

**Literature Review****Balloon sinuplasty versus surgical therapy for chronic rhinosinusitis****Felicia Halim\*, Budi Sutikno\*\***

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**ABSTRACT**

**Background:** An inflammation of the nose and paranasal sinuses is known as rhinosinusitis, and should it persist for 12 weeks or longer, it becomes chronic rhinosinusitis (CRS). Compared to medical therapy, balloon dilatation has been shown to produce statistically significant improvements in symptoms, quality of life, nasal endoscopy scores, and Computed Tomography Paranasal Sinuses (CT-PNS) scores. The outcomes are comparable to those of Functional Endoscopic Sinus Surgery (FESS). Furthermore, it was discovered to be a method that was both safe and bearable. **Purpose:** To ascertain the role of balloon dilatation in the management of CRS, by comparing the result of Balloon Sinuplasty versus Functional Endoscopic Sinus Surgery. **Literature review:** A search of Google Scholar over the last 10 years found 375 results, and 14 could used as reference sources. **Conclusion:** Balloon sinuplasty is a useful method to overcome CRS. Balloon sinuplasty is minimally invasive, avoiding more aggressive and drastic procedures, for cases that are severe and unresponsive to medical treatment.

**Keywords:** chronic rhinosinusitis, functional endoscopic sinus surgery, balloon sinuplasty, balloon catheter dilatation, endoscopic sinus surgery

**ABSTRAK**

**Latar belakang:** Proses peradangan pada sinus paranasal dan hidung dikenal sebagai rinosinusitis, dan jika berlangsung selama lebih dari 12 minggu, disebut sebagai rinosinusitis kronis (RSK). Dibandingkan dengan terapi medis, dilatasi balon telah terbukti menghasilkan perbaikan yang signifikan secara statistik pada gejala, kualitas hidup, skor endoskopi nasal, dan skor Computed Tomography Scan of the Paranasal Sinuses (CT-PNS). Hasilnya sebanding dengan Bedah Sinus Endoskopi Fungsional (BSEF). Selain itu, metode ini didapati aman dan dapat ditoleransi. **Tujuan:** Untuk mengetahui peran metode bedah dilatasi balon dalam penatalaksanaan RSK, dengan membandingkan Sinuplasti Balon (SPB) dengan BSEF. **Tinjauan pustaka:** Penelusuran Google Scholar selama 10 tahun terakhir berdasarkan kata kunci, ditemukan 375 artikel dan 14 di antaranya dapat digunakan sebagai sumber referensi dalam artikel ini. **Kesimpulan:** Sinuplasti balon adalah cara yang bermanfaat untuk mengatasi RSK, oleh karena SPB tidak invasif, menghindari prosedur yang lebih agresif dan drastis, untuk penatalaksanaan kasus RSK yang berat dan tidak membaik dengan terapi medikamentosa.

**Kata kunci:** rinosinusitis kronik, bedah sinus endoskopi fungsional, sinuplasti balon, pelebaran balon, bedah sinus endoskopi

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## INTRODUCTION

An inflammation of the paranasal sinuses and nose is known as rhinosinusitis. Rhinosinusitis was classified by the Rhinosinusitis Task Force (RSTF) in 2007. Acute rhinosinusitis (ARS) has symptoms that go away completely after four weeks or less. Subacute rhinosinusitis progresses in 4–12 weeks. Chronic rhinosinusitis (CRS) is characterized by symptoms that persist for more than 12 weeks, without complete resolution. Recurrent ARS has at least four episodes annually, with a full recovery period between episodes, lasting at least seven to ten days. Acute aggravation of CRS: abrupt deterioration of baseline CRS, followed by a return to baseline upon therapy.<sup>1,2</sup> It has two or more symptoms, such as a nasal blockage, obstruction, congestion, or nasal discharge (anterior/posterior), with the addition of pressure (or pain) in the face and/or anosmia/hyposmia.<sup>1-3</sup>

CRS has various causes, which include environmental factors (such as allergens, viruses, bacteria, biofilms, fungi, and pollution); local host factors (like ongoing localized osteomeatal complex (OMC) inflammation, tumors, dental issues, and structural irregularities); general host factors (including immune deficiencies, genetic predispositions or disorders, primary or acquired ciliary dysfunction, and granulomatous conditions).<sup>1,3</sup>

