CASE REPORT

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Ethmoid roof CSF-leak following frontal sinus balloon sinuplasty*

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SUMMARY

Introduction: *Though clear indications for its clinical application are not established yet, balloon sinuplasty technology per se is considered safe and very few severe complications have been mentioned in literature as of today.*

Case Report: *We report the case of a 36-year-old female patient who presented with right sided rhinorrhea from a CSF-leak in the ethmoidal roof after balloon sinuplasty, aimed at her right frontal sinus. Apparently, the surgeon was unaware of having penetrated the skull base through the lateral lamella of the cribriform plate intraoperatively. CSF rhinorrhea became evident 3 weeks postoperatively only when fever, headaches and moderate nausea developed. Upon revision, diameter, size and shape of the bony defect exactly matched with the tip of a standard sinus balloon catheter device, as could be demonstrated and documented. A small posttraumatic encephalocele had intermittently blocked the leak. Endoscopic surgery and duraplasty were performed under intrathecal fluorescein control, applying CT image-guided navigation. Since two-layer fascia lata closure of the defect, the patient has remained free of symptoms without any evidence of CSF leakage.*

Conclusion: *Balloon sinuplasty per se is considered a safe technique, though in inexperienced hands or wrongly applied, complications may occur, as with any surgical tool rigid enough to breach through skull base.*

Key words: balloon sinuplasty, complications, CSF-leak, sinus balloon catheter

INTRODUCTION

Since the first studies on feasibility and safety of balloon sinuplasty were published by Bolger and Vaughan [1], Brown and Bolger [2] in 2006, and later by Stamm et al. [3], the topic has remained heavily debated in rhinology [4-6]. The underlying principle is that of balloon dilation of narrow sinus passages and ostia, rather than traditional surgical resection of bone and mucosa. To achieve this goal, rigid guiding "catheters" with different tip angulations are placed near the area in question, under endoscopic control. A flexible "guide wire" is then fed through the "catheter" and under either fluoroscopic or transillumination control, advanced into the respective passage, ostium or sinus. Once a correct position has been verified, the balloon catheter proper is advanced over the guide wire and inflated (with saline solution or contrast medium) in situ. Pressure applied may vary from 8 - 12 bar and is to be maintained for a few seconds only. Thus, thin bony walls of cells, ostia or stenotic areas are dilated, compressed or even fractured, resulting in a wider, hopefully permanent, passage to the respective sinuses, allowing for recovery of the latter.

Especially for endonasal frontal sinus approaches, which remain difficult for many surgeons in conventional FESS, the technique appears promising. Other authors have described it as minimal invasive treatment for (acute) sinusitis in immune-compromised patients or children, with a lower complication rate, fewer traumas and less blood loss as compared to resection of bone or mucosa [7-10].

As of today only three major complications in over 85.000 (0.0035%) operated sinuses have been reported. These were two penetrations of lamina papyracea and one CSF-leak inferior and anterior to the sella turcica after attempt of frontal sinus balloon dilatation. In the latter case, a so-called hybrid procedure was performed and the leak was rather attributed to the simultaneous use of conventional through-cutting instruments [6,11].

The so-called CLEAR (CLinical Evaluation to Confirm SAfety and Efficacy of Sinuplasty in the PaRanasal sinuses) study [12-14] an international, multi-center study evaluated patient data at 6 months, 1 year and 2 years follow-up. Within two years no adverse events were reported among 65 patients with 195 sinuses dilated [14].

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The case presented here therefore, is the first documentation of an intracranial entry with balloon sinuplasty equipment alone.

CASE REPORT

We report the case of a 36-year-old female patient who was referred to our hospital with CSF rhinorrhea from her right nose. Around six weeks earlier she had undergone septoplasty, inferior turbinate coblation and balloon sinuplasty of left sphenoid and maxillary sinuses as well as right frontal sinus at a hospital abroad, with initially uneventful postoperative course. Between the 3rd and 4th postoperative week the patient started to suffer from headaches and after blowing her nose experienced right-sided clear liquid rhinorrhea followed by fever, some nausea and general feeling of illness without any signs of meningitis.

On the day of referral to our hospital, rhinorrhea was clinically evident especially when the patient was leaning forward. The fluid was found beta-trace protein positive.

Imaging

When compared with the initial preoperative CT scans (Figures 1 a-d), a breach in the lateral lamella of the cribriform plate was evident on the right visible both on coronal and sagittal planes. On MRI, a circumscribed brain herniation was suspected (Figure 2, Figures 3a–d) Preoperative opacification of the left maxillary sinus had disappeared; sphenoid sinus opacification on the left had improved, but was still present, as was frontal sinus opacification on the right. The effects of balloon sinuplasty were best seen on coronal scans in anterior ethmoid on the right, where uncinate process and medial wall of the bulla appeared lateralized with a passage wider than preoperatively, between the latter structures and the middle turbinate. This passage leads straight towards the skull base defect in ethmoidal roof (Figure 6).

