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Balloon Sinuplasty And Its Effectiveness Measured Using SNOT-20 Scoring.

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ABSTRACT

Patients who underwent conventional FESS often report with circumferential scarring and adhesions in follow up, limiting the ability of sinus ostial openings to remain patent. These are the patients who become potential candidates for revision surgeries. Endoscopic Balloon sinuplasty surgery is specially designed to micro fracture bones surrounding the sinus Ostia causing desired widening of sinus Ostia and transition spaces with minimal iatrogenic mucosal injury and maximizing tissue preservation. To assess the efficacy and ease of Endoscopic Balloon sinuplasty when compared with other techniques of FESS. A cohort study was conducted at Dept of Otorhinolaryngology of Base Hospital Delhi Cantt BHDC, involving 15 cases who underwent balloon sinuplasty and 15 cases who underwent conventional FESS and postoperative follow-up assessments were conducted at 1wk, 3mth, 6mth and 12 months using Sino-Nasal Outcome Test (SNOT-20) scoring system. The mean (±SD) SNOT-20 score improvement was1.67 ±1.10 in the balloon sinuplasty group, confirming that individuals who underwent balloon dilation had fewer post-operative symptoms and recovered quickly in comparison to those patients who underwent conventional FESS (p < 0.05). Balloon dilation results in fewer postoperative debridement than FESS, indicating superiority of the balloon arm. Patients who underwent balloon dilatation had significantly shorter intra operative duration, shorter recovery time, and short-term symptomatic improvement was all significantly better when compared with conventional FESS.

Keywords: Endoscopy Balloon Sinuplasty, SNOT-20, Balloon sinus surgery, FESS.

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INTRODUCTION

Stammberger and Kennedy have standardized and popularized the Messerklinger technique described in 1978, which is now accepted worldwide as FESS as an adjuvant therapy in patients of CRS who do not respond to medical therapy [1]. Since the mid-1980s, there has been an enormous improvement both in our understanding of rhinosinusitis and in our ability to manage patients with this disorder.

Since first described in 1965 by Neumann, the concept of the ostiomeatal unit, or complex, continues to play a role in mucosal disease of the paranasal sinuses. The ostiomeatal complex theory states that most inflammatory conditions of the maxillary, ethmoid, and frontal sinuses arise from blockage of this common drainage pathway. The stoppage of normal mucociliary flow results in the onset of stasis, which leads to infection. Therefore, most rhinologists state that ESS should be a "disease-directed" and mucosal-sparing operation, for re-establishing drainage and mucosal recovery of the dependent sinuses, the surgical procedure therefore, can be limited to an absolute minimum even in cases with significant radiological involvement [2]. Preservation of normal structures, restoration of sinus ventilation and physiologic mucous drainage are central, time tested principles used in treating patients with sinusitis.

Our approach in managing these cases has evolved over a period of time with numerous surgical techniques. Functional endoscopic sinus surgery provides a method of excellent visualization that aids in the precise and meticulous eradication of paranasal sinus disease [3]. Tissue cutting instruments such as Heymann turbinectomy scissors, sickle knifes, Blakesley Thru-cut forceps, Stammberger backbiting forceps, Kerrison Punch forceps and even latest microdebriders are routinely used to perform various Endoscopic sinus surgeries. However intra-operative and post-operative complications are common during FESS even with these sophisticated instruments because of iatrogenic mucosal injuries caused by these tissue cutting instruments [4, 5]. Mucosal injuries leading to bleeding and blood field obscures intra-operative visualization, leading to injury to surrounding vital structures such as orbital injury, injury to anterior ethmoidal artery, injury to lacrimal duct and even accidental penetration of the brain is also possible [5]. Powered instruments such as microdebriders with oscillating blades when used at higher speeds can easily cut through the bony barriers and rapidly escalate the significance of complications with disastrous outcomes [6]. Many patients may report with circumferential scarring and adhesions in follow up, limiting the ability of sinus ostial openings to remain patent. These are the patients who become potential candidates for revision surgeries.

One of the surgical techniques used to overcome these above mentioned complications is Endoscopic Balloon sinuplasty. The paranasal balloon devices has been specially designed to micro-fracture bones surrounding the sinus Ostia by inflatting to a specific diameter under high pressure causing desired widening of sinus Ostia and transition spaces with minimal iatrogenic mucosal injury and maximizing tissue preservation.

