Retraction Notice

10.5152/tjg.2017.160217

ORIGINAL ARTICLE

The following article is retracted from publication in the Turkish Journal of Gastroenterology by decision of editors of the journal since it is a duplicate publication, which has been previously published in Clin Exp Gastroenterol 2010;3:147-51

TJG The Turkish Journal of Gastroenterology

Comparison of esophageal placement of Bravo capsule system under direct endoscopic guidance with conventional placement method

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Background/aims: *Conventional placement of a wireless esophageal pH monitoring device in the esophagus requires initial endoscopy to determine the distance to the gastroesophageal junction. Blind placement of the capsule by the Bravo delivery system is followed by repeat endoscopy to confirm placement. Alternatively, the capsule can be placed under direct vision during endoscopy. Currently there is no published data comparing the efficiency of one method over the other. The objective of this study was to compare the method of Bravo wireless pH device placement under direct visualization with the conventional method.* ***Methods:*** *This retrospective study involved 58 patients (29 patients with indirect and 29 patients with direct visualization) who underwent Bravo capsule placement. The physician's endoscopy procedure notes, nurse's notes, post-procedure notes, recovery notes, and pH monitoring results were reviewed. The safety of the procedure, length of the procedure and patient tolerability were evaluated.* ***Results:*** *None of the 58 patients had early detachment of the device or any immediate procedure-related complications. Overall incidence of complications in both groups was similar. No failures due to the technique were noted in either group. The average amount of time taken for the procedure was similar in the two groups.* ***Conclusions:*** *The technique of placing Bravo pH device under direct visualization is as safe and effective as the conventional method. In addition, the direct visualization technique has an added advantage of avoiding a second endoscopic intubation. The length of the procedure is similar between the two techniques.*

Key words: Bravo capsule, technique, direct/indirect

Bravo kapsül sisteminin doğrudan endoskopi kılavuzluğunda özefagusa yerleştirilmesi ile konvansiyonel yöntemin karşılaştırılması

Amaç: *ÖzefaguspHmonitorizasyonunda kullanılan kablosuz cihazın yerleştirilmesinden önce gastroözefagial bileşkeye uzaklığın tespit edilmesi için endoskopi yapılması gerekmektedir. Kapsülün Bravo sistemi ile yerleştirilmesinden sonra yerinin kontrol edilmesi için ikinci endoskopiye gerek duyulur. Alternatif olarak kapsül endoskopi sırasında doğrudan gözlem altında da yerleştirilebilir. Halen yöntemlerden birini diğeri ile karşılaştıran yayınlanmış bir veri bulunmamaktadır. Bu çalışmanın amacı, Bravo kablosuz pHmonitorizasyon cihazının endoskopi sırasında doğrudan gözlem altında yerleştirilmesinin konvansiyonel yöntem ile karşılaştırılması amaçlanmıştır.* ***Yöntem:*** *Bu retrospektif çalışmaya Bravo kapsülü yerleştirilen 58 hasta (29 hasta endirekt yöntem, 29 hasta doğrudan gözlem altında) dahil edildi. Doktorun endoskopi prosedürü sırasında kaydettiği notlar, hemşirenin kayıtları, işlem ertesi kayıtlar, derlenmede tutulan kayıtlar ve pHmonitorizasyonunun sonuçları incelendi. İşlemin güvenliği, süresi ve hasta tolerasyonu değerlendirildi.* ***Bulgular:*** *Elli sekiz hastanın hiçbirinde cihazın erken ayrılması veya işleme bağlı erken dönem komplikasyonu görülmedi. Komplikasyon sıklığı her iki grupta benzer bulundu. Tekniğe bağlı başarısızlık hiçbir grupta görülmedi. Prosedürün uygulanması için gereken süre her iki grupta benzer bulundu.* ***Sonuç:*** *Bravo pH cihazının doğrudan gözlem altında yerleştirilmesi konvansiyonel yöntem gibi güvenli ve etkindir. Ek olarak, doğrudan gözlem yöntemi ile ikinci endoskopi girişimine gerek duyulmamaktadır. İşlem süresi her iki grupta benzer bulunmuştur.*

Anahtar kelimeler: Bravo kapsül, teknik, direk/endirek

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Manuscript received: 17.06.2010 **Accepted:** 09.12.2010

