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Feasibility and Safety of String Wireless Capsule Endoscopy in the Diagnosis of Esophageal Varices

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OBJECTIVE: To assess the feasibility, safety, accuracy, and acceptability of "string-capsule endoscopy" in the evaluation of esophageal varices.

MATERIAL AND METHODS: Strings were attached to the wireless capsule endoscopy device to allow its controlled movement up and down the esophagus. Time of recording and discomfort associated with the procedure was documented. Patient's preference compared to conventional esophago-gastro-duodenoscopy (EGD) was recorded. An independent endoscopist blinded to EGD diagnoses assessed the diagnostic accuracy of pictures obtained.

RESULTS: Thirty patients with clinical liver cirrhosis (mean age: 54.4 yr; mean MELD score: 12.5, and mean Child-Pugh score: 6.3) were enrolled; 19 for surveillance and 11 for screening purposes. The procedure was safe (no strings were disrupted and no capsule was lost). The mean recording time was 5.8 min (2.9–8.7), the accuracy 96.7%, and discomfort was minimal. The majority (83.3%) of patients preferred string-capsule endoscopy to EGD.

CONCLUSIONS: String-capsule endoscopy was feasible, safe, accurate, highly acceptable, and preferred by cirrhotic patients undergoing screening/surveillance of esophageal varices. The technique may prove to be more cost effective than conventional EGD.

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INTRODUCTION

Esophago-gastro-duodenoscopy (EGD) with or without sedation is the most sensitive method to investigate disorders affecting the esophagus. The procedure, however, is costly, may be unpleasant, and still has a small but potential risk for complications (1, 2). EGD is used for evaluation of cirrhotic patients, both for screening and surveillance purposes (3). The use of conscious sedation with endoscopy not only adds the costs derived from the sedation itself (drugs, monitoring during and after the procedure) but also adds the indirect costs associated with the loss of productivity by part of the patient and his/her accompanying person and may be associated with more complications in patients with cirrhosis. The use of an alternative safe and comparable method for evaluating the esophagus, especially in the setting of a screening strategy (*i.e.,* esophageal varices) is needed. Unsedated EGD using ultrathin scopes is being evaluated as an alternative to conventional endoscopy to avoid the direct and indirect costs resultant from conscious sedation (4–6). We present the data on a feasibility and safety study of an alternative endoscopic technique for evaluating esophageal varices in patients with clinical cirrhosis. The technique involves the use of the wireless capsule endoscopy device (M2A Capsule. Given Imaging Ltd., Yoqneam, Israel) to which strings are attached in order to control the movement of the device up and down the esophagus, and thus provide endoscopic images of this organ transforming a physiologically dependent into an operator-dependent procedure not feasible otherwise with conventional wireless capsule.

MATERIAL AND METHODS

Based on our experience with string-capsule endoscopy in the diagnosis of Barrett's esophagus (7), patients with clinical cirrhosis were invited to participate in this study and did so after signing an informed consent. Clearance from the FDA was obtained prior to the approval of the protocol. After reviewing the research proposal, the FDA indicated that the proposed device should qualify as a nonsignificant risk device, no IDE would be required, and since the capsule would be cleaned the same way as endoscopy equipment is, this would not be an issue. The capsule endoscopy device itself can be considered a semicritical device (*i.e.,* it comes in contact with intact mucous membranes and does not ordinarily penetrates sterile tissue) in the Spaulding classification and for which at least high-level disinfection is recommended as per the most recent guideline for reprocessing (8). Thus, the

capsule can be reused after proper high-level disinfection. For such purpose, the capsule is first rinsed with water after each use, manually cleaned with an enzymatic solution and then immersed for at least 45 min in a container with 2% glutaraldehyde. The container is placed over a magnet to deactivate the capsule's battery during this process. The capsule surface is then rinsed off to remove glutaraldehyde, and cleaned with alcohol. The preliminary data yielded negative microbiological studies after high-level disinfection (7).

The strings were attached to the capsule (M2A Capsule, Given Imaging Ltd., Yoqneam, Israel) prior to each use and discarded immediately after the procedure was terminated and before the capsule underwent high-level disinfection. The attachment of the strings to the capsule was manually performed and did not use any glue or adhesive substances. This involved tying four strings (each string is 0.32-mm thick and when assembled together, the string thickness is 0.4 mm) in the middle of the device at approximately four equidistant points. The four strings then were brought to the back of the capsule and tied up again to form a basket and secure the capsule even further. In addition, this allowed the capsule to travel on its longitudinal axis (Fig. 1). A mark (a knot) at approximately 50 cm from the capsule was also made for reference purposes.

