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Mini Review

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New Frontiers in Balloon Sinuplasty

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Abstract

Chronic rhinosinusitis is defined as a condition that presents two or more sinus-nasal symptoms, including nasal obstruction, nasal blockage, nasal congestion or discharge-with or without facial pain-, facial pressure and decreased sense of smell or loss of smell over a period of more than 12 weeks.

Balloon sinuplasty is a technique employed in endoscopic sinus surgery that involves minimally invasive procedures to dilate obstructed anatomical passages or sinus stenosis and, accordingly, to restore proper ventilation of the affected sinuses.

Starting from the history and evolution of balloons, we aimed to evaluate the possibility of using angioplasty balloons for peripheral vessels for sinus dilation, considering that patients present an array of symptoms and manifestations of the disease itself, as well as the sinuses involved and anatomical varieties. Our goal was to evaluate, on a case-by-case basis, the possibility for nasal surgery professionals with decades of experience to use different balloons as an alternative to those commonly used in the department of Otolaryngology.

Keywords: Rhinosinusitis; Sinuplasty; Balloon treatment; Balloon angioplasty

Abbreviations: Chronic rhinosinusitis (CRS), Functional endoscopic dilatation of the sinuses (FEDS)

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Chronic rhinosinusitis (CRS) is a common disease that affects almost 10% of the population and has a major impact on quality of life, as well as economic repercussions such as job loss or school absenteeism [1, 2]. Treatment for CRS is challenging, with medical therapy as the primary treatment method and surgery offered in the event of unsuccessful medical therapy [3]. CRS is defined as a condition that presents two or more sinonasal symptoms, one of which includes nasal obstruction, nasal blockage, nasal congestion or discharge with or without facial pain, facial pressure and decreased sense of smell or loss of smell for more than 12 weeks. Symptoms reported by patients include the need for nasal cleansing, nasal patency, sneezing, runny nose, cough, post-nasal drip, cough

with phlegm, clogged ears, dizziness, earache, facial pain/pressure, smell/taste changes, difficulty falling asleep, waking up at night, sleep deprivation, waking up tired, fatigue, decreased productivity, decreased concentration, frustration/restlessness/irritation, sadness, and embarrassment. Endoscopic evidence of pus and/or edema and CT scan results indicating blocked osteomeatal unit are useful for confirming the diagnosis. The normal physiological functioning of the sinuses depends on the patency of the osteomeatal unit, frontal stenosis, normal mucociliary transport and normal quantity and quality of secretions. Preservation of the uncinate process in balloon sinuplasty helps maintain nitric oxide levels within the sinus as well as sinus physiology.



Balloon sinuplasty is a technique employed in endoscopic sinus surgery that involves minimally invasive procedures to dilate obstructed anatomical passages or treat sinus stenosis. The procedure derives from the well-known angioplasty technique. Balloon dilation to treat stenosis of a human organ dates back to 1977, and since then it has become an established procedure in medical specialties such as cardiology, gastroenterology and urology [2]. In 2002, the balloon dilation technique for sinus surgery was developed by engineers in California [4, 5]. Balloon sinuplasty is described as a less invasive technique to dilate without damaging the surrounding mucosa, resulting in reduced intraoperative bleeding and minimal damage to the mucous membrane of the ostium of the paranasal sinuses [6, 7]. Balloon sinuplasty was introduced as a minimally invasive tool for treating CRS 19 years ago and has been the subject of much debate ever since. The principle behind balloon sinuplasty is to dilate the ostium without removing any bone or tissue while preserving the lining of the epithelial mucosa surrounding the ostium. The technique is performed with a flexible instrument (balloon catheter) that allows surgeons to endoscopically create an opening in the ostia of the patient's sinuses and transitional spaces that are obstructed or significantly narrowed, maximizing tissue preservation, dilating the natural ostium and minimizing iatrogenic damage to the mucosa. The catheter is advanced into the maxillary ostium and the correct position is verified via transillumination or navigation. The balloon is inflated to 8-12 bars for 10 seconds, resulting in a wider passage towards the blocked sinus. The balloon sinusplasty devices by 2 manufacturers are Acclarent and Entellus. The device is used to dilate the maxillary and frontal ostium in accordance with the manufacturer's instructions.

Using the history of the evolution of sinus balloons as our point of departure, we set out to explore the possibility of using balloons already existing on the market for coronary dilatation which could also be used in the otorhinolaryngology field. We needed to consider that patients present with various symptoms and manifestations of the disease itself, the sinuses involved and the anatomical varieties [8]. Accordingly, we could not merely use a small number of balloons marketed for the department of Otolaryngology, but rather our goal was to evaluate, on a case-by-case basis, the possibility for nasal surgery professionals with decades of experience to use different balloons.

