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ORIGINAL ARTICLE

Efficacy & Outcomes of Balloon Sinuplasty in Chronic Rhinosinusitis: A Prospective Study

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Abstract Balloon Sinuplasty is a new technique which has revolutionized sinus surgery in recent times. Since its introduction in USA in 2004, it has become popular worldwide, due to its sophisticated technology, which uses balloon dilatational systems for dilating the sinus ostia through a minimally invasive approach and has provided satisfactory results in patients with chronic rhinosinusitis. Recent world literature supports the efficacy and outcomes of Balloon Sinuplasty system, with large multi-centric studies proving it to be a very effective tool in the management of various sinus pathologies. We performed this prospective clinical study to assess the efficacy & outcomes of Balloon Sinuplasty among 20 patients at our institution, who were followed up for 12 months after surgery. Patients were included as per inclusion criteria formulated for this study & were analyzed with respect to their pre-operative & post-operative symptomatology scores in comparison with their objective Diagnostic Nasal Endoscopy (DNE) & Computerized Tomography Scan of Paranasal Sinuses (CT-PNS) scoring systems. Significant improvements were recorded in patient's symptoms, from the first post-operative week until the end of the study period, and were objectively confirmed by the DNE & CT-PNS scores. The observations & results of our study highlight the efficacy of Balloon Sinuplasty technology in comparison to similar studies reported in recent world literature.

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Introduction

The surgical management of sinusitis has evolved rapidly by leaps and bounds over the last three decades. The advent of Rigid Nasal Endoscopes in 1970's favored the propagation of functional endoscopic sinus surgery (FESS) worldwide. This technique has become standardized & very popular, by following the Messerklinger principle for maximal preservation of the nasal mucosal integrity, while providing optimal disease clearance. FESS procedure has become an integral part of the armamentarium of every rhinologist today.

The introduction of a new technological innovation called Balloon Sinuplasty in 2004, took the field of sinus surgery a step further. This cutting edge innovation was based on the principles of Balloon Angioplasty performed by Cardio-thoracic & Vascular Surgeons. The Balloon Sinus Dilatational system uses a series of intricate high pressure, low volume balloons similar to angioplasty balloon catheters, to effectively cannulate the natural ostia of the blocked sinuses under endoscopic & fluoroscopic guidance, to optimally dilate the occluded sinus ostia and restore natural sinus ventilation & drainage.

This FDA approved technique has provided excellent results and outcomes in various centers across the world. Since 2007, this technology has made its mark in India, with many centres successfully performing Balloon Sinuplasty surgery. Till date, an estimated 30,000 surgeries have been performed worldwide, with around 200 surgeries having

been done at various centers across India. Today, this system has added an efficient, minimally invasive tool in the armamentarium of the endoscopic rhinologist.

Study Methodology

Balloon Sinuplasty has been performed at our institution, since its introduction in India in December 2007. Till date 40 patients have successfully undergone this procedure at our institution with gratifying results. This prospective study was conducted over a period of 18 months from December 2007 to July 2009. The principal aim of our study was to assess the efficacy and outcomes of this new surgical technique, in a consecutive series of 20 patients with chronic rhino-sinusitis, who underwent Balloon Sinuplasty & were meticulously followed up over a period of 1 year.

All these patients were selected based upon the inclusion and exclusion criteria for the study, as formulated below. A diagnosis of chronic rhino-sinusitis was arrived at as per the Lund–Kennedy criteria (1995) i.e., patients having 8 weeks or more of persistent symptoms and signs of sinusitis, not resolving with 3 weeks of medications or 4 episodes per year or more of recurrent acute sinusitis, each lasting at least 10 days, in association with persistent changes noted on CT-PNS scans, done 4 weeks after completion of medical treatment [1–3].

Inclusion criteria, was the presence of unilateral or bilateral maxillary, frontal or sphenoidal chronic rhino-sinusitis, which had been unresponsive to 3 weeks of trial with medical management (Fig. 1). Exclusion criteria was the presence of distorted ostio-meatal unit anatomy, extensive sino-nasal polyps, isolated ethmoidal sinus or infundibular disease, obstructive adenoid hypertrophy, previous sino-nasal surgery or nasal trauma, allergic fungal rhino-sinusitis & associated conditions like ciliary dysmotility syndrome, mucopolysaccharidosis or cystic fibrosis.