Turk J Gastroenterol 2011; 22 (3): 243-248
doi: 10.4318/tjg.2011.0208

This study was presented at the ACG-Annual Meeting, USA, 2007

INTRODUCTION

Esophageal pH monitoring is an essential investigation in patients with suspected gastroesophageal reflux disease (GERD) with refractory symptoms and in patients who are considered for antireflux surgery in the absence of endoscopic changes of GERD (1). It is also utilized for the evaluation of patients with extra-esophageal manifestations of GERD. Esophageal pH monitoring was traditionally performed by passing a catheter with pH electrode transnasally and positioning the electrode 5 cm above the upper border of the lower esophageal sphincter (LES). There were several drawbacks with the conventional method of testing, which included nose and throat discomfort, dysphagia and nasal discharge as a result of the catheter passing through the nose and throat into the lower esophagus. In the majority of cases, the patient is unable to perform daily activities with these catheters in place (2). Further, the pH probe could potentially become displaced with changing body position, talking or swallowing, which could alter the study results (3).

In the recent years, the traditional approach of catheter-based pH monitoring has been replaced by wireless pH monitor - Bravo ™ pH testing system (Medtronic Inc., Shoreview, MN, USA). In this system, the Bravo capsule is placed into the esophagus with the assistance of the Bravo delivery system. The conventional ('indirect') method of placing the capsule in the esophagus involves an initial endoscopy to determine the distance from incisor teeth to the GE junction. The endoscope is then removed and the device is placed blindly using the Bravo delivery system as per the measurements obtained by endoscopy. After the placement of the Bravo capsule, the endoscope is re-inserted to confirm its attachment and location. This conventional method is a blind technique and usually requires performing endoscopy twice to confirm the attachment and correct positioning of the capsule in the esophageal wall (4).

Another technique that has been used for placing the Bravo capsule provides accurate positioning and confirms attachment of the capsule under direct endoscopic visualization. In this technique ('direct' method), the Bravo delivery system is concurrently placed without removing the endoscope and the device is released at a desired location (5).

Endoscopists have their own arbitrary preference for a particular technique of placing a device. There are no studies to compare one method of placing the device with the other in terms of safety, patient tolerability and reliability of the technique. The objective of this study was to compare the safety, performance and tolerability of the technique of Bravo wireless pH device placement under direct endoscopic visualization (direct method) with that of the conventional (indirect) technique of capsule placement.

MATERIALS AND METHODS

After approval from the institutional review board (IRB), we conducted a retrospective study involving 58 patients who had the Bravo capsule placed in the esophagus by either direct visualization or indirect conventional method (29 patients in each group). The physician's endoscopy procedure notes, nurse's notes, post-procedure notes, recovery notes, and patient questionnaire were all reviewed. Data on pH results, time taken in the procedure, complications during the procedure, symptoms and complications during the data recording period, patient tolerability, and degree of satisfaction with the test in both groups were obtained. In addition, data were obtained on patient experience with the procedure, willingness to repeat the procedure if needed and number of workdays taken off following the procedure. Patient experience was graded as good, average or bad as recorded from the questionnaire given to the patients. Patient satisfaction was recorded using a 10-point visual analog scale with 0 signifying very unsatisfactory and 10 as very satisfactory. Values of 1-4 were graded as unsatisfactory, 5-8 as average and 9-10 as very satisfactory. Endoscopists were questioned about their views of the procedure. Intravenous diazepam was used as sedative in both groups. The primary outcome of the study was to compare the safety of the two methods. The secondary outcomes were to evaluate any difference in the procedure time, patient tolerability of the procedure and the operator experience with the two methods. In the direct method of Bravo capsule placement, upper endoscopy was performed to examine the esophagus, stomach and duodenum and to identify the squamocolumnar junction. Next, while keeping the endoscope in the esophagus with the GE junction in view, the Bravo delivery system was inserted orally and passed through the throat alongside the endoscope until it was visualized in the endoscopic field. The measurements on the endoscope and the delivery device were

matched. The scope was then withdrawn to 8 cm above the GE junction and then, under direct view of the delivery system, the Bravo capsule was deployed 6 cm above the GE junction the same way it is done using the conventional technique.

In the conventional (indirect) method, upper endoscopy was performed similarly to examine the duodenum, stomach and esophagus and then the distance between the squamocolumnar junction and the incisors was measured. The endoscope was then removed and the Bravo pH monitoring device was deployed blindly using the Bravo delivery system guided by the measurements obtained from endoscopy. After the placement of the Bravo capsule, the endoscope was re-inserted to confirm its attachment and location. For analysis of the length of the procedure, *t*-test was used. For analysis of time taken in procedures performed before noon versus those performed after noon, one-way ANOVA was used. Chi-square analysis was used to analyze all other data.

