Review Article: Balloon Sinuplasty

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FESS is nowadays the gold standard surgical treatment for chronic rhinosinusitis not responding to medical treatment. The principal aim behind this surgical procedure was the maximum preservation of the nasal mucosal integrity, while providing optimal disease clearance. One of the recent technical developments in endoscopic sinus surgery is balloon sinuplasty. Balloon sinuplasty is described as a less invasive technique to open the paranasal sinus ostia without injuring the surrounding mucosa, which results in reduced intraoperative bleeding and minimal mucosal damage. The objective of this work is to provide an overview of the procedure and to explain the surgical technique and its indications and limitations and to discuss the results through articles published so far about the subject. Most of the studies show that this surgical procedure is safe, feasible, and effective in selected patients and its advantages include that it is a daily surgery (outpatient basis, can be done under L.A), low time off work, rapid recovery time and it does not limit further treatment options.

Keywords: Functional endoscopic sinus surgery (FESS), balloon sinuplasty, rhinosinusitis.
injuring the surrounding mucosa, which results in reduced intraoperative bleeding and minimal mucosal damage.\(^5\)

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.\(^3\) Its advantages include that it is a daily surgery (outpatient basis, can be done under L.A), low time off work, rapid recovery time and it does not limit further treatment options.

The objective of this work is to provide an overview of the procedure and to explain the surgical technique and its indications and limitations and to discuss the results through articles published so far about this new surgical procedure.

**SURGICAL TECHNIQUE**

The procedure is carried out under partial endoscopic viewing and may be made with local or general anesthesia. Rigid endoscopes of 0\(^o\), 30\(^o\) and 45\(^o\) are used in the procedure. In addition to the catheters with balloons (Fig. 1), there are guide catheters with several angulations (Fig. 2), required to lead the catheters with balloon to the margins of the region to be dilated. The set also includes catheters for sinus lavage and a device coupled to a monometer (Fig. 3) used to inflate the balloons. The balloons are inflated with an iodized contrast diluted in water or sterile saline, in an approximate concentration of 150-180mg/ml. The contrast is used to enable the location of the inflated balloon through fluoroscopy. Generally 6 to 8 ml of contrast are required to achieve the desired pressures. The normal balloon has 5 mm, but there are also with 3 to 7 mm. Generally pressures from 8 to 12/ atm are sufficient for dilation, and the maximum recommended pressure is of 16 atm. Pressures above these increase the risks, for instance, of Agger Nasi cell fracture and of the terminal recess in cases of frontal recess dilation.\(^6\) Recently an optical fiber system used for location of the sinus through dermametropathism. Under endoscopic viewing, the guide-catheter is placed close to the sinusal ostium. A guide thread is passed across the guide-catheter, by fluoroscopy, through the sinus. The balloon catheter is then passed on the guide thread through the sinusal ostium region. After the correct location of the balloon in the sinusal ostium by fluoroscopy, the pressure inside the balloon is gradually increased by the iodized contrast infusion. After dilation, the balloon is gradually emptied and the catheter is removed.\(^15\) Steps in using these devices are shown in (Fig. 4).

![Fig 1. Catheters with balloons for sinusal dilatation of different sizes (Acclarent Inc., Melano Park, CA).](image)
Fig 2. Semi-flexible guide-catheters of several angulations (Acclarent Inc., Melano Park, CA).

Fig 3. Device to inflate balloon (Acclarent Inc., Melano Park, CA).
To gain initial sinus access, the Sinus Guide Catheter is introduced into the target sinus under endoscopic visualization. A flexible Sinus Guidewire is introduced through the Sinus Guide Catheter and gently advanced into the target sinus. The Sinus Balloon Catheter tracks smoothly over the Sinus Guidewire and positioned across the blocked ostium. It is gradually inflated to gently restructure the blocked ostium. The Balloon Sinuplasty™ system is removed, leaving the ostium open and allowing the return of normal sinus drainage and function. There is little to no disruption to mucosal lining.

![Fig 4. Balloon sinuplasty technique (Acclarent Inc., Melano Park, CA).](image)

**INDICATIONS**

The indications for balloon sinus dilation (BSD) treatment for sinus disease are the same as those for standard functional endoscopic sinus surgery (FESS) (Table 1). Like FESS, BSD is intended to allow as permanent as possible access to and ventilation of obstructed sinuses, thereby allowing normal function to resume and ongoing maintenance therapies to be effective.