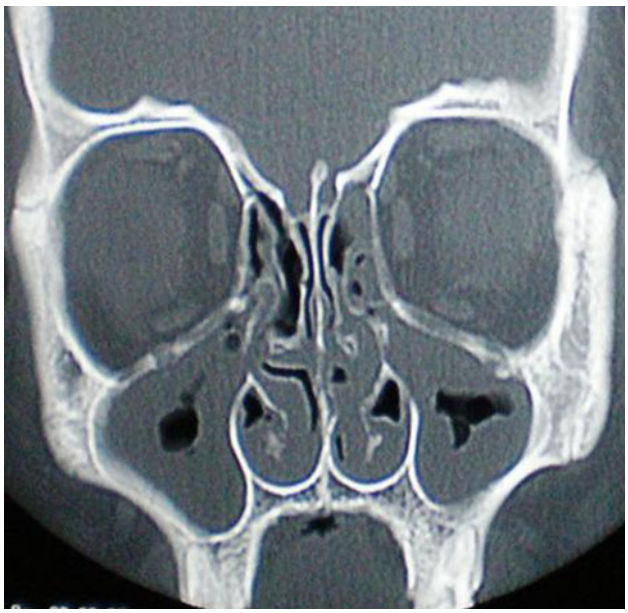

Fig. 1 Maxillary sinusitis: pre-operative CT scan

After obtaining informed consent for participation in the study, the selected cohort of 20 patients underwent a complete clinical examination with Diagnostic Nasal Endoscopic assessment (DNE) and High Resolution Computed Tomographic Scans of the nose & paranasal sinuses (CT-PNS). At the pre-operative assessment, symptoms of these patients were graded, based on the Piccirillo's sino-nasal outcome test (SNOT-20 scoring system) [4] and correlated with their diagnostic nasal endoscopic findings (Kennedy & Lanza scoring system) [5] and computed tomographic (CT) scan pictures of the paranasal sinuses (Lund and Mackay scoring system), [5, 6] for categorizing the exact type & grade of sinus pathology.

The selected cohort of 20 patients, were prepared for Balloon Sinuplasty surgery in the same way as for conventional FESS and were operated by the our surgical team between the period from December 2007 to July 2008. In addition to the standard endoscopic sinus surgery equipment, a C-arm fluoroscope was utilized during the surgery to locate, cannulate & dilate the occluded sinus ostia. The patient, surgical team & operating room staff wore appropriate radiological shields standardized as per international protocols. Intra-operative fluoroscopy was monitored with dosimetry & the radiation exposure time was recorded throughout all of these procedures. The mean fluoroscopic radiation exposure time, during each procedure was well within the standardized acceptable limits [7, 8].

Sinus balloon catheter system (Acclarent Inc, CA) used during the procedure included sinus guiding catheters, sinus lavage catheters, sinus guide wires, sinus balloon catheters injectable with a dilute radio-opaque dye (Iohexol) & a calibrated pressure control gauge to dilate the ostia under vision (Fig. 2). The guide catheter was introduced into the nasal cavity under endoscopic visualization & placed adjacent to the occluded maxillary, sphenoidal or frontal ostium/frontal recess. Subsequently, the occluded sinus was catheterized via its natural ostium under fluoroscopic guidance & the ostium was dilated up to a maximum of 12 cms of water pressure with a 5, 6, or 7 mm balloon catheter, as was necessary (Fig. 3) [9].

The mucopurulent discharge draining from within the sinus was collected for microbiological studies. After adequate dilatation, the sinus mucosa was inspected endoscopically & irrigated using the sinus lavage catheter with an antibiotic (Gentamycin) & saline solution. There was no intra-operative or post-operative bleeding; hence

