CLINICAL ASSESSMENT OF PATIENT REPORTED QUALITY OF LIFE FOLLOWING ENDOSCOPIC SKULL BASE SURGERIES

Dr SURAJ GOPAL

MCh NEUROSURGERY THESIS

2023

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

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A THESIS SUBMITTED BY

Dr SURAJ GOPAL

TO

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM.

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE AWARD OF

MCh NEUROSURGERY

2023

DECLARATION BY THE STUDENT

CERTIFICATE

I, Dr Suraj Gopal hereby certify that I had personally carried out the work depicted in the thesis titled, "**Clinical Assessment Of Patient Reported Quality Of Life Following Endoscopic Skull Base Surgeries**"

No part of this thesis has been submitted for the award of any other degree or diploma prior to this date.

Signature

Name of the Candidate Dr SURAJ GOPAL

Date 18/08/2023

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The thesis entitled, "**Clinical Assessment Of Patient Reported Quality Of Life Following Endoscopic Skull Base Surgeries**" was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date. Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

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APPROVAL OF THE THESIS

The thesis entitled

"Clinical Assessment Of Patient Reported Quality Of Life Following Endoscopic Skull Base Surgeries"

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MCh Neurosurgery

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SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

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ACKNOWLEDGEMENTS

I owe a deep sense of gratitude to Dr. Prakash Nair, Associate Professor Department of Neurosurgery, for his invaluable advice, encouragement, and guidance, without which this work would not have been possible. His critical remarks, suggestions, helped me in achieving a high standard of work.

The guidance of Prof Easwer HV and Prof Krishnakumar K, has been invaluable and I am extremely grateful and indebted for his contributions and suggestions, which were of invaluable help during the entire work. They will always be a constant source of inspiration to me.

I am deeply indebted to Dr. George C Vilanilam, Dr. Jayanand Sudhir, Dr. Ganesh Divakar for their constant encouragement and support.

I thank my colleagues , friends and my parents for their help and guidance in this study

I owe a deep sense of gratitude to all my patients without whom this work would not have been possible.

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LIST OF ABBREVIATIONS

Abbreviation	Full Form
1. QoL	Quality of life
2. SNOT 22	Sino Nasal Outcome Test 22
3. ASBQ	Anterior Skull Base Questionnaire
4. SBI	Skull Base Inventory
5. EES	Endoscopic Endonasal Surgery
6. PRQoL	Patient-Reported Quality Of Life
7. ENT	Ear Nose Throat
8. EASB	Endoscopic Anterior Skull Base
9. NSF	Nasoseptal Flap
10. CRS	Chronic Rhinosinusitis
11. ESBS	Endoscopic Skull Base Surgery
12. ASA	American Society of Anesthesiologists
13. MRI	Magnetic Resonance Imaging
14. CT	Computed Tomography
15. Pre -op	Preoperative
16. Post – op	Postoperative
17. PROM	Patient Reported Outcome Measure

SYNOPSIS

Objectives:

1) To assess the patient reported quality of life pertaining to the nasal domain and towards the overall QoL using sinonasal outcome test (SNOT-22), anterior skull base questionnaire (ASBQ) and the anterior skull base inventory (SBI) following endoscopic endonasal skull base surgery.
2) To evaluate the changes in QoL preoperatively, 1 month and 3 months after surgery.
3) To determine the concurrent validity between SNOT 22, SBI and ASBQ.

Background :

Endoscopic endonasal surgery (EES) is a widely utilized approach for managing ventral skull base pathologies. Evaluating patient-reported quality of life (PRQoL) following EES is crucial for assessing its effectiveness and improving patient outcomes. Apart from accurately determining critical disease characteristics and detecting treatment-induced changes, evaluating the impact of EES on health-related QoL are vital components of this assessment. No single QoL assessment tool has been found to be superior in accurately estimating the PRQoL.

Methods :

Prospective study involving patients scheduled for elective endoscopic surgeries targeting anterior skull base lesions. Baseline scores were obtained using three questionnaires : SNOT-22, anterior skull base questionnaire (ASBQ) and skull

base inventory (SBI). Follow-up questionnaires were administered at 1 month and 3 months post-surgery.

Results:

Seventy-two eligible patients were included in the analysis. SNOT-22 scores demonstrated significant improvement in all five domains and the total symptom score compared to pre-operative baseline values at both 1 month and 3 months post-surgery. Friedman test analysis revealed significant improvements in total scores and four out of five domains at 1 month, and significant improvements in all domains and total scores at 3 months. The SBI scores showed significant improvement over time across all other domains except the nasal domain. Bonferroni Post-hoc test showed that the over all scores were significantly lower at 1month ($p = .001$) and 3month ($p = .001$) when compared with baseline scores. Similarly, ASBQ scores demonstrated significant improvement over time, except for the pain domain, across all other domains, Bonferroni Post-hoc test showed that the overall scores were significantly lower at 1m ($p = .001$) and 3m ($p = .001$) than at baseline

Conclusion :

The study highlights the positive impact of EES on patient-reported QoL across multiple domains, as evidenced by improvements in the QoL when assessed with the SNOT-22, SBI and ASBQ scores. All three questionnaires showed good concurrent validity with each other. Certain domains reflect these changes on PRQoL better than others. These findings reaffirm the effectiveness of EES in enhancing patient outcomes and emphasize the importance of incorporating patient perspectives into treatment decision-making for optimal results.

INTRODUCTION

Endoscopic skull base surgery is now an accepted modality for managing a variety of anterior skull base problems and is fast emerging as an alternative to open and classical neurosurgical techniques.

Evolution of endosocopic endonasal surgeries :

Endoscopic trans sphenoidal techniques were introduced and became popular due to the close association between neurosurgeons and ENT surgeons. Endoscopes were used initially as an adjunct to the more conventional microscopic techniques and later the procedures evolved into purely endoscopic techniques (Carrau RL, 1996) Due to the development of endoscopic technology over the years along with the development of adjuncts for endoscopic surgery such as neuronavigation and microvascular doppler, endoscopic surgery has enormously progressed to address pathologies not only limited to the sella but to adjacent areas of the skull base leading the way for extended endonasal approaches (Jho et al., 2003 ; Kaptain et al., 2001, n.d.; Locatelli et al., 2000).

Accessibility of endoscopic techniques:

The sphenoid sinus is an important landmark for extended skull base surgeries (Kassam et al., 2005). The posterior wall of the sphenoid sinus provides a neurosurgical corridor to manage sellar and supra sellar pathologies like pituitary adenoma, meningioma and craniopharyngioma. The optic-carotid recess can be identified on the supero lateral walls of the sphenoid sinus, harboring the optic nerves and carotid arteries. The cavernous sinus can be accessed by removing bone

lateral to the carotid artery to enter and remove lesions in the cavernous sinus**.** A maxillary antrostomy provides another endoscopic corridor to the infratemporal fossa through the pterygopalatine fossa. Anteriorly one can address pathologies of the midline anterior cranial fossa floor by resecting the sphenoid roof or planum sphenoidale. Posteriorly the clivus, foramen magnum, basilar artery and brainstem structures can be addressed (Kassam et al., 2005). Exposure through the nasopharynx allows access to atlas and odontoid process thus providing a variety of corridors for the endoscopic neurosurgeon.

Advantages of endoscopic surgeries:

Endoscopic endonasal surgery (EES) has gained popularity in the last two decades due to its advantages over traditional open surgery, including shorter hospital stays, decreased morbidity, and faster recovery times. The process for creating an optimal corridor for surgical access often necessitates interventions like posterior septectomy, middle turbinectomy and the elevation of a nasoseptal flap.

Morbidity of endoscopic surgeries:

On one hand, creation of wide surgical corridor improves the visualization of surgical landmarks, allows dexterous manipulation of instruments within the corridor and provides vascularized tissue for repair of the skull base following surgery. On the other hand, surgery that traverses the sinonasal tract has the potential to disrupt normal physiologic processes, including mucociliary function, regulation of airflow, and olfaction which have been linked to long term sequelae like crusting, nasal discharge and anosmia that follow these procedures. These contribute to the

sinonasal morbidity occuring after these procedures and leave an everlasting impact on patient percieved outcomes.

Endoscopic anterior skull base (EASB) surgery has been significantly impacted by the extensive utilization of the nasoseptal flap (NSF)(Hadad et al.,2006) . The sphenopalatine artery is the main vascular supply for the nasoseptal flap around which the flap can be rotated. Due to these factors, it has become a standard and crucial component of the multilayered repair process for reconstructing anterior skull base defects, making it the go-to flap for surgeons (McCoul et al.,2014 ; Raza et al.,2015).

The sequelae of surgery involving the anterior skull base can have a profound impact on a patient's ability to eat, speak, sleep, and socialize, resulting in a significant lifestyle change. Additionally, procedures used to extract anterior skull base tumors carry a high risk of complications such as cerebrospinal fluid leakage, meningitis, brain herniation, tension pneumocephalus, anosmia, osteoradionecrosis, fistula, mucocele, facial deformities, and visual disturbances (Enepekides et al., 2000; Fliss et al., 2007). These postoperative complications can further reduce the patient's quality of life.

AIM AND OBJECTIVES

AIM

To assess the patient reported quality of life pertaining to the nasal domain and towards the overall QoL following endoscopic endonasal skull base surgery.

OBJECTIVE

1) To assess the patient reported quality of life (QoL) using sinonasal outcome test (SNOT-22), anterior skull base questionnaire (ASBQ) and the skull base inventory (SBI).
2) To evaluate the changes in QoL preoperatively, 1 month and 3 months after surgery.
3) To determine the concurrent validity among the three questionnaires used.

REVIEW OF LITERATURE

In neurosurgery, assessing PRQoL is evolving into a critical measure of the effectiveness of EES. This entails gathering data directly from patients about their physical, emotional, and social well-being following the surgery. A comprehensive understanding of the patient's reported QoL can assist clinicians in making informed decisions about treatment strategies and delivering more patient-centered care rather than disease control measures or morbidity and mortality figures. Therefore, evaluating patient reported QoL following EES in neurosurgery is crucial for determining the approach's effectiveness and enhancing patient outcomes.

Various studies have evaluated the impact of endoscopic anterior skull base (EASB) surgery on patients' quality of life (QoL). Earlier studies discovered that patients who underwent endoscopic resections of skull base tumors had a better short-term postoperative QoL than those who underwent a cranial approach. However, sinonasal QoL was found to decline during the early postoperative period (3-12 weeks after surgery) following EASB (Abergel et al., 2012; Balaker et al., 2010).

The need for standardized tools to assess QoL:

The way each person perceives their well-being can vary significantly. Even individuals with similar complaints may interpret their symptoms differently, which means they may be impacted by them in unique ways (Witgert et al., 2010). There are a lot of socio-cultural and economic influences that guide these perceptions of wellbeing.

In contrast to the conventional medical history that relies on the clinician's subjective estimation through directed questioning, QoL is a measure reported by the patient that seeks to eliminate observer bias. QoL assessments can be either generalized or disease-specific, and offer several potential benefits, such as providing improved preoperative counselling by the surgeon, better anticipation of the surgery's impact and recovery by the patient, and greater acceptance of the surgical procedure. Furthermore, QoL measures can eventually serve as reportable indicators of the surgical intervention's success and can be used to compare the effectiveness of various interventions (Gil et al.2010). There is a growing trend in healthcare that these Patient Related Outcome Measures (PROM) are more suitable for disease evaluation. Subjective health-related QoL questionnaires that have been validated are becoming more accepted and recommended as tools for evaluating the outcomes of surgery (Juniper et al., 1991; Lund 2001)

To be effective, it must assess the characteristics of the disease, be able to detect changes resulting after an intervention and represent the change in the quality of life over time. Tools like the widely used SF 36 is not disease specific and may show inaccuracies in patients with other preexisting condition. They may also fail to highlight a specific symptom that a patient has (Benninger et al.,1997). In contrast, disease-specific questionnaires are designed to concentrate on the symptoms or symptom complex that are relevant to a particular disease (Lund, 2007).

Gill and Fenstein have proposed several suggestions to enhance the measurement of quality of life (QoL) (Gill et al., 1994). They recommend the use of two scores one

for measuring the overall wellbeing and one specific to their health and then derive a final score to measure wellbeing. Moreover, they suggested that patients should be allowed to include additional items they consider significant and have been excluded. However, due to the importance of symptom severity and importance, some sinonasal specific outcome measures were not deemed suitable for practice and potential global use.

Criteria for QOL assessment tools:

To be considered as health-related quality of life tools, certain criteria must be met, including reliability, validity, responsiveness, and ease of use.

Reliability in health-related quality of life tools refers to the ability of the tool to produce the same results if measured again on the same individual. Reliability is important for ensuring that the tool is free from random errors and that the results obtained are trustworthy. Validity is the degree to which a tool actually measures what it is supposed to measure. Responsiveness is the sensitivity of the parameter to change over a certain period of time. Ease of use is a determinant of how easily it can be administered. If a tool such as a questionnaire is difficult to administer by the health care professional, it precludes further use. This can be due to factors such as too many forms, complex wordings, or difficult scales.

Our study used three validated questionnaires which includes the sinonasal outcome test (SNOT-22), anterior skull base questionnaire (ASBQ) and the skull base inventory (SBI).

SNOT 22 questionnaire:

The SNOT 22 questionnaire is specifically focuses on complaints of the nose, throat and ears in patients with non malignant pathologies (Morley et al., 2006) This questionnaire has been extrapolated to endoscopic endonasal surgeries (McCoul et al., 2012; McCoul et al., 2014; Pant et al., 2010; Wu et al., 2018; Shah et al.,2014). A higher score implies a worse reporting of symptoms by the patient. The score has also shown to improve following treatment (Hopkins et al., 2009).

The SNOT-22 questionnaire consists of 22 items that cover five domains. The first domain of nasal symptoms includes items that assess nasal congestion, postnasal drip, nasal discharge. The second domain, ear/ facial includes items that assess for ear fullness, dizziness or facial pain. The third domain, sleep dysfunction, assess falling asleep and waking up tired. The fourth domain is of function which that assess fatigue, difficulty concentrating, and irritability. The fifth domain is emotion that assess the degree to which they feel sad or embarrassed.

The SNOT 22 questionnaire is a simple questionnaire that mainly focuses on the nasal complaints of the patient. Each of these items pertains to a specific symptom and is scored by the patient on a scale of 0 (absence of symptoms) to 5 (extreme symptoms). The score for each item is then added up, with a maximum score of 110. Higher scores implies a worse quality of life

After receiving criticism regarding the content-related validity of SNOT-16 and SNOT-20, the SNOT-22 questionnaire was developed to improve upon these issues, specifically incorporating items to assess nasal blockage and loss of olfaction or taste (Hopkins et al., 2006). The previous versions' validity is retained in the current version, which has also been independently validated. It has been extensively

used to study the effects of surgery after interventions for nasal polyps and chronic rhinosinusitis.

The SNOT-22 questionnaire performs well in terms of reliability, validity, and responsiveness. With many items, the questionnaire has been shown to have construct-related validity through high correlations.

The SNOT-22 questionnaire is considered the most appropriate outcome tool for assessing the QoL in the management of chronic rhinosinusitis (CRS) by ESS. One of its strengths is its ability to integrate both sinonasal-specific and general health questions, allowing for pre- and post-operative assessments (Morley et al., 2006).

One study (Morley et al., 2006) aimed to identify the most appropriate sinonasal outcome scoring system for use in patients undergoing endoscopic sinus surgery for chronic rhinosinusitis. The authors evaluated 15 known disease-specific sinonasal outcome indices based on their reliability, validity, and responsiveness. They concluded that the SNOT-22 was the most ideal questionnaire as it satisfied all parameters of a good tool to measure outcomes, it was easy to administer, it could show the difference between those who had a disease condition and those who did not and also reflected the change in QoL that occurs with well.

The study of Glicksman et al (Glicksman et al.,2017) monitoring 145 patients who received endoscopic resection of both benign and malignant sinonasal tumors for a period of 2 years after surgery. The authors observed a significant improvement in SNOT-22 scores from the baseline level at 3 months, which was maintained

throughout the 2-year follow-up period. However, the QoL scores were consistently lower for patients with malignant tumors than for those with benign tumors at all time points.

According to Harrow et al, (Harrow et al., 2013) average SNOT-20 scores, along with scores for questions pertaining to the rhinologic and ear/facial subdomains, were enhanced at 3 and 6 months after surgery as compared to preoperative levels. However, the improvement was limited to patients with benign tumors. When assessing long-term results, the notable improvements observed in patients with benign tumors six months after the surgery did not persist at 1 or 2 years after the surgery. Conversely, patients with malignant tumors showed improved psychological and sleep subdomain scores at these later time points (Derousseau et al., 2015).

Studies on sinonasal QoL scores with the use of nasal septal flaps (NSF) show conflicting results, with some suggesting a transient worsening of short-term outcome scores followed by a return to baseline (Pant et al.,2010). However, Chaaban et al. found no significant difference in University of Pennsylvania Smell Identification Test scores and no adverse effects on postoperative scores with the use of NSF for reconstruction in endoscopic trans nasal pituitary surgery (Jalessi et al.,2015). Similarly, Jalessi et al. reported a temporary decrease in QoL with NSF harvest in patients with pituitary adenomas undergoing endoscopic endonasal transsphenoidal surgery, which returned to baseline within three months. Nonetheless, overall improvement in SNOT-22 scores was significant at 12 months after surgery when compared to preoperative data (Jalessi et al., 2015).

Anterior Skull Base Questionnaire (ASBQ):

The primary tool used for assessing quality of life following surgery on the anterior skull base is the ASBQ, which has been widely adopted. Initially published in 2003, it has been validated specifically for patients undergoing surgery for anterior skull base tumors (Gil et al., 2004). It comprises 35 items categorized into six domains, with scores for each item ranging from 1 to 5. Therefore, the total score range is between 35 and 175, with higher scores indicating better outcomes. The questions aim to cover various aspects of postoperative changes, such as taste, smell, appearance, nasal function, visual function, mood, energy levels, and pain. The ASBQ consists of 35 items that can be classified into six distinct QoL domains, which include performance (six items), physical function (seven items), vitality (seven items), pain (three items), influence on emotions (five items), and specific symptoms (seven items). The ASBQ is designed to detect changes from preoperative levels. The questionnaire has demonstrated its ability to predict postoperative QoL among patients undergoing skull base tumor surgery even before the operation takes place (Fliss et al., 2010).

The absence of a strong association between the overall QoL questions and the individual domains of the ASBQ indicates that either general questions may not be able to accurately detect changes in a specific disease process, or specific questions may be too narrow to identify changes in the overall QoL. This finding suggests that using both site-specific and general QoL tools can provide a more comprehensive assessment of the patient's QoL following anterior skull base surgery (Gil et al, 2004).

According to recent prospective data on endoscopic surgery, there is evidence to suggest that ASBQ scores significantly improve as early as 12 weeks after surgery when compared to preoperative levels (McCoul et al., 2012). However, in this particular cohort of endoscopic surgery patients, it was observed that the only domain to deteriorate postoperatively was the specific symptoms domain, which was a transient deterioration.

There is no significant association between postoperative ASBQ score and various factors, including undergoing endoscopic surgery, malignancy, age, radiation therapy, comorbidities, prior surgery, type of pathology (pituitary or non pituitary tumor), secreting versus non secreting tumor, anatomical region involved, use of a nasoseptal flap reconstruction, use of a second surgical donor site, and presence of postoperative complications, according to recent studies (Abergel et al., 2012; McCoul et al., 2012). However, complete resection was seen to be associated with better outcomes at 12 weeks and 6 months after endoscopic endonasal surge (Abergel et al., 2012; McCoul et al.,2012).

