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ROLE OF BALLOON SINUPLASTY IN RELIEVING SYMPTOMS OF CHRONIC RHINOSINUSITIS

Otorhinolaryngology

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ABSTRACT

Introduction: Balloon sinuplasty is a newer sinus surgery technique which uses a balloon dilatational system to restore paranasal sinus ostial patency, drainage and ventilation with minimal damage to the mucosa. **Material & Methods:** This was a prospective interventional study conducted at tertiary care centre from January 2021 to September 2024, comprising 300 patients aged 18-55 years, with refractory chronic rhinosinusitis who underwent balloon sinuplasty with anterior ethmoidectomy. Patients were evaluated for clinical criteria, quality of life (Sino-Nasal Outcome Questionnaire Test-20 [SNOT-20]), preoperatively and post operatively at one week, one month & six months. **Results:** Mean age group of the study population was 33.98 ± 10.06. Total number of sinuses dilated with balloon were 964. There was marked improvement in symptoms of sinusitis after 1 month and 6 months of surgery. Balloon sinuplasty significantly reduced all symptoms enumerated in SNOT 20 criteria. P value was less than 0.0001. No patient had any significant complications like excessive bleeding, CSF rhinorrhoea or orbital complications. **Conclusion:** Balloon sinuplasty with anterior ethmoidectomy appears to be a safe and effective option for adult patients with chronic rhinosinusitis refractory to medical therapy.

KEYWORDS

SNOT, balloon sinuplasty, chronic rhinosinusitis

INTRODUCTION

Balloon Sinuplasty is a new technique which has revolutionized sinus surgery in recent times. Since its introduction in USA in 2004, it has become popular worldwide, due to its sophisticated technology, which uses balloon dilatational systems for dilating the sinus ostia through a minimally invasive approach and has provided satisfactory results in patients with chronic rhinosinusitis.

Often used in combination with surgery, balloon sinuplasty aims to restore ostial patency with minimal mucosal damage. The technology gently displaces, microfractures, and moulds the bone surrounding the sinus outflow and may be used alone or in combination with conventional endoscopic surgery. Effectiveness and safety of balloon sinuplasty have been established in many studies. [1-3]

Chronic rhinosinusitis (CRS) is a common and debilitating disorder, affecting nearly 10–12% of the global population and significantly impairing quality of life, work productivity, and healthcare resources [4,5]. In India, the prevalence is estimated at around 10.9%, ranking CRS among the most frequent chronic illnesses encountered in otorhinolaryngology practice [6]. Patients typically present with persistent nasal obstruction, rhinorrhoea, facial pressure, postnasal drip, and sleep disturbances, which often persist despite medical therapy.

Conservative management with intranasal corticosteroids, antibiotics, antihistamines, and saline irrigation remains the first-line treatment. However, a subset of patients remain refractory, necessitating surgical intervention. Functional endoscopic sinus surgery (FESS), introduced in the 1980s, became the standard surgical approach for CRS by restoring ventilation and mucociliary clearance through removal of diseased mucosa and sinus ostial obstruction [7]. While effective, FESS may be associated with complications such as mucosal trauma, postoperative bleeding, synechiae formation, and prolonged recovery [8,9].

Compared to FESS, balloon sinuplasty is associated with less tissue trauma, reduced risk of complications, shorter hospital stays, and faster recovery [1,10]. Additionally, it can be performed under local anaesthesia in carefully selected cases, expanding its applicability [11].

The safety and effectiveness of balloon sinuplasty have been confirmed by multiple clinical studies. Improvements in quality-of-life indices, particularly the Sino-Nasal Outcome Test (SNOT-20/22), have been consistently reported [12,13]. Large multicenter trials and registry data have demonstrated sustained symptom relief, reduced rates of revision surgery, and favourable safety outcomes [1,10]. Comparative analyses also highlight lower postoperative morbidity relative to conventional approaches [14,15].

Despite its increasing global acceptance, Indian literature on balloon sinuplasty remains limited, particularly in large patient cohorts. Considering the high prevalence of CRS and the demand for minimally invasive, cost-effective surgical solutions, further evaluation in the Indian setting is warranted. This prospective study of 300 patients aims to assess the role of balloon sinuplasty in relieving CRS symptoms using validated outcome measures, thereby contributing region-specific evidence to existing literature.

