Balloon sinuplasty – the first Indian experience

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Abstract The surgical management of sinusitis was revolutionized worldwide with the advent of the rigid Hopkins rod nasal endoscopes three decades ago. The traditional Messerklinger technique, was thus propagated worldwide by Prof. Stammberger, from the University of Graz in Austria and has come into vogue as functional endoscopic sinus surgery (FESS). The principal aim behind this procedure was the maximal preservation of the nasal mucosal integrity, while providing optimal disease clearance. Today, the introduction of a new technological innovation called ‘balloon sinuplasty’, has taken the field of sinus surgery a step further. This new technology is very similar to the principles of balloon angioplasty and today, this system has added an efficient, non-invasive tool in the armamentarium of the innovative endoscopic rhinologist. This FDA approved technique, in recent times has provided excellent results in various centers across the western world. We share our first surgical experience with the introduction of this cutting-edge technology in India.

Keywords Osteo-meatal obstruction · Chronic rhinosinusitis · Functional endoscopic sinus surgery (FESS) · Sino-nasal outcome test (SNOT-20) · C-arm fluoroscopic imaging · Balloon sinuplasty/balloon catheter sinusotomy

Introduction

Surgery for rhino-sinusitis has undergone remarkable and dramatic changes, since the introduction of the now widely popular functional endoscopic sinus surgery (FESS) technique three decades ago. This innovative technique was based on the principle of draining and ventilating occluded paranasal sinuses by endoscopic removal of the anatomical structures blocking the sinus ostia at the osteo-meatal complex and beyond. The surgical outcomes were highly rewarding and thus today, the FESS procedure has become standardized, with the concept of maximal disease clearance with minimal nasal mucosal trauma receiving worldwide acceptance. The indications for FESS have now grown far and wide, encompassing the endoscopic approaches to the orbit, anterior skull base, nasopharynx and the pituitary fossa.

Present day cutting-edge technology has taken sinus surgery to the next higher level with the innovation of catheter based balloon dilatational systems for the paranasal sinuses, similar to those used by interventional cardiologists, urologists and vascular surgeons. This FDA approved balloon sinus dilatational system, is used to widen the natural ostia of the paranasal sinuses with endoscopic assistance and fluoroscopic C-arm guidance, without compromising the integrity of the osteo-meatal complex. The main advantage of this surgical technique over the conventional FESS, is the preservation of the normal anatomy while bypassing the osteo-meatal complex, to access the occluded natural ostia of the paranasal sinuses for dilatation. This surgical technique is capable of completely clearing all the disease within the blocked sinuses, in a virtually painless and bloodless procedure.

The balloon sinuplasty system was first introduced in the United States in 2004, by its patented manufacturer, Accurant Inc, California, USA. Till date about 24,000 patients world over have undergone the balloon sinuplasty procedure. Most of these surgeries have been performed within the US, along with a few centers in UK and across Europe,

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Australia and Singapore. The surgical team of Madras ENT Research Foundation, Chennai have been successful in performing the first series of balloon sinuplasty surgeries in India, since December 2007. We present our surgical experience and the postoperative outcomes of our first five patients, who have been meticulously followed-up over the last three months.

Materials and methods

A consecutive series of five adult patients with chronic rhino-sinusitis, unresponsive to medical management, were chosen to undergo balloon catheter sinusotomy surgery after fulfilling the inclusion criteria formulated for this study. The inclusion criteria was the selection of adults 16 years or older, with presence of unilateral or bilateral maxillary, frontal or sphenoidal sinusitis which has been unresponsive to three weeks of trial with medical management. Exclusion criteria were the presence of distorted osteo-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 and associated conditions such as ciliary dysmotility syndrome, mucopolysaccharidosis or cystic fibrosis.

