Accuracy of transnasal cannulation and dilation of the maxillary ostium in cadavers with intact uncintes

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ABSTRACT

Background: Transnasal cannulation of the natural ostium in patients with an intact uncinate process is complicated by the lack of direct visualization of the ostium. Accuracy of transnasal dilation of the maxillary ostium was evaluated for a malleable-tipped balloon device that was bent to specific angles for avoiding the fontanelle during cannulation.

Methods: Transnasal cannulation and dilation of 42 cadaver maxillary sinus ostia was attempted by 6 surgeons including 3 with very limited clinical experience using the study device. All physicians received procedure training including the technique to shape the balloon device into the recommended 135° maxillary configuration. Tissue dissection was prohibited. Canine fossa trephination and transantral endoscopy were used to evaluate cannulation and dilation outcomes. Physician operators were blinded to transantral images and results were documented by two observers.

Results: Appropriate transnasal cannulation and dilation of natural maxillary sinus ostia occurred in 92.9% (39/42) of attempts. Two failures emanated from procedural deviations. In one deviation, the bend angle was changed to 90° and the device tip did not cannulate the ostium. In the second, the device was passed through a preexisting hole in the uncinate and cannulated the natural ostium. A third failure occurred when the device was passed through the fontanelle creating a false lumen.

Conclusion: Using recommended procedural techniques and a malleable-tipped balloon device, newly trained and experienced physicians alike can perform uncinate-preserving transnasal cannulation and dilation of the maxillary ostium with a high rate of success.


Balloon devices are available to transnasally access and dilate the maxillary, frontal, and sphenoid sinus drainage pathways.1 Dilatation of the maxillary ostium and ethmoid infundibulum for disease contained within the maxillary and anterior ethmoid sinuses can also be achieved via canine fossa trephination and direct, transantral access into the maxillary outflow tract.2 Balloon dilation can either be combined with conventional sinus surgery during a “hybrid” procedure or as the sole sinus intervention during stand-alone, balloon-only treatment. Safety and outcomes up to 2 years after balloon dilation of the frontal, sphenoid, and maxillary sinuses have been well documented.3–5

Factors including sinus surgery history, disease severity, comorbid conditions, accessory pathways, and the amount of open volume within the sinonasal anatomy to maneuver standard tools such as a sinus seeker, an endoscope, or the balloon devices can add to the complexity of a stand-alone balloon procedure. According to one of the first cadaveric studies of a system that uses a transnasally placed guide catheter and guide wire system to position the balloon, the maxillary sinus was hardest to cannulate because of the acute angle required to navigate around the uncinate process.6 However, clinical trials of both transnasal and transantral systems have subsequently shown a high procedure success rate during balloon dilation without concomitant endoscopic sinus surgical techniques such as sinusotony, antrostomy, or uncinctomy.7–9

Recently, a cadaver study designed to observe transnasal balloon dilation and evaluate its effects on ostial size and irrigant penetration into the sinuses reported that 100% of 10 separate attempts to cannulate 10 maxillary sinus ostia with a guide wire before ostial dilation resulted in the creation of a false lumen in a fontanelle.10 Because of the unique challenges faced when positioning a transnasal balloon device into the ethmoid infundibulum to dilate the maxillary ostium, a subsequent cadaver study was designed to assess the accuracy and repeatability by which physicians with varying balloon dilation experience could accurately and repeatedly cannulate and dilate the maxillary ostium with a malleable-tipped transnasal balloon device without creating an accessory pathway.