CRS can present with or without nasal polyps. CRS without polyps comes from bacteria, some of which have been identified. Acute rhinosinusitis and CRS have distinct bacteriologies. *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, and *Escherichia coli*, are among the organisms detected in CRS. There are also aerobic bacteria. As a result, bacteriology is diverse and multimicrobial. Acute rhinosinusitis is frequently followed by this condition, in which the bacteria have developed resistance as a result of insufficient

antibiotic treatment in terms of dosage and time. Additionally, there are predisposing variables that either start or accelerate the disease's progression.<sup>1,2</sup>

Primary ciliary dyskinesia, cystic fibrosis, the Samter triad (aspirin sensitivity, nasal polyps, and asthma), asthma 7% of patients with asthma have polyps), Churg Strauss syndrome (asthma, peripheral eosinophilia, pulmonary infiltrates, and systemic eosinophilic vasculitis), and allergic fungal sinusitis are among the infectious processes or systemic disorders, that can cause polyp formation in the nose and sinuses. The symptoms are comparable to those of CRS without polyps, but a nose inspection reveals several nasal polyps. Ethmoidal polyps can grow to such a size that they reach to the anterior cerebral fossa or erode into the orbit. There may be sinuses full of purulent discharge and an additional infection.<sup>1,2</sup>

Corticosteroids, antibiotics, decongestants, anti-allergy medications, and saline irrigations are all part of the medical care of CRS. In some cases, surgical intervention is also required.<sup>1,3</sup>

This study aimed to determine the role of balloon dilatation surgery should play in the management of CRS, by comparing Balloon Sinuplasty versus Functional Endoscopic Sinus Surgery.

## LITERATURE REVIEW

Treatment for CRS primarily is medicamentous, but quite often has to be supported by surgical intervention.

### *Medicamentous treatment*

#### Corticosteroids

Corticosteroids, commonly administered as nasal sprays or nasal drops such as mometasone, fluticasone, or beclomethasone. They are effective in chronic rhinosinusitis (CRS) by reducing eosinophil-mediated inflammation. In daily use, symptom relief

is typically appearing after seven days; and they are generally safe for long-term intranasal treatment, despite possible side effects like dryness, crusting, and epistaxis. Systemic corticosteroids are usually avoided in CRS without nasal polyps, due to the risk of serious long-term complications.<sup>1,3</sup>

### **Antibiotics**

For CRS, antibiotics are a crucial therapy option that can be given either short-term or long-term. Short-course (less than four weeks) antibiotics, which include broad-spectrum medications like doxycycline, amoxicillin/clavulanic acid, cephalosporins, and macrolides, are typically used for acute infectious exacerbations. In addition to any antimicrobial effects, there is evidence that long-term antibiotic use may affect the inflammatory response in CRS. The most often used macrolide antibiotics are clarithromycin and azithromycin, however, doxycycline is an alternate formulation. When saline irrigation and nasal steroid spray treatment are ineffective in controlling symptoms, long-term antibiotics should be considered for CRS.<sup>2,3</sup>

### **Saline nasal irrigation**

Saline nasal irrigation has become increasingly popular as a therapy for chronic rhinosinusitis (CRS) in recent times. Consistent use of saline irrigation may alleviate symptoms, potentially by clearing out pus-filled secretions. This treatment is generally well-accepted and has only a few side effects.<sup>2,3</sup>

### **Topical decongestants**

Topical decongestants help alleviate nasal blockage and allow the sinus openings to become clear. It is recommended to use them shortly before a steroid spray, enabling the spray to access all areas that have been decongested.<sup>2</sup>

### **Anti-allergy treatment**

Patients who are allergic, benefit by the use of antihistamines and leukotriene receptor antagonists (such as montelukast). Antihistamines thicken the mucus. Montelukast is authorized for the treatment of inhalant allergies. Antileukotriene treatment is typically well-accepted, with the most frequent side effects being headaches and digestive discomfort.<sup>2,3</sup>

### **Surgical treatment**

Endoscopic sinus surgery (ESS) is reserved for a small subset of chronic rhinosinusitis (CRS) patients unresponsive to medical therapy, and is particularly beneficial in cases with anatomical abnormalities, massive polyposis, suspected fungal infections, or mucocoeles, as it helps restore sinus drainage, improve symptoms, facilitate topical corticosteroid delivery. ESS must be followed by ongoing medical management to ensure long-term success.<sup>1-3</sup>

### **Functional endoscopic sinus surgery**

Functional endoscopic sinus surgery (FESS) is only used for patients with problems, or when medication therapy has failed. FESS improves mucosal clearance by widening the sinus drainage channels. The term “functional” highlights how the natural anatomic drainage channels maintain normal mucosal clearance.<sup>4,5</sup>

### **Uncinectomy**

Sometimes the first step in FESS is uncinectomy. Uncinectomy can be performed without intermediate steps, if the uncinate process is visible without contacting the central turbinate. The Freer elevator's curved part is used to carefully perform medialization to reduce mucosal irritation, and the risk of breaking the central turbinate.