However, BSD by itself is appropriate for only a subset of patients who qualify for FESS. Since BSD is used solely for dilation of obstructed ostia, its use is limited to the frontal, sphenoid, and maxillary (ie, extranasal) sinuses. BSD may be considered the treatment of choice for limited or moderate disease involving these sinuses. In patients with significant ethmoid disease, BSD can be used as an adjunct to standard ethmoidectomy. BSD is performed either before or after ethmoidectomy, depending upon the preference of the surgeon to preserve normal anatomy for BSD landmark purposes. The ideal patient for BSD would be that with a chronic or acute recurrent rhinosinusitis record, without improvement with the use of antibiotics, topical corticosteroids and/or allergy management. The patients studied in the first works presented with an altered computerized tomography with a Lund-McKay score of (6) < 10 or 12. In addition to its use in patients with chronic rhinosinusitis, this system may also be a good option in those patients at intensive care units, where there is a suspicion of sinusoidal focus resulting in a febrile picture. As these patients are generally anticoagulated and in a critical clinical state, a minimally invasive approach, with low risk of bleeding and short time duration (by the anesthetic risk), would be an excellent option. After the ostium dilation, material collection for culture, and sinus lavage are possible. The sphenoidal ostium, for example, may be easily dilated to an extent of allowing access to a 4mm-endoscope. Patients with coagulopathy may also benefit from less bleeding risk. The use of balloon has other indications of great interest. It may be an alternate for the Silent Sinus Syndrome, in which the uncinctomy, in a fine uncinated and lateralized

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Balloon Sinuplasty

process, represents a risk of lesion of the orbitary contents. Another possible indication would be its use in combination with the functional surgery, especially in the difficult review cases. The cannulation guided by fluoroscopy and dermametropathism may be very helpful in the frontal review surgeries.

Table 1. Main indications and contraindications of the balloon sinuplasty (6,9-11)

<table>
<thead>
<tr>
<th>Main indications</th>
<th>Main contraindications</th>
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<tbody>
<tr>
<td>Chronic rhinosinusitis without improvement with clinical treatment</td>
<td>Significant ethmoidal disease</td>
</tr>
<tr>
<td>Recurrent acute rhinosinusitis</td>
<td>Presence of polyps</td>
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<tr>
<td>ICU febrile patients with sinusal focus</td>
<td>Mucocele</td>
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<tr>
<td>Frontal sinus recess treatment</td>
<td>Allergic fungal rhinosinusitis</td>
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<tr>
<td>Patients with high anesthetic risk</td>
<td>Osseous neoformation signs</td>
</tr>
<tr>
<td>Patients with bleeding risk</td>
<td>Cystic Fibrosis</td>
</tr>
<tr>
<td>Ciliary dysfunction</td>
<td>Nasosinusal Tumor</td>
</tr>
</tbody>
</table>

CONTRAINDICATIONS

Patients with pansinus polyposis, extensive fungal disease, advanced connective tissue disease, or suspected neoplasm should not be considered for BSD as the principal modality (Table 1).

Opacification of a sinus by solid tissue inhibits view and access with the Entellus device, and such disease cannot be cleared with either the Entellus or the Acclarent device. The surgeon must consider that the access to these sinuses afforded by dilation of the native ostium would likely be inadequate for extirpation of disease or for maintenance of drainage postoperatively with topical treatment. BSD is not appropriate for use in patients who require revision surgery or in those with severe disease in which bony thickening or dehiscence of the orbital wall or skull base bone have occurred.

No surgical treatment should be offered in the absence of comprehensive medical treatment, including antibiotics, steroids, nasal hygiene, and liberal use of topical nasal therapies.

RESULT ANALYSIS

Brown CL et al (9) concomitant with ESS, they performed balloon catheterization and dilatation of a total of 18 paranasal sinus ostia as follows: ten maxillary sinuses ostia, five sphenoid ostia, and three dilatation of the frontal recess and concluded that no significant complications were noted, trauma to the mucosa and bleeding much less than that encountered in conventional ESS.

Bolger et al (11) published the results of a prospective multicenter analysis describing a 24-week post-balloon sinuplasty follow-up with regards to complication rates, patency of dilated ostia and post-operative patient symptom outcome (Sino-nasal Outcome Test, SNOT 20). In this follow-up period: Patency as determined by endoscopic examination 80.5% (247/307) of cases, non-patency 1.6% (5/307) of cases and Patency could not be assessed endoscopically 17.9% (55/307) due to anatomical problems but patency could still exist in these cases.