This questionnaire is a comprehensive instrument that enables the assessment of both general and disease specific QoL measures for patients with anterior skull base tumors. It may assist the decision-making process regarding primary and adjuvant therapies and provide information that will facilitate accurate explanation of the disease process and its management to patients and their families.

A study was conducted by Ziv Gil et al (Gil et al.,2014) performed a study to develop a disease-specific, multidimensional QoL assessment instrument for patients undergoing surgical extirpation of anterior skull base tumors. This investigation included 35 patients who had been surgically treated for more than 3 months before the study was begun. Relevant QoL questions were generated from a review of the literature and interviews with health professionals, patients, and their caregivers. The initial multidimensional, 80-item questionnaire was reduced to a 35-item questionnaire by using standard psychometric criteria. Six relevant domains were identified using factor analysis: performance, physical function, vitality, pain, specific symptoms, and influence on emotions The validity of the construct was assessed by testing whether the clinical variable of the patient influenced his QoL domain score as hypothesized. Older patients had worse outcomes as compared to younger individuals. Worse outcomes were also were in patients with malignant pathologies, those receiving radiotherapy and those having other preexisting conditions. Their study also showed that the questionnaire could be either directly administered to the patient or administered remotely.

Vijay K. Anand conducted a study (McCoul et al. 2012) with the aim of prospectively evaluating the QoL of adult patients undergoing endoscopic skull base surgery (ESBS) for anterior skull base lesions. SNOT-22 and the ASBQ were

administered to the patients preoperatively, as well as at 3 weeks, 6 weeks, 12 weeks, 6 months, and 1 year postoperatively.

A total of 85 patients were enrolled in the study, with a majority of patients being treated for pituitary adenomas, they found that SNOT 22 scores increased immediately after surgery but showed an improvement after a period of 1 year after surgery. The type of skull base reconstruction, tumor histology and secretory nature of the tumor did not influence their outcomes. They also found a good concurrent validity between SNOT22 and ASBQ.

To fully understand outcomes of these surgeries, they recommended using both sinonasal-related and site-specific QOL instruments in a prospective assessment.

Skull Base Inventory (SBI):

The SBI is a multidimensional, disease-specific tool that measures the quality of life of patients who have undergone surgical treatment for anterior or central skull base pathologies, regardless of the surgical approach (de Almeida et al., 2012). Developed using expert and patient input, the SBI is designed to be applicable to patients who undergo both open and endoscopic approaches. The SBI is designed for both discriminative and evaluative purposes and can capture temporal changes in QOL while differentiating between the QOL of different patient populations. It consists of 41 questions that cover 11 disease-specific domains, including social, emotional, physical, cognitive, family, financial, spiritual, endocrine, nasal, neurologic, and visual (Larjani et al., 2016). Each question is given a score from 0 to 6. A higher score is indicative of a better outcome. The SBI has been shown to have sound

reliability and validity in assessing disease specific and overall QOL of patients who undergo skull base surgery with both endoscopic and open surgical approaches (Larjani et al, 2016).

In a study, patients underwent endoscopic endonasal surgeries completed three quality of life instruments at six different time points (preoperative, 2 weeks, 3 months, 6 months,12 months postoperative). SBI, ASBQ and the SNOT-22 questionnaires were used (Hopkins et al., 2009). The SBI was assessed to determine its psychometric properties in this setting, while the ASB and SNOT-22 were used for comparison purposes. The study concluded that the SBI questionnaire is reliable and valid for patients undergoing both endoscopic and open approaches and can be utilized to assess HR-QOL in these settings. The research included 187 patients across five centers, out of which 121 underwent an endoscopic procedure. They showed a strong correlation between SBI and ASBQ and moderate correlation between the nasal parameters of SBI and SNOT 22.

Assessing patient reported Outcomes:

Endoscopic skull base surgery has been found to be a less invasive approach that can potentially improve patients' quality of life compared to open surgical approaches. The endonasal route used in this type of surgery can specifically impact sinonasal quality of life, which may ultimately have a greater influence on overall PRQoL. The patient's perception of well-being and QoL following skull base surgery

is influenced by the resolution of sinonasal complaints postoperatively. In the past, outcomes following such surgeries have been evaluated based on parameters such as extent of resection, cranial nerve deficits, mortality, and morbidity, which do not necessarily consider the patient's own perspective on their QoL(Borg et al., 2013). To address this, several instruments have been developed to assess the post-operative QoL of patients undergoing endoscopic skull base surgery, with scores provided either by the physician or reported by the patient themselves.

Georgalas et al. conducted a study to evaluate the impact of extended endonasal approaches with NSF reconstruction on the QoL of patients with benign skull base tumors. The Rhinosinusitis Outcome Measure-31 questionnaire was used to assess QoL, and the study results showed that the impact was limited, with most of the impact being related to headache and reduced olfaction (Georgalas et al., 2012).

According to Harvey et al.(Harvey et al. 2015) sinonasal quality of life was more influenced by skull base pathology rather than the use of NSF. They hypothesized that the reduction in sinonasal function resulting from radiation therapy or the removal of functional regions, such as olfactory mucosa, may have a greater impact on QoL.

Greig et al. conducted a systematic review on objective sinonasal outcomes such as olfaction, mucociliary clearance, and nasal airflow. They reviewed 10 articles and found that NSF elevation resulted in a decline in olfactory function. The

authors suggested that avoiding routine NSF elevation in sellar and parasellar procedures could be an option, and if an NSF is used, reconstruction of the donor site defect should be considered (Greig et al., 2016).

PROM are considered superior tools to assess QoL compared to physician reported measures. This is because there is often a poor correlation between a patient's self-reported QoL and a physician's perception of their QoL. Therefore, using PROMs can provide a more accurate and comprehensive understanding of a patient's post-operative QoL following endoscopic skull base surgery (Gil et al., 2004)

The main goal of evaluating the QoL of patients with malignancy is to enhance their daily functioning and hasten their return to normalcy. A comprehensive comprehension of the various components of QoL can assist surgeons in improving the evaluation and treatment of these patients. Additionally, it can enable the identification of potential impediments during the follow-up period and provide specific medical interventions to those at higher risk for unfavourable outcomes. Moreover, providing cancer patients with detailed information about their condition at an early stage can lead to better adjustment to their medical condition (Semple et al., 2014).

Clinician-based assessment of QoL can be affected by observer bias, inconsistent data collection, and incorrect assumptions about patient well-being. Therefore, obtaining direct feedback from the patient is a crucial aspect of assessing QoL. Research has shown that surgeons' perceptions of their patients' QoL after

surgery may not be accurate, underscoring the importance of incorporating patients' perspectives into the assessment process (Gil et al., 2004). However, previous assessments of sinonasal QoL in endonasal skull base surgery have been limited by the use of retrospective analysis (Gil et al.,2012; Suberman et al., 2011), unpaired postoperative data(Gil et al., 2003; Graham et al., 2009; Pant et al., 2010) Therefore, our aim was to prospectively investigate the impact of ESBS on sinonasal and site-specific QoL using validated outcome measures administered both preoperatively and postoperatively.

METHODOLOGY

This is a prospective study performed in the Department of Neurosurgery at Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, a tertiary care medical center in India. The study was conducted from August 2021 to January 2023 after obtaining our institute's ethical clearance.

The patients for the study were recruited consecutively from the elective neurosurgical operation theatre list. Patients of ASA grade I, II and III posted for elective endoscopic surgeries for anterior skull base lesion based on preoperative MRI were included in the study. Patients who refused to consent for the study, those who were unable to fill the questionnaires and ASA grades IV excluded from the study.

All patients were evaluated clinically with a history and detailed clinical examination. All patients had a preoperative MRI / CT scan required for the diagnosis of the pathology. Patients who required intraoperative neuro navigation underwent a CT scan preoperatively to aid in navigation.

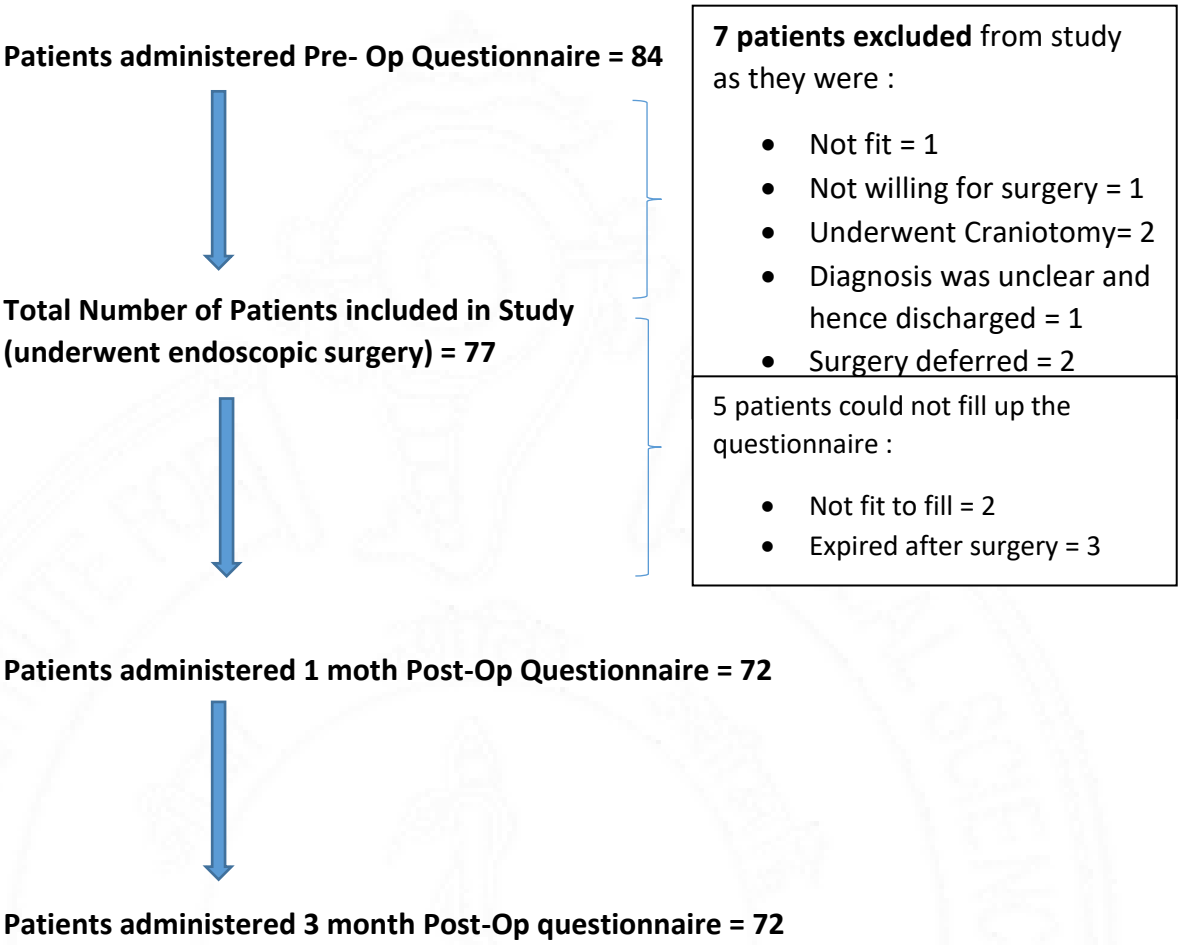
Three questionnaires SNOT 22, ASBQ and the SBI were given to patients before surgery after admission to obtain the baseline score.

Lumbar drains for those deemed necessary by the operating surgeon were inserted preopearatively by the anesthesiologists after induction of anesthesia. Rigid 0-degree endoscopes were utilized for the entire procedure. Partial inferior turbinectomy and posterior septectomy were performed in patients to provide improved access for the surgical instrumentation used to perform a bi-nostril technique. Following tumor resection,a multilayer reconstruction of the skull base

defect was performed in all cases, which included fat with or without fascia from the thigh, surgicel, gelfoam and the nasoseptal flap.

The patients were then re-administered the questionnaire during their outpatient visits or were contacted telephonically 1 month and 3 months following surgery and re administered the questionnaire. The questionnaires were administered by a person who was not part of the operating team to avoid bias. Demographic and other clinical details including intra operative details were also obtained.

The primary outcome measured were the SNOT-22, ASBQ and SBI scores following endoscopic endonasal surgery. The Scores at follow-up intervals were grouped as preoperative, at 1 month and 3 months following surgery.



Statistical Analysis :

The data was entered in Microsoft Excel spreadsheet and analysis was done using Epi-Info, JASP and Statistical Package for Social Sciences (SPSS) version 23.0.Continuous variables are represented as mean ± SD or medians with Inter-quartile range. Categorical variables are represented as number and percentages (%).

The variables were tested for normality with the Kolmogorov-Smirnov test for normality, Q-Q plots, visual inspection of the histograms and the z-scores for the degree of skewness and kurtosis. All tests of significance were two-tailed and statistical significance was defined as $p< 0.05$. Scatter diagrams were used to

describe the relationship between two quantitative variables. Friedman test and Bonferroni Post-hoc test were used to determine the significance of change in scores over time

Not all variables met the assumptions required for parametric; therefore, non-parametric tests (i.e., Pearson's correlation, Mann-Whitney test, Spearman correlation) were used for all analyses for consistency. Appropriate graphs such as pie charts, bar diagrams and histograms have been constructed.

RESULTS

Ours was a prospective study conducted in the Department of Neurosurgery, Sree Chitra Tirunal Institute for Medical Sciences, Trivandrum. For the study, subjects undergoing elective endoscopic surgeries for anterior skull base were included.

After the application of appropriate inclusion and exclusion criteria, a total of 72 subjects were included. Their baseline details including the demographic parameters, clinical details and quality of life parameters were recorded. The subjects were followed up after a period of 1 month and 3 months and their responses to the various QoL questionnaires were recorded.

Our main aim was to evaluate the change in quality of life of subjects following the surgery. For evaluating the QoL , three validated questionnaires were used - SNOT 22, SBI and ASBQ.

Patient Demographics :

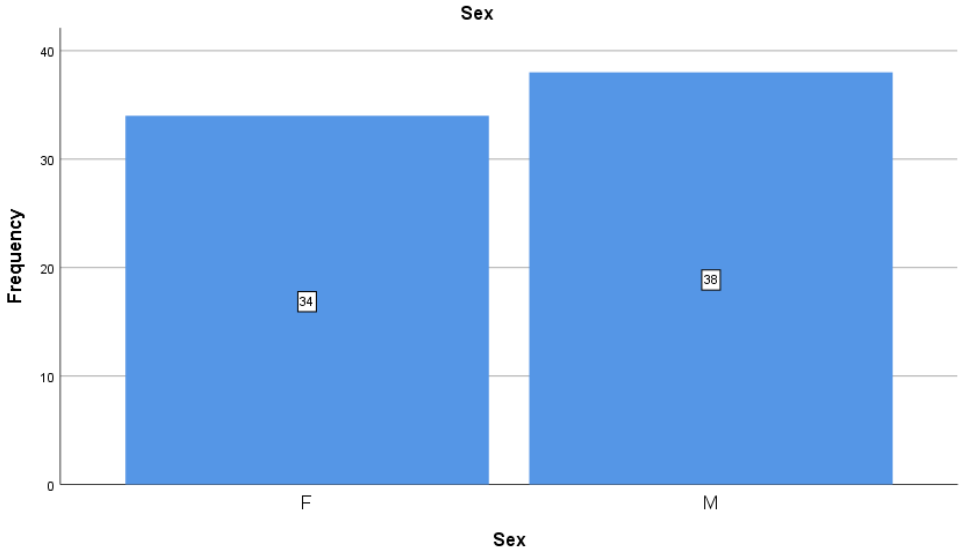
Sex Distribution :

Of the 72 patients included in the study conducted from August 2021 to January 2023, 38 (52.8%) were males and 34 (47.2%) were females.

Table 1: Gender Distribution

Gender	Number	Percentage
Male	38	52.8
Female	34	47.2

Figure 1 : Gender distribution of study population



Age Distribution :

The mean age of the patients in this study was 41.6 ± 15.82 (Mean ± SD) with minimum and maximum ages of 10 years and 69 years respectively.

Figure 2: Participant's age distribution

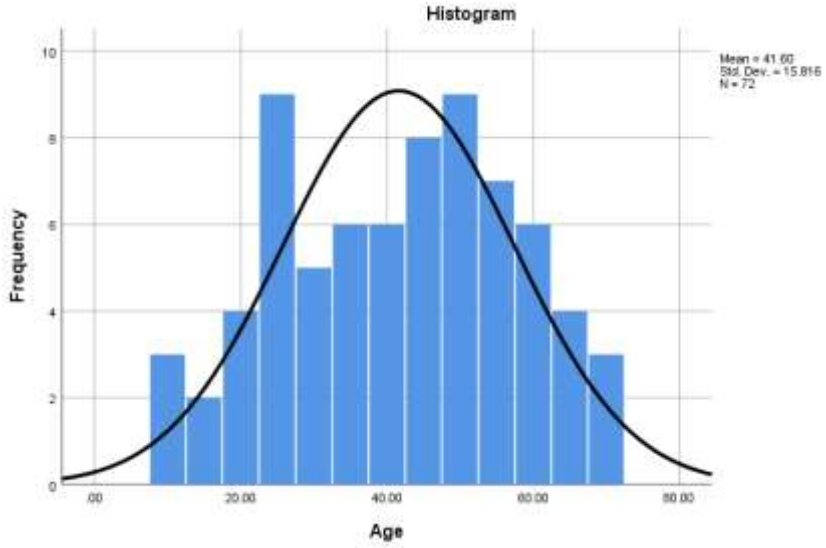
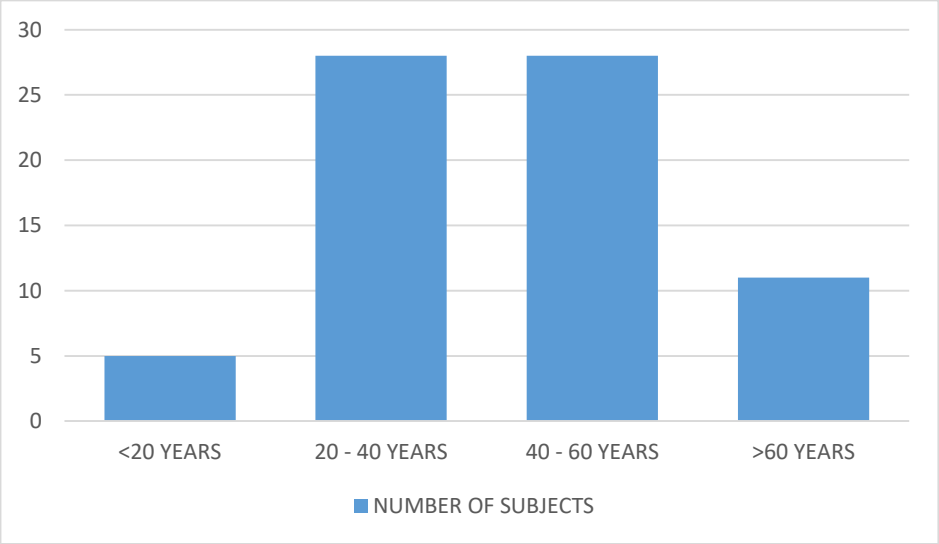


Figure 3 : Age intervals of study population



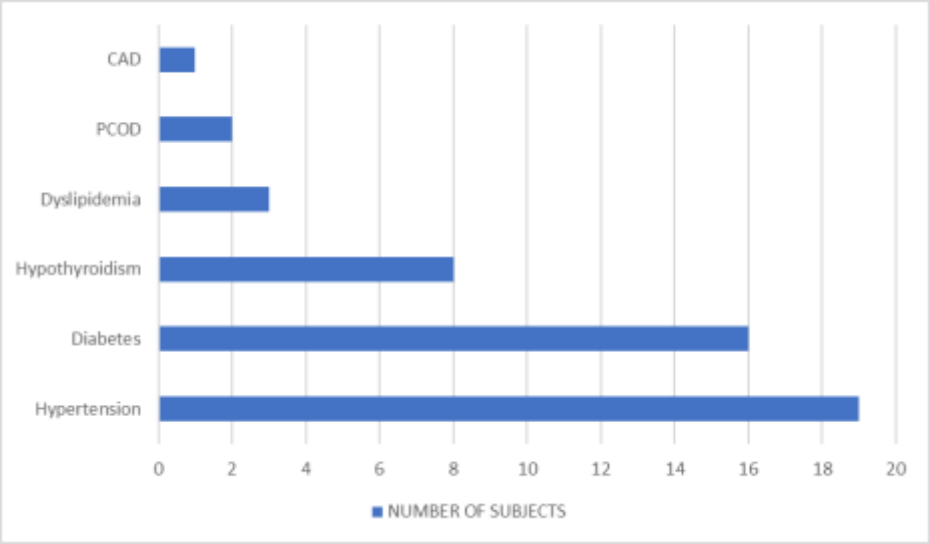
Comorbidities:

In our study, hypertension was the most common comorbidity, present in 19 (26.4%) of the subjects. This was followed by diabetes (n = 16, 22.2%), hypothyroidism (n = 8, 11.1%) and dyslipidemia (n = 3, 4.2%). 2 subjects (2.8%) had a history of PCOD and 1 (1.4%) subject had a history of ischemic heart disease.