Endoscopic revision

Endoscopic endonasal closure of the CSF-leak was performed under CT image guided navigation (Medtronic FUSION™ ENT Image Guidance System, Medtronic Navigation, Louisville, CO, USA) after application of 0.5 ml of a 5% sodium fluorescein solution intrathecally. Nasal endoscopy revealed no lesion anywhere medial to the turbinates in the cribriform plate region. Small amounts of CSF escaped through the cleft between middle and superior turbinates, from out of the ethmoid complex. Under blue light however, a CSF-leak at the medial aspect of ethmoidal roof through the lateral lamella of cribriform plate could clearly be identified, with fluorescein-stained CSF pulsating into anterior ethmoid compartments (Figures 4 and 5). On sagittal plane it was located at the transition of anterior to posterior ethmoid roof (Figure 3b).

When endoscopically approached via the middle meatus, a "preformed passageway" would lead directly to the lesion. The bony defect was strictly circular (Figure 4) and precisely matched in size and shape with a standard balloon catheter device, which we gently placed into the defect for verification and documentation during revision surgery. Anatomically, there was no possibility to reach the defect site from medially, i.e. the septal side, with any instrument.

A circumscribed herniation of partially colliquated brain tissue with granulomatous surface was encountered partially "plugging" the defect, indicating a lesion of brain surface at the time of trauma. Tiny pieces of bone were removed from intracranially and after denuding the defect, it was closed with two layers of fascia lata in an underlay-overlay technique. Additionally, a pedicled muco-periosteal flap from the middle turbinate was rotated over the fasciae. The grafting materials were secured with fibrin glue and resorbable packing material (Tabotamp® Johnson&Johnson Medical Ltd, Gargrave, North Yorkshire, UK). No intralumbar drain was used.

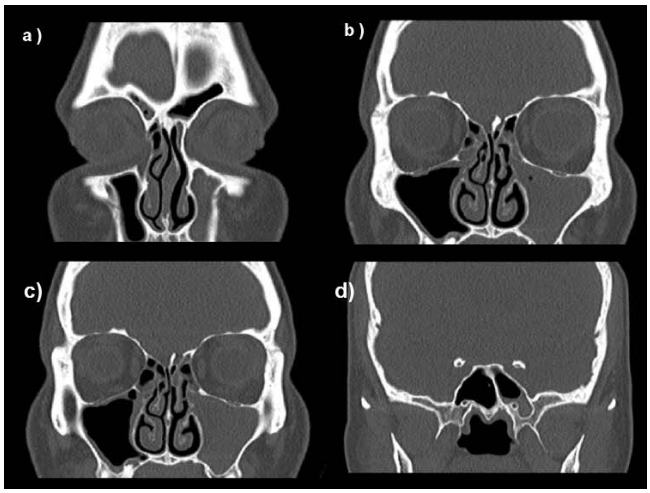

Figure 1. CT scans prior to balloon sinuplasty at levels of a) agger nasi and frontal sinus, b) ethmoidal infundibulum, c) ethmoidal bulla and d) sphenoid sinus. Note intact ethmoidal roof in b) and c).

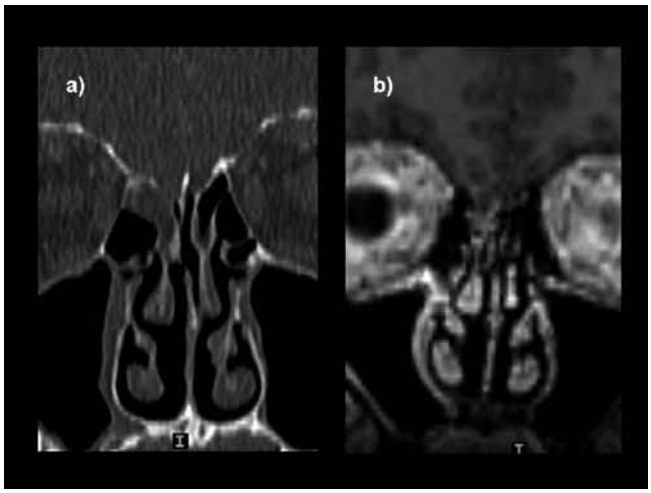

Figure 2. a) Coronal CT and b) MRI at the level of breach through lateral lamella of cribriform plate on patient´s right side. Note encephalocele through defect in MRI.

