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Upper esophageal pH monitoring: Transnasal placement of the Bravo wireless capsule system

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Laryngopharyngeal reflux (LPR) is a common entity and is known to be associated with many common aerodigestive disorders. The diagnosis of LPR based on symptoms or laryngeal findings alone is unreliable. Upper esophageal pH monitoring enables the otolaryngologist to objectively confirm the presence of LPR and to gauge the response and effectiveness of medical therapy. In this article, we present the technique for transnasal placement of a wireless pH monitoring capsule for the diagnosis of LPR. This technique can be performed by otolaryngologists in the office. It is safe and can be done under local anesthesia, in conjunction with transnasal esophagoscopy. The main advantage is that, unlike single- or double-probe pH monitoring devices, wireless capsule monitoring does not interfere with patients' daily activities and diet, giving a more accurate measurement of reflux episodes in the upper esophagus. The technique has a low potential for complications, and monitoring can be performed for 24- and 48-hour periods.

It is estimated that laryngopharyngeal reflux (LPR) may be the etiologic cause in up to 50% of patients that present to otolaryngologists complaining of laryngeal and voice disorders.[1] The symptoms of LPR are numerous and, because they differ significantly from the presentation of classic gastroesophageal reflux disease, patients do not attribute them to acid reflux. In fact, patients with LPR have less than 40% incidence of heartburn, and only 25% incidence of esophagitis.[2] Hoarseness, globus sensation, chronic cough, and excessive throat clearing are all common symptoms to numerous voice disorders, which can have several potential causes. Moreover, laryngoscopic findings often associated with LPR, such as thickening or edema of the posterior wall of the glottis (posterior laryngitis), are not pathognomonic and may indeed be present in patients without LPR.[3]

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Recently, a wireless pH monitoring system (Bravo; Medtronic, Shoreview, MN) was introduced as an alternative to conventional single- or double-probe pH monitoring. This technique has been previously shown to be a comparable alternative in quantifying esophageal acid exposure.[4] Wireless monitoring offers several advantages over pH-probe monitoring. It eliminates the need for a transnasal catheter that can significantly alter, because of discomfort and pain, the patient's physical activity, sleeping patterns, diet, and social schedule, thus potentially causing false-negative readings as the result of reflux-reducing behavior.[5]

Operative technique

The delivery system comes as a prepackaged assembly, incorporating both the capsule and the delivery probe. The handle of the delivery system, 80 cm in length, is separated from the end, which houses the capsule in a 6-F tubular

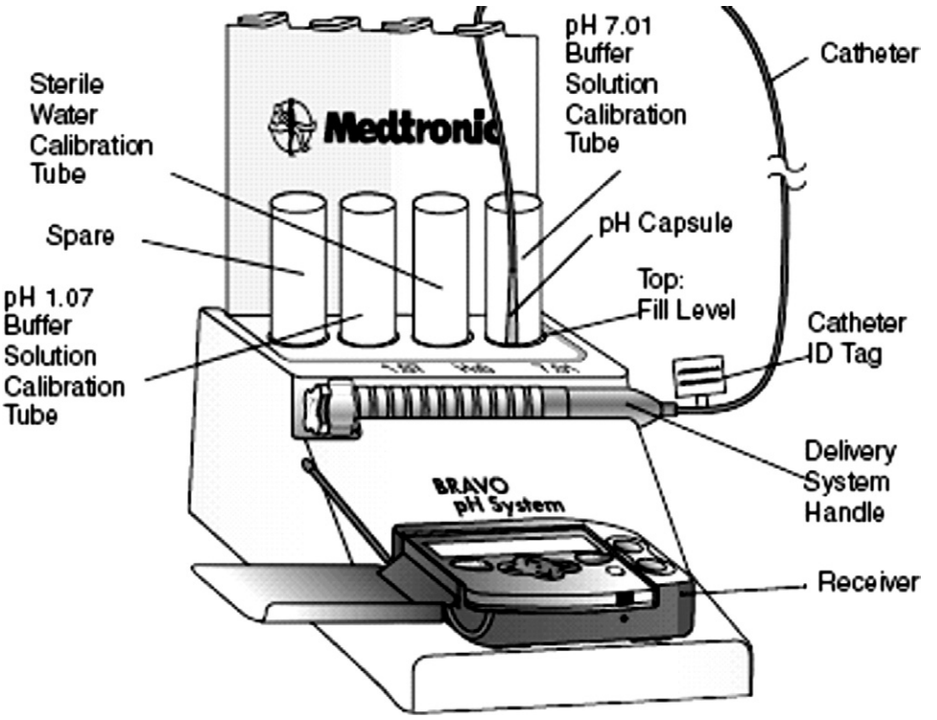

Figure 1 The Bravo wireless pH monitoring system (image courtesy of Medtronic Inc., Shoreview, MN).

