

Balloon Dilation Technology: Let the Truth Be Told

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Abstract Balloon dilation technology (BDT), also known as balloon sinuplasty, has been in clinical use since September, 2005. Prior to BDT, surgeons performed a procedure called FESS, or functional endoscopic sinus surgery, for patients with chronic sinusitis. As is true with any new technology or procedure in medicine, a debate often ensues between early adopters and mainstream practitioners. Over the past 7 years, much has been discussed, debated, and learned about BDT. What follows is a review of the origins of the BDT: the theory, technology, indications and applications; and a review of the pertinent outcomes literature. Independent of how one feels about BDT, the evidence strongly supports its safety, efficacy, and growing popularity among patients and physicians alike.

Keywords Balloon dilation technology · Sinusitis · Endoscopic sinus surgery · Outcomes data · Indications

Introduction

Balloon Dilation Technology (BDT) was introduced in September, 2005 at the American Academy of Otolaryngology Annual meeting in Los Angeles, CA, USA. This technology is considered “disruptive”, not because it interfered with conventional treatment or patient care, but because it introduced a paradigm shift for the treatment of patients with chronic

rhinosinusitis (CRS), and it required the otolaryngologist to learn catheter-based surgical techniques, a new skill set not previously taught. Over the past 25 years, there have been 4 major technological advances in rhinology: the endoscope, the powered micro-debrider, image guidance systems, and BDT. The minimally invasive concepts of Messerklinger, which are founded on understanding the pathophysiology within the transition space, have been validated by BDT. Hence BDT is considered a “transition space tool”. The functional elegance of BDT, coupled with its relative conceptual simplicity, earned BDT descriptors such as innovative, revolutionary, and ingenious. Unfortunately, disruptive technologies are not easily or quickly embraced in medicine. There are many reasons for this, including the belief by many practitioners that they already deliver quality care to their patients and feel comfortable with their existing skill set. There are well-known examples of disruptive technologies in other areas of medicine. Today, cardiac catheterization is considered routine for patients with cardiac disease, arthroscopic knee surgery is the standard of care for orthopedists, and laparoscopic and robotic surgery has replaced the majority of open abdominal procedures performed by general surgeons, urologists, and gynecologists. In fact, it took 15 years for arthroscopic surgery to be considered the standard of care for most knee injuries!

In what follows, we will discuss the tools required and the theory behind BDT, its application in the treatment of patients with CRS, including exciting data on “functional preservation”, the role of the uncinate process, and physiologic gas exchange principles within the sinus. A review of the pertinent current literature as it relates to BDT is then followed by a discussion of clinical indications.

The “Tools”

The basic BDT system is comprised of several disposable components including suction capable guide catheters,

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flexible kink-resistant guide-wires, balloon dilation catheters of various diameters (3.5, 5, 6, and 7 mm), and a manual pump mechanism to inflate and deflate the balloon catheters. Fiberoptic guide-wires (e.g. LUMA™), irrigation catheters (e.g. Vortex™), and drug elution balloon catheters (e.g. Releiva Stratus™) have replaced first generation tools. Fluoroscopy, initially a requirement of the technology to help guide and confirm proper wire and balloon placement, is now optional due to the introduction of sinus transillumination through a light wire. Under endoscopic control, the balloon catheter is then threaded over the guide-wire, positioned properly within the sinus transition space, inflated, and removed. The balloons themselves are non-conforming and therefore can displace bone and tissue within the sinus transition space and/or ostia. Balloons are inflated to between 8 and 12 atmospheres to achieve a clinical effect (note that a car tire's maximum inflation is 2 atms!). In 2008, new sinus balloons were introduced and provide an important benefit of shape retention between dilations. These balloons deflate in 1/4 the time of the original balloons and resume their original compressed, wrapped configuration to permit easier passage through the sinus guides and transition spaces on subsequent applications in the same patient. In 2009, soft bevel-tipped, flexible suction-ready sinus guides were introduced to permit atraumatic access to the targeted transition space with the option for suction at the tip of the guide.

The next generation of improvements, first introduced by Entellus and then by Acclarent emphasize functional independence by permitting the surgeon to hold the endoscope in one hand while placing the guide, introducing the guide-wire and advancing the balloon catheter with the other. An assistant is only needed to inflate and deflate the balloon.

The Theory

As previously mentioned, BDT is essentially a transition space tool, targeting primarily the ethmoidal infundibulum and frontal recess. The sphenoid sinus does not have a transition space and is rarely involved with inflammatory disease. These transition spaces, per Setliff [1], or “pre-chambers”, per Messerklinger [2], are slit-like in nature, having a maximum diameter of 1.5–2 mm, and even less in many symptomatic patients. Placement of a sub-millimeter guide-wire and plus-millimeter balloon catheter into the transition space can be challenging at times, yet still represents the least traumatic means to access this anatomic area. Once in place, the balloon catheter is slowly inflated to 10 atm, and during this process the opposing walls of the transition space are separated an amount equal to the diameter of the chosen balloon. This prying open of the transition space occurs via micro-greenstick fractures of the immediate peripheral bone (i.e. uncinate process), which usually retains

its new position as the sub-structure heals. Thus, no stent is required to maintain the enlarged lumen.