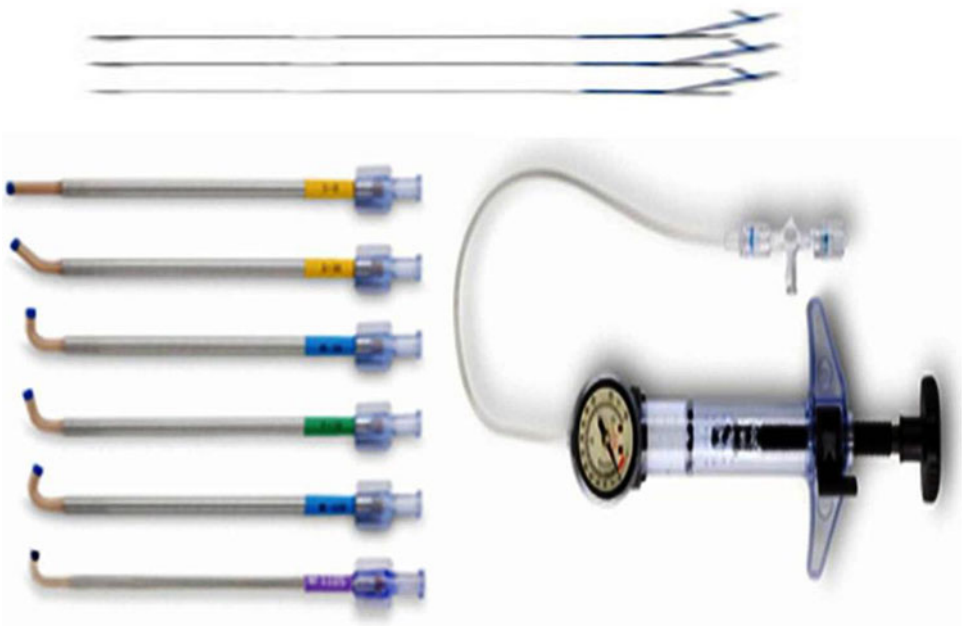

Fig. 2 Balloon Sinuplasty system (Acclarent Inc, CA)

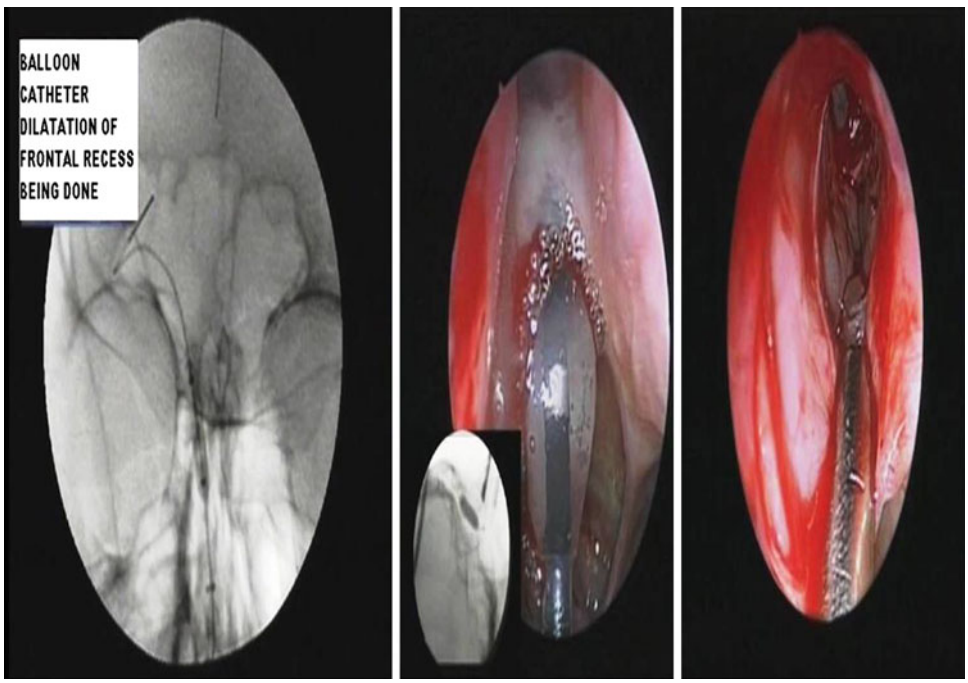

Fig. 3 Frontal sinuplasty: intra-operative fluoroscopy & endoscopic Images

nasal packing was not necessary for any of these patients. Standard endoscopic sinus surgery post-op care was given in the immediate post-operative period. All these patients were treated as *'Day Care'* & were discharged with oral antibiotics & normal saline nasal spray.

