Journal of Allergy & Therapy
ISSN: 2155-6121
OPEN ACCESS Freely available online
Review Article

Balloon Catheter Sinusotomy- Review of Literature

Abhijit Kumar[*1], **Ajay Gupta**[1], **Nibha N Kumar**[2]

[1]*Department of ENT and Head Neck Surgery, Tata Main Hospital, Bistupur, Jamshedpur, Jharkhand, India*

[2]*Department of ENT, Rajendra Institute of Medical Sciences, Ranchi, Jharkhand, India*

Abstract

Chronic rhinosinusitis affects millions of people every year with significant health and economic impact (1). With advances in technology in the last couple of decades, sinus surgeries have evolved from the days of open surgeries to endoscopic surgeries. Despite these advances, problems such as bleeding, orbital or intracranial complications and cicatrisation still occur (2). Introduced in 2006, Balloon catheter sinusotomy (BCS) is considered as a tool used in endoscopic sinus (3). These are a suite of small, flexible tools that enable surgery whose role continues to evolve surgeons to endoscopically create an opening in a patient's blocked or significantly narrowed sinus ostia and transition spaces while maximizing tissue preservation and minimizing iatrogenic mucosal injury (4). Its ability to preserve mucosa has received a lot of attention3. There is an increasing body of evidence supporting its excellent safety profile. But evidence is insufficient with regard to its indications, efficacy and long-term outcome. We attempt a review of literature to assess the current applications of BCS in otolaryngology.

Keywords: Sinusotomy; Otolaryngology;Endoscopy.

History

Balloon catheter technology has been around and is being successfully used in cardiology, urology, gastroenterology, and vascular surgery. The concept and development of balloon sinus catheter is being credited to Jashua Makower in 2004. The first available information about the use of BCS comes from the minutes of Annual Meeting of American Rhinologic Society in September 2006. Friedman et al and Wynn et al presented their papers on the use of BCS in Functional endoscopic sinus surgery (FESS) and observed that they were safe to use with reduced postoperative recovery time and higher patient satisfaction. Brown et al were the first to publish their findings in the Annals of otology, rhinology and laryngology in April 2006 (4). They conducted a non-randomized prospective study in which 10 patients requiring ESS were offered this technique with favourable results. The largest non-randomized study reported till date is a multicentre analysis of data by Levine et al. (5) They collected data from 1036 patients from various centres over a period of 18 months. Although multiple studies have been published in the following years there is a need for a large randomized control trial to provide level I evidence about the use of this technique since nonrandomized trials are known to suffer from various biases.

Indications

BCS has been developed as a tool to aid FESS. Bolger et al (2) suggested it in patients who were 18 years or older, with a diagnosis of chronic rhinosinusitis (CRS) unresponsive to medical management and planned endoscopic sinus surgery. BCS was not offered in patients with extensive sinonasal polyps, extensive previous sinonasal surgery, extensive sinonasal osteoneogenesis, cystic fibrosis, sinonasal tumors, history of facial trauma that distorted sinus anatomy, ciliary dysfunction, and pregnancy. Nogueira et al (6) selected patients with chronic sinusitis without nasal polyposis. They also included patients with allergic rhinitis. Weiss et al included all patients who underwent BCS and were followed up for 2 years. The inclusion criterion was all patients with chronic sinusitis who had failed medical management. Brown et al (4) had similar inclusion criterion however they excluded patients who underwent previous FESS. For a brief while these were considered the standard indications for BCS. In 2009, Ramadan et al (8) published his paper on the application of BCS in children in the age group of 2 to 11 years. He concluded that since there is no bone or tissue removal the procedure is suitable for use in children. A hypoplastic sinus was considered a contraindication to use of this technique.