SNOT 20 used for subjective evaluation by patients showed continuously improved trend and revision surgery was required in three sinuses 0.98% (3/307 sinuses) in three patients 2.75% (3/109 patients), no serious adverse events reported (only 9 cases of bacterial sinusitis treated with oral antibiotics). Devices malfunctioned in 12 of 358 applications/sinuses, 7 cases: balloon ruptured, 4 cases: the catheter tip malfunctioned, 1 case balloon device deflated slowly. The median fluoroscopy time per sinus was 0.81 minutes; the average radiation dose per patient was approximately 730 mrem.
The number of days the patients used analgesic medication was also significantly lower in the patients submitted to sinuplasty (0.80 ± 0.72 days) against FESS patients (1.34 ± 0.99 days; p = 0.011).

The expenditures with sinuplasty were of approximately US$ 12,656.57 ± 3,184.08 against US$ 14,471.14 ± 2,743.68 for FESS, and this difference is significant (p = 0.013). The author confirms the sinuplasty and FESS were similar in the postoperative symptoms improvement; however, the sinuplasty obtained a better performance in the patient’s satisfaction and in the postoperative pain.\(^{(15)}\)

LEVINE HL et al\(^{(16)}\) carried out a retrospective study of patients submitted to nasosinusal endoscopic surgery with the use of balloon dilation in 27 American services from December 2005 through May 2007, including a total of 1036 patients. Out of whom, 855 (82.5%) had never been submitted to sinusal surgery and 181 (17.5%) were revisional. A total of 3276 sinuses were treated with balloon dilation. These were followed-up on an average of 40.2 weeks after the procedure. No major adverse event regarding the procedure was reported. The average bleeding was of 77.5ml, and it was of 27.7ml in cases where only balloon was used and 101.6ml in the cases combined with FESS. A total of 2.4% of the patients required revision due to the disease’s recurrence. They represented 1.3% of the sinuses treated by balloon dilation. As far as the symptoms are concerned, 95.5% of the patients had an improvement. They concluded the balloon dilation is safe, effective and improves the quality of life of patients who didn’t have a response to the clinical treatment. ICU patients who have a higher anesthetic risk and present with isolated sphenoidal disease may benefit from the use of balloons, since this provides a fast treatment and with low bleeding risk.\(^{(6,8,10)}\)

As for the frontal recess region, VAUGHAN WC\(^{(4)}\) reports this area surgery may lead to severe complications relating to the cranial base, anterior ethmoidal artery, olfactory mucosa and periorbitary tissues. This region is the one which requires more review due to cicatricial stenosis. The large removal of mucosa, edema, infection and incomplete surgery also lead to the disease’s recurrence. One of the main advantages relating to the use of balloon is its potential to a minimally invasive treatment of the frontal recess. The use of balloon combined to the endoscopic surgical approach may minimize the surgical complications relating to the frontal recess. REHL et al\(^{(17)}\) reviewed a series of patients in whom 136 frontal recesses were treated with balloon dilation. Out of 95 recesses that could be reevaluated, 99% were patent. PAYNE SC et al\(^{(18)}\) reported the frontal recess dilation of 20 patients with chronic rhinosinusitis. In a follow-up of 5 months, they described the absence of complications and the significant tomographic improvement in the Lund-Mackay score. As for the risks, these seem to be low, in spite of the possibility of noble structures lesion, such as the cranial orbit and base. To avoid serious complications in these structures, BOLGER et al\(^{(10)}\) reported we should evaluate the structures carefully as the cranial base for dehiscence and also anatomic variations of the ethmoid roof, such as KEROS’ ranking\(^{(19)}\) type III for instance, therefore, the analysis of the anatomic region of the frontal region on the preoperative CT-scan for existing anatomic variations in each patient is mandatory.\(^{(15)}\) BROWN CL et al\(^{(10)}\) also mention the care we must take in patients with Keros type III. They also recommend caution in patients with osseous neoformation signs, because an attempt to dilate may not be efficient and there’s the risk, in case we use an exaggerated pressure, it is transmitted to adjacent structures such as the cranial base and orbit. We must also take a lot of care during the procedure to avoid postoperative complications, such as the middle infundibulum lateralization and its adherence with the uncinate process.\(^{(6,8,15)}\) LEVINE et al\(^{(10)}\) reported 3 cases of liquoric fistula in patients submitted to balloon dilation. However they related these events to the functional endoscopic surgery that was performed simultaneously to dilation.

