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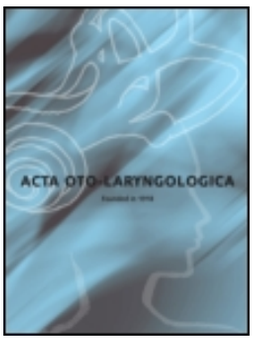

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RESEARCH ARTICLE

Long-term follow-up after ESS and balloon sinuplasty: Comparison of symptom reduction and patient satisfaction

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ABSTRACT

Conclusion This is the first controlled study of balloon sinuplasty's long-term efficacy with the follow-up time over 5 years. The results are in accordance with a previous 2-year-follow-up study. Both techniques retained the efficacy and patient satisfaction on average 6 years after the surgery.

Background Endoscopic sinus surgery (ESS) and balloon sinuplasty are considered as a treatment for chronic rhinosinusitis (CRS) after a failure of conservative therapy. High cost and lack of long-term follow-up studies restrain the use of balloon sinuplasty.

Objective The aim of this study was to compare long-term efficacy and satisfaction in CRS patients who had undergone maxillary sinus operation with either balloon sinuplasty or ESS technique. Previous or additional sinonasal operations were exclusion criteria.

Materials and methods Study patients were recruited from 208 CRS-patients who underwent either ESS or balloon sinuplasty. Patients with nasal polyposis (gradus ≥ 2), previous sinonasal surgery, unilateral disease, or immune deficiency were excluded. Altogether 45 patients in the ESS group and 40 patients in the balloon group were included. Of these, 30 and 28, respectively, answered to a phone interview held on average 6 years after primary surgery. Symptom reduction and long-term satisfaction were evaluated by using symptom scores of 19 parameters altogether.

Results Both groups experienced improvement in symptoms and were equally satisfied with the operation. The number of patient-reported acute exacerbations was higher among the balloon dilated patients. Also, the reduction of thick nasal discharge was less evident in the balloon sinuplasty group. Four patients in the balloon sinuplasty group underwent revision surgery. There were no revisions in the ESS group.

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Balloon sinuplasty; chronic rhinosinusitis; endoscopic sinus surgery; long-term efficacy; satisfaction

Introduction

Chronic rhinosinusitis (CRS) is a common, diverse, and multifactorial disease of the nose and paranasal sinuses, with a prevalence of ~10% [1]. It has a severe impact on quality-of-life and national economy [2,3]. Diagnosis is based on characteristic symptoms lasting more than 12 weeks, computed tomography (CT) scan and/or endoscopic changes [4]. Conservative treatment of CRS with intranasal saline irrigations and corticosteroids is always prior to surgery.

Internationally, endoscopic sinus surgery (ESS) is considered as a treatment modality in CRS after the failure of medical treatment, even though the Cochrane Collaboration has stated that ESS offers no additional benefit to that obtained by medical treatment in relieving the symptoms of CRS. Nevertheless, patients with a prolonged and chronic disease with a severe impact on quality-of-life might benefit more from surgery than continued medical therapy [5]. Controlled studies have shown quality-of-life (QoL) improvement after ESS and balloon sinuplasty [2,6,7].

Balloon sinuplasty has been under an intensive evaluation during the last decade. The principle of balloon sinuplasty is to dilate the ostium without removing any bone or tissue [8]. The guide wire is advanced into the maxillary sinus and the right place is verified with transillumination or fluoroscopy technique [8]. The balloon catheter is steered into the ostium via the guide wire and inflated up to 8–12 bars for a few seconds, resulting in a wider passage to the blocked sinus and facilitating the drainage of the mucus. The disadvantages of the procedure are the lack of knowledge of its long-term effect, the high costs of the disposable instruments, and its technical limitations in ethmoidal area or in removal of atypical mucosa [9]. Several uncontrolled and controlled studies have suggested balloon sinuplasty to be a safe and effective method [6,7,10–13]. However, the limitations of these studies are the heterogeneity of patients and procedures as well as short follow-up time, which makes the conclusions difficult to draw. In our 2-year follow-up study we demonstrated that patient satisfaction and symptom reduction were equal in both groups. However, in

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number of acute exacerbations ESS seems to be superior to balloon sinuplasty [14].