Wittkopf et al (9) was the first to publish a series where he used BCS in immunocompromised and critically ill patients with acute rhinosinusitis (ARS). The results were favorable and they concluded that since BCS is less invasive than standard surgical procedures it may be considered in this group of patients. Hopkins et al (10)

Correspondence to: Abhijit Kumar, Department of ENT and Head Neck Surgery, Tata Main Hospital, Bistupur, Jamshedpur, Jharkhand, India, Tel: +91-9645018334; E-mail: drak30@gmail.com

Received: July 06, 2020; **Accepted date:** July 13, 2020; **Published date:** July 20, 2020

Citation: Kumar A (2020) Balloon Catheter Sinusotomy- Review of Literature. J Allergy Ther. 11: 296.

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introduced the procedure in the management of ARS in normal healthy adults. With the evolution of this technique surgeons all over are reporting newer (11) indications like reformation of concha bullosa with indications for this technique which includes antral lavage crushing technique (12), reduction of frontal sinus fractures (13) and ethmoid sinusitis (14). It's an evolving area of interest and with time the uses will be extended in other areas as well.

Age group

BCS was at first offered for adult patients above 18 years of age (2). The age range of patients in Bolger et al series was 21-76 years and mean age was 47.8. In the Nogueira et al varied between 7 and 58 years and mean age was 28.6 years. In the Ramadan et al (8) series the age range was 2 to 11 years. After a detailed review of literature, it can be deduced that BCS can be safely carried out in any patient older than 2 years of age. The use of BCS in children below 2 years of age has not been reported yet.

Role of radiology and SNOT scores in assessment and follow up

Although the primary diagnosis of CRS is based on symptom and signs, CT scan findings are an important component of severity staging systems for CRS (15). There are several staging systems for CRS based on the CT scan. In 1991, Kennedy et al were the first to propose the need for staging systems in the evaluation of the extent of sinonasal disease, as well as the outcome of (16). Lund et al (17) reported the Lund and Mackay staging system in 1997 and is currently recommended by the American academy of otolaryngology. Several authors have included this staging system in their study so that the reader can gain insight into the radiographic profile of the study population (2).

Weiss et al (7) in their study compared the preoperative and post op scores. They found that mean Lund-MacKay CT scores decreased significantly, from 9.66 preoperatively to 2.69 postoperatively at two years ($p<0.001$). CT scores decreased in the balloon-only group from 5.67 preoperative to 1.75 at two years postoperative ($p< 0.015$). The corresponding decline in the hybrid group (combined BCS and ESS) was from 12.05 preoperative to 3.25 at two years postoperative ($p< 0.001$). Bolger et al in their study found the mean score as 8.33 (range 1-21). Those patients selected for BCS only showed a mean score of 6.1 (range 1-17) and the hybrid group had a mean score of 10.4 (range 1-21). They did not provide any postoperative scores18. Ramadan et al reported a mean preoperative score of 7.5. It was observed that the CT scores in cases undergoing BCS only were in general lower than average. This is because of the fact that Lund-Mackay system was devised keeping the ethmoids as a focal point and higher scores were given for them. Since BCS is not done for ethmoid sinuses the scores can be misleading. Hence a combination of pre and post-operative scoring may be more useful for assessment.

Sino nasal outcome test (SNOT 20) is a validated quality of life questionnaire in CRS (19). Most authors have used SNOT 20 to assess pre and post-operative symptomatic improvement. Bolger et al reported a pre-op value of 2.09 in BCS patients and 2.27 in hybrids. The 24 weeks follow up values of BCS was 1.07 ($p< 0.0001$) and hybrid was 0.92($p< 0.0001$). 1 year follow up values were BCS 0.99 and hybrid 0.68. 2 years follow up values for BCS was 1.09 and hybrid was 0.64. Weiss et al (7) reported a preop score of 2.18 and two years postop score of 0.87 ($p=0.001$). The SNOT results in these studies have been clinically and statistically significant (2, 7, 20). Although individually results of endoscopic sinus surgery in patients with CRS may be related to the Lund-Mackay CT score system (22), there appears to be a lack of correlation between SNOT 20 and CT scores (15,22). Bhattacharyya et al. compared SNOT-20 and CT-scan with respect to the severity of mucosal thickening. The authors found no significant correlation between various severity score measures in CT and SNOT-20. In fact, they found that patients with significant facial pain symptoms had lower mean CT severity scores (15). However, Moghaddasi et al (23) found facial pain symptoms had lower mean CT severity scores correlation study between Lund-Mackay score and SNOT 20. They concluded that the outcome of FESS in patients with CRS is moderately related to primary symptoms according to SNOT-20 as well as the Lund-Mackay score.