MATERIALS AND METHODS

Prospective interventional study for 3 years at Tertiary care centre , on 300 patients who met inclusion criteria:

1) Patients aged 18-55 years
2) Patients diagnosed as having chronic rhinosinusitis without polyposis. (on the basis of criteria laid by American Academy of Otorhinolaryngology - Head and Neck Surgery) [4]
3) Refractory to conservative treatment (4 weeks course of antibiotics, antihistaminics, topical and systemic steroids)

Exclusion criteria:

1) Rhinosinusitis along with other causes of headache like migraine.
2) Involvement of posterior ethmoids and sphenoid sinuses.
3) Patients with nasal polyps and previous nasal surgery.

Symptom evaluation was done through a standardized questionnaire, and severity was assessed through the Sino-nasal outcome questionnaire test (SNOT-20).[12]

Under general anaesthesia, anterior ethmoidectomy was done in all patients. Balloon sinuplasty was performed under endoscopic visualisation with 0^0, 30^0 and 45^0 endoscopes. After placing the (MESIRE™) guide catheter near the sinus ostium, a guidewire was passed through it and placement confirmed using transillumination catheter. The MESIRE™ balloon catheter was then passed over the guidewire into the sinus ostium region. On correctly placing the balloon at the sinus ostia, pressure inside the flask was gradually increased by saline infusion. After keeping balloon inflated for 2 minutes, the balloon was deflated and the catheter was gradually withdrawn. This was followed by irrigation of sinus cavity with saline solution. Inspection of sinonasal structures done before concluding the procedure.

Patients were asked to fill up SNOT 20 questionnaire preoperatively and on each postoperative visit. Follow up was done postoperatively at

1 week, 1 month and 6 months.

Statistical Analysis Details:
Data were analysed using SPSS software 2.0. Paired t-tests compared preoperative and postoperative SNOT-20 scores.

RESULTS

The total number of patients undergoing intervention were 300. Mean age group of the study population was 33.98 ± 10.06. Total number of sinuses dilated with balloon were 964, out of which 452 were frontal and 512 were maxillary. All maxillary sinuses were dilated by balloon sinuplasty without any difficulty. In certain cases of frontal sinuses there was bony obstruction for which axilla of middle turbinate and bony septae were removed by punch.

The study found that balloon sinuplasty significantly reduced all symptoms enumerated in the SNOT-20 criteria, with the P value less than 0.0001 for the overall results.

Looking at the post-operative means for both 1 month and 6 months:

After 1 Month: The P value was <0.001 for all 20 symptoms listed in the SNOT-20 criteria, indicating a statistically significant improvement for every symptom. (graph 1)

At 6 months: most symptoms remained significantly improved (P<0.001), except sneezing (P=0.113), runny nose (P=0.105), and difficulty falling asleep (P=0.497), which showed no statistically significant change. (Graph 2)

Table 1 and Graph 1 show there was marked improvement in symptoms of sinusitis after 1 months of surgery. Balloon sinuplasty significantly reduced all symptoms enumerated in SNOT 20 criteria. P value was less than 0.0001.

Table 2 and Graph 2 show the symptomatic improvement after 6 months of surgery. Balloon sinuplasty proved to be significantly effective in decreasing symptoms like need to blow nose, cough, postnasal discharge, dizziness and reduced productivity and concentration.

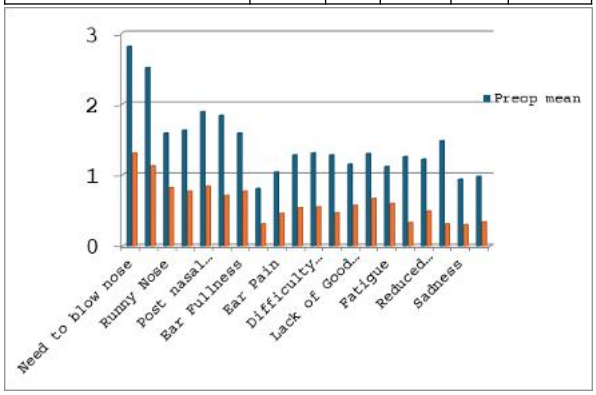
No patient had any significant complications like excessive bleeding, CSF rhinorrhoea or orbital complications.

