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Long-Term Follow-Up After Maxillary Sinus Balloon Sinuplasty and ESS

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Abstract

Objectives: The aim of this controlled follow-up study was to compare the need for revision surgery, long-term efficacy, and satisfaction in chronic rhinosinusitis patients who had undergone maxillary sinus operation with either balloon sinuplasty or traditional endoscopic sinus surgery (ESS) technique. **Methods:** Thirty-nine ESS patients and 36 balloon patients of our previously described cohort, who had been primarily operated in 2008 to 2010, were contacted by phone. Symptoms, satisfaction, and need for revision surgery were asked. In addition, we collected data of patients who had undergone primary maxillary sinus balloon sinuplasty in the Helsinki University Hospital during the years 2005 to 2019. As a control group, we collected data of patients who had undergone primary maxillary sinus ESS at 3 Finnish University Hospitals, and 1 Central Hospital in years 2005, 2008, and 2011. **Results:** Altogether, 77 balloon patients and 82 ESS patients were included. The mean follow-up time was 5.3 years in balloon group and 9.8 years in ESS group. Revision surgery was performed on 17 balloon patients and 6 ESS patients. In the survival analysis, the balloon sinuplasty associated significantly with a higher risk of revision surgery compared to ESS. According to the phone interviews, 82% of ESS patients and 75% of balloon patients were very satisfied with the primary operation. **Conclusion:** Although the patient groups expressed equal satisfaction and change in symptoms after the operations, the need for revision surgery was higher after balloon sinuplasty than after ESS. This should be emphasized when counselling patients regarding surgical options.

Keywords

balloon sinuplasty, chronic rhinosinusitis, endoscopic sinus surgery, revision surgery, satisfaction

Introduction

Chronic rhinosinusitis (CRS) is a common, inflammatory disease of the nose and paranasal sinuses with a prevalence of around 10%.[1] Given its chronic nature, it has a severe impact on quality of life and leads to substantial economic burden.[2,3] Despite being complex and multifactorial disease, CRS is commonly divided into 2 main groups: chronic rhinosinusitis without polyps (CRSsNP). Diagnosis is based on specific sinonasal symptoms lasting 12 or more weeks, computed tomography (CT) scan and/or endoscopic changes.[1] Surgery is considered after a failure of appropriate medical treatment with intranasal saline irrigations, corticosteroids, and possible long-term antibiotics.[1]

Endoscopic sinus surgery (ESS) is considered as a treatment modality in CRS for patients unresponsive to conservative treatment, even though trials providing high-level evidence of the efficacy of ESS for CRS are missing even today.[1,4] Nevertheless, patients with a prolonged and chronic disease

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with a severe impact on quality of life seem to benefit more from surgery than continued medical therapy.[5] The extent of surgery should be tailored to the extent of disease, and in primary surgery, surgical conservatism is recommended.[1]

Balloon sinuplasty was introduced as a minimal invasive tool for treatment of CRS 15 years ago and has been under debate since. The principle of balloon sinuplasty is to dilate the ostium without removing any bone or tissue while still preserving the epithelial mucosal lining surrounding the ostium. The idea is that the normal anatomy of the ostiomeatal region is not disturbed in the procedure. The catheter is advanced into the maxillary ostium, and the right place is verified with transillumination or navigation. The balloon is inflated up to 8 to 12 bars for a few seconds, resulting a wider passage to the blocked sinus. Advantages of this procedure are suggested to be faster recovery, no need for postoperative debridement, and possibility to in-office procedure.[6-8] The disadvantages are thought to be the lack of knowledge on its long-term effect and the high costs of the disposable instruments.[9] The use of balloon sinuplasty as monotherapy is also limited in patients who require removal of diseased tissue (eg, polyps, mucosa) or fungal ball.[10]

Several uncontrolled and controlled studies have suggested balloon sinuplasty to be a safe and effective method in treating uncomplicated CRS,[8,9,11-13] and over the past decade, the utilization of this technique has increased widely, especially in the United States.[14,15] However, in recent years, the research interest toward balloon sinuplasty seems to have decreased. Therefore, we still lack knowledge on balloon sinuplasty's long-term efficacy and specifically the need for revision surgery.

The aim of this controlled follow-up study was to compare the need of revision surgery among CRS patients who had undergone maxillary sinus operation with either balloon sinuplasty or traditional ESS technique, without any additional procedures.