Ahmed J, Pal S, Hopkins C, Jayaraj S.et al [7] in their study in 2011 of functional endoscopic balloon dilation of sinus ostia for chronic rhinosinusitis. Concluded that there is no convincing evidence supporting the use of endoscopic balloon sinus ostial dilation compared to conventional surgical modalities in the management of CRS refractory to medical treatment. With the escalating use of balloon sinuplasty, there is an urgent need for more randomized controlled trials to determine its efficacy over conventional surgical treatment modalities.

So a case control study was conducted at Dept of Otorhinolaryngology of Base Hospital Delhi Cantt BHDC, a tertiary care ENT-HNS Center from Mar'14 to Mar'16 center to assess the efficacy and ease of Endoscopic Balloon sinupasty when compared with other techniques of FESS.

MATERIALS AND METHODS

Aim is to study safety, feasibility & long term surgical Outcomes of Balloon catheter dilation of paranasal sinus ostia in comparison to conventional endoscopic sinus surgery.

Sample size and statistical analysis

Sample size for both primary endpoints was calculated using PASS 2008. The minimum required sample size was driven by the long term symptom improvement (SNOT-20) endpoint. A minimum of 15

subjects was required in each study arm to have 90% power to show non inferiority of balloon dilation with a margin of 0.8 compared with FESS at a one-sided α- level of 0.025. The margin was established as the clinically meaningful difference from the developer of the validated Sino-Nasal Outcome Test (SNOT-20) instrument [8]. A minimum of 15 subjects was required in each arm to have 90% power to show superiority of balloon dilation over FESS for postoperative debridement rate at a one-sided level of 0.025.

One-sided Student's *t*-test was used for normally distributed independent samples to compare symptom improvement between study arms and a Wilcoxon signed-rank test along with Mann-Whitney U test were used for non-normally distributed quantitative data to compare postoperative debridement per patient between study arms. Probability values of $p < 0.05$ were considered statistically significant. Repeated measures regression modeling was used to compare short term symptom improvement between study arms. Two-sided Student's *t*-tests were used to compare other continuous measures and Fisher's exact tests were used to compare other categorical measures [9]. For the secondary endpoint measures evaluated, a Benjamini-Hochberg 17 adjustment for multiple comparisons was used to determine statistical significance and control the overall for the family of tests at 0.05. For other statistical tests, values of p <0.05 were deemed statistically significant. An independent statistician calculated the required sample sizes and performed all statistical analyses. All analyses were performed using Microsoft Excel 2007(Microsoft Corporation, NY, USA) and SPSS Version 21(Statistical Package for the Social Science; SPSS Inc.,Chicago,IL,USA)

Method

A comparative cohort study was conducted which comprised of 30 cases of chronic rhinusinusitis involving maxillary sinus attending ENT OPD at BHDC between 16-61 age groups. Cases were identified and disease severity was graded according to Lund-MacKay radiological scoring system. Cases with previous or concomitant additional sinonasal surgery, unilateral or bilateral sinonasal polyposis, aspirin sensitivity cases, chronic bronchitis, cystic fibrosis and primary ciliary dyskinesia were excluded from this study. These patients were divided randomly into two groups of 15 each. Patients in group A underwent balloon dilation of the maxillary sinus ostia, and individuals in group B underwent conventional FESS consisting of maxillary antrostomy and uncinectomy with or without anterior ethmoidectomy. No other concomitant sinonasal surgeries were permitted or performed in either group. Postoperative follow-up assessments were conducted at 1wk, 3mth, 6mth and 12 months using Sino-Nasal Outcome Test (SNOT-20) scoring system. SNOT-20 scoring system rates the severity of 20 different symptoms on a scale of 0 (no problem) to 5 (problem as bad as it can be) (Fig.1). Rhinosinusitis symptoms have been linked to depression, fatigue, poor sleep, and anxiety, QOL instruments like the SNOT-20 can also help physicians tailor patient treatment to achieve clinically meaningful improvements and optimal outcomes. Although QOL surveys are subject to patient recall bias, this was mitigated in our study by the frequency of follow-up survey use. In addition, assessment of QOL at 6 months has been established as an acceptable long-term primary endpoint for use in rhinosinusitis clinical trials.

SNOT 20	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	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. Wake up at night	0	1	2	3	4	5
13. Lack of a good night sleep	0	1	2	3	4	5
14. Wake 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 concertation	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

Figure 1: SNOT 20 questioner.