These patients were meticulously followed up over the next 1 year at the Rhinology Clinic, with periodic diagnostic nasal endoscopic examination done at 1 week, 4 weeks (Fig. 4), 3 months, 6 months and 1 year of review, with emphasis on recording the appearance & patency of the balloon dilated ostium at each visit. In the first post operative week, periostial edema was noted, which usually resolved by the second post operative week, to leave a well dilated ostia, maintained over time. The post-operative healing process of the dilated sinus ostia, showed no complications like re-stenosis or cicatrisation on follow up endoscopy & all dilated sinuses remained adequately patent during the entire follow up period.

A post operative CT scan imaging of the paranasal sinuses was done, at the completion of 1 month (Fig. 5), 6 month & 1 year of review. These patients were also evaluated symptomatically throughout the study period,

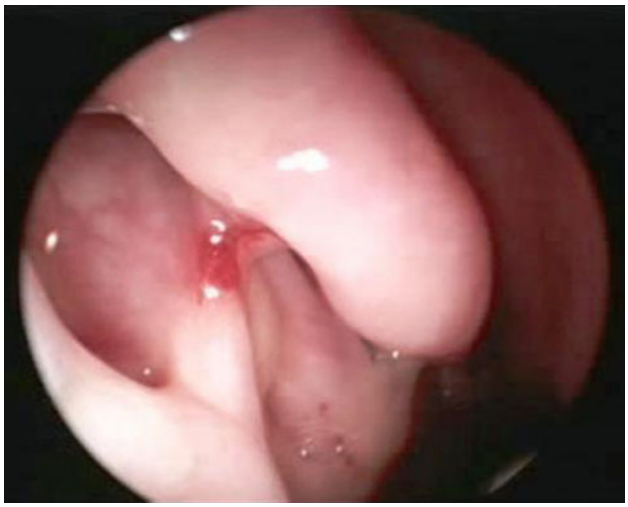

Fig. 4 Maxillary sinuplasty: DNE 1 month postoperatively

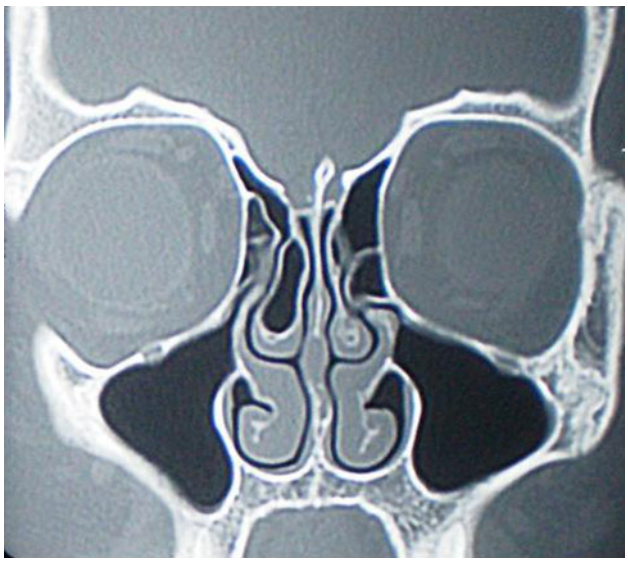

Fig. 5 Maxillary sinuplasty: CT scan 1 month postoperatively

using a standardized questionnaire as per the Piccirillo's sino-nasal outcome test (SNOT-20). For all patients, a mean symptom score, DNE score & CT-PNS score was recorded periodically at follow up. Results of this prospective clinical study were analyzed by paired student't' test method, to assess the efficacy and outcomes of Balloon Sinuplasty in our study group (Figs. 6, 7 and 8).

Observations and Results

A comprehensive data analysis provided statistically significant results comparable to similar larger studies published in recent world literature, supporting the efficacy of