The uncinectomy can then be performed by making an incision with a sickle knife, or the pointed end of a Freer elevator. Since the anterior portion of the uncinate process is softer than the more rigid lacrimal bone, which contains the nasolacrimal duct, the incision should be performed there. Blakesley forceps are then used to remove the free uncinate edge.<sup>5,6</sup>

### **Antrostomy and ethmoidectomy**

After the uncinate process has been removed, the natural ostium of the maxillary sinus can be found. At this stage, the lamina papyracea can be palpated to confirm its positioning over the protected eye and to check for dehiscence. The ostium is normally positioned at the level of the inferior edge of the middle turbinate, one-third of the way back. A cutting tool is used to widen the natural ostium radially. Although the ideal diameter for a maxillary antrostomy is debatable, 1 cm is typically enough for proper outflow and office postoperative surveillance. At all costs, refrain from puncturing the papyraceous lamina.<sup>5,6</sup>

### **Anterior ethmoidectomy**

Anterior ethmoidectomy involves identifying and opening the ethmoid bulla—typically using a J-shaped curette to access the inner and medial walls—followed by removal of the bony components with a microdebrider or true-cutting forceps, and complete excision of the lateral bulla. It enhances visibility and allows for more precise posterior dissection, while careful preservation of the lateral lamina papyracea remains essential throughout the procedure.

The remaining anterior ethmoid cells can be uncapped using a J curette; the cells can be further opened with a microdebrider or true cutting forceps. A curette can be used to feel the bone, measure its thickness, and make sure it is oriented correctly before further opening

of cells with powered devices. Improved postoperative results are the result of mucosal preservation. Every effort must be made to reduce mucosal stripping.

The surgeon must carry out meticulously as they approach the ethmoid roof and guided by the endoscopic imaging and the preoperative CT scan, to clear the anterior ethmoid cells up to the skull base. A thorough understanding of the human body cannot be replaced by image-guided or computer-assisted surgery, although it can help surgeons determine the distance to the base of the skull.

When moving posteriorly to the next air cells, the surgeon should always enter inferiorly and medially. After determining the utmost distal anatomy by feeling and sight, the surgeon should next open laterally and superiorly. The anterior ethmoidectomy is completed when the middle turbinate's basal lamella is reached.<sup>5,6</sup>

### **Posterior ethmoidectomy**

Posterior ethmoidectomy begins by perforating the basal lamella just superior and lateral to the junction of the vertical and horizontal segments of the middle turbinate, with careful preservation of the posterior sagittal part of the turbinate and the inferior coronal portion of the basal lamella—forming an essential L-shaped strut for turbinate stability—after which the superior and lateral portions of the lamella can be safely removed using a microdebrider.

By using a similar technique and being mindful of the location of the lamina and skull base, additional posterior ethmoid cells can be removed. The surgeon must understand that the base of the skull often slopes downward at an angle of about 30° from front to back. This indicates that the base of the skull is oriented more dorsally than frontally. For this dissection, the sphenoid is reviewed.<sup>5,6</sup>



## Balloon sinuplasty

Balloon Sinuplasty or Balloon Catheter Dilatation (BCD) is a relatively recent procedure for treating chronic rhinosinusitis that is based on the success of minimally invasive balloon dilatation technologies in other surgical specialties. This idea was initially presented by Lanza in 1993, and the US Food and Drug Administration authorized it as a less intrusive therapy option for chronic rhinosinusitis in 2005.

Over the past ten years, balloon sinuplasty has been the subject of a thorough examination. The idea behind balloon sinuplasty is to expand the ostium without cutting away any tissue or bone. The guide wire is inserted into the maxillary sinus, and the location is confirmed using a fluoroscopy or transillumination technique. The guide wire is used to lead the balloon catheter into the ostium, where it is inflated to 8–12 bars for a brief period. This widens the entrance to the obstructed sinus and makes it easier for the mucus to drain. The procedure's drawbacks include its technical limits in the ethmoidal area or in the removal of atypical mucosa, the expensive cost of disposable instruments, and the lack of knowledge regarding its long-term effects. According to several controlled and uncontrolled investigations, balloon sinuplasty is a safe and efficient technique. These studies are limited, nevertheless, by the variability of patients and procedures as well as the small follow-up period, which makes it challenging to draw conclusions.<sup>4,7</sup>

