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RHINOLOGY

Limitations of balloon sinuplasty in frontal sinus surgery

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Abstract Balloon sinuplasty is a tool that is used to treat selected patients with paranasal sinus pathologies. No studies have investigated the aetiology of failed access to the frontal sinus. The aim of our study was to specify the intraoperative technical failure rate and to analyse the aetiology of the failed access to predict potential technical difficulties before surgery. We retrospectively analysed the charts of patients who underwent balloon sinuplasty from November 2007 to July 2010 at three different ENT-Centres. CT-analysis of the patients with failed access was performed. Of the 104 frontal sinuses, dilation of 12 (12%) sinuses failed. The anatomy of all failed cases revealed variations in the frontal recess (frontoethmoidal-cell, frontal-bulla-cell or agger-nasi-cell) or osteoneogenesis. In one patient, a lymphoma was overlooked during a balloon only procedure. The lymphoma was diagnosed 6 months later with a biopsy during functional endoscopic sinus surgery. In complex anatomical situations of the frontal recess, balloon sinuplasty may be challenging or impossible. In these situations, it is essential to have knowledge of classical functional endoscopic sinus surgery of the frontal recess area. The drawbacks of not including a histopathologic exam should be considered in balloon only procedures.

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Introduction

Functional endoscopic sinus surgery is recommended for patients with chronic rhinosinusitis who have failed maximal medical therapy, including appropriate antibiotics and anti-inflammatory therapy, according to the EPOS guidelines [1]. One of the recent technical developments in endoscopic sinus surgery is balloon sinuplasty.

The concept of balloon dilation of a stenosed human organ was first reported in 1977, when the first cardiac angioplasty was successfully performed on a patient. Balloon dilation has become an established procedure in medical specialties such as cardiology, gastroenterology and urology [2].

In 2002, California-based engineers developed the technique of balloon dilation for sinus surgery [3]. It became well recognised in the worldwide media as a new procedure that offered more treatment options for patients with chronic rhinosinusitis [4, 5]. Balloon sinuplasty is described as a less invasive technique to open the paranasal sinus ostias without injuring the surrounding mucosa, which results in reduced intraoperative bleeding and minimal mucosal damage [4]. Due to anatomical complexity and variations, functional endoscopic sinus surgery of the frontal recess is technically demanding, and the risk for re-stenosis is high, an estimated 29% 6 years after surgery [6].

The medical literature has mainly concentrated on clinical and radiological outcome analysis of patients who underwent balloon sinuplasty [7–11]. Weiss [8] showed, in his 2-year-follow up study, a significant and stable improvement in the Lund–MacKay CT score and the

SNOT-20 score. There have been limited reports on the intraoperative technical failure rate of achieving a dilation of the frontal recess. This failure rate is between 6 and 19% [2, 10, 12]. To date, no studies have investigated the aetiology of these failures. The aim of our retrospective, multicenter study was to analyse the use of balloon sinuplasty on different sinuses, to characterise the intraoperative technical failure rate and to predict potential technical difficulties before surgery.

One of the drawbacks of the balloon only sinuplasty is that no samples are obtained for histopathological examination. We illustrate this disadvantage with a clinical case.

Materials and methods

We retrospectively analysed the charts of 64 patients who underwent balloon sinuplasty from November 2007 to July 2010 at the following three clinical locations: the Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital, Berne, Switzerland; the ENT-Centre, Hirslanden Clinic, Zurich, Switzerland; and the Department of Otorhinolaryngology, Klinikum Grosshadern, Munich. The data analysed included patient demographics, the use of the balloon sinuplasty on the different sinuses and the intraoperative technical failure rate. CT-analysis of the patients with the failed balloon sinuplasty was done. All patients who underwent balloon sinuplasty during the specified period were included in the study.

Results

A total of 64 patients were included in the study. There were 34 male and 30 female patients within the study population, and the average age was 45 (18–74) years.

