centimetre of surface area on each side of the nose and spans over the undersurface of the cribriform plate, the medial surface of the superior turbinate, the upper nasal septum and on the medial surface of the middle turbinates. Olfactory and taste sensory neurons are unique as they are able to regenerate and replace themselves throughout the lifespan. (2)

Traditionally, transcranial and transsphenoidal microscopic approaches have been used for pituitary tumours and other skull base tumours since the introduction of the surgical microscope since the 1960s.(3)

In the last twenty years, endoscopic endonasal surgery for skull base pathology has emerged as a treatment alternative to traditional open approaches. This approach has comparable disease control rates and shorter hospital stays.
This approach however is associated with post-operative nasal morbidity like impaired olfaction, nasal obstruction and altered taste sensation. (4)
Nasal morbidity following endoscopic sinus surgery has been studied extensively. However in endoscopic sinus surgery, this is done for pre-existing nasal conditions.

In endoscopic approach to the skull base the native nasal mucosa is non – inflammatory and pristine and the aggressive mucosal resection that is required for exposure or for the vascular flap is the reason for the morbidity.(4)
In expanded endoscopic approach, middle turbinectomy, superior turbinectomy, and posterior septotomy is done for wide exposure and improved accessibility to the tumour. A wide sphenoidotomy and ethmoidectomy were later performed to identify anatomical landmarks within the sphenoid bone.(5)

In this study, our goal was to look at the immediate and long term iatrogenic nasal complications in patients undergoing the expanded endoscopic approach to skull base tumours in the context of olfaction and quality of life questionnaire. The importance of informing the patient about the possible nasal morbidity and olfactory dysfunction associated with this approach was explored.

AIMS AND OBJECTIVES

AIM

To assess the post-operative olfactory impairment, quality of life and nasal morbidity in expanded endoscopic approach (EEA)

OBJECTIVES

In patients undergoing expanded endoscopic approach for skull base tumours:

- To assess the extent of olfaction impairment following an expanded endoscopic approach
- To follow up these patient over 3 months and to see the extent of recovery olfaction in these patients
- To assess how quality of life affected in the context of sinonasal symptoms in these patients

REVIEW OF LITERATURE

ANATOMY

The nose is the sense organ for olfaction and respiration in the body. The anterior limit of the nasal cavity is the nostrils and it extends posteriorly upto the choanae, where it opens into the nasopharynx. It is divided into left and right by a central nasal septum.

Each half has a roof, floor, medial wall and lateral wall and measures 5 to 7 cm in length, 5cm in height and 1.5cm in width at the floor. The width at the roof is however only 1-2mm.The roof of the nasal cavity is formed by the skull base which slopes downwards antero-posteriorly. The superior aspect of the nasal cavity – the superior turbinate, upper aspect of the middle turbinate and postero-superior part of the nasal septum is lined by olfactory mucosa. The rest of the nasal cavity is lined by respiratory mucosa except for the vestibule which is lined by squamous epithelium.

Nasal septum

The nasal septum serves many functions including support of dorsum of nose, dividing the nasal cavity into two halves, maintaining the nasal tip, and olfaction. (6) It consists of a bony, a cartilaginous and a membranous part.

The bony portion of the septum is formed by the perpendicular plate of the ethmoid bone, the vomer, palatine bone and the maxillary crest. The upper third of the bony nasal septum is formed by the ethmoid bone which is continuous with the cribriform plate and crista galli. The perpendicular plate also articulates with the sphenoid crest posteriorly, the vomer postero-inferiorly and the septal cartilage antero-inferiorly. The

vomer forms the postero-inferior part of the bony nasal septum. It has two alae which articulates with the maxillary and palatine crest. The posterior edge of the vomer forms the free edge of the nasal septum posteriorly. The cartilaginous portion of the nasal septum consists of the quadrilateral cartilage which is also called septal cartilage (6)

The superior part of the septum is supplied by the internal nasal branch of the anterior ethmoidal nerve. The postero-inferior part is supplied by the nasopalatine branch of the pterygopalatine ganglion. Special sensory nerves or olfactory nerves are confined to the upper part or olfactory area. (2)

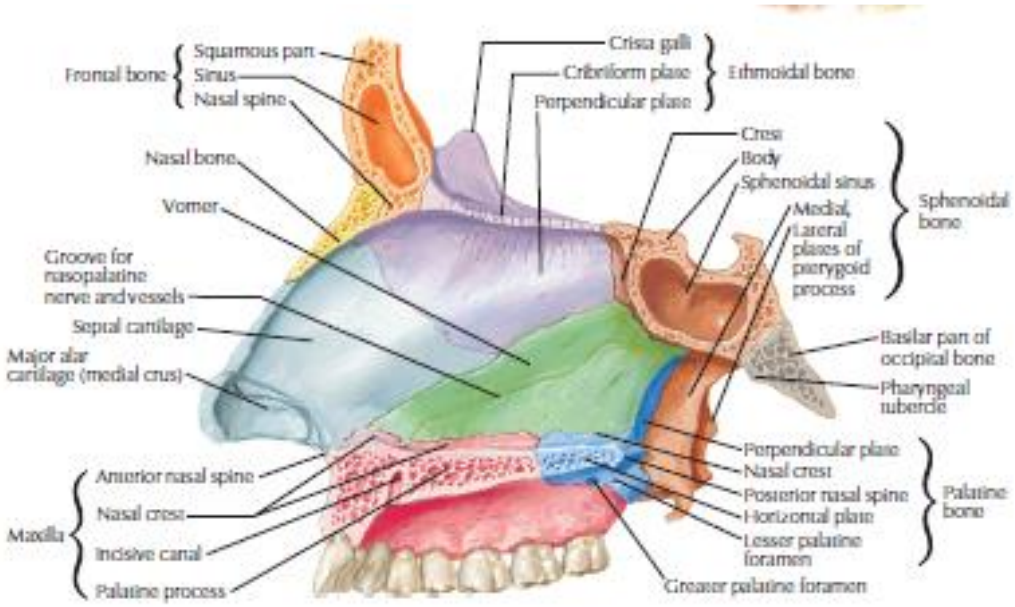


Figure 1 - Nasal septum (Netter's Atlas of the human anatomy)

Lateral wall of nose

The lateral wall of the nasal cavity has 3 projections called the turbinates- the inferior, middle and the superior.

The middle and superior turbinates are part of the ethmoid bone while the inferior turbinate is an independent osseous tissue. The turbinates are osseous projections which are mucosa covered and are filled with vascular structures and venous sinusoids. This serves to warm and humidify air and modify air resistance.
The space between the lateral nasal wall and the turbinates' forms spaces called the inferior, middle and superior meatus.

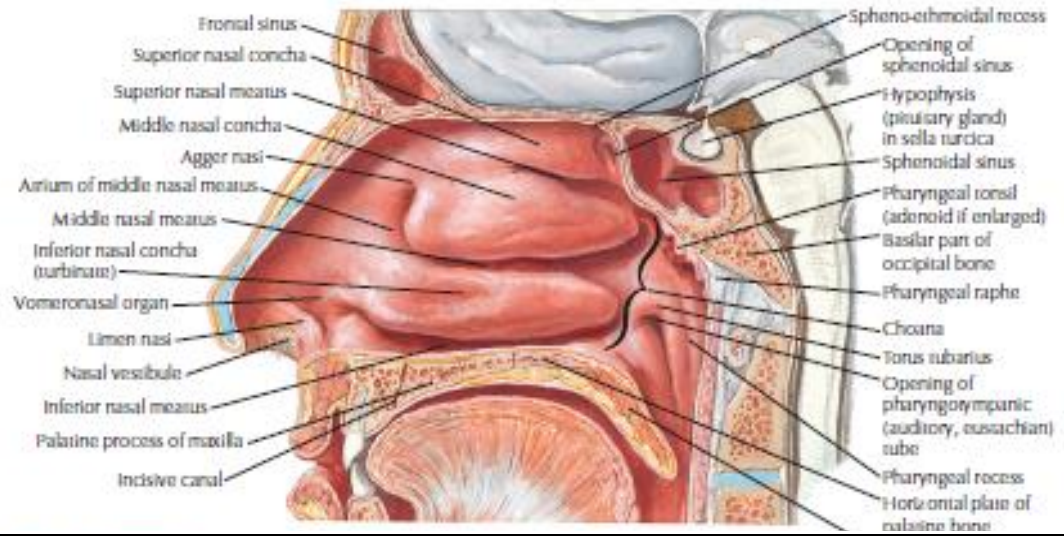


Figure 2 - Lateral wall of nose showing the turbinates (Netter's atlas of the human anatomy)

Olfactory epithelium

In humans, olfactory epithelium is located high within the nasal vault. It appears slightly yellowish on gross examination. (7) It measures around one square centimetre of area on each side. It covers the under-surface of the cribriform plate, the medial surface of the superior turbinate, the medial surface of the middle turbinates and the upper part of the nasal septum. (2)

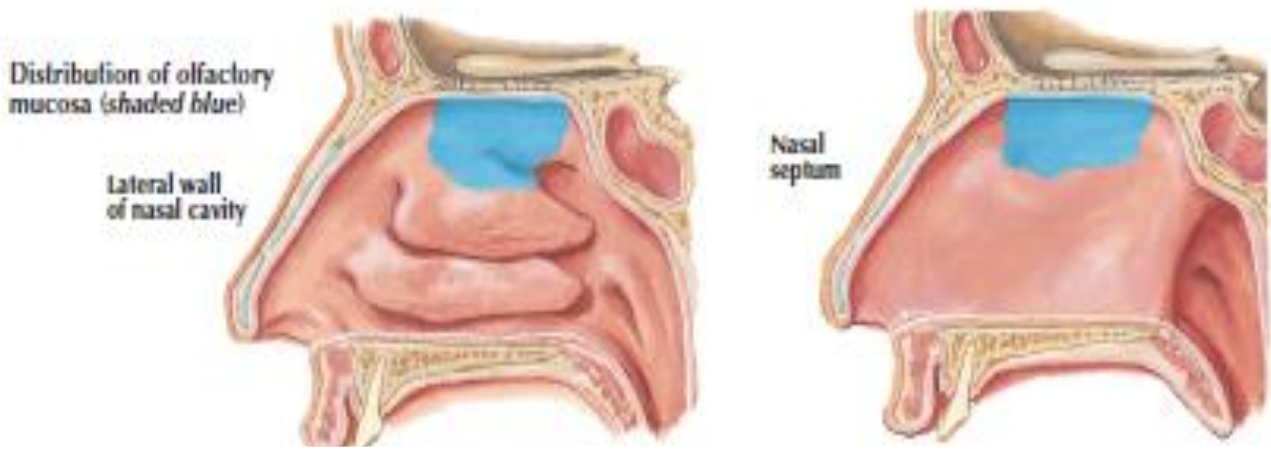


Figure 3 - Area inside nasal cavity covered by olfactory mucosa (Netter's atlas of human anatomy)

The epithelium is pseudo stratified columnar without cilia or goblet cells. It rests on a lamina propia which is very vascular with no submucosal layer. Histologically, olfactory mucosa is made of three layers, epithelial layer, basal lamina and lamina propria which adheres to the underlying bone or cartilaginous tissue.

The underlying lamina propria contains the tubuloacinar olfactory glands – Bowman's glands. The small nerves located within the lamina are the olfactory nerves. (8)

The olfactory epithelium is found be continuous and sheet-like in the foetus. However it is gradually replaced by non-olfactory respiratory epithelium with progress in age. This explains the reason for diminishing olfaction with age or disease.(2)

The olfactory pits are invaginations of the olfactory epithelium into the underlying connective tissue. These structures measure 150 to 200 μm in depth and 50 to 100 μm in diameter. It is hypothesized that these pit create a pouched environment to prolong the odorant association with the specific receptors. They are useful markers to distinguish olfactory mucosa from the respiratory mucosa.(7)

HISTOLOGY OF THE OLFACTORY EPITHELIUM

The olfactory epithelium consists of many types of cells. There are five principle types:(9)

- Olfactory receptor neurons
- Sustentacular cells
- Basal cells
- Microvillar cells
- Bowman's glands

Olfactory receptor neuron

This is a true bipolar neuron which is a specialised sensory cell for detecting odorants. It projects a single dendrite to the surface of the olfactory epithelium and a single axon to the olfactory bulb. There are ten to twenty million olfactory receptor neurons in the nasal cavity. They are found interspersed with the sustentacular cells and can be at various stages of maturity.

The dendrite has a thickened club-like ending known as the olfactory vesicle. This extends upto the epithelial surface in the form of non-motile cilia. The odour molecules are believed to bond to receptors on the cell membrane of these cilia. The cilia increase the effective surface area of olfactory epithelium to 22 square centimetre.

The proximal end of the olfactory receptor neuron is a thin unmyelinated axon. The axons all join to together to form fascicles which are then myelinated. These

myelinated fibres pass through the foramina in the cribriform plate to form the first order synapse in the olfactory bulb.

Olfactory receptors are expressed on the cilia of the matured olfactory receptor neurons. It is believed that there are more than 1000 different gene sequences that encode different olfactory receptor types. Each receptor neuron expresses only one type of olfactory receptor. All the axons of the olfactory receptor neurons expressing a particular receptor type converge onto a few specific glomeruli in the olfactory bulb.'

Sustentacular cells

Sustentacular cells or supporting cells are irregular columnar cells with large nuclei and multiple long villi that are found in the olfactory mucosa surrounding and superficial to the olfactory receptor neurons. It helps in regulating and maintaining the ionic milieu around the olfactory receptors for signal transduction to occur. It is also believed to help in proliferation of the olfactory receptor neurons. There are tight barrier junctions between the dendrites of the olfactory receptor neurons and the sustentacular cells.

Basal cells

The olfactory mucosa consists of 2 types of basal cells: horizontal and globose. They are the stem cells of the olfactory epithelium and is important for normal cell turnover and for regeneration of damaged cells.

Globose cells are thought to be the precursors that differentiate into olfactory neurons. Olfactory neurons are unique as they have the ability to regenerate from a precursor population.

Horizontal basal cells are thought to have the ability to differentiate into all cell lineages of the olfactory mucosa.(10)

Microvillar cells

These are small cells which are found near the epithelial surface and are covered in microvilli. They are flask shaped cells with a tuft of microvilli that extends into the mucus layer of the epithelium. It also has a thin axon like cytoplasmic process extending into the epithelium, making it a bipolar cell. Their role in olfaction is unknown.

Bowman's glands

The Bowman's glands are found within the lamina propria. It produces olfactory mucus which is secreted onto the surface of the olfactory epithelium. The ionic composition and fluid content of the olfactory mucus differs from that of the non-olfactory mucosa covering the rest of the nasal cavity.

The ionic microenvironment is necessary for the sensory transduction to occur. The cilia of the olfactory receptor neurons are suspended in the olfactory mucus layer.

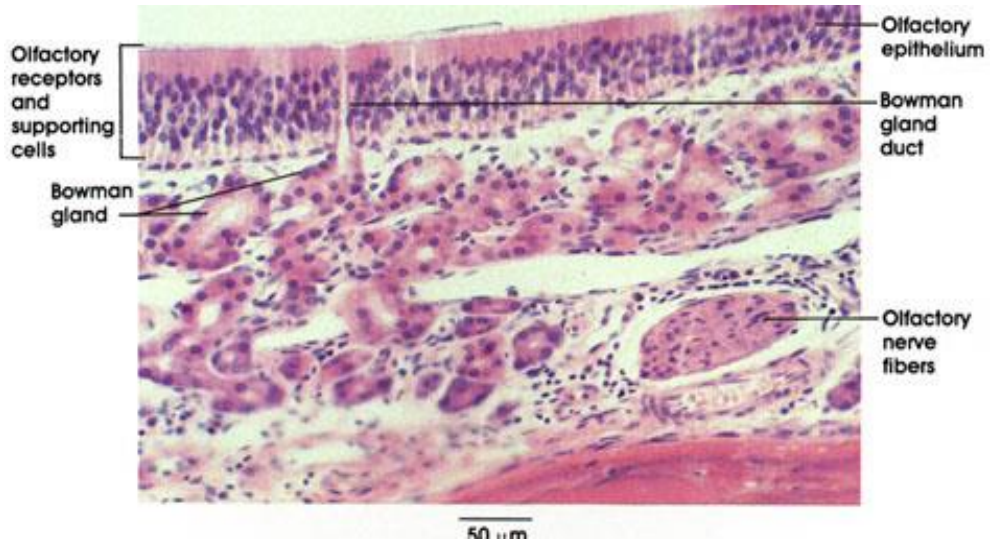


Figure 4 - Histology of olfactory mucosa (Source: https://lookfordiagnosis.com/mesh_in)

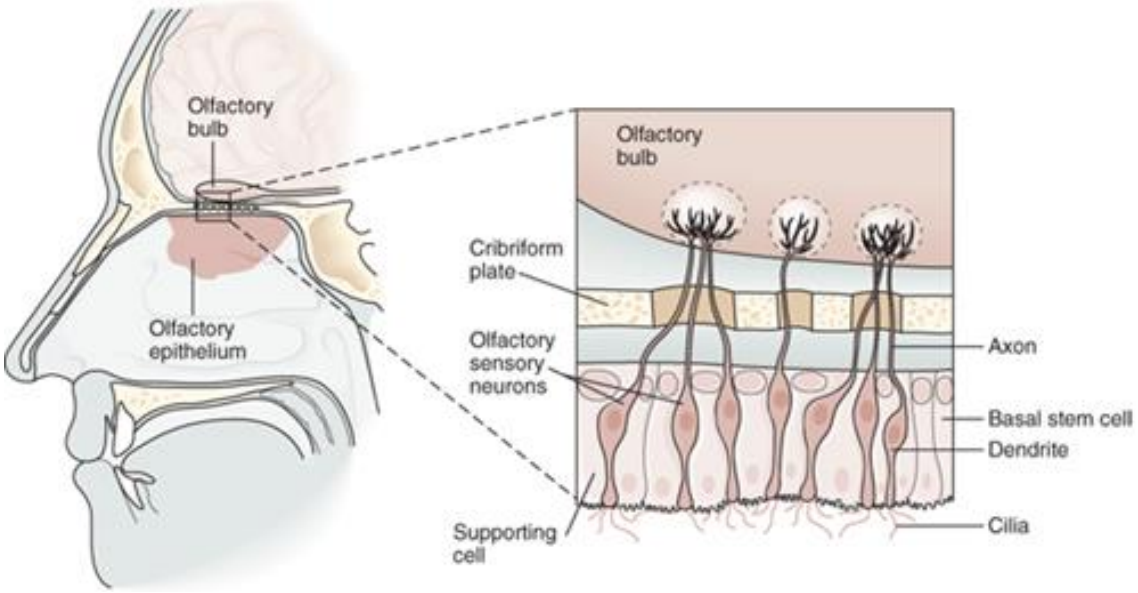


Figure 5 - Olfactory epithelium (Source: Ganong's review of Medical physiology 25th edition)

PHYSIOLOGY

Odour perception is a function as a result of input of from four cranial nerves – the olfactory, the vagus, the trigeminal and the glosso-pharyngeal.

The olfactory nerve, which is the first cranial, requires the odorant molecules to reach the olfactory mucosa which is in the postero-superior part of the nasal cavity to get stimulated. This is by diffusion and more importantly by inhalation (orthonasal flow). It can also be stimulated by eating when a retronasal flow of the molecules contributes greatly to the taste of the food.

At physiological airflow rates, 50% of the total airflow passes through the middle meatus, 35% through the inferior meatus and 15% through the olfactory region. (11)

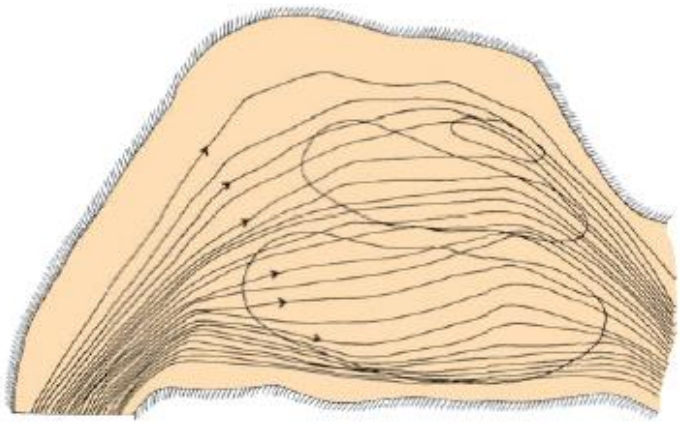


Figure 6 -Streamline patterns for resting inspiratory flow through a scale model of a healthy human adult (Source: The biophysics of nasal airflow: Otolaryngology Clin North Am 1989:22:265)

Olfaction occurs when odorant molecules enter the nose along with the inspired air. This then binds to the olfactory receptor neuron. Sniffing increases turbulence in airflow and causes greater delivery of airflow to the olfactory region.(2)

In order to detect odours, the odoriferous substance should be dissolved first. The dissolved odour molecules then bind to odour receptors molecules which are present on the olfactory cilia. The olfactory epithelium is kept moist by a serous secretion produced by the Bowman's glands which lie within the olfactory epithelium. This secretion is delivered to the surface via ducts. This helps to dissolve the odorant molecules. This stimulates the odour-binding receptors in the epithelium which fires an impulse.