Methods

Patients

The study was approved by the ethical committee of the Pirkanmaa Hospital District. Overall, 208 patients suffering from chronic rhinosinusitis, who were evaluated to benefit from maxillary sinus operation, were enrolled in this study. Altogether 103 patients underwent bilateral balloon sinuplasty and 105 patients bilateral ESS of the maxillary sinuses. Balloon procedures were carried out between 2008–2009 at two private clinics (Terveystalo Healthcare OYJ of Finland and Koskiklinikka Tampereen lääkärikeskus Oy) in Tampere, Finland. ESS, partial uncinectomy, and middle meatal antrostomy were carried out at Päijät-Häme Central Hospital, in Lahti, Finland, during 2008–2010. Only patients having a simple bilateral maxillary sinus operation were included.

Patients' medical records and pre-operative computed tomography or magnetic resonance (CT/MRI) scans were used for patient selection and collecting background and follow-up data. CRS diagnosis and operative indications fulfilled European position paper on rhinosinusitis and nasal polyps recommendations [15].

The exclusion criteria were: age <13 years; previous or concomitant additional sinonasal surgery, unilateral CRS or odontogenic sinusitis, endoscopic signs of nasal polyposis (grade ≥2) during the operation, a history of aspirin sensitivity, chronic bronchitis, cystic fibrosis, primary ciliary dyskinesia, tumor, or another disease with a severe impact on general immunity [16]. Altogether 39 patients in the ESS group and 36 patients in the balloon sinuplasty group met the inclusion criteria.

Operations

The balloon sinuplasty system was used to dilate the ostium according to instructions provided by the manufacturer (Acclarent Inc., a member of Johnson & Johnson Company, New Brunswick, NJ). To create local anesthesia, three cotton-tipped applicators soaked in local anesthetic (cocaine hydrochloride 120 mg + 2.5 ml epinephrine 0.1 mg/ml) were placed on each side and 3 ml 1% lidocaine adrenalin was infiltrated around the middle turbinate. Nine out of 25 balloon-patients that were operated on under local anesthesia also received additional intravenous sedation, usually midazolam 1–3 mg. During the operation they were given alfentanil total dose 0.5–1.5 mg as analgesic. Balloon sinuplasty was performed for 11 (39%) patients in an in-office setting under local anesthesia without intravenous sedation. No packing was placed and no post-operative debridement was performed after balloon dilation.

In the ESS group, partial uncinectomy and middle meatal antrostomy were performed on both sides. Two thirds of the lower part of the uncinate process was cut with the backbiting forceps. The maxillary ostium was enlarged to posterior–inferior direction to double its diameter. Local anesthesia was created by placing three cotton-tipped applicators soaked in local anesthetic (75 mg cocaine hydrochloride + 2 ml 40 mg/ml lidocaine + 0.75 ml epinephrine 1 mg/ml) on each side and infiltrating 1.5 ml 1% lidocaine adrenalin around the middle turbinate. A small pack (3.5 × 0.6 × 1.2 cm, Merocel, Medtronic-Xomed, Jacksonville, FL) was placed into middle meatus for 24 h. Debridement control was ∼4 weeks post-operatively. There were no reports of a missed ostium in the patient records of the ESS or balloon sinuplasty operations.

Phone-interview

A phone interview was conducted in spring 2015. The mean (min–max) follow-up time was 6.0 (4.9–6.9) years in the ESS group and 6.4 (5.6–7.3) years in the balloon sinuplasty group. The phone interview included questions about the patient's medical history, e.g. asthma, allergic, aspirin sensitivity, medication, and smoking habits. Job exposure was evaluated according to reported current occupation and characterization of the workplace. The patient was thought to be exposed to poor indoor air quality if he/she was currently or had been previously staying longer periods (years) in a place with discovered mold or water damage. Family history of recurrent acute/chronic rhinosinusitis or nasal polyposis was determined. Also the number of sinusitis, lavation of maxillary sinuses during the past year, and the current use of nasal corticosteroids were asked about.