Balloon catheters were used in 136 sinuses (maxillary, frontal and sphenoid) for an average of 2.1 sinuses per patient. The distribution of the different sinuses is detailed in Fig. 1. Twenty three patients (36%) were treated with a balloon only procedure, and 41 patients (64%) were treated with a balloon in combination with conventional functional endoscopic sinus surgery (hybrid operation). All hybrid procedures were performed under general anaesthesia. Of the 23 patients treated with the balloon only procedure, 21 were under general anaesthesia and 2 had local anaesthesia with intravenous sedation. The indications based on primary or secondary cases are depicted in Fig. 2. Primary cases were the main indication for balloon sinuplasty ($n = 41$), and 23 were revision cases. 27 (66%) of the primary cases and 14 (61%) of the revision cases were treated with a hybrid operation.

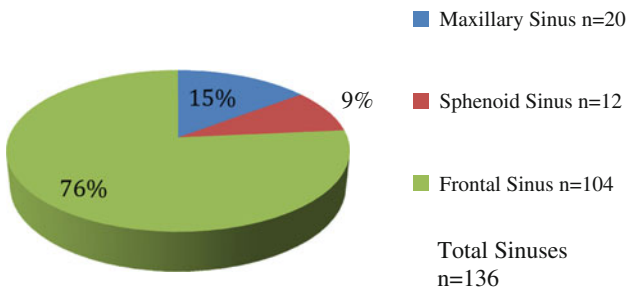

Fig. 1 Distribution of balloon sinuplasty based on the sinuses

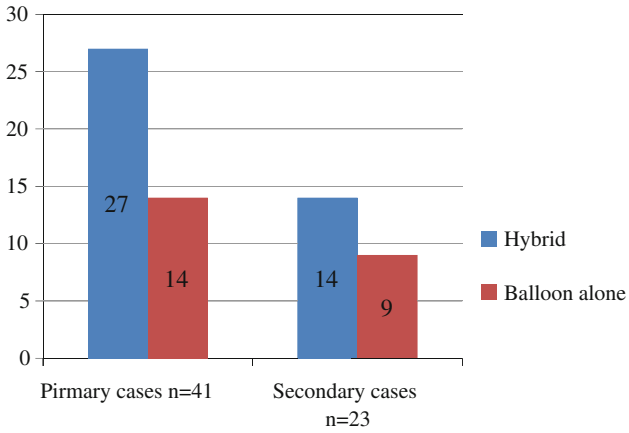

Fig. 2 Use of balloon only or hybrid operation based on primary or revision cases

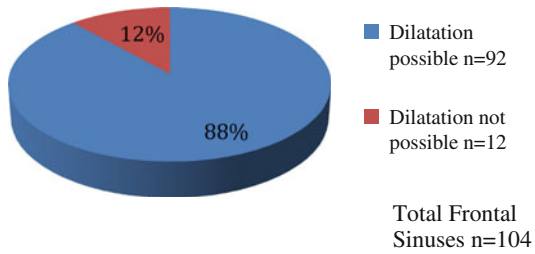

Fig. 3 Success rate for the dilation of the frontal recess

No adverse events occurred during the study period

Dilation was achieved in all maxillary and sphenoid sinuses. Of the 104 frontal sinuses in which balloon sinuplasty was attempted, dilation of 12 (12%) sinuses in 10 patients failed (Fig. 3). Of these cases, seven (8 sinuses) were primary cases, and three (4 sinuses) were revision cases. The aetiology of the failed dilations is depicted in Table 1 and Figs. 4, 5. No statistically significant difference in failure rate was found between the two methods used: fluoroscopy (63 frontal sinuses, 7 failed) and LUMA (41 frontal sinuses, 5 failed).

The CT-scan of one patient (Fig. 6a–d) showed signs of chronic rhinosinusitis and no suspicion of a malignancy.

Table 1 Aetiology of the technical failure of balloon dilation in 12 frontal recesses in 10 patients

Patient Number	Failed side	Pre-surgery	Failed dilation due to	Figures
1	Right	Yes	Osteoneogenesis, Agger nasi cell	4a
2	Both	Yes	Osteoneogenesis both sides Bulla frontalis left Frontoethmoidal cell right Type I	4b–d
3	Right	No	Hypoplasia frontal sinus, mild symptoms right side	4e–f
4	Right	No	Frontoethmoidal cell Type I	5a
5	Right	No	Frontoethmoidal cell Type I	5b
6	Right	No	Frontal bulla cell	5c
7	Left	Yes	Osteoneogenesis	5d
8	Right	No	Agger nasi cell	5e
9	Both	No	Osteoneogenesis	5f
10	Right	No	Agger nasi cell, Lymphoma	6a–d