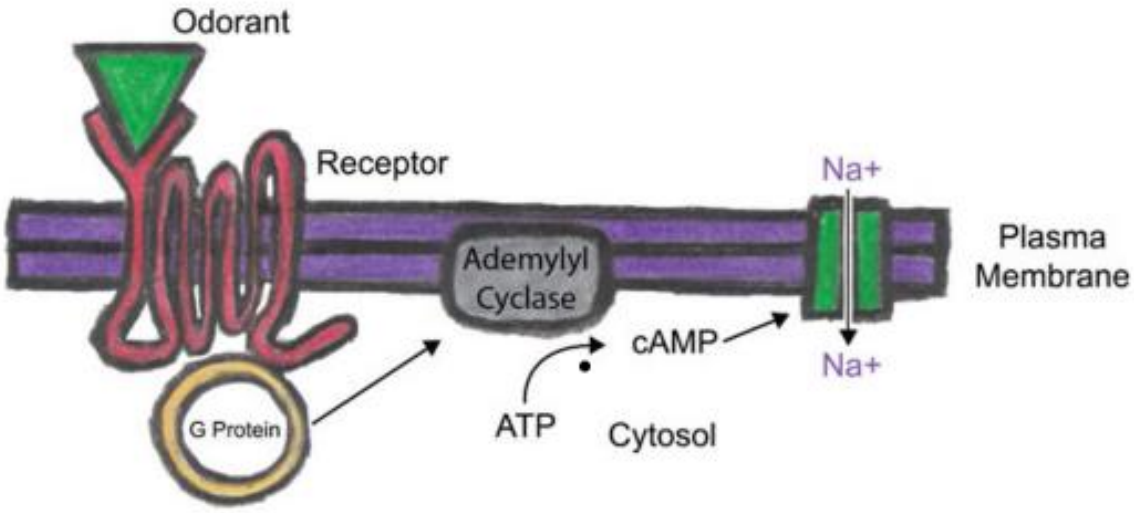


Figure 7: Sequence of events in chemical process of olfaction (Source John Kimball – The sense of olfaction)

The binding of the molecule will lead to activation of the receptor coupled G- protein which leads to signal transduction. The unmyelinated axons of the olfactory cells leave the epithelium and form many small olfactory nerves within the lamina propria. These impulses are then conducted in the nerves that pass through the cribriform plate and synapse on the olfactory bulbs. (8)

OLFACTORY PATHWAY

The olfactory pathway can be divided into peripheral and central systems.

Peripheral olfactory pathway

There are approximately 10 to 20 million olfactory cells present in the nasal olfactory mucosa. These olfactory receptor neurons have unmyelinated axons proximally that joins to form mylinated fibres called fila olfactoria. The fila pass through the foramina in the cribriform plate to synapse onto the olfactory bulb.

The distal end of these receptor neurons have cilia which project into olfactory mucus layer in order to bind to odorant molecules.

Central olfactory pathway

The olfactory receptor neurons has axon bundles that pass through the foramina in the cribriform plate to converge onto the olfactory bulb. The olfactory bulb is seen in the anterior cranial fossa adjacent to the frontal cortex. The layers of the bulb include: the olfactory nerve layer, the glomerular layer, external plexiform layer, mitral cell layer, internal plexiform layer and the granular layer.

In the olfactory bulb, there is a complex signal transmission that is transmitted to the various parts of the central nervous parts.

The second order neurons from the olfactory bulb form the olfactory tract. This tract travels along the base of the frontal lobe. This terminates on the apical dendrites of the pyramidal cells present in olfactory cortex.

There are five principle regions – anterior olfactory nucleus, olfactory tubercle, amygdala, pyriform cortex and entorhinal cortex. The information is then transmitted to frontal cortex directly or via thalamus to orbitofrontal cortex. From these regions, information travels directly to the frontal cortex or via the thalamus to the orbitofrontal cortex. Conscious discrimination of odours is dependent on the pathway to the orbitofrontal cortex. The cortical representation of olfaction is asymmetric as the orbitofrontal activation is generally greater on the right side than on the left. The pathway to the amygdala is believed to be involved with the emotional responses to olfactory stimuli, and the pathway to the entorhinal cortex is concerned with olfactory memories.

Free endings of many trigeminal pain fibres are also found on the olfactory epithelium. Irritants such as menthol, ammonia, chlorine and peppermint stimulate them. These irritants may also initiate sneezing, respiratory inhibition or lacrimation. (12)

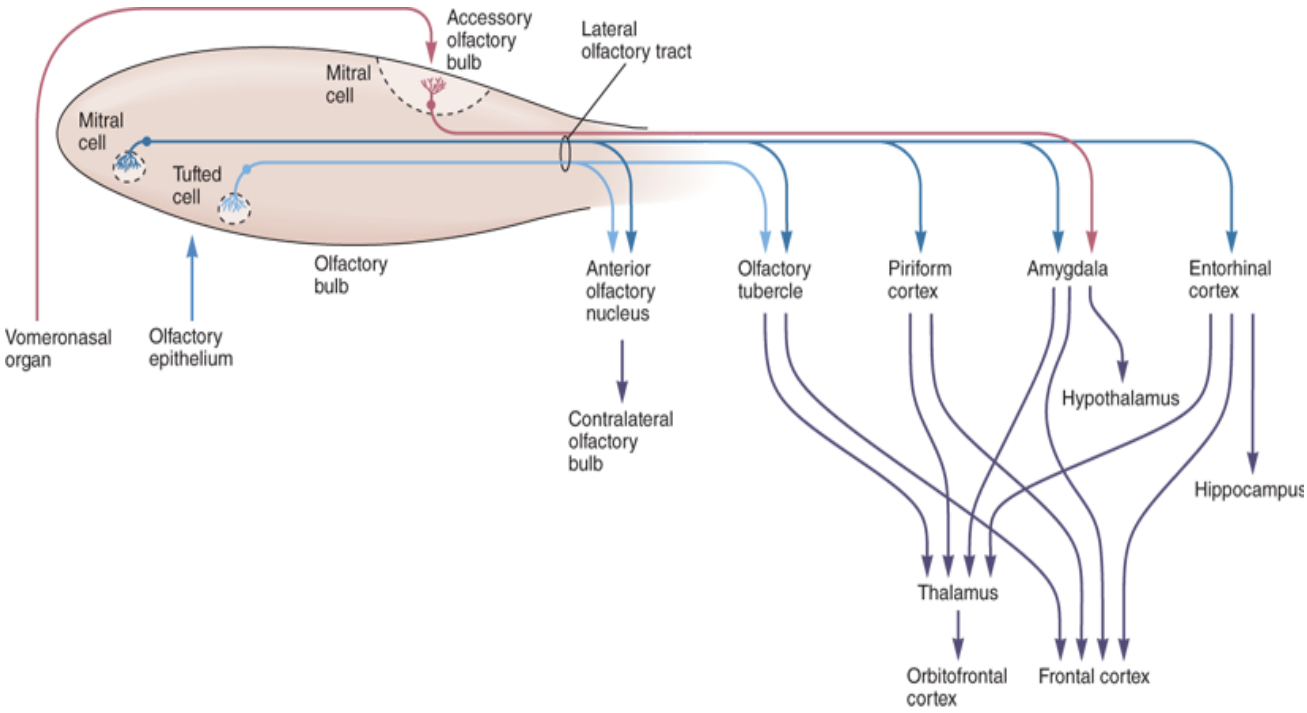


Figure 8 : Olfactory pathway (source: Ganong's review of medical physiology 25th edition)

THEORIES OF OLFACTION

In the past years, many theories linking odour to molecular structure have been proposed. However it is still poorly understood.

The vibrational theory of olfaction

This theory was first proposed by Malcolm Dyson in 1928. This suggested that the odorant quality is based on vibrational recurrence of a molecule in the infrared range.

Spectroscopic studies conducted by Dyson revealed a correlation between certain odours and the vibration frequencies of molecules. However limited success was obtained in finding correlations between odour character and low-frequency molecular vibrations. This theory also failed to explain the fact that some enantiomers produce different smells although their vibrational spectra were identical. Moreover, no biological mechanism was identified as a plausible protein-based spectroscope able to convert molecular vibrations into neuronal activation. As a result, the theory has been largely disregarded.(15)

The 'profile-functional group' theory of olfaction

The presence of certain chemical groups in a molecule was associated with a particular odour. In 1957, Beets proposed the 'profile functional group' theory. He proposed that odour is determined by two separate contributions: one from the form, size and bulk shape of the molecule, the other from its functional group or groups that determine the molecular orientation at the receptor site. The ability of a functional

group to orient effectively the odorant at the site, was supposed to be partly determined by its tendency to participate in hydrogen bonding interactions.(13)

Electrochemical theory of olfaction

This was proposed by Briggs and Duncan in 1962. They hypothesized that since the olfactory region of the nasal cavity is yellow while the respiratory epithelium is not, it contains carotenoids which form the protein bound molecular receptors of the odorant molecules. (49)

Chromatographic theory of olfaction

In 1967, Mozell proposed the theory that olfactory discrimination like chromatography depends on the ability with which the molecules of each odorant migrates along the mucosa. The molecules of some chemicals which had a greater capacity to migrate along the mucosa could reach the olfactory regions faster. (50)

The steric theory of olfaction

This theory suggests that air-borne molecules are smelt when they fit into the complementary receptor sites. Hence specific odour quality is due to the specific shape and size of the molecule. (14) This was like a lock and key mechanism. The binding of the molecule will lead to activation of the receptor coupled G- protein which leads to signal transduction.

TESTS OF OLFACTION

The usual tests done for olfaction during a routine neurological work up only seeks to establish if the olfactory nerve is functional. There is no objective measurement of the degree of functioning.

The test usually entails the testing of 3 odorants for identification (like coffee powder/ cloves) It does not quantify the degree of olfaction. In a routine examination this suffices. However when patients seek medical attention for olfactory complaints or in studies to specifically look at the degree to which olfaction is affected, an objective test is required to quantify it. An ideal test would be able to detect severity of the loss and to measure improvement or deterioration with intervention or over time. (16)

Many smell tests have been created for the screening of olfactory dysfunction. These include tests of odour identification, detection, discrimination and memory.

University of Pennsylvania Smell Identification Test (UPSIT)

The UPSIT is a smell identification test which is marketed by Sensonics International. It is one of the most commonly used tests in the world.

It comprises of a kit containing 40 “scratch and sniff” microencapsulated odorant trips. These strips are divided into 4 booklets containing 10 each. For each strip the patient is asked to identify the correct smell from a choice of four possible answers. The total number answered correctly is compared with age and sex specific

thresholds. Its advantage is its ability to be self-administered and to be able to assess the severity of olfaction dysfunction. (17)

Sniffin' test

The Sniffin' Sticks test (Burghardt®, Wedel, Germany) is another test that is used for psychophysical testing of olfaction. It was developed in 1997 by Hummel and it is validated in several European countries. (18)A semi-objective assessment of the patient's olfaction can be done by 3 parts – threshold test, identification test and discrimination test. The 3 subgroups finally give a global olfactory score and the results are interpreted according to normal values for gender and age groups. The test is comprised of felt pens. The tips are impregnated with odorant substance in propylene glycol. Each pen is presented for 3 to 4 seconds, 2cm from nostril and patient is asked to sniff twice. Although it is not practical in routine clinical evaluation this test can be useful for looking at olfaction in pathological conditions. (19)

CCCRC

The Connecticut Chemosensory Clinical Research Centre developed a two part test comprising of odour identification and odour threshold. The odour threshold test comprises of n-butyl alcohol (1-butanol) as the odorant.

This is ideal as odorant as it is highly soluble in water, has low toxicity, is readily available, and has neutral odour quality.

The threshold testing comprises of aqueous dilutions of 1-butamol in successive dilutions differing by a factor of 3. The highest dilution is 4%. The test solution is

taken in 250ml polyethylene bottles with a pop up spout and that fitted into the nostril. The bottle is then squeezed and the patient is asked to sniff simultaneously. The test kit also contains six bottles containing distilled water as blanks. The patient is given a test bottle along with a blank and is asked to decide which bottle has a detectable odour or smelled stronger. If incorrect, the patient was given the next higher concentration with a blank. Four correct answers in a row marked the end of testing. Each nostril is separately tested.(20)

The point of transition between no detection of smell to identification of smell is considered as the threshold for that individual. Based on the results of the 3 components of the CCCRC test, a composite score is calculated. A diagnosis of anosmia, hyposmia and normosmia may be made, depending on the composite score obtained. As the CCCRC test is easy to perform and can be administered within a few minutes, it is the preferred test for assessment of olfaction.

Odour identification test consisted of an item presented to the patient. The patient was then asked to identify the substance. A kit comprises of 180ml opaque plastic jars containing the odorant. Each nostril was tested separately. Patient was then asked to identify the substance from list of 20 items.

Electro-olfactogram

These are the electrical potentials originated in the olfactory epithelium in response to odour stimulation. The previously mentioned tests were psychophysical whereas this is an objective test. The EOG was first demonstrated and termed by Ottoson in 1959.(21)

It represents the sum of the electrical potentials of the olfactory receptor neurons. EOGs have been used for functional characterisation of the olfactory epithelium, the topographical distribution of the receptors and the expression of olfactory receptors to odorants.(22)

HISTORY OF ENDOSCOPIC SKULL BASE SURGERY

Since the beginning of the 20th century, the nasal cavity as a corridor to the skull base has been explored. The initial attempts at excision of the pituitary via transcranial route were associated with a high mortality rate. Pituitary tumour excision via the transsphenoidal route was initially tried in the 1890s to avoid the complications associated with the transcranial approach. In 1906, Schloffer promoted the use of a transsphenoidal route as a safer approach to the sella turcica. He reported the first successful transsphenoidal excision of pituitary tumour.(23)

Cushing refined the transsphenoidal route from 1910 to 1925 and used it to operate on 231 pituitary adenomas with a mortality rate of 5.6%. But with increasing expertise with transcranial approach, he was able to reduce mortality to 4.5%. He found that he was able to get better decompression of the optic apparatus, which resulted in better recovery of vision and lower recurrence rate.

Hence the transsphenoidal approach was abandoned in favour of the transcranial approach. Norman Dott, a contemporary of Cushing, continued practising the transsphenoidal approach in Scotland and also introduced it to Gerard Guiot.(23)

In the 1960s, Gerard Guiot published excellent results with the transsphenoidal approach. This revived the transsphenoidal approach. Jules Hardy, another contemporary of Gerard Guiot introduced the operating microscope to refine the

procedure. This made a great impact on its efficacy and also decreased surgical morbidity.

In the 1960s, Harold Hopkins came up with the rod-lens system which was a great bound in the area of endoscopy. When endoscopes were combined with cameras and videos, it made its mark in the medical field. While otorhinolaryngologists began using it to develop endoscopic sinus surgery, it helped neurosurgeons as an alternative approach to skull base tumours.

In the 1990s, the first multidisciplinary endoscopic skull base teams were forged. (24)

In the modern era, endoscopic endonasal surgery has become an essential route. Since its inception, one of the major issues in transsphenoidal surgery has been the adequate visualization of anatomical structures. As transsphenoidal surgery evolved, technical advancements improved the surgical view of the operative field and the orientation. The operating microscope replaced Cushing's headlight and Dott's lighted speculum retractor, and fluoroscopy provided intraoperative imaging. These advances led to the modern concept of microsurgical transsphenoidal procedures in the early 1970s. For the past 30 years the endoscope has been used for the treatment of diseases of the sinus and, more recently, in the surgical treatment of pituitary tumours. The collaboration between neurological and otorhinolaryngological surgeons has led to the development of novel surgical procedures for the treatment of various pathological conditions in the skull base. The anterior, middle and posterior cranial fossa can be approached. It has proven to be a safe route however it has a learning curve and requires the surgeon to have a thorough understanding of the skull base anatomy.

ENDOSCOPIC SKULL BASE ANATOMY

The anatomy of the skull base from the frontal sinus to the clivus is very important in the context of transnasal endoscopic approach.

The sphenoid bone

The sphenoid bone is located at the centre of the skull base. A detailed knowledge of sphenoid bone anatomy is essential to understanding endonasal approach. It resembles a bat with its wings outstretched. The central body is cuboidal in shape. The body has the sphenoid sinus at its centre.

The sella turcica is located just superior to the sphenoid sinus. The clivus is found posteriorly. The lesser wings extend from the supero-lateral surface of the body of the sphenoid and from the inferior aspect, arises the greater wings. The space between the lesser and greater wings is called the superior orbital fissure. The pterygoid processes and the pterygoid plates are seen to be projecting downwards from the body of the sphenoid from both sides.

The inferior surface of the lesser wings forms the posterior roof of the orbits. The lesser wings also extend laterally to form the floor of the anterior cranial fossa. The planum sphenoidale forms the roof of the sphenoid sinus join with the lesser wings medially. Anteriorly the cribriform plate articulates with the planum. The posteromedial ends of the lesser wings form 2 processes called anterior clinoid process. This is where the optic canals are located.

A bony strut called optic strut extends from the body of the sphenoid bone to the anterior clinoid process. This separates the optic canal from the superior orbital fissure.

The chiasmatic groove or the prechiasmatic sulcus is a shallow depression which lies between the two optic foramina which is bounded anteriorly by the planum sphenoidal and posteriorly by the tuberculum sellae. The chiasmatic groove and the planum sphenoidale is separated by a bony ridge called limbus of the sphenoid.

Sella turcica

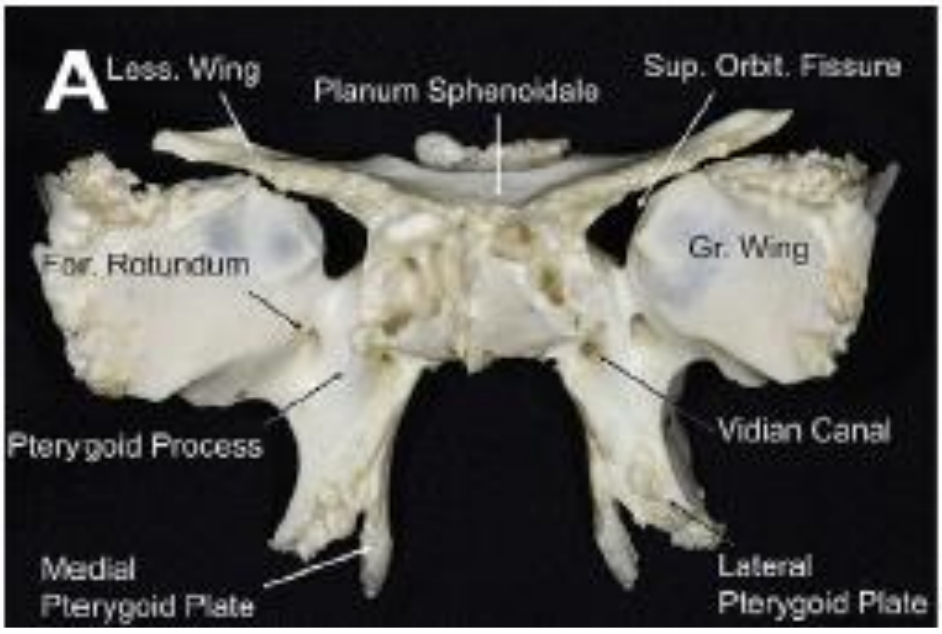
Axial view of the skull base from above shows the centre of the sphenoid which contains the sella turcica which is a saddle shaped depression on the roof of the sphenoid body. It houses the pituitary gland. The sella turcica is bounded anteriorly by the tuberculum sella and posteriorly by the dorsum sella.

The posterior clinoid processes are bony projections from the supero-lateral aspect of the dorsum sella. The cavernous sinuses and the carotid arteries lie on either side of the sella. The lateral boundary of the sella is the medial wall of the cavernous sinus. The middle clinoid are paired projections of bone that extends from the supero-lateral aspect of the sella to the apex of anterior clinoid. If it attaches to the anterior clinoid, it forms a complete osseous ring called caroticoclinoid ring. But usually the most common finding is a short segment of bone that does not extend all the way to the anterior clinoid. The middle clinoid is located at the inner bend of the anterior genu of the internal carotid in the parasellar region as it loops around it. This is an important

landmark in the endonasal route. It marks the level of the roof of the cavernous sinus. It also shows the transition point between the cavernous segment and the paraclinoid segment of the internal carotid artery.(25)

The roof of the sella is formed by a dural structure called the diaphragma sella. This extends from the tuberculum sella to the dorsum sella. The diaphragm sella extends laterally to continue with the roof of the cavernous sinus. The pituitary stalk traverses through an opening in the diaphragma sella called the pituitary aperture. There is no cerebrospinal fluid within the sella.