Table 2: Distribution of subjects based on their comorbidities

Comorbidity	Frequency	Percent
Hypertension	19	26.40%
Diabetes	16	22.20%
Hypothyroidism	8	11.10%
Dyslipidemia	3	4.20%
PCOD	2	2.80%
CAD	1	1.40%

Figure 4: Distribution of subjects based on their comorbidities



Presenting Preoperative Symptoms :

During pre-operative evaluation headache was reported in 30 (41.7%) of individuals. Visual problems were reported in 37 (51.42%) individuals. Blurring of one eye was seen in 16(22.2%) individuals , blurring of both eyes in 18(25%) ,

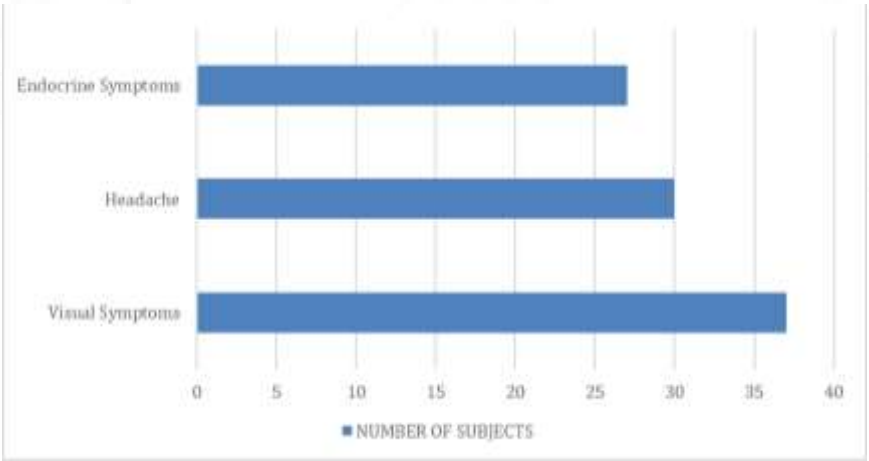
decreased peripheral vision in one or both eyes in 21(29.1%), decreased distant vision in 15(20.8%), double vision in 1 (1.3%), difficulty in reading in 1 (1.3%).

Endocrine problems in the form of menstrual irregularity, excessive weight gain, milk discharge from breasts, increase in hand/ feet / jaws/ nose , thickening of hand and feet, change in facial symmetry, delayed puberty , cold intolerance , constipation , erectile dysfunction , infertility , facial hair , increased micturition were reported in 25 (34.7%) individuals.

Table 3: Presenting Symptoms among participants

Symptoms	Present	
	n	%
Headache	30	41.7
Visual problems	37	51.4
Blurring of one eye	16	22.4%
Blurring of both eyes	18	25
Decreased peripheral vision	21	29.1
Double vision	1	1.3
Difficulty reading	1	1.3
Endocrine problems	25	34.7

Figure 5: Distribution of subjects based on their symptoms



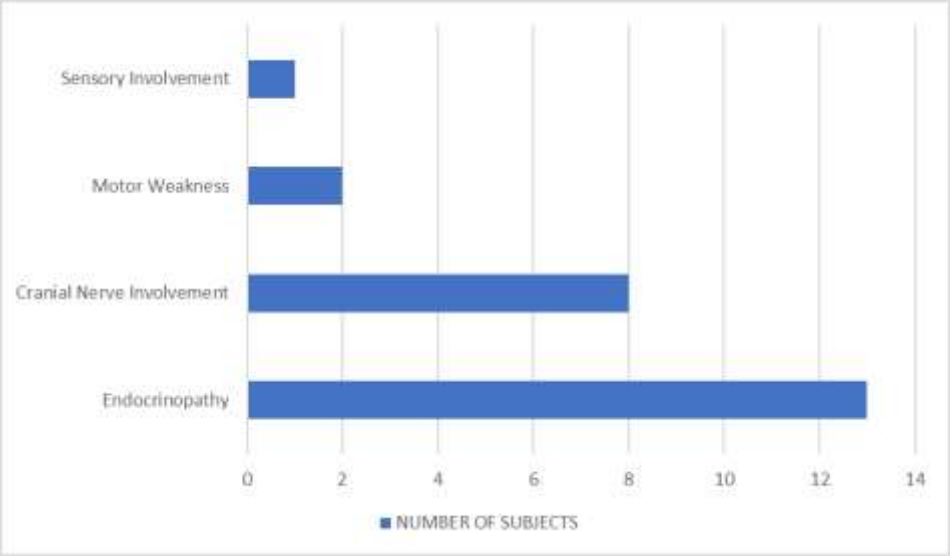
Examination findings :

In our study, clinical features of endocrinopathy in the form of enlarged hands or feet, jaw protrusion, prominent supraorbital ridge, thickening of heel fat pad were present in 13 (26.4%) of the subjects. There features included features of cranial nerve involvement was found in 8 (11.1%), motor weakness was present in 2 (2.8%) and sensory abnormality in the form of facial paresthesia was found to be present in 1 (1.4%) subject.

Table 4: Distribution of subjects based on clinical examination findings

Clinical Finding	**Frequency**	**Percent**
Endocrinopathy	13	18.10%
Cranial Nerve Involvement	8	11.10%
Motor Weakness	2	2.80%
Facial parasthesia	1	1.40%

Figure 6 : Distribution of subjects based on clinical examination findings



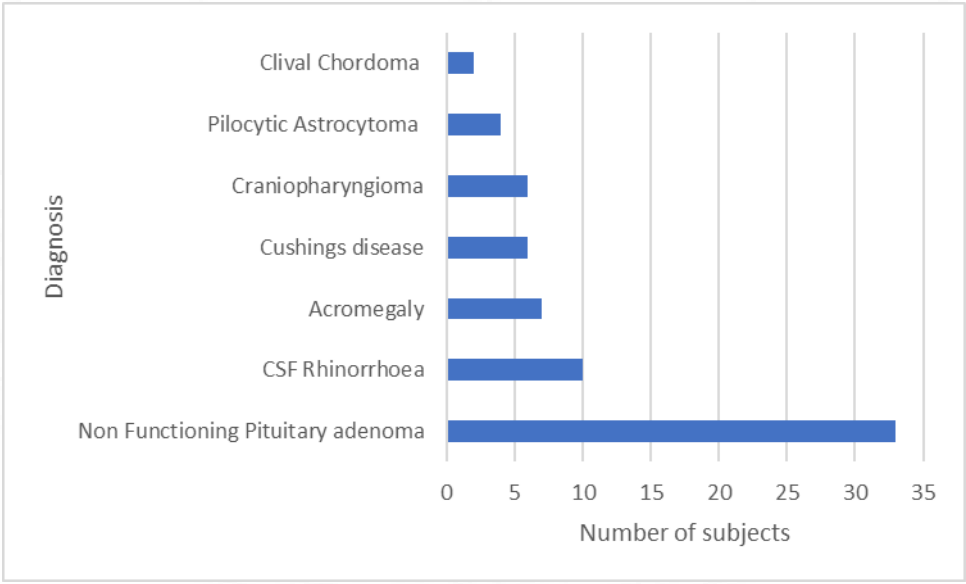
Diagnosis :

Among the 72 patients, the most common pathology for which endoscopic surgery was performed was for nonfunctioning pituitary adenomas 33(45.8%) followed by CSF rhinorrhoea 10(13.9%), acromegaly 7(9.7%), Cushing's disease 6(8.3%), craniopharyngiomas 6 (8.3%) , pilocytic astrocytomas 4(5.6%) and clival chordomas 2(2.8%).

Table 5: Distribution of subjects based on diagnosis

Diagnosis	**Number**	**Percentage**
Non-Functioning Pituitary adenoma	33	45.8
CSF Rhinorrhoea	10	13.9
Acromegaly	7	9.7
Cushings disease	6	8.3
Craniopharyngioma	6	8.3
Pilocytic Astrocytoma	4	5.6
Clival Chordoma	2	2.8

Figure 7: Distribution of subjects based on the clinical diagnosis



Surgical Approach:

Among the 72 patients who were operated upon a trans sellar route was taken in 69(95.8%) of individuals and the remaining 3(4.2%) underwent an extended endonasal approach.

Table 6: Surgical approaches

Surgical Approach	Number	Percentage
Trans sellar	69	95.8
Extended endonasal	3	4.2

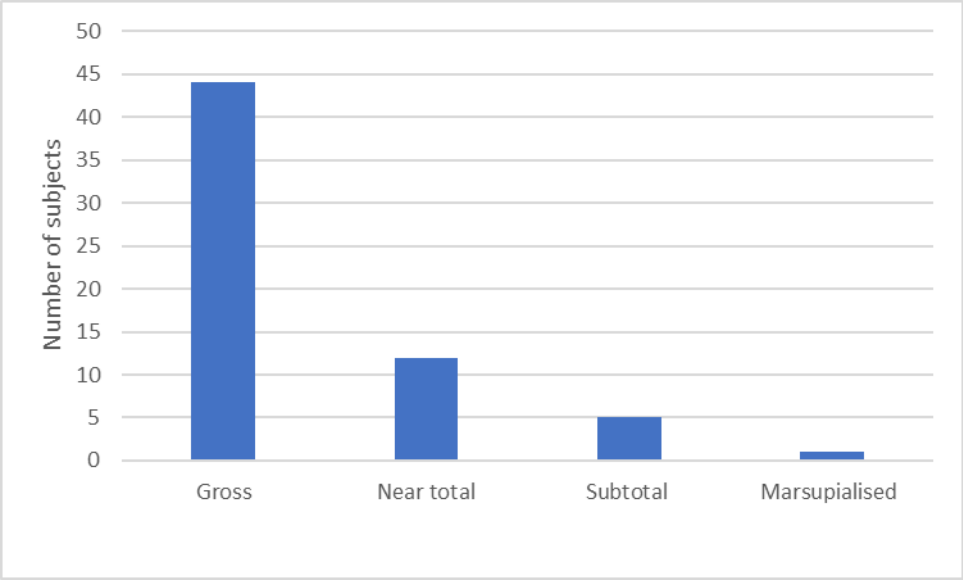
Extent of Tumour Resection:

Among 72 participants 10 were diagnosed with CSF rhinorrhea. The remaining 62 participants were diagnosed with tumors (N = 62). 44(70.9%) of these tumours underwent gross total resection, 12(19.3%) underwent near total resection, 5(8%) underwent subtotal decompression and 1(1.6%) patient underwent marsupialization of the cyst

Table 7: Extent of tumour resection

Extent of resection	Number of subjects	Percentage
Gross	44	70.9
Near total	12	19.3
Subtotal	5	8
Marsupialised	1	1.6

Figure 8 : Distribution of subjects based on extent of tumour resection



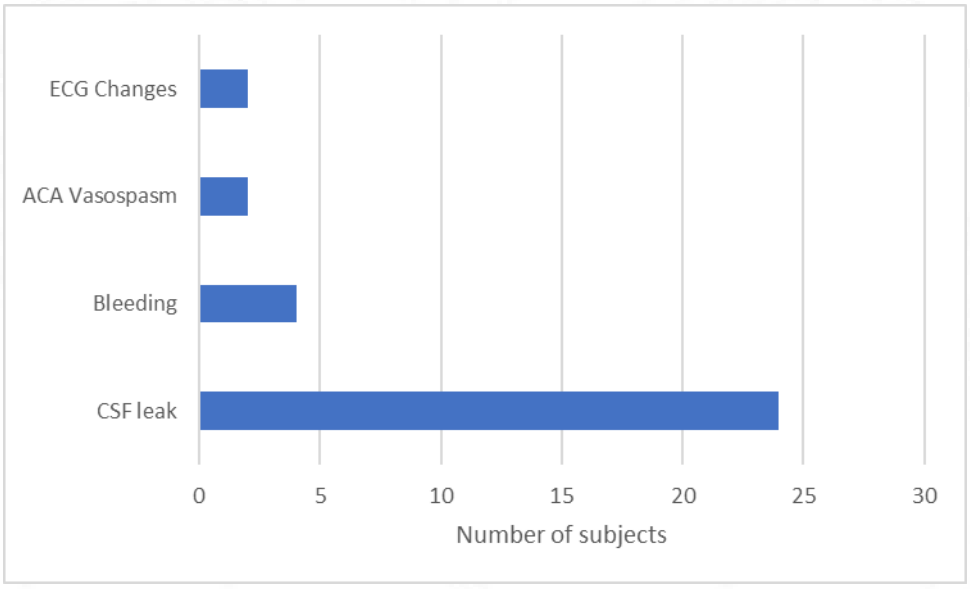
Intraoperative Complications:

Of the 72 subjects in our study, 24 (33.33%) of subjects had an intraoperative CSF leak, 4 (5.56%) subjects had significant bleeding most commonly from the cavernous sinus, 2(2.78%) had ACA vasospasm and 2 (2.78%) subjects had intraoperative ECG Changes. No other significant intraoperative complications were found in the remaining subjects.

Table 8: Distribution of subjects based on intraoperative complications

Intraoperative Complications	Frequency	Percent
None	40	55.56
CSF leak	24	33.33
Bleeding	4	5.56
ACA Vasospasm	2	2.78
ECG Changes	2	2.78

Figure 9: Distribution of subjects based on intraoperative complications



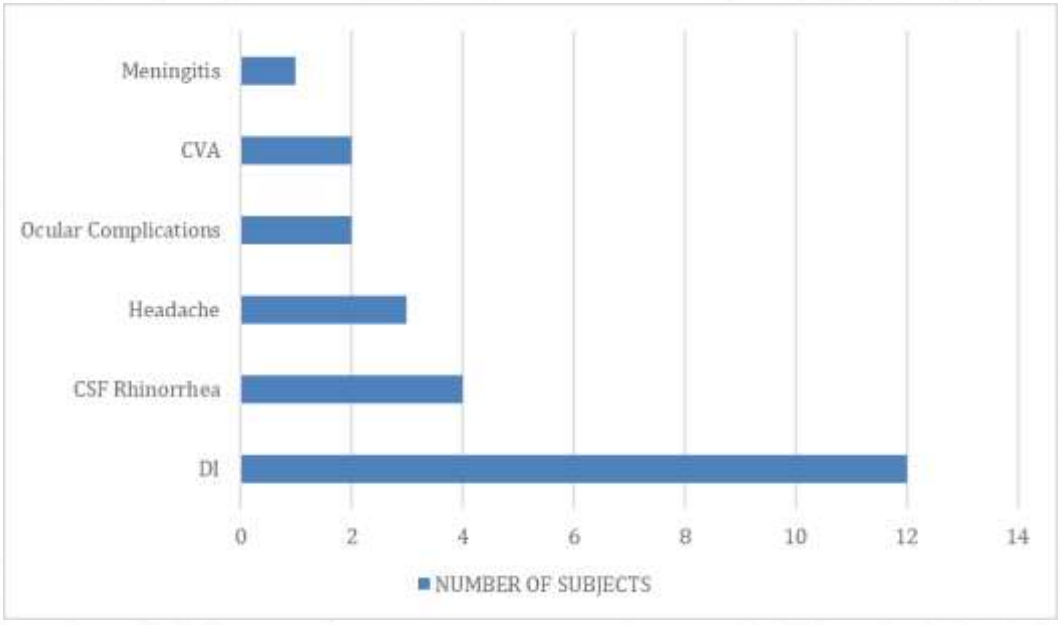
Post Operative Complications:

Of the 72 subjects in our study, 12 (16.67%) developed post operative diabetes insipidus (DI), 4 (5.56%) had a CSF rhinorrhea requiring a surgical repair , 3 (4.17%) subjects had post-operative headache, 2 (2.78%) each had ocular complications(in the form of sudden worsening of vision post operatively) and cerebro vascular accident (CVA) and 1 patient had meningitis

Table 9 : Distribution of subjects based on postoperative complications

Post Operative Complications	Frequency	Percent
DI	12	16.67
CSF Rhinorrhea	4	5.56
Headache	3	4.17
Ocular Complications	2	2.78
CVA	2	2.78
Meningitis	1	1.39

Figure 10: Distribution of subjects based on postoperative complications



Use of Hadad flap and Lumbar drain

Hadad flap was used in 33(45.8%) of patients. Lumbar drain was inserted preoperatively in 24(33.3%) of patients.

Table 10: Patients with Hadad flap and lumbar drain

Requirement	Present	
	n	%
Hadad flap	33	45.8
Lumbar drain	24	33.3

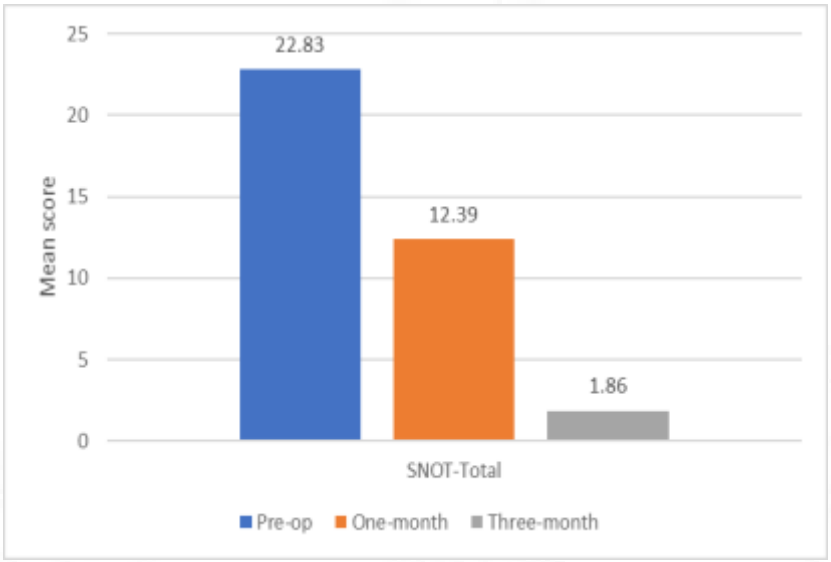
SNOT 22 Questionnaire :

As depicted in the table below the mean(SD) pre-operative SNOT22 total score ie the score comprising all domains of SNOT 22 was 22.83(18.17) with a range of 0 to 74. The mean postoperative 1 month SNOT 22 total score was 12.39 (16.18) with a range of 0 to 79. The mean postoperative 3 month SNOT 22 total score was of 1.86 (5.11) with a range of 0 to 31.