As for limitations of balloon sinuplasty in frontal sinus surgery, Helmgartner et al\(^{(20)}\) reported a multicenter study investigated the aetiology of failed access to the frontal sinus, the study analyzed retrospectively the charts of patients who underwent balloon sinuplasty over three years at three different ENT-centers. CT-analysis of the patients with failed access was performed. Of the 104 frontal sinuses, dilatation of 12 (12%) sinuses failed. The anatomy of all failed cases revealed variations in the frontal recess (frontoethmoidal-cell, frontal-bulla-cell or agger-nasi-cell) or osteoneogenesis, and they conclude that in complex anatomical situations of the frontal recess, balloon sinuplasty may be impossible and it is essential in these situations to have knowledge of classical functional endoscopic sinus surgery of the frontal recess area.

Ramadan et al\(^{(21)}\) assess the surgical outcomes in children undergoing sinus balloon catheter dilatation for whom previous adenoidectomy has failed and conclude that balloon dilatation is effective in children for whom previous adenoidectomy has failed, and balloon dilatation may be considered prior to proceeding to functional endoscopic sinus surgery in children with chronic rhinosinusitis.
**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-meatl complex, while precisely focusing on the occluded sinus ostium and the diseased sinus cavity beyond it.\(^9\)\(^{10}\)\(^{23}\)

The safety of balloon dilatation technology has been well established through large registries and cumulative patients experience.\(^9\)\(^{11}\) Although complications have been described,\(^{23}\) it also important to recognize and define the limitations of balloon technology, for example, current publications studied patients with milder symptoms and or radiologic disease but the feasibility of balloon dilatation in severe disease has not been well studied or documented, the inability to remove tissue in balloon only procedures is another potential limitation. For disease such as maxillary sinus fungus ball, balloon dilatation would be contraindicated as alone procedure, in other situations, the lack of tissue removal in balloon-only procedures may lead to a missed diagnosis of neoplasm.\(^{10}\)\(^{20}\) Efficacy has been demonstrated by technical success of cannulating the sinus ostium and completion of the balloon dilatation, the technique is largely successful, with 80% to 97% rates of procedure completion in most series.\(^9\) 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 polyps, isolated ethmoidal disease, deformed osteomeatal anatomy or extensive previous surgery with significant osteoneogenesis.\(^{11}\)\(^{24}\) Some Authors commented that not always possible to cannulate the frontal sinus as the anatomy sometimes prevent the passage of the Guide Wire into the ostium of the frontal sinus. Attachment of Uncinate process- type A-attached to the lateral nasal wall- Easy to cannulate, while Type B-attached to the skull base or middle turbinate-difficult, you have to resect the UP, because of all of this, BS should be done by expert in conventional FESS.\(^{25}\)

Hence, careful case evaluation and selection remains paramount in providing the best outcomes with this technique.

Church et al CA\(^{25}\) and CHANDRA RK\(^{26}\) demonstrated the radiation dosages to which surgeons and patients are exposed during fluoroscopy are very low, but we must take care to minimize such exposure as much as possible. CHANDRA RK\(^{26}\) advises the surgeons to use specific clothes, goggles and cervical protectors against radiation, he also mentioned that the left eye of the patient is more exposed to radiation, because the radiation source is normally located on his left side.

Children who have persistent rhinosinusitis after adenoidectomy are often treated with FESS. FESS has a reliable profile in children, having a low complications rate and a success rate of 75%-88%.\(^{27}\) It is, however, an invasive procedure, and serious complications can occurred include hemorrhage, CSF leakage, and orbital complications.\(^{28}\)

Also, concerns regarding facial growth persist despite negative findings in photographic and radiographic studies in humans.\(^{29}\) Balloon dilatation is effective in children for whom previous adenoidectomy has failed, and balloon dilatation may be considered prior to proceeding to functional endoscopic sinus surgery in children with chronic rhinosinusitis.\(^{20}\)

What will be the future of Balloon Sinuplasty? Feasible, safe in selected cases but re-usable catheter and balloon will encourage further extend of its use (cost factor). Possible further usage in rhinology in the future includes fractures of anterior wall of frontal sinus, recurrent choanal atresia, etc.

**FINAL COMMENTS**

The Balloon Sinuplasty seems to be a feasible, safe and well tolerated procedure, and in properly selected patients, balloon dilatation appears to lead to clinical improvement. It is also important to recognize and define the limitations of balloon technology. Studies to confirm its cost in the Middle East and Arab countries are still necessary to evaluate its economic feasibility. The feasibility of balloon dilatation in severe disease has not been well studied or documented.

**REFERENCES**


