

## Study Protocol

### **Utility of Rescue flap in the reconstruction of skull base defects following transnasal endoscopic excision of sellar/supra-sellar lesions.**

#### **Abstract:**

**Background:** Naso-septal Rescue Flap(NSRF) technique involves preservation of the unilateral posterior septal artery pedicle without harvesting full Naso-Septal Flap (NSF). This enables usage of NSF flap when needed while allowing enough exposure to resect tumor completely. This also provides with added advantage of tailoring flap according to preference to cover the defect post tumor removal. This technique involves partial harvestation of only the most superior and posterior aspect of the flap to protect its pedicle, providing better instrumentation for the sphenoid sinus. At the end of the procedure, if there is unexpected CSF rhinorrhea or resultant bony defect is large then Nasoseptal flap is harvested from the the rescue flap. As very few studies have been conducted for rescue flap technique in anterior skull base defects reconstruction following excision of sellar/supra-sellar lesions, the technique requires further validation, hence the present study is being undertaken.

#### **Objectives:**

1. To study the post-operative outcome of Nasal Septal Rescue Flap (NSRF) in terms of donor site morbidity and CSF leak.
2. To study the post-operative outcome of posterior nasoseptal flap in terms of donor site morbidity and CSF leak.

**Methodology:** A cross-sectional study will be conducted at Department of E.N.T, AVBRH, Sawangi, Wardha during a period of August 2020 to August 2021. A sample size of 20, within 18-70 years of age with sellar/supra-sellar lesions will be included for the research, after "Institutional ethics committee" approval. Findings obtained will be entered in proforma meant for the study. Informed consent will also be obtained.

**Results:** The observations obtained will be analyzed statistically and will be discussed in light of literature available.

**Conclusion:** This study will help formulating the guidelines for the NSF harvest with the goal of preventing unnecessary harvest, thereby decreasing peri-operative and post-operative disadvantages as well as preserving the flap for reconstruction in patients requiring revision surgery.

**Keywords:** Rescue flap, Hadad Flap, Pituitary, Trans-sphenoidal approach

#### **INTRODUCTION:**

Both traumatic and non-traumatic injuries can lead to skull base defects.. The most common cause of skull base defect in traumatic group is non-surgical trauma while surgical damage is contributes to a very less extent. In the non-traumatic group, skull base erosion is commonly encountered due to high intracranial pressure by tumors or neoplasms while less common factors are infections and post-radiotherapy. Idiopathic spontaneous cerebrospinal fluid leaks may also be encountered. Surgical evolution has taken place in the last decade with the introduction of

endoscopic endonasal approaches (EEAs) leading to advancement in excision of extradural and intradural skull base lesions as well as in reconstruction<sup>(1)</sup>.

Hadad et al introduced the Nasoseptal flap based on posterior septal artery in 2006 and since then it been the workhorse for reconstruction of anterior skull defects<sup>(2)</sup>. NSF use has reduced the rates of CSF leaks to less than 10% in endonasal endoscopic approaches<sup>(3,4)</sup>. Advantages of NSF has been playing pivotal role in reconstruction and has been favored by surgeons in endoscopic skull base surgeries<sup>(5,6)</sup>. However also with the pros, there are some cons including donor site morbidity. Cons include longer duration of surgery, prolonged mucosilation and healing, crusting in the nasal cavity and risk of hyposmia or anosmia<sup>(7,8)</sup>. Lund-Mackay scale and Sino-Nasal Outcome Test (SNOT-22) scale has been used in a study indicating post-operative increase in nasal symptom subdomain<sup>(9)</sup>. Small skull base defects with low-flow CSF leaks can be well repaired with biosynthetic materials and/or avascular free grafts in monolayer or multilayer design with low morbidity.<sup>(4,10)</sup> In these patients use of NSF may be unnecessary.

The concept of Rescue flap or the nasoseptal rescue flap was then introduced with modification of the nasoseptal flap in 2011<sup>(11)</sup>. Preserving unilateral posterior septal artery, this technique provided with the advantage of not only better instrumentation with wide exposure but also preventing unnecessary harvest of NSF reducing operative time and donor site morbidity<sup>(10)</sup>. Also provides with the advantage of designing the flap according to surgeon's preference. Many surgeons have identified ways to change the NSRF technique so that bilateral posterior septal artery pedicles can be preserved.<sup>(12-14)</sup> This technique involves partial harvesting of only the most superior and posterior aspect of the flap to protect its pedicle, providing better instrumentation for the sphenoid sinus. At the end of the procedure, if there is unexpected CSF rhinorrhea is encountered or resultant bony defect is large then Nasoseptal flap is harvested from the the rescue flap<sup>(15)</sup>.

As very few studies have been conducted for rescue flap technique in anterior skull base defects reconstruction following excision of sellar/supra-sellar lesions, the technique requires further validation, hence the present study is being undertaken.