component. The pH capsule is designed to transmit a radiofrequency signal to a receiver-pager (Figure 1).[6] The set-up procedure before capsule placement is simple and takes about 10 to 15 minutes to complete.

The technique for transnasal placement of the wireless pH capsule monitor is most easily performed when the patient is in the upright position. The patient's nose is sprayed with a mixture of topical 2% lidocaine with 1% neosynephrine about 5 minutes before the initial transnasal esophagoscopy, followed by 4% viscous lidocaine, which acts as a lubricant as well. Anterior rhinoscopy and flexible nasal endoscopy are performed, to ascertain the patency of the nasal airway and document septal deformities and turbinate size, which could affect the passage of the endoscope and the delivery system. A flexible esophagoscope is inserted through the nose and advanced into the hypopharynx. The patient is then given a cup of water with a straw and asked to swallow small sips of water while the scope is advanced into the piriform sinus and into the esophageal inlet. The scope is slowly advanced until the gastroesophageal junction is visualized. Transnasal esophagoscopy allows visualization and inspection of the mucosa to document the presence of ulcers, erosions or edema. The scope is slowly withdrawn until the level of the cricopharyngeus is reached, at which point, a measurement is taken to determine the distance between the incisors and the upper esophagus, just below the cricopharyngeus. We add 5 cm from the piriform sinus, to ensure placement below the upper esophageal sphincter, and this corresponds to the final insertion depth, which usually ranges from 17 to 20 cm. The final measurement is marked on the delivery system with a piece of tape (Figure 2).

The capsule is previously calibrated with standard pH 1.07 and 7.01 solutions, and linked to the receiver, following manufacturer's instructions. The delivery system containing the capsule at the tip is then inserted through the same nare through which transnasal esophagoscopy was performed. The probe can be passed along the nasal floor or above the inferior turbinate, depending on intranasal findings. The surgeon should lubricate the capsule and the tip of the catheter, taking care not to clog the suction port in the capsule, which could cause problems with the attachment to the mucosa. The patient is instructed to swallow small sips of water after the delivery system is passed through the nasopharynx, as it is advanced into the hypopharynx and into the esophagus. Once the delivery catheter has been advanced all the way to the previously marked depth, the system is connected to a vacuum pump. The vacuum suctions esophageal mucosa into the port of the capsule, to which the capsule will attach once the attachment pin is deployed (Figure 3). The vacuum pump is run for at least 30 seconds after the pressure has stabilized at about 75 kPa (>510 mm Hg). After the 30 seconds elapses, the safety is removed from the handle and the activation button is pressed all the way in, which activates the steel pin that attaches to the mucosa in the suction chamber. A clockwise 90° turn of the button then follows, which releases the capsule from the delivery system (Figure 4). It is important to make sure the button goes back to its original position once it is released, otherwise the capsule might not be deployed from the delivery system. The suction should be left on while deploying the capsule, which ensures better attachment of the capsule. It is also very important to turn the suction pump off before the delivery system is removed from the patient's esophagus; otherwise, there is a risk of injuring the mucosa or perforating the esophagus.