Patients and Methods

The study was approved by the ethics committee of Helsinki University Hospital (No. 31/13/03/00/2015 and 3401/2019) and Pirkanmaa Hospital District (R09144).

Patients

Patients of our previous follow-up study were contacted by phone.[11,16] These 75 CRSsNP patients had undergone primary balloon sinuplasty (n = 36) or ESS (n = 39) of maxillary sinuses in 2008 to 2010. Only patients having a simple bilateral maxillary sinus operation, without any additional procedures (eg, septoplasty, ethmoidectomy, or dilation of other sinuses than maxillary sinus), or previous sinonasal, operations were included. The recruitment process, detailed inclusion and exclusion criteria, and study procedures have been previously described.[11,16] Twenty-four balloon and 28 ESS patients answered to the phone interview. Patients were asked whether they had undergone revision surgery and if answered yes, when and what kind of surgery. Symptom change was evaluated by asking the patients to compare the present symptom level with the preoperative situation. 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 gone significantly worse, and 3 that the patient was now asymptomatic. Satisfaction was evaluated by a question "Would you be willing to undergo the same operation now, knowing how much it would affect your symptoms? Scale from −3 to 3, −3 meaning definitely no and 3 definitely yes. Patients who had undergone revision surgery were specifically asked about their willingness to the primary balloon operation, knowing they would need revision surgery later.

In addition to reach a representative amount of balloon patients, we collected and evaluated retrospective data of all patients who had undergone primary maxillary sinus balloon sinuplasty at the Department of Otorhinolaryngology of Helsinki University Hospital between years 2008 and 2019. Altogether, 55 patients were found. Patients with nasal polyps or any additional procedures (eg, septoplasty, ethmoidectomy, dilation of other sinuses than maxillary sinus) or previous sinonasal operations were excluded, leaving 53 patients.

As a control group, we used data of CRS patients, which had been retrospectively collected of a random sample of patients who had undergone primary maxillary sinus ESS at the Departments of Otorhinolaryngology at Helsinki, Tampere and Kuopio University Hospitals, and Päijät-Häme Central Hospital in years 2005, 2008, and 2011. Patients with nasal polyps or who had undergone previous sinonasal surgery or had any additional surgery (eg, septoplasty, ethmoidectomy) were excluded. Altogether, 54 patients were included.

All patients were referred to a specialist for surgical evaluation due to CRS symptoms. The operative technique was chosen at the discretion of the specialist treating the patient. The operative indications fulfilled European position paper on rhinosinusitis and nasal polyps recommendations.[17-19] Patients' medical records and CT or magnetic resonance imaging scans were used for data collecting.

Operations

Balloon sinuplasty devices from the 3 manufacturers: Acclarent, Entellus, and Meril were used. The device was used to dilate the maxillary ostium according to instructions provided by the manufacturer. In the ESS group, partial uncinectomy and middle meatal antrostomy were performed using cutting instruments and/or shaver.

Statistical Analysis

Statistics were performed with IBM SPSS version 25 (IBM Corp). The nonparametric Fisher's exact test and Mann-Whitney *U* tests were used for comparisons of groups. Kaplan-Meier method and log-rank test were used in survival analysis. Cox's proportional hazards model was used to estimate the associations between different background variables and revision surgery. *P* value of less than .05 was considered significant in all tests.

Table 1. Patient Characteristics of All Study Patients.[a]

	Balloon sinuplasty		ESS		
	n = 77		n = 82		
Patient characteristics	n/mean	%/min-max	n/mean	%/min-max	*P* value
Age (years)	44	14-71	44	13-79	.81
Male gender	21	27	24	29	.86
Smokers	7	9	15	12	.11
Allergic rhinitis	27	35	24	29	.73
Asthma	12	16	21	26	.12
Total LM-score	3.7	0-12	6.2	0-16	**.001**

Abbreviations: ESS, endoscopic sinus surgery; LM, Lund-Mackay.
[a]*P* values from Fisher's exact test (for dichotomous variables) and from Mann-Whitney *U* test (for continuous variables), statistically significant values in bold.

Table 2. The Mean Follow-Up Time, Number of Revisions, and Time From Baseline Surgery to Revision.[a]

	Balloon sinuplasty		ESS		
	n = 77		n = 82		
	n/mean	%/min-max	n/mean	%/min-max	*P* value
Follow-up time (years)	5.3	1-11	9.8	5-15	**<.001**
Revisions during the follow-up period	17	22	6	7	**.01**
Time from baseline surgery to revision, mean (months)	22	4-81	22	3-75	.44

Abbreviation: ESS, endoscopic sinus surgery.
[a]*P* value from Mann-Whitney *U* test, statistically significant values in bold.