All the patients included in the study group were counseled in detail about this new surgical procedure and an informed consent was obtained to participate in the study. They underwent a thorough clinical oto-rhino-laryngological examination and were investigated for sinus pathology. The symptoms of these patients were graded based on the Sino-Nasal Outcome Test (SNOT-20 scoring system) and correlated with their diagnostic nasal endoscopic findings and computed tomographic (CT) scan pictures of the paranasal sinuses, for identifying the type of sinus pathology.

The operative technique

The selected cohort group of five patients, were prepared for balloon sinuplasty surgery in the same way as for conventional FESS and were operated by the MERF surgical team between 12 December 2007 and 5 January 2008. In addition to the standard endoscopic sinus surgery equipment, a C-arm fluoroscope was utilized during the surgery to locate, cannulate and dilate the occluded sinus ostia. The 'learning curve' was not steep for cannulation and dilatation of the various sinus ostia and all sinuses could be comfortably accessed with prior adequate practice on cadaveric models [1, 2]. The patient, surgical team and operating room staff wore appropriate radiological shields standardized as per the international protocols. Intraoperative fluoroscopy was monitored with dosimetry and the radiation exposure time was recorded throughout all of these procedures [3].

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 radio-opaque dye and a calibrated pressure control gauge to dilate the ostia under vision. The guide catheter was introduced into the nasal cavity under endoscopic visualization and 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 and the ostium was dilated using a 5, 6 or 7 mm balloon catheter as was necessary. The muco-purulent discharge draining from within the sinus was collected for microbiological studies. After adequate dilatation the sinus mucosa was inspected endoscopically and irrigated using the sinus lavage catheter with an injectable antibiotic (gentamycin) and saline solution. Standard endoscopic sinus surgery post-op care was given in the immediate postoperative period. No post-op nasal packing was necessary in any of the cases. All these patients were treated as 'day care' and were discharged the same evening with oral antibiotics and normal saline nasal drops.

All these patients were meticulously followed-up over the next three months with periodic diagnostic nasal endoscopic examination done at 1, 2, 4, 8 and 12 weeks of review, with emphasis on recording the appearance and patency of the balloon dilated ostium at each visit. A postoperative CT scan imaging of the paranasal sinuses was done, at the completion of their third month of review. These patients were also evaluated symptomatically throughout the study period, using a standardized questionnaire as per the SNOT-20 scoring system. For all patients, a mean symptom score was established at each of their visits, based on the rating of their symptomatology on a 6 point scale, as postulated by Piccirillo et al. in the SNOT-20 protocol [4].

Results

The cohort group comprised five adult patients, age ranging from 16 years to 52 years (mean age = 34 years). Three patients were male and two were female. Two patients had isolated unilateral maxillary sinusitis, one patient had unilateral sphenoidal and maxillary sinusitis, while the other two patients had bilateral maxillary and frontal sinusitis. Appropriate balloon catheter sinusotomy procedures were done, using specialized balloon dilatational system for each of the sinuses. The balloon dilatations of all the occluded ostia were achieved successfully, without impairing the mucosal circumference. Immediately after dilatation, sinusotomies were approximately the size of the inflated balloon diameter.

The mean fluoroscopic radiation exposure time, during each procedure was well within the standardized accept-

Figs. 1a and 1b An intraoperative fluoroscopic image depicting passage of the sinus guide-wire into a diseased frontal sinus with the balloon catheter positioned at the frontal sinus ostium

Figs. 2a and 2b Balloon catheter sinusotomy and dilatation of the frontal sinus ostium is performed with endoscopic and fluoroscopic guidance

able limits. There was no intraoperative or postoperative bleeding, and hence nasal packing was not necessary for

any of these patients. In the first postoperative week, peri-ostial oedema was noted which resolved by the second

post-op week, to leave well dilated ostia, maintained over time. The postoperative healing process of the dilated sinus ostia, showed no complications like re-stenosis or cicatrization on follow-up endoscopy and all dilated sinuses remained adequately patent during the follow-up period. The three month postoperative CT scan pictures of the operated paranasal sinuses showed a normal picture, within the sinus cavity and in the osteo-meatal complexes (Figs. 1–6).