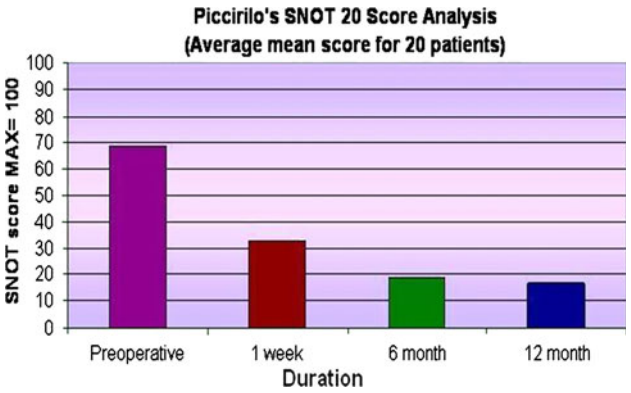

Fig. 6 Pre & post-operative SNOT-20 scores

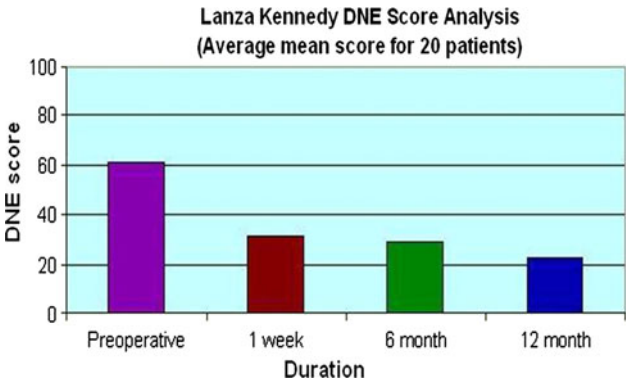

Fig. 7 Pre & post-operative DNE scores

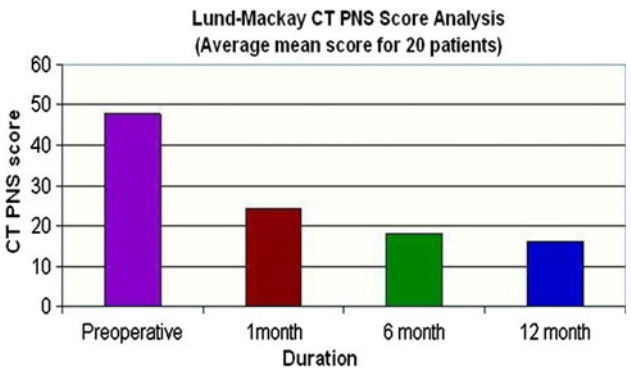

Fig. 8 Pre & post-operative CT-PNS scores

Balloon Sinuplasty technology in the treatment of chronic rhino-sinusitis**.** In our study, the overall mean average Piccirillo's sinonasal outcome test (SNOT) Score was 68.60% pre-operatively, which reduced to 38.20% in the first post-operative week and further onto 23.45% at 4 weeks, 20.00% at 3 months, 18.60% at 6 months and 16.65% at the completion of study period at 1 year. The SNOT 20 symptomatology rating showed a significant reduction by 35.80% in the 1st postoperative week. The

subsequent SNOT 20 scores were persistently low in the same range until the completion of our study.

The overall mean average Lanza Kennedy nasal endoscopy score was 61.25% preoperatively, which reduced to 31.67% in the 1st postoperative week and further onto 27.50% at 4 weeks, 30.00% at 3 months, 29.17% at 6 months and 22.50% at the completion of study period at 1 year. DNE scores had reduced by 29.90% in the first postoperative week and further persisted in the same range during further follow up at 3, 6 and 12 months. The overall mean average Lund Mackay CT-PNS score was 47.71% preoperatively, which reduced to 24.40% by the 4th post-operative week and further to 18.25% at 6 months and 16.25% at the completion of study period at 1 year. CT PNS scores had reduced by an average of 23.30% in the 1st post-operative month and were found to be in the same range at 6 and 12 months of follow up.

Discussion

Balloon Sinuplasty technology uses a small, flexible, balloon catheter to open up the blocked sinus ostium, by inflation with a calibrated pressure gauge. When the sinus balloon is inflated optimally, it gently restructures the sinus ostium by inducing micro-fractures & bony displacement around the occluded ostium, thus circumferentially widening the walls of the ostium, while maintaining the integrity of the sinus mucosal lining around the ostium. The benefits of using the Balloon Sinuplasty technology include preservation of the normal anatomy of the vital ostio-meatal complex, while precisely focusing on the occluded sinus ostium & the diseased sinus cavity beyond it [9].