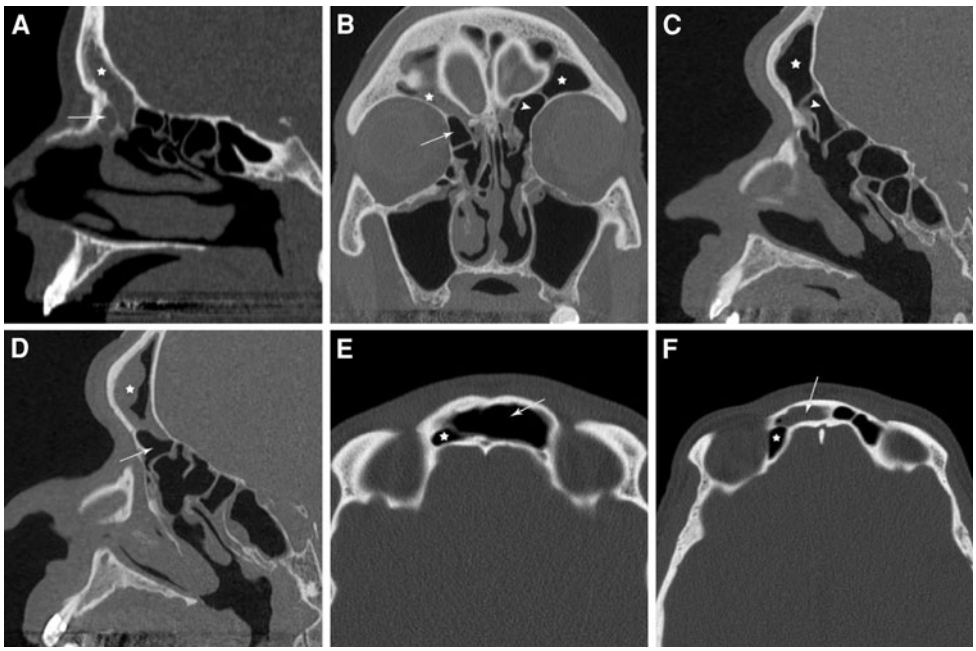

Fig. 4 **a** (Patient 1): severe osteoneogenesis of the frontal sinus/frontal recess (*star*) with an agger nasi cell (*arrow*). **b–d** (Patient 2): chronic rhinosinusitis of the frontal sinus (*star*) with osteoneogenesis of the frontal recess on both sides, a frontal bulla cell on the left side (*arrowhead*) and a frontoethmoidal cell on the right side (*arrow*). **e–f** (Patient 3): pneumosinus dilatans with chronic rhinosinusitis of the left frontal sinus (*arrow*) crossing the midline to the right side and hypoplasia of the right frontal sinus (*star*). Because patients' symptoms were most likely related to the successfully dilated left side, further effort to dilate the right side was stopped after three failed attempts

The left frontal sinus was opened by conventional endoscopic frontoethmoidectomy. Balloon sinuplasty of the right frontal sinus failed. 6 months later, the patient presented with a right-sided frontal headache. The CT-scan at that time showed an air-fluid level in the right frontal sinus. The right frontal sinus was then opened with conventional sinus surgery. Surprisingly, histopathological investigations revealed a lymphoma in the frontal recess.

Discussion

Since the introduction of balloon sinuplasty, the medical literature has mainly focused on follow up analysis. Weiss et al. [8] described a significant and stable improvement in the SNOT-20 symptom score and the Lund–MacKay CT score in his 2-year-follow up study on patients who underwent balloon catheter sinusotomy. There have been limited studies on the technical failure rate of balloon dilation of the frontal recess, and to date, no study has focused on the aetiology of such failures. In the literature, the failure rate of balloon dilation of the frontal recess is estimated at 6–19% [2, 11, 12]. In our study, the technical failure rate for balloon sinuplasty of the frontal recess was 12%, whereas the technical failure rate for the procedure of the maxillary and sphenoid sinus was 0%. As we showed in our failed cases, balloon dilation may be difficult in patients with anatomic variations of the frontal recess, such as agger nasi cell, frontoethmoidal cell or frontal bulla cell or in cases with significant osteoneogenesis. Leunig [13] studied the

