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The role of balloon sinuplasty in the treatment of sinus headache

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ABSTRACT

Introduction: Headache attributed to rhinosinusitis, commonly called sinus headache (SH), is probably one of the most prevalent secondary headaches. The purpose of our study was to examine further sinus headache comparing the effect of conventional functional endoscopic sinus surgery and the balloon sinuplasty. **Material and methods:** Eighty-three consecutive patients were enrolled from 2009 to 2012, who were diagnosed sinus headache according the diagnostic criteria of AAO-HNS and of HIS. 40 patients were randomized to Conventional Endoscopy Sinus Surgery for frontal sinus (ESS Group), 35 to balloon sinuplasty of frontal sinus (BS Group). **Results:** The mean operative time was 65 ± 15 min for ESS group patients and 32 ± 7 min for 23 patients (BS1 Group) and 55 ± 18 min for 12 treated with hybrid technique (BS2 Group). The preoperative mean of SNOT-22 scores improved from 28.6 ± 1.2 in ESS group and 27.3 ± 0.8 in BS group to a 1-month postoperative scores of 14.5 ± 0.6 in ESS group and 10.3 ± 0.5 in BS group and to a 6-month postoperative scores of 7.8 ± 0.6 and 5.3 ± 0.3, respectively ($p < 0.0001$). The headache scores base on analog visual scale improved from a preoperative mean of 6.5 ± 0.3 in ESS group and 7.1 ± 0.4 in Bs group to a 1-month postoperative scores of 5.4 ± 0.4 in ESS group and 5.5 ± 0.4 in BS group and to a 6-month postoperative scores of 2.7 ± 0.5 and 1.2 ± 0.1, respectively, representing a statistically significant reduction in headache score in both group. **Conclusion:** Our data prove that improvement in headache can be expected in patients treated with balloon catheter.

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Introduction

Headache attributed to rhinosinusitis, commonly called sinus headache (SH), is probably one of the most prevalent secondary headaches. Therefore due to their similar locations, primary headaches such as migraine, cluster and tension-type headache are often confused with SH and it is mandatory before treat patients for SH to differentiate true sinus headache from migraine and cluster headache.

A major challenge to studying and to treat headache attributed to sinus disease is the lack of uniform diagnostic criteria. Both the International Headache Society (IHS) and the American Academy of Otolaryngology-head and Neck

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Table I – Diagnostic criteria for chronic rhinosinusitis and headache attributed to rhinosinusitis

AAO-HNS: Two major factors or one major and two minor factors for at least 12 weeks	
Major Factors	**Minor Factors**
Facial pain/pressure	Headache
Nasal obstruction/blockage	Fever (all non-acute)
Nasal discarge/purulence	Halitosis
Hyposmia/anosmia	Dental pain
Purulence in nasal cavity on examination	Fatigue
Fever (acute rhinosinusitis)	Cough
	Ear pain/pressure/fullness
One of these signs of inflammation must be present and identified in association with ongoing symptoms consistent with chronic rhinosinusitis:	
A	Discolored nasal drainage from the nasal passage, nasal polyps or polypoid swelling as identified on physical examination with anterior rhinoscopy after decongestion or nasal endoscopy
B	Oedema or erythema of the middle meatus or ethmoid bulla on nasal endoscopy
C	Generalized or localized erythema, oedema or granulation tissue (if the middle meatus or ethmoid bulla is not involved, radiological imaging is required to confirm a diagnosis)
D	Imaging modalities confirming the diagnosis
HIS: Headache attributed to rhinosinusitis	
A	frontal headache accompanied by pain in one or more regions of the face, ears or teeth and fulfilling criteria C and D
B	Clinical, nasal endoscopic, CT and/or MRI imaging and/or Laboratory evidence of acute or acute on chronic rhinosinusitis
C	Headache and facial pain develop simultaneously with onset or acute exacerbation of rhinosinusitis
D	Headache and facial pain resolve within 7 days after remission or successful treatment of acute or acute on chronic rhinosinusitis

Notes: (1) Clinical evidence may include purulence in the nasal cavity, nasal obstruction, hyposmia/anosmia and/or fever. (2) Chronic sinusitis is not validated as a cause of headache or facial pain unless relapsing into an acute stage.