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RESULTS

15 balloon dilation and 15 FESS patients were treated and followed-up for 6-months post-operatively. There were no significant differences in any of the baseline characteristics between treatment study arms (Table 1).

Table 1: Baseline demographics and patient characteristics by study arm

Characteristic	Balloon Dilation (*n*15)	control (FESS) (*n 15*)	*p* Value*
	Mean SD or *n* (%)	Mean SD or *n* (%)	
Age (yr)	30.13±13.63	41.27±15.41	0.045
Gender			0.205
Male	26%	20%)	
Female	30%	20%)	
Smoking history	29(58.00%)	27(64.3%)	0.828
Never smoked	14(28.00)%	10(23.8%)	
Former smoker	7(14.00)%	5(11.9%)	
Current smoker			
Allergies	16(32.00%)	13(31%)	1
None	21(42.00%)	17(40.5%)	
All year	13(26.00%)	12(28.6%)	
Seasonal			
Septal deviation	30(60.00%)	25(59.5%)	1
Lund-MacKay score	23.87±5.60	24.93±6.53	0.635
Symptom severity score			
Radiology score (LT)/(RT)	2.60 ±1.45/2.00±1.77	2.15±1.13/2.47±1.55	0.334/0.449
Surgery score (LT)/(RT)	0.80±1.08/0.47±0.92	1.53±0.99/1.40±0.99	0.063/0.012
Endoscopy score (Baseline)	2.520±1.370	0.783±0.998	<0.05
Maxillary only	31(62.00%)	26(61.9%)	
Maxillary and anterior ethmoid	19(38.00%)	16(38.1%)	
Duration of rhinosinusitis (yr; *n* 15,15)	12.4 ±13.0	12.7 ±13.9	0.934
Baseline SNOT-20 score	2.54 ±0.91	2.54 ± 0.79	0.972

*The p value from two-sample two-sided Student's t-test or Fisher's exact test.CRS _ chronic rhinosinusitis; FESS _ functional endoscopic sinus surgery; SNOT-20 _ 20-item Sino-Nasal Outcome Test.

Figure 2 depicts the time taken to finish the surgery along the x axis and the percentage of cases. Figure clearly explains that intra operative time taken for balloon sinuplasty was less in comparison to conventional FESS. About 47% of balloon sinuplasty cases were finished within an hour and about 80% of cases were finished within 2 hours. Whereas only 33% of conventional FESS cases were completed within the 1st hour of surgery. It was also noted that around 20% of Balloon sinuplasty surgery lasted upto 3 hours which is higher in comparison to only 7% of conventional FESS cases.

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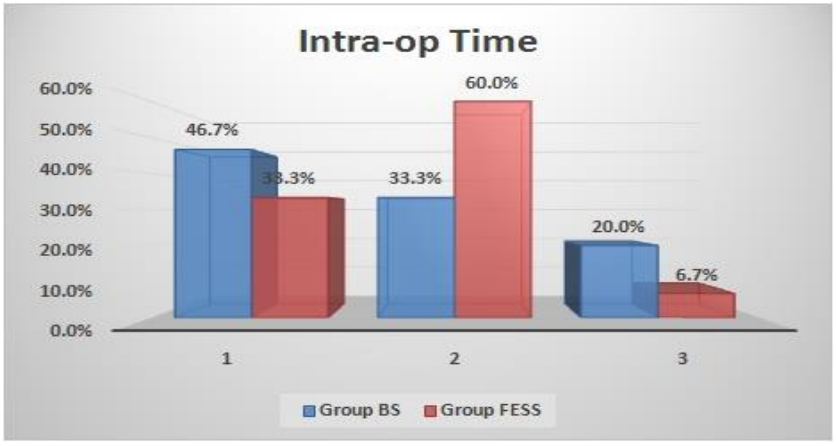

Figure 2: Intra operative time in hours.