The greater wing of the sphenoid extends laterally to articulate with the zygomatic bone and posteriorly with the petrous part of the temporal bone. It forms part of the floor of the middle cranial fossa. (26)



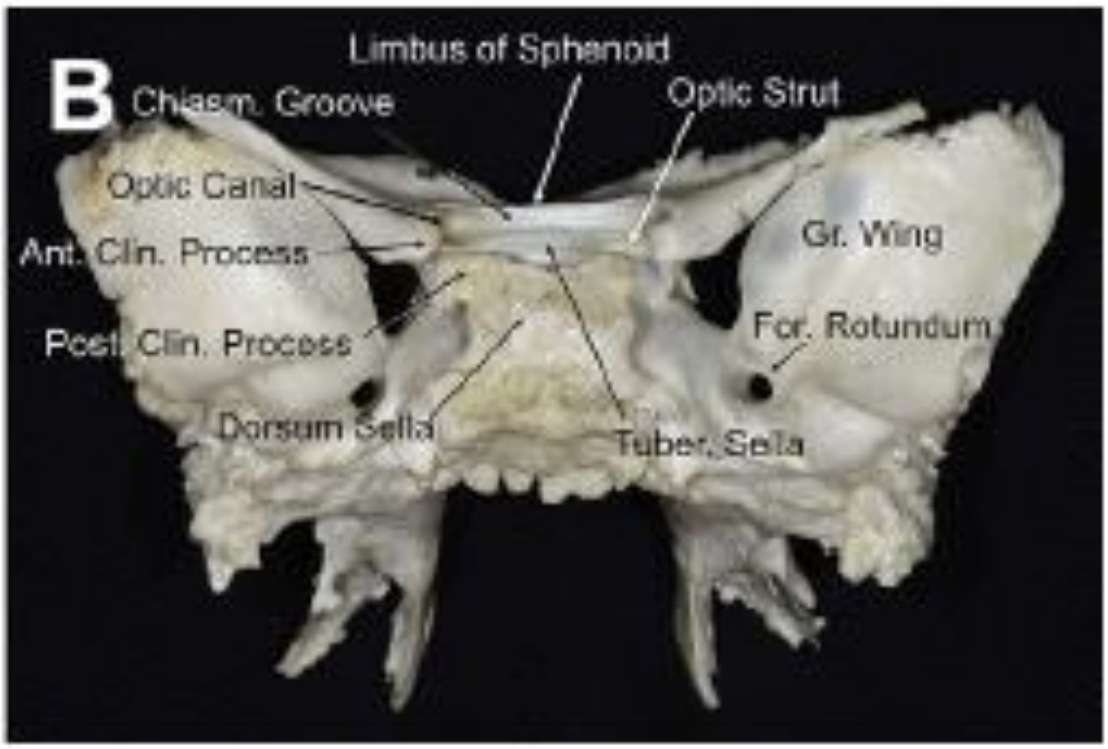


Figure 9 : Anatomy of the sphenoid bone (Source: Skull base anatomy; Chirag R Patel et al)

The sphenoid sinus

The sphenoid sinus varies from person to person in size, pneumatisation and septation.

Degree of pneumatisation varies with age.

There are 3 types of pneumatisation patterns described:

- Conchal
- Presellar
- Sellar

The conchal type has very less or no pneumatisation. The presellar type has some pneumatisation however it does not extend beyond the tubercullum sella. The sellar type which is the most common has the cavity extending beyond the floor of sella and occasionally into the clivus. This creates a depression called the clival recess.

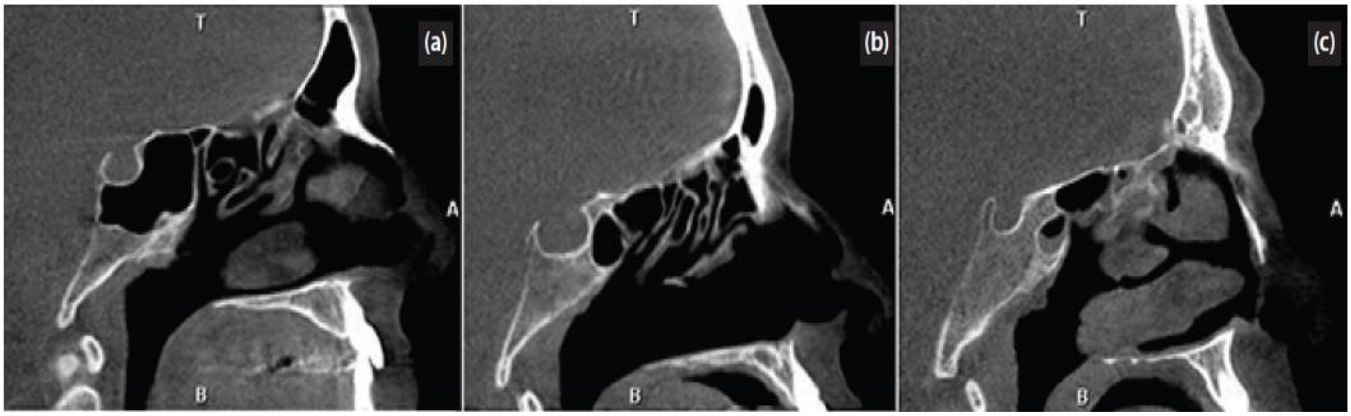


Figure 10 : Types of sphenoid sinus (Source Scott Brown textbook of otorhinolaryngology 8th edition)

The major sphenoidal landmarks become apparent with pneumatisation of the sphenoid. When viewed axially from below, in the centre we see the sella turcica, which is a bulge into the sinus. Beneath the sella, the middle clivus and the clival recess can be seen. The vertical paraclival segment of the internal carotid artery is covered by a plate of bone that lies on either side of the clival recess.

The internal carotid artery bifurcates from the common carotid in the neck and courses upward till it enters the carotid canal in the skull anterior to the jugular foramen. It ascends a short distance within the petrous portion of the temporal bone and then curves anteriorly and medially. It then enters the cavernous sinus. It first ascends towards the posterior clinoid process, then passes forward by the side of the sphenoid sinus and then curves upward on the medial side of the anterior clinoid process. This

loop occurs around the middle clinoid process. This anterior genu of the carotid forms a prominence in the lateral wall of the side of the sella. Above the prominence of the carotid, the optic nerve prominence can be seen as it traverses from the cisternal segment to the optic canal.

The opticocarotid recess is a depression seen just lateral to and between the carotid and optic nerve. This is formed due to the pneumatisation of the optic strut. This is an important landmark to identify the location of the optic nerve and carotid artery. Dehiscence of the bony covering of the carotid and the optic nerve should be noted in the imaging before proceeding for surgery.

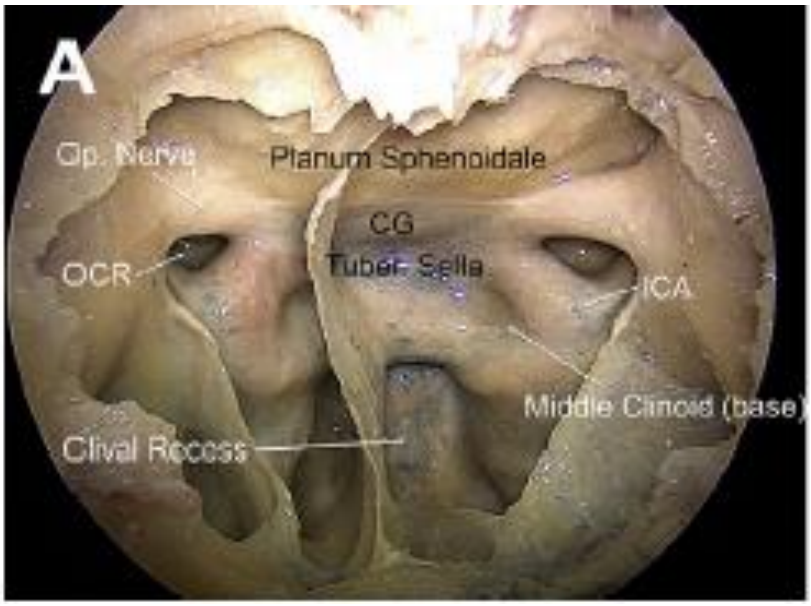


Figure 11 :Planum sphenoidale (Source: Skull base anatomy Chirag R Patel et al)

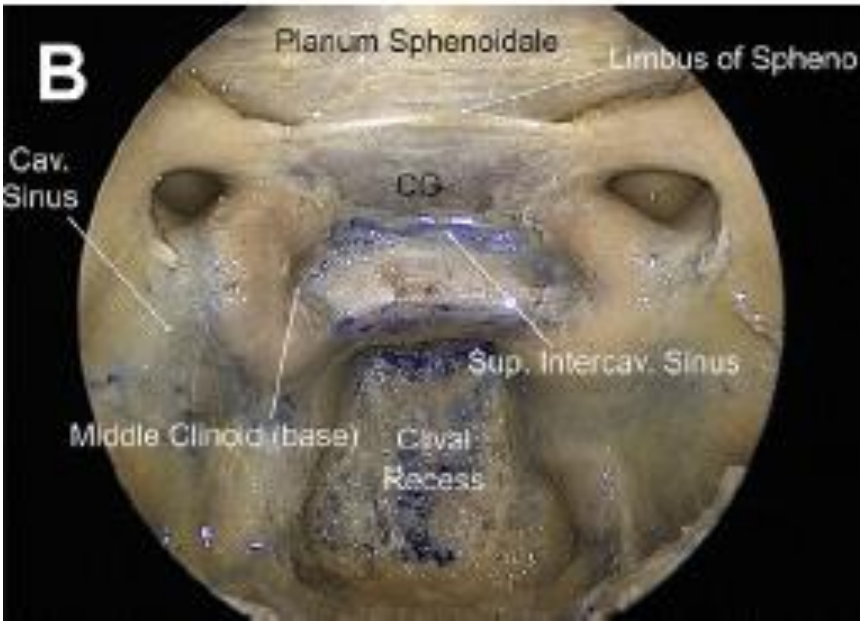


Figure 12 : Clivus (Source: Skull base anatomy, Chirag R Patel et al)

Anterior skull base

The ethmoid and the frontal bones form the anterior two-thirds of the anterior skull base. The planum sphenoidale forms the posterior one-third. The ethmoid bone has the cribriform plate and crista galli in the midline, the lamina papyracea laterally (which separates the orbit from the ethmoid sinuses and the fovea ethmoidalis superiorly which forms the roof.

The perpendicular plate of the ethmoid forms part of the bony septum by articulating with the vomer.(27)

The planum sphenoidale to the frontal sinus is seen once the ethmoid roof is exposed.. Across the ethmoid roof, the posterior ethmoid artery and the anterior ethmoid artery

can be seen. The posterior ethmoid artery is seen at the junction of the cribriform plate and the planum sphenoidale while the anterior ethmoidal artery is seen in the posterior aspect of the frontal recess. The posterior ethmoidal artery almost always runs within the bone in a lateral to medial direction. The anterior ethmoidal artery may be sometimes found running in a bony mesentry obliquely from postero-lateral to antero-medial direction across the skull base. These vessels need to be identified during an endonasal approach to avoid transecting them close to the orbit which may result in the vessels retracting and causing retrobulbar bleed.

The cribriform plate has multiple small openings through which the olfactory filae are transmitted. These filae are covered with dural invaginations hence the cribriform plate is an area which is prone for iatrogenic or spontaneous CSF leak. The roof of the ethmoid is another region that is thin bone and susceptible for CSF leak. (27)

The clivus

The clivus can be divided into 3 parts. The upper third is called the sellar clivus. This is formed by the dorsum sella and the posterior clinoids. It extends upto the level of the floor of the sella.

Dorrello's canal is a canal located at the transition point of the upper and middle clivus. The abducens nerve traverses the canal.

The middle third is called the sphenoidal clivus. This extends from the floor of the sella to the arch of choana. The lower third is called the nasopharyngeal clivus. This extends from the arch of choanae upto the foramen magnum.

The upper part of the clivus, that is the sellar clivus and sphenoidal clivus are part of the sphenoid bone. The lower nasopharyngeal clivus is part of the occipital bone. The sphenoidal clivus is the tallest out of the three parts. It is bounded laterally by the petroclival fissure, vertical paraclival carotid arteries and foramen lacerum. As the foramen lacerum and the arch of choana are at approximately the same level, the foramen is a landmark of the transition between the middle and lower clivus.

Transclival approaches

Middle transclival approach can provide access to the prepontine cistern. Here the basilar trunk, anterior inferior cerebellar artery, abducens nerve, ventral surface of pons can be found. Gently lateralising the paraclival carotid can allow access to the petrous apex, trochlear nerve, free edge of the tentorium and posterior root of the trigeminal nerve.

Inferior transclival approach provides access to the premedullary cistern. The contents of the cistern are the vertebral arteries, posterior inferior cerebellar artery, hypoglossal canal, anterior spinal arteries, and lower cranial nerves. The inferior clivus is covered by the pharyngobasilar fascia, rectus capitus muscles and longus capitus muscles.(25)

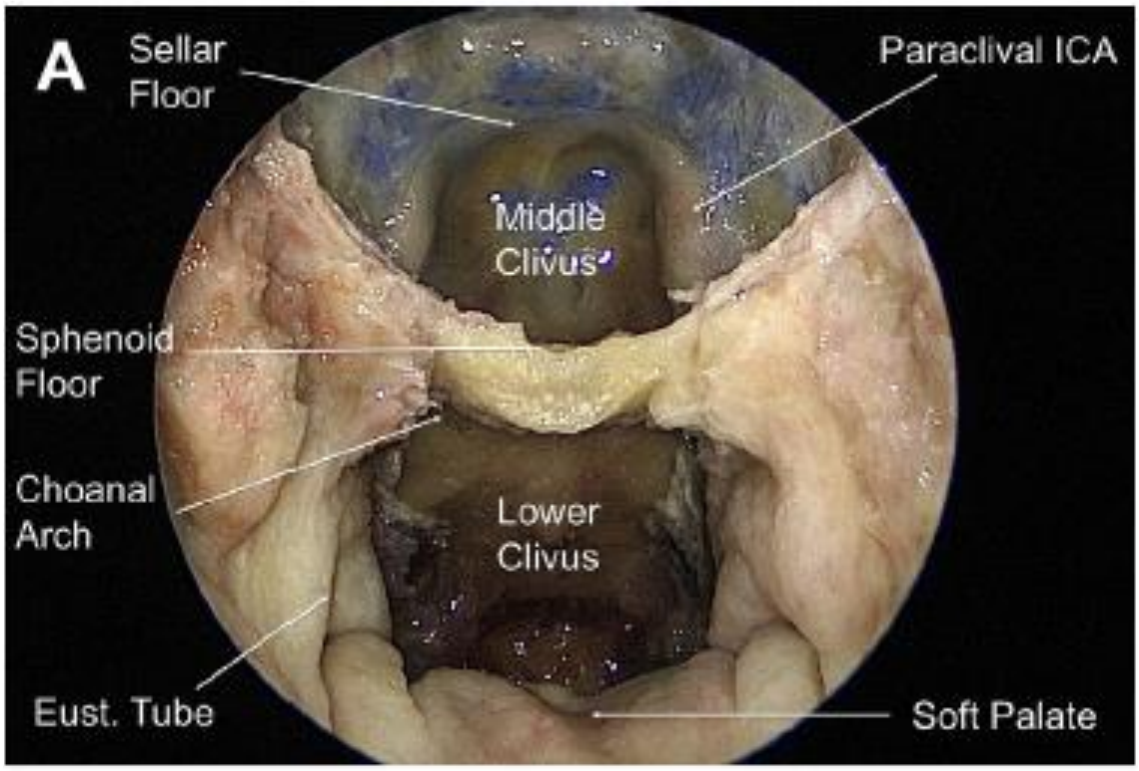


Figure 13 :Transclival approaches (Source : Skull base anatomy - Chirag R Patel et al)

Suprasellar space

This space extends from the diaphragm sella inferiorly to the third ventricle. The suprasellar space is divided into the suprachiasmatic, infrachiasmatic and retrochiasmatic areas. Access to this space is by removing the tuberculum sella, prechiasmatic sulcus and the planum sphenoidale. This region is important as it is the site of tumours like tubercullum sellae meningiomas, cranipharyngiomas, planum meningiomas which can be approached via the endonasal route.

The inferior surface of the optic chiasm and the infundibulum in the midline are found within the infrachiasmatic space. The suprasellar cistern arachnoid anteriorly and the membrane of Lillequist posteriorly covers the infundibulum.
Tuberculum sellae meningiomas often extends into this area displacing the infundibulum and superior hypophyseal arteries posteriorly.

The suprachiasmatic space is seen extending above the optic chiasm. The posterior aspect of each olfactory tract is found here as they divide to become the olfactory striae just above each optic nerve. Typically planum meningiomas occupy this anatomic region and as they progress in size tend to displace the optic chiasm and associated vascular structures posteriorly and inferiorly.

The retrochiasmatic space extends from the infundibulum anteroinferiorly to the posterior perforated substance and cerebral peduncles posteriorly and is bounded by the floor of the third ventricle superiorly. This anatomical space is occupied by craniopharyngiomas. (28)

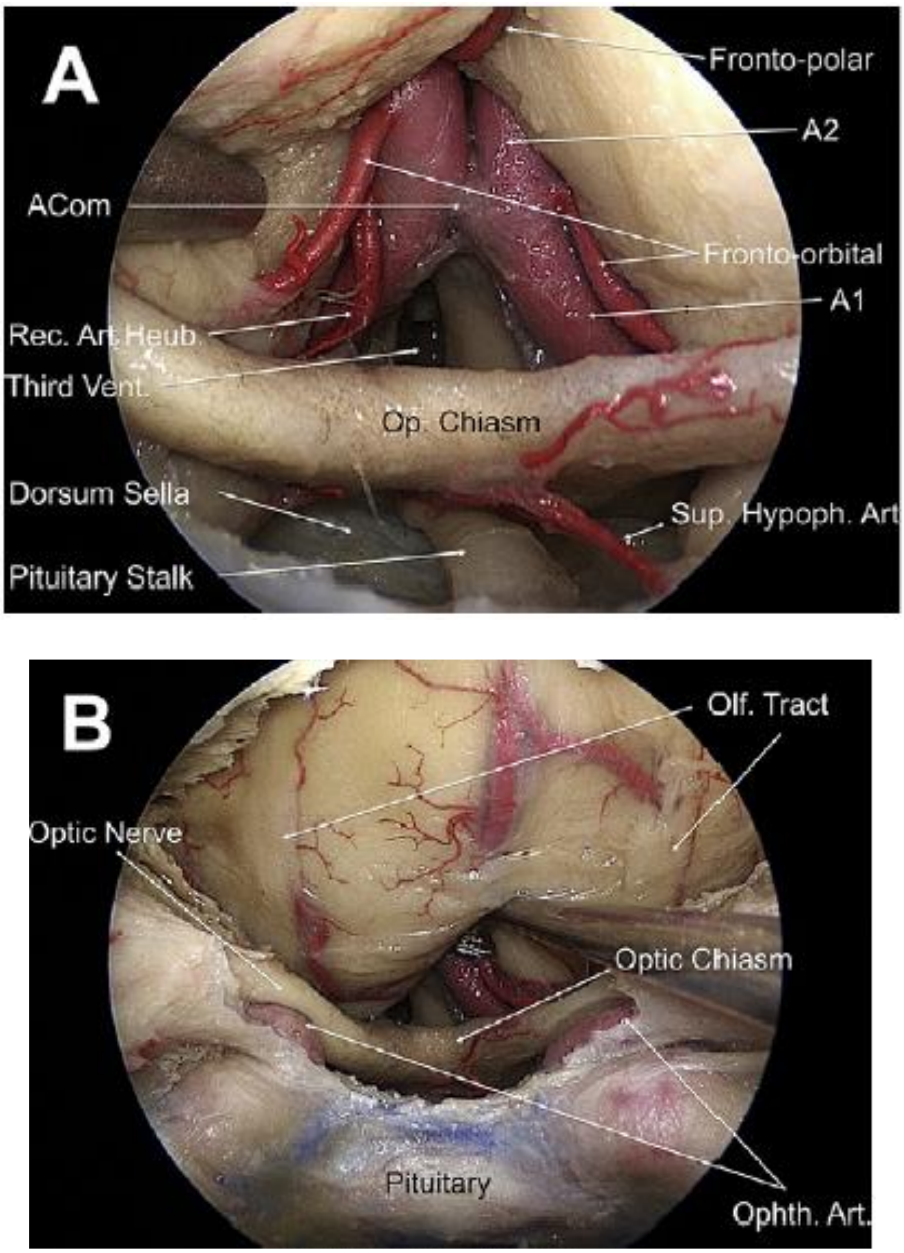


Figure 14 Optic chiasm (Source: Skull base anatomy, Chirag et al)

EXPANDED ENDOSCOPIC APPROACH

The expanded endoscopic approach (EEA) is a binostril approach to the skull base which allows wider access of the skull base to allow adequate resection of skull base tumours.

The traditional boundaries defined for transsphenoidal approach is expanded to include the region antero-posteriorly from the cribriform plate (part of anterior cranial fossa) to the foramen magnum. The advancements in the field of endoscopy have provided a wider field of view and better illumination. Hence the expanded approach has given us a lot of potential for the resection of a wide variety of cranial base lesions.(29)

The traditional transnasal transsphenoidal endoscopic approach required only resection of the posterior part of the septum to gain access to the sella.