Table 11: Pre op, 1 month post op and 3 month post op SNOT 22 scores for various domains and total scores

SNOT 22	N	Mean	Std. Deviation	Min	Max
Preop Nasal-Domain	72	6.43	7.96	0	35
Preop Ear-Domain	72	2.87	4.06	0	19
Preop Sleep-Domain	72	5.26	5.23	0	20
Preop Function-Domain	72	3.92	3.80	0	14
Preop Emotion-Domain	72	4.35	4.44	0	15
Preop SNOT-Total	72	22.83	18.17	0	74
One month postop-Nasal-Domain	72	4.50	6.31	0	29
One month postop-Ear-Domain	72	1.42	3.14	0	16
One month postop-Sleep-Domain	72	3.31	5.18	0	20
One month postop-Function-Domain	72	1.86	2.80	0	12
One month postop-Emotion-Domain	72	1.31	2.52	0	11
One month postop-SNOT-Total	72	12.39	16.18	0	79
Three month postop-Nasal-Domain	72	.78	3.03	0	19
Three month postop-Ear-Domain	72	.10	.48	0	3
Three month postop-Sleep-Domain	72	.69	2.56	0	20
Three month postop-Function-Domain	72	.25	.90	0	5
Three month postop-Emotion-Domain	72	.04	.26	0	2
Three month postop-SNOT-Total	72	1.86	5.11	0	31

Figure 11: Changes in mean SNOT22 score at pre op, 1 month post op and 3 month post op periods



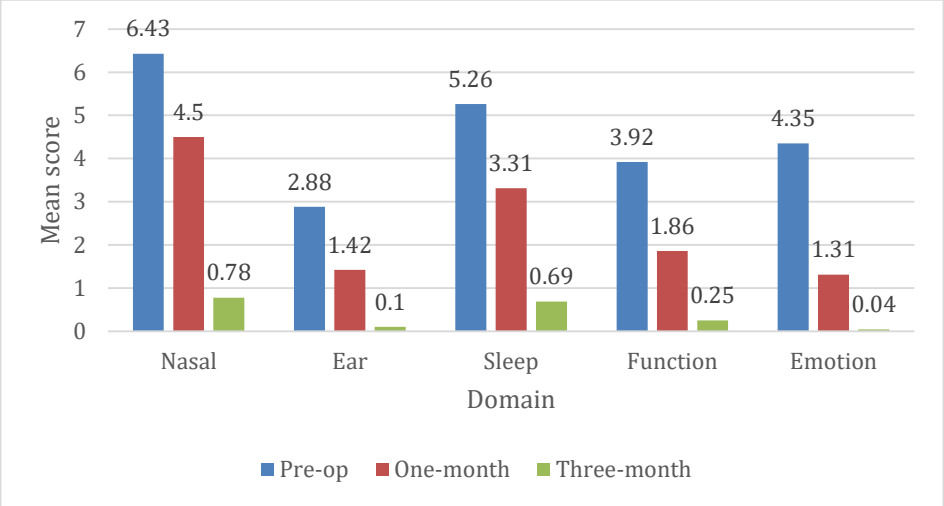
The depicted in the table below total mean (SD) SNOT 22 score at each of the three time intervals measured was 22.83(18.17), 12.39(16.18) and 1.86(5.10). There was a decrease in the total SNOT 22 scores at each of these time intervals and this decrease was found to be significant ($p<0.05$).

A similar decrease in the SNOT 22 scores was seen in each of the domains of the SNOT 22 score (as shown in the graph below) and this decrease was found to be statistically significant ($p<0.05$)

Table 12 : Domain score and overall SNOT 22 score comparison at pre-op, one-month post-op and three-month post-op

	Time	Mean	Std. Deviation	N	F	p-value
SNOT-Total	Pre-op	22.83	18.17	72	173.17	<0.001
	One-month	12.39	16.18	72		
	Three-month	1.86	5.10	72		
Nasal	Pre-op	6.43	7.96	72	98.41	<0.001
	One-month	4.50	6.31	72		
	Three-month	0.78	3.03	72		
Ear/facial	Pre-op	2.88	4.06	72	64.65	<0.001
	One-month	1.42	3.14	72		
	Three-month	0.10	0.48	72		
Sleep	Pre-op	5.26	5.23	72	95.46	<0.001
	One-month	3.31	5.18	72		
	Three-month	0.69	2.56	72		
Function	Pre-op	3.92	3.80	72	111.89	<0.001
	One-month	1.86	2.80	72		
	Three-month	0.25	0.90	72		
Emotion	Pre-op	4.35	4.44	72	95.31	<0.001
	One-month	1.31	2.52	72		
	Three-month	0.04	0.26	72		

Figure 12: SNOT 22 domain scores and its change from pre op, 1 month post op and 3 months post op period



As depicted in the table below, when the preoperative SNOT22 score was compared with the 1 month post-operative score the median was -1.00, -1.46, -1.00, -1.00, and -2.00 for each of its domains namely nasal, ear/facial, sleep, function, emotion. The median for the total SNOT 22 score being -9.00.

Table 13: Post-operative (1m) SNOT-22 improvement as a function of Pre-operative SNOT-22

Pre-operative-score	Median (IQR) of absolute change in SNOT score
Nasal	-1.00 (-7.00 – 3.75)
Ear/ Facial	-1.46 (-3.75 – 0.00)
Sleep	-1.00 (-6.75 – 1.75)
Function	-1.00 (-5.00 – 0.00)
Emotion	-2.00 (-5.00 – 0.00)
Total	-9.00 (-25.00 – 0.75)

As depicted in the table below, when the pre operative SNOT 22 score was compared with the 3 month post operative score the median was -2.00, -1.00, -3.00, -

3.00, -3.50 for each of the SNOT 22 domains namely nasal, ear/facial, sleep, function, emotion. The median for the total SNOT 22 score -17.50.

Table 14: Post-operative (3m) SNOT-22 improvement as a function of Pre-operative SNOT-22

Pre-operative-score	Median (IQR) of absolute change in SNOT score
Nasal	-2.00 (-8.75 – 0.00)
Ear/ Facial	-1.00 (-3.75 – 0.00)
Sleep	-3.00 (-8.75 – 0.00)
Function	-3.00 (-6.75 – 0.00)
Emotion	-3.50 (-7.00 – 0.00)
Total	-17.50 (-33.75 – -4.25)

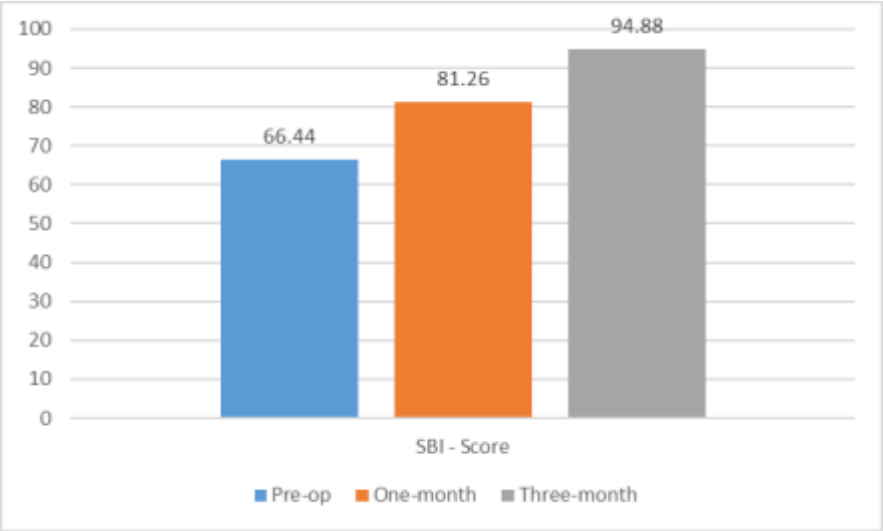
Skull Base Inventory:

The total SBI mean scores increased from 66.44 preoperatively to 81.26 at 1 month and to 94.88 three months post operatively. A similar trend of increase in scores was seen for each of the domains of the SBI except for the nasal domain at 1 month interval. The increase for all domains for the SBI scores were significant with a p value of <0.001. This shows that the quality of life significantly improved after surgery for all domains and for the overall SBI scores except for the nasal domain at 1 month postoperative interval. This is depicted in the table and graph below.

Table 15: Various domains and total mean SBI scores and its changes from pre op , 1month and 3 month post-surgery

SBI	Pre-op baseline Mean(SD)	1 month		3 months	
		Total Score (Mean difference)	p value	Total Score (Mean difference)	p value
Cognitive (C)	67.67 (25.28)	95.42(22.74)	0.001	96.28(28.61)	0.001
Emotional (E)	54.95 (34.56)	82.7(27.75)	0.001	94.62(39.67)	0.001
Family (Fa)	61.28 (32.57)	78.19(16.91)	0.002	94.49(33.21)	0.001
Financial (F)	50.37 (31.50)	138.37(26.62)	0.001	94.09(43.72)	0.001
Social (So)	65.19 (28.18)	66.71(14.52)	0.001	92.37(27.18)	0.001
Spiritual (Sp)	69.81 (25.45)	81.28(11.47)	0.008	94.57(24.76)	0.001
Endocrine (P-E)	71.87 (21.93)	83.56(11.69)	0.004	97.33(25.46)	0.001
Nasal (P-Na)	81.17 (17.83)	80.32(-0.85)	**0.762**	97.33(16.16)	0.001
Neurologic (P-Ne)	70.97 (23.88)	85.03(14.06)	0.001	97.51(26.54)	0.001
Visual (P-V)	67.67 (26.69)	87.98(20.31)	0.001	96.93(29.26)	0.001
Other (P-O)	73.60 (20.07)	82.82(9.22)	0.002	96.56(22.96)	0.001
Total/ overall	**66.44** (19.82)	**81.26**(14.82)	0.001	**94.88**(28.44)	0.001

Figure 13: Graphical representation of changes in mean SBI scores from pre operative , 1 month and 3 months post surgery



Anterior Skull Base Questionnaire (ASBQ) :

Preoperative ASBQ scores:

The mean total ASBQ score at the pre operative time interval was calculated to be 107.24 with a median score of 109.50 and a mode of 86. Standard deviation was 23.98 and the scores ranged from 48 to 158. The overall total ASBQ score along with the scores for each of the domains of the ASBQ scores are shown in the table below.

Table 16 Pre-operative scores for each ASBQ domain and total scores

ASBQ Scores	Mean	Standard Deviation	Minimum	Maximum
Performance	18.08	4.568	4	28
Physical Functioning	21.01	6.129	9	35
Vitality	20.92	6.493	2	35
Pain	10.82	3.789	0	15
Emotion	16.00	4.596	0	25
Specific	20.40	5.561	6	35
Total	**107.24**	23.981	48	158

One Month Post operative ASBQ scores:

The mean total ASBQ scores at 1 month interval was 128.18 with a median of 127.5, mode of 127. The standard deviation was 27.88 and scores ranged from 53 to 175. The overall total ASBQ scores along with the scores for each of the domains of the ASBQ scores are shown in the table below

Table 17 : One month scores for each ASBQ domain and total scores

ASBQ Scores	Mean	Standard Deviation	Minimum	Maximum
Performance	20.81	5.03	9	30
Physical Functioning	24.76	7.792	4	35
Vitality	24.83	7.260	1	35
Pain	11.68	2.787	2	15
Emotion	19.11	4.796	0	25
Specific	26.99	7.181	2	53
Total	**128.18**	27.887	53	175

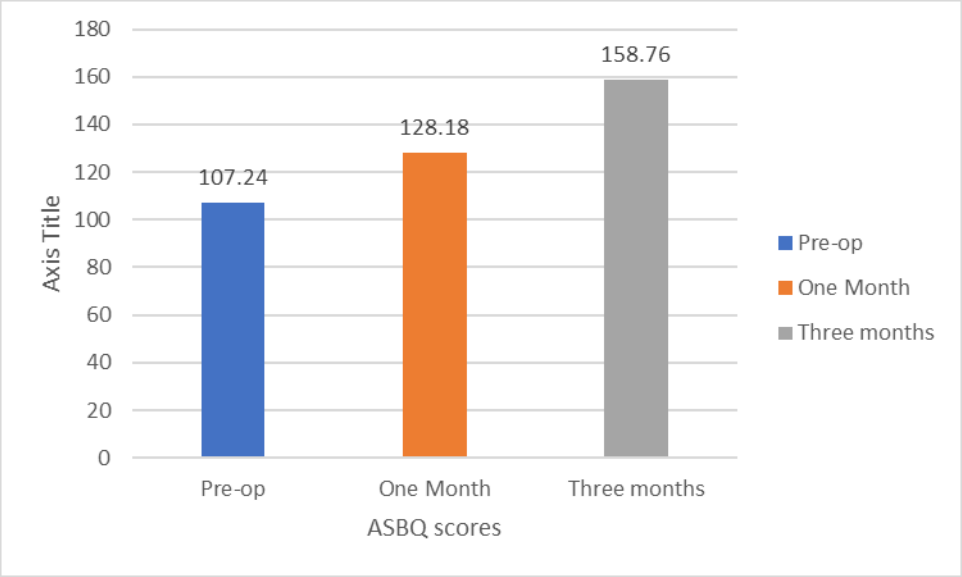
Three month ASBQ scores :

The mean total ASBQ scores at 3 month interval was 158.76 with a median of 168.50 , mode of 175. The standard deviation was 20.65 and scores ranged from 95 to 175.

Table 18: Three month scores for each ASBQ domain and total scores

ASBQ Scores	Mean	Standard Deviation	Minimum	Maximum
Performance	26.18	4.795	15	30
Physical Functioning	32.25	4.867	12	35
Vitality	31.36	4.971	17	35
Pain	14.13	1.768	17	35
Emotion	22.5	3.565	9	25
Specific	35.00	4.621	14	35
Total	**158.76**	20.65	95	175

Figure 14: Changes in mean SBI scores from pre operative , 1 month and 3 month post surgery



Responsiveness of the ASBQ and its domains to clinical change:

The total ASBQ mean scores increased from 107.24 preoperatively to 128.18 at 1 month interval and to 158.77 three months post operatively. A similar trend of increase in scores were seen for each of the ASBQ domains. The increase in scores for all domains of ASBQ scores were significant ($p<0.05$) except for the pain domain at 1 month interval($p=0.129$). This shows that the quality of life significantly improved during these time intervals for all domains. The improvement in quality of life was significant for all domains during these time intervals except for the pain domain at 1 month interval.

Table 19: Responsiveness of the ASBQ and its domains to clinical change

ASBQ	Pre-op baseline	1 month		3 months	
		Total (Mean difference)	P value	Total (Mean difference)	P value
Performance	18.08 (4.57)	20.8 (2.72)	0.002	26.18 (8.10)	0.001
Physical	21.01 (6.13)	24.76 (3.75)	0.002	32.25 (11.24)	0.001
Vitality	20.92 (6.49)	34.84 (3.92)	0.001	31.36 (10.44)	0.001
Pain	10.82 (3.79)	11.68 (0.86)	**0.129**	14.13 (3.31)	0.001
Emotion	16.00 (4.60)	19.11 (3.11)	0.001	22.72 (6.72)	0.001
Specific symptoms	20.40 (5.56)	26.98 (6.58)	0.001	32.12 (11.72)	0.001
Overall total	**107.24** (23.98)	**128.18** (20.94)	0.001	**158.77** (51.53)	0.001

Concurrent validity between SBI and the SNOT 22 scores :

Using Pearson correlation SBI and SNOT22 scores showed a negative correlation. As the SBI scores increased during the pre operative , 1 month post operative and 3 months post operative periods the SNOT 22 scores decreased during these time intervals. This correlation was significant ($p<0.05$) at all three time points which shows that the quality of life improved among participants when assessed with both the SBI and SNOT 22.

Table 20: Concurrent validity between SBI and the SNOT 22 scores

Timepoint	Pearson correlation	P Value
Pre-operative	-0.576	0.001
1 month	-0.360	0.002
3 months	-0.623	0.001

Concurrent validity between SBI and ASBQ scores :

Using Pearsons correlation SBI and ASBQ scores showed a positive correlation with each other. SBI scores increased from the pre operative, 1 month post operative to 3 month post operative period. This similar trend was seen with ASBQ scores. This correlation was significant ($p<0.05$) at 1 month and 3 month time point but not during the pre operative period ($p=0.293$)

Table 21: Concurrent validity between SBI and ASBQ scores

Timepoint	Pearson correlation	P Value
Pre-operative	0.126	**0.293**
1 month	0.690	0.001
3 months	0.623	0.001

Concurrent validity between the ASBQ and the SNOT-22

Using Pearson correlation ASBQ and SNOT 22 showed negative correlation. As the ASBQ scores increased from pre operative , 1 month post operative to 3 month post operative period the SNOT 22 scores decreased. This change was significant ($p<0.05$) in the 1 month and 3 months interval but not in the pre operative period. This shows an improvement in the quality of life from pre operative to the 3 month timepoint.