Surgery (AAO-HNS) suggest diagnostic criteria for Rhinosinusitis related to headache (Table I) [1]. The IHS requires the existence of specific pathophysiological condition that explain the headache and still consider that chronic rhinosinusitis is ''not validated cause of headache or facial pain unless relapsing into acute stage'', whereas the AAO-HNS criteria include a series of major and minor clinical symptoms and signs. A diagnosis of rhinosinusitis requires at least 2 major factors or at least 1 major and 2 minor factors [2].

According to task force on rhinosinusitis facial symptoms in the criteria include facial congestion, facial pain-pressure-fullness, and headache. Facial pain or pressure is regarded as a major symptom, whereas headache is considered a minor symptom but remains the most common symptoms complaint among patients diagnosed with rhinosinusitis. Chronic rhinosinusitis is not always associated with headache, but in selected populations headache is experienced in three out of four patients with this syndrome [3]. In a recent study by Bhattacharyya, 83% of 322 patients diagnosed with CRS reported headache as a symptom [4].

Already Stammberger and Wolf in 1988 postulated that variations in anatomy of nasal cavity result in mucus stasis, infection and facial pain. The effectiveness of endoscopic sinus surgery (ESS) in the treatment of facial pain due to rhinosinusitis has been described by several authors in the last 10 years [5, 6].

The purpose of our study was to examine further sinus headache comparing the effect of conventional functional endoscopic sinus surgery and the balloon sinuplasty recently introduced as a minimally invasive tool for dilation of the frontal sinus drainage pathways [7, 8].

Material and methods

The present study is an unfounded, with no monetary support from any source, study and was approved by the

hospital ethics and research committee. Eighty-three consecutive patients (48 male, 35 female) with a mean age of 45 (range 22–72 years) arrived to our department for suspect of rhinosinusitis from 2009 to 2012, who were diagnosed sinus headache according the diagnostic criteria of AAO-HNS and of IHS[1] (Table I), were enrolled into a randomized surgical protocol. The data were collected prospectively and analyzed in a retrospective fashion.

The participants were examined with physical examination, which include nasal endoscopy. A coronal sinus CT was used to evaluate the evidence of acute-on-chronic rhinosinusitis, to evaluate isolated or diffuse mucosal thickening of frontal sinus and also to planning the surgical approach. On evidence of CT we also completed preoperatively Lund-Mackay score for each patients but we consider that there is not correlation between pain severity and disease severity by CT scan as reported in the literature [9].

Exclusion criteria were: nasal polyposis, nasal deformity, valve collapse, abnormal nasal septal deviation, epistaxis or vestibulitis, rhinitis medicamentosa, headache pain as a solitary symptom, prior surgical intervention for rhinosinusitis and general contraindications to surgery.

The validated 22-item SINO-Nasal Outcome Test (SNOT-22) [10], which examines general nasal symptoms, and subjective headache scored based on a 0–10 visual analogy scale were completed by each patient to rated symptoms referred before and after surgery.

The patients were followed with headache score and SNOT-22 testing 1 and 6 months postoperatively. The postoperative assessment included a complete head and neck examination, with emphasis on the endoscopic evaluation of the nasal cavity. Informed consent was given by each patient. Patients were randomized to undergo either conventional endoscopic sinus surgery (Draft I/IIa) or balloon sinuplasty for frontal sinus. Two specific outcomes were identified and addressed: (1) the efficacy of balloon sinuplasty in the treatment of SH; (2) the morbidity associated with these two techniques. 45 patients were randomized to Conventional ESS, 38 to balloon sinuplasty of frontal sinus, post operative medications included antibiotic suspension for 10 days and acetaminophen as needed for pain relief.

In both surgical procedures a partial endoscopic septoplasty was first performed if necessary to introduce the endoscope for frontal sinus approach.

Statistical analysis

The results were statistically evaluated by comparing preoperative and postoperative mean values of headache visual analogy scale and SNOT-22 in the two surgical techniques groups using the unpaired *t* test. The *t* test was used also to determine if there was any difference between the 2 groups with respect to demographic parameter (age and sex) and also to evaluate potential differences in pre-operative Lund-Mackay score between two groups.

Results

Seventy-five (91.4%) out of 83 patients completed all preoperative and postoperative protocol. No statistically significant differences were noted between the two groups with regards to any demographic or disease severity parameter used in this trial.