Symptom change was evaluated by asking the patient to compare present symptom level with the situation before the operation. Patients were instructed to give their answer on a scale from −3 to 3, 0 meaning that the symptom had not changed, −3 meaning that the symptom had become significantly worse, and 3 that the patient was now asymptomatic. Satisfaction was evaluated by the question 'Would you be willing to have the same operation now, knowing how much it would decrease your symptoms?' Patients who had undergone revision surgery were advised to give their answer according to the present status.

No patient reported being unable to answer the interview because of an inability to remember his/her pre-operative symptoms.

Statistical analysis

Statistics were performed with SPSS Base 20 Statistical Software Package (SPSS, Chicago, IL) by AK, ST-S, and professional statistician H.H. The non-parametric Fisher's exact test, Kruskal Wallis, and Mann Whitney U-tests were used for comparisons of groups. A two-tailed p-value of less than 0.05 was considered significant in all tests.

Results

Patient characteristics

The ESS and balloon sinuplasty groups were identical in the duration of CRS symptoms and other patient history factors (Tables 1 and 2). The pre-operative median radiological

Lund-Mackay (LM) score of maxillary sinuses did not differ between the ESS group and the balloon sinuplasty group ($p > 0.05$, data not shown). On the right side the pre-operative median LM total score and the median LM score of ostiomeatal complex were significantly lower in the balloon sinuplasty group compared to the ESS group ($p = 0.009$ and $p = 0.002$, respectively). On the left side there were no significant differences of these LM scores between the ESS group and balloon sinuplasty group ($p > 0.05$). Twenty-five out of 28 balloon sinuplasty patients and 22 out of 30 ESS patients were operated upon under local anesthesia. Eleven patients in the balloon sinuplasty group had the procedure in an office setting.

Table 1. Patient characteristics.

Patient characteristics	Balloon sinuplasty ($n = 28$)	ESS ($n = 30$)	p-value
Age, years, mean (min–max)	44 (17–64)	44 (13–75)	0.76
No. of patients with male sex (%)	11 (39)	12 (40)	1.00
Duration of symptoms, mean years (min–max)	17.4 (0–40)	16.5 (0–55)	0.59
No. of smokers (%)	2 (7)	7 (23)	0.15
No. of patients reporting a doctor-diagnosed (%)			
Allergic rhinitis	8 (29)	15 (50)	0.11
Asthma	8 (29)	10 (33)	0.78
No. of patients (%)			
With family history of sinusitis/NP	13 (46)	12 (40)	0.51
Using regularly topical nasal steroid	10 (36)	11 (37)	1.00

p-values by Fisher's exact test (for dichotomous variables) and by Mann-Whitney U-test (for continuous variables). No., number.

Table 2. Percentage of patients who pre-operatively suffered from listed symptoms.

	Balloon ($n = 28$)	ESS ($n = 30$)	p-value
Decreased sense of smell	46.4	56.7	0.60
Runny nose	96.4	93.3	1.00
Post nasal-disharge	89.3	93.3	0.67
Thick nasal-disharge	85.7	93.3	0.42
Sneezing	89.3	63.3	0.03
Headache	60.7	60.0	1.00
Cough	78.6	50.0	0.03
Fever	46.4	50.0	0.80
Fatigue	82.1	80.0	1.00
Nasal blockage			
Right	96.4	100.0	0.48
Left	96.4	100.0	0.48
Facial pain/pressure			
Right	89.3	86.7	1.00
Left	89.3	86.7	1.00
Ear pain/pressure			
Right	35.7	50.0	0.30
Left	35.7	50.0	0.30
Watery eyes			
Right	53.6	30.0	0.11
Left	53.6	30.0	0.11

p-values by Fisher's exact test.

Symptom reduction

Both groups experienced equal symptom reduction. The number of acute sinusitis, thick nasal discharge, and right-sided nasal blockage were less evidently decreased in the balloon sinuplasty group (Table 4) No difference was found between the groups in nasal symptom-score (nasal blockage, discharge, decreased sense of smell, and facial pain/pressure) ($p > 0.05$).

Results remained similar when patients who had undergone revision surgery were excluded from the analysis (data not shown).

Exacerbations

The acute exacerbations were treated according to EPOS, with inclusion of a Finnish clinical practice of maxillary sinus lavation or puncture when necessary. The number of maxillary punctures or lavages during the last year did not differ between the groups, nor did the number of antibiotic courses for acute sinusitis (Table 3). Patient-reported number of acute sinusitis was reduced significantly more in the ESS group (Table 4).