Technique

The Patients are prepared for surgery in the same way as for endoscopic sinus surgery procedure is performed under C-arm fluoroscopic guidance. The guide catheter is introduced into the nasal cavity under endoscopic visualization and placed adjacent to the obstructed maxillary, sphenoid, or frontal ostium/recess. Thereafter, the sinus ostium is catheterized and dilated under fluoroscopic control with the use of a 5-, 6-, or 7-mm balloon catheter. If indicated, the sinus is irrigated with the use of a sinus lavage catheter. Cases where cannulation fails, or ostial dilation is inadequate can be treated with a standard endoscopic procedure. Brown et al (4) based on the ease of dilations, rated sphenoid followed by frontal followed by maxillary sinus, as the easiest to dilate. In 50% of their patients they observed some difficulty in cannulation of maxillary sinus. They felt it to be due to lack of removal of uncinate and ethmoid air cells. Bolger et al (2) reported a successful cannulation and dilation in 94.8% patients. In 5.2% patients' cannulation failed. In 4.3% patients they reported inadequate dilation and so it was further dilated with standard technique. Ramadan et al reported a successful cannulation rate of 91%. The commonest reasons for technical failure to cannulate were previous surgery, anatomic restrictions in sinuses, polypoid mucosal edema, hypoplastic sinus especially maxillary and frontal sinus (2,8). Therefore, it can be inferred that BCS can't be used for all cases of sinusitis. Its potential use is limited to ostial obstruction of the frontal, sphenoid or maxillary sinuses but not ethmoid sinus disease which is usually associated with chronic sinusitis and requires surgical intervention (2,24).

Complications

Tomazic et al (25) reported first major complication of BCS in 2010. They reported a case of right sided CSF rhinorrhea post BCS for right frontal sinusitis in a 36-year-old female. It had gone unnoticed initially and patient presented with symptoms 3 weeks post op. Noguiera et al (6) reported one case of immediate post-operative bleeding which was easily controlled. Most authors reported excellent tolerance, good mucosal preservation, minimal bleeding and less postoperative care (2-5). It can be concluded that BCS is safe but can lead to complications in inexperienced hands.

Radiation dose

BCS requires use of fluoroscopy and despite all the precautions a small risk remains since the lens, skull base and brain are so closely related to the sinuses. Bolger et al observed the median fluoroscopy time per sinus as 0.81 minutes and the average

radiation dose per patient as 730 mrem. Chandra (26) reported a study on radiation dose to the eye during BCS. They observed that mean exposure was 0.041 in the right eye and 0.284 in the left eye mGy/sec (P=0.037). The higher dose to the left eye was because it is closer to the radiation source during the lateral projections. The average radiation dose of 730 mrem is comparable to head CT scan (200mrem), chest CT (800 mrem), and angioplasty (750-5700 mrem) (2). The threshold for lenticular opacity has been estimated as 500mGy, which would occur in the left eye after approximately 29 minutes of fluoroscopy (26).

With adequate precautions the exposure to the patients can be reduced significantly but further study needs to be conducted to assess the effects of cumulative exposure to surgeons. Recently, Zeiders et al (27) reported the use of luma transillumination wire as an alternative to the use of fluoroscopy in BCS.

Recurrent cases

Bolger et al (2) found that revision treatment was required in 3 sinuses (0.98%) in 3 patients (2.75%). Weiss et al observed revision treatment was required in 3.6% sinuses and 9.2% (14) observed a revision surgery rate of 6.6%. Levine et al observed the rate patients. Kutluhan et al to be 1.3%. The mean revision rate from above studies comes to 3.2%. It is reported that18-25% (28,29). Currently it can be surmised that the incorporation of minimally invasive BCS at least does not increase, and may even decrease, the revision rates for endoscopic sinus surgery (7) in the future.