40 patients were randomized to Conventional Endoscopy Sinus Surgery for frontal sinus (ESS Group), 35 to balloon sinuplasty of frontal sinus (BS Group). In BS group on 35 patients 23 (BS1 Group) were ''only frontal sinus balloon'' (balloon catheters were the only tools used for frontal sinus sinusotomy), 12 (BS2 Group) were ''hybrid'' (balloon catheters and traditional endoscopic approach to frontal sinus concurrently were used). In ESS group partial endoscopic septoplasty was also performed on 15 (42.8%), in BS group was also performed on 20 (57%). In some patients of two groups we also performed conventional ESS for other sinuses when involved. In all cases (100%) inferior turbinates reduction with coblation tools was performed.

The mean operative time was 65 ± 15 min for ESS group patients and 32 ± 7 min for 23 patients (BS1 Group) and 55 ± 18 min for 12 treated with hybrid technique (BS2 Group).

There were no complications in all groups; specifically no patients with primary or secondary hemorrhage. None of

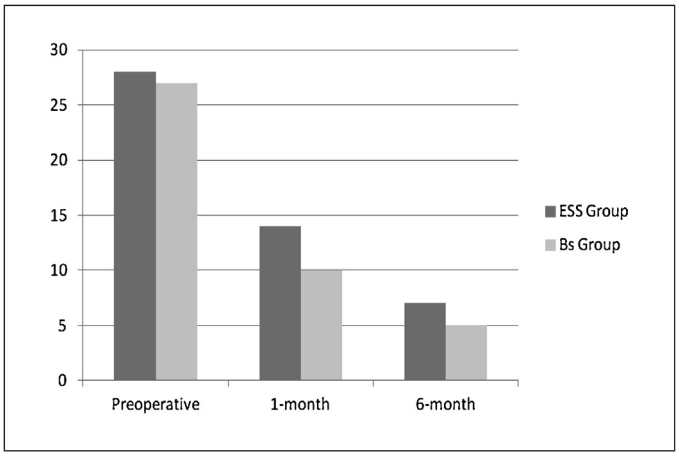

Fig. 1 – Preoperative, 1-month and 6-month postoperative SNOT-22

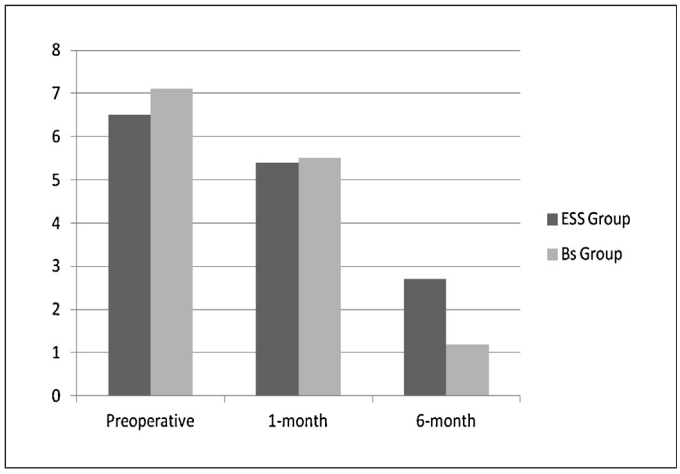

Fig. 2 – Preoperative, 1-month and 6-month postoperative headache score in both groups

the patients needed analgesics for more than 10 days or re-hospitalization for intractable pain.

The preoperative mean of SNOT-22 scores improved from 28.6 ± 1.2 in ESS group and 27.3 ± 0.8 in BS group to a 1-month postoperative scores of 14.5 ± 0.6 in ESS group and 10.3 ± 0.5 in BS group and to a 6-month postoperative scores of 7.8 ± 0.6 and 5.3 ± 0.3, respectively ($p < 0.0001$; Fig. 1).

The headache scores base on analog visual scale improved from a preoperative mean of 6.5 ± 0.3 in ESS group and 7.1 ± 0.4 in Bs group to a 1-month postoperative scores of 5.4 ± 0.4 in ESS group and 5.5 ± 0.4 in BS group and to a 6-month postoperative scores of 2.7 ± 0.5 and 1.2 ± 0.1, respectively, representing a statistically significant reduction in headache score in both group ($p < 0.0001$; Fig. 2).