Repeat transnasal esophagoscopy is then performed to confirm successful placement and to identify the exact location of the wireless pH monitoring capsule (Figure 5). The capsule normally sloughs off together with the

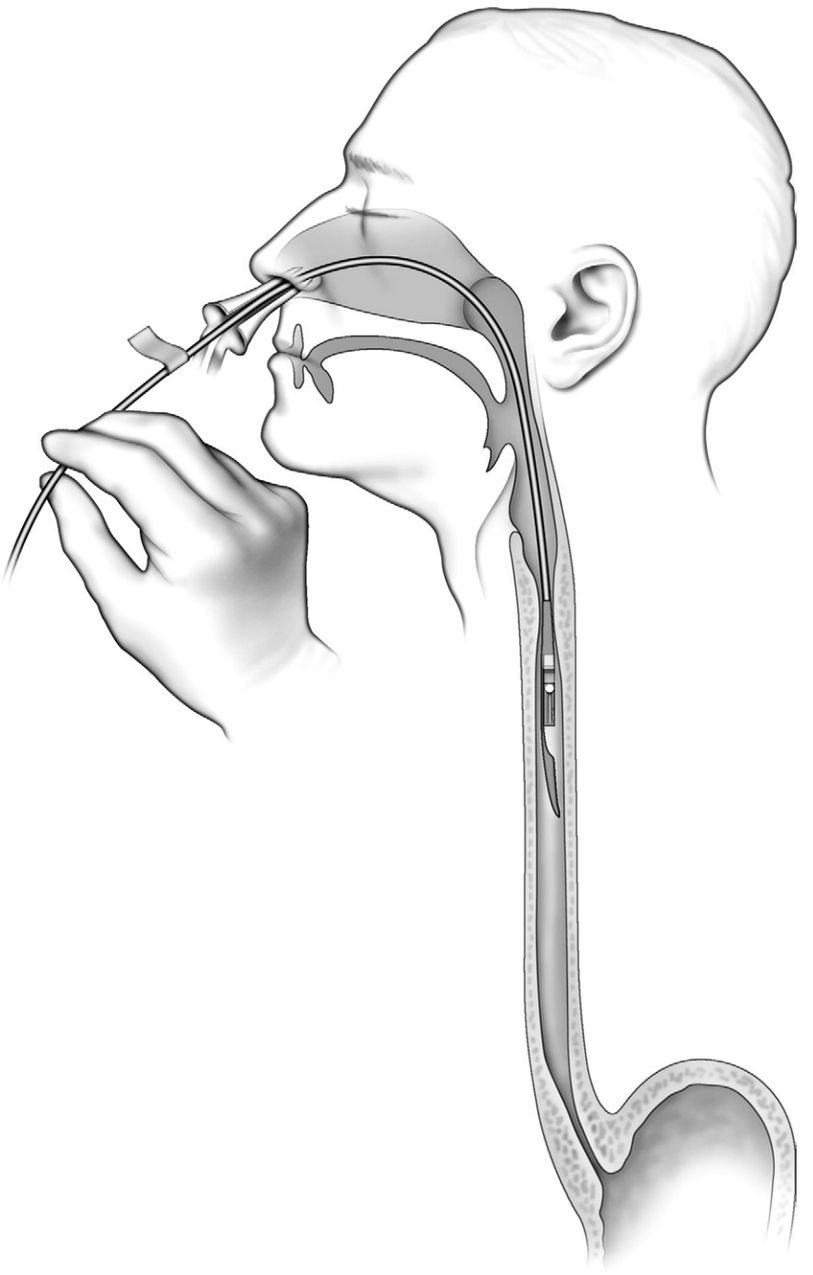

Figure 2 Transnasal placement of the wireless capsule in the upper esophagus with the help of a nasal speculum. Note the piece of tape indicating the exact distance from the nostril to the level just below the cricopharyngeus.

esophageal mucosa by days 7-10, and it is passed through the bowel and eliminated with the stool without being noticed.

Postoperative management and complications

The wireless pH monitoring capsule transmits information to a receiver (designed to be carried as a pager, Figure 1), which the patient needs to keep at a distance of no more than 3 to 5 feet away from his body throughout the 24 to 48 hours of monitoring. Patients are asked to keep a detailed log of all meals and symptoms, as well as situations when the patients are in supine position (eg, naps or bedtime). Emphasis should be made on the importance of maintaining normal diet and activity as well as avoiding antireflux medications. After monitoring is concluded, patients return the pager and the data contained in it is downloaded to a computer. A software program provided by the manufacturer then generates a report that should be interpreted by the treating physician.