Table 22: Concurrent validity between the ASBQ and the SNOT-22

Timepoint	Pearson correlation	P Value
Pre-operative	-0.024	0.84
1 month	-0.324	0.01
3 months	-0.527	<0.001

Figure 15: Scatter plot depicting pre op SNOT total scores with ASBQ total scores

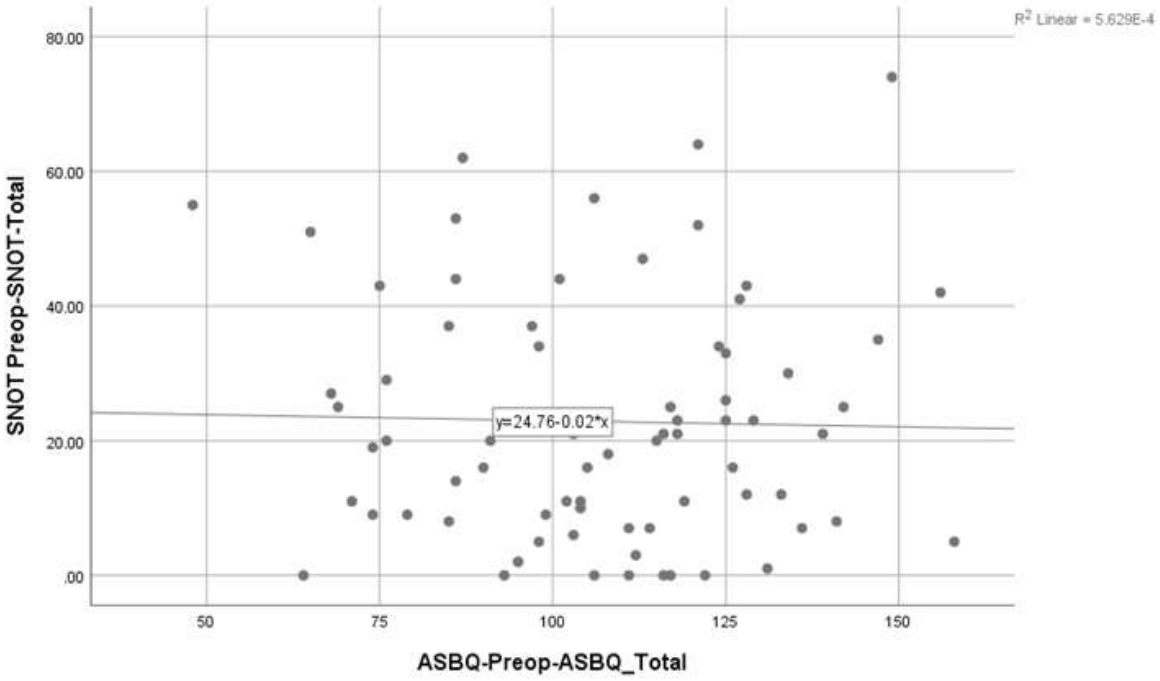


Figure 16: Scatter plot depicting 1 month post op SNOT total scores with ASBQ total scores

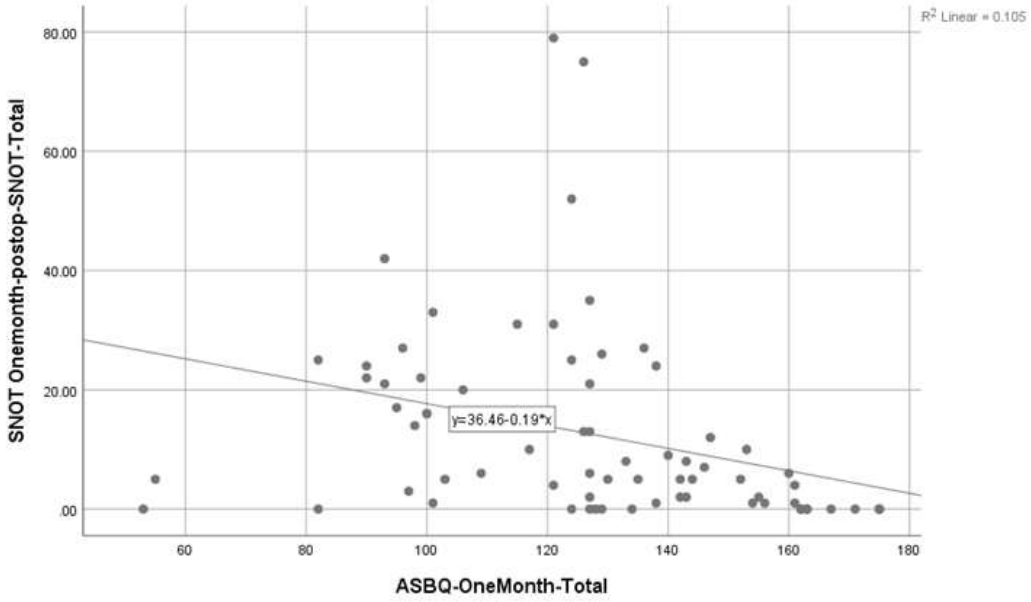
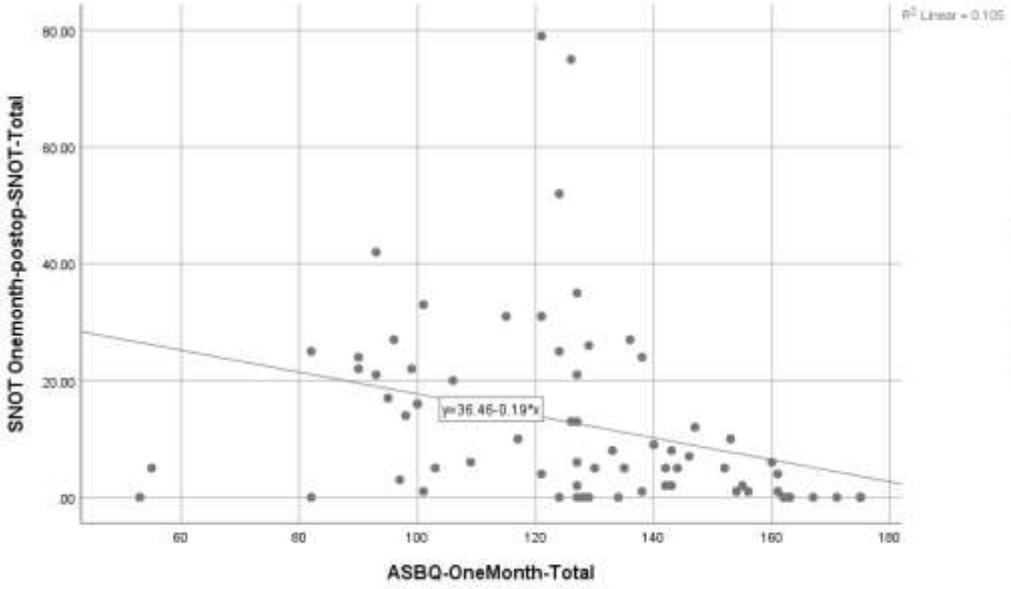


Figure 17: Scatter plot depicting 3 months post op SNOT total scores with ASBQ total scores



Subgroup Analysis for Patients with Hadad flap and Acromegaly :

Hadad Flap

SNOT 22 acores for patients with and without Hadad flap:

The mean (SD) SNOT 22 scores for patients in which Hadad flap was used was 22.03(17.95) , 8.36(10.597) and 2.15(5.026) at each of the three time intervals The mean (SD) SNOT 22 scores for patients in which no Hadad flap was used was 24.58(20.19), 16.92(22.48) and 2.17(6.51).

There was no significant difference in the SNOT 22 scores among those patients in which Hadad flap was used and in whom Hadad flap was not used in each of the three-time intervals (p>0.05)

Table 23: SNOT 22 scores for patients with and without a Hadad flap

SNOT 22 score	Hadad flap	N	Mean	Std Deviation	Mean difference	p value
Preop	Yes	33	22.03	17.950	-2.553	.617
	No	24	24.58	20.190		
One- Month	Yes	33	8.36	10.597	-8.553	.060
	No	24	16.92	22.481		
Thee- Month	Yes	33	2.15	5.026	-0.015	.992
	No	24	2.17	6.512		

SBI scores for patients with and without Hadad flap:

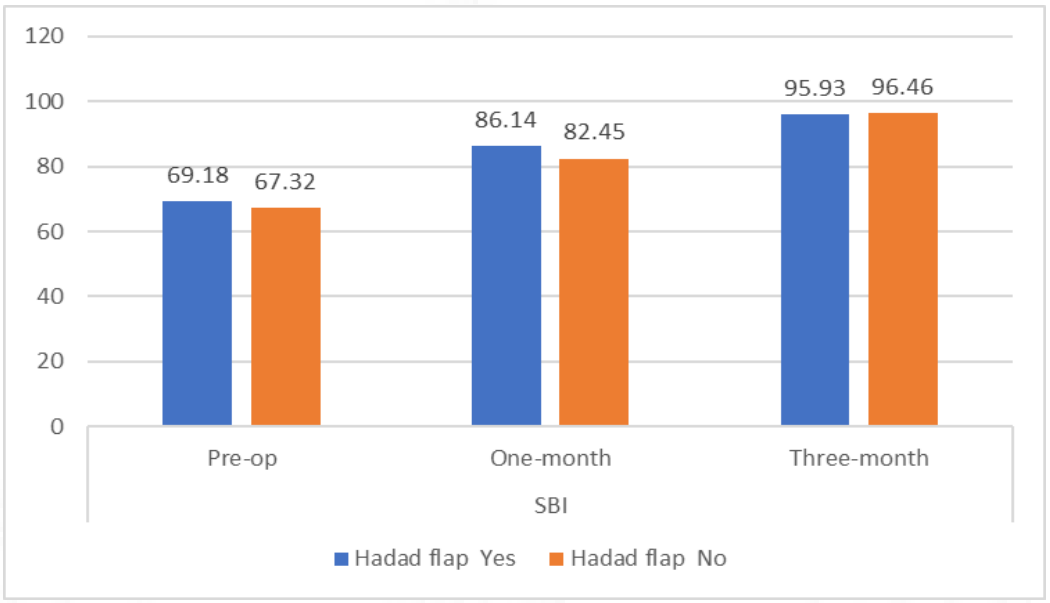
The mean (SD) SBI scores for individuals where Hadad flap was used during the endonasal procedure for skull base reconstruction was 69.18 (17.96) preoperatively, 86.14 (10.12) at 1 month post operatively and 95.93 (6.83) at 3 months post operatively.

The mean (SD) SBI scores for individuals where Hadad flap was not used was 67.31 (23.41) preoperatively, 82.44 (7.99) at one month post operatively and 96.45 (6.20) at 3 months post operatively. The difference between the SBI scores at each of these time intervals was not significant ($p>0.05$).

Table 24: SBI scores for patients with and without Hadad flap

Hadad flap					
Time Intervals	**Hadad Flap (n)**	**Mean (SD)**	**t**	**Mean difference**	**p-value**
Pre-op	Yes (33)	69.18 (17.96)	0.34	1.86	0.735
	No (24)	67.31 (23.41)			
One-month	Yes (33)	86.14 (10.12)	1.48	3.70	0.144
	No (24)	82.44 (7.99)			
Three-month	Yes (33)	95.93 (6.83)	-0.30	-0.53	0.766
	No (24)	96.45 (6.20)			

Figure 18: SBI scores for patients with and without Hadad flap



ASBQ scores for patients with and without Hadad flap:

The mean(SD) ASBQ scores for patients with a Hadad flap was 110.03 (26.174), 130.73 (31.623) and 156.00(20.993) pre operatively , 1 month post operatively and at 3 months post operatively respectfully.

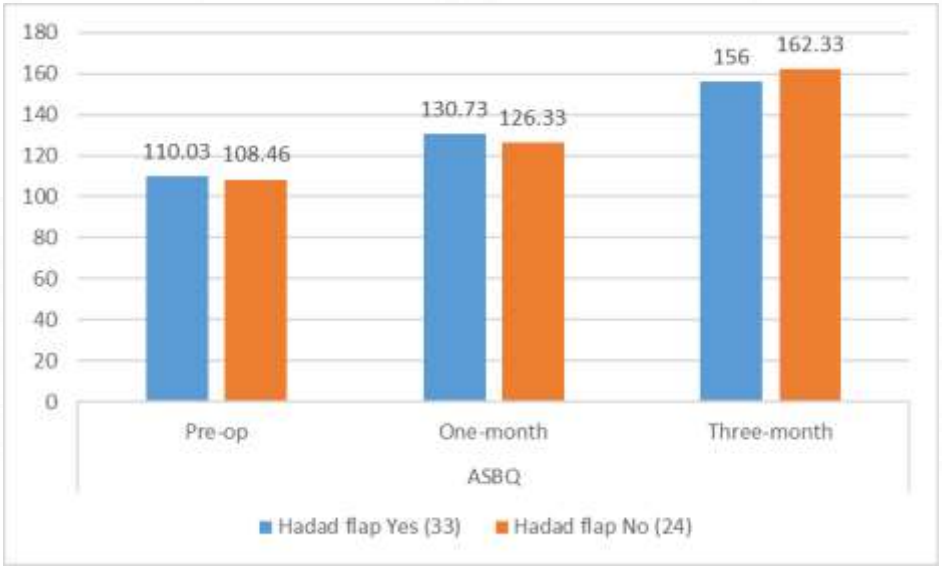
The mean ASBQ scores for patients without a Hadad flap was 108.46(19.013), 126.33(23.498) and 162.33(21.675) pre operatively, 1 month post operatively and at 3 months post operatively.

The difference between the SBI scores at each of these time intervals was not significant ($p>0.05$)

Table 25: ASBQ scores for patients with and without Hadad flap

ASBQ Score	Hadad flap	N	Mean	Std. Deviation	Std. Error Mean	p-value
Preop-ASBQ_Total	Yes	33	110.03	26.174	4.556	0.804
	No	24	108.46	19.013	3.881	
Preop-ASBQ (%)	Yes	33	65.19314	15.260114	2.656445	0.887
	No	24	64.67083	11.067102	2.259063	
Onemonth_ASBQ_Total	Yes	33	130.73	31.623	5.505	0.568
	No	24	126.33	23.498	4.796	
OneMonth_ASBQ(%)	Yes	33	77.89774	14.745826	2.566919	0.465
	No	24	75.10764	13.278533	2.710469	
Threemonth_ASBQ_Total	Yes	33	156.00	20.993	3.654	0.272
	No	24	162.33	21.675	4.424	
ThreeMonth_ASBQ(%)	Yes	33	91.03093	11.577731	2.015424	0.366
	No	24	93.85119	11.447465	2.336704	

Figure 19 : Changes in ASBQ scores among patients with and without a Hadad flap



Acromegaly:

SNOT 22 scores and Acromegaly:

There were 7 patients who had acromegaly. The mean (SD) SNOT 22 score for the patients with acromegaly was 21.00(12.702) , 10.86(8.66) and 6.43(11.326) preoperatively , at 1 month post operatively and 3 months post operatively.

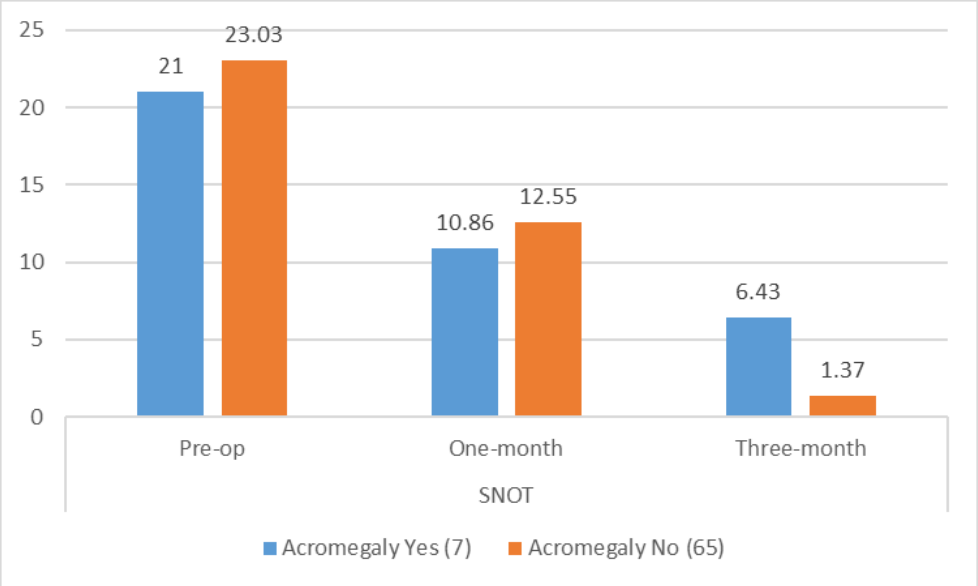
Among the patients who did not have acromegaly the mean (SD) SNOT 22 scores were 23.03(18.732), 12.55(16.825), 1.37(3.790) preoperatively , at 1 month post operatively and 3 months post operatively.

Although the mean SNOT 22 score for patients with acromegaly was higher at 3 months , there was no significant difference in the SNOT 22 scores at each of these time frames ($p<0.05$)

Table 26: SNOT 22 scores for patients with and without acromegaly

SNOT 22 score	Acromegaly	N	Mean	Std. Deviation	Std. Error Mean	p-value
Preop-SNOT-Total	Yes	7	21.00	12.702	4.801	0.781
	No	65	23.03	18.732	2.323	
Onemonth-postop-SNOT-Total	Yes	7	10.86	8.668	3.276	0.794
	No	65	12.55	16.825	2.087	
Threemonth-postop-SNOT-Total	Yes	7	6.43	11.326	4.281	0.012
	No	65	1.37	3.790	.470	

Figure 20: Graphical representation of SNOT 22 scores among patients who had acromegaly and those who did not



SBI scores and acromegaly:

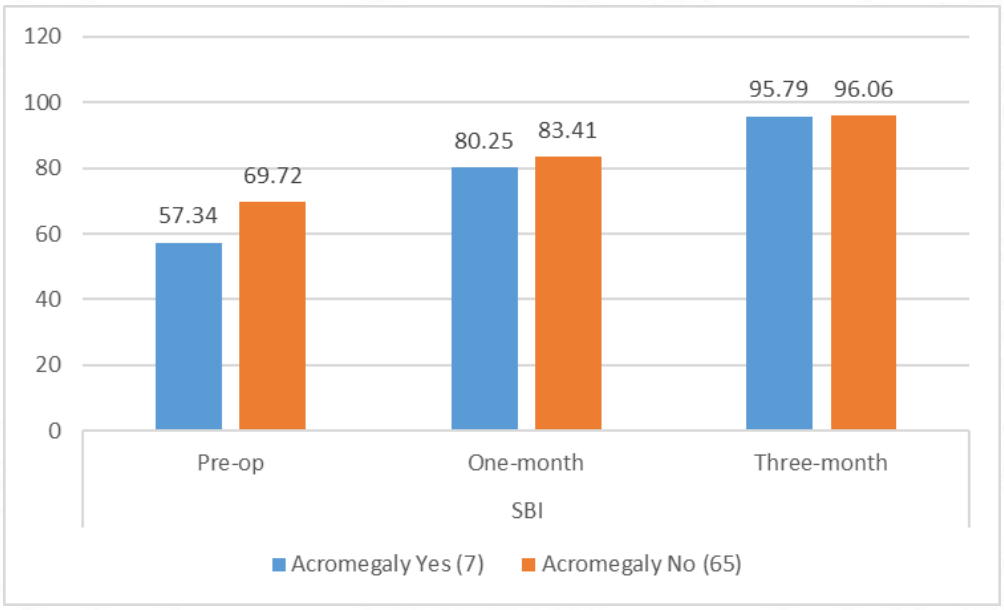
The mean (SD) SBI scores for patients with acromegaly was 57.34(30.45), 80.251(5.68) and 95.795(7.38) preoperatively, at 1 month and at 3 months interval. The mean (SD) of the SBI scores for patients without acromegaly was 69.71(17.9), 83.41(11.89), 96.06(6.46) preoperatively, at 1 month and at 3 months interval.

The SBI scores for patients without acromegaly was higher in patients without acromegaly at all three time intervals however this difference in SBI scores between the two groups was not significant.

Table 27 : SBI mean scores for patients with acromegaly and those without

	Acromegaly	N	Mean	Std. Deviation	Std. Error Mean	p-value
SBI-Preop-Final-score	Yes	7	57.33984	30.450093	11.509054	0.111
	No	65	69.71530	17.899589	2.220171	
SBI-One-month-Final-score	Yes	7	80.25138	5.688820	2.150172	0.491
	No	65	83.41493	11.893413	1.475196	
SBI-Threemonth-Final-score	Yes	7	95.79589	7.388187	2.792472	0.919
	No	65	96.06229	6.467719	.802222	

Figure 21 : Showing the changes in SBI mean scores among the patients with and without acromegaly



ASBQ scores and Acromegaly :

The mean(SD) ASBQ scores for patients with acromegaly was 105.57(21.991), 113.14(31.58) and 150.71(26.87) at each of the time intervals measured

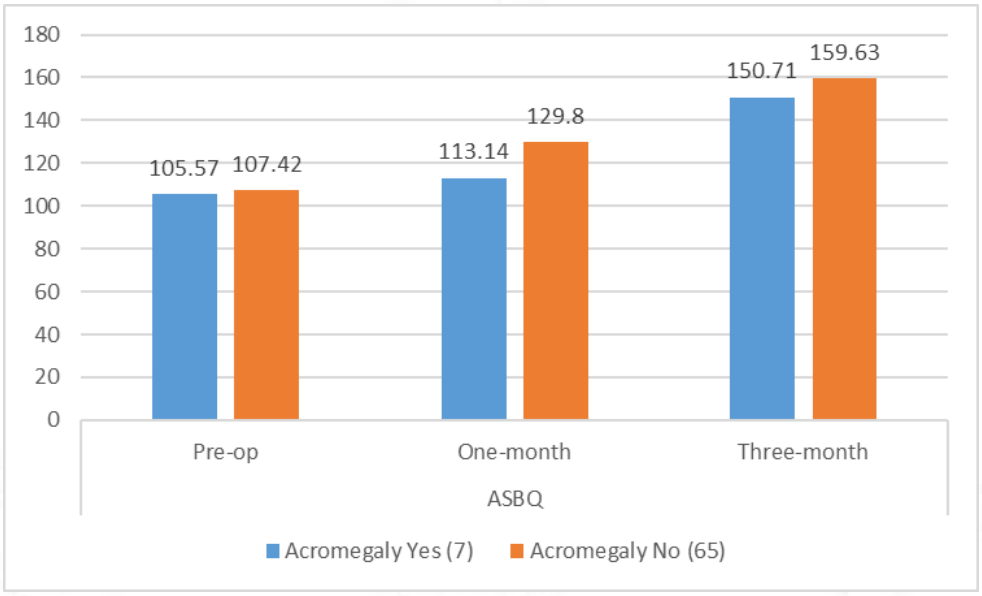
The mean(SD) ASBQ scores for patients without acromegaly was 107.42(24.34), 129.80(27.24) and 150.71(26.9)

The ASBQ scores measured at each of these time intervals showed that patients with acromegaly had a lower ASBQ scores as compared to patients without acromegaly. However this difference in scores between the two groups was not statistically significant (p>0.05).