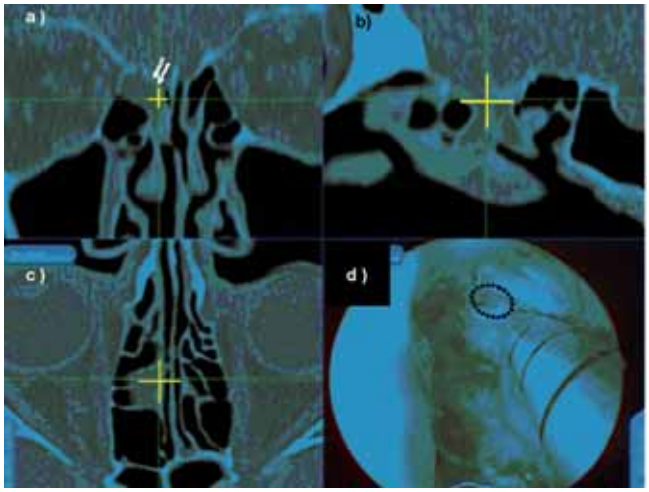

Figure 3. Crosshairs (partially digitally enhanced) marking position of tip of navigational instrument in ethmoid at skull base attachment of middle / superior turbinate, 2 mm below and slightly posterior to defect (dotted circle in d). a) arrows: breach through lateral lamella of cribriform plate. c) note crosshair position medial to turbinates.

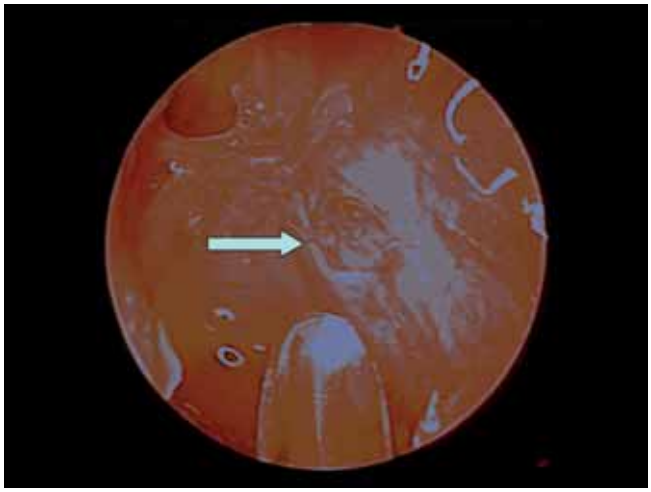

Figure 4. Endoscopic close-up: the perfectly circular 3 mm defect is partially "plugged" by granular herniated substrate (arrow).Only moderate flow of CSF is encountered. Tip of J – curette approaching from below. 30° endoscope with blocking filter attached, white Xenon light.

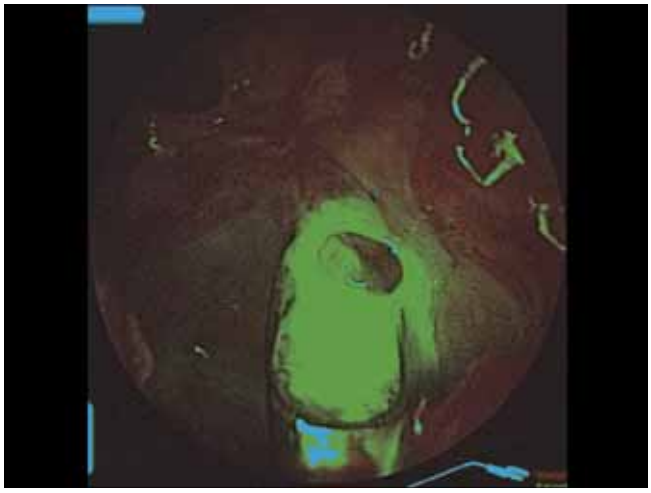

Figure 5. Situation as in fig. 4 seen under blocking filter and blue light, inducing florescence: massive escape of CSF, especially when herniating material is gently elevated with curette.

Postoperative course was uneventful and watertight closure was achieved. The patient is now ten months free of symptoms, especially no meningitis or CSF rhinorhea have occurred.

DISCUSSION

Balloon sinuplasty per se is considered a safe technology: only one case of CSF-leak after balloon sinuplasty for frontal sinus was reported in the MAUDE adverse event report database by the FDA in 2006, caused by a traditional instrument in a hybrid procedure [11]. Levine et al. [15] published a multicenter study in 2008 with 1,036 patients and 3,276 sinuses treated using balloon sinuplasty. Apart from two CSF leaks in ethmoids, which were also clearly attributed to classical FESS instruments no major adverse events had occurred. Bolger et al. [12] published a multicenter study in 2007 (CLEAR study) including 115 patients with 358 sinuses operated. Of these, 124 frontal recesses had been balloon - dilated. Neither intraoperatively nor over a 24-week follow-up period was any CSF-leak encountered [12]. Over a follow-up period of two years no adverse events were reported by Weiss et al. [14] in 2008 among the remaining 65 patients with 195 sinuses dilated from the original CLEAR study.