Data for analysis contained in a report includes total recording time, total number of reflux episodes (defined as a pH $\leq$4), number of reflux episodes longer than 5 minutes, duration of longest reflux episode, and total and percentage of time with pH $<$4.0. A breakdown of reflux episodes recorded in the upright and supine positions is also included in the report. According to Postma and coworkers[7] a decrease in pH level to $\leq$4 is defined as a reflux event, as long as it s not associated with meals. The

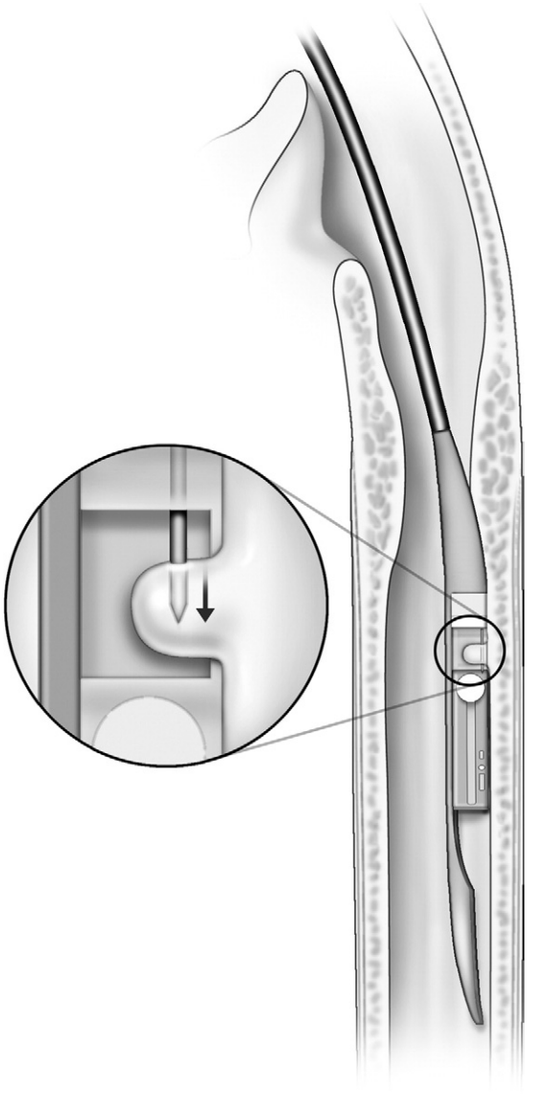

Figure 3 The vacuum suctions esophageal mucosa into the capsule chamber, into which the attachment pin is deployed.

decrease should be sharp and rapid, not gradual. Consistent with methodology from other authors, four or more episodes of reflux in a 24-hour period were considered to be positive for LPR. To be valid, a study must contain at least 16 hours of continuous pH monitoring recording.[4]

Friedman and coworkers[8] reported that, of a total of 89 patients that underwent transnasal upper esophageal placement of the wireless monitoring capsule, 6 patients (6.7%) did not tolerate the procedure because of pain during transnasal insertion or excessive gag reflex. Two patients had unsuccessful capsule attachment during the procedure. Two patients had recordings less than 16 hours long, 1 patient had an invalid study because of noncapture of data by the receiver, and 1 patient had a premature capsule detachment after confirmatory transnasal esophagoscopy. Capsule placement success rate was 86.5%. There were no instances of laryngospasm or vaso-vagal reactions. Four patients that had an unsuccessful initial capsule placement attempt (confirmed by means of control transnasal esophagoscopy); in one of these 3 cases, a second attempt was also unsuccessful.

Potential side effects of the procedure include difficulty swallowing, pain, and inability to eat a normal diet. All patients do experience some degree of chest discomfort or pain during the first 48 hours after capsule placement. These symptoms usually subside after 72 hours without the need for pain medication. More serious complications include failed detachment of the capsule after 72 hours, which may

