

Balloon Sinuplasty: A New Tool in the Armamentarium

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Abstract—Advent of new technologies has always helped to explore new dimensions in the management of different diseases. In last three decades Endoscopic sinus surgery has consolidated its place in the management protocol for patients of chronic rhinosinusitis (CRS) and it is nearly one decade when Balloon sinuplasty stepped in as a less invasive or less traumatic interventional procedure for the vast number of CRS patients, using a balloon guided by a catheter to widen the ostia of the sinuses. Balloon sinuplasty has turned out to be a technique at par with Endoscopic Sinus Surgery for some specific conditions, the balloon dilation of frontal recess and sphenoid ostium has given good results with less chances of stenosis or synechiae formation. The surgery can be carried out under local anaesthesia. Although Functional Endoscopic Sinus Surgery (FESS) has got wider application in management of a broad spectrum of pathologies in which balloon sinuplasty can't be implicated but keeping the lesser complications in consideration balloon sinuplasty turns out to be a reliable option in several conditions. Balloon sinuplasty has specifically useful application in widening of frontal recess area, sphenoid ostia and maxillary ostia in patients with contraindications for general anaesthesia, patients having bleeding diathesis or patients in Intensive Care Unit (ICU). This technique causes less post operative complications as well as less pre and post operative bleeding as compared to FESS.

1. INTRODUCTION

Sinuses are the air spaces present in a normal skull with specific highly defined physiological functions of humidifying the air entering through nasal cavity in the lungs and providing resonance to the voice generated by the person. A human skull has one pair of maxillary sinuses, one pair of frontal sinuses, one pair of sphenoid sinuses and two labyrinths of ethmoid sinuses. These sinuses are lined by mucosal layer which secretes mucus and this mucus is drained out of sinus through their normal anatomical opening or ostia. Whenever there is any obstruction in normal discharge pathways of sinuses which can be due to inflammation of the nasal or sinus mucosa the mucus gets collected in the sinus, leading to pressure symptoms and features of sinusitis. Sinusitis is very prevalent disease which severely affects the quality of life (QOL) of the person, In USA nearly 37 million people are affected each year by sinusitis [1,14] and infact it is found to be more prevalent than heart disease and asthma and exerts greater impact on QOL than chronic backpain or congestive heart

failure.[7]. For nearly 3 decades Functional Endoscopic Sinus Surgery (FESS) has revolutionized the management of chronic rhinosinusitis (CRS). The basic concept behind the FESS is reestablishment of the normal physiological drainage pathways of sinuses, this technique involves punching out or debriding the mucosa and bony edges from the ostia by means of a variety of surgical instruments.

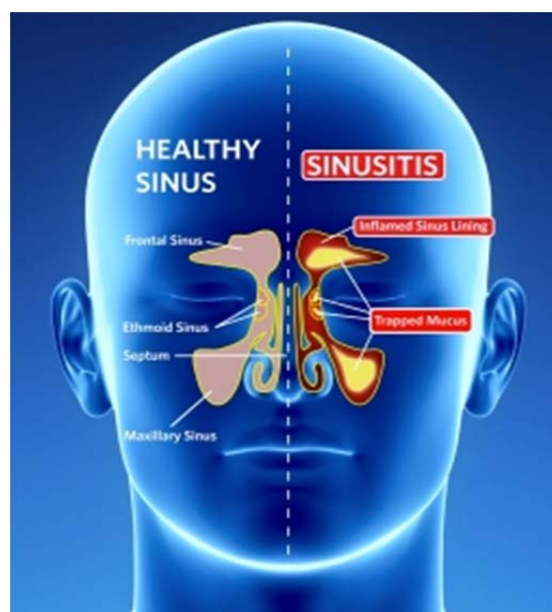


Fig. 1: Comparison of healthy and diseased sinuses

Table 1: Main indications and contraindications of the balloon sinuplasty

Indications	Contraindications
Chronic rhinosinusitis without improvement with clinical treatment	Significant ethmoidal disease
Recurrent acute rhinosinusitis	Presence of polyps
ICU febrile patients with sinusal focus	Mucocele
Frontal sinus recess treatment	Allergic fungal rhinosinusitis
Patients with high anaesthetic risk	Osseous neoformation signs

Patients with bleeding risks	Cystic fibrosis
Ciliary dysfunction	
Sinonasal tumour	

Courtsey <http://www.entnet.org/content/sinusitis>[10]

Symptoms of sinusitis :

- Facial fullness, pressure or pain
- Headache
- Nasal blockage
- Hyposmia or anosmia
- Yellowish or greenish nasal discharge
- Toothache
- Fatigue
- Halitosis or bad breath
- Ear ache or ear fullness

FESS technique however has its own bag of complications the important being- haemorrhage, synechiae formation, stenosis, edema, crusting etc.

The advent of new technology like balloon sinuplasty (BST) has taken sinus surgeries to the next level of innovative interventional techniques. The balloon sinuplasty was first introduced in the USA in 2004 by its manufacturer Acclarent Inc., California, USA and was approved by Food and Drug Administration (FDA). This technique is used to widen the natural ostia of the paranasal sinuses by inflating balloon in the occluded ostia with endoscopic assistance and fluoroscopic C- arm guidance, the basic principle of this technique is similar to the technique already being used successfully in fields of urology, gastroenterology, vascular surgery and cardiology [4]. The acute infection of nose and sinuses i.e. acute rhinosinusitis is often treated by use of medicines like antibiotics, decongestants, Steroid nasal sprays and pain killers, while the chronic rhinosinusitis usually requires surgical intervention along with medicinal treatment. The benefits of using the balloon sinuplasty technique include preservation of the important osteo meatal complex unit while simultaneously focusing on the occluded sinus ostium and diseased sinus cavity beyond it [4,6] . Thus effectively avoiding the complications written above associated with FESS.