Table 28: ASBQ mean scores for patients with and without acromegaly

	Acromegaly	N	Mean	Std. Deviation	Std. Error Mean	p-value
Preop-ASBQ_Total	Yes	7	105.57	21.991	8.312	0.848
	No	65	107.42	24.337	3.019	
Preop-ASBQ(%)	Yes	7	63.54404	12.024274	4.544748	0.913
	No	65	64.12457	13.455202	1.668912	
Onemonth_ASBQ_Total	Yes	7	113.14	31.578	11.935	0.134
	No	65	129.80	27.237	3.378	
OneMonth_ASBQ(%)	Yes	7	71.35949	13.243134	5.005434	0.330
	No	65	76.91018	14.322786	1.776523	
Threemonth_ASBQ_Total	Yes	7	150.71	26.868	10.155	0.281
	No	65	159.63	19.939	2.473	
ThreeMonth_ASBQ(%)	Yes	7	88.32824	13.464712	5.089183	0.332
	No	65	92.66443	10.913255	1.353623	

Figure 22: Mean ASBQ scores for patients with and without acromegaly at each of the time intervals



DISCUSSION

Endoscopic surgeries have become popular as they offer several benefits over the traditional open methods which includes faster recovery and early discharge after the procedure.

The fundamental nuance of endoscopic surgery involves creating an optimal corridor to access various skull base pathologies to improve visualization of important surgical landmarks and to also allow manipulation of endoscopic instruments. Creation of this surgical corridor can potentially disrupt the normal physiology of the nasal and paranasal cavities which could cause some of the subjective morbidities that occur after the procedure which includes their inability to breathe through their nose, speak, and eat and other social functions which could potentially impact their quality of life.

Assessment of the patient's reported quality of life is crucial to measure the outcome of endoscopic surgery. This requires collecting inputs directly from the patient about their physical, emotional and social well-being following surgery. Conventional medical history and examination of the patient post operatively to assess their quality of life is inadequate as each person may interpret their symptoms in a different way and their perception of well-being can vary significantly.

This has led to the development of subjective health related quality of life questionnaires for evaluating these outcomes after surgery. These questionnaires need to be reliable, valid, responsive and should be easy to use for both the patient as well as for the health care professional.

The SNOTT 22 questionnaire which is a PROM, was developed for measuring sino nasal complaints in diseases like rhinosinusitis. It consists of 22 items that cover five domains. Each of these items pertains to a specific symptom and is scored by the patient on a scale of 0 (absence of symptoms) to 5 (extreme symptoms). The score for each item is then added up, with a maximum score of 110. A higher score is associated with greater burden of sino nasal complaints.

The ASBQ has been validated for patients undergoing surgery for anterior skull base tumors. This questionnaire enables the assessment of both general and disease specific QOL measures. It comprises 35 items categorized into six domains, with scores for each item ranging from 1 to 5. Therefore, the total score range is between 35 and 175, with higher scores indicating better outcomes.

The SBI is a disease specific tool that helps to assess the QOL for patients who have undergone treatment for anterior or central skull base pathologies. It consists of 41 questions that cover 11 disease-specific domains.

Traditionally outcomes of endoscopic surgery have been measured in terms of extent of resection, cranial nerve dysfunction, morbidity and mortality which do not take the patient's perception of his symptoms into account. Patient reported outcomes are superior to assess quality of life compared to physician reported measures. Use of PROMs help understand the impact of the surgical procedure on the overall health of the patient and the change in outcomes that occur over time.

In this study our aim was to assess the patient reported quality of life pertaining to the nasal domain and towards the overall QoL by using all these three validated questionnaires and to determine the changes that occur with these scores

following endoscopic endonasal skull base surgery. Ours was a prospective study that recruited all patients undergoing endoscopic endonasal surgeries who fit into the inclusion criteria. Unlike previous studies done, we used all three questionnaires i.e. SNOT 22, SBI and ASBQ. These questionnaires were originally available in English only and had to be appropriately translated into Malayalam language.

Patient Demographics:

In our study of 72 patients, 52.8% were males. The mean age of the study population was 41.6± 15.82 years. Large majority of the study group belonged to the 20-39 years and 40-59 years age group. Both males and females were well represented in our study.

In a similar study done by Edward D. McCoul et al to assess the impact of endonasal surgery on the quality of life 42(49.4%) patients were male and 43 (50.6%) were female, with a mean (range) age of 52.5 (20–83) years (McCoul et al., 2012).

Clinical Characteristics:

Hypertension was the most common comorbidity seen in our study population seen in 26.4% of individuals which was followed by diabetes (22.20%) and hypothyroidism (11.10%).

The most common presenting symptom was visual which was in the form of blurring of one or both eyes, decreased peripheral vision in one or both eyes, decreased distant vision, double vision, difficulty in reading. The next most common symptom was headache followed by endocrine problems.

On examination the most common finding noted were features of endocrinopathy seen in 18.1% of individuals. This was followed by cranial nerve deficits seen in 11.1% of individuals.

Among the 72 patients who underwent endoscopic trans nasal surgery 33(45.8%) were diagnosed to have a nonfunctioning pituitary adenoma. The next most common diagnosis was CSF rhinorrhea (13.9%) and acromegaly (9.7%).

In a study which was done to assess the impact of endoscopic surgery on sinonasal quality of life they found that among 85 patients operated 55.3% had a pituitary adenoma out of which 22.4% were nonfunctional. The next most common indication for endoscopic surgery were chordomas and meningiomas (McCoul et al., 2012). In most other studies done to assess sinonasal outcomes, pituitary adenomas were the most common pathologies encountered.

Surgical Techniques and Complications:

Sixty-nine (95.8%) of the 72 patient underwent trans sphenoidal trans sellar surgery and the remaining 3 individuals underwent an extended trans nasal surgery. Similarly in another study done by Edward D. McCoul et al (McCoul et al., 2012) the transsphenoidal trans sellar route was the most common route employed endoscopically.

Gross total resection was achieved in 44(70.95) of individuals the rest underwent a near total (19.3%) or a subtotal (8%) resection.

Intraoperatively 24 (33.33%) of patients had CSF leak, the next most common complication was bleeding which was seen in 8.3% of individuals. This

was similar to the complications reported by Edward D. McCoul et al (McCoul et al., 2012) in which almost 64% of patients had CSF leak intraoperatively.

Post operatively 12(16.67%) patients developed diabetes insipidus, 4(5.56%) developed post-operative CSF rhinorrhoea that needed surgical repair. In another study by Riley et al where they looked into the outcomes of endoscopic skull base surgery with the use of nasoseptal flap they found a CSF leak rate post surgery to be 2.2%(Riley et al., 2018).

In another similar study the most common complication postoperatively was CSF leak followed by abducent nerve palsy, sellar hematoma, permanent diabetes insipidus (McCoul et al., 2014).

Preoperative lumbar drain was used in 24(33.3%) of individuals and Hadad flap was used for reconstruction of the skull base defect in 33(45.8%) of individuals. In a study done by Charles A Riley et al (Riley et al., 2018), among 374 patients who underwent endonasal endoscopic surgery 44.1 % required a naso septal flap and a planned lumbar drain was used in 50% of patients. Their use of preoperative lumbar drain and the requirement for a nasoseptal flap for skull base reconstruction was higher than the rates seen in our study.

SNOT 22 Questionnaire

The mean SNOT 22 scores decreased from the preoperative to the 3 month interval period. The mean total SNOT 22 score preoperatively was 22.83 which reduced to 12.39 after 1 month, which further reduced to 1.86 after 3 months. This implies that the QoL improved significantly from preoperative to the three month

time interval. This improvement in SNOT 22 scores was also reflected in each of its domains mainly the nasal, ear, sleep, function and emotional.

Harrow et al (Harrow et al., 2013) found similar results using the SNOT 20 scores and found that the mean scores as well as the nasal and ear/facial domains improved at 3 months and 6 months after surgery compared to their baseline preoperative value. They found this association with benign tumors only.

Glicksman et al in their study of 145 patients who underwent endoscopic resection of both benign and malignant sinonasal tumours found a similar increase in the SNOT22 scores from the baseline values when measured at 3 months and at 2 years after surgery (Glicksman et al., 2017). They also reported a worse quality of life for patients with malignant tumors as compared to benign ones.

In the study done by Edward D. McCoul et al (McCoul et al., 2012) in which they compared SNOT 22 scores at 3 weeks, 6 weeks and 12 weeks after surgery they found that higher SNOT 22 scores were seen at the 3 weeks interval which subsequently decreased at the 12 weeks and 6 months interval to become comparable to the preoperative SNOT 22 scores. This initial worsening of the QoL was not seen in our study most probably because by the time the first assessment of patient wellbeing was done at 1 month postoperatively their QoL would have significantly improved from the immediate post operative period. An earlier assessment of QoL following surgery would have probably shown this early decline in QoL.

In a study which asseses the long term sinonasal outcomes after endoscopic skull base surgery with the use of a nasoseptal flap they found that there was no statistically significant difference for the total, ear/facial pain or emotional function

subdomain of the SNOT 22 scores after surgery. They also noted a statistically significant increase in subdomain scores for the nasal symptoms after surgery indicating a fall in quality of life(Riley et al., 2018).

Hence, although most studies consistently show that long term QoL improves after endoscopic surgery there exits some inconsistency regarding the immediate post operative QoL. Some studies reported a fall in QoL while others have reported a steady increase in QoL immediately following surgery. This probably depends on the time interval after which the first QoL was assessed. In our study the first post operative QoL was assessed at the 1 month post operative period by which most of the immediate deleterious effects of surgery may have resolved reflecting a steady increase in the QOL compared to their baseline.

SBI Questionnaire :

SBI scores increased from the baseline value at the 1 month and the 3 month interval. This increase in the SBI scores was statistically significant. Since a higher SBI score indicates a better quality of life our findings were suggestive of an overall increase in the QoL after surgery. This trend in increase in SBI scored was seen in all its domains which include cognitive, emotional, family, financial, social, spiritual, endocrine, neurological and visual except for the nasal domain at the one month post operative period.

David Forner et al (Forner et al., 2020) used the SNOT 22 , ASBQ and the SBI in order to test the psychometric properties of the SBI in patients undergoing open and endoscopic surgeries and administered these questionnaires at six time points which were preoperative, 2 weeks, 3 months, 6 months and 12 months

postoperatively. They found a very strong correlation between the total SBI scores and ASBQ scores at all time points along with a moderate negative correlation between the nasal domains of SBI scores and with SNOT 22 scores. The SBI scores showed a significant increase in mean difference between the preoperative and 2 weeks post operative periods for both the total scores and seven of its domains and also a steady improvement of the total SBI scores over the first postoperative year. In their study they also showed significant cross cultural variations in SBI scores and suggested that the English language SBI instrument could be used as long as there was a fluency in English among the study population.

In our study most of the individuals were not fluent in English and were administered the questionnaire in Malyalam language. For those patients not familiar with Malyalam the questionnaire was verbally translated into a language understood by them. Although we did not assess the cultural differences among the patients we did observe that proficiency of the language is an important factor to consider when patients fill this questionnaire. Further studies would be required to see if a well translated questionnaire would be as effective as the original English version of the questionnaire.

ASB Questionnaire

The total mean ASBQ scores increased from the baseline value at the 1 month and the 3 month interval. This trend was observed in each of the domains of the ASBQ score. The increase in overall ASBQ score and the scores for each of its domain was found to be significant except for the pain domain at the 1 month

interval. Hence the QoL improved from the baseline value to 1 month and 3 months post operatively.

In another study (Bedrosian et al.,2013) , they divided 85 patients into those who underwent surgery for a pituitary adenoma and those who underwent an endoscopic surgery for other pathologies. They were evaluated for their change in QoL using the ASBQ preoperatively and upto 1 year post operatively. They found that the preoperative smell and taste domain were significantly lower in the non-pituitary group. In the pituitary group both taste and smell domains significantly worsened 6 weeks after surgery with a return to baseline after 1 year.

McCoul et al (McCoul et al., 2012) evaluated the QOL of patients undergoing endoscopic surgeries for pituitary and non pituitary pathologies. They found that the overall ASBQ scores did not differ significantly between preoperative scores and at 3 weeks and 6 weeks post surgery. Further they noted that ASBQ scores improved at 3 months which was maintained at 6 months postoperatively.

Quinlan D. Buchlak et al conducted a study to determine the QOL of patients undergoing endoscopic endonasal surgery by using the anterior skull base surgery questionnaire. Among the 451 patients that they analysed they found that the ASBQ score was significantly higher at the 12 month follow up period than compared to the pre operative score (Buchlak et al., 2022).

Unlike the SNOT 22 scoring system , the questions with the ASBQ require a greater understanding ones disease condition and require better language and comprehension skills. The validity of the questionnaire when translated to a local language such as Malyalam which has been done in our study had not been validated. Further many

patients require assistance from the person administering this questionnaire as they sometimes find a specific question difficult to understand or to quantify.

Concurrent validity between SBI and the SNOT 22 scores :

Using Pearson correlation, the SBI and SNOT22 scores showed a negative correlation. As the SBI scores increased the SNOT 22 scores decreased during the three time intervals. This correlation was significant at all three time intervals. This showed that the quality of life improved among participants when assessed with both SBI and SNOT 22 questionnaire.

Similarly in another study which aimed to evaluate the correlation between the SBI scores with ASBQ and SNOT 22 found a moderate negative correlation of the nasal domain of the SBI with SNOT 22 scores (Forner et al., 2020).

Concurrent validity between SBI and ASBQ scores :

Pearsons correlation showed a positive correlation between SBI and ASBQ during the three time intervals. This correlation was significant at 1 month and 3 month interval ($p<0.05$).

In a study that was designed to measure the psychometric properties of the SBI , patients were asked to complete the ASBQ and the SNOT 22 to allow comparison to the SBI (Forner et al., 2020). The concurrent validity was seen to show very strong correlation between total SBI scores and ASBQ scores and moderate correlation between SBI and SNOT 22 scores.

Concurrent validity between the ASBQ and the SNOT-22:

Pearson correlation of ASBQ and SNOT 22 showed negative correlation. As the ASBQ scores increased the SNOT22 scores decreased during this period. This change was significant at the 1month and 3 month interval but not in the pre operative period.

In a similar study in which patients undergoing endoscopic endonasal surgery were evaluated with both the SNOT22 and ASBQ scores , an significant inverse correlation was found preoperatively and at all times post operatively(McCoul et al., 2012).

In a study done to assess the QOL metrics after endoscopic surgery for sinonasal neoplasms using both the SNOT 20 and ASBQ questionnaires they found a strong correlation between SNOT 20 and ASBQ and moderate correlation between SNOT 20 and EQ5D questionnaire(Deckard et al.,2015).

In our study all three questionnaires showed a consistent improvement in the patient's QOL from the preoperative period when measured at 1 month and 3 month interval. These questionnaires showed good correlation with each other. In the immediate post operative period patients undergoing endonasal surgeries are likely to experience a worse QOL owing to the immediate post operative discomfort, use of nasal packs or lumbar drains. After the immediate post operative period these patients are likely to experience dramatic changes in their pre operative complaints mainly being visual field defects and headaches that existed pre operatively. Most of our patients underwent a nasal cleaning procedure by an ENT surgeon 2 weeks postoperatively which probably also contributes to improvement of their sino nasal

functions. This improvement in their QOL has probably been reflected well in the one month post operative assessment of their wellbeing.

During their next assessment at 3 months after surgery the significant improvement in their quality of life reflects the effectiveness of the surgical procedure to alleviate the preexisting morbidity.

SNOT 22, SBI and ASBQ score and Hadad flap:

When we compared the SNOT 22 scores in patients in whom a Hadad flap had been used with those in which no Hadad flap was used we found no significant difference among the two groups in terms of improvement in their quality of life.

Similarly, when we compared the SBI and ASBQ scores in patients with and without a Hadad flap there was no significant difference among the two groups in terms of improvement of their quality of life.

Although there are contradictory findings, literature regarding the QOL changes that occur with the use of a nasoseptal flap shows a transient worsening of QOL scores with a return to baseline(Pant et al., 2010). However, in a study conducted by Chaaban et al using the Pennsylvania Smell Identification Test they found in patients undergoing endoscopic transnasal surgery scores were not significantly different when patients who had a nasoseptal flap reconstruction done were compared with those who did not (Chaaban et al., 2015).

In a systematic review done by Greig et al in which they compared sino nasal functional outcomes life airflow, olfaction and mucociliary clearance they concluded an elevation of naso septal flap led to a worse functional outcome. They

recommended avoiding a routine elevation of a flap and that if a flap is deemed required then a donor area reconstruction should considered (Greig et al.,2016).

SNOT 22, SBI and ASBQ score and Acromegaly:

When we compared the SNOT 22 scores in patients with acromegaly and other patients we found no significant difference among the two groups in terms of their baseline QOL and the improvement with time. Although the mean SNOT22 score for patients with acromegaly was higher at the 3 month interval, it was not statistically significant.

The SBI scores for patients without acromegaly were higher in patients without acromegaly at all three time intervals however this difference in SBI scores between the two groups was not significant.

The ASBQ scores measured at each of these time intervals showed that patients with acromegaly had a lower ASBQ scores as compared to patients without acromegaly. However this difference in scores between the two groups was not statistically significant ($p>0.05$).

Although the number of patients with acromegaly in our study was too small to be statistically significant there are various studies that have reported the influence of tumour pathology on the changes in QOL scores. In a study done by J-C Ahn et al (Ahn et al.,2019) they found no association between the type of pathology and the impact on QOL scores using the SNOT 22 scoring system.

In a similar study which used the SNOT 22 questionnaire on 45 patients undergoing endoscopic endonasal surgery they found that the pathology of the tumor did not affect the QOL scores at any of their follow up intervals (Wu et al.,2018).

In another study which assed the impact on nasal symptoms and the quality of life comparing functional and nonfunctional tumors, they found no negative impact of operated functional tumors compared to their nonfunctional counterparts.

Some studies have reported a decreased QOL using the SF-36 scores among different types of functioning adenomas (Johnson et al., 2003; Lindsay et al., 2006). Patients with acromegaly showed impairment in physical domains of their QOL whereas patients with prolactinomas had an impairment in their mental health domains. Nonfunctioning adenomas showed impairment in both physical and mental domain.

SUMMARY AND CONCLUSION

Our study consisted of 72 patients who were administered the SNOT 22 , ASBQ and the SBI at three time intervals that is preoperatively, 1 month post operatively and 3 months post operatively after undergoing endoscopic endonasal surgeries.

We found that the total mean SNOT 22 scores for these individuals was highest during the preoperative period and showed a significant decline of the same scores when measured at one month and three months. This improvement was seen in each of the domains of the SNOT 22 ie nasal, ear, sleep, function and emotion. This decrease in scores signified an improvement in the QOL measured at these time intervals. The change in overall scores and the domain scores was significant ($p<0.05$).