RESULTS

Table 1 shows the baseline characteristics of the patient populations in the two groups. All the procedures were performed by two endoscopists (ID and CF). Both endoscopists used either of the methods to place the device. The two groups were similar in terms of age, gender and underlying diseases. Two patients in the direct group and 4 patients in the indirect group had previously undergone Nissen fundoplication. There were no early detachments of the device and no prolonged retention of the device in any patient in either group. One of the patients in the indirect group had an esophageal stricture and needed dilatation before placement of the Bravo capsule. This patient also had previously undergone Nissen fundoplication. Procedural complications occurred in a total of 3 patients (2 in the direct group and 1 in the indirect group). Two patients in the direct group developed severe chest pain after the procedure, which required patient observation for 3 and 5 hours (h), respectively, before discharge. One of the patients in the indirect group had 3 attempts for device insertion due to malfunction of the device. None of the patients in either group had early dislodgement or prolonged retention of the device. The device failed to transmit signals soon after deployment in 2 patients in the indirect group and in 1 patient in the direct group. One patient in each group had pH recording for only 12 h and 19 h, respectively. This could have potentially occurred due to technical problems with the device as reported in earlier studies (4, 6). Two patients in the indirect group and 1 patient in the direct group were scheduled for 24-h monitoring only. All other patients had two-day monitoring. The average recording time in the two groups was similar (Mean- 22 h 51 min vs. 22 h 39 min for direct and indirect, respectively, on day 1 and 20 h 31 sec and 18 h 10 sec on

Table 1. Patient demographics and indication of pH monitoring

	Direct n- 29	**Indirect n- 29**
Mean age (range) in years	51 (26-80)	46 (27-87)
Sex (M: F)	9 : 20	8 : 21
Indication for pH monitoring		
Intractable symptoms on PPI	14	10
Extra-esophageal symptoms	14	12
Pre-operative evaluation	0	3
Reflux symptoms after Nissen's procedure	1	4

PPI: Proton pump inhibitors.

Table 2. Adverse events in patients in the direct and indirect groups

Characteristics	**Direct group (%)**	**Indirect group (%)**	***p*-value**
Sore throat	7 (24.1%)	12 (41.4%)	*0.13*
Dysphagia	9 (31.0%)	8 (27.6%)	*0.77*
Chest pain	6 (20.7%)	7 (24.1%)	*0.75*
Cough	4 (13.8%)	2 (6.9%)	*0.74*
Procedural complication	1 (3.4%)	2 (6.9%)	*0.5*
Days off work - no. of patients	6 (20.7%)	6 (20.7%)	*1*

day 2). The mean DeMeester scores on the first day of recording in the direct and indirect groups were 29.84 (SD 35.51) and 29.9 (SD 34.5), respectively. The DeMeester scores on the second day of recording were 16.23 (SD 13.6) and 23.1 (SD 33.15) in the direct and indirect groups, respectively. Post-procedural complications in the two groups are given in Table 2. In terms of patient experience and satisfaction with the test, the difference between the two groups was not statistically significant (Table 3). The willingness to repeat the test (if needed) between the two groups was also statistically insignificant. An equal number of patients in the two groups required days off from work after the procedure. There was no difference in the time taken for the procedure between the two groups (Table 4). From the endoscopist's (ID and CF) viewpoint, there was no difference between the procedures except for the ease of placement with the direct method.

DISCUSSION

The wireless esophageal pH monitoring system is a highly tolerable method of investigation available for patients with GERD. Since the introduction of this technology in 2001 (7), several methods of placement of the capsule in the esophagus have been described. These methods include calculating the site of placement of the device by endoscopy followed by either transoral (4) or transnasal (8) insertions of the capsule delivery system, then placing the device at the site determined by prior calculation. Deployment of the device under direct endoscopic view has also been described (5). In addition, non-endoscopic methods of placing the device have also been described (9). In the non-endoscopic technique of device placement, the position of the LES is determined by esophageal manometry, which is then followed by blind deployment of the capsule guided by measurements obtained from manometry. However, the endoscopic method of placing the capsule is the most commonly used worldwide because it allows evaluation of the upper gastrointestinal tract for the presence of other concomitant pathologies that would otherwise preclude the use of these devices (10). Furthermore, it allows evaluation of the esophagus in patients with GERD. Some authors have suggested using the manometry method in patients who underwent recent endoscopy without any alarm signs (10). This technique could be potentially useful in patients with long-segment Barrett's esophagus where the squamocolumnar junction is no longer the landmark of the LES (11). However, this technique involves placing the capsule by the transnasal route, which is not well tolerated by patients and poses a risk of significant epistaxis. Using the transoral route for placing the device requires usage of a conversion factor proposed by Lacy et al. (6). However, this conversion factor has its own limitations; it cannot be used in patients with a hiatal hernia or in patients who are very tall or very short. In view of all these limitations, the endoscopic method of placing the device is currently the most commonly used method.