Results

Altogether, 77 balloon patients and 82 ESS patients were included to the study. Groups were equal in terms of age, sex, smoking, prevalence of asthma, and allergic rhinitis. There were no patients with nasal polyps. Preoperative total Lund-Mackay (LM) score was significantly higher in ESS group (Table 1). Sixty-nine (90%) balloon and 61 (74%) ESS patients were operated under local anesthesia. The mean follow-up time was 5.3 years in balloon sinuplasty and 9.8 years in ESS group (Table 2). Balloon sinuplasty was performed utilizing device by Acclarent in 42 (55%) patients, by Entellus in 23 (30%) patients, and by Meril 6 (8%) patients. Six patients lacked data on device label.

Revisions: Kaplan Meier Survival and Cox regression Analyses

During the follow-up, 17 (22%) patients underwent revision surgery in the balloon sinuplasty group and 6 (7%) patients in the ESS group ($P = .01$). Of the balloon patients undergoing revision surgery, 14 had their primary balloon sinuplasty performed utilizing device by Acclarent, 2 by Entellus, and 1 by Meril. The mean time interval from baseline to revision surgery was 22 (Table 2) months. The Kaplan-Meier survival curve with log-rank test affirmed that baseline balloon sinuplasty increased the risk of revision CRS surgery when compared with baseline ESS ($P = .003$, Figure 1). In Cox proportional hazards univariate model of the following predictors: age, gender, asthma, allergic rhinitis, smoking, baseline balloon sinuplasty, and ESS, only baseline balloon sinuplasty was significantly associated with revision surgery (Hazard ratio [95%CI] = 3.71 [1.44-9.56], $P = .007$).

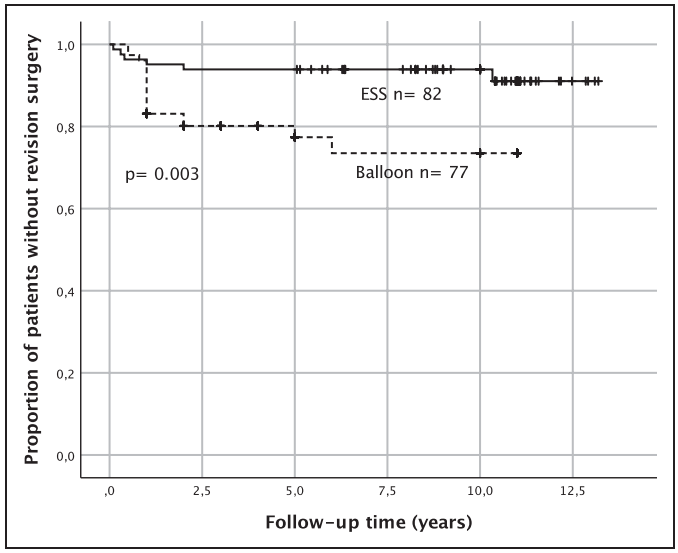

Figure 1. Predictive effect of ESS and balloon sinuplasty (balloon) to the time until the revision according to the Kaplan-Meier method. ESS indicates endoscopic sinus surgery.

Table 3. Patient Characteristics of Patients Who Participated in the Phone Interview.[a]

	Balloon sinuplasty		ESS		
	n = 24		n = 28		
Patient characteristics	n/mean	%/min-max	n/mean	%/min-max	*P* value
Age (years)	57	25-80	57	24-83	.84
Male gender	10	42	11	39	1.00
Duration of symptoms (years)	19	0-40	17	0-55	.59
Total LM score	4.8	0-11	7.2	0-16	.08
Smokers	1	4	6	21	.12
Allergic rhinitis	7	29	12	43	.39
Asthma	4	17	9	32	.34

Abbreviations: ESS, endoscopic sinus surgery; LM, Lund-Mackay.
[a]*P* values from Fisher's exact test (for dichotomous variables) and from Mann-Whitney *U* test (for continuous variables).