In EEA, unilateral middle turbinectomy, resection of posterior part of bilateral superior turbinate is done to improve accessibility to the tumour. *Two parallel incisions are made in the sagittal plane of the septum. One incision follows the maxillary crest and nasal floor while a parallel incision follows a line that lies at least 1 cm below the superior aspect of the septum (olfactory sulcus) and then posterior part of the septum is drilled out.*

A wide sphenoidotomy and ethmoidectomy is also done to identify landmarks within sphenoid bone. The nasoseptal flap is designed according to the size and shape of the anticipated skull base defect. Reconstruction is done with multilayer of dural substitute positioned in the extradural space between the dura and the surrounding

bone to provide a watertight closure. Then the vascularised mucosal flap is used to cover the skull base reconstruction and the previously denuded surrounding bone.(30)

The exposure in EEA is tailor made according to type, size of tumour and relation with surrounding neurovasculature. Intraoperative neuronavigation and micro-Doppler probe is used to define the anatomical structures. (5)

Expanded endoscopic approach itself has undergone many advances over the years.

Advantages

The main advantages of the expanded endoscopic approach over transcranial approach is to reduce the extent of bone removal, eliminating brain retraction and reducing manipulation of the vascular and neural structures which may reduce overall morbidity to the patient. It has been found to reduce post-operative recovery time and may even improve outcomes. It approaches from an anteromedial and inferior direction hence ophthalmic functions may be better preserved as compared to the traditional approach which displaces the optic apparatus. (31)

Also the primary vascular supply of tumours like skull base meningiomas is usually the cranial base dura. Hence through this approach, we can get early access to the vascular supply and greatly reduce the intraoperative blood loss. While performing optic canal decompression in skull base tumours, this approach relatively avoids the risk of an ischemic optic apparatus. (32)

Skull base tumours are a diverse group of neoplasms. This approach has been used for skull base tumours like pituitary adenomas, skull base meningiomas, craniopharyngiomas, clival chordomas, and other supra sellar lesions. These tumours have historically been approached by a transcranial route or a microscopic endonasal route.

The transsphenoidal approach to midline anterior cranial base had been introduced more than a century ago. This was initially limited to lesions of the sellar region and the pituitary fossa. The advent of the operating microscope and micro-instruments increased the visual field to go beyond the sellae turcica to include a host of lesions involving the central cranial base anteroposteriorly from the crista galli to the foramen magnum. However its application to lesions beyond the sella and suprasellar region was limited. The endoscopic technique and the expanded approach has given a safe, feasible and less morbid route to these lesions. The endoscope also provided a near-field magnification of the lesion and vital structures. (33)

Indications for EEA

The boundaries for the expanded endoscopic endonasal approach are the frontal sinus and the cribriform plate anteriorly; the medial orbital walls laterally, the cavernous sinus and the carotid arteries in the sellar region and the posterior clinoids and dorsum sella posteriorly. (34)

Small or medium sized tumours located in the midline without vascular involvement and without much extension superiorly and laterally are ideal for this technique. The

primary factor while deciding for an expanded approach should be that the final objective of the surgery should be the same as when using an open approach from above, whether it is for total resection or a partial biopsy. If it is not possible to get radical removal of the tumour with free margins through the endonasal route then open approach should be opted for.

Patient with craniopharyngiomas with extra-arachnoid moderate sellar or intrasellar components are good candidates for EEA.

Suprasellar cysts, including Rathke's pouch cyst, which deviate from the midline, are also amenable to this approach. If the objective of surgery is primary cyst drainage or subtotal removal, this approach is minimally invasive as compared to the open approach. It is also recommended for large or giant pituitary adenomas with anterior cranial base extension and significant suprasellar extension as long as they do not have much lateral extension.

Small or medium- sized meningiomas of the midline tuberculum sellae/planum sphenoidale and olfactory groove region that do not encase the anterior cerebral arteries, do not have significant underlying brain edema (breach of the pia-arachnoidal planes), and do not show a lateral or parasellar extension are potential candidates for the EEA.(35)

Minimal extension of tumour into optic canal medially or inferiorly can be managed. But any significant lateral extension into optic canal is a contraindication for endoscopic removal. Size of tumour and peritumoral brain edema are also relative factors that affect decision to choose endoscopic versus transcranial.

Other select cases like angiofibroma, mucocele, and encephalocele can also be approached with EEA.(36), (37)

The EEA has also been used effectively for pituitary stalk, suprasellar, and basal hypothalamic lesions for which the objective is only biopsy or partial removal. Another limiting factor is the learning curve. These surgeries may initially take more time to complete than a standard craniotomy.

Risk of EEA

The expanded endoscopic approach was found to have low rates of complications and new neurological and endocrinological deficits. The most common complication associated with this approach was CSF leak. In previously reported series with microscopic approach, the incidence ranged from 2 to 33%.(38–40)

Frank et al, in a series for an expanded approach for craniopharyngiomas reported a 30% rate of post-operative CSF leaks. (41) More recent series have shown significantly less CSF leak, especially with the use of a nasal septal vascularised flap. (42)

It is difficult to draw definite conclusions about whether CSF leaks are more due to the approach used as the pathologies involved are so varied. Although approach to planum, sellar and suprasellar lesions may have an increased chance of CSF leak, the important factor is the quality of reconstruction. CSF leak, although decreasing in

occurrence, is still a hurdle that needs to be addressed in order for this technique to challenge open approaches. Other risks include meningitis, cranial nerve injury and arterial vessel injury although these are uncommon. (29)

NASAL MORBIDITY AND QUALITY OF LIFE

Although the transnasal route is a less invasive, the morbidity associated with resection on nasal mucosa is significant. The unique set of nasal morbidities associated with the endonasal corridor and nasoseptal flap reconstruction affects quality of life.

The olfactory epithelium as described before is located high in the nasal cavity on the inferior part of superior turbinate, medial part of the middle turbinate, the cribriform plate and the postero-superior portion of the septum.

Nasal morbidity has been extensively studied for endoscopic approach for inflammatory disease like chronic rhinosinusitis and nasal polypi. However in skull base surgery, the native mucosa is healthy and the morbidity is caused iatrogenically by the vascular flap raised or resection for better visualisation.(43) The nasoseptal flap reconstruction also is a contributor to the olfaction impairment.

Olfactory loss has been reported after the traditional transseptal with a variable incidence of 10 to 30%.(44), (45) The discrepancy in olfactory outcomes may be due

to several factors like surgical technique, tissues spared, local trauma, and flap harvesting.

Very little is known about the long-term effects of the expanded endoscopic approach. Radical removal of the malignant or the benign tumours along with the need to create an adequate surgical corridor that allows comfortable handling of the instrumentation along with good visualisation requires the removal of healthy anatomical structures. This leads to morbidity on normal physiological processes. (30)

In addition to this, the nasospetal flap, if harvested to cover skull base defects and avoid CSF leak also may contribute to nasal morbidity. The harvesting of flap causes denudation of mucoperiosteum and mucoperichondrium of the septum which heals by secondary intention. This contributes to nasal crusting post operatively which causes nasal discomfort and may contribute to nasal obstruction and impaired olfaction post operatively.

Post-operative quality of life is an important factor when planning a major procedure.

Early data on quality of life and sinonasal morbidity following the endonasal approach to skull base tumours show that there may be greater disruption of normal sinonasal anatomy and physiology compared to standard external approach. But the morbidity associated appears to be only temporary.(43)

The quality of life results show that the overall quality of life is very good and achieved early as compared to external approach.

In 2014, Zimmer et al noted that although portions of neuroepithelium are permanently removed by their approach to the sella, patients reported only a temporary, although significant, decrease in olfactory changes at 1 month that had returned to preoperative levels at 3 months. Recovery of olfaction in these patients was likely related to the resolution of mucosal edema and the abundant nasal crusting .This is caused by the disruption of mucociliary clearance in the sphenoid sinus and along the cut edges of the septum rather than the loss of olfactory neuroepithelium. (46)

In a prospective study using the University of Pennsylvania Smell Identification Test to evaluate how endoscopic pituitary surgery affected one's sense of smell, Hart et al noted patients experienced a temporary decrease in olfaction at 1 month but had recovered preoperative baseline scores by 3 months. This finding contrasts with the observation of longer-term olfactory dysfunction after pituitary surgery using a nasal septal flap.

In 2010, a study was done by Pant et al to assess the quality of life outcomes and sinonasal morbidity in patients who underwent endonasal cranial base surgery for management of various skull base tumours. The results show that although sinonasal morbidity is increased, this is temporary, and the vast majority of patients have a very good QOL by 4 to 6 months after endonasal approach to the cranial base.(43)

The disease-specific validated SNOT-22 questionnaire, which provides a symptom score (range 0 to 5.0) for parameters relating to sinonasal function, was used in 51 patients who underwent the endonasal approach. A higher score indicates worse

outcome. There was a significant difference in the mean SNOT-22 scores over time. The five most common items identified by patients that were considered to be the most important items affecting their health included loss of smell or taste, nasal obstruction, postnasal discharge, waking up at night, and lack of a good night's sleep. Overall, 27% of patients scored 4.0 or greater in the various parameters indicating a severe problem relating to loss of smell or taste. (46)

In the prospective observational study by Zimmer et al mentioned earlier, the SNOT-22 questionnaire was administered preoperatively, and post operatively at 1 and 3 month follow up visits. SNOT-22 scores (5-point scale; total: 110) averaged 23.4 preoperatively and 27.6 at 1 month but had significantly improved to 16.2 at 3 months ($p < 0.03$). Emotional well-being parameters (e.g., sadness, frustration, concentration, productivity, fatigue) significantly improved 3 months postoperatively ($p < 0.05$). Physiologic parameters (e.g., olfaction, obstruction, postnasal drainage) that had worsened at 1 month (< 0.05) then normalized at 3 months.

The current study is being done to assess whether there is any significant olfactory dysfunction post operatively in patients undergoing EEA. It will also assess the quality of life in these patients.

If there is a significant loss of olfaction found in these patients, then this will help us

1. In consenting the patients and explaining the extent of olfaction loss that is likely to occur and also the recovery of olfaction over a period of time.
2. To search for factors causing post-operative olfactory dysfunction - any particular surgical step to look at modification of surgical technique to reduce post-operative olfactory dysfunction

MATERIALS AND METHODS

Study design

This was a prospective observational study in a hospital set up.

Study population

Patients over the age of 18 who were diagnosed with skull base tumours who underwent expanded endoscopic approach and were willing to take part in the study were recruited.

Inclusion criteria

- Patients undergoing expanded endoscopic approach (EEA) for skull base tumours
- Patients with normal olfaction at pre-operative visit

Exclusion criteria

- Patients below age of 18 years
- Pregnant women
- Patients who have undergone recent sinonasal surgery
- Patients with lesions in the olfactory fossa
- Recurrent skull base tumours who have undergone endonasal surgery in the past
- Patients with grossly abnormal olfaction at pre-operative visit

Study period

Prospective observational study conducted between February 2018 and April 2019

Ethics committee approval

The study proposal was submitted to the Institutional review board. After the proposal was approved study was initiated in February 2018.

Patient recruitment

Patients who were diagnosed with skull base tumours planned for expanded endoscopic approach were recruited from the neurosurgery department.

In the first part of the study, the pre-operative olfactory function in these patients was assessed using the CCRC (Connecticut chemosensory clinical research centre) olfaction test which includes olfactory threshold, odour identification and odour discrimination. Olfactory threshold was assessed by the butanol threshold test. A composite score was obtained from the threshold test and the identification test.

The threshold testing comprises of aqueous dilutions of 1-butamol in successive dilutions differing by a factor of 3. The highest dilution is 4%. The test solution is taken in six 250ml polyethylene bottles with a pop up spout and that fitted into the nostril. The bottle is then squeezed and the patient is asked to sniff simultaneously. The test kit also contains six bottles containing distilled water as blanks. The patient is given a test bottle along with a blank and is asked to decide which bottle has a detectable odour or smelled stronger. If incorrect, the patient was given the next higher concentration with a blank. Four correct answers in a row marked the end of testing. Each nostril is separately tested.(20)

The point of transition between no detection of smell to identification of smell is considered as the threshold for that individual.

Odour identification test consisted of an item presented to the patient. The patient was then asked to identify the substance. A kit comprises of seven 180ml opaque plastic jars containing the odorant. In our setting the odorants used were: cinnamon, tea, coffee, clove, pepper, asafoetida, and baby powder. Each nostril was tested separately. Patient was then asked to identify the substance.

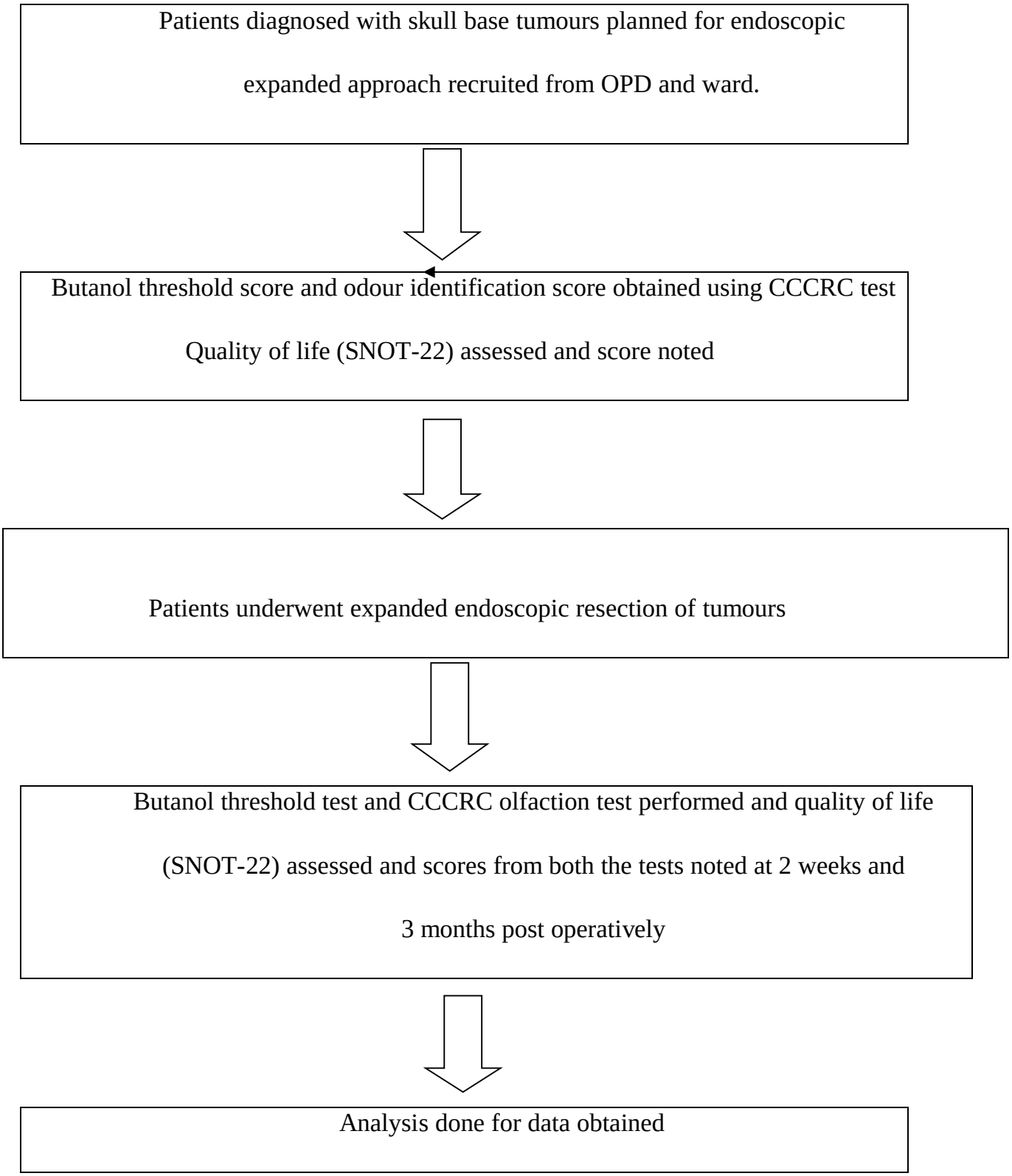
The quality of life was assessed using the Sinonasal outcome -22 (SNOT-22) questionnaire. The baseline SNOT -22 questionnaire was assessed preoperatively.

The patients then underwent tumour resection by expanded endoscopic approach.

All patients were then reviewed 2 weeks post operatively and after 3 months for a repeat olfaction test in order to evaluate if there is any worsening in the olfaction post operatively. Post operatively patients were administered the SNOT-22 questionnaire again to assess the quality of life following the surgery.

Patients who did not come back for follow up were contacted over the telephone and the quality of life questionnaire was administered and scores calculated.

Detailed diagrammatic algorithm of the study



Statistical analysis

Statistical analysis was done using SPSS and Excel.

Wilcoxon signed rank test and paired t test were used to calculate the statistical significance of the date.

RESULTS

A total of 29 patients were recruited for the study. All patients were tested for olfaction at pre-operative visit and at the 2 week post-operative follow up visit. Four patients were lost to follow up for the olfaction test at the 3 month post-operative visit and they were excluded from the follow up analysis for olfaction. However the SNOT-22 questionnaire was administered to them over the telephone

Demographics

Gender distribution (Table 1)

Table - Gender distribution (N = 29)

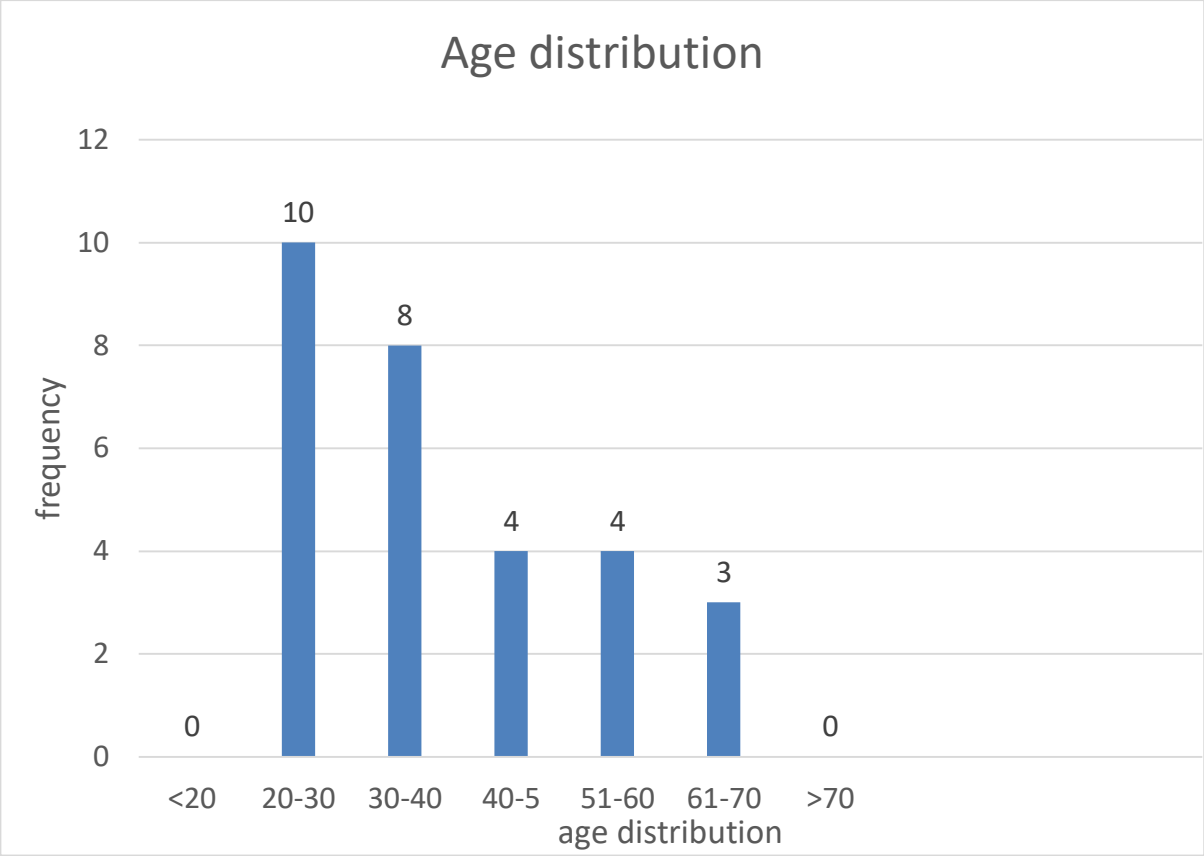
Gender	Number	Percentage (%)
Male	13	44.8
Female	16	55.2
Total	29	100

Age distribution (Figure 1)

Patients' age ranged from 23 to 66 years (mean age- 39.55 years, SD = 12.81).

Most of the patients were below the age of 40.

