



SINONASAL POLYPOSIS; COMPARISON OF EFFICACY OF FUNCTIONAL ENDOSCOPIC SINUS SURGERY (FESS) AND CONVENTIONAL INTRANASAL POLYPECTOMY IN SINONASAL POLYPOSIS: A RANDOMIZED CONTROLLED TRIAL.

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ABSTRACT... Introduction: Nasal polyposis (NP) is a chronic inflammatory disease involving mucous membrane in paranasal sinuses and nose. It presents as gelatinous, semitranslucent, smooth, pedunculated pear or round shaped masses comprising of inflamed mucosa that out-pouches into nose. The available surgical options are Functional Endoscopic Sinus Surgery (FESS) and Conventional Intranasal Polypectomy (CIP). The study aims to compare FESS and CIP in sinonasal polyposis patient in term of symptomatic improvement. **Study Design:** Randomized controlled trial. **Setting:** Department of head n' neck surgery and Otorhinolaryngology, Pakistan Institute of Medical Sciences, Islamabad. **Period:** 01-01-2015 to 20-08-2015. **Methodology:** A total of 84 patients presenting with nasal polyposis were enrolled. Out of these 84 patients, 42 patients were randomly selected for FESS (Group-A). Rest of the 42 patients were selected for CIP (Group-B). All the information recorded on the Performa was entered and analysed using SPSS version 17. The entire study duration was 31 weeks. Regarding ethical consideration, the study was approved from ethics committee of hospital. Informed consent was obtained from the study participants. Moreover, confidentiality and anonymity of subjects was assured. The patients were followed-up for 2 months duration. The entire study duration was about 8 months. **Results:** On the basis of scoring of nasal obstruction, in FESS Group-A, 32 (76.19%) patients had completely patent nose after two months and only 10 (23.81%) patients had partially blocked nose. On the other hand in CIP Group-B, only 16 (38.10%) patients had completely patent nose while 26 (60.90%) patients had partially blocked nose after two months. The comparison of sense of smell between both groups also showed that the outcome of Group-A was significantly (p -value = 0.000) better as compared to Group-B. The complete sense of smell was found present in 37 (88.10%) patients in group A in contrast with 19 (45.23%) patients in group B. **Conclusion:** FESS seems to be a better treatment option for sinonasal polyposis than conventional intranasal polypectomy. However study with larger population size and longer follow up duration is recommended to rationalize the results.

Key words: Conventional Intranasal Polypectomy, Functional Endoscopic Sinus Surgery, Intranasal Polypectomy, Intranasal Ethmoidectomy, Nasal Polyps,.

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INTRODUCTION

Nasal polyposis (NP) is a chronic inflammatory disease involving mucous membrane in paranasal sinuses and nose. It presents as gelatinous, semitranslucent, smooth, pedunculated pear or round shaped masses comprising of inflamed mucosa that out-pouches into nose.¹ Prevalence of nasal polyposis is estimated to be between 1% and 4%,² with a slight male predominance³, however in few studies the rates are even up to 32%.⁴

The locally acting allergic mechanisms without involvement of systemic features are thought to intervene in pathogenesis of polyp.⁵ Medical conditions that are most commonly related with polyps usually include bronchiectasis, cystic fibrosis and asthma. Almost 10% of total cases of NP are associated with Samnter's triad which comprises of aspirin hypersensitivity, asthma and polyposis.⁶ One-third cases of nasal polyposis are associated with asthma, however only in 7% of patients with asthma have got polyps.⁶

Another significant cause in formation of polyps is considered to be infection.⁷ Studies reveal presence of olfactory alterations in 19% of general population⁸ in different forms including dysosmia, hyposmia and anosmia. Major causes include trauma, sinusitis, congenital abnormalities, upper airway disorders and idiopathic.^{9,10} Diagnosis is carried out by taking comprehensive history, conducting detailed examination, nasal endoscopy, radiography, bacteriology, pulmonary function tests and tests for aspirin sensitivity and allergy.¹¹