## DISCUSSION

Although there have been numerous studies since the Federal Drug Administration (FDA)'s clearance in 2005, including control trials and long-term follow-up data, with positive outcomes, balloon sinuplasty has continued to be the subject of contentious discussions. Since it was shown that 53% of patients had underlying inflammation,

rhinologists have not supported the idea of opening the ostia by mucosal and bony compression as opposed to removing the diseased bone and mucus lining. Most surgeons are still concerned about the recurrence of inflammation.<sup>4,8</sup>

However, according to the research, FESS does not eliminate all the inflammatory tissue, which feeds the argument even more.<sup>4,8</sup> The revision rate of balloon sinuplasty versus FESS is another hotly debated topic based on the previously indicated point of contention. The Royal College of Surgeons of England included 3128 patients who had FESS in a prospective nationwide assessment of sinus operations. The rate of serious complications was minimal, occurring in only 0.4% of cases, which was consistent with the literature; 6.6% experienced minor problems, including adhesions, stenosis, surgical infection, and significant preoperative bleeding. According to published research, the revision rate of FESS varies between 2% and 24%, and revision procedures are associated with noticeably greater failure and complication rates. One issue is that balloon dilatation is changing at a much faster rate. Large trials have not examined revision rates; however, the REMODEL (randomized evaluation) study of maxillary antrostomy versus ostial dilation efficacy through long term follow up assessed revision rates at 18 months, albeit with a limited sample size. The results showed that the revision rates were 2.7% for balloon sinuplasty and 6.9% for FESS arms, but they were not statistically significant.<sup>4,8</sup> In a different study of 65 patients, Weiss et al, cited by Dsouza R et al.<sup>4</sup> discovered that 3.6% of the total number of sinuses dilated—or 9.2% of the patient pool—required revision balloon dilatation.

The group of individuals with chronic rhinosinusitis for whom balloon sinuplasty is appropriate is another topic of discussion. When disease clearance is crucial, such as in cases of neoplasia, fungal sinusitis, or

nasal polyposis, balloon dilatation cannot be utilized as a stand-alone operation. Patients with unilateral or bilateral maxillary, frontal, or sphenoidal sinusitis that is not improving with medical treatment are typically included in research. Other than the previously listed conditions, the exclusion criteria included nasal trauma, ciliary dysmotility syndrome, isolated ethmoidal sinus or infundibular illness, deformed osteomeatal anatomy, prior sinonasal surgery, and cystic fibrosis.<sup>4</sup> Despite the fact that most people consider balloon sinuplasty to be a stand-alone technique that can be utilized in place of FESS, few studies have combined balloon dilation and FESS in a hybrid approach. For the frontal recess, which has a comparatively high risk of stenosis, this is very helpful.<sup>4,9</sup>

Compared to medical therapy, balloon dilation has been shown to produce statistically significant improvements in symptoms, quality of life, nasal endoscopy scores, and Computed Tomography Paranasal Sinuses (CT-PNS) scores. The outcomes are comparable to those of FESS. Furthermore, it was discovered to be a method that was both safe and bearable. In the United States, the number of balloon sinuplasty procedures per 10,000 beneficiaries rose by 3.7% yearly between 2000 and 2014 and by 59% annually between 2011 and 2014.<sup>4,8</sup> Since the technology was first used in the subcontinent in the 2000s, the number of procedures in India has also increased. Even though the number of treatments performed has significantly increased in both India and the West, one of the main barriers to their acceptance was determined to be their expense.<sup>4,9</sup> According to Bizaki et al.<sup>7</sup>, balloon sinuplasty's higher material cost relative to FESS resulted in a lower uptake rate. The authors discussed the necessity of increasing cost savings through in-office treatments or lowering material costs to increase surgeons' acceptance of their practice.<sup>4,10,11</sup>

In their one-year follow-up study, Bikhazi et al.<sup>7</sup> reported no difference in the exacerbation rate between the balloon and Endoscopic Sinus Surgery (ESS) groups. The ESS group underwent no revision surgeries throughout the 6-year follow-up period after surgery, while the balloon sinuplasty group underwent four revisions (14%). This result was statistically significant and may suggest that balloon sinuplasty is not the best option for achieving maxillary sinus ostium patency following ESS. Surgeons other than the one who performed the balloon sinuplasty made the revisions in the balloon group, which may have influenced the surgical choice. According to our research, even seven years after the procedure, balloon sinuplasty maintains its effectiveness and patient satisfaction on par with ESS (Endoscopic Sinus Surgery). There were only slight variations amongst the methods, most likely having no clinical relevance.<sup>7,12</sup>