Surgery

All procedures were performed under general anesthesia. Topical anesthesia (5% lidocaine in 1: 1000 adrenaline) was used to prepare the nose prior to the procedure. The Spiggle & Theis introducer was employed near the various peripheral balloons, then slid at the level of the treated paranasal sinus. Each balloon is connected to a water pump which pressures the balloon and, depending on the type of balloon, is brought to a pressure of 10-12 atm. The balloons used included Semi-compliant Rialto NC PTA

Balloon Catheter 0.014 OTW (Nominal Pressure: 12atm, Rated Burst Pressure (RBP), Non-compliant Erasmus NC PTA Balloon Catheter 0.018 OTW, Semi-compliant Minerva PTA Balloon Catheter, over the wire 0.18, Non-compliant Castor Nc PTA balloon catheter 0.014 OTW, Non-compliant Achilles PTA Balloon catheter 0,018 OTW, Semi-compliant Polux SC PTA Balloon Catheter 0.014 OTW by ITC (international technology company) srl , with registered office in Cucciago (Como, Italy). In Functional endoscopic dilatation of the sinuses (FEDS), 2 instruments (Acclarent, Entellus) are used to gain initial access to the sinus ostium, then a sinus guide catheter is introduced into the target sinus ostium via endoscopic visualization. A flexible sinus guidewire is introduced through the sinus guide catheter and gently advanced into the target sinus. The balloon sinus catheter slides smoothly over the sinus guidewire and is placed through the blocked ostium. The position of the sinus balloon catheter is confirmed by relying on fluoroscopic guidance. It is gradually inflated so as to gently restructure the blocked ostium. The balloon sinuplasty system is then removed, leaving the ostium open and allowing for normal sinus drainage and function to be restored. These balloons cannot reflect the individual needs of all cases, which vary according to the anatomical variants and pathological variations presented by each patient.

Hence, the need for more personalized surgery, starting with the endovascular balloons used in angioplasty that have evolved and are of different lengths, diameters and resistances. Therefore, we aimed to propose and prepare targeted and specific intervention surgery for the patient based on previous functional endoscopic sinus surgery (FESS).

The purpose of balloon sinuplasty (the opening of the sinus using a balloon) is to clear the outflow of the sinus by dilating the ostium, allowing for the remodeling of the area without any excision of the bones and mucosa. As compared with traditional endoscopic nasal surgery, these mini-invasive techniques using endovascular balloons facilitate healing, whereby mucosa and cilia regain their physiological function. This balloon procedure does not necessarily require general anesthesia, thus allowing for ambulatory surgery. Endoscopic sinus surgery and balloon sinus dilation share similar indications (with some advantages to be had by using balloons in terms of safety such as structural preservation and mucosal functional results). Both aim to gain better access to the sinus and better ventilation, thus restoring the physiologic function and improving the effects of medical maintenance therapy.

We also used drug-eluting medicated balloons, sharp balloons, balloons emitting shock waves, thanks to the technology refined during our vast experience in hemodynamics and interventional radiology. Therefore, our goal was to set aside our prior know-how and to rediscover a virtuous and synergistic relationship between clinician and surgeon.

Intercepting diseases before they become chronic, thus saving billions of dollars or euros in terms of social costs by

using the new tools available in our operating rooms and in our clinics, represents a challenge that requires interdisciplinary dialogue. Functional treatments according to Thinvasive protocols (as these new approaches are known) simplify the surgical procedure by minimizing trauma and removing structures, thus reducing complications and clinical risks of damage to the barrier mechanisms of the upper airways, protecting against infection and controlling hyperreactivity [8].

When the subtle mucosal and ultrastructural functional mechanisms were not fully grasped, osteocartilaginous portions of the internal nose and paranasal sinuses used to be removed. Today, we understood that the opposite is true, which also applies for extensive and massive pathologies. With the use of new technologies and devices according to Thinvasive protocols, limited removals and minimal dilation enlargements are sufficient to restore correct ventilation of the nasosinus spaces, that recover their function progressively and definitively.

Thanks to this innovative Thinvasive functional mini-invasive surgical procedure developed and ratified according to our modern integrated research protocol, it is possible to improve and restore the correct functioning and physiology of the respiratory system with great benefits for the entire organism (heart, metabolism, quality of sleep, physical resistance, reduced consumption of drugs and infections). The Thinvasive surgical protocol, already used by thousands of people, is swiftly performed in Day-Surgery and in complete safety, after careful and advanced diagnostic investigations carried out on all patients suffering from respiratory disorders or needing to improve the ventilation of the paranasal sinuses. The minimally invasive surgical techniques of the Thinvasive DRB System for the treatment of Respiratory Syndrome minimize pain and anesthesia, convalescence, eliminate bleeding and allow the patient to recover and quickly resume normal activities.

Conclusion

The variety of balloons available has allowed us to be much more specific for improved treatment of both symptoms reported by the

patient and the pathology affecting the paranasal sinus, making our selection as previously mentioned, also based on anatomical variety. The preliminary results have yielded good outcomes, as well as a wide range of possibilities for using different balloons at the level of the paranasal sinuses. This technique has proved to be possible and feasible thanks to the expertise of surgeons specializing in balloon sinuplasty.

Acknowledgement

None.

Conflict of Interest

No conflict of interest.

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