BDT can be used alone as a sole intervention for one or more sinuses, or in combination with more conventional endoscopic sinus surgical techniques (ESS), the so-called “hybrid” procedure.

It is most important for the reader to understand that BDT surgery, like ESS, only addresses the structural relationship between the sinus cavity and its communication or connection to the nasal cavity. Neither intervention changes the patient's biology, allergy status, or reactive airway. By enlarging the sinus drainage pathway, the patients “mucosal reactivity” will likely still occur, yet is less likely to cause sinus obstruction with its associated pain and/or subsequent infection.

Preservation of Structure and Function: The Natural Mechanical and Chemical Defense Mechanisms

The role of the uncinate process remains in question. However, research to evaluate sinus airflow may provide some important clues. Several years ago, Nayak, an otolaryngologist in India, performed a few studies to try to determine the role of the uncinate process. Nayak [3] first used simple inhalational dye studies with methylene blue comparing dye deposition within the nose and sinuses in 2 groups of post-operative patients, those with and without preservation of the uncinate process. He found dye within the maxillary and ethmoid cavities when a maxillary antrostomy (MMA) was performed; however, dye remained only on the anterior middle turbinate and uncinate process when the latter were preserved. A MMA is a man-made enlargement of the natural maxillary os that remove part of the medial wall of the maxilla.

In 2008, Xiong's group [4] in China designed mechanical airflow simulation models using actual human anatomic CT scan data. In their model, there is minimal to no air entering any sinus cavity in the human head during either phase of respiration! Airflow arched through the nose with highest flow rates between the middle turbinate and lateral nasal wall. Xiong et al. then repeated their experiments using CT images from post-ESS patients who had a surgical ethmoidectomy and MMA [5]. In these patients, there was a striking increase in maxillary and ethmoid sinus airflow. In a recent study Kiriheine et al. [6] also measured intra-sinus airflow before and after various sized MMAs, and found that measurable airflow occurred within the maxillary sinus once the size of the middle meatal opening exceeded 20 mm². Coincidentally, the cross-sectional area of the maxillary os after dilation with a 5-mm diameter sinus balloon is exactly 20 mm².

This natural *mechanical defense mechanism* of the sinuses suggests that the uncinate process and anterior middle turbinate help filter inspired air and prevent exposure of

the sinus mucosa to inhaled debris in the form of pollutants, allergens, carcinogens, etc.

There is a second natural defense mechanism that exists within the paranasal sinuses, here termed the *chemical defense mechanism*. The latter consists of an interesting molecule called “NO”, or nitric oxide. The molecule is not the same as nitrous oxide (N₂O), the general anesthetic. NO is made within the maxillary sinus by the enzyme nitric oxide synthase [7]. Research has shown that the natural concentration of NO within the normal maxillary sinus reaches toxic concentrations if inhaled. However, at these higher concentrations, NO has local antiviral, antibiotic, and antifungal properties, and will also increase ciliary beat frequency [8–14].

We have come to learn that NO comes in many forms. The free radical form is present within the vascular system and has a very short half-life, whereas the form active within the sinuses and airway is not a free radical and can persist for up to 11 min [9]. It has also been shown that small amounts of NO (approximately 30 parts per billion), are inhaled into the lungs with each breath. Inhaled NO has a vasodilatory effect on the lung increasing oxygen absorption (16). Inhalation of NO is today used as a therapy for hypoxic infants with immature pulmonary systems [16].

NO is also heavier than air, thus the highest concentrations of NO occur at the floor of the maxillary pyramid depending upon the patient’s position. Note that the maxillary os is always at the apex of the pyramid when we are in either the upright, supine, or lateral position. Thus, under normal circumstances, a small amount of NO flows out of the maxillary sinus and into the lung with each inspiration. Subsequently, NO has a positive physiologic effect on oxygen uptake in the lung [15]. Furthermore, NO levels in inspired or exhaled air are undetectable after ESS in which a MMA has been performed [5, 17]. Thus, the washout of maxillary sinus NO, as predicted by Xiong, may have untoward physiologic consequences on sinus health.

Can all these findings relative to sinus airflow and NO production and function be purely coincidental? Is the loss of NO from the sinus after a MMA in any way related to the fact that the bacteriology of recurrent CRS after ESS includes virulent, atypical organisms (i.e. *Pseudomonas*, *E. coli*, and *Klebsiella*)? Is uncinate preservation more important to the delicate balance of the gaseous physiology of the sinuses than many are willing to acknowledge? How else do we explain the high concentrations of NO within the normal maxillary sinus, its absence in CRS, and its vasodilatory effects on the pulmonary vasculature when inhaled in minute concentrations? One could argue that not all patients who have an MMA are disadvantaged, or are colonized by virulent pathogens, or show any measurable adverse pulmonary effects. While this may be true, the converse is as well, and thus knowingly creating a MMA when a clinically valid and physiologically superior alternative exists, seems irresponsible. I submit that a

majority of patients given these facts would opt for conservatism, tissue preservation, and a more functional procedure.