Table 4. Patient-reported change of symptoms an average 6 years after primary surgery (scale from −3 to 3, where −3 = the symptom had become significantly worse, 0 = no difference in symptom between pre- and post-operative situation, 3 = total reduction of symptoms).

	Balloon ($n = 28$) Median (min–max)	ESS ($n = 30$) Median (min–max)	p-value
Decreased sense of smell	0 (−1–3)	0 (−1–3)	0.71
Runny nose	1 (−1–3)	1 (−2–3)	0.51
Post nasal-disharge	0 (−2–3)	1 (−2–3)	0.50
Thick nasal disharge	1 (−1–3)	2 (−2–3)	0.05
Sneezing	0 (−2–3)	0 (−2–2)	0.66
Headache	1 (0–2)	2 (−1–3)	0.85
Cough	0 (−2–3)	1 (−2–3)	0.38
Fever	1 (0–3)	2 (0–3)	0.99
Fatigue	0 (0–3)	0.5 (−1–2)	0.24
Nasal blockage			
Right	1 (−2–3)	2 (−1–3)	0.02
Left	2 (−2–3)	2 (−1–3)	0.19
Facial pain/pressure			
Right	2 (0–3)	2 (−1–3)	0.53
Left	2 (0–3)	2 (−1–3)	0.53
Ear pain/pressure			
Right	0.5 (−2–3)	2 (−1–3)	0.41
Left	0.5 (−2–3)	1 (−1–3)	0.61
Watery eyes			
Right	0 (−1–3)	0 (0–2)	0.19
Left	0 (−1–3)	0 (0–2)	0.19
Willingness to have the same operation			
Right	3 (−2–3)	3 (−2–3)	0.77
Left	3 (−2–3)	3 (−2–3)	0.94
Number of common colds	0 (0–3)	2 (0–3)	0.16
Duration of common colds	0 (0–3)	0 (0–3)	0.23
Number of acute sinusitis	2 (−2–3)	3 (0–3)	0.01

p-values by Mann-Whitney U-test.

Table 3. Exacerbations and revisions ~6 years after primary surgery.

	Balloon ($n = 28$)	ESS ($n = 30$)	p-value
Median (min–max) number of maxillary punctures/lavages during the last year	0 (0–4)	0.5 (0–3)	0.23
Median (min–max) number of antibiotic courses on acute sinusitis during the last year	0 (0–10)	0 (0–3)	0.53
No. of patients with revisions during the follow-up period	4	0	0.05

p-value by Fisher's exact test (for dichotomous variable) and by Mann-Whitney U-test (for continuous variables).

Satisfaction

Patients in both groups were equally and well satisfied with the operation (Table 4). In the ESS group, 22 out of 30 (73%) patients, and in the balloon group, 18 out of 28 (64%) patients would definitely be willing to have the same operation.

Revisions

During the follow-up period, from the operation (2008–2010) until March 2015, four revisions were made in the balloon sinuplasty group and none in the ESS group ($p = 0.048$ by Fisher's exact test, Table 3). Of these four patients, three underwent ESS: one after 1 year, the second after 2 years, and the third patient after 4 years from the primary surgery. The fourth patient had undergone several sinonasal operations during the follow-up period: ESS of both maxillary sinuses and anterior ethmoidectomy, one failed attempt of the left frontal sinus balloon dilation, followed by traditional Draft I procedure of the left frontal sinus. The third patient was operated on in a private hospital by the same surgeon who did the primary balloon sinuplasty. The rest of the four revisions were performed in Tampere University Hospital, by surgeons other than the one who performed the primary operation. According to the patient records, revision operation was performed due to progression of CRS with intra-operative endoscopic signs of sinus mucosal inflammation and/or infection. There were no reported signs of failure of the primary balloon sinuplasty operation, such as missed ostium.