Recovery and cost

Friedman et al presented a paper comparing the cost of FESS with BCS. They observed that during primary surgery, FESS costs $ 13,574 and BCS costs $ 14,021 (p=0.55) and during revision surgery, FESS costs $ 16,190 and BCS costs $ 10, 346(p<0.0001). Hence the costs are comparable. They reported that procedure was well tolerated by most patients and the requirement for narcotic medication for FESS was 1.34 days and BCS was 0.8 days (p=0.011). Hence the patients were discharged earlier and recovery was faster. They also reported a lesser requirement for postop debridement, epistaxis and greater patient satisfaction.

Conclusions

BCS is minimally invasive surgical treatment option in acute and chronic rhinosinusitis. Available literature shows excellent safety profile and results in both children as well as adults are encouraging. Like any new surgical tool, surgeons all over are exploring and reporting hitherto unknown uses of this technology. Elderly, immune compromised and high risks patients who are otherwise unfit for any other procedure have been offered BCS with quick recovery and minimal additional morbidity. Most authors with large series are experienced endoscopic surgeons and therefore reported few technical errors. We feel the need of the hour is a randomized control trial comparing ESS with BCS in patients with similar CRS disease status.

REFERENCES

1. Kim E, Cutler JL. Balloon Dilatation of the Paranasal Sinuses: A Tool in Sinus Surgery. Otolaryngol Clin North Am. 2009; 42(5): 847-856.
2. Bolger WE, Brown CL, Church CA, Goldberg AN, Karanfilov B, Kuhn FA et al. Safety and outcomes of balloon catheter sinusotomy: a multicenter 24-week analysis in 115 patients. Otolaryngol Head Neck Surg. 2007;137(1):10-20.
3. Bhandarkar ND, Smith TL. Revision frontal sinusotomy using stepwise balloon dilation and powered instrumentation. Laryngoscope. 2010;120(10):2015-2017.
4. Brown C, Bolger WE. Safety and feasibility of balloon catheter dilation of paranasal sinus ostia: a preliminary investigation. Ann Otol Rhinol Laryngol 2006;115:293–299.
5. Levine HL, Sertich AP, Hoisington DR, Weiss RL, Pritikin J, PatiENT Registry Study Group. Multicenter registry of balloon catheter sinusotomy outcomes for 1,036 patients. Ann Otol Rhinol Laryngol. 2008 ;117(4):263-270.
6. Nogueira Júnior JF, Stamm AC, Pignatari S. Balloon sinuplasty, an initial assessment: 10 cases, results and follow-up. Braz J Otorhinolaryngol. 2010;76(5):588-595.
7. Weiss RL, Church CA, Kuhn FA, Levine HL, Sillers MJ, Vaughan WC. Long-term outcome analysis of balloon catheter sinusotomy: two-year follow-up. Otolaryngol Head Neck Surg. 2008;139(3 Suppl 3):S38-46.
8. Ramadan HH. Safety and feasibility of balloon sinuplasty for treatment of chronic rhinosinusitis in children. Ann Otol Rhinol Laryngol. 2009;118(3):161-165.
9. Wittkopf ML, Becker SS, Duncavage JA, Russell PT. Balloon sinuplasty for the surgical management of immunocompromised and critically ill patients with acute rhinosinusitis. Otolaryngol Head Neck Surg. 2009;140(4):596-598.
10. Hopkins C, Noon E, Roberts D. Balloon sinuplasty in acute frontal sinusitis. Rhinology. 2009 Dec;47(4):375-378.
11. Zeiders JW, Dahya ZJ. Antral lavage using the luma transilluminaton wire and vortex irrigator-A safe and effective advance in treating pediatric sinusitis. Int J Pediatr Otorhinolaryngol. 2011;75(4):461-463.
12. Kieff DA, Busaba NY. Reformation of concha bullosa following treatment by crushing surgical technique: implication for balloon sinuplasty. Laryngoscope. 2009;119(12):2454-2456.
13. Hueman K, Eller R. Reduction of anterior frontal sinus fracture involving the frontal outflow tract using balloon sinuplasty. Otolaryngol Head Neck Surg. 2008;139(1):170-171.
14. Kutluhan A, Bozdemir K, Cetin H, Yalçiner G, Salviz M, Sari N, et al. Endoscopic balloon dilation sinuplasty including ethmoidal air cells in chronic rhinosinusitis. Ann Otol Rhinol Laryngol. 2009;118(12):881-886.
15. Bhattacharyya T, Piccirillo J, Wippold FJ. Relationship between patient-based 47 descriptions of sinusitis and paranasal sinus CT. Arch Otolaryngol Head Neck Surg 1997 Nov;123(11):1189-1192.
16. Kennedy DW. Prognostic factors, outcomes and staging in ethmoid sinus surgery. Laryngoscope. 1992; 102:1-18.
17. Lund VJ, Kennedy DW. Staging for rhinosinusitis. Otolaryngol Head Neck Surg 1997;117:S35-40.
18. Ramadan HH, Terrell AM. Balloon catheter sinuplasty and adenoidectomy in children with chronic rhinosinusitis. Ann Otol Rhinol Laryngol. 2010;119(9):578-582.
19. Piccirillo JF, Merritt MG, Michele RI. Psychometrics and clinimetric validity of the 2015 item sino-nasal outcome test (SNOT-20). Otolaryngol Head Neck Surg 2002;126:41–47.
20. Kuhn FA, Church CA, Goldberg AN, Levine HL, Sillers MJ, Vaughan WC, et al. Balloon catheter sinusotomy: one-year follow-up--outcomes and role in functional endoscopic sinus surgery. Otolaryngol Head Neck Surg. 2008;139(3 Suppl 3):S27-37.
21. Sharp HR, Rowe-Jones JM, Mackay IS. The outcome of endoscopicsinus surgery: correlation with computerized tomography score and systemic