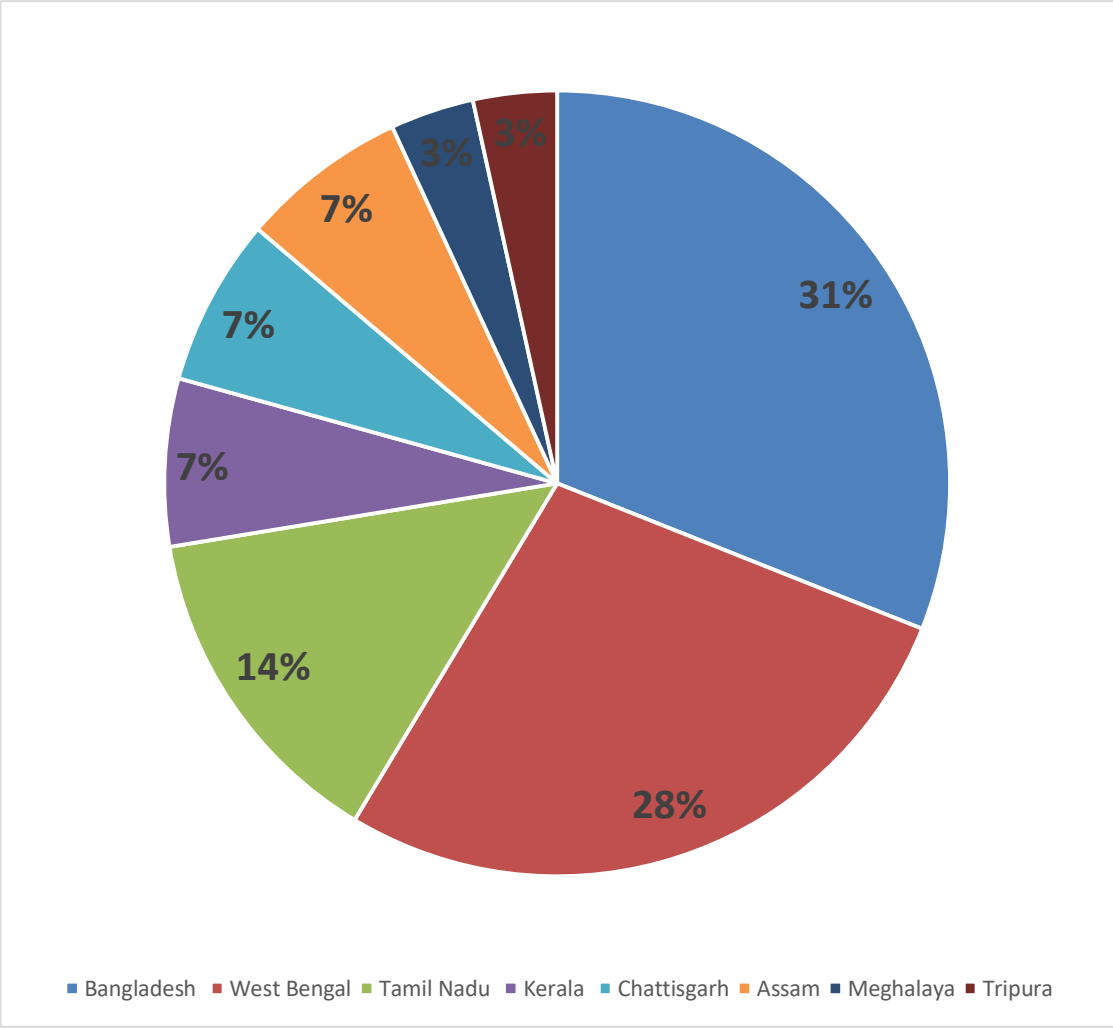
Figure 1 – Age distribution graph (N=29)



Geographical distribution (Figure 2)

Most of the patients were from Bangladesh and West Bengal.

Figure 2 - Distribution according to place



Diagnosis (Table 2)

The most common diagnosis was noted to be growth hormone secreting pituitary adenoma, followed by non-functioning pituitary adenoma.

Table 2 – Distribution of diagnosis

Diagnosis	Number (N = 29)
Clival chordoma	1
Tuberculum sella meningioma	2
GH secreting pituitary adenoma	15
Planum sphenoidal meningioma	1
ACTH secreting pituitary adenoma	2
Non-functioning pituitary adenoma	7
Plurihormonal pituitary macroadenoma	1

Olfaction

Out of a total 29 patients recruited for the study, 4 were lost for the final follow up and hence has been excluded from the final olfaction comparison analysis.

Pre-operative visit (C1)

At the first contact (which will hereafter be referred to as C1), olfaction was tested using the CCCRC test. This includes the butanol threshold score and the odour identification score.

Butanol threshold (Table 3)

The butanol threshold was tested individually for each nostril and the average of the left and right was taken as the final score. Out of a maximum score of 6, the highest obtained was 6 and the lowest was 3 for the left side and 4 for the right.

The mean final butanol threshold score was 5.46 (SD =0.8281)

Table 3 - Butanol threshold (C1) (N=25)

	Left	Right	Final score
Mean	5.44	5.48	5.46
Median	6.00	6.00	6.00
Standard deviation	0.9165	0.8225	0.8281
Minimum	3	4	3.5
Maximum	6	6	6

Odour identification (Table 4)

The odour identification was tested individually for each nostril and the average of the left and right was taken as the final score. Out of a maximum score of 7, the highest obtained was 7 and the lowest was 5 for the left side and 4 for the right.

The mean final odour identification score was 6.46 (SD = 0.7626)

Table 4 – Odour identification (C1) (N=25)

	Left	Right	Final
Mean	6.48	6.44	6.46
Median	7	7	7
Standard deviation	0.7141	0.8205	0.7626
Minimum	5	4	4.5
Maximum	7	7	7

Composite score (Table 5)

The average of the butanol threshold and the odour identification was taken as composite score for that side of the nose and the average of the left and right composite score was taken as the final score. Out of a maximum score of 6.5, the highest obtained was 6.5 and the lowest was 5.

The mean final composite score was 5.99 (SD = 0.4920)

Table 5 – Composite score (C1) (N=25)

	Left	Right	Final
Mean	5.98	6.00	5.99
Median	6	6	6
Standard deviation	0.5299	0.5000	0.4920
Minimum	5	5	5
Maximum	6.5	6.5	6.5

Post-operative visit (C2)

At the first post-operative visit 2 weeks after surgery (which will hereafter be referred to as C2), olfaction was tested again.

Butanol threshold (Table 6)

Out of a maximum score of 6, the highest obtained was 5 for the right and 6 for the left and least score was 0.

The mean final score of butanol threshold was found to be decreased to 1.76 (SD = 1.4442) compared to the pre-operative score.

Table 6 - Butanol threshold (C2)

	Left	Right	Final
Mean	1.76	1.76	1.76
Median	2	1	1.5
Standard deviation	1.3625	1.6653	1.4442
Minimum	0	0	0
Maximum	5	6	4.5

Odour identification (Table 7)

Out of a maximum score of 7, the highest obtained was 7 and the lowest was 0.

The mean final score of odour identification was decreased to 3.40 (SD = 0.7626) compared to the pre-operative value.

Table 7 – Odour identification (C2)

	Left	Right	Final
Mean	3.32	3.48	3.40
Median	3	3	3
Standard deviation	1.7492	1.7107	1.6832
Minimum	0	0	0
Maximum	7	7	7

Composite score (Table 8)

Out of a maximum score of 6.5, the highest obtained was 5.5 and the lowest was 0.

The mean final composite score was decreased to 2.64 (SD = 1.2769) compared to the pre-operative value.

Table 8 - Composite score (C2)

	Left	Right	Final
Mean	2.6	2.68	2.64
Median	2.5	2.5	2.5
Standard deviation	1.3149	1.3140	1.2769
Minimum	0.5	0.5	0.5
Maximum	5.5	5.5	5.5

Post-operative visit (C3)

At the final post-operative visit 3 months after surgery (which will hereafter be referred to as C3), olfaction was tested again.

Butanol threshold (Table 9)

Out of a maximum score of 6, the highest obtained was 6 and least score was 2.

The mean final score of butanol threshold was found have increased to 4.72 (SD = 1.1733) compared to the first post-operative score(C2) .

Table 9 - Butanol threshold (C3)

	Left	Right	Final
Mean	4.68	4.76	4.72
Median	5	5	5
Standard deviation	1.2151	1.1647	1.1733
Minimum	2.0	2.0	2.0
Maximum	6.0	6.0	6.0

Odour identification (Table 10)

Out of a maximum score of 7, the highest obtained was 7 and the lowest was 5.

The mean final score of odour identification was increased to 5.780 (SD = 0.7371) compared to the first post-operative score(C2) .

Table 10 – Odour identification (C3)

	Left	Right	Final
Mean	5.800	5.760	5.780
Median	6	6	6
Standard deviation	0.7071	0.7788	0.7371
Minimum	5.0	4.0	4.5
Maximum	7.0	7.0	7.0

Composite score (Table 11)

Out of a maximum score of 6.5, the highest obtained was 5.5 and the lowest was 0.

The mean final score was found to have increased to 5.250 (SD = 0.6291) compared to the first post-operative value(C2).

Table 11 - Composite score (C3)

	Left	Right	Final
Mean	5.240	5.260	5.250
Median	5	5.5	5
Standard deviation	0.6311	0.6474	0.6291
Minimum	4	4	4.25
Maximum	6	6	6.0

Comparison of olfactory dysfunction (Table 12 and 13)

The final composite olfactory scores were analysed and classified into normosmia, mild hyposmia, moderate hyposmia, severe hyposmia and anosmia based on scores.

It was found that 92% had normosmia and 8% mild hyposmia at pre- operative visit.

At the 2 week post-operative visit, only 1 subject had normosmia. It was noted that 48% had moderate hyposmia, 20% had anosmia, 12% had severe hyposmia and 16 % had mild hyposmiaAt the 3 month follow up visit, the olfactory scores seemed to have improved with almost half the subjects (48%) with a normal olfaction score and the rest with mild hyposmia. Only 1 subject had persistent moderate hyposmia at 3 month visit.

Table 12 – Composite scores at C1, C2 and C3

	Final (C1)	Final (C2)	Final (C3)
Mean	5.99	2.64	5.25
Standard deviation	0.4920	1.2769	0.6291
Median	6	2.5	5

Table 13 – Frequency distribution of olfaction scores (based on final composite scores) **N = 25**

Degree of olfactory function	C1 (%)	C2 (%)	C3 (%)
Normosmia (5.5-7)	23 (92)	1 (4)	12 (48)
Mild Hyposmia (3.75-5.4)	2 (8)	4 (16)	12 (48)
Moderate Hyposmia (2.5-3.74)	0 (0)	12 (48)	1 (4)
Severe Hyposmia (1.75-2.24)	0 (0)	3 (12)	0 (0)
Anosmia (less than 1.75)	0 (0)	5 (20)	0 (0)

Table 14: Change in median olfaction scores from C1 to C2

Variables	C1	C2	Difference (C1-C2)	p value
Butanol threshold	6.000	1.5000	3.500	**<0.001**
Odour identification	7.000	3.000	3.000	**<0.001**
Composite score	6.000	2.5000	3.500	**<0.001**

The change in median scores of all 3 variables are statistically highly significant from pre-operative visit to immediate post-operative visit.

Table 15: Change in median olfaction scores from C1 to C3

Variables	C1	C3	Difference (C1-C3)	p value
Butanol threshold	6.000	5.000	1.000	**0.022**
Odour identification	7.000	6.0000	1.000	**0.004**
Composite score	6.000	5.000	0.500	**<0.001**

The change in median scores of all 3 variables are statistically significant from pre-operative visit to late post-operative visit although less compared to the immediate post-operative visit.

Table 16: Paired t-test for comparison of mean olfaction scores

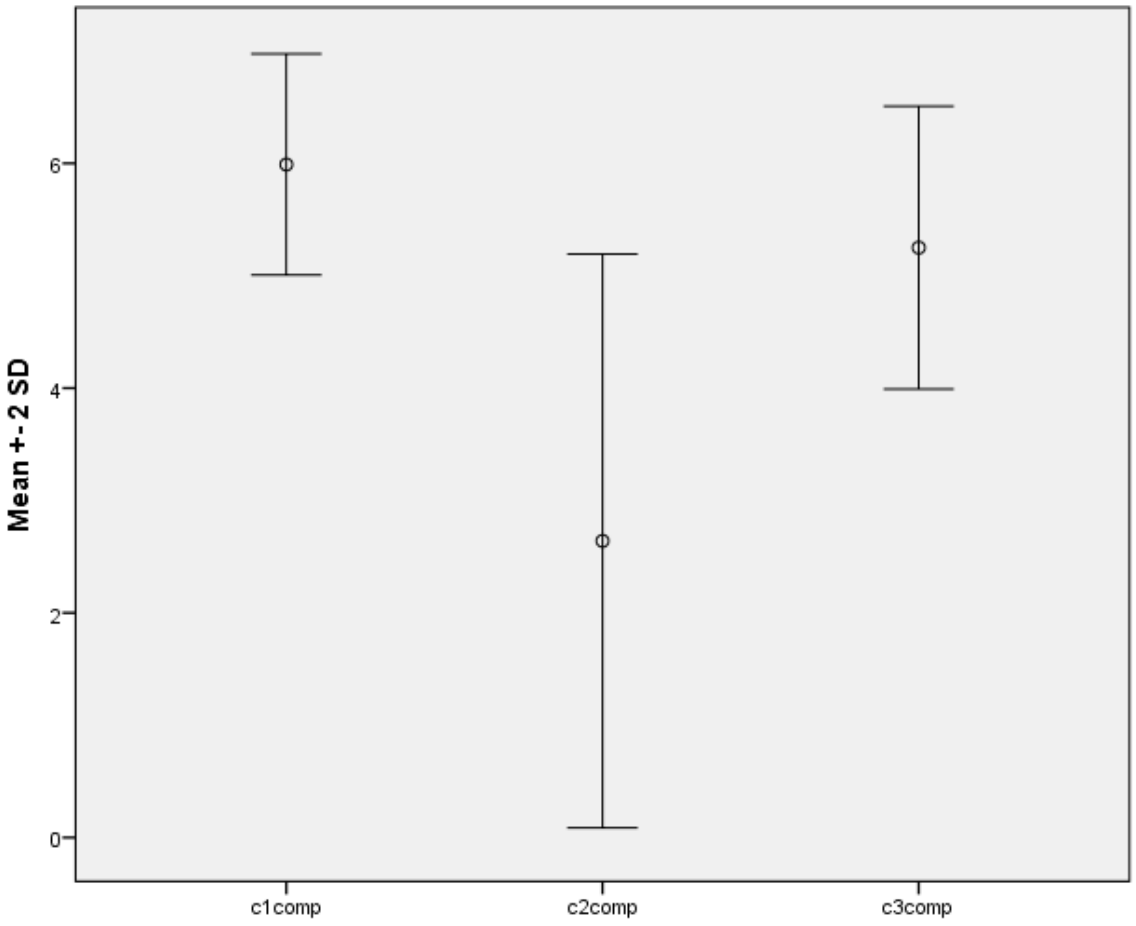
Variables	Comparison	P value
Butanol threshold	C1 to C2	<0.001
Odour identification	C1 to C2	<0.001
Composite score	C1 to C2	<0.001

Variables	Comparison	P value
Butanol threshold	C1 to C3	.017
Odour identification	C1 to C3	.001
Composite score	C1 to C3	<0.001

The change in mean olfaction scores of all 3 variables are statistically highly significant from pre-operative visit to immediate post-operative visit.

The change in mean scores of all 3 variables are statistically significant from pre-operative visit to late post-operative visit although less significant compared to the immediate post-operative visit.

Figure 3: Comparison of mean olfaction scores at C1, C2, and C3



Quality of life

The quality of life questionnaire used was the Sino- nasal outcome test -22 (SNOT-22). This is a validated questionnaire with 22 questions. Each question was graded from 0 to 5 with 0 being "No problem" and 5 being "Problem as bad as it can be"

The maximum score obtainable was 110 and the minimum 0.

Most patients had a score of 0 for most of the parameters prior to the surgery with scores increasing immediate post-surgery.

The maximum grand total score was 6 at C1, 32 at C2 and 7 at C3.

The mean grand total scores were 0.62+/-1.29 at C1 which increased to 14.24 +/-4.98 at C2. It decreased back to 2.45 +/-1.92 at C3. The change is statistically significant from C1 to C2 as well as C1 to C3 with a p value <0.001 in both cases.

Table 17 shows the change in average score for each parameter of the SNOT -22 questionnaire at each visit.

Table 18 shows the change in the grand total scores for each visit.

Table 17 – Comparison of average scores of SNOT -22

	C1	C2	C3
Need to blow nose	0	1.41 +/- 0.99	0.10 +/- 0.31
Sneezing	0.14 +/- 0.52	1.82 +/- 0.97	0.38 +/- 0.62
Runny nose	0.03 +/- 0.19	2.10 +/- 0.49	0.34 +/- 0.67
Nasal obstruction	0.10 +/- 0.41	3.13 +/- 0.79	0.66 +/- 0.77
Loss of smell or taste	0	3.13 +/ 1.03	0.97 +/- 0.91
Cough	0	0.03 +/- 0.19	0
Post-nasal discharge	0	0.49 +/- 0.99	0
Thick nasal discharge	0	0.34 +/- 0.81	0
Ear fullness	0	0.07 +/- 0.37	0
Dizziness	0	0	0
Ear pain	0	0	0
Facial pain/pressure	0	0	0
Difficulty falling asleep	0	0	0
Waking up at night	0	0	0
Lack of a good night's sleep	0	0	0
Waking up tired	0	0	0
Fatigue	0.28 +/- 0.70	0.97 +/- 1.29	0
Reduced productivity	0.70 +/- 0.38	0.56 +/- 0.95	0
Reduced concentration	0	0.17 +/- 0.66	0
Frustrated/restless/irritable	0	0	0
Sad	0	0	0
Embarrassed	0	0	0
Grand total	0.62 +/- 1.29	14.24 +/- 4.98	2.45 +/- 1.92

Table 18 – Comparison of grand total SNOT -22 scores

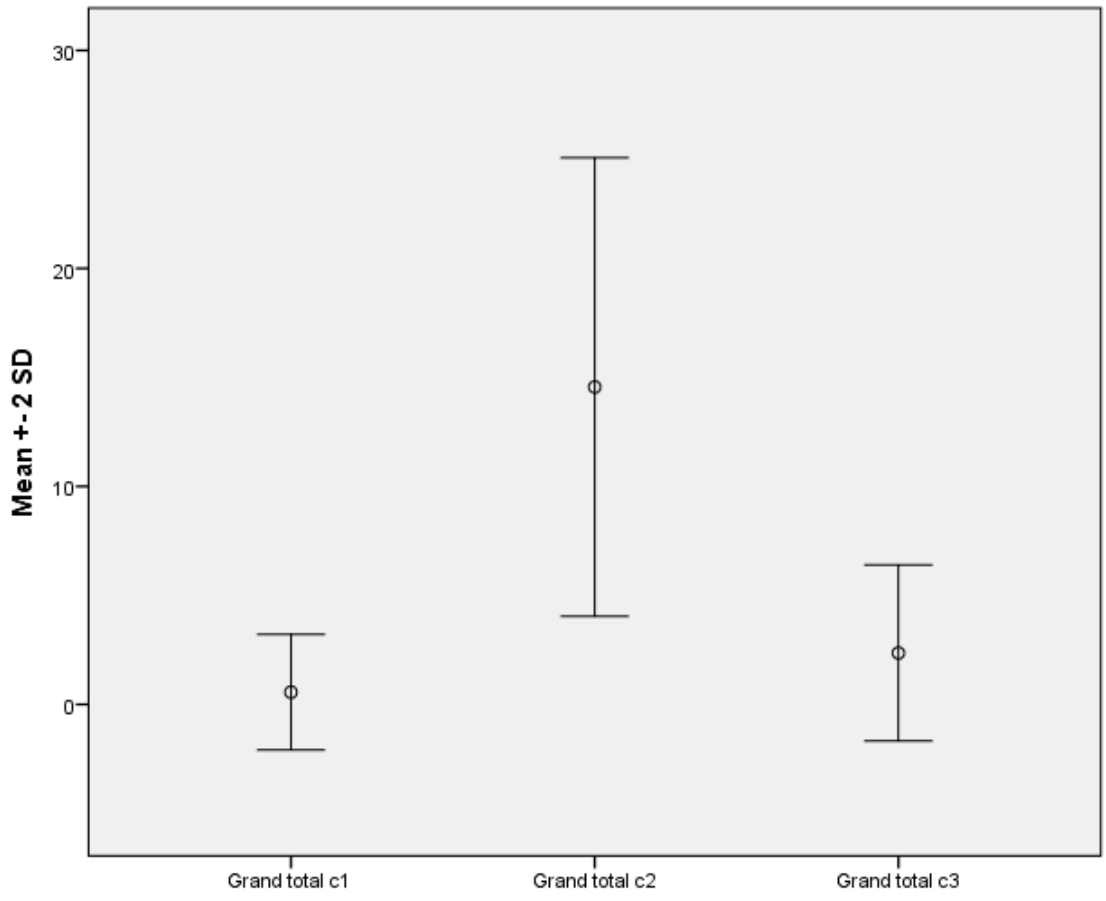
	Grand score(C1)	Grand score (C2)	Grand score(C3)
Mean	0.62	14.24	2.45
Standard deviation	1.29	4.98	1.92
Median	0	14.00	2.00
Minimum	0	4.00	0
Maximum	6.00	32.00	7.00

Table 19 shows the difference between the grand total scores at pre-operative visit compared to the first and second post-operative visits. The changes in scores were statistically significant.