Sub-group analysis

Gender did not affect the results, nor did age or duration of CRS symptoms. No additional differences were found between sub-group analysis in patients with allergic rhinitis, asthma, or nasal polyposis. There was no difference in symptom changes or satisfaction between patients who had been exposed to bad indoor air (discovered mold or water damage) or were smoking. Nasal blockage on both sides (right side: median = 2, min–max = 1–3, $p = 0.001$, left side: median = 2, min–max = 1–3, $p = 0.007$), and the number of sinusitis (median = 3, min–max = 2–3, $p = 0.012$) were reduced significantly more in the ESS group compared to the balloon group (nasal blockage right side: median = 0, min–max = 0–2, left side: median = 0, min–max = 0–2; number of sinusitis: median = 2, min–max = −2–3), among patients with occupational risk factors (textile/wood dust, bad indoor air quality).

Patients reported positive family history of sinusitis or nasal polyposis did not influence symptom reduction or satisfaction ($p > 0.05$).

Discussion

This study was to compare symptom reduction and satisfaction after maxillary sinus surgery with ESS or balloon sinuplasty techniques. We demonstrated that both ESS and balloon sinuplasty seem to retain their efficacy equally, as measured by reported symptoms and patient satisfaction. To the knowledge of the authors there exist no previous controlled studies of balloon sinuplasty with an over 5-years follow-up. These results are in accordance with our previous study of symptom improvement with 2-years follow-up, the subjects of which consisted largely of the same patients [7].

An uncontrolled prospective study performed in-office balloon sinuplasty on 37 subjects. At 52 weeks, 95% indicated a willingness to have the procedure again, and 100% (21/21) would recommend it to family or close friends [17]. This is in line with our observations of high satisfactions with both ESS and balloon techniques.

In our study, patients in the balloon sinuplasty group reported more acute sinusitis during the last year. However, the number of maxillary punctures/lavages or antibiotic courses for sinusitis did not differ between the groups. In our 2-year follow-up study the balloon sinuplasty group reported a higher number of doctor performed maxillary sinus punctures, ultrasonography examinations, and prescribed antibiotic courses for acute sinusitis during the last 12 months, which differed statistically significantly from the ESS group [7]. Bikhazi et al. [18] show no difference in exacerbation rate between balloon and ESS groups in their 1-year follow-up study.

During the follow-up period of ~6 years post-operatively no revision procedures were performed in the ESS group, whereas four revisions (14%) were performed in the balloon sinuplasty group. This finding was statistically significant and could indicate that maxillary sinus ostium patency might be better achieved after ESS than balloon sinuplasty. The revisions in the balloon group were performed by surgeons other than the one who performed the balloon sinuplasty, which might have affected the operative decision.

We repeated our analysis after excluding the revision patients, because we wanted to see if the results had been biased due to the fact that the revision patients answered according to their current status. This, however, had no effect on the results.

The revision rates vary considerably between different studies due to the heterogeneous study design and follow-up time. Cutler et al. [13] had a revision rate of 2.0% after 6-months follow-up, and Levine et al. [19] had a rate of 5.8% after 1-year follow-up. Our revision rate of 14% needs to be established by other studies with equal follow-up time.

The diversity of the disease restrains the use of balloon as a single tool in many cases. Further controlled prospective studies with increased patient numbers are, thus, needed to show which patients benefit the most from the balloon sinuplasty, so that the obvious benefits of this tool can be efficiently utilized. Moreover, it could be possible to speculate that balloon sinuplasty might establish a position as an in-office treatment option for CRS patients with plain obstructive disease [20].

We acknowledge that the retrospective nature and relatively small patient number limit partly the interpretation of the results. The retrospective study design limited the option to use a validated quality-of-life test (such as SNOT-22), as the focus was on the comparison of change in symptoms after the operation. Yet, the questions used in this study partly correspond to the questions of SNOT-22. A shortcoming is that some patients might have had a limited ability to recall pre-operative symptoms and, thus, to report change in

symptoms 6 years after the operation. The advantage of the phone interview was that it was equally performed to both groups; and it enabled interviewing of the long-distance patients.

Conclusion

Our study shows that balloon sinuplasty retains its efficacy and patient satisfaction equally compared to ESS, even after 7 years from the surgery. Only minor differences were found between the techniques, with presumably no clinical significance.

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Declaration of interest

MP is a stockholder in a medical instrument company (Otoplug Oy, Tampere, Finland) that is marketing both balloon sinuplasty and ESS surgical instruments. The other authors report no conflicts of interest.

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