The treatment options for nasal polyps include medical treatment as well as surgery. The prolonged use of steroids that are taken orally is usually not recommended. Majority of nasal steroids including budesonide and fluticasone provide an effective relief and help in increasing the airflow to nose.¹²

Surgical modalities include intranasal ethmoidectomy, functional endoscopic sinus surgery (FESS), simple intranasal polypectomy and external ethmoidectomy.⁹ FESS is a technique that is minimally invasive and utilizes endoscope for drainage and improving the ventilation process apart from removal of polyp. This technique is comparatively better than other conventional modalities because it is involved not only in polyps removal rather it also helps in opening of middle meatus clefts and thus playing its significant role in the minimizing the recurrence.

In past 25 years endoscopic sinus surgery has largely replaced older, more radical forms of surgery that are intranasal procedure. FESS is now a well-established strategy for the treatment of sinonasal polyposis which combines several techniques to open the sinuses under direct visualization.^{13,14} FESS is a superior and safer procedure compared to conventional intranasal polypectomy. There is also an overall decrease in complication rate and recurrence rate of nasal polyposis.¹⁵

The current study was conducted to compare Functional endoscopic sinus surgery and

conventional intranasal polypectomy in sinonasal polyposis patients in term of symptomatic improvement

METHODOLOGY

A randomized controlled trial was conducted at department of head n' neck surgery and Otorhinolaryngology, Pakistan Institute of Medical Sciences, Islamabad. Total 84 patients with nasal polyposis were inducted. Patients were randomly selected on the basis of inclusion and exclusion criteria. Out of these 84 patients, 42 patients were enrolled for FESS (Group-A) while rest of the 42 patients were selected CIP (Group-B). Sample size was calculated by using WHO calculator with level of significance equal to 5, power of test equal to 90. A total of 84 patients (42 patients in each group) with nasal polyposis were enrolled.

All patients operated having sinonasal polyposis with loss of smell sense and nasal obstruction between ages 15 years to 50 years old regardless of gender were included. Patients having nasal obstruction due to other causes like deviated nasal septum, mass in nasal cavity (benign or malignant) and patients with bleeding diathesis and head injury were excluded from the study. The study was approved from ethics committee of hospital. Patients were explained about both surgical techniques and an informed consent for either procedure was taken. Moreover, confidentiality and anonymity of subjects was assured.

The socio-demographic information and past history of disease of patients was recorded. Comprehensive clinical examination performed. Hematological and biochemical test were advised as a prerequisite for General Anesthesia. Patients had routine radiographs of nose and Para nasal sinuses and computed tomography where relevant. The speculum examination of nasal cavity was performed by trainee researcher. Patency of nose was tested and graded by using Visual Analogue Scale (VAS). Olfactory threshold assessed by squeeze bottle technique by researcher and graded by 2-point scale. Both groups underwent the procedure under General Anesthesia after a senior anesthetist had

declared the patient fit for surgery. Post-operative care was given to both the groups. Efficacy of both the interventions was assessed in term of post operative improvement in nasal obstruction and sense of smell. Each patient was followed up for two months. All the data was entered in a predesigned pro forma by trainee researcher. Bias was controlled by exclusion criteria and brief counseling of the patients. All patients were investigated and followed up by trainee researcher. For this purpose telephonic contact of patients was taken.

The data were entered and analyzed by using SPSS version 16. Descriptive statistics used to calculate for both quantitative and qualitative variables. For qualitative variables like gender, nasal obstruction and sense of smell frequencies and percentages were calculated. For quantitative variables standard deviation and mean was calculated. Chi square test was performed to determine the difference in two groups in term of symptomatic improvement and p value of < 0.05 was considered statistically significant. The entire study duration was 31 weeks.