The structured patient questionnaire regarding the change in sinusitis symptoms, as compared with those before the balloon dilatation procedure revealed a significant improvement at follow-up. The SNOT-20 mean symptom score recorded a dramatic 65–80% improvement in all the patients who underwent balloon dilatation of their sinuses, within the first postoperative week and progressed to nearly 100% symptom relief, by the time of conclusion of their participation in this study. All the five patients in our study group provided an overall positive feedback, describing their balloon sinuplasty surgery as a gratifying experience, providing marked relief from their symptoms with minimal discomfort. All these patients were completely symptom free by the end of their three months of review and remain asymptomatic till date. Further follow up has been recommended for these patients, for an ongoing longer prospective study.

Discussion

The 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 microfractures and 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 osteo-meatal complex, while precisely focusing on the occluded sinus ostium and the diseased sinus cavity beyond it [5, 6].

Balloon catheter sinusotomy has been widely performed under general and local anesthesia in various centres, as a ‘day care’ procedure. Results prove its safety and effectiveness with improved postoperative recovery time. In a few cases, where sinus ostia could not be visualized and catheterized intraoperatively due to technical reasons, this does not limit further treatment options, like conversion into the conventional FESS procedure [5, 6].

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 and sphenoidal sinuses, with near normal middle meatal integrity. It has been deemed inappropriate for patients with sino-nasal polyposis, isolated ethmoidal disease, deformed osteomeatal anatomy or extensive previous surgery with significant osteoneogenesis [7, 8]. Hence, careful case evaluation and selection remains paramount in providing the best outcomes with this technique.

A recent study by Church et al. determined the extent of radiation exposure to the patient and the surgeon during balloon catheter dilation. This study concluded that the use

Figs. 3a and 3b Three month postdilatation follow-up CT scan image of the frontal recess and the endoscopic picture of the patent frontal sinus ostium

Figs. 4 and 4a Preoperative endoscopic and CT scan images of empyema of the right maxillary sinus

Figs. 5 and 5a Intraoperative endoscopic and fluoroscopic images of the balloon catheter sinusotomy procedure

Figs. 6 and 6a Three month postoperative follow-up endoscopic and CT scan images showing the normal right maxillary sinus with a patent ostium

of fluoroscopy in balloon catheter dilation exposes both the patient and surgeon to very low doses of radiation, well within standardized, acceptable levels [9].

An exhaustive multicentric prospective study, conducted recently in the US by Brown, Bolger, Levine and Kuhn has successfully demonstrated the safety and efficacy of these balloon sinuplasty devices and has confirmed the reliable outcomes of this technique in a large study group, comprising 115 patients followed-up over a six month period [7].

Eventhough, some reservations have been expressed for this procedure, for its failure to remove tissue and bone for complete disease clearance, especially as in the setting of sino-nasal polyposis or ethmoidal/infundibular disease, the emerging clinical data from world-over suggests excellent outcomes with balloon catheter sinusotomy in selected indications, comparable to that of the standard FESS procedure [10–12].

The present study done at our institution, has shown satisfactory results in a small cohort, comparable to that of

larger clinical trials published in recent world literature. A larger prospective study is presently underway 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. As this new technology is evolving, debates linger over its advantages, disadvantages, indications and contraindications in certain scientific panels, but the overall consensus today, is that this technology has arrived as the most ideal and effective way for opening up blocked sinus ostia in order to restore normal, physiological sinus drainage and ventilation. Present day research is focused on developing surgical strategies for combining balloon catheter technology with

standard functional endoscopic sinus surgery procedures, similar to the addition of microdebriders in FESS. Further incorporation of this technology into image guided sinus surgery systems, would expand the indications for balloon sinuplasty, to include the whole spectrum of sinus disease in the near future.

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