Table 1 Important indications and contra indications for the BST

Surgical Technique

The set for ballon sinuplasty includes

- i) Catheters with balloons (Picture 1)
- ii) Guide catheters with different angulations (Picture 2)
- iii) Catheters for sinus lavage
- iv) Device coupled to a monometer to inflate the balloons (Picture 3)

The balloons can be inflated with an iodized contrast diluted in water or sterile normal saline (concentration of 150 to 180 mg/ ml). The contrast enables localizing the balloon with fluoroscopy. Desired pressure in balloons can be usually achieved by 6 to 8 ml of contrast. The size of balloons can be from 3mm to 7mm, 5 mm being most commonly used. This procedure is carried out under endoscopic guidance and the endoscopes used are rigid Hopkins rod endoscopes of 0, 30, 45 degree angled views, so under endoscopic guidance a guide catheter is passed close to the sinus ostium, a guide thread is then passed through catheter into the sinus ostium, the balloon catheter is then passed on the guide thread and is positioned accurately in the ostium by using fluoroscopy. Now pressure inside the balloon is increased gradually by the iodized contrast infusion. Normally pressure ranging from 8 to 12 Atm. is sufficient to dilate ostium by causing micro fractures of the bony edges of ostium. After completing the procedure, balloon is emptied and catheter is removed.

2. REVIEW OF LITERATURE

Indications for ballon sinuplasty include – patients not responding to medicinal treatment for chronic rhinosinusitis (i.e. antibiotics, topical corticosteroids, decongestants etc.) are the candidates which should be considered for surgical interventions.

If patients admitted in intensive care units require sinus surgery for sinusitis which may be nidus of infection in the debilitated patient, then BST can play an important role. The benefit here is that BST causes less or minimal bleeding compared to FESS and the patients in ICU are usually on anticoagulants, so BST can be a boon in these patients as it is a minimally invasive approach with low risk of bleeding, requires less time and can be taken up under local anaesthesia thus also avoiding general anaesthesia risks [2,5]. After dilating the ostia samples can be collected for culture or histopathological examination.[2,7]

BST can be a useful tool for patients having high risk of injury to adjacent vital structures like orbital contents as in silent sinus syndrome. BST can be used in combination with FESS. It can be efficiently used for frontal sinus surgeries. Hueman et al, 2008 reported the use of ballon for reducing fractures in the anterior table of frontal sinus [11].

Bolger WE et al [2] reported their experience about the BST in cadavers and found it effective in dilating ostia without inflicting damage to the adjacent important structures.

Brown CL et al [5] found in their study that the sinus easiest to be cannulated was sphenoid followed by frontal and the most difficult was maxillary sinus due to its angulation.

In a study of 115 patients Bolger et al reported improvement on SNOT 20 score system (score of 1 or 2) in 85% patients (41 of 48) at one week, 98% (41 of 42) at 12 weeks and 80% (35 of 44) at 24 weeks [3].

A prospective multi centre CLEAR (clinical evaluation to confirm safety and efficacy of sinuplasty in the para nasal sinuses) study of 115 patients across 9 physician practices reported an impressive safety profile (zero adverse events), durability of patency (98% patency of observed ostia after 6 months) and there was significant improvement in symptoms of the patients and QOL [12].

Raymond Weiss et al, in 2008 reported about their study on long term analysis of BST for a period of 2 years in 65 patients, they found that mean Lund-Mackay CT scores decreased significantly at follow up.[15] A multi centric prospective study conducted in US by Brown, Bolger, Levine and Kuhn demonstrated the safety and efficacy of this technique and reported the reliable outcomes of this technique in a large study group of 115 patients, followed up over a 6 month period .[3]



Picture 3 Device coupled with a monometer to inflate the balloons (courtesy; Acclarent Inc.) [9]

3. DISCUSSION

The balloon sinuplasty technique opens up the blocked sinus ostium with use of flexible balloon catheter, inflated with a calibrated pressure gauge. The optimal inflation of the balloon gently restructures the sinus ostium by inducing micro fractures and bony displacements around the occluded ostium, simultaneously maintaining the integrity of the sinus mucosal lining around the ostium. Thus preserving the normal anatomy of the osteo- meatal complex while focussing on the occluded sinus ostium and the diseased sinus cavity beyond it. [4,6]

BST has been widely performed in various centres as a ‘day care’ procedure. Results show its safety and effectiveness with improved post operative recovery time.

Ideal candidates for this procedure would include, chronic sinusitis limited mostly to ostial obstruction of the frontal, maxillary and sphenoidal sinusitis. This technique is considered inappropriate for patients with sino-nasal polyposis, isolated ethmoidal disease, deformed osteo-meatal anatomy or extensive previous surgery with significant osteoneogenesis. [3,13]

4. CONCLUSION

The emergence of balloon sinuplasty as a new minimally invasive procedure has provided an exciting tool in the closets of rhinologists worldwide. As this technology is gradually evolving, continuous scrutiny is going on among the clinicians about its possible spectrum of indications and contraindication, but overall consensus today is that this technique is the most preferable, effective and ideal way for opening up blocked sinus ostia to re-establish normal anatomical and physiological pathway of sinus drainage. Further researches are going on to combine this technique with standard FESS procedure and image guided sinus surgery systems so that in near future the indications of this technique can expand to include a wider spectrum of sinus diseases.



Picture -1 Catheters with balloons (courtesy; Acclarent Inc.) [9]



Picture- 2 Guide catheters with different angulations

(courtesy; Acclarent Inc.) [9]

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