MATERIALS AND METHODS

This study was designed to assess the accuracy of transnasal cannulation of the maxillary-ostium by having noninvestigator observers record transantral endoscopic views of the natural ostium while study investigators who were blinded to these transantral views attempted to cannulate the natural maxillary ostium using transnasal endoscopy and a malleable-tipped sinus balloon dilation device. A total of 22 fresh, frozen cadaveric specimens were provided for the study by an independent donor tissue company certified by the American Association of Tissue Banks. The study was exempt from Institutional Review Board analysis because none of the study materials or specimens contained any personal identifiers. Specimens from adult donors aged 18–96 years with sinuses unadulterated by previous sinus surgery or prior cadaveric studies were provided. Computed tomography scans of the sinuses were obtained from each specimen before the start of the study. Standard sinus surgery equipment including Freer elevators, maxillary sinus seekers, 2.7- and 4.0-mm 0° endoscopes; 4.0-mm angled endoscopes (30°, 45°, and 70°); and video equipment including cameras, light sources, light cables, and monitors were provided for use during the study. Proprietary devices including the XprESS Multi-Sinus Dilation Tool (study device; Fig. 1), FinESS 0° endoscopes, the balloon device bending tool (Fig. 2), Light Fibers (i.e., illuminated guide wires), and micro-trocars were provided by the study sponsor (Entellus Medical; Plymouth, MN).

Six physicians with experience performing transnasal balloon dilation of the maxillary ostia and ethmoid infundibula with commer-
cially available balloon devices from two manufacturers agreed to participate in the study. The surgeons have a combined average of 7 years (range, 3–11 years) of professional experience and are all working within a large rhinology-based medical practice. Three of the investigators had very little clinical experience (<5 total procedures) with the study device and the other three had significant experience (>10 total procedures) with the study device. To ensure consistency between operators, the study sponsor provided device and procedure training to each physician before the start of the study. Techniques to cannulate and dilate the ethmoid infundibulum and maxillary ostium through transnasal access were reviewed and demonstrated in cadaveric specimens. Before the start of each first attempt at maxillary access, the bend angle of the device tip was changed from the 78° frontal sinus configuration by using a standardized bending tool (Fig. 2) to a preferred maxillary bend angle of 135° as shown in Fig. 3. Investigators were trained to start the cannulation attempt with a 135° bend angle of the device tip and to change the tip angle to 120° only when the 135° angle of the tip did not permit placement behind the uncinate process. Investigators were also trained to observe the ball-tipped device deflect the uncinate as the ostium cannulation was attempted. CT scans of the specimens were available and reviewed by the investigators at the start of the study and none of the specimens were rejected because of anatomic obstacles. The protocol required each maxillary ostium cannulation attempt to be performed without tissue removal (e.g., no partial uncinectomy, total uncinectomy, concha bullosa resection, etc. were allowed) using tactile feel, Light Fiber confirmation, and transnasal endoscopic visualization.

Two observers were also present throughout each study to prepare the specimens and record the results of each investigator as described later. Specimens were secured in a supine position. Each maxillary sinus was accessed to allow transantral endoscopic viewing of the maxillary antrum and the natural ostium. Canine fossa trephination at the intersection of a midpupillary line and a horizontal line through the floor of the nasal vestibule was performed using the FinESS micro-trocar. The FinESS endoscope was advanced into the maxillary antrum to visualize the natural ostium during each transnasal cannulation attempt. The presence of any accessory ostia was recorded and the endoscope was positioned to allow real-time observation and recording of the results of each attempted transnasal cannulation and dilation of the natural maxillary ostium. None of the surgeons were informed of the presence of any accessory ostia and no attempts were aborted or specimens rejected due to accessory ostia. To eliminate the potential for real-time transantral feedback resulting in technique bias, each study investigator was blinded to all transantral video and images throughout the study. Study investigators also did not receive any communication from the observers during cannulation attempts.

RESULTS

A total of 42 maxillary ostium cannulations were attempted in 22 cadavers. Appropriate cannulation and dilation of the natural maxillary ostium occurred in 39 of 42 attempts (92.9%) and successful cannulation of the natural ostium occurred in 40 of 42 attempts (95.2%). Two attempts failed to cannulate the natural maxillary sinus ostium. One failure occurred after the physician endoscopically observed the transnasal anatomy and concluded a 90° bend would better accommodate the specimen anatomy. Using palpation and tactile feedback during attempted positioning of the device tip, the physician speculated that the tip was likely not in the correct position before inflation because the tip resistance did not decrease as is typical when correct ostial positioning is achieved. However, the investigator decided to inflate the balloon with the device tip out of position resulting in this failure. In the second failure to cannulate the natural maxillary sinus ostium, the device tip was formed to a 135° angle and punctured the posterior fontanelle during attempted cannulation of the natural ostium.