The protocol was approved by the Institutional Review Board of our hospital. We elected to investigate the feasibility and safety of string-capsule endoscopy in patients with known cirrhosis for evaluating the presence or absence of esophageal varices. Patients underwent string-capsule endoscopy and conventional EGD. Patients were asked their preference between the two procedures.

The study was carried out in the outpatient setting after informed consent was obtained. The string-capsule device was swallowed with water and the study performed in the sitting position. No sedation or topical anesthetic was used. Keeping the string under control by the investigator, the capsule was allowed to travel down into the stomach (approximately 50 cm mark on the string) by repeated wet swallows. The lower esophageal sphincter (LES) was tentatively located and identified by the mild resistance felt upon pulling the string up. At this point to facilitate the retrograde passage of the capsule into the esophagus, the patient was asked to swallow a sip of water to allow the LES to relax, and at the same time by gently pulling up the string, the capsule was felt to slip into the lower esophagus. From there, pulling the strings out slowly allowed the capsule to travel up the esophagus. A second resistance to the pulling signaled the upper esophageal sphincter (UES). The capsule was then allowed to travel down into the stomach again with wet swallows and the process was repeated for a total of three passages up and down. To facilitate retrieval of the string-capsule device from esophagus, the patient was asked to give a dry swallow when the resistance for the UES was felt, and the capsule was retrieved from the mouth by a gentle pull on the string. A complete EGD exam was carried out in the outpatient setting under conscious sedation using a combination of meperidine and midazolam and utilizing a diagnostic video endoscope (GIF-160 video gastroscope, Olympus Inc) of 8.8 mm in diameter.

In order to evaluate the patients' acceptance of the procedure, a questionnaire was administered to patients after each procedure (see the Appendix). In this questionnaire, patients graded the ease of swallowing the string-capsule device, the discomfort triggered by the string (throat discomfort, gagging), and from moving the capsule up and down, and retrieval of the capsule on a scale from 0 to 3 (0 = no; 1 = mild/minimal; 2 = moderate; and 3 = severe/very difficult). Patients who already have had prior experience with EGD were asked at this time as to which method they would prefer (EGD *vs* string-capsule endoscopy) if their esophageal examination had to be repeated; otherwise they were contacted at least 24 h after their EGD to assess their preference via telephone call. An independent nurse administered all the information regarding the procedure-related discomfort and the procedure preference (EGD *vs* string-capsule endoscopy).

An independent experienced endoscopist, unaware of the patients' diagnoses reviewed the pictures obtained with the capsule endoscopy and rendered an opinion as to whether or not the patient had evidence of esophageal varices. Since

Figure 1. Picture of the strings attached to the capsule.

Table 1. Grading System and Its Corresponding EGD Grading for Varices

Size Varices as Evaluated by String-Capsule Endoscopy	Corresponding EGD Grade (I–IV)
Small to medium size varices	Grade I
Medium size varices	Grade II
Large size varices	Grade III
Very large size varices	Grade IV

For therapeutic purposes (primary or secondary prophylaxis) varices grades III and IV or the presence of "red signs".

the main limitation for grading esophageal varices with the string-capsule endoscopy is the lack of air insufflation, a grading system was developed and correlated with the conventional EGD grading system used for esophageal varices. The grading system was based on the estimated size of the varices and the presence of red signs (Table 1).

RESULTS

A total of 30 patients with clinical cirrhosis were enrolled in the study. All patients were men, with a mean age of 54.4 yr (range: 43–69), a mean MELD score of 12.5 and a Child-Pugh score of 6.3 (Table 2). Nineteen patients had their procedures performed for surveillance whereas the remaining 11 patients did so for screening purposes. The etiology of their underlying liver disease included: HCV infection alone in 14 patients, alcohol alone in 8, HCV and alcohol in 7, and 1 patient with cryptogenic cirrhosis. There were five patients (1 in the surveillance group) with no varices found on EGD. Twenty-two patients had had prior experience with EGD. Twenty patients had an EGD the same day as the string-capsule endoscopy study, 3 patients within 24 h, 2 within 14 days, 1 patient within 1 month, and 4 patients after 1 month. Conventional EGD was performed under conscious sedation in all but one patient and the mean time for the procedure was 4.9 min (range: 3–10 min); 5 patients underwent band ligation of their varices during the same setting.

There were no complications related to either procedure (EGD and string-capsule endoscopy). In no instance were the strings damaged or ruptured and no capsule was lost in any of the studies.

Information regarding the discomfort associated with string-capsule endoscopy and the preference between string-capsule endoscopy and EGD was available in 29 patients. Overall, the string-capsule device was deemed to be easy or mildly difficult to swallow by 79.3% (23/29) of patients, moderately difficult by 17.2% (5/29), and very difficult to swallow by 3.5% (1/29) of patients. The strings attached to the capsule caused no or only minimal throat discomfort or gagging in 100% (29/29) patients