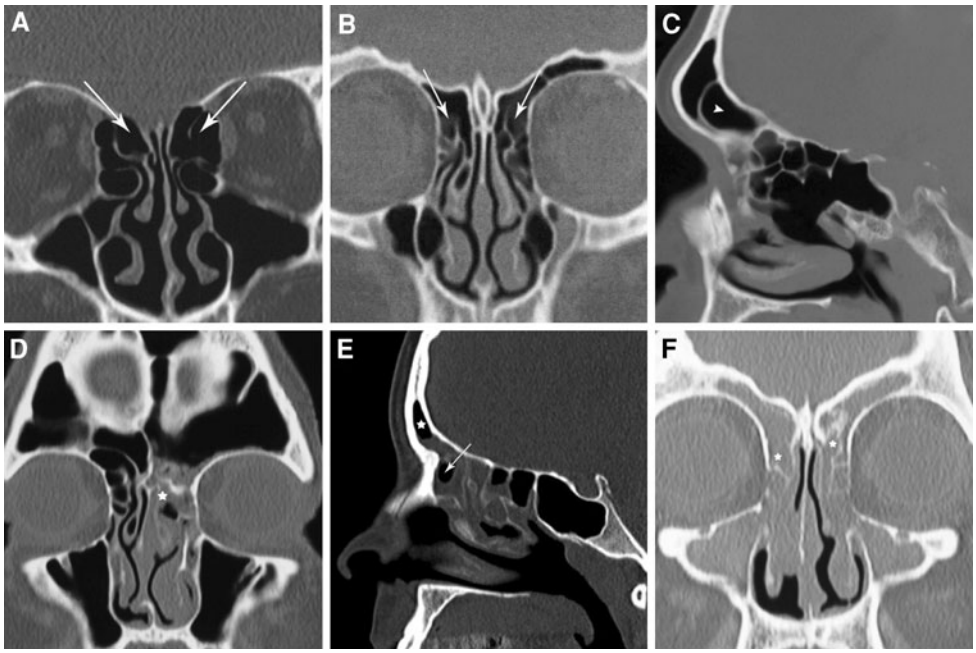

Fig. 5 **a, b** (Patients 4 and 5): frontoethmoidal cell both sides (*arrow*). **c** (Patient 6): frontal bulla cell on the right side (*arrowhead*). **d** (Patient 7): osteoneogenesis on the left side (*star*). **e** (Patient 8): Agger nasi cell (*arrow*) with obstruction of the frontal recess/frontal sinus (*star*). **f** (Patient 9): osteoneogenesis on both sides (*stars*)

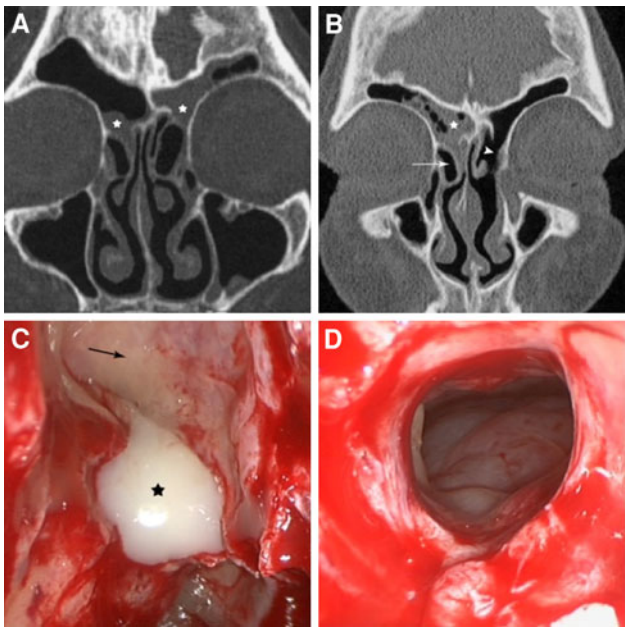

Fig. 6 (Patient 10) **a** Preoperative CT scan showing chronic rhinosinusitis of the frontal recess (*star*). **b** CT scan 6 months after conventional frontoethmoidectomy on the left (*arrowhead*) and failed balloon dilation of the frontal recess on the right due to an agger nasi cell (*arrow*) and missed lymphoma (*star*). **c** Obstruction and secretion (*star*) in the frontal recess due to an agger nasi cell (*arrowhead*). **d** After frontal sinusotomy on the right, histopathological exam showed a lymphoma of the frontal recess