The scores on the SBI increased from the baseline value at each of the time intervals where it was measured. Except for the nasal domain of the SBI all other domains showed a similar increase in scores. This showed that the quality of life improved significantly ($p<0.05$) after surgery when assed with the SBI

The ASBQ scores also increased from the preoperative baseline values after surgery. A similar trend of increase in scores were seen for each of the ASBQ domains. The increase in scores for all domains of ASBQ scores were significant ($p<0.05$) except for the pain domain at 1 month interval. This shows that the quality of life significantly improved from the preoperative baseline when measured with the ASBQ.

When assessed for the concurrent validity between the three scores we found that SBI and ASBQ showed good positive correlation whereas the SNOT 22 score showed a good negative correlation with the both SBI and ASBQ. This implies that

the trend in improvement of the patient's quality of life was well represented by all three questionnaires.

There was no significant difference in the change in the QOL when we compared those patients in whom a nasoseptal flap was used with those in which no nasoseptal flap was used.

Similarly, no significant difference in the change in QOL in patients with acromegaly compared with the rest.

The results from our study shows that the quality of life improved which was well represented in all three questionnaires. This improvement is seen at one month postoperatively which improves further at 3 months postoperatively. Immediately following endoscopic surgery the QOL of patients fall owing to the post operative nasal discomfort, nasal pack placement and the use of a lumbar drain. After this initial period the QOL improves and becomes significantly better than their preoperative scores. This significant improvement can be attributed to the effects of endonasal surgery on their preoperative complaints, especially visual complaints and headache which tends to improve almost after surgery.

The results of our study gives a better understanding about the impact that endonasal procedures have on the patient's self reported Qol measures. This would aid in better preoperative counselling and improve patient's acceptance of the procedure. Moreover the significant improvement of QoL emphasizes the effectiveness that endoscopic surgeries have in addressing some of the anterior skull base pathologies.

A study comprising of a larger cohort of individuals followed up for a longer period of time would probably yield a better understanding as to the changes in the QOL that these individuals experience as a result of endonasal endoscopic surgeries.

LIMITATIONS OF THE STUDY

- Small sample size
- The assesment of preoperative QOL was done by administering the questionnaire directly to the patient. However, the 1month and 3 month questionnaires were administered both directly and telephonically
- Questionnaire was translated in English and Malayalam only. For those patients who were not familiar with either of the languages a verbal translation of the questionnaire had to be done

REFERENCES

Abergel A (2012) Comparison of Quality of Life After Transnasal Endoscopic vs Open Skull Base Tumor Resection. *Archives of Otolaryngology–Head & Neck Surgery* 138(2). American Medical Association (AMA): 142. DOI: 10.1001/archoto.2011.1146.

Ahn J-C, Cho S-W, Kim D-K, et al. (2019) Recovery period of sinonasal quality of life and its associated factors after endoscopic endonasal approach for anterior skull base tumors. *Acta Oto-Laryngologica* 139(5). Informa UK Limited: 461–466. DOI: 10.1080/00016489.2019.1574982.

Balaker A, Bergsneider M, Martin N, et al. (2010) Evolution of Sinonasal Symptoms Following Endoscopic Anterior Skull Base Surgery. *Skull Base* 20(04). Georg Thieme Verlag KG: 245–251. DOI: 10.1055/s-0030-1249248.

Bedrosian JC, McCoul ED, Raithatha R, et al. (2013) A prospective study of postoperative symptoms in sinonasal quality-of-life following endoscopic skull-base surgery: dissociations based on specific symptoms. *International Forum of Allergy & Rhinology* 3(8). Wiley: 664–669. DOI: 10.1002/alr.21161.

Benninger MS and Senior BA (1997) The Development of the Rhinosinusitis Disability Index. *Archives of Otolaryngology - Head and Neck Surgery* 123(11). American Medical Association (AMA): 1175–1179. DOI: 10.1001/archotol.1997.01900110025004.

Buchlak QD, Esmaili N, Bennett C, et al. (2022) Predictors of improvement in quality of life at 12-month follow-up in patients undergoing anterior endoscopic

skull base surgery. *PLOS ONE* Mockridge J (ed.) 17(7). Public Library of Science (PLoS): e0272147. DOI: 10.1371/journal.pone.0272147.

Carrau RL, Jho H-D and Ko Y (1996) Transnasal-Transsphenoidal Endoscopic Surgery of the Pituitary Gland. *The Laryngoscope* 106(7). Wiley: 914–918. DOI: 10.1097/00005537-199607000-00025.

Chaaban MR, Chaudhry AL, Riley KO, et al. (2015) Objective Assessment of Olfaction after Transsphenoidal Pituitary Surgery. *American Journal of Rhinology & Allergy* 29(5). SAGE Publications: 365–368. DOI: 10.2500/ajra.2015.29.4206.

Hopkins C, Browne JP, Slack R, et al. (2006) The national comparative audit of surgery for nasal polyposis and chronic rhinosinusitis. *Clinical Otolaryngology* 31(5). Wiley: 390–398. DOI: 10.1111/j.1749-4486.2006.01275.x.

de Almeida JR, Vescan AD, Gullane PJ, et al. (2012) Development of a disease-specific quality-of-life questionnaire for anterior and central skull base pathology-The skull base inventory. *The Laryngoscope* 122(9). Wiley: 1933–1942. DOI: 10.1002/lary.23426.

Deckard NA, Harrow BR, Barnett SL, et al. (2015) Comparative Analysis of Quality-of-Life Metrics after Endoscopic Surgery for Sinonasal Neoplasms. *American Journal of Rhinology & Allergy* 29(2). SAGE Publications: 151–155. DOI: 10.2500/ajra.2015.29.4137.

Derousseau T, Manjunath L, Harrow B, et al. (2015) Long-term changes in quality of life after endoscopic resection of sinonasal and skull-base tumors. *International Forum of Allergy & Rhinology* 5(12). Wiley: 1129–1135. DOI: 10.1002/alr.21608.

Enepekides DJ and Donald PJ (2000) Long-term outcomes of anterior skull base surgery. *Current Opinion in Otolaryngology & Head and Neck Surgery* 8(2). Ovid Technologies (Wolters Kluwer Health): 130–136. DOI: 10.1097/00020840-200004000-00011.

Fliss DM, Abergel A, Cavel O, et al. (2007) Combined Subcranial Approaches for Excision of Complex Anterior Skull Base Tumors. *Archives of Otolaryngology–Head & Neck Surgery* 133(9). American Medical Association (AMA): 888. DOI: 10.1001/archotol.133.9.888.

Fliss DM, Zucker G, Cohen A, et al. (1999) Early outcome and complications of the extended subcranial approach to the anterior skull base. *The Laryngoscope* 109(1). Wiley: 153–160. DOI: 10.1097/00005537-199901000-00029.

Forner D, Hueniken K, Yoannidis T, et al. (2020) Psychometric testing of the Skull Base Inventory health-related quality of life questionnaire in a multi-institutional study of patients undergoing open and endoscopic surgery. *Quality of Life Research* 30(1). Springer Science and Business Media LLC: 293–301. DOI: 10.1007/s11136-020-02609-z.

Georgalas C, Badloe R, van Furth W, et al. (2012) Quality of life in extended endonasal approaches for skull base tumours. *Rhinology journal* 50(3). Stichting Nase: 255–261. DOI: 10.4193/rhino12.050.

Gil Z, Abergel A, Spektor S, et al. (2003) Quality of Life Following Surgery for Anterior Skull Base Tumors. *Archives of Otolaryngology–Head & Neck Surgery*

129(12). American Medical Association (AMA): 1303. DOI: 10.1001/archotol.129.12.1303.

Gil Z, Abergel A, Spektor S, et al. (2004) Patient, Caregiver, and Surgeon Perceptions of Quality of Life Following Anterior Skull Base Surgery. *Archives of Otolaryngology–Head & Neck Surgery* 130(11). American Medical Association (AMA): 1276. DOI: 10.1001/archotol.130.11.1276.

Gil Z, Abergel A, Spektor S, et al. (2004) Development of a cancer-specific anterior skull base quality-of-life questionnaire. *Journal of Neurosurgery* 100(5). Journal of Neurosurgery Publishing Group (JNSPG): 813–819. DOI: 10.3171/jns.2004.100.5.0813.

Gil Z and Fliss D (2010) Quality of Life in Patients with Skull Base Tumors: Current Status and Future Challenges. *Skull Base* 20(01). Georg Thieme Verlag KG: 011–018. DOI: 10.1055/s-0029-1242979.

Gill TM (1994) A critical appraisal of the quality of quality-of-life measurements. *JAMA: The Journal of the American Medical Association* 272(8). American Medical Association (AMA): 619–626. DOI: 10.1001/jama.272.8.619.

Glicksman JT, Parasher AK, Brooks SG, et al. (2017) Sinonasal quality of life after endoscopic resection of malignant sinonasal and skull base tumors. *The Laryngoscope* 128(4). Wiley: 789–793. DOI: 10.1002/lary.26833.

Graham SM, Iseli TA, Karnell LH, et al. (2009) Endoscopic Approach for Pituitary Surgery Improves Rhinologic Outcomes. *Annals of Otology, Rhinology &*

Laryngology 118(9). SAGE Publications: 630–635. DOI: 10.1177/000348940911800905.

Greig SR, Cooper TJ, Sommer DD, et al. (2016) Objective sinonasal functional outcomes in endoscopic anterior skull-base surgery: an evidence-based review with recommendations. *International Forum of Allergy & Rhinology* 6(10). Wiley: 1040–1046. DOI: 10.1002/alr.21760.

Hadad G, Bassagasteguy L, Carrau RL, et al. (2006) A Novel Reconstructive Technique After Endoscopic Expanded Endonasal Approaches: Vascular Pedicle Nasoseptal Flap. *The Laryngoscope* 116(10). Wiley: 1882–1886. DOI: 10.1097/01.mlg.0000234933.37779.e4.

Harrow BR and Batra PS (2013) Sinonasal quality of life outcomes after minimally invasive resection of sinonasal and skull-base tumors. *International Forum of Allergy & Rhinology* 3(12). Wiley: 1013–1020. DOI: 10.1002/alr.21200.

Harvey RJ, Malek J, Winder M, et al. (2015) Sinonasal morbidity following tumour resection with and without nasoseptal flap reconstruction. *Rhinology journal* 53(2). Stichting Nase: 122` – 128. DOI: 10.4193/rhino14.247.

Hopkins C, Gillett S, Slack R, et al. (2009) Psychometric validity of the 22-item Sinonasal Outcome Test. *Clinical Otolaryngology* 34(5). Wiley: 447–454. DOI: 10.1111/j.1749-4486.2009.01995.x.

Jalessi M, Jahanbakhshi A, Amini E, et al. (2015) Impact of nasoseptal flap elevation on sinonasal quality of life in endoscopic endonasal approach to pituitary adenomas.

European Archives of Oto-Rhino-Laryngology 273(5). Springer Science and Business Media LLC: 1199–1205. DOI: 10.1007/s00405-015-3729-z.

H-D Jho, H-G Ha (2004) Endoscopic Endonasal Skull Base Surgery: Part 1 - The Midline Anterior Fossa Skull Base. 47(1). *Minimally Invasive Neurosurgery*, Georg Thieme Verlag KG: 1–8. DOI: 10.1055/s-2003-812538.

H-D Jho, H-G Ha (2004) Endoscopic Endonasal Skull Base Surgery: Part 2 - The Cavernous Sinus. 47(1). *Minimally Invasive Neurosurgery*, Georg Thieme Verlag KG: 9–15. DOI: 10.1055/s-2004-818346.

H-D Jho, H-G Ha (2004) Endoscopic Endonasal Skull Base Surgery: Part 3 - The Clivus and Posterior Fossa. 47(1). *Minimally Invasive Neurosurgery* Georg Thieme Verlag KG: 16–23. DOI: 10.1055/s-2004-818347.

Johnson MD, Woodburn CJ and Vance ML (2003) Quality of Life in Patients with a Pituitary Adenoma. *Pituitary* 6(2). Springer Science and Business Media LLC: 81–87. DOI: 10.1023/b:pitu.0000004798.27230.ed.

JUNIPER EF and GUYATT GH (1991) Development and testing of a new measure of health status for clinical trials in rhinoconjunctivitis. *Clinical <html_ent glyph="@amp;" ascii="&"/> Experimental Allergy* 21(1). Wiley: 77–83. DOI: 10.1111/j.1365-2222.1991.tb00807.x.

Kaptain GJ, Vincent DA, Sheehan JP, et al. (2001) Transsphenoidal Approaches for the Extracapsular Resection of Midline Suprasellar and Anterior Cranial Base Lesions. *Neurosurgery* 49(1). Ovid Technologies (Wolters Kluwer Health): 94–101. DOI: 10.1227/00006123-200107000-00014.

Kassam A, Snyderman CH, Mintz A, et al. (2005) Expanded endonasal approach: the rostrocaudal axis. Part I. Crista galli to the sella turcica. *Neurosurgical Focus* 19(1). Journal of Neurosurgery Publishing Group (JNSPG): 1–12. DOI: 10.3171/foc.2005.19.1.4.

Kassam A, Snyderman CH, Mintz A, et al. (2005) Expanded endonasal approach: the rostrocaudal axis. Part II. Posterior clinoids to the foramen magnum. *Neurosurgical Focus* 19(1). Journal of Neurosurgery Publishing Group (JNSPG): 1–7. DOI: 10.3171/foc.2005.19.1.5.

Kassam AB, Gardner P, Snyderman C, et al. (2005) Expanded endonasal approach: fully endoscopic, completely transnasal approach to the middle third of the clivus, petrous bone, middle cranial fossa, and infratemporal fossa. *Neurosurgical Focus* 19(1). Journal of Neurosurgery Publishing Group (JNSPG): 1–10. DOI: 10.3171/foc.2005.19.1.7.

Kassam AB, Snyderman C, Gardner P, et al. (2005) The Expanded Endonasal Approach: A Fully Endoscopic Transnasal Approach and Resection of the Odontoid Process: Technical Case Report. *Operative Neurosurgery* 57(suppl_1). Ovid Technologies (Wolters Kluwer Health): E213–E213. DOI: 10.1227/01.neu.0000163687.64774.e4.

Borg A, Al-Mousa A, Haliasos N, et al. (2013) Quality-of-Life after Anterior Skull Base Surgery: A Systematic Review. *Journal of Neurological Surgery Part B: Skull Base* 75(02). Georg Thieme Verlag KG: 073–089. DOI: 10.1055/s-0033-1359303.

LANZA D and KENNEDY D (1997) Adult rhinosinusitis defined. *Otolaryngology - Head and Neck Surgery* 117(3). Wiley: S1–S7. DOI: 10.1016/s0194-5998(97)70001-9.

Larjani S, Monteiro E, Witterick I, et al. (2016) Preliminary cross-sectional reliability and validity of the Skull Base Inventory (SBI) quality of life questionnaire. *Journal of Otolaryngology - Head & Neck Surgery* 45(1). Springer Science and Business Media LLC. DOI: 10.1186/s40463-016-0158-y.

Lindsay JR, Nansel T, Baid S, et al. (2006) Long-Term Impaired Quality of Life in Cushing's Syndrome despite Initial Improvement after Surgical Remission. *The Journal of Clinical Endocrinology & Metabolism* 91(2). The Endocrine Society: 447–453. DOI: 10.1210/jc.2005-1058.

Locatelli D, Castelnuovo P, Santi L, et al. (2000) Endoscopic approaches to the cranial base: perspectives and realities. *Child's Nervous System* 16(10–11). Springer Science and Business Media LLC: 686–691. DOI: 10.1007/s003810000323.

Lund V.J (2001) Health related quality of life in sinonasal disease. Rhinology 39, 182–186.

McCoul ED, Anand VK, Bedrosian JC, et al. (2012) Endoscopic skull base surgery and its impact on sinonasal-related quality of life. *International Forum of Allergy & Rhinology* 2(2). Wiley: 174–181. DOI: 10.1002/alr.21008.

McCoul ED, Anand VK and Schwartz TH (2012) Improvements in site-specific quality of life 6 months after endoscopic anterior skull base surgery: a prospective

study. *Journal of Neurosurgery* 117(3). Journal of Neurosurgery Publishing Group (JNSPG): 498–506. DOI: 10.3171/2012.6.jns111066.

McCoul ED, Anand VK, Singh A, et al. (2014) Long-Term Effectiveness of a Reconstructive Protocol Using the Nasoseptal Flap After Endoscopic Skull Base Surgery. *World Neurosurgery* 81(1). Elsevier BV: 136–143. DOI: 10.1016/j.wneu.2012.08.011.

McCoul ED, Anand VK, Bedrosian JC, et al. (2012) Endoscopic skull base surgery and its impact on sinonasal-related quality of life. *International Forum of Allergy & Rhinology* 2(2). Wiley: 174–181. DOI: 10.1002/alr.21008.

Morley AD and Sharp HR (2006) A review of sinonasal outcome scoring systems - which is best? *Clinical Otolaryngology* 31(2). Wiley: 103–109. DOI: 10.1111/j.1749-4486.2006.01155.x.

Pant H, Bhatki A, Snyderman C, et al. (2010) Quality of Life Following Endonasal Skull Base Surgery. *Skull Base* 20(01). Georg Thieme Verlag KG: 035–040. DOI: 10.1055/s-0029-1242983.

Semple CJ and Killough SA (2014) Quality of life issues in head and neck cancer. *Dental Update* 41(4). Mark Allen Group: 346–353. DOI: 10.12968/denu.2014.41.4.346.

Raza SM and Schwartz TH (2015) Multi-Layer Reconstruction During Endoscopic Endonasal Surgery: How Much Is Necessary? *World Neurosurgery* 83(2). Elsevier BV: 138–139. DOI: 10.1016/j.wneu.2014.07.004.

Riley CA, Tabaee A, Conley L, et al. (2018) Long-term sinonasal outcomes after endoscopic skull base surgery with nasoseptal flap reconstruction. *The Laryngoscope* 129(5). Wiley: 1035–1040. DOI: 10.1002/lary.27637.

Suberman TA, Zanation AM, Ewend MG, et al. (2011) Sinonasal quality-of-life before and after endoscopic, endonasal, minimally invasive pituitary surgery. *International Forum of Allergy & Rhinology* 1(3). Wiley: 161–166. DOI: 10.1002/alr.20029.

Witgert M, Veramonti T and Hanna E (2010) Instruments for Estimation of Health-Related Quality of Life in Patients with Skull Base Neoplasms. *Skull Base* 20(01). Georg Thieme Verlag KG: 005–010. DOI: 10.1055/s-0029-1242978.

Wu V, Cusimano MD and Lee JM (2018) Extent of Surgery in Endoscopic Transsphenoidal Skull Base Approaches and the Effects on Sinonasal Morbidity. *American Journal of Rhinology & Allergy* 32(1). SAGE Publications: 52–56. DOI: 10.2500/ajra.2018.32.4499.

Shah O, Theodosopoulos P and Zimmer L (2014) Short-Term Quality-of-Life Changes after Endoscopic Pituitary Surgery Rated with SNOT-22. *Journal of Neurological Surgery Part B: Skull Base* 75(04). Georg Thieme Verlag KG: 288–292. DOI: 10.1055/s-0034-1372464.

ANNEXURES

Patient Information Sheet

TITLE OF THE STUDY: Clinical assessment of patient reported quality of life in following endoscopic skull base surgeries.

You are being requested to participate in a study to see the impact of endoscopic surgery on the quality of the functions of the nose. We hope to include 200 patients in this study.

If you take part what will you have to do?

The study will be conducted during your routine visits to the hospital. If you agree to participate in this study, you have to undergo a formal general examination to know your present general condition along with answering sino-nasal quality of life questionnaire and skull base inventory which will entail answering a proforma based on functions of your nose and quality of life. All treatments that you have already received will be reviewed and your regular treatment will not be changed during this study. The participation in the study is purely voluntary and there will be no difference in your treatment or follow up if you decide not to cooperate for the study.

Will you have to pay for the investigations?