There was one instance in which the device bent into a 135° tip angle successfully cannulated the natural ostium but was not considered an appropriate dilation because the device was inserted through a preexisting hole in the anterior/inferior portion of the uncinate process. The physician observed this hole via transnasal endoscopy.
Table 1  Maxillary sinus ostial dilation success rate

<table>
<thead>
<tr>
<th>Surgeon</th>
<th>Professional Experience (yr)</th>
<th>Experience with Study Device (no. of procedures)</th>
<th>Maxillary Ostium Attempts</th>
<th>Maxillary Ostium Successes</th>
<th>No. of Accessory Ostia Observed</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>10</td>
<td>&lt;5</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>100.0%</td>
</tr>
<tr>
<td>B</td>
<td>3</td>
<td>&gt;10</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>71.4%</td>
</tr>
<tr>
<td>C</td>
<td>3</td>
<td>&lt;5</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>80.0%</td>
</tr>
<tr>
<td>D</td>
<td>10</td>
<td>&lt;5</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>100.0%</td>
</tr>
<tr>
<td>E</td>
<td>5</td>
<td>&gt;10</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>100.0%</td>
</tr>
<tr>
<td>F</td>
<td>11</td>
<td>&gt;10</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100.0%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>21</td>
<td>21</td>
<td>18</td>
<td>92.9%</td>
</tr>
</tbody>
</table>

before attempted maxillary cannulation and chose to cannulate and dilate the natural ostium through this hole rather than navigate the device tip behind the uncinate process because he believed this access would provide an easier route to the natural ostium. Although the natural ostium was successfully cannulated and dilated through this existing hole, this attempt was considered a failure because the dilation of the ethmoid infundibulum would be lessened with this technique compared with the appropriate technique of inserting the device tip and balloon around the posterior margin of the uncinate process and then into the maxillary ostium before balloon inflation.

A total of four maxillary sinuses (9.5%) in four different specimens were observed to exhibit an accessory ostium. In no instances was the tip of the balloon device placed into an accessory ostium. Table 1 provides a summary of the success rates by physician and prior experience with the study device. A majority of the procedures (37/42) were completed with the malleable tip shaped with a 135° maxillary configuration. Ninety-five percent (35/37) of these attempts were successful but there was one failure to cannulate the natural ostium when using the 135° bend angle and one suboptimal cannulation and dilation of the natural ostium through a preexisting hole in the uncinate process. In four cannulation attempts, the investigator reduced the bend angle from an initial 135° to an angle ranging from 110 to 120°. All of these ostial cannulation attempts were successful. One procedure was attempted with a bend angle of –90° and cannulation of the natural ostium was unsuccessful as described previously.

**DISCUSSION**

As with conventional surgical techniques to treat sinus disease, good outcomes after balloon dilation of the drainage pathways rely on precise deployment of the surgical tools to the targeted treatment areas without inadvertent trauma to the surrounding healthy mucosa or other paranasal structures. Successful cannulation of the natural maxillary ostium with a transnasal balloon catheter requires retrograde device delivery through the ethmoid infundibulum. The ethmoid infundibulum is bounded by the uncinate process, lamina papyracea, ethmoid bulla, and the fontanelles. Because it is not always possible to use nasal endoscopy to view the infundibulum and maxillary ostium with the uncinate intact, an understanding of the three-dimensional geometry (i.e., angles and distances) of the nasal cavity and infundibular anatomy is vital to achieve safe and successful ostial dilation. The width of the nasal cavity from the septum to the natural maxillary ostium has been previously measured and recorded to be ~11 mm for both the left and the right sides. One early study to quantify infundibular dimensions concluded the height of the uncinate process determined the depth of the infundibulum and varied between 0.5 and 10 mm and another reported a mean infundibular length of 5 mm. Using these dimensions and prior sponsor cadaver studies that assessed various bend angles to optimally allow avoidance of the orbit and soft fontanelle during cannulation of the natural maxillary ostium, it was determined that a bend angle of 135° was optimal. It was also observed that a sinus dilation device should extend approximately ≥8 mm to traverse the distance from the posterior margin of the uncinate process to extend 1–2 mm through the natural maxillary ostium into the maxillary sinus. Both of these concepts are illustrated in Fig. 4.