Table 19: Paired t test comparing mean total SNOT 22 scores

	P value
Grand total difference (C1-C2)	<0.001
Grand total difference (C1- C3)	<0.001

Figure 4: Comparison of mean grand total QOL scores at C1, C2 and C3



SYMPTOMATOLOGY

The individual parameters were assessed at each visit and scored from a scale of 0 to 5. Figures 3, 4, 5, and 6 show the symptomatology at each visit.

The most common complaints 2 weeks after surgery was runny nose and loss of smell/taste followed by nasal obstruction.

3 months post operatively, the most common symptoms noted were loss of smell/taste and nasal obstruction. However it was noted that the severity was decreased for both.

Figure 4 – Pre-operative visit C1 symptomatology

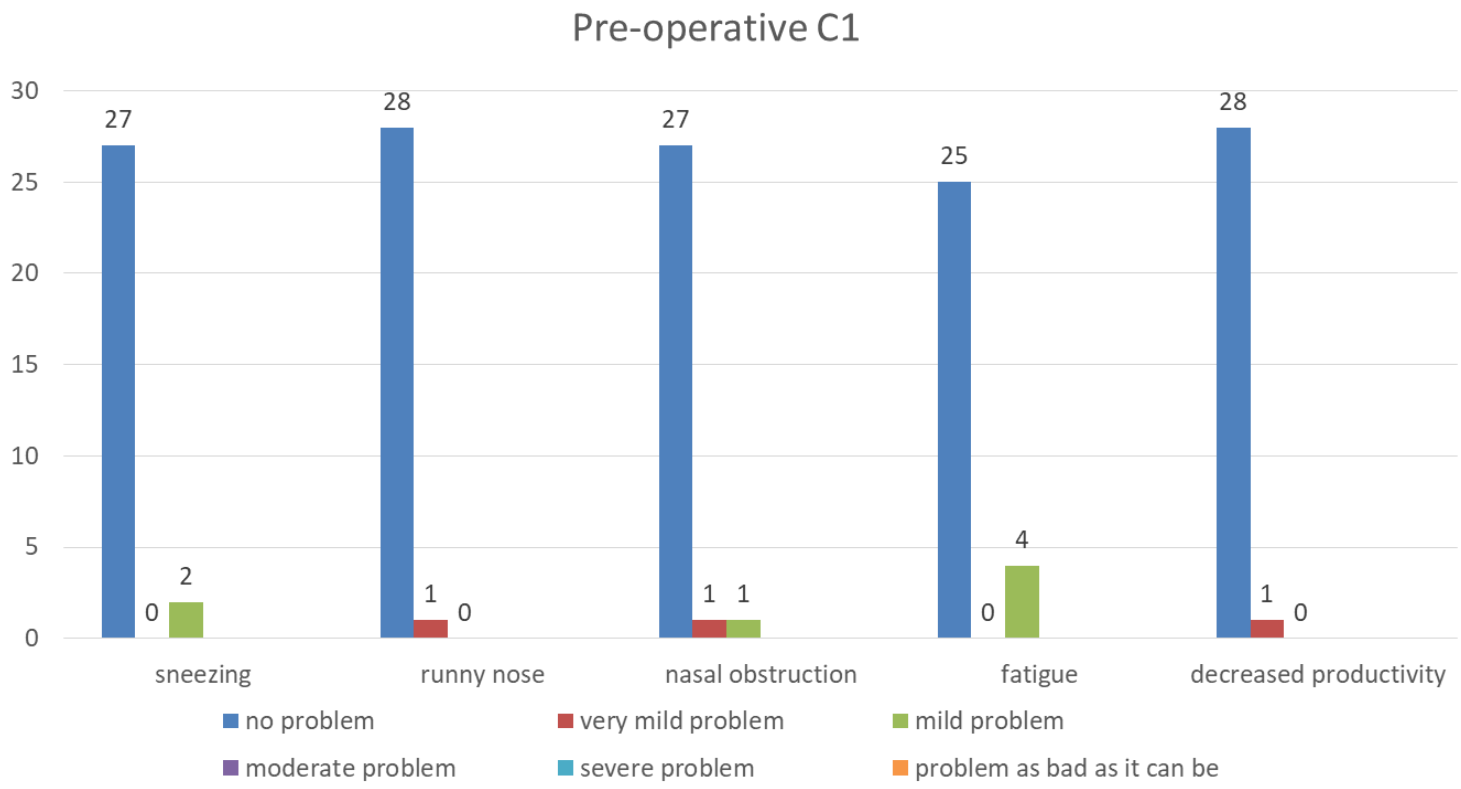


Figure 5 – Post-operative visit C2 sinonasal symptomatology

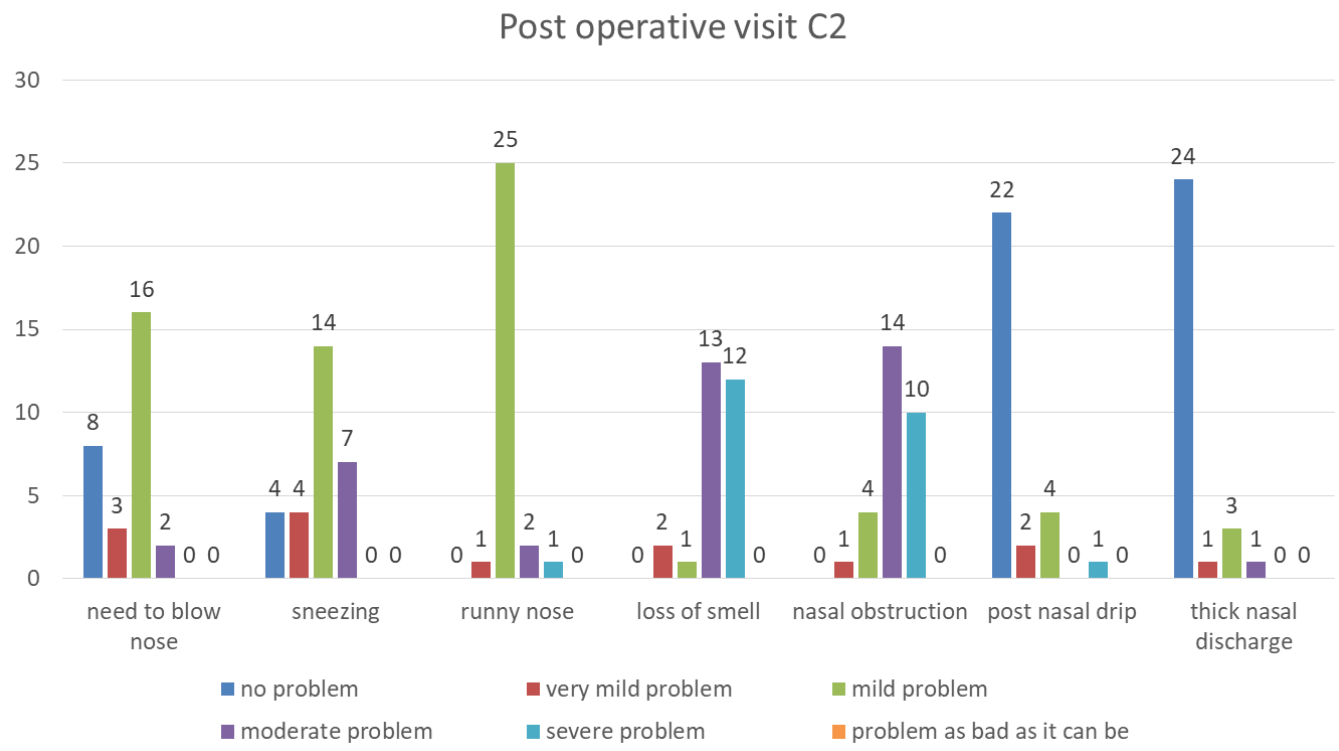


Figure 6 – Post-operative visit C2 other symptomatology

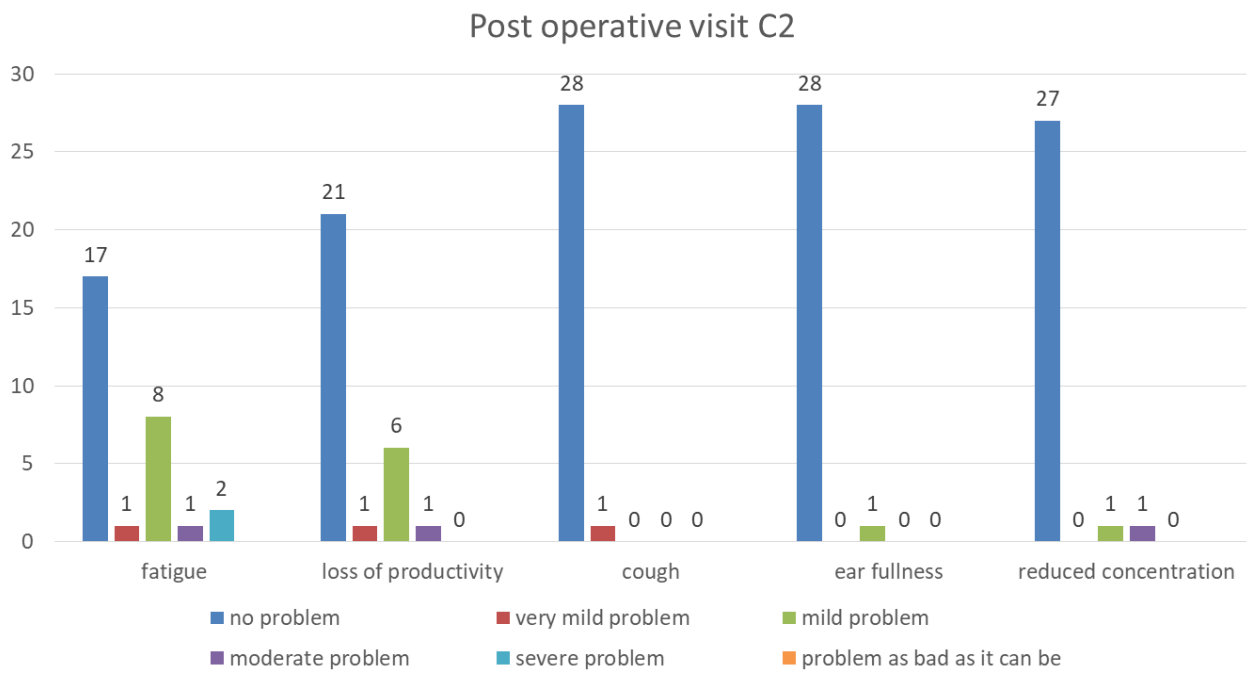


Figure 7 – Post-operative visit C3 symptomatology

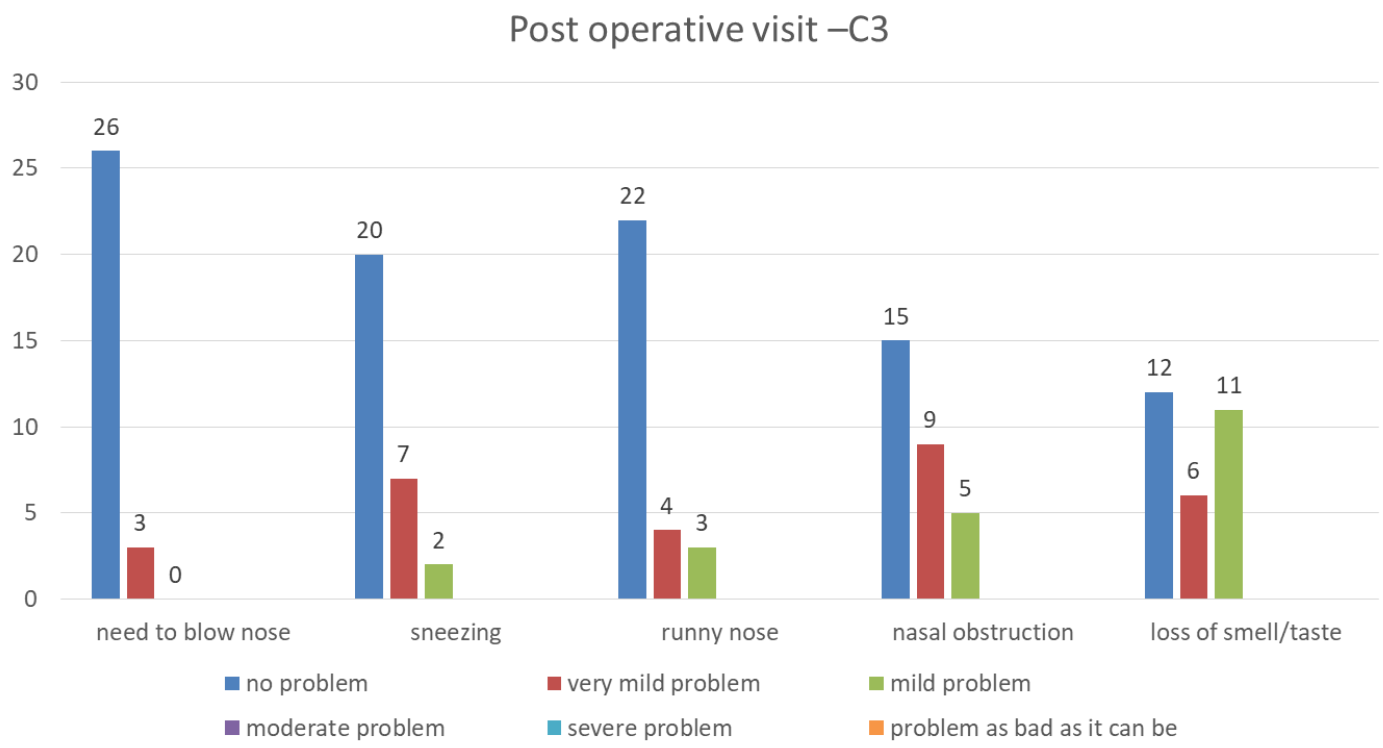


Figure 8 – Comparison of frequency of nasal obstruction at all 3 visits

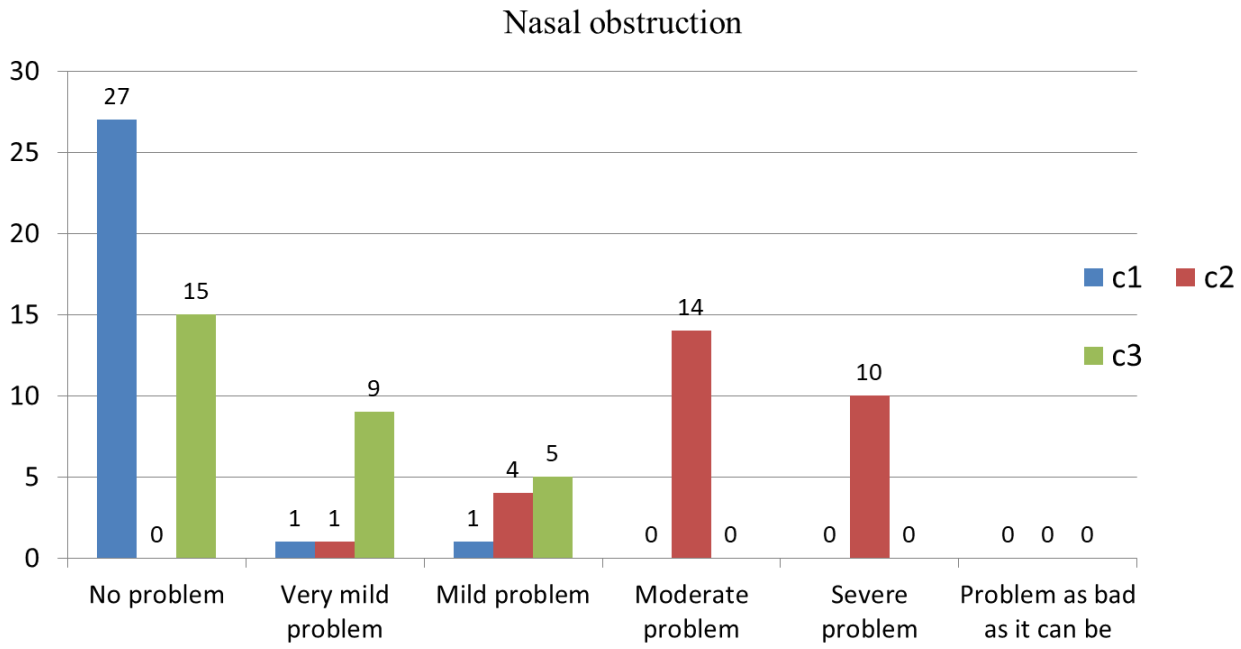
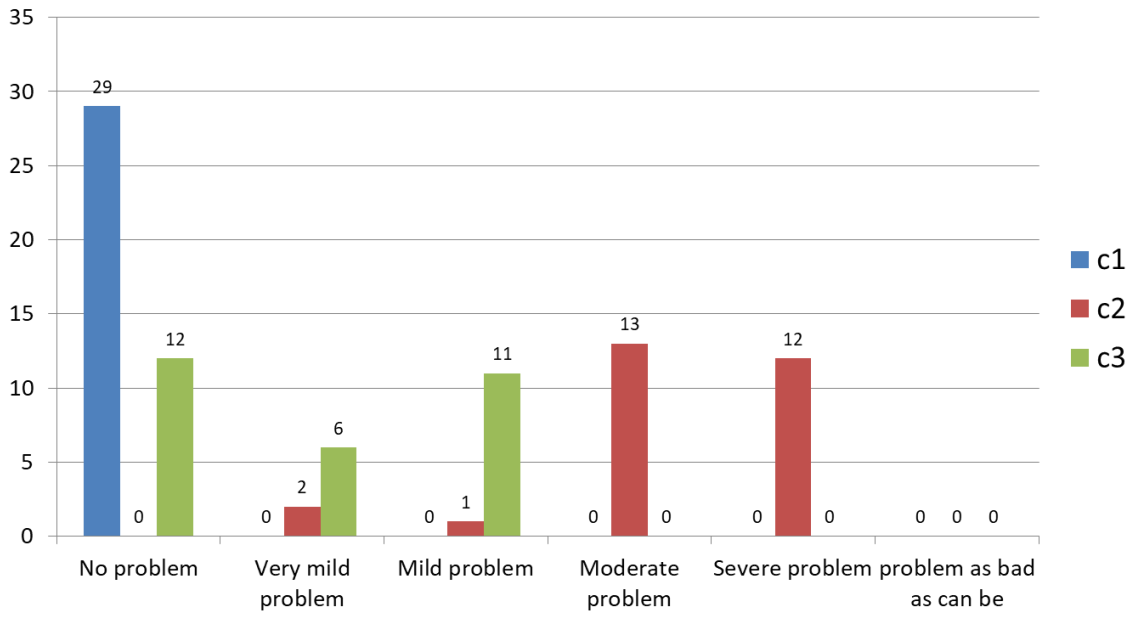


Figure 9 – Comparison of frequency of loss of smell/taste at all 3 visits



DISCUSSION

A total of 29 patients were recruited for the study. All patients were tested for olfaction at pre-operative visit and at the 2 week post-operative follow up visit. Four patients were lost to follow up for the olfaction test at the 3 month post-operative visit and they were excluded from the follow up analysis for olfaction. However the SNOT-22 questionnaire was administered to them over the telephone.

16 females and 13 males were recruited for the study. Patients' age ranged from 23 to 66 years (mean age- 39.55 years, SD = 12.81). Most of the patients were below the age of 40.

In our study, we found that the objective olfaction score were significantly disturbed at the first preoperative visit and the scores were restored to almost normal at the second post-operative visit.

The mean composite score at pre-operative visit was 5.99 +/- 0.49 which decreased to 2.64 +/- 1.27 at the first post-operative visit (p value <0.001)

Although the mean composite scores improved to 5.25+/-0.62 at the 3 month post-operative visit, it did not return to baseline and there was a statistically significant drop (p value <0.001)

On comparing the median and mean olfaction scores, we found that the butanol threshold, odour identification and the composite scores significantly dropped in the

immediate post operative period (p value < 0.001 for all variables) however the change from pre-operative to late post-operative was less significant comparatively.

In our study, only 1 patient had normosmia at the first post-operative visit. 16% had mild hyposmia, 48% had moderate hyposmia, 12% had severe hyposmia and 20% had anosmia. By the third post-operative month, 48% of the patients returned to normosmia by the third month. 48% were found to have mild hyposmia and 4 % had persistent moderate hyposmia.

Looking at the quality of life, in our study we found that the SNOT -22 scores were elevated at the post-operative visit at 2 weeks but came back down to almost to baseline by the 3 month visit. The main subjective complaints faced by the patients were: runny nose, nasal obstruction, loss of smell/taste, post nasal discharge and thick nasal discharge.