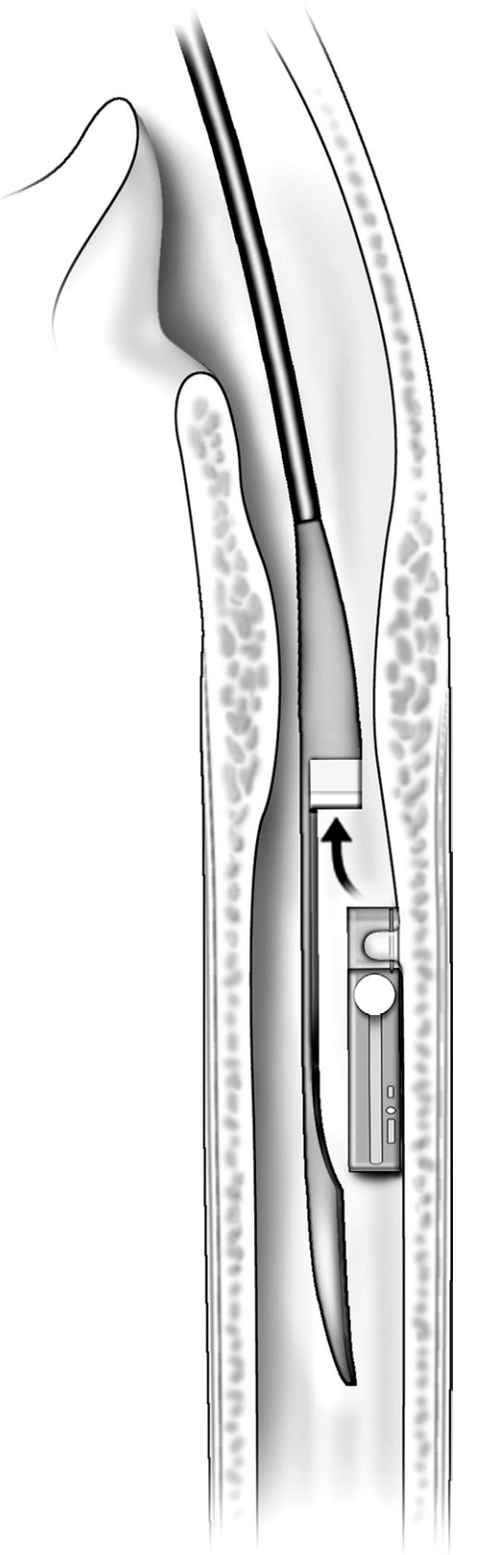

Figure 4 The capsule is released from the delivery system.

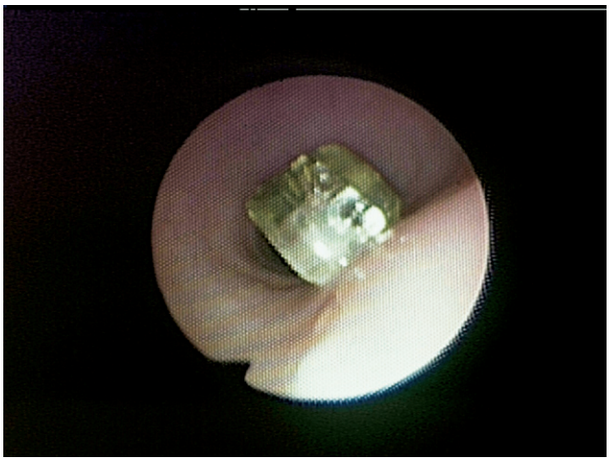

Figure 5 The wireless pH capsule after transnasal endoscopic placement on the wall of the upper esophagus.

lead to persistent pain and esophageal perforation. In these cases, endoscopic removal might be required. In cases of prolonged chest pain or discomfort, esophageal perforation should be ruled out. Epistaxis, although rare, might also be an immediate or delayed complication of transnasal esophagoscopy and capsule placement, and should be managed accordingly.

Conclusions

Although many expert otolaryngologists can detect the laryngeal changes suggestive of LPR, some studies have shown that the changes often associated with LPR are not patognomonic and may indeed be present in patients without LPR. Wireless upper-esophageal pH monitoring is a valuable diagnostic tool for patients with suspected LPR. Transnasal placement of the capsule can effectively be performed with topical nasal anesthesia with minimal potential for complications and is acceptable to most patients. The technique is safe and reliable, for it has been shown to be comparable to conventional single- or double-probe pH monitoring. The most significant advantage is its low incidence of complications, and the decreased impact on the patient's daily routine, diet and sleep. This technique may be used by otolaryngologists for the evaluation of LPR, to determine the effectiveness of medical therapy, and make any adjustments as necessary.

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