No additional payment will be required. You will need to come only on your usual review date for the study. Routine follow up visits are required.

What happens if you are detected to have any fresh problems during the study?

During the course of the study, if you are detected to have any evidence of fresh deficit related to the illness, you will be advised the appropriate management for the same. Will additional follow up be required for the purpose of study. No additional follow up be required for this study. Patient will be assessed on Post-operative 1, 3, 28 and after 3 months. Patient will only require routine follow for the skull base surgery after 1 month and 3 months of surgery. QoL will be assessed during routine follow up study which will require 15- 30mins of additional 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, without your additional permission.

If you have any further questions, please ask Dr. Suraj Gopal (Mob: 9844637287) email: surajgopal2010@gmail.com

For any clarifications regarding the study's ethics clearance you may contact the Member Secretary of the SCTIMST-IEC. The phone number is: 234(O) 0471- 2524689 and the email id is srinivasg@sctimst.ac.in

Patient Consent Form

CONSENT FORM

TITLE OF THE STUDY: Clinical assessment of patient reported quality of life in following endoscopic skull base surgeries.

Study number:

Participant's name: _____

Date of Birth / Age (in years): _____

Son/daughter of _____

(Please tick boxes) •

I declare that I have read the above information provided to me regarding the study – "**Clinical assessment of patient reported quality of life in following endoscopic skull base surgeries.**"- and have clarified any doubts that I had. [ ]

I understand that my participation in this study is entirely voluntary and that i am free to withdraw the permission to continue my participation at any time without affecting my usual treatment or my legal rights. [ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if i withdraw from the trial. I agree to this access. [ ]

I understand that my identity will not be revealed in any information released to third parties or published [ ]

I voluntarily agree to take part in this study [ ]

I have received a copy of this signed consent form [ ]

Name: _____

Signature: _____

Date: _____

Name of witness: _____

Relation to participant: _____

Date: _____

(Person Obtaining Consent) I, _____ attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that i encouraged the participant to ask questions and that all questions asked were answered.

_____ _____

Name and Signature of Person Obtaining Consent

SNOTT 22 Questionnaire

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

TOTAL: ____ ____ ____ ____ ____

GRAND TOTAL:

Skull Base Inventory (SBI)

The Skull Base Inventory

Sl no	Questions	Severe problem	Major problem	Moderate problem	Some problem	Little problem	Hardly a problem	No problem
1	Headache?	0	1	2	3	4	5	6
2	A runny nose?	0	1	2	3	4	5	6
3	Crust in your nose?	0	1	2	3	4	5	6
4	Double vision?	0	1	2	3	4	5	6
5	Peripheral vision?	0	1	2	3	4	5	6
6	Irritation in your eyes?	0	1	2	3	4	5	6
7	Having to urinate often?	0	1	2	3	4	5	6
8	Dry mouth?	0	1	2	3	4	5	6
9	Numbness & tingling?	0	1	2	3	4	5	6
10	Muscle weakness?	0	1	2	3	4	5	6
11	Swallowing food and beverage?	0	1	2	3	4	5	6
12	Being irritable or cranky?	0	1	2	3	4	5	6
13	Being unable to control your anger?	0	1	2	3	4	5	6
In Past 2 weeks, Please rate (Q 14-23)								
		None	**very poor**	**Poor**	**Adequate**	**Good**	**Very good**	**excellent**
14	Your ability to smell	0	1	2	3	4	5	6
15	Your ability to taste	0	1	2	3	4	5	6
16	Your ability to breathe through your nose	0	1	2	3	4	5	6
17	Your ability to see clearly	0	1	2	3	4	5	6
18	Your energy level	0	1	2	3	4	5	6
19	Your sleep	0	1	2	3	4	5	6
20	Your sense of balance	0	1	2	3	4	5	6
21	Your memory	0	1	2	3	4	5	6
22	Your ability to concentrate	0	1	2	3	4	5	6
23	Your sexual function		1	2	3	4	5	6
In past 2 weeks , how concern have you been with (Q 24-27)								
		To much	**A lot**	**Quite a bit**	**Moderately**	**A fair bit**	**A little**	**Not at all**
24	Your appearance?	0	1	2	3	4	5	6
25	Your weight?	0	1	2	3	4	5	6
26	Change in your skin appearance?	0	1	2	3	4	5	6

27	Easy bruising?	0	1	2	3	4	5	6
In past 2 weeks, has your condition (Q 28-40)								
		To much	**A lot**	**Quite a bit**	**Moderately**	**A fair bit**	**A little**	**Not at all**
28	Interfered with your participation in activities?	0	1	2	3	4	5	6
29	Interfered with your participation in activities?	0	1	2	3	4	5	6
30	Interfered with your work duties?	0	1	2	3	4	5	6
31	Interfered with your family duties	0	1	2	3	4	5	6
32	Put a stress with relationship with your friends?	0	1	2	3	4	5	6
33	Put a stress on family relationship?	0	1	2	3	4	5	6
34	Made you question on your religious beliefs?	0	1	2	3	4	5	6
35	Made you feel sad or depressed?	0	1	2	3	4	5	6
36	Made you worried about your health?	0	1	2	3	4	5	6
37	Made you feel frustrated?	0	1	2	3	4	5	6
38	Made you stressed?	0	1	2	3	4	5	6
39	Caused you financial difficulty?	0	1	2	3	4	5	6
40	Made you feel overly depended on others?	0	1	2	3	4	5	6
How would you rate (Q41)								
		Awful	**Very poor**	**Poor**	**Average**	**Good**	**Very good**	**Excellent**
41	Your ability to appreciate small things in life?	0	1	2	3	4	5	6

Anterior Skull Base Questionnaire (ASBQ)

TABLE 1

The anterior skull base questionnaire

Below is a list of statements that other people with your illness have said are important. By circling one number per item, please indicate how true each statement has been for you.

1. How would you define your general performance?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

2. How would you define your performance at work?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

3. How would you define your performance at home?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

4. During the past 4 weeks, how much did you participate in social activities?

Very much	Quite a bit	Moderately	A little bit	Not at all
5	4	3	2	1

5. How would you define your communication with people?

Excellent	Very good	Good	Fair	Poor
5	4	3	2	1

6. During the past 4 weeks, how much did your health interfere with your performance?

Extremely	Quite a bit	Moderately	A little bit	Not at all
1	2	3	4	5

How well do you perform the following activities (please refer to questions 7–10)?

7. Climbing stairs

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

8. Leaning and standing

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

9. Walking for around 100 meters

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

10. Walking for around 10 meters

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

11. During the past 4 weeks, how frequently did you stay in bed during the day?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

12. How would you define your ability to carry out routine activities?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

13. During the past 4 weeks, how much has your health affected your activity?

Extremely	Quite a bit	Moderately	A little bit	Not at all
1	2	3	4	5

14. During the past 4 weeks, did you feel physically weak or strong?

Very weak	Quite weak	Neither strong nor weak	Quite strong	Very strong
1	2	3	4	5

15. During the past 4 weeks, how frequently did you feel tired?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

16. How much did you accomplish during the last 4 weeks?

Nothing at all	A little bit	Moderately	Quite a bit	Quite a lot
1	2	3	4	5

17. During the past 4 weeks, did you feel depressed or happy?

Very much depressed	A bit depressed	Neither depressed nor happy	A bit happy	Very much happy
1	2	3	4	5

TABLE 1 *(continued)*

Below is a list of statements that other people with your illness have said are important. By circling one number per item, please indicate how true each statement has been for you.

18. How would you define your motivation to perform various activities?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

19. During the past 4 weeks, how frequently did you feel energetic?

None of the time	A little of the time	Some of the time	Most of the time	All of the time
1	2	3	4	5

20. How would you define your relations with your partner?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

21. During the past 4 weeks, how frequently did you experience pain?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

22. During the past 4 weeks, how much did pain interfere with your ability to perform?

Extremely	Quite a bit	Moderately	A little bit	Not at all
1	2	3	4	5

23. During the past 4 weeks, how frequently did you have to take painkillers?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

24. During the past 4 weeks, how frequently did you feel tense and nervous?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

25. During the past 4 weeks, how frequently did you have a problem falling asleep?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

26. During the past 4 weeks, how frequently did you feel worried?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

27. During the past 4 weeks, how frequently did you feel relaxed or calm?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

28. How would you define your financial or economic status?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

29. How would you define your appetite?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

30. How would you define your sense of taste?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

31. How would you define your sense of smell?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

32. How would you define your appearance?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

33. How would you define the extent of your nasal secretions?

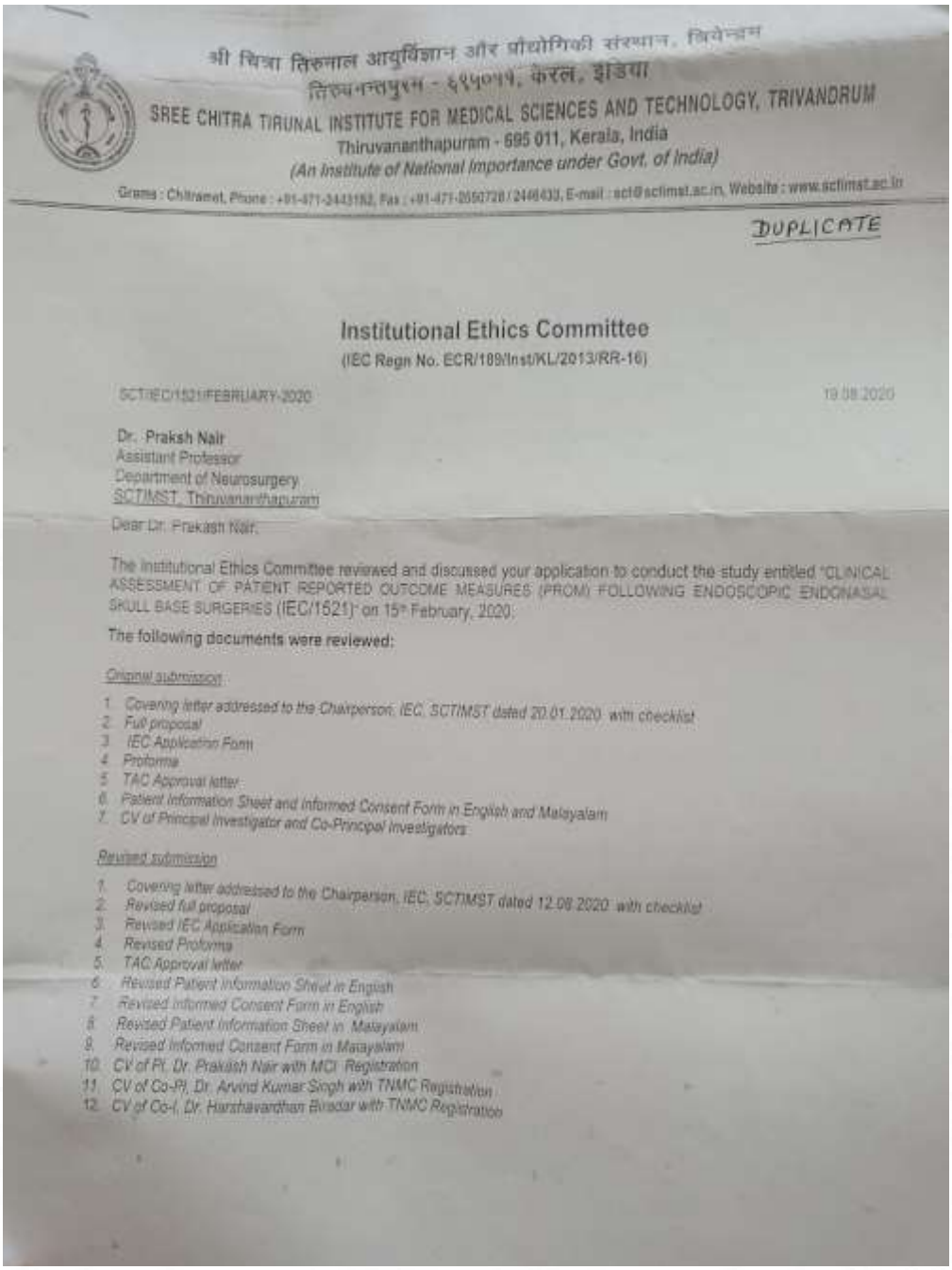
Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

34. How would you define your eye secretions and tears?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

35. How would you define your eyesight?

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
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DUPLICATE

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/1521/FEBRUARY-2020 19.09.2020

Dr. **Praksh Nair**
Assistant Professor
Department of Neurosurgery
SCTIMST, Thiruvananthapuram

Dear Dr. Prakash Nair,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "CLINICAL ASSESSMENT OF PATIENT REPORTED OUTCOME MEASURES (PROM) FOLLOWING ENDOSCOPIC ENDONASAL SKULL BASE SURGERIES (IEC/1521)" on 15th February, 2020.

The following documents were reviewed:

Original submission

1. *Covering letter addressed to the Chairperson, IEC, SCTIMST dated 20.01.2020 with checklist*
2. *Full proposal*
3. *IEC Application Form*
4. *Proforma*
5. *TAC Approval letter*
6. *Patient Information Sheet and Informed Consent Form in English and Malayalam*
7. *CV of Principal Investigator and Co-Principal Investigators*

Revised submission

1. *Covering letter addressed to the Chairperson, IEC, SCTIMST dated 12.09.2020 with checklist*
2. *Revised full proposal*
3. *Revised IEC Application Form*
4. *Revised Proforma*
5. *TAC Approval letter*
6. *Revised Patient Information Sheet in English*
7. *Revised Informed Consent Form in English*
8. *Revised Patient Information Sheet in Malayalam*
9. *Revised Informed Consent Form in Malayalam*
10. *CV of PI, Dr. Prakash Nair with MCI Registration*
11. *CV of Co-PI, Dr. Arvind Kumar Singh with TNMC Registration*
12. *CV of Co-I, Dr. Harshavardhan Bvadar with TNMC Registration*

The following members of the Ethics Committee were present at the meeting held on 15th February, 2020 at G. Parthasarathi Board Room, AMCHSS, SCTIMST

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation w Institution(s
1.	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2.	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
3.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
4.	Dr. K R S Krishnan	M.E., Ph.D.	Male	Medical Technology	Yes
5.	Dr. Harikrishna Varma PR	Ph.D(Materials Science)	Male	Medical Technology	Yes
6.	Dr. S S Giri Sankar	LL.M. Ph.D.	Male	Legal Expert	No
7.	Dr. Anand Kumar A	MD, DM	Male	Clinician	No
8.	Dr. Aneesh V Pillai	BA. LLB (Hons.), LLM, Ph. D, SET (Law)	Male	Legal Expert	No
9.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
10.	Dr. P. Manickam	BSMS, MSc (Epid).,PhD	Male	Health Science Expert/ Social Scientist	No
11.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
12.	Mr. Satheesh Chandran	MSW, PGDPM	Male	Lay person/ NGO/ Social Scientist	No
13.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of M. ical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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(An Institute of National Importance under Govt. of India)
Grams : Chitramed, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-21)

SCT/IEC/1521/APRIL-2023 27.04.2023

Dr. Suraj Gopal
Senior Resident
Department of Neurosurgery
SCTIMST, Thiruvananthapuram

Dear Dr. Suraj Gopal,

The Institutional Ethics Committee reviewed your project titled "**CLINICAL ASSESSMENT OF PATIENT REPORTED OUTCOME MEASURES (PROM) FOLLOWING ENDOCSCOPIC ENDONASAL SKULL BASE SURGERIES** (IEC/1521)" on 27th April 2023. The initial Ethics Committee Approval Letter No: SCT/IEC/1521/February-2020 dated 19.08.2020.

The following documents were reviewed:

Original submission

1. *Covering Letter addressed to the Member Secretary, IEC, SCTIMST dated 09.01.2023 regarding the inclusion of Principal Investigator in the study- Dr. Suraj Gopal, Senior Resident, Department of Neurosurgery, SCTIMST*
2. *IEC Application Form*
3. *CV of Principal Investigators – Dr. Suraj Gopal*
4. *Copy of IEC Approval letter dated 19.08.2020*
5. *Acceptance for Principal Investigator – Dr. Suraj Gopal*
6. *Patient Information Sheet*
7. *Consent Form*

The IEC Review Criteria
The study fulfils the expedited criteria from ethics review criteria vide section 9.1 of the Standard Operating Procedures (August 2021) of the SCTIMST-IEC

IEC Decision
The IEC approved the conduct of the study in the present form.

Remarks:
The Institutional Ethics Committee expects to be provided a copy of the final report/publication.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Dr. G. Srinivas
Member Secretary, IEC

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, THIRUVANANTHAPURAM

Curriculum vitae

Address :

Indiranagar , Bangalore 560038

Karnataka

Ph : 9844637287

Email: surajgopal2010@gmail.com

Languages : English , Kannada , Hindi , Tamil , Malyalam

Academic Qualification:

- MBBS : St Johm's Medical College , Bangalore (2010-2016)
  - Best outgoing student
- MS General Surgery : Safdarjung Hospital , Delhi (2017-2020)
  - Highest overall marks among students in the university (General Surgery)
  -
- MCh Neurosurgery (pursuing) : Sree Chitra Tirunal Institute for Medical Sciences and Technology

Publications :

- Pratibha CB, Satish D, Gopal S, Balasubramanya AM. An Interesting Case of Spontaneous Pneumomediastinum with Subcutaneous Emphysema following Oral Provocative Manoeuvre. Int J Otorhinolaryngol Clin
- Sristi Ganguly , Suraj Gopal, Arvind Kasthuri, Padmini Devi. Potential drug interactions among elderly outpatients in a tertiary care hospital – a cross sectional study. Internatiomal Journal of Current and Advanced Research
- Meera George, Naveen Ramesh, Suraj Gopal, Vishnu Mohan, Farah N Fathima.Diabetes and hypertension - A comprehensive assessment among workers in selected tea plantations, South India.International Journal of Medical Science and Public Health

- Suraj Gopal, Dubey Indu Bhushan, Junaid AhmadSofi. Acidental multiple magnet ingestion by an adult: a case report. International Surgery Journal

- Suraj Gopal, Easwer HV, Jayanand B. Sudhir, Prakash Nair, Syam Krishnan. Hemichorea after internal carotid artery bifurcation aneurysm clipping. Annals of Movement Disorders

Conferences and Presentations

- Central Travancore Neurocon, NSI Kerala October 2022 Poster Presentation : . Hemichorea after internal carotid artery bifurcation aneurysm clipping

- Cadaveric workshop on transforaminal lumbar spine endoscopy

- Trivandrum Neurological Society : Journal presentation : Middle meningeal artery embolization for chronic SDH

- Skullbasecon 2022 Paper presentation “Endoscopic Endonasal Transclival Resections – A single Institutional Analysis”

- Prof Damodar Rout Oration. Chitra Neurosurgery Update, February 2023

- Prof RM Varma Memorial Oration , Neurosurgery CME , May 2023

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ORIGINALITY REPORT

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SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	thejns.org Internet Source	1%
2	Edward D. McCoul, Vijay K. Anand, Jeffrey C. Bedrosian, Theodore H. Schwartz. "Endoscopic skull base surgery and its impact on sinonasal-related quality of life", International Forum of Allergy & Rhinology, 2012 Publication	1%
3	Charles A. Riley, Abtin Tabaee, Lindsey Conley, Muhamad Amine, Christian P. Soneru, Vijay K. Anand, Theodore H. Schwartz. "Long - term sinonasal outcomes after endoscopic skull base surgery with nasoseptal flap reconstruction", The Laryngoscope, 2018 Publication	1%
4	David Forner, Katrina Hueniken, Tom Yoannidis, Ian Witterick et al. "Psychometric testing of the Skull Base Inventory health-related quality of life questionnaire in a multi-institutional study of patients undergoing	1%