**Aim:** To study the clinical outcomes of nasal septal rescue flap (NSRF) in endonasal reconstruction of anterior skull base defects following transnasal endoscopic excision of sellar/supra-sellar lesions.

### Objectives:

1. To study the post-operative outcome of Nasal Septal Rescue Flap (NSRF) in terms of donor site morbidity and CSF leak.
2. To study the post-operative outcome of posterior nasoseptal flap in terms of donor site morbidity and CSF leak.

### RATIONALE

1. 'Improvisation of workhorse'. Rescue flap provide the advantages of a Hadad flap if and when required for reconstruction and prevents the disadvantages of Hadad where reconstruction is not need.

2. This being a relatively new technique with ongoing modifications and few research studies, the present study is being undertaken to further validate this novel technique

### MATERIAL AND METHODS:

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**Comment [gg2]:** Can delete the marked part to sound grammatically correct

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**Study Design-** Cross-sectional Study

**Duration of Study-** 2020-2021

**Sample size:** 20

**Inclusion Criteria:**

1. Patients in age group of 18-70 yrs
2. Patients requiring skull base reconstruction after endonasal surgery
3. Patient willing for surgery and regular follow up.

**Exclusion Criteria:**

1. Less than 18 years of age.
2. Patients with nasal septal injury due to trauma.
3. History of previous surgery.
4. Tumors that infiltrate the nasal septum, pterygoid fossa or the anterior wall of sphenoid sinus.
5. Uncontrolled Diabetes mellitus.
6. Granulomatous and malignant lesions of nasal cavity.
7. Patients with septal perforation and patients with cardiovascular and neurological disorder.

**Comment [gg4]:** When u say age 18-70 yr in inclusion criteria, it automatically means <18 yr are excluded!! No need to mention separately again exclusion criteria

**Place of Study-** Dept. of ENT, Acharya Vinoba Bhave Rural Hospital (AVBRH), Datta Meghe Institute of Medical Sciences (DMIMS), Sawangi (Meghe), Wardha.

**Ethics approval-** Ethical clearance from the Institutional Ethical Committee will be taken before enrolling patient for the research.

**Enrollment-**

Patients will be selected as participants according to the inclusion criteria. Every patient will be explained the type of the study and written/verbal/informed consent will be taken. A detailed history with thorough ENT examination as per the proforma enclosed, from the individual patient selected with inclusion and exclusion criteria. Photographic documentation of some interesting cases will be taken. Anterior rhinoscopy, Posterior rhinoscopy, DNE and Dynamic slow motion video endoscopy shall be done. Diagnostic nasal endoscopy with 0 degree nasal endoscope to assess nasal septal deformity with regard to site, degree and type of deviation apart from any other notable findings.

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**Intervention-**

1. Endonasal endoscopic surgery for removing skull base tumors/lesions by creating Bilateral Rescue Flap (NSRF) before tumor excision.
2. Reconstructing post-operative anterior skull base defect by converting Rescue flap into Nasoseptal/ Hadad flap (NSF), if required in cases with per-operative CSF leak/ Large defects.
3. Pack removal on post-operative day 5 in suspected cases of CSF leak and on day 3 of those not suspected for CSF leak.
4. Follow up at post-operative 5<sup>th</sup> day, 1 month, 3 months - DNE with DSVE, MRI and CT if required.

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**Expected Results:**

Naso-septal Rescue flap will decrease peri-operative and post-operative disadvantages associated with Naso-septal flap.

**DISCUSSION:**

Prof. Paolo Cappabianca from Naples, a well-known skull base surgeon, suggested that it **is** the resection that is less problematic than the reconstruction. It is the advancement in reconstructive techniques that has lead to the progress in endoscopic skull base surgery<sup>(16)</sup>.

The goals to be kept in mind while reconstructing the skull base defects are the stable separation between cranial cavity and nose, preservation of neurovascular structures, cosmesis reconstruction, reconstitution and preservation **of** function while avoiding dead spaces. Cranial cavity and nasal cavity separation is foremost important<sup>(16)</sup>. Wide range of endoscopic methods and techniques have been developed to manage iatrogenic CSF rhinorrhea, post-traumatic CSF rhinorrhea and spontaneous CSF rhinorrhea, however, these techniques have mostly failed in reconstructing large defects<sup>(17-20)</sup>. The neuro-endoscope used initially for EEA resulted in various hazards, such as CSF rhinorrhea, meningitis and **encephalocele**. Carrabba, *et al.* performed EEA to manage skull base lesions and encountered increased cases of CSF rhinorrhea upto 24%<sup>(21)</sup>. This signifies importance of well-reconstructed skull base bony defect to prevent complications<sup>(22,23)</sup>. Hadad-Bassagasteguy flap, which is local vascularized flap, reduced the incidences of CSF leaks developing post-operatively to less than 5 % even after expanded resections and became the 'workhorse for reconstruction'<sup>(24)</sup>. In this study Hadad et al, introduced HB flap and reported post-operative CSF leak of 4.5%. This had been without any flap loss, whether partial or incomplete<sup>(25)</sup>.