Physician experience using the study device in either cadavers or in patients before participation in the study was not a predictor of procedure success rate. Although the number of participating investigators was small and each received the same training before each first attempt, the physicians with more extensive experience with the device were more comfortable deviating from the study procedure documented in the protocol and instead relied more on their own individual experience. It is not clear why a recently trained investigator would choose to deviate from procedural training completed immediately before the study; however, both instances of deviations resulted either in failure to cannulate or dilate in the appropriate location.

In the one instance of failure in which a 135 or 120° bend angle was not successful in cannulating the natural ostium, the most likely cause of failure was the absence of palpation of the ball tip along the posterolateral side of the uncinate process resulting in device insertion that was too posterior and inferior. It was hypothesized that palpation of the uncinate process with a sinus seeker to create clearance between uncinate process and ethmoid bulla before attempted
positioning of the device may have facilitated appropriate cannulation and dilation of the natural ostium. Another technique that could be used to avoid fontanelle puncture is to use an optical fiber in the tip of the balloon device to observe the transillumination of the uncinate as the ball tip of the balloon device rides along the lateral aspect of the uncinate during an ostial cannulation attempt. This technique also ensures good contact of the lateral aspect of the uncinate during cannulation, thus avoiding the fontanelle. It should be noted that this can only be routinely achieved with acute bend angles such as 120–135°.

The clinical impact on patient outcomes after inadvertent creation of a false lumen or cannulation of an existing accessory ostium or false pathway with a balloon device is not fully understood. Evidence, to date, in patients with secondary pathways has shown that preexisting accessory pathways as well as surgically created secondary or false lumens may result in mucous recirculation. However, these same studies have shown that not all accessory pathways result in circular mucous flow and not all patients with recirculation are symptomatic and require surgery.14

There are several study limitations that may contribute to easier access to the maxillary ostium when using cadaveric specimens. First, active inflammation in the sinus mucosa and nasal passages that are often present in patients with chronic sinus disease are nonfactors in preserved tissue. Although this acute swelling can be managed with decongestants and anti-inflammatory nasal steroid sprays before surgery, native patient anatomy may limit the free space in the nasal cavity required to accommodate insertion, rotation, palpation, and removal of the balloon device. Although hybrid balloon procedures and balloon-only dilation can be performed under general anesthesia to control patient discomfort during the procedure, recent studies have shown balloon dilation can also be performed under local anesthesia in the physician office.7–9 Although these data show balloon dilation is well tolerated in awake patients, aggressive manipulation of the balloon device and ancillary equipment may not always be possible in an awake patient because of anatomic factors or patient anxiety. Finally, tissue specimens with intact sinuses and nasal structures were provided for the study, but there were no additional inclusion criteria to require each cadaver to have a known medical history of chronic sinus disease or nasal congestion. Therefore, the rate of occurrence of the variations in sinus anatomy that may increase the difficulty of successful cannulation of the maxillary sinuses were negligible in the study specimens. For example, severe polyps, septal deviations, septal spurs, concha bullosa, prominent ethmoid bullae, and atelectatic/hypoplastic sinuses were rare if present at all although accessory ostia were present in 9.5% (4/42) of the maxillary sinuses and within the rate of occurrence reported in literature.15,16 Despite these limitations, this study protocol was adequately designed to assess the accuracy of ostial cannulation when a specific balloon device was used in accordance with the manufacturer's instructions.

**CONCLUSION**

Endoscopic transnasal visualization and tactile response are valid methods to successfully access and dilate the natural ostium of the maxillary sinus using a malleable-tipped balloon device. In this study, successful cannulation and dilation of the natural maxillary sinus ostium was 92.9% and the results indicate that the study procedure, when followed, makes it possible for newly trained as well as experienced physicians to cannulate and dilate the natural maxillary ostium with a high rate of success as long as the recommended bend angles of 135 or 120° are maintained for the malleable balloon device.

**REFERENCES**