TABLE 1: PREOP AND POST OP MEAN AFTER 1 MONTH OF SURGERY

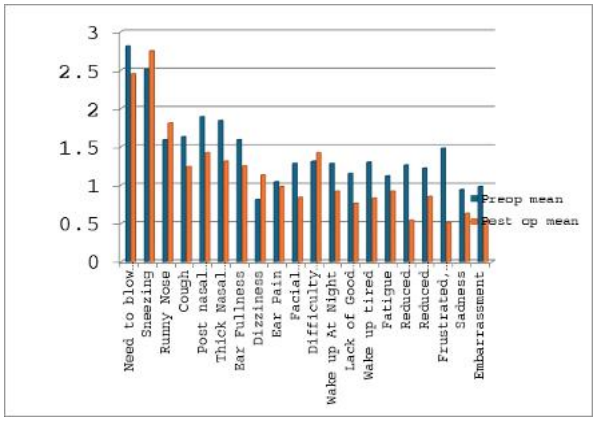
	Preop (mean±SD)		Postop (mean±SD)		p value
Need to blow nose	2.84 ±	1.36	1.34 ±	1.18	<0.001
Sneezing	2.54 ±	1.73	1.16 ±	1.21	<0.001
Runny Nose	1.62 ±	1.63	0.85 ±	1.17	<0.001
Cough	1.66 ±	1.69	0.80 ±	0.94	<0.001
Post nasal discharge	1.92 ±	1.4	0.87 ±	0.95	<0.001
Thick Nasal Discharge	1.87 ±	1.42	0.74 ±	1	<0.001
Ear Fullness	1.62 ±	1.85	0.80 ±	1.38	<0.001
Dizziness	0.84 ±	1.09	0.34 ±	0.74	<0.001
Ear Pain	1.07 ±	1.51	0.49 ±	1.05	<0.001
Facial Pain/Pressure	1.31 ±	1.6	0.57 ±	1.11	<0.001
Difficulty Falling Asleep	1.34 ±	1.6	0.58 ±	0.99	<0.001
Wake up At Night	1.31 ±	1.55	0.50 ±	0.89	<0.001
Lack of Good Night's Sleep	1.18 ±	1.57	0.60 ±	1.13	<0.001
Wake up tired	1.33 ±	1.8	0.70 ±	1.38	<0.001
Fatigue	1.15 ±	1.64	0.63 ±	1.12	<0.001
Reduced Productivity	1.29 ±	1.43	0.36 ±	0.82	<0.001
Reduced Concentration	1.25 ±	1.49	0.52 ±	1.22	<0.001
Frustrated, restless, Irritable	1.51 ±	1.8	0.34 ±	0.94	<0.001
Sadness	0.97 ±	1.42	0.33 ±	0.71	<0.001
Embarrassment	1.01 ±	1.46	0.37 ±	0.94	<0.001

TABLE 2: PREOP AND POST OP MEAN AFTER 6 MONTHS OF SURGERY

	Preop (mean±SD)		Postop (mean±SD)		p value
Need to blow nose	2.84 ±	1.36	1.92±	1.31	<0.001
Sneezing	2.54 ±	1.73	2.68±	1.5	0.113
Runny Nose	1.62 ±	1.63	1.81±	1.20	0.105
Cough	1.66 ±	1.69	0.94±	1.20	<0.001
Post nasal discharge	1.92 ±	1.4	1.02±	1.30	<0.001
Thick Nasal Discharge	1.87 ±	1.42	1.31±	1.18	<0.001
Ear Fullness	1.62 ±	1.85	1.25±	1.40	0.006
Dizziness	0.84 ±	1.09	0.41±	0.90	<0.001
Ear Pain	1.07 ±	1.51	0.68±	1.20	<0.001
Facial Pain/Pressure	1.31 ±	1.6	0.84±	1.35	<0.001
Difficulty Falling Asleep	1.34 ±	1.6	1.42±	1.26	0.497
Wake up At Night	1.31 ±	1.55	0.92±	1.02	<0.001
Lack of Good Night's Sleep	1.18 ±	1.57	0.76±	1.32	<0.001
Wake up tired	1.33 ±	1.8	0.83±	1.43	<0.001
Fatigue	1.15 ±	1.64	0.82±	1.43	0.009
Reduced Productivity	1.29 ±	1.43	0.54±	0.86	<0.001
Reduced Concentration	1.25 ±	1.49	0.85±	1.22	<0.001
Frustrated, restless, Irritable	1.51 ±	1.8	0.51±	1.31	<0.001
Sadness	0.97 ±	1.42	0.53±	1.14	<0.001
Embarrassment	1.01 ±	1.46	0.53±	1.21	<0.001