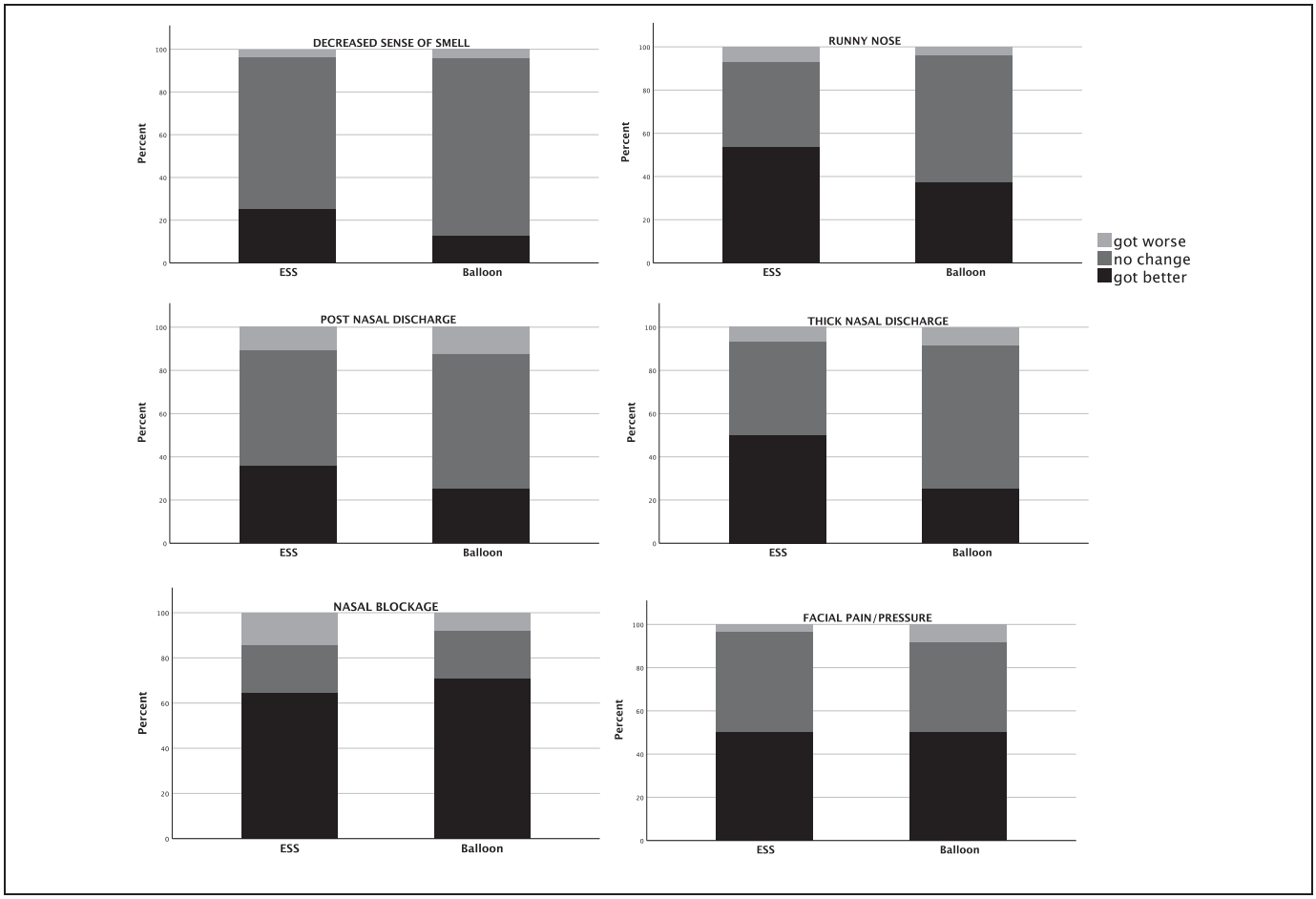

Figure 2. Phone interview: Proportion of patients reporting worsening, no change, or improvement of symptoms when comparing the preoperative and current status.

Phone Interview: Symptom Reduction and Satisfaction

Twenty-four (66%) patients in the balloon sinuplasty group and 28 (72%) patients in the ESS group answered to the phone-interview. The mean follow-up time of these patients was 10 (range 9-11) years. These groups were equal in terms of sex, age, duration of CRS symptoms, smoking, preoperative total LM-score, and prevalence of asthma and allergic rhinitis (Table 3).