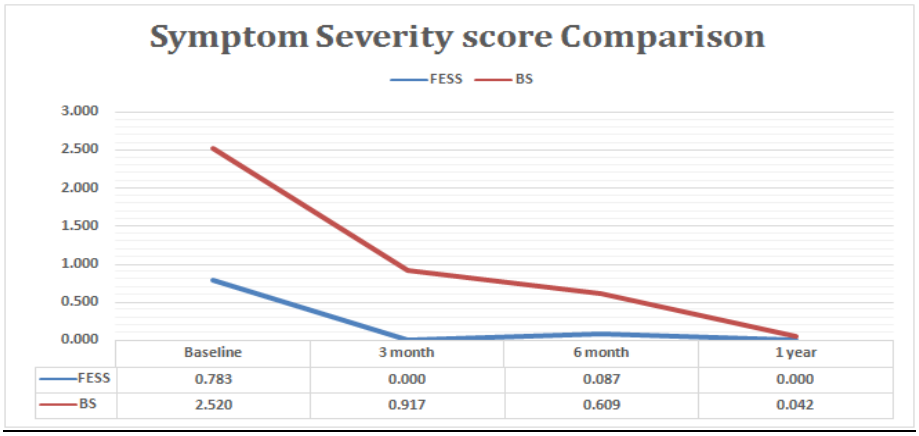

Figure 3: Mean change inSNOT-20 symptom score between baseline and 6-month follow-up by study arm.

Figure 3 shows the first primary endpoint of mean change in SNOT-20 symptom score between baseline and 6-month follow-up by study arm. The mean (±SD) SNOT-20 score improvement was1.67 ±1.10 in the balloon arm and 1.60±0.96 in the FESS arm. Comparison of these changes between groups confirms that individuals who underwent balloon dilation had fewer post-operative symptoms and recovered quickly in comparison to those patients who underwent conventional FESS ($p < 0.05$). Both study groups experienced clinically meaningful (mean change in score of ≥0.8) and statistically significant ($p< 0.05$) improvement.

Post-operative debridement rate was chosen as a relevant point of assessment as it is essential for healing of sinus mucosa and re-establish mucocilliary function. These procedures are uncomfortable for patients, require frequent visits to the office, and add to the overall cost of sinus surgery[10]. The mean number of postoperative debridements per patient is shown in Table 2. There was a mean of 0.1 ± 0.6(0%) postoperative debridement per patient in the balloon sinuplasty arm compared with 1.2 ±1.0 (20%) in the conventional FESS arm. This difference was significant ($p < 0.05$) for balloon sinuplasty requiring no post-operative debridement than conventional FESS. In the conventional FESS group, surgeon removed clots in 55% of patients, removed scabs in 43%, cleared early synechiae in 26%, removed crusting in14%, and removed scar tissue in 5% of patients.

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Table 2: Mean number of postoperative debridement per patient by study arm

No. of Patients	Balloon Dilation	Mean SD	No. of Patients	Control (FESS)	Mean SD	*p* Value*
	Total No. of Debridement			Total No. of Debridement		
15	0	0.1± 0.6(0%)	15	6	1.2±0.9 (20%)	<0.05

*Based on a one-sided two-sample Wilcoxon test for superiority. Statistical significance is determined by comparing the p value to 0.025. In conclusion, the mean number of debridements for patients undergoing balloon dilation is superior (i.e., less debridements) to that for patients undergoing FESS.

FESS _ functional endoscopic sinus surgery.

Postoperative recovery outcomes by study group are provided in Table 3. On an average, balloon dilation patients were able to return to normal daily activities faster (1.6 days) than FESS patients (4.8 days; p= 0.002). The balloon dilation patients took prescription pain medications for fewer days (0.9 days) compared with the FESS patients (2.8 days; $p < 0.001$).

Table 3: Recovery outcomes by study arm

	Recovery Time	Balloon Dilation	Control (FESS)	*p* Value*
		(*n*15)	(*n*15)	
		Mean SD or *n*(%)	Mean SD or *n* (%)	
Post discharge nausea		3 (6.0%)	7 (16.7%)	0.177
Discharged with nasal bleeding		14 (28.0%)	23 (54.8%)	0.011
Recovery time (days)		1.6±1.1	4.8±6.2	0.002
(return to normal daily activities)				
Duration of prescription pain medications (days)		0.9±1.4	2.8±2.7	0.001
Duration of OTC pain medications (days)		1.6±2.0	2.7±4.0	0.126

*The p value from two-sample two-sided Student's t-test or Fisher's Exact test .FESS _ functional endoscopic sinus surgery; OTC _ over the counter.