GRAPH 1: PREOP AND POST OP MEAN AFTER 1 MONTH OF SURGERY



GRAPH 2: PREOP AND POST OP MEAN AFTER 6 MONTHS OF SURGERY

DISCUSSION

Primary aim of both functional endoscopic sinus surgery (FESS) and balloon sinuplasty is to relieve the sinus ostia blockage and restore the mucociliary clearance.[7]

Surgical removal of diseased tissues involving the osteomeatal complex, sinus ostia, uncinate, and all proximal anatomical obstructions, improves mucociliary clearance and aeration, enhances the delivery of topical medications, and decreases recurring sinus disease. [8,9]

With balloon sinuplasty, restoration of sinus ostia drainage is achieved in a less traumatic way. Expansion of ostia is achieved by microfracture caused by the pressure of balloon.

Balloon sinuplasty can be done under local anaesthesia, however, we have done the procedure under general anaesthesia.

In our study, involvement of 300 patients and use of authentic standardized instrument, such as the SNOT-20 questionnaire, allowed to quantify the improvement in symptoms.

An adult population study reported that at 24 weeks, 80% of patients

who underwent balloon sinuplasty alone and 88% who underwent balloon sinuplasty with ethmoidectomy reported improvement of sinusitis symptoms. [13]

A large retrospective review by Levine and colleagues[1] showed that 73.8% of 1036 patients maintained improved symptoms at a mean follow-up of 40.2 weeks. A multicentre prospective trial, specifically assessing outcomes of balloon dilation in the office, showed significant reduction of disease specific quality of life measures (P <.0001) at 1 year with significantly fewer acute sinus infections (P <.0001), less antibiotic use (P <.0001), and fewer physician-related visits (P <.0001). One patient underwent revision surgery with no reported device or procedure related adverse events.

Complication rates following balloon sinuplasty have been reported to be lower than those secondary to FESS.[11,14] The advantage of balloon sinuplasty is avoidance of complications like CSF leaks, meningitis, frontal recess stenosis, nasolacrimal duct laceration, epiphora, and orbital hematoma due to its preservation of sinus anatomy and reduction of collateral damage to surrounding tissues during the procedure.[15] There is also reduced chances of post operative complications like bleeding, infections and synechiae owing to the nature of procedure. The disadvantages are that it has limited role in extensive disease and cannot be used in all pathologies involving sinuses, such as those which require severe polyposis, cystic fibrosis or history of nasal trauma or previous sino-nasal surgery.

Limitations of the study:
The follow-up period was limited to six months, which restricts evaluation of long-term outcomes of balloon sinuplasty. Patients with nasal polyps, posterior ethmoid and sphenoid involvement, or prior nasal surgery were excluded, reducing generalizability to more extensive or complex CRS cases. Outcome assessment was based on SNOT-20 scores; objective radiological evaluation was not included. Being a single-centre study, the findings may not be universally generalizable, highlighting the need for larger multicentric prospective studies.

CONCLUSION

Balloon sinuplasty with anterior ethmoidectomy is an effective and safe surgical tool in relieving the symptoms of chronic rhinosinusitis resistant to medical management. Our results demonstrated a significant overall decrease in sinus symptoms with balloon sinuplasty and ethmoidectomy. There were no complications or adverse events recorded intraoperatively or postoperatively. Patients experience shorter hospital stays, faster recovery and higher satisfaction. Larger prospective studies with long term data are needed to determine who will benefit the most from this procedure, and to examine if balloon sinuplasty alone or in combination with ethmoidectomy provides a lasting resolution of sinus complaints, with less morbidity compared to traditional FESS.

DECLARATIONS:

ETHICAL APPROVAL : This study was approved by the Institutional ethics committee, Pacific Medical College and Hospital, Udaipur, India, ref. no. PMU/PMCH/IEC/2021/184A dated 17/02/2021.

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Patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Conflict of interest: There are no conflicts of interest

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