RESULTS

After analyzing the results it was revealed that the mean age of group A, FESS group was 33.79 ± 10.283 years, ranging from 17 to 51 years and in group B, CIP group the mean age was almost same with a mean of 32.43 ± 10.687 years, having a range from 17 to 50 years. In FESS group A, there were 24 (57.14%) males and 18 (42.16%) females and in CIP group B, 26 (61.90%) were males and 16 (38.01%) females in our study sample. Table-1 shows the descriptive statistics for age of patients in both groups.

The narrowing of the nasal cavity caused by nasal polyps was assessed by the help of 10-point visual analogue scale (VAS) from 0 (meaning no obstruction) to 10 (worse nasal obstruction). The mean nasal obstruction VAS score in FESS group A, on start of study was 7.38 ± 1.396 and in CIP group B, it was 7.74 ± 1.483 as given in Table-II.

On the basis of this nasal obstruction VAS score 12 (28.57%) patients had partially blocked nose

and 30 (71.43%) patients had completely blocked nose in both groups A and B. After two months of treatment in both groups the nasal obstruction on the basis of VAS score decreased significantly. The mean VAS score in FESS group A just remained 0.60 ± 1.170 after two months of treatment and in CIP group B it decreased to a mean VAS score of 2.07 ± 1.759 , which is although significantly (p-value = 0.000) greater than the mean VAS score as depicted in Table-III.

On the basis of this nasal obstruction score the final outcome of nasal obstruction become as in FESS group A, 32 (76.19%) patients had completely patent nose after two months and only 10 (23.81%) patients had partially blocked nose. On the other hand in CIP group only 16 (38.10%) patients had complete recovery i.e. completely patent nose but 26 (60.90%) patients had partially blocked nose after two months.

At the start of the study all 84 patient in both groups had no sense of smell on the basis of olfactory threshold rated by 2-point scale. The post operative symptomatic improvement was found better in Functional Endoscopic Sinus Surgery group as compared to Conventional Intranasal Polypectomy. It was noted that in FESS group A, only 5 (11.90%) patients had sense of smell absent and in 37 (88.10%) patients the sense of smell was present after two months. But in CIP group B, only 19 (45.24%) patients had symptomatic improvement and in 23 (54.76%) patients the sense of smell was absent.

The comparison of symptomatic improvement in with regard to sense of smell and nasal obstruction was made by using chi-square test between both groups after two months and it was found that the nasal obstruction outcome was significantly (p-value = 0.000) better in FESS group A in which 32 (76.19%) patients had completely patent nose as compared to CIP group B in which only 16 (38.10%) patients had completely patent nose after two months as elaborated in Table-IV.

The comparison of sense of smell between both groups also showed that the outcome of FESS (group A) was significantly (p-value = 0.000)

better as compared to CIP (group B). The normal sense of smell was found in 37 (88.10%) patients

in FESS group A in contrast with 19 (45.23%) patients in CIP group B as elaborated in Table-V.

Group	N	Minimum	Maximum	Mean	Std. Deviation
Group A (FESS)	42	17	51	33.79	10.283
Group B (CIP)	42	17	50	32.43	10.687

Table-I. Descriptive statistics for age of patients in both groups

Group	N	Minimum	Maximum	Mean	Std. Deviation
Group A (FESS)	42	5	10	7.38	1.396
Group B (CIP)	42	5	10	7.74	1.483

Table-II. Descriptive statistics for Initial Nasal obstruction Score

Group	N	Minimum	Maximum	Mean	Std. Deviation	P-value
Group A (FESS)	42	0	4	0.60	1.170	0.000
Group B (CIP)	42	0	5	2.07	1.759	

Table-III. Descriptive statistics for Nasal obstruction score outcome

Nasal obstruction Outcome	Group		Total	P-value
	Group A (FESS)	Group B (CIP)		
Completely Patent	32	16	48	0.000
Partially Blocked	10	26	36	
Total	42	42	84	