They also faced other symptoms like fatigue, decreased productivity and difficulty to get a good nights' sleep. The patients did not face any significant sinonasal symptoms at the 3 month post-operative visit.

We found the mean grand total score for the SNOT-22 was 0.62 +/- 1.29 at the first visit. This increased to 14.24 +/- 4.98 at the first post-operative visit and decreased back to 2.45 +/-1.92 by the third visit. The changes in post-operative scores (immediate and late) were statistically significant with a p value <0.001.

The median scores were 0 at the pre-operative visit and it increased to 14 at immediate postoperative visit. The median score was 2 at C3 – which was decreased compared to the immediate post-operative period but had not reached baseline scores.

Our study was limited by the short term follow up. The 6 month and the 1 year follow-up would give us a better idea about the extent of recovery of the olfaction and quality of life.

Other studies

In 2010, Hart et al looked at the olfactory dysfunction post transnasal endoscopic approach. They did the UPSIT olfaction test pre-operatively, 1 month post-operatively and 3 months post-operatively. The average UPSIT score (out of 40) was 31.8 preoperatively, 30.5 at one month, and 32.6 at three months The decrease in average UPSIT score was found to be statistically significant at 1 month however the 3 month scores were found to return to baseline. They concluded that even though this approach damages olfactory structures, the olfactory dysfunction is transient. However this approach did not include extensive resection like in expanded endoscopic approach hence the complete resolution of olfactory dysfunction compared to our results.

In 2012, Alobid et al looked at nasal morbidity on patients undergoing transnasal transphenoidal endoscopic approach versus expanded endonasal approach (EEA) with a vascularised flap. They looked at the Visual Analogue Scale, objective olfaction (Barcelona Smell Test) and mucociliary clearance time pre-operatively and 3 months post-operatively. They reported that pre-operatively both groups had similar sinonasal symptoms and olfaction scores. Post-operatively they observed significant dysfunction

in terms of loss of smell and posterior nasal discharge compared to baseline Visual analogue scale. They noted that the expanded endoscopic approach patients had worse scores compared to the transnasal transsphenoidal group. They also noted a prolonged mucociliary clearance time post-operatively for both groups with the expanded endoscopic group having worse outcomes. The expanded approach increases damage to the olfactory neuroepithelium due to the middle turbinate resection and the vascular septal flap reconstruction. Denuded mucosa surface of the harvested flap site are left to heal by secondary intention. This may be the cause of nasal crusting which leads to nasal obstruction. (5)

In a study by Kim et al in 2014, a total of 226 patients who underwent binostril endoscopic endonasal transsphenoidal approach were assessed preoperatively and 6 months post operatively for objective olfaction. They were divided into 2 groups based on the surgical approach.

In group A, a conventional nasoseptal flap was created from the inferior border of the ostium of the sphenoid sinus 1cm below the superior border and along the sagittal plane of the septum.

In group B, a modified nasoseptal flap was designed using a curvilinear incision from the inferior border of the ostium of the sphenoid along the septum to anteriorly at the level of the middle turbinate. This is located farther away from the olfactory epithelium.

It was found that both groups had significant decrease in olfactory scores. However, the worsened olfactory scores according to CCCRC was less severe in group B.

This shows that type of nasoseptal flap can influence the outcome.

In another study by Rotenberg et al in 2011, they looked at olfactory dysfunction in endoscopic approach to the pituitary fossa. They followed a middle turbinate preservation protocol with partial superior turbinectomy if required. They raised a Hadad-Bassagasteguy vascularized septal flap in all cases using a low-power cutting cautery to reconstruct the defect left by the surgical resection. They reported a mean UPSIT score of 37.2 pre-operatively (normosmia) which decreased to 30.8 at the 6 months after surgery (mild to moderate hyposmia) (p value <0.0001). They concluded that there is significant olfactory dysfunction post-operatively with the use of nasoseptal flaps. The worse outcomes at 6 months were probably related to the flap. used. (48)

A study by Balaker et al was done in 2010 to assess the severity of sinonasal symptoms following endoscopic anterior skull base surgery. They looked at 69 patients who underwent the endoscopic skull base approach and looked at SNOT- 20 questionnaire as the outcome. They reported that the scores for need to blow nose, runny nose, sneezing, post nasal discharge and thick nasal discharge showed significant worsening at the early post-operative period. These scores show significant improvement over time however remain higher than baseline even at late post-operative period. This was similar to our findings. (47)

In the study done by Pant et al in 2010, they looked quality of life scores using different methods for patients undergoing endoscopic skull base approach. They used the SNOT-22 questionnaire in 51 patients. (43) They reported a significant difference in the mean SNOT-22 scores over time. A statistically significant improvement in the mean score was found in the 1 to 3 month period and the 6 to 12 month period. They also reported that the best scores were achieved 6 to 12 months post-surgery.

In 2014, Zimmer et al did a prospective study in 39 patients who underwent endoscopic transsphenoidal pituitary surgery with preserved middle turbinates, partial resection of superior turbinates and a posterior septotomy preserving 1cm of mucosa superiorly to preserve the olfactory epithelium. They looked at the SNOT-22 questionnaire pre-operatively and 1 and 3 months post-operatively. The patients were also given saline nasal spray to be used every 2 hourly for 1 week and and twice a day following that. (46)

They reported that mean SNOT-22 scores were 23.4 pre-operatively and 27.6 at 1 month after surgery and it significantly improved to 16.2 at 3 months. Sinonasal symptoms like olfaction, nasal obstruction and posterior nasal discharge worsened at 1 month but normalised at 3 months. Recovery of olfaction was probably related to the resolution of mucosal edema and abundant nasal crusting which required endoscopic cleaning at the first post-operative month but had resolved for most patients by the third month after surgery.

In 2014, Hong et al did a retrospective review of 49 patients who underwent endoscopic resection of pituitary adenoma with a nasoseptal flap. This study excluded expanded approach. The patients were divided into 2 arms based on whether flap was raised using monopolar sharp electrocautery or by cold knife. Middle turbinates were preserved and 1cm of superior part of septum was preserved. Olfaction was measured using the visual analog scale and Cross-Cultural Smell IdentificationTest(CC-SIT). They reported that mean change of visual analogue scale for cautery group was more than for cold knife group although it was not statistically significant. 26.3% patients from cautery group suffered from significant olfactory loss compared with the cold steel group(3.3%).

Coagulation-mode electrocautery can cause epithelial loss up to 76.9% whereas cold knife surgery resulted in a loss of around 20%. Hence unintended olfactory epithelium loss can attribute to olfactory loss.

Study	Parameters	Results	Conclusion
Our study	Expanded endoscopic approach Olfaction with CCCRC QOL with SNOT -22	Mean olfaction scores decrease at 2 weeks post op, but improve at 3 months. Mean QOL scores also decrease immediate post op but improve at 3 months Both scores are significantly decreased compared to baseline immediate and late post op.	Significant olfactory and nasal morbidity at immediate post op which resolves to an extent in late post op period.
Hart et al, 2010	Olfactory dysfunction post transnasal endoscopic approach. UPSIT olfaction test pre-operatively, 1 month post-operatively and 3 months post-operatively.	UPSIT score was found to be statistically significant at 1 month 3 month scores were found to return to baseline.	Only transient olfactory dysfunction
Alobid et al, 2012	Nasal morbidity on patients undergoing transnasal transphenoidal endoscopic approach versus expanded endonasal approach (EEA) with a vascularised flap Visual Analogue Scale, objective olfaction (Barcelona Smell Test) and mucociliary clearance time pre-operatively and 3 months post-operatively.	Post-operatively significant dysfunction in terms of loss of smell and posterior nasal discharge compared to baseline Visual analogue scale. Expanded endoscopic approach patients had worse scores compared to the transnasal transsphenoidal group.	Expanded endoscopic approach patients had worse olfactory outcomes compared to the transnasal transsphenoidal group.

Kim et al,2014	Conventional flap versus olfactory epithelium sparing flap. Olfaction using CCCRC pre-operartively and at 6 months	Both groups had significant decrease in olfactory scores. However, the worsened olfactory scores was less severe in sparing flap.	Type of nasoseptal flap can determine olfactory dysfunction.
Rotenberg et al, 2011	Olfactory dysfunction in endoscopic approach to the pituitary fossa with middle turbinate preservation protocol with partial superior turbinectomy and Hadad-Bassagasteguy vascularized septal flap UPSIT olfaction scores assessed	Mean UPSIT score of 37.2 pre-operatively (normosmia) which decreased to 30.8 at the 6 months after surgery (mild to moderate hyposmia)	Significant olfactory dysfunction post-operatively with the use of nasoseptal flaps.
Balaker et al,2010	Quality of life in endoscopic skull base approach SNOT- 20 questionnaire as the outcome	Scores for need to blow nose, runny nose, sneezing, post nasal discharge and thick nasal discharge showed significant worsening at the early post-operative period. Scores show significant improvement over time however remain higher than baseline even at late post-operative period.	Nasal morbidity associated with endoscopic skull base surgery.
Pant et al, 2010	Quality of life scores using SNOT- 22 questionnaire for patients undergoing	Statistically significant improvement in the mean scores was found in the 1 to 3	

	endoscopic skull base appraoch	month period and the 6 to 12 month period Best scores were achieved 6 to 12 months post-surgery	Good improvement in QOL scores after 6 to 12 months post surgery
Zimmer et al,2014	Endoscopic transsphenoidal pituitary surgery with preserved middle turbinates, partial resection of superior turbinates and a posterior septotomy preserving 1cm of mucosa superiorly to preserve the olfactory epithelium. SNOT-22 questionnaire pre-operatively and 1 and 3 months post-operatively.	Mean SNOT-22 scores were 23.4 pre-operatively and 27.6 at 1 month after surgery and it significantly improved to 16.2 at 3 months. Sinonasal symptoms like olfaction, nasal obstruction and posterior nasal discharge worsened at 1 month but normalised at 3 months.	Recovery of olfaction was probably related to the resolution of mucosal edema and abundant nasal crusting which required endoscopic cleaning at the first post-operative month but had resolved for most patients by the third month after surgery. Saline douching helps in recovery.
Hong et al, 2014	Endoscopic resection of pituitary adenoma with a nasoseptal flap. The patients were divided into 2 arms based on whether flap was raised using monopolar sharp electrocautery or by cold knife. Olfaction was measured using the visual analog scale and Cross-Cultural Smell IdentificationTest(CC-SIT).	Mean change of visual analogue scale for cautery group was more than for cold knife group (not statistically significant) 26.3% patients from cautery group suffered from significant olfactory loss compared with the cold steel group (3.3%).	Coagulation-mode electrocautery can cause epithelial loss up to 76.9% whereas cold knife surgery resulted in a loss of around 20%. Hence unintended olfactory epithelium loss can attribute to olfactory loss.

LIMITATIONS

We were not able to make up the sample size of40 patients due to lack of time and difficulty finding patients fitting the inclusion criteria. A larger sample size would give us a better picture and statistically significant results.

We would have a better understanding about the small group of patients who had persistent hyposmia even after 3 months if we had analysed intra operative findings like extent of posterior septotomy and if a nasoseptal rescue flap had been used in these patients.

A graded diagnostic endoscopy post operatively would have also given us information about the status of the healed mucosa in the resected part post operatively.

A longer follow-up would help us look at the full extent of recovery.

CONCLUSION

Our aim was to look at the post-operative morbidity in the context of sinonasal symptoms in patients undergoing the expanded endoscopic approach. On assessing the olfaction, there is significant olfactory disturbance causing loss of smell/ taste in the first 2 weeks post operatively. This may be related to the thick crusting and the resected mucosa in the olfactory region. However, most patients do recover their olfactory function almost upto normal levels by 3 months post operatively, although some patients continued to have mild dysfunction.

Loss of smell/taste, nasal obstruction, runny nose were the main symptoms patients faced immediately post operatively. However 3 months post operatively most of them had little or no symptoms in the context of sinonasal symptoms.

A longer follow-up would help us assess the full extent of recovery of olfaction.

We need to keep in mind the risk of olfactory damage and the discomfort faced by patients in terms of nasal obstruction and other nasal symptoms while planning for this approach. Patients need to understand the temporary nasal morbidity associated with this approach prior to the surgery.

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ANNEXURES

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

April 06, 2018

Dr. Lidia Dennis Chiramal,
PG Registrar,
Department of ENT - 1,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant: New Proposal:**
Assessment of post operative olfactory dysfunction, nasal morbidity and Quality of life in patient's undergoing Expanded endoscopic approach.
Dr. Lidia Dennis Chiramal, Post Graduate Registrar/ ENT/1, Employment Number: 29668, Dr. Regi Thomas, ENT, Dr. Ari Chacko, Neurosurgery, Dr. Krishna Prabhu, Neurosurgery, Dr. John Mathew, ENT, Dr. Tunny Sebastian, Employment number:32291, Biostatistics.

Ref: IRB Min. No. 11019 [OBSERVE] dated 04.12.2017

Dear Dr. Lidia Dennis Chiramal,

The Institutional Review Board (**Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Assessment of post operative olfactory dysfunction, nasal morbidity and Quality of life in patient's undergoing Expanded endoscopic approach" on December 04th 2017.

The Committee reviewed the following documents:

1. IRB application format
2. Proforma for Data Collection Form
3. Consent and Informed Consent Form (English, Tamil and Hindi)
4. Cvs of Drs. John Mathew, Tunny S, Ari, Krishna Prabhu, Regi T,
5. No. of documents 1- 4

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on December 04th 2017 in the CK Job Hall, Paul Brand Building, Christian Medical College, Vellore 632 004.

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
Dr. Anuradha Rose	MBBS, MD, MHSC (Bioethics)	Associate Professor, Community Health, CMC, Vellore	Internal, Clinician
Dr. Thomas V Paul	MBBS, MD, DNB, PhD	Professor, Endocrinology, CMC, Vellore	Internal, Clinician
Dr. RekhaPai	BSc, MSc, PhD	Associate Professor, Pathology, CMC, Vellore	Internal, Basic Medical Scientist
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL,	Sr. Legal Officer, CMC, Vellore	Internal, Legal Expert
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Ms. Grace Rebekha	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr Sneha Varkki	MBBS, DCH, DNB	Professor, Paediatrics, CMC, Vellore	Internal, Clinician
Dr. Sowmya Sathyendra	MBBS, MD (Gen. Medicine)	Professor, Medicine III, CMC, Vellore	Internal, Clinician
Dr. Asha Solomon	MSc Nursing	Associate Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. Sathish Kumar	MBBS, MD, DCH	Professor, Child Health, CMC, Vellore	Internal, Clinician

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Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Mrs. Emily Daniel	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. Mathew Joseph	MBBS, MCH	Professor, Neurosurgery, CMC, Vellore	Internal, Clinician
Dr. Shyam Kumar NK	MBBS, DMRD, DNB, FRCR, FRANZCR	Professor, Radiology, CMC, Vellore	Internal, Clinician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Mrs. Sheela Durai	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. John Antony Jude Prakash	MBBS, MD	Professor, Clinical Microbiology, CMC, Vellore.	Internal, Clinician.

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "Assessment of post operative olfactory dysfunction, nasal morbidity and Quality of life in patient's undergoing Expanded endoscopic approach" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 46,000/- INR (Rupees Forty Six thousand Only) will be granted for 2 years.

Yours sincerely,

Dr. BIJU GEORGE
MBBS., MD., DM.,
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

IRB Min. No. 11019 [OBSERVE] dated 04.12.2017 4 of 4

INFORMATION SHEET

Assessment of post-operative olfactory dysfunction, nasal morbidity and quality of life in patients undergoing expanded endoscopic approach

Information sheet

You are being requested to participate in a study. In this study we test your olfaction (ability to smell), using butanol threshold test and also assess the quality of your life using a questionnaire.

In this test you will be given a solution at different concentrations and you will be asked at which concentration you can identify the smell. You will also be asked to smell different odours and identify each odour.

You will be assessed once before your operation and twice after your operation at 2 weeks and after 3 months. This is to assess if there is any change in your sense of smell because of the operation and to see if it improves over time.

What are butanol test, odour identification and odour discrimination test? Butanol is butyl alcohol (chemical) which is given at different dilutions and you are asked to smell the different concentrations and tell us at which concentration you can identify the smell. This test is repeated independently in each nostril. In odour identification and discrimination you are asked to smell different odours that we use in daily life like coffee powder, cinnamon etc. and you will be asked to identify each odour and differentiate it from the other one.

Does butanol test have any side effect?
There are no side effects for this test. This will just help us identify the extent of your sense of smell.

If you take part what will you have to do?
As mentioned above you have to undergo the butanol test and odour tests and also answer a simple questionnaire related to your symptoms. This will be documented preoperatively and post operatively at your 2 week and 3month visit. There is no extra cost you have to pay for this study.

Can you withdraw from this study after it starts?
Your participation in this study is entirely voluntary and you are free to decide to withdraw permission to participate in this study. If you do so, it will not affect your usual treatment in this hospital in any way.

Will you have to pay for this test?
You need not pay for this test. The rest of your treatment will be charged according to the hospital charges.

What happens after the study is over?
After the study is over, you will be able to see if there is change in your sense of smell and if it improves over time.

Will your personal details be kept confidential?
The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, should you decide to participate in this study.

INFORMED CONSENT

Assessment of post-operative olfactory dysfunction, nasal morbidity and quality of life in patients undergoing expanded endoscopic approach

- **Study Number: _____**
- **Subject's Initials: _____**
- **Subject's Name: _____**
- **Date of Birth / Age (in years) : _____**
-

1) I confirm that I have read and understood the information sheet dated for the above study and have had the opportunity to ask questions.
   [ ]

2) 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. [ ]

3) I understand that study staff, 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 voluntarily agree to take part in the above study. [ ]

Name of subject: _____

Signature (or Thumb impression) of the Subject:

Date: _____/_____/_____

Name of the Investigator: _____

Signature:

Date: _____/_____/_____

Name of the Witness: _____

Signature or thumb impression of the Witness:

Date: _____/_____/_____

PROFORMA FOR DATA COLLECTION

Study no.:

NAME:

AGE:

Male/Female:

DIAGNOSIS:

OLFACTION SCORE

Pre –operative visit (C1)

Butanol threshold: Left: Right:

Odour identification: Left: Right:

Composite score: Left: Right:

Post-operative (2 weeks) (C2):

Butanol threshold: Left: Right:

Odour identification: Left: Right:

Composite score: Left: Right:

Post-operative (3months) (C3):

Butanol threshold: Left: Right:

Odour identification: Left: Right:

Composite score: Left: Right:

QUALITY OF LIFE (SNOT-22) COMPOSITE SCORE:

Pre-operative:

Post-operative (2 weeks):

Post-operative (3months):

Consent for Olfaction Testing

Department of ENT, Rhinology Service
Christian Medical College, Vellore

Name: Age: Hospital Number:

The procedure of the clinical test of smell has been explained to me. I understand that this test is non invasive and will not harm me. I also have no objection to the results of this test being used for therapeutic, academic and research purposes.
I hereby give full informed consent to undergo Clinical Olfaction testing.