In 2006, Christopher Brown and William Bolger studied the safety and feasibility of balloon catheter Dilatation of Paranasal Sinus Ostia in ten patients. A total of 18 sinuses (average of 3.2 sinuses per patient) were operated, including 10 maxillary, 5 sphenoid, and 3 frontal recesses. They reported successful dilatation with no complications in all the patients [7, 9]. In our study, performed in a cohort of 20 patients with chronic rhinosinusitis, the average number of sinuses involved was 2.35 per patient. A total of 47 sinuses were treated by balloon catheter dilatation which included 27 maxillary, 14 frontal and 6 sphenoid sinuses. All diseased sinuses were successfully dilated with no failures in cannulation.

In a 2007 study by William Bolger and Christopher Brown et al. safety and outcomes of balloon catheter sinusotomy were analyzed on 115 patients over 24 weeks. Sinusotomy using balloon catheter devices was attempted in 358 sinuses with successful cannulation in 347 sinuses (96.9%). The median fluoroscopy time per sinus was 0.81 min & the average radiation dose per patient was approximately 730 mrem [10]. In our experience, the average radiation dose per patient and exposure to the operating team during fluoroscopy procedures was well within the standardized risk levels of 750 mrem per surgery.

In the study of 115 patients by Bolger et al. the percentage of patients that reported improvement on SNOT 20 score system (score of 1 or 2) was 85% (41 of 48) at 1 week, 98% (41 of 42) at 12 weeks, and 80% (35 of 44) at 24 weeks [10]. In our study, the structured patient questionnaire regarding change in sinusitis symptoms compared with those before balloon sinusotomy revealed dramatic improvement in symptomatology in 92.8% of the patients in the 1st post-operative week. Gratifying results were sustained throughout the study period in 87.5% of the study group while 12.5% patients had intermittent exacerbations of symptoms due to allergy which required oral medications.

In a 2008 multicenter registry of balloon catheter sinusotomy outcomes for 1,036 patients, a total of 3,276 sinuses (an average of 3.2 sinuses per patient) underwent balloon catheter dilation. The average surgery time was 73 min. Of the 1,036 patients treated, 25 patients (2.4%) required revision of sinuses [11]. In our study the mean average operating time for dilatation of maxillary sinus was 7 min, frontal recess was 12 min and sphenoid sinus was 15 min. The overall procedure time for the completion of the multiple sinus dilatations did not extend beyond 40 min.

A prospective multicenter CLEAR (Clinical evaluation to confirm safety and efficacy of sinuplasty in the paranasal sinuses) study of 115 patients across 9 physician practices, highlighted an impressive safety profile (zero adverse events), durability of patency (98% patency of observed ostia after 6 months), and significant improvement in patient symptoms and quality of life [12]. Of the 20 patients in our study assessed by diagnostic nasal endoscopy at periodic intervals, 92% had widely patent ostia from their first review at 1 week postoperatively till the completion of 1 year of follow up. 8% of sinus ostia showed features of partial occlusion due to edema or stenosis, but the ostium were still ventilating and draining optimally. The average ostium patency size was 7–10 mm for maxillary sinus and 3–5 mm for the sphenoid and frontal sinuses. Marginal reduction in the ostia size by 1–2 mm were noted at completion of follow up period, which did not compromise normal sinus function.

In a 2008 study by Raymond Weiss et al. on long term analysis of balloon catheter Sinusotomy for a period of 2 years in 65 patients, the mean Lund–Mackay CT scores decreased significantly at follow up. The resolution of disease on CT scan observed at 1 year, were sustained at the completion of this 2 year analysis [13]. In our study,

the postoperative CT-PNS assessment at periodic intervals showed successful eradication of the intra-sinusal pathology in 89% of the case study group. Three patients with recurrent sinus pathology due to superadded allergy were successfully treated with steroid nasal spray and anti-allergic medications, following which sinuses reverted back to normal.

Recent literature has documented clear indications for the Balloon Sinuplasty surgery. Ideal candidates for this procedure would include, chronic sinusitis limited mostly to ostial obstruction of the frontal, maxillary & sphenoidal sinuses, with near normal middle meatal integrity. Many investigators reported that use of balloon catheter dilatation obviated the need for & decreased the frequency of post-operative debridements and endoscopies. In a few cases, sinus ostia could not be visualized & catheterized intra-operatively due to technical reasons, however this did not limit further treatment options, like conversion to the Conventional FESS procedure.