disease. Clin Otolaryngolog Allied Sci 1999; 24(1);39-42.

22. Stewart MG, Sicard MW, Piccirillo JF, Diaz-Marchan PJ. Severity staging in chronic sinusitis: are CT scan findings related to patient symptoms? Am J Rhinol 1999; 13(3):161-167.

23. Moghaddasi H,Sanei Taheri,Jalali AH,Shakiba MD. Correlation of Lund-Mackay and 42 SNOT-20 Before and After Functional Endoscopic Sinus Surgery (FESS): Does the Baseline Data Predict the Response Rate?. Iran J Radiol. 2009;6(4):207-214.

24. Vaughan WC. Review of balloon sinuplasty. Curr Opin Otolaryngol Head Neck Surg. 2008;16(1):2-9.

25. Tomazic PV, Stammberger H, Koele W, Gerstenberger C. Ethmoid roof CSF-leakfollowing frontal sinus balloon sinuplasty. Rhinology. 2010;48(2):247-250.

26. Chandra RK. Estimate of radiation dose to the lens in balloon sinuplasty. Otolaryngol Head Neck Surg. 2007 Dec;137(6):953-955.

27. Zeiders JW, Dahya ZJ. Antral lavage using the luma transilluminaton wire and vortex irrigator-A safe and effective advance in treating pediatric sinusitis. Int J Pediatr Otorhinolaryngol. 2011;75(4):461-463.

28. Senior BA, Kennedy DW, Tanabodee J. Long-term results of functional endoscopic sinus surgery. Laryngoscope 1998;108:151–157.

29. Schaitkin B, May M, Shapiro A. Endoscopic sinus surgery: 4-year follow-up on the first 100 patients. Laryngoscope 1993;103:1117–1120.

30. Friedman M, Schalch P, Mazloom N, et al. Functional endoscopic dilation of the sinuses: quality of life, patient satisfaction, post-operative pain and cost.