Table-IV. Comparison of nasal obstruction outcome in both groups

Sense of Smell Outcome	Group		Total	P-value
	Group A (FESS)	Group B (CIP)		
Absent	5	23	28	0.000
Normal	37	19	56	
Total	42	42	84	

Table-V. Comparison of sense of smell outcome in both groups

DISCUSSION

The overall prevalence of nasal polyposis is between 1% to 4%², with a slight male predominance.³ however few studies indicate rates even upto 32%.⁴ The treatment aims are to significantly reduce or eliminate NP eventually causing sinus drainage improvement, relief from nasal obstruction, and restoration of taste and sense of olfaction.¹⁶

In our study, the mean age of group A, FESS group was 33.79±10.283 years, ranging from 17 to 51 years and in group B, Conventional Intranasal Polypectomy group the mean age be almost same with a mean of 32.43 years and standard deviation of 10.687 years, having a range from 17 to 50 years. A study from Iran reported a mean age of 41 years (ranging from 11-71 y) for all patients with nasal polyposis, slightly higher than what we have found in our study. In their study 65

were male and 35 were female.¹⁷

The mean nasal obstruction VAS score in our study FESS group A, on start of study was 7.38±1.396 and in CIP group B, it was 7.74±1.483 and 84 patients in both groups had no sense of smell on the basis of olfactory threshold rated by 2-point scale. Two months postoperatively the nasal obstruction outcome was significantly (p-value = 0.000) better in FESS group A in which 32 (76.19%) patients had completely patent nose as compared to CIP group B in which only 16 (38.10%) patients had completely patent nose and showed that the outcome of FESS group A was significantly (p-value = 0.000) better as compared to CIP group B at the time of two month follow up. Damm et al observed sinonasal polyposis treated by FESS, nasal obstruction improved in 84% patients.¹⁸ These results are very close to our study regarding nasal obstruction in

NP patients.

A local study showed that surgery has very encouraging outcome. Even at first visit after surgery, 90% patients were symptoms free. Surgical options for ethmoidal nasal polyp include intranasal polypectomy with intranasal ethmoidectomy, external ethmoidectomy: Caldwell lucs approach and FESS using Wigand and Stammberger technique. Minimal invasive surgery i.e. using FESS technique is gaining popularity nowadays.¹⁹

Regarding the sense of smell we found that complete sense of smell recovered in 37 (88.10%) patients in FESS group A in contrast with 19 (45.23%) patients in CIP group B, which shows that sense of smell markedly improved in patients who were operated by FESS. In view of these findings, results of our study regarding symptomatic improvement of patients are within the expected range. Olfactory dysfunction affects 65% to 80% of total patients with CRS.²⁰

Another study conducted by Pade et al. in which he inducted 206 patients presenting with impairment of sense of olfaction who opted for elected ESS, revealed that the symptoms of 23% improved, 9% got worsened and 68% remained same with no obvious change.²¹ Soler et al., in 2010, assessed the overall impact of different histologic markers on the outcome of olfaction following ESS.²² It was revealed that impairment of olfaction is associated with the eosinophilia of tissue and thickening of basement membrane.

These variations of results in literature are probably due to different parameters to assess the nasal obstruction and sense of smell and variation in demographics of study participants. Small sample size, limited study period and short follow-up plan are some of the limitations of our study. Larger country-wide studies are required to generalize the results.

CONCLUSION

FESS has got more advantages including better visualization, preservation of normal mucosa of nasal cavity and better recovery. Keeping these

advantages in views, FESS is better treatment option for sinonasal polyposis than CIP in term of improvement of sense of olfaction and nasal obstruction. However for the purpose of generalizing the results, study with larger sample size and prolong follow up is recommended.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
1	Farhan Salam	Conceived the idea, planned the study, and drafted the manuscript.	
2	Ejaz Ahmad	Did statistical analysis.	
3	M. Salman Haider Qureshi	Critically revised the manuscript and performed literature review.	Muhammad 
4	Muhammad Aslam Khan	Got the ethical approval and cloected the data.	