The mean short-term improvement in SNOT-20 score was better for patients in the balloon dilation arm than for patients undergoing FESS ($p=0.014$ Table 4)

Table 4: Short-term change in Endoscopy Score from baseline by study arm

Follow-Up		Balloon Dilation		Control (FESS)	Difference Balloon Dilation	*p* Value*
Interval	*N*	Mean Change SD	*N*	Mean Change SD	FESS (95% CI)	
1 wk	15	1.49±0.87	15	0.96±1.12	0.3 (0.5, 0.1)	<0.05
1 mo	15	0.917± 0.98	15	1.62±0.95		

*Based on a repeated measures regression model using the combined 1-wk and 1-mo changes in SNOT-20 from baseline. Model adjusted for baseline SNOT-20score, study arm, and follow-up visit. In conclusion, the mean short-term improvement in SNOT-20 score for patients undergoing balloon dilation is significantly better than that for patients undergoing FESS.FESS _ functional endoscopic sinus surgery; SNOT-20 _ 20-item Sino-Nasal Outcome Test.

DISCUSSION

This catheter based approach is prompted by the success of catheter technology in other medical disciplines including cardiology, urology, gastroenterology and vascular surgery and provides another tool for otolaryngologists performing sinus surgery, especially in cases in which sinus disease is due to ostial obstruction [4, 5]. By means of combination of guiding catheters, guidewires the paranasal balloon devices has been specially design to microfracture and mold bone surrounding the sinus ostia by inflating to a specific diameter under high pressure and represents a recently developed suite of small flexible tools that enable surgeons to endoscopically create an opening in a patient of blocked or significantly narrowed sinus ostia and transition spaces while maximizing tissue preservation and minimizing iatrogenic mucosal injury. The approach is also well suited in cases of maxillary sinus hypoplasia, atelectatic infundibulum, or silent sinus syndrome [11].

Frederick A. Kuhn, MD & Christopher A. Church, MD et al [12] in a prospective multicenter study of 01 year post surgery analysis of balloon catheter sinus ostial dilatation in 66 patient with sinusitis to assess its long term effectiveness by using nasal endoscopy, CT Scan and sinonasal outcome test (SNOT-20), found that use of balloon catheters appears to be relatively safe and effective. The results were durable over the study period showing long term effectiveness.

Raymond L. Weiss MD et al [13] in their prospective multicenter two-year study of balloon catheter dilation devices in 65 patients with CRS extended to one year period (supervised) in a tertiary care center were followed for 02 yrs post-surgery. The study was carried out in two arms including 34 balloon only and 31hybrid patients. Patients who receive balloon catheter sinusotomy in ESS have significant improvement in symptom severity score. Radiographic evidence also confirms resolution of disease after 02 yrs.

Jeffrey Cutler M.D, Bikhazi, M.D., et al [14] in their study of standalone balloon dilation versus sinus surgery for chronic rhinosinusitis which was a prospective, multicenter, randomized controlled trial carried out on Ninety-two patients (50 balloon dilation; 42 FESS) with uncomplicated CRS of the maxillary sinuses with or without anterior ethmoid disease who met criteria for medically necessary FESS were randomized and office balloon dilation or FESS were carried out. These patients were then followed for 6 months and symptom improvement using the validated 20-item Sino-Nasal Outcome Test (SNOT-20) survey, debridement, recovery outcomes, complications and revision surgeries were compared between groups. It was found that Balloon dilation is non inferior to FESS for symptom improvement and superior to FESS for postoperative debridement in patients with maxillary and anterior ethmoid disease. Balloon dilation is an effective treatment in patients with uncomplicated CRS who meet the criteria for medically necessary FESS.

These above mentioned studies are some of the examples which are in concurrence with our study findings and promote the use of balloon catheters as safe, efficient and least traumatic technique. Balloon dilatation can been viewed as an alternative operating technique which preserves the native mucociliary function of the sinus mucosa while performing sinuplasty or sinus antrostomy.

CONCLUSION

Adult patients with maxillary sinus disease who fail medical management and meet surgical criteria for uncomplicated CRS experience long-term symptom improvement after balloon dilation that is not inferior to the improvement occurring after FESS. Balloon dilation results in fewer postoperative debridement than FESS, indicating superiority of the balloon arm. Patients who underwent balloon dilatation had significantly shorter intra operative duration, shorter recovery time, and short-term symptomatic improvements were all significantly better when compared with conventional FESS. Balloon dilation and FESS are both safe because neither procedure produced any serious adverse events and the durability of each has been established through very low reported rates of revision surgery within each treatment arm.

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