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Further attempts to validate need for vascularized reconstruction in **ESBS** has been done. NSF has come to **foreplay** the role of reconstruction due to its easy harvestation and reduced complications<sup>(26,27,28,29)</sup>. Unfortunately, this has lead to overworking of the workhorse for reconstruction. **Favoring this statement was supported by review of use of various approaches such as sublabial and transseptal to the pituitary which demonstrated less than 7% intraoperative CSF leak rates.** The defects in these approaches were repaired using synthetic graft with/without fat graft reconstruction<sup>(30)</sup>. **More Many** studies have shown that it is completely appropriate to use non-vascularized flaps for low-flow CSF leaks reconstruction<sup>(31)</sup>. Furthermore, various grafts such as **fascia lata and fat** before the invention of Hadad flap have been used successfully especially in small and large reconstructions<sup>(32-35)</sup>. Many surgeons are "over working the workhorse," and overusing flap which have been reported in a recent survey<sup>(36)</sup>. **This may be due routinely harvestation of the NSF flap, which at the end of every procedure may not actually be needed.**

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**Comment [gg11]:** Use a better phrase to convey the correct meaning

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**Comment [gg13]:** If these and sublabial and trans septal flaps are good enough, then why NSF and why this study?

**Comment [gg14]:** Correct grammar mistakes.

The location of the defect and size often decides the peri-operative CSF leak risk. Factors increasing the postoperative CSF leaks risk should always be kept in mind. Various factors should be kept in mind like obesity leading to high ventricular pressure, craniopharyngiomas, Cushing disease, and radiotherapy history indicating poor tissue healing or revision cases in which local vascularized tissue is compromised. Key factor for determination of reconstruction option need is location of defect. Various authors have suggested that inlay grafts can be used for anterior fossa lesions, as brain pressure helps in holding the graft in position preventing migration. Pedicled flaps have close proximity to ventricles and anterior brain cisterns and therefore are best for clival and tuberculum sellae defects reconstruction. Defects smaller than 1 cm and low pressure CSF leaks can be managed well with high success rate using free grafts in multilayer fashion, allografts and sealants<sup>(37-39)</sup>. Vascularized reconstructions are reserved for beds with poor vascularization or to cover dural defects that are larger than 3 cm and high pressure CSF leaks large dural defects (>3 cm) and high-flow CSF leaks<sup>(37,38,40)</sup>.

Rescue flap has been primarily introduced to prevent unnecessary harvesting of the Hadad flap<sup>(41)</sup>. Rivera-Serrano et al suggested that use of rescue flap helped by decreasing operative

time, shortening postoperative care with reduced hospital stay enhancing cost affordability of the patient and minimizing donor-site morbidity<sup>(42)</sup>. Although septectomy provides better instrumentation and visualization, theoretically it may lead to increased crusting postoperatively<sup>(43)</sup>. Septal perforation in patients may lead to operative dry nose, crusting, bleeding and sometimes change in voice. However in some studies posterior perforations may not lead to bothersome clinical symptoms post-operatively<sup>(44)</sup>. Kim et al provided with modification of nasoseptal flap using bilateral modified rescue flaps by publishing a study focusing on outcomes of patients operated for pituitary adenoma patients by endonasal endoscopic approach. Subjective olfaction function worsened in these patients as interpreted by VAS scale<sup>(45)</sup>. Another variation of flap was published by Ozawa et al using sigmoid incision rescue in 19 patients. However it was not statistically significant<sup>(46)</sup>. Few reports on olfactory function evaluation post-operatively are present. Rothenberg noted 36% patients post-operatively with anosmia of variable degrees<sup>(47,48)</sup>. To prevent this, the incision is to be made horizontal to the level of the sphenoid sinus opening thereby preventing injury to olfactory region<sup>(47,48)</sup>.

“Rescue” flap could be used efficiently in reconstruction of the sella bony defect whenever chances of CSF fistula are encountered intra-operatively with advantage of reduced time of surgery and reduced chances of hyposmia/anosmia postoperatively<sup>(49)</sup>.

## CONCLUSION:

Harvesting Naso-septal Rescue flap would be a flexible choice of reconstruction after endonasal endoscopic anterior skull base surgeries due to several advantages such as reduction in morbidity, decrease operative time, wound complications and as an option for reconstruction in revision cases.

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**Comment [gg15]:** U mean post operative dry nose?

**Comment [gg16]:** Full form?

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