anatomical variations of the frontal recess in 1,282 separately assessed sides of 641 patients who were referred for CT-scans due to chronic rhinosinusitis. In that patient population, the incidence of anatomical variations of the frontal recess were as follows: agger nasi cell, 80%; frontoethmoidal cell, 36.4% (Type I, 17%; Type II 6.8%; Type III, 12.5%; and Type IV, 0.1%) and frontal bulla cell, 16%. All of our failed cases showed this anatomic variations, in addition to frontal sinus hypoplasia or severe osteoneogenesis. No patient with failed balloon dilation had conventional anatomy of the frontal recess. Therefore, the analysis of the anatomic region of the frontal recess on the preoperative CT-scan for existing anatomic variations in each patient is mandatory and allows the prediction of the potential difficulties in achieving a dilation of the frontal recess. A profound understanding of the anatomy of the frontal recess in individual patients can be only achieved by analysing the CT-scans in multiplanar reconstructions. A discordance of up to 40% has been reported if the frontal recess is analysed in the coronal plane only versus analysis of the recess in multiplanar CT-reconstructions that include the sagittal, coronal and axial planes [14].

Wexler [15] suggests the image-guided frontal mini-trephination approach for guide-wire insertion in a retrograde fashion to introduce the balloon catheter when cannulation of the frontal recess fails. This method maximises the potential for frontal cannulation and dilation while minimising the fluoroscopic search time. Leventhal [16] performed balloon dilation of 31 sinuses using an image-guided sinus guiding catheter. This may lead to increased accuracy of device placement and a reduction in the duration of fluoroscopy. Whether the mini-trephination approach or image-guided catheter placement would have helped in our cases is unknown. Nevertheless, these techniques have the potential to help when balloon dilation with the conventional balloon sinuplasty technique fails.

Doubtless factors other than basic anatomic variations of the frontal recess are relevant for the technical failure for balloon sinuplasty. The size of the agger nasi cells, the frontoethmoidal cell and the frontal bulla cell and the angulation of these cells probably play a role in cannulation of the recess. Further anatomic studies are needed to answer the specific influence to this factors. Furthermore, the learning curve plays a role in the failure rate of balloon sinuplasty. As this is a multicenter study with different surgeons and the patient number is limited, statistical analysis of this factor was not reasonable. Our failure with 12% is in concordance with the failure rate in the literature specified with 6–19% [2, 11, 12]. Therefore, we can speculate that the learning curve was not the major factor for failure rate in our study.

It is not common practice to obtain a sample for histopathological examination during the balloon only procedure, and we present a case of an initially overlooked lymphoma of the frontal recess during one of these procedures. The lymphoma was confirmed following endoscopic frontoethmoidectomy, which was performed 6 months after the original balloon procedure. To our best knowledge, this is the first reported case of an overlooked malignancy in a case that involved a balloon only procedure. This drawback of not including a histopathological exam in a balloon only procedure should be considered.

Conclusion

Particularly in complex anatomical situations of the frontal recess, such as with an agger nasi cell, frontoethmoidal cell, frontal bulla cell or combinations of these, or in cases of severe osteoneogenesis, dilation of the frontal recess may be challenging or impossible. Therefore, despite the elegance of balloon sinuplasty, the surgeon should have a profound understanding of the underlying anatomy in each individual case and should know how to perform classical functional endoscopic sinus surgery in the frontal recess area in the event of a technical failure of the balloon dilation.

Because it is not common practice to obtain a sample for histopathological examination during the balloon only procedure, there is a potential risk of overlooking a pathology, which may require additional treatment. Therefore, conventional surgical techniques with the option of obtaining biopsies are recommended if there is any suspicion of neoplastic disease.

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