There have been no studies to date comparing the direct and indirect methods of Bravo capsule placement in the esophagus. Currently, the indirect method is the most commonly used for deploying the device in the lower esophagus.

The incidence of complications in our study was not different from those reported in other studies. Sore throat was the most common adverse effect

Table 3. Patient tolerability and experience

Characteristic	Direct	Indirect	*p*-value
Patient experience			
Good	10	8	*0.821*
Average	16	17	
Bad	3	4	
Satisfaction (score)			
Very satisfactory (9-10)	22	18	*0.115*
Average (5-8)	3	4	
Unsatisfactory (1-4)	4	8	
Willingness to repeat the procedure			
Yes	26	23	*0.094*
No	3	6	

Table 4. Mean time taken in the direct and indirect method of capsule placement

	Direct	Indirect	*p*-value
No. of AM to PM procedures (AM : PM)	18 : 11	22 : 7	
Overall average time-period for procedure *(in minutes)*	14.44	13.31	*0.122*
Average time for AM procedure *(in minutes)*	14.58	13.46	*0.662*
Average time for PM procedure *(in minutes)*	14.14	13.00	*0.303*

reported by our patients (32.7%), followed by post-procedure dysphagia (29.3%). This was comparable to the incidence of dysphagia reported in other studies (6). Chest pain was seen in 22.4% of cases. Chest pain was predominantly reported by patients who complained of dysphagia.

In theory, the direct method of placing the device would be expected to take less time than the conventional method, as the latter technique requires repeat endoscopic intubation. However, in our study, we found that the average time taken for the procedure was similar between the two groups. Further, there was no difference in the time taken in the procedures performed in the mornings compared to those performed in the afternoon (Table 4).

In our pilot study, we found that placing the Bravo capsule system under direct visualization is a safe procedure. The safety of this method is comparable to that of the indirect method given the similar frequency of complications seen in the two groups. In addition, the added advantage with the direct method is the avoidance of the second look endoscopy to confirm the site of attachment of the device. The placement of the device by direct method is precise. This is important, as the device could be wrongly deployed at an undesirable location including the stomach wall (9) or oropharynx (12) using the indirect method. Therefore, there would be a remote chance of deploying the capsule at an undesirable location with the direct method. Further, the direct method of placing the capsule allows the esophagus to be cleared of air under direct vision, which ensures the successful placement of the device by enhancing the contact between the esophageal wall and the well of the capsule. This is important because early detachment is a well-known complication with the Bravo system, and its incidence could be as high as 2-12% (4), (13).

In our study, we found that patient experience and satisfaction with the procedure were similar in the direct group and indirect group (75.9% vs. 66.06% and 34.4% vs. 27.5%, respectively). The patient's willingness to repeat the test, if necessary, was also similar between the two groups (89.7% vs. 75.5%). The explanation for the small observed difference, although not statistically significant, could be the fact that in the indirect group, patients had to undergo endoscopy twice in the same sitting. This could apparently be more uncomfortable than undergoing a single endoscopy. For the endoscopist, the direct method may be preferable as it avoids performing endoscopy twice in the same patient.

Our study has a few limitations. Firstly, it is retrospective by design, and secondly, the smaller sample size of the study groups cannot rule out the possibility of type II error. Nonetheless, the results of this study suggest an advantage of the direct method over the conventional (indirect) method of placement of the Bravo capsule system.

In conclusion, the direct method of deploying the wireless pH monitoring device is safe and effective. Patient tolerance, acceptance and the length of the procedure were similar with those of the indirect method. There is an additional advantage of avoiding a second endoscopy in the direct group, although there is no difference in the length of the procedure between these two techniques. A larger prospective study, however, is needed to provide more information regarding complications and adverse events using these two methods of capsule placement.

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