Emerging clinical data from world-over suggests excellent outcomes with balloon catheter Sinusotomy in select indications, comparable to that of the standard functional endoscopic sinus surgery procedure. Careful case evaluation & selection remains paramount in providing the best outcomes with this technique. Balloon Sinuplasty has tangible benefits such as a reduction in invasiveness of the intervention, hospital stay, recovery time, post-operative debridements, post-operative medications, and office follow-up visits [11–13].

Our prospective case study has provided significant inferences on the efficacy and outcomes of this cutting-edge technology, comparable to larger multi-centric clinical trials published in recent world literature. All patients in our study group had dramatic relief from their symptoms within the 1st postoperative week as reflected by the reduction in the Piccirillo's SNOT 20 scores. All patients were found to be symptom free during further follow up as recorded by the low SNOT 20 scores. Objective confirmation of these gratifying results were made by significant reduction in DNE and CT PNS scores, within the 1st postoperative week and at further follow up. A larger prospective clinical study is underway at our institution, in order to establish the long term outcomes of this technology among our patients.

Conclusion

The technological innovation of Balloon Sinuplasty represents the emergence of an exciting era in Rhinology, focused on the concept of minimally invasive sinus surgery. Debates linger over its advantages, disadvantages, indications and contraindications in certain scientific panels, but the overall consensus today, is that this new technology has evolved as an effective way of opening up blocked sinus ostia to restore normal, physiological sinus drainage & ventilation. Present day research is focused on developing surgical strategies for combining balloon catheter technology with standard functional endoscopic sinus surgery procedures. Further incorporation of this technology into image guided sinus surgery systems, would expand its indications, to include the whole spectrum of sinus disease in the future.

References

1. Lund VJ, Mackay IS (1993) Staging in rhinosinusitis. Rhinology 107:183–184
2. Lund VJ, Kennedy DW (1997) Staging for rhinosinusitis. Otolaryngol Head Neck Surg 117:535–540
3. Meltzer EO, Hamilos DL et al (2004) Rhinosinusitis: establishing definitions for clinical research and patient care. Suppl Otolaryngol Head Neck Surg 131:S1–S54
4. Piccirillo JF, Merrit MG, Michele RL (2002) Psychometric and clinimetric validity of the 20 item sino-nasal outcome test (SNOT-20). Otolaryngol Head Neck Surg 126:41–47
5. Jorgensen RA (1991) Endoscopic and computed tomography findings in osteomeatal sinus disease. Arch Otol Head Neck Surg 117:279–287
6. Wabnitz DA, Nair SN, Wormald PJ (2005) Correlation between preoperative symptom scores, quality-of-life questionnaires & staging with computer tomography in patients with chronic rhinosinusitis. Am J Rhinol 19:91–96
7. Brown C, Bolger WE (2006) Safety and feasibility of balloon catheter dilation of paranasal sinus ostia: a preliminary investigation. Ann Otol Rhinol Laryngol 115:293–299
8. Church CA, Kuhn FA, Mikhail J, Vaughan WC, Weiss RL (2008) Patient and surgeon radiation exposure in balloon catheter sinus ostial dilation. Otolaryngol Head Neck Surg 138(2):187–191
9. Brehmer D (2008) Catheter-based balloon dilatation of the frontal, maxillary, and sphenoid ostia: a new procedure in sinus surgery. HNO 56(1):65–70
10. Bolger WE, Brown CL, Kuhn FA, Levine HL (2007) Safety and outcomes of balloon catheter sinusotomy : a multicenter 24 week analysis in 115 patients. Otolaryngol Head Neck Surg 137(1): 10–20
11. Levine HL, Sertich AP, Hoisington D et al (2008) A multi-center registry of balloon catheter sinusotomy outcomes for 1,036 patients. Ann Otol Rhinol Laryngol 117:263–270
12. Kuhn FA, Church CA, Goldberg AN et al (2008) Balloon catheter sinusotomy: one-year follow-up outcomes and role in functional endoscopic sinus surgery. Otolaryngol Head Neck Surg 139(3S3):S27–S37
13. Weiss RL, Church CA, Kuhn FA, Levine HL, Sillers MJ (2008) Long-term outcome analysis of balloon catheter sinusotomy: 2 year follow-up. Otolaryngol Head Neck Surg 139(3S3):S27–S37