As previously stated, it is evident that using BCD to dilate the sinus ostia or their outflow pathways may improve mucosal preservation, lessen local damage, and restore sinus patency. The idea of BCD utilization in the frontal sinus includes microfracturing and remodeling the bone in the frontal recess. This enhanced mucosal and bone patency may be sufficient to traumatizingly restore the sinuses' ability to drain. Re-dilation or advanced endoscopic conventional surgery are two options for additional intervention in addition for the frontal sinuses that did not exhibit clinical and radiological recovery.<sup>10,12</sup>

With numerous indications currently documented and reviews concluding that indications are no different from those for performing traditional ESS, there is a wealth of evidence regarding the utility, efficacy, and safety of BCD as a potentially helpful technique that surgeons can use to treat all cases of CRS (even in frontal sinuses), in addition to classical endoscopic surgery.<sup>10,13</sup>

However, due to the many anatomical differences of the frontal recess and the uncommon practice of obtaining a sample for histopathological analysis during the balloon-alone procedure, some writers believe that BCD is a technique that should only be utilized in a limited number of instances.<sup>10</sup>

Additionally, BCD may be useful in the treatment of critically ill and immunocompromised patients with acute rhinosinusitis for potentially dangerous complications, or in the setting of anatomic variants like obstructing type III or IV frontal cells that are less accessible to current endoscopic instrumentation.<sup>10</sup> The fact that the equipment used in BCD cannot be reused between patients could be a disadvantage, and the expense of the disposable equipment could raise the procedure's overall cost.<sup>7,10</sup>

Furthermore, as the purpose of treatment in these circumstances is to remove edematous, inflamed mucosa, patients with significant mucosal illness, such as polyps, are typically not candidates for the current generation of catheters. Other authors confirmed that BCD is contraindicated and that traditional ESS is required in individuals with severe illness, polyps or fungal debris, mucocoele, cystic fibrosis, or face traumas that alter the sinus structure.<sup>10,14</sup>

As we can see, the function of BCD is yet unknown, and more research is required to fully assess its effects in particular patient groups, such as those with nasal polyposis, prior ESS, and moderate to severe sinus disease.<sup>10,14</sup>

Based on radiological results at Lund-MacKay modified by Zinreich score, Minni et al.<sup>10</sup> separated the afflicted population into two groups: one with light/mild frontal CRS and the other with moderate/severe frontal CRS. Each group was split up into two smaller groups, one of which underwent standard surgery and the other BCD. Using the Lund-Mackay modified by Zinreich score,

the results demonstrated that there was no statistically significant difference between BCD and traditional ESS of the frontal sinus at one year-control in patients with light/mild CRS ( $p>0.05$ ) and in patients with moderate/severe CRS ( $p>0.05$ ). Comparing the SNOT-20 questionnaire results at one year of control in the group with light/mild frontal chronic rhinosinusitis revealed the same non-statistically significant difference ( $p>0.05$ ).<sup>10</sup>

The assessment of SNOT-20 in patients with moderate to severe chronic rhinosinusitis of the frontal sinus after a year of follow-up yielded an intriguing result instead; that patients treated with BCD had a statistically significant higher SNOT-20 score than those treated with conventional endoscopic sinus surgery ( $p<0.05$ ). Additionally, in both groups (light/mild and moderate/severe CRS), the rate of patency of frontal ostia at the endoscopic examination was statistically comparable between patients treated with a balloon and those treated with standard surgery at the one-year follow-up ( $p>0.05$ ). In light/mild disease and moderate/severe disease, the rate of complications appeared to be the same for both BCD and traditional surgery ( $p>0.05$ ), indicating that the two approaches are similar. Furthermore, the two methods were found had the same rate of surgical failure ( $p>0.05$ ), and these instances required more drastic surgery.<sup>10</sup>

In conclusion, Balloon Sinuplasty is a safe, minimally invasive alternative to FESS for selected cases of chronic rhinosinusitis, offering comparable outcomes in symptom relief and sinus patency. While not suitable for severe disease, polyposis, or fungal infections, it can be an effective option in mild to moderate cases. High costs and unclear long-term revision rates remain as matter of concerns, but with proper patient selection, BCD serves as a valuable tool alongside traditional endoscopic surgery.

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