Discussion

Headache is the most common symptom accompanying frontal acute and chronic rhinosinusitis in acute stage. It is severe, intractable, often interferes with sleep and is poorly relieved by narcotics. Temporal, frontal or occipital and periorbital pain are the most common presentation of sinus headache.

It's clear that headache alone should not constitute a suggestive history for rhinosinusitis without other major and minor signs, but is possible to argue that in case of rhinosinusitis an obstruction of the sinus ostia can in turn cause negative pressure within sinus cavities and subsequent facial pain like ''barosinusitis''.

Endoscopic sinus surgery in the past has also been advocated for sinus headache with increasingly encouraging results, since about 1994 Cook et al. [11] advocated ESS in patients with haeadache and sings of rhinosinusitis with a significant reduction of pain in 12 of 18 patients. Senior et al. [12] reported improvement in headache in 47 of 51 patients at 7.8-year after ESS, while Moretz in 2006 [13] reported that 91.9% of patients with headache symptoms improvement 2 years after surgery.

In the last few years one of the hallmarks of ESS has been an minimally invasive technique with maximal preservation of mucosa, the same goal has been achieved recently by the continued introduction of new innovative instrumentation like balloon catheters, whose benefits have already been demonstrated in surgical treatment of rhinosinusitis by several studies with very large series [14].

On the basis of these studies our report shows how balloon sinuplasty could be useful in the treatment of rhinosinusitis but also in sinus headache. We reported an improvement of headache score from a preoperative mean of 6.5 ± 0.3 in ESS group and 7.1 ± 0.4 in BS group to a 6-month postoperative scores of 2.7 ± 0.5 and 1.2 ± 0.1, representing a statistically ($p < 0.0001$; Fig. 2) significant reduction in headache score in all of forty patients treated with conventional ESS but also in 35 treated with balloon sinuplasty.

This result confirms the safety and feasibility of using balloon catheter technology to treat paranasal sinus also expanding its application to sinus headache.

The SNOT-22 provided insight into patient outcome and patients satisfaction and in line with the results proposed in literature our study showed how the preoperative mean of SNOT-22 scores improved from 28.6 ± 1.2 in ESS group and 27.3 ± 0.8 in BS group to a 6-month postoperative scores of 7.8 ± 0.6 and 5.3 ± 0.3, respectively ($p < 0.0001$; Fig. 1).

Balloon catheter devices permitted a safe sinusotomy that was durable and according several studies without related adverse events like cerebrospinal fluid leak, diplopia, visual loss or significant intraoperative bleeding.

Furthermore it is also important to stress that none of the two groups of patients required revision surgery during the 6 post-operative months, but certainly for evaluating the actual results we will need to lengthen the months of follow-up.

Regards the surgery duration, even if there were no any comparative study on surgery duration in patients who underwent conventional ESS and balloon technique, it's important to stress that our results show that the surgery duration was shorter in patients treated with balloon sinuplasty (55 ± 18 min) if compared with surgery time of conventional ESS (65 ± 15 min) and we can also say that surgery time was shorter (32 ± 7 min) in 23 patients (BS1 Group) treated with ''only frontal sinus balloon'' if compared

with ''hybrid'' technique (BS2 Group). This means that it is not only the surgical procedure shorter, but also the entire anesthesia time. We must also observe that the procedures time were longer in first patients probably due to the learning curve concerning the surgeon's experience.

Conclusion

Determining whether facial pain is due to rhinosinusitis should be the first goal of the otolaryngologist as headache is a common symptom present in 73.6% of patients undergoing ESS [13] for rhinosinusitis but often it can be confusing with migraine.

Our data prove that improvement in headache can be expected in patients treated with balloon catheter. We know that ESS has a high rate of success ranging 75–95% improvement in the symptoms [15] and in this study we shows that balloon sinuplasty find a place in the treatment of sinus headache for the significant improvement of symptom, being relatively safe and effective with no demonstrated adverse events with improvements rates comparable with ESS results.

Authors' contributions/Wkład autorów

According to order.

Conflict of interest/Konflikt interesu

None declared.

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None declared.

Ethics/Etyka

The work described in this article has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans; EU Directive 2010/63/EU for animal experiments; Uniform Requirements for manuscripts submitted to Biomedical journals.

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