Date: Patient:

Doctor/Sister: Witness:

Butanol Threshold Test

Patient: Hospital No:

Age: Sex: Referred by:

Diagnosis:

Any Treatment:

First Visit / Second Visit Tested by:

Date:

Left Nostril				**Right Nostril**			
11	11	11	11	11	11	11	11
10	10	10	10	10	10	10	10
9	9	9	9	9	9	9	9
8	8	8	8	8	8	8	8
7	7	7	7	7	7	7	7
6	6	6	6	6	6	6	6
5	5	5	5	5	5	5	5
4	4	4	4	4	4	4	4
3	3	3	3	3	3	3	3
2	2	2	2	2	2	2	2
1	1	1	1	1	1	1	1
0	0	0	0	0	0	0	0
Bottle #				Bottle #			

Composite Score:

6.0 – 7.0	Normosmia
5.0 – 5.75	Mild hyposmia
4.0 – 4.75	Moderate hyposmia
2.0-3.75	Severe hyposmia
0 – 1.75	Anosmia

SCORE	**Left N**	**Right N**
Butanol Threshold		
Odor Identification		
Composite Score		

Odor Identification Test

Patient: Hospital No:

Age: Sex: Referred by:

Diagnosis:

Treatment history :

First Visit / Second Visit Tested by:

Date:

Odorant	Left Nostril Trial1	Left Nostril Trial2	Right Nostril Trial1	Right Nostril Trial2
Cinnamon				
Asafoetida				
Coffee				
Tea				
Pepper				
Clove Oil				
Baby Powder				
Total # correct				
Vicks/Eucalyptus (TrigeminalN)				
Lemon				
Rose				
Key :	√ - Correct	NS – No sensation	DK- Don't know	Misidentification to be specified

advanced ent

Sino-Nasal Outcome Test (SNOT-22) Questionnaire

Name: _____ DOB: _____

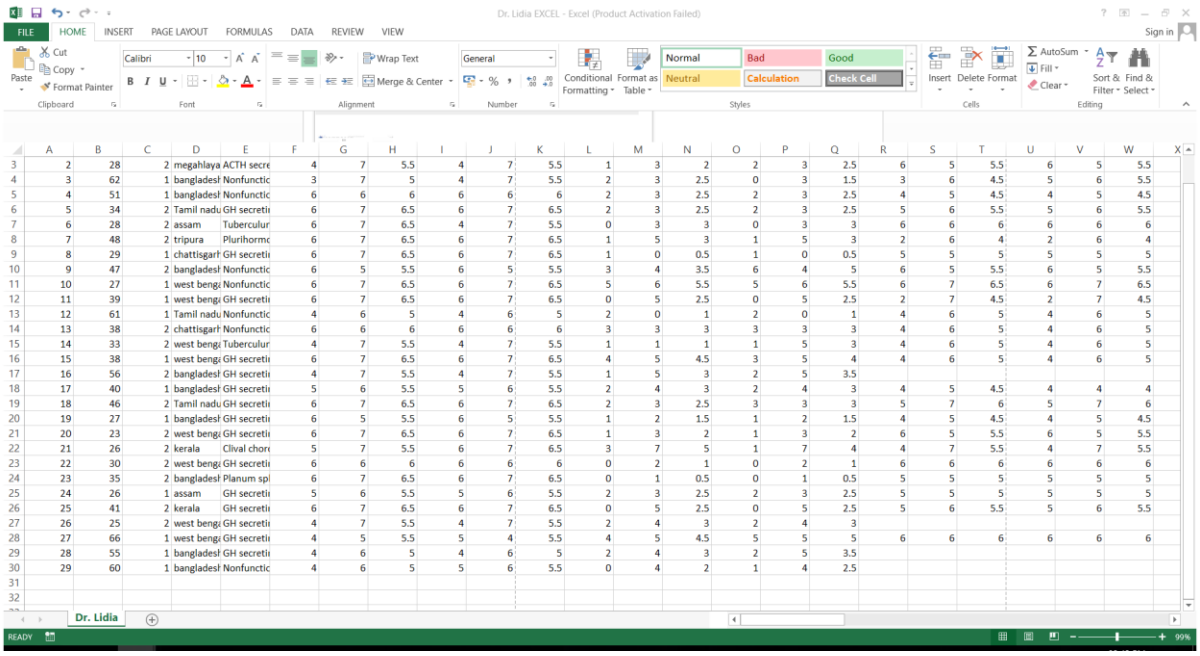
Date: _____

Below you will find a list of symptoms and social/emotional consequences of your nasal disorder. We would like to know more about these problems and would appreciate your answering the following questions to the best of your ability. There are no right or wrong answers, and only you can provide us with this information. Please rate your problems as they have been over the past two weeks. Thank you for your participation.

A. Considering how severe the problem is when you experience it and how frequently it happens, please rate each item below on how "bad" it is by circling the number that corresponds with how you feel using this scale:

	No Problem	Very Mild Problem	Mild or Slight Problem	Moderate Problem	Severe Problem	Problem as bad as it can be	Most important items
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. Nasal obstruction	0	1	2	3	4	5	[ ]
5. Loss of smell or taste	0	1	2	3	4	5	[ ]
6. Cough	0	1	2	3	4	5	[ ]
7. Post-nasal discharge	0	1	2	3	4	5	[ ]
8. Thick nasal discharge	0	1	2	3	4	5	[ ]
9. Ear fullness	0	1	2	3	4	5	[ ]
10. Dizziness	0	1	2	3	4	5	[ ]
11. Ear pain	0	1	2	3	4	5	[ ]
12. Facial pain/pressure	0	1	2	3	4	5	[ ]
13. Difficulty falling asleep	0	1	2	3	4	5	[ ]
14. Waking up at night	0	1	2	3	4	5	[ ]
15. Lack of a good night's sleep	0	1	2	3	4	5	[ ]
16. Waking up tired	0	1	2	3	4	5	[ ]
17. Fatigue	0	1	2	3	4	5	[ ]
18. Reduced productivity	0	1	2	3	4	5	[ ]
19. Reduced concentration	0	1	2	3	4	5	[ ]
20. Frustrated/restless/irritable	0	1	2	3	4	5	[ ]
21. Sad	0	1	2	3	4	5	[ ]
22. Embarrassed	0	1	2	3	4	5	[ ]
TOTALS (each column):							
GRAND TOTAL SCORE (all columns together):							

B. Please check off the most important items affecting your health in the last column (max of five items)



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X
3	2	28	2	megahlaya	ACTH secre	4	7	5.5	4	7	5.5	1	3	2	2	3	2.5	6	5	5.5	6	5	5.5	
4	3	62	1	bangladesh	Nonfunctic	3	7	5	4	7	5.5	2	3	2.5	0	3	1.5	3	6	4.5	5	6	5.5	
5	4	51	1	bangladesh	Nonfunctic	6	6	6	6	6	6	2	3	2.5	2	3	2.5	4	5	4.5	4	5	4.5	
6	5	34	2	Tamil nadu	GH secreti	6	7	6.5	6	7	6.5	2	3	2.5	2	3	2.5	5	6	5.5	5	6	5.5	
7	6	28	2	assam	Tuberculur	6	7	6.5	4	7	5.5	0	3	3	0	3	3	6	6	6	6	6	6	
8	7	48	2	tripura	Plurihormc	6	7	6.5	6	7	6.5	1	5	3	1	5	3	2	6	4	2	6	4	
9	8	29	1	chattisgarh	GH secreti	6	7	6.5	6	7	6.5	1	0	0.5	1	0	0.5	5	5	5	5	5	5	
10	9	47	2	bangladesh	Nonfunctic	6	5	5.5	6	5	5.5	3	4	3.5	6	4	5	6	5	5.5	6	5	5.5	
11	10	27	1	west bengi	Nonfunctic	6	7	6.5	6	7	6.5	5	6	5.5	5	6	5.5	6	7	6.5	6	7	6.5	
12	11	39	1	west bengi	GH secreti	6	7	6.5	6	7	6.5	0	5	2.5	0	5	2.5	2	7	4.5	2	7	4.5	
13	12	61	1	Tamil nadu	Nonfunctic	4	6	5	4	6	5	2	0	1	2	0	1	4	6	5	4	6	5	
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15	14	33	2	west bengi	Tuberculur	4	7	5.5	4	7	5.5	1	1	1	1	5	3	4	6	5	4	6	5	
16	15	38	1	west bengi	GH secreti	6	7	6.5	6	7	6.5	4	5	4.5	3	5	4	4	6	5	4	6	5	
17	16	56	2	bangladesh	GH secreti	4	7	5.5	4	7	5.5	1	5	3	2	5	3.5							
18	17	40	1	bangladesh	GH secreti	5	6	5.5	5	6	5.5	2	4	3	2	4	3	4	5	4.5	4	4	4	
19	18	46	2	Tamil nadu	GH secreti	6	7	6.5	6	7	6.5	2	3	2.5	3	3	3	5	7	6	5	7	6	
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21	20	23	2	west bengi	GH secreti	6	7	6.5	6	7	6.5	1	3	2	1	3	2	6	5	5.5	6	5	5.5	
22	21	26	2	kerala	Clival chor	5	7	5.5	6	7	6.5	3	7	5	1	7	4	4	7	5.5	4	7	5.5	
23	22	30	2	west bengi	GH secreti	6	6	6	6	6	6	0	2	1	0	2	1	6	6	6	6	6	6	
24	23	35	2	bangladesh	Planum spl	6	7	6.5	6	7	6.5	0	1	0.5	0	1	0.5	5	5	5	5	5	5	
25	24	26	1	assam	GH secreti	5	6	5.5	5	6	5.5	2	3	2.5	2	3	2.5	5	5	5	5	5	5	
26	25	41	2	kerala	GH secreti	6	7	6.5	6	7	6.5	0	5	2.5	0	5	2.5	5	6	5.5	5	6	5.5	
27	26	25	2	west bengi	GH secreti	4	7	5.5	4	7	5.5	2	4	3	2	4	3							
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29	28	55	1	bangladesh	GH secreti	4	6	5	4	6	5	2	4	3	2	5	3.5							
30	29	60	1	bangladesh	Nonfunctic	4	6	5	5	6	5.5	0	4	2	1	4	2.5							
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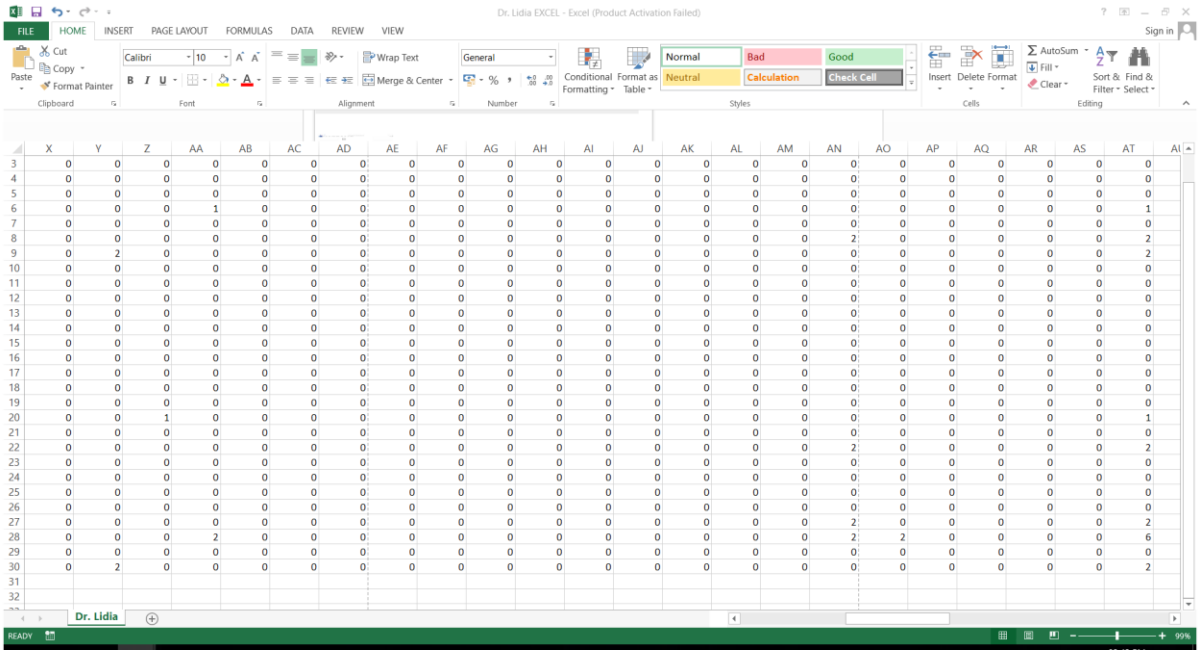
32																								



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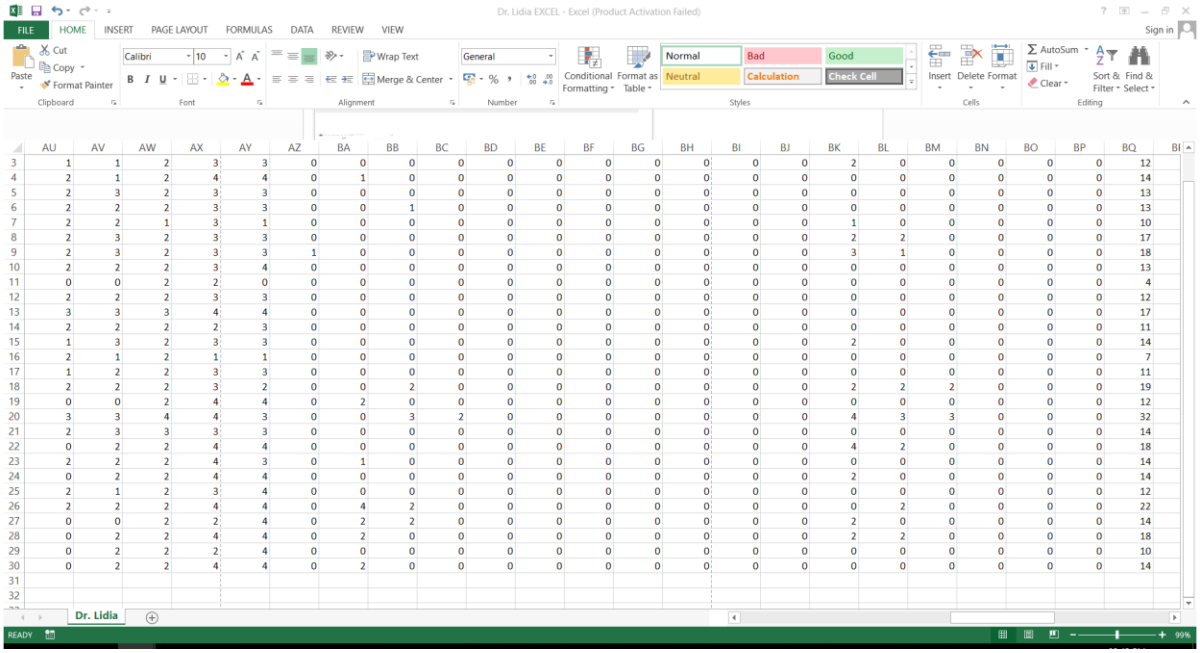

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5	2	3	2	3	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	13
6	2	2	2	3	3	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	13
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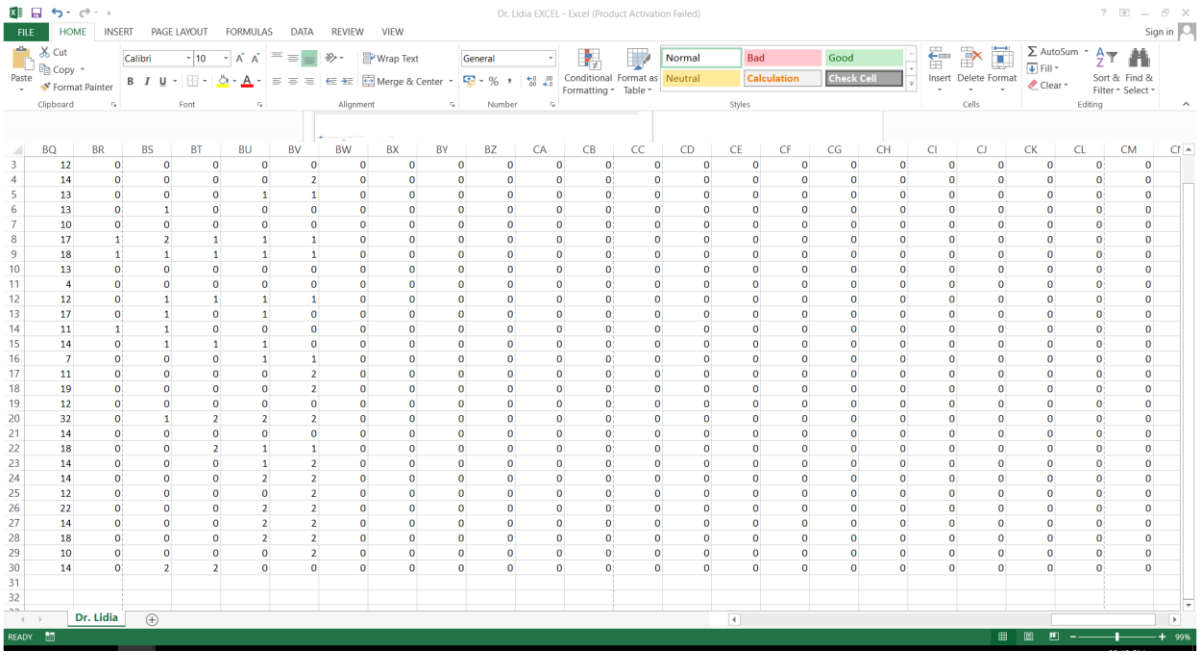

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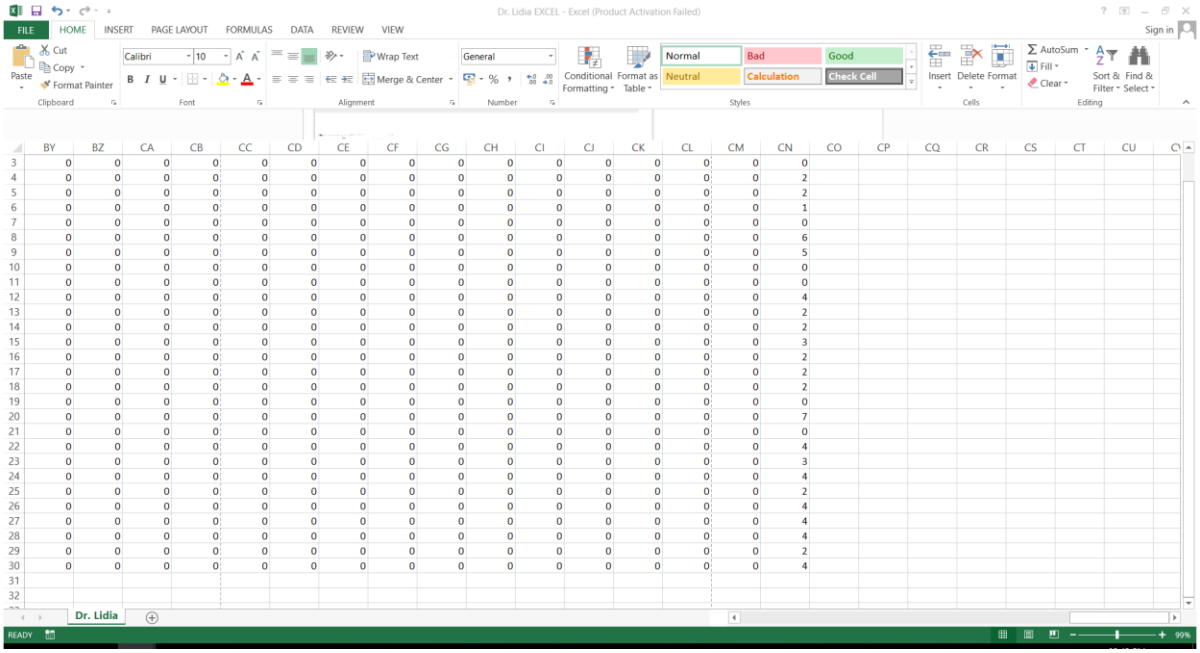
Dr. Lidia EXCEL - Excel (Product Activation Failed)
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Wrap Text
Merge & Center
General
Conditional Formatting
Format as Table
Normal
Bad
Good
Neutral
Calculation
Check Cell
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Format
AutoSum
Fill
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Number
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Editing
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31
32
Dr. Lidia
READY
99%

ABSTRACT

TITLE

Assessment of post-operative olfactory dysfunction, nasal morbidity and quality of life in patients undergoing expanded endoscopic approach.

BACKGROUND:

Human beings rely on their sense of smell for the detection of potential harms. Any dysfunction of the sense of smell can hence cause distress to the patient. In endoscopic approach to the skull base, especially the expanded approach the pristine normal native nasal mucosa undergoes aggressive mucosal resection for exposure. There is a lacunae of information about the long term impact of this approach. The importance of informing the patient about the possible nasal morbidity and olfactory dysfunction associated with this approach was explored.

AIM

To assess the post-operative olfactory impairment, quality of life and nasal morbidity in expanded endoscopic approach (EEA)

OBJECTIVES:

In patients undergoing expanded endoscopic approach for skull base tumours:

- To assess the extent of olfaction impairment following an expanded endoscopic approach

- To follow up these patient over 3 months and to see the extent of recovery olfaction in these patients
- To assess how quality of life affected in the context of sinonasal symptoms in these patients

METHODS:

This was a prospective observational study in a hospital set up. Patients over the age of 18 who were diagnosed with skull base tumours planned for expanded endoscopic approach were recruited.

We assessed the olfactory function in these patients using the CCCRC olfaction test and quality of life was evaluated with the baseline SNOT -22 questionnaire pre-operatively, and post-operatively at 2 weeks and 3 months

RESULTS

There was a female preponderance with age ranging from 23 to 66 years.

The most common diagnosis was noted to be growth hormone secreting pituitary adenoma, followed by non-functioning pituitary adenoma. It was found that 92% had normosmia and 8% mild hyposmia at pre- operative visit. At the 2 week post-operative visit, only 1 subject had normosmia, 48% had moderate hyposmia, 20% had anosmia, 12% had severe hyposmia and 16 % had mild hyposmia.

At the 3 month follow up visit, the olfactory scores seemed to have improved with almost half the subjects (48%) with a normal olfaction score and the rest with mild hyposmia. Only 1 subject had persistent moderate hyposmia at 3 month visit.

Quality of life scores significantly increased in the immediate post- operative period and although it decreased over 3 months, it did not touch baseline at 3 months.

CONCLUSION

There is significant post-operative morbidity in the context of sinonasal symptoms in patients undergoing the expanded endoscopic approach in the immediate post-operative period. There was statistically significant olfactory disturbance in the first 2 weeks post operatively. However, most patients recovered their olfactory function almost upto normal levels by 3 months post operatively, although some patients continued to have mild dysfunction.

Loss of smell/taste, nasal obstruction, runny nose were the main symptoms patients faced immediately post operatively. However 3 months post operatively most of these symptoms resolved.

We need to keep in mind the risk of olfactory damage and nasal morbidity by patients while planning for this approach