Outcomes Data

Numerous articles have been published on many aspects of BDT. Of the more relevant are the CLEAR studies (I, II, and III) which followed patients treated with either BDT alone or a hybrid option, for 6 months, 1 year, and 2 years, respectively [18–20]. The CLEAR study used validated outcome instruments (SNOT-20 and Lund-Mackay) to evaluate a patient’s sinus health at the various time points after surgery. The results show a statistically significant difference between pre- and post-operative SNOT-20 and Lund-Mackay scores at each of the three time points, which validates the durable results seen by practising surgeons. The Lund-Mackay score is assigned to each sinus based on the degree of mucosal inflammation or hypertrophy within it.

Complications from BDT were rare, and remain rare to this day. In fact, in almost all cases where a CSF leak has been reported following the use of BDT tools, the surgeon in questions has reported first using conventional tools to try and open the frontal sinus and then reverted to BDT to try and salvage unsuccessful traditional frontal sinus surgery (see MAUDE website). The major complications associated from conventional ESS, such as blindness, meningitis, CSF leak, and hemorrhage, can be devastating and irreversible. However, these complications have never been reported when BDT has been performed alone. Thus, the safety of BDT as a surgical tool is unmatched in rhinology.

Many other articles have been written about various aspects of BDT. One by Friedman et al. [21] looked at the cost of sinus surgery with and without the use of BDT. While disposable costs are higher when BDT is used, the shorter OR procedure and elimination of the need for serial post-operative sinus debridements in the office setting make surgery with BDT more cost-effective than surgery without. This economic advantage was realized without including the significant reduction in post-operative morbidity permitting patients to return to work within 24 h of surgery, as opposed to needing an average of 10–14 days off work to recover from conventional sinus surgery.

Another article by Catalano and Payne [22] evaluated the efficacy of BDT for the frontal sinus in patients with advanced frontal sinus disease (i.e. Samter’s Triad, hyperplastic sinusitis, or fungal sinusitis). All study patients had at least 1 frontal sinus that was either completely or near-completely opacified pre-operatively. Using only a 5-mm-diameter balloon (larger balloons were not yet available), 50 % of patients had radiologic clearing of their frontal sinus post-procedure that was durable over the 6-month follow-up period. Thus, 50 % of patients with advanced frontal sinus disease were spared from a more aggressive and more morbid surgical intervention. In an attempt to be purely objective, Lund-Mackay score was the only

outcome metric used, thus we cannot say how many additional patients had reduction or elimination of frontal sinus symptoms after BDT surgery, despite residual mucosal inflammation within the frontal sinus. It is well known that in sinuses with advanced biology (i.e. Samter's triad), complete resolution of mucosal inflammation is not expected, while sinus symptoms are markedly reduced with appropriate resolution of ostial obstruction. SNOT-20 scores were not used because patients had surgery on other sinuses in addition to the frontal, and the inability to correctly apportion benefit to the various parts of the procedure made subjective metrics less appealing.

Indications

The indications for BDT are no different than those for performing endoscopic sinus surgery, as BDT is a tool, not necessarily a procedure unto itself. That said, BDT is especially suited for patients with recurrent acute sinusitis (RARS) or chronic sinusitis without nasal polyps (CRSw/oNP), as these patients tend to have a biology that is not progressive and rarely requires aggressive topical medical management. These groups are currently being targeted for office applications of BDT. Patients with advanced inflammatory biology such as CRS with polyps (CRSwP), Samter's Triad, allergic fungal sinusitis, or hyperplastic sinusitis usually require removal of tissue as opposed to reorientation of tissue, and thus are not well suited for BDT as a stand-alone intervention. BDT may be used in a hybrid procedure in these patients with conventional surgery being performed on the maxillary and ethmoid sinuses and BDT being applied to the frontal and possibly sphenoid sinuses. Fortunately, the majority of patients with inflammatory sinus disease fall into the RARS and CRSw/oNP groups, making BDT an appealing option for many sinus sufferers.

Conclusions

Interventions to correct inflammatory sinus disease are trending toward less invasive procedures. From a conceptual standpoint, BDT is a safe, effective, and appropriate first choice for the majority of sinus sufferers who require surgical intervention. In addition, the procedure is less morbid, less costly, and BDT failures can be easily revised. Data have shown the positive results after BDT are durable for a minimum of 2 years [20], which equals or exceeds those reported after conventional FESS. Facility with BDT has allowed many surgeons to treat sinus sufferers earlier than would be recommended for conventional FESS due to its lower morbidity, and the ability to perform BDT procedures in the office setting under a combination of local and topical anesthesia.

While BDT can also have a role in patients with advanced mucosal disease, it is best used in these situations as a

hybrid procedure. BDT technology continues to evolve along with our knowledge of sinus physiology and pathophysiology, and the body of evidence thus far suggests that when it comes to sinus surgery, less is often better.

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