Theoretically, the following complications might occur with balloon sinuplasty equipment:
Creation of a false passage with either catheter, guide wire or balloon into the orbit or intracranially. In the sphenoid sinus, dehiscent internal carotid arteries and optic nerves might be at risk of injury, especially when the latter travel freely through the sinus – the guide wire might "wrap around" the nerve resulting in potential damage when followed by the balloon to be inflated. Thin bone fragments resulting from fractures induced deliberately by balloon dilatation might pierce or tear dura. Finally, balloons might rupture when inflated at higher than recommended pressure or damaged by sharp bony edges.

None of the above theoretical possibilities has been reported in the literature to date, underlining the good safety profile of the technology. The only cases of CSF-leaks reported occurred during hybrid procedures and were attributed to traditional FESS instruments [11,15]. Our case is the first report in literature, where a postoperative CSF-leak occurred after a "balloon-only" procedure.
Neither with the use of fluoroscopy nor with newer sinus illuminations systems should it be possible to place balloons at a wrong location since both systems clearly indicate the guide wire's position over which the balloon is inserted into the sinus. In our case frontal balloon sinuplasty was attempted and per-

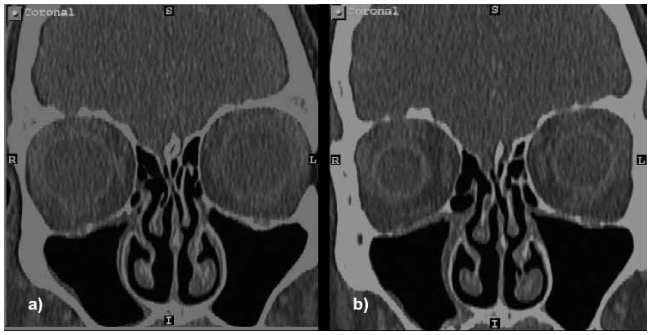

Figure 6. Coronal CT scans 5 weeks after balloon sinuplasty, prior to repair of CSF leak: the wider passage between middle turbinate and a), uncinate process, b) the ethmoidal bulla is evident when compared to Figures 1b and 1c. Endoscopically and verified by navigation, this "passage" would lead directly to the defect site medial to the turbinate.

formed, with a resulting postoperative CSF-leak located at lateral cribriform lamella at the transition of anterior to posterior ethmoid some two centimetres posterior to frontal sinus access. During an attempt to place the (rigid) sinus catheter near or into the frontal recess on the right, the surgeon must have penetrated the thin lateral lamella of the cribriform plate with the tip and consequently, the adjacent dura of the olfactory fossa. This passage of approach was clearly seen endoscopically and on the CT scans (Figure 6). At revision surgery, a circumscribed brain herniation was encountered (Figures 4 and 5), indicative of trauma to the surface of the brain. Whether or not this was caused by the cannula and/or the guide wire cannot be determined in retrospect. MRI scans demonstrated this lesion, but findings do not point towards a balloon having been passed or even inflated intracranially – but cannot rule it out either (Figure 2b). According to the primary surgeon´s description, no instrument other than balloon sinuplasty equipment was used for this approach – no mention is made of any erroneous or unsuccessful attempt to reach the frontal sinus. Anatomically, the site of the breach cannot be reached during septoplasty as performed in this patient. We therefore conclude, that the surgeon did not realise that they had created the bony and dural defects. The resulting edema and circumscribed brain herniation most likely prevented a more pronounced CSF rhinorrhea during the early postoperative period.

CONCLUSIONS

Based on reports in the literature and our own experience, balloon sinuplasty technology has a good safety profile. Whereas clinical indications still remain controversial, few specific complications have been published to date. As documented in this case however, the potential for complication exists both theoretically and in practice.

When indicated, in our opinion balloon sinuplasty should only be performed strictly following the manufacturers´ guidelines; never without a pre-operative CT scan and always under direct endoscopic vision when inserting catheters, guide wires and balloon devices. Balloons must never be inflated without absolute certainty of their exact positioning, be it by fluoroscopy or transillumination. We consider it mandatory to obtain full informed consent to the same extent as that obtained for conventional endoscopic sinus surgery, to avoid potential legal problems.

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