The majority of patients reported improvement or no change in all symptoms (Figure 2). Both groups experienced equal symptom change (Table 4). No difference was found between the groups in the sum score of all symptoms either. The results

Table 4. Phone Interview.[a]

Balloon n = 24 ESS n = 28	−3	−2	−1	0	1	2	3	*P* value
Decreased sense of smell								.38
Balloon	0	0	1	20	0	1	2	
ESS	1	0	0	20	2	3	2	
Runny nose								.18
Balloon	0	1	0	14	5	4	0	
ESS	0	1	1	11	5	6	4	
Post nasal discharge								.37
Balloon	0	2	1	15	2	3	1	
ESS	0	2	1	15	2	4	4	
Thick nasal discharge								.08
Balloon	0	0	2	16	3	2	1	
ESS	0	1	1	12	4	6	4	
Nasal blockage (right)								.77
Balloon	0	1	1	5	7	7	3	
ESS	0	2	1	9	1	8	7	
Nasal blockage (left)								.74
Balloon	0	0	1	7	5	7	4	
ESS	0	0	2	8	4	6	8	
Facial pain/pressure (right)								.40
Balloon	0	1	1	10	5	7	0	
ESS	0	0	1	13	4	3	7	
Facial pain/pressure (left)								.32
Balloon	0	0	1	12	4	7	0	
ESS	0	0	2	11	4	4	7	
Willingness to the same operation (right)								.52
Balloon	2	0	1	0	0	3	18	
ESS	1	0	0	1	0	3	23	
Willingness to the same operation (left)								.52
Balloon	2	0	1	0	0	3	18	
ESS	1	0	0	1	0	3	23	

Abbreviation: ESS, endoscopic sinus surgery.

[a]The change of symptoms (preoperative vs current status) reported by patients (scale from −3 to 3, −3 = the symptom had gone significantly worse, 0 = no change in symptom, 3 = total reduction of symptoms) and patient-reported willingness to the same operation (scale from −3 to 3, −3 = definitely no, 3 = definitely yes). The number of patients in all grades in both patient groups was reported. *P* values from Mann-Whitney *U* test.

remained similar when the patients who had undergone revision surgery were excluded from the analysis (data not shown). One patient reported difficulties remembering the preoperative symptoms.

Patients in both groups were equally and well satisfied with the operation (Table 4). In the ESS group, 23 (82%) of 28 patients and in the balloon group 18 (75%) of 24 patients would definitely be willing to the same operation. When the patients who had undergone revision surgery were excluded from the analysis, the results remained similar (data not shown).

Discussion

Our main interest was to compare the long-term need for revision surgery after maxillary sinus balloon sinuplasty and ESS. The hypothesis was that the low revision rates of balloon sinuplasty reported in the current literature are partly due to short follow-up times. In this study, we obtained mean follow-up time of 5.3 years in the balloon sinuplasty group and 9.8 years in the ESS group, with 31% of balloon and 70% of ESS patients reaching 10 years or longer follow-up. The revision surgery rate after balloon sinuplasty was 22% and only 7% after ESS. The revision rate of balloon sinuplasty is higher than previously reported, suggesting that not all revision cases have been detected in studies with shorter follow-up time. In the REMODEL study by Chandra et al, overall revision rates after 18 months were 2.7% and 6.9% in the balloon and ESS arms, respectively.[6] Levine et al showed revision rate of 5.8% after balloon sinuplasty during 1-year follow-up.[20] In our 5-year follow-up study, the revision rates after balloon sinuplasty and ESS were 14% and 0%, respectively.[16] However, studies with over 5-year follow-up time after balloon sinuplasty have been missing so far.

Patients undergoing ESS can have a greatly varying disease, from extensive polyposis to a plain obstruction of a single sinus. Thus, different extent of surgery addressing variable number of sinuses is needed. These factors result in considerable variation in ESS-revision numbers in different studies. According to a large prospective cohort study, the revision rate after ESS in patients with CRSsNP is 15%,[21] and in a recent retrospective

analysis, with a mean follow-up time of 10 years, the revision rate was 9.6% in similar patients.[22] In this study, the revision numbers of specific sinuses were reported and the revision rate after maxillary sinus operation was 4.3%.[22] Our ESS revision rate (7%) with equal follow-up time is in line with this.

In the survival analysis, baseline balloon sinuplasty was associated with higher revision rate during the follow-up. This finding was statistically significant and could indicate that maxillary sinus ostium patency might be better achieved after ESS than balloon sinuplasty. Jensen et al evaluated the intraoperative accuracy of maxillary sinus balloon attempts. The success rate was modest, only 62%.[23] Another explanation for the higher revision rate may be that due to the intact uncinate process the ostium patency after balloon sinuplasty is relatively hard to confirm endoscopically in office, nor is it possible to lavage the sinus appropriately. Thus, it can be speculated that if the patients keep on returning to physician with sinus complaints after balloon sinuplasty, they might end up having a revision ESS more easily than patients whose ostium patency and sinus status can be directly confirmed by endoscopy.

One of balloon sinuplasty's advantages has been considered to be that it can be utilized in-office. Office-based procedures are shown to lead to significant cost-savings compared to procedures in operating room.[24] Several studies also state that other benefits of balloon sinuplasty compared to ESS are faster recovery, decreased postprocedural pain and less requirement for debridement, and due to these advantages should be equally considered as a treatment modality for patients with uncomplicated CRSsNP.[6,10] However, as stated above, due to the short follow-up times of these studies, they often lack the data of revisions in the long run. Supposing that the revision need is higher after balloon sinuplasty than after ESS, the putative savings resulting from spared operating room time or faster recovery might be compensated for benefit of ESS in the long run.

In a retrospective review, Cooper et al show that patients with more advanced disease, as manifested by higher radiographic score, neo-osteogenesis, prior surgery, nasal polyps, and gram-negative infections are more likely to need revision surgery after balloon sinuplasty.[25] In our study, patients with nasal polyps, revision surgery, and more complicated disease were excluded. In the risk analysis, balloon sinuplasty was the only factor that significantly associated with the revision surgery, thus confirming that patients with uncomplicated, low volume disease are truly in a higher risk to end up having revision surgery after balloon sinuplasty than after ESS.

The results of the phone interview on patient satisfaction and symptom relief are in accordance with the previous results from our 2- and 5-year follow-up studies.[11,16] It seems that both traditional ESS and balloon sinuplasty are equal in relieving CRS symptoms and patient satisfaction, which was retained excellent for 10 years. These results are supported by numerous other studies concluding that in terms of satisfaction and symptom, relief balloon sinuplasty is an efficient and effective management option for uncomplicated CRS.[6-8,10]

The higher preoperative LM score of ESS patients suggests that they had more severe disease compared to balloon patients. It can be thus speculated whether balloon sinuplasty is considered as a treatment option for patients with less severe disease.

We acknowledge that the retrospective nature of this study partly limits the interpretation of these results. Unfortunately, the data of a validated questionnaire (eg, SNOT-22) was not available of our cohort. For the patients who underwent the phone interview, we used our own questionnaire with similar questions to SNOT-22, as at that time a validated SNOT-22 was not available in Finland. Having a different follow-up time between the groups is a limitation of this study. However, the follow-up being longer in the ESS group, rather supports the conclusion that the risk of revision is higher after balloon sinuplasty than after ESS. Since even with a longer follow-up, ESS-operated patients had fewer revisions. It is possible that some patients might have had revisions outside the public medical care system not known to us, but as the Finnish public system covers more than 90% of operations in Finland, the bias is limited.[26] In addition, a recall bias in reporting the symptom change might have occurred, especially among patients who had undergone revision surgery. Yet, in the phone interview, only 1 patient-reported difficulties remembering the preoperative symptoms. Patients might give more optimistic opinion of their symptoms and satisfaction putatively partly due to placebo effect or the tendency to please the surgeon. To avoid the patients' need to embellish their condition to the surgeon the interview was performed by a research assistant.

It seems that patients having uncomplicated, low-volume CRS undergoing balloon sinuplasty are at a higher risk of revision surgery than patients undergoing ESS. This has implications when counselling patients regarding surgical options.

Authors' Note

AK, MLu, KB, MP, JM, and ST-S provided the study plan, made the applications, and collected the data. AK performed the analyses and manuscript writing with ST-S and MLu. All authors critically reviewed the manuscript.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: ST-S has acted as paid consultant for ERT, Sanofi Pharma, Novartis and Roche Products and MLu for Chordate Medical LTD. All these are outside the submitted work. MP is a minor stockholder and medical adviser in medical instrument company (Otoplug Oy, Tampere, Finland), which markets endoscopic sinus surgery and balloon catheter dilation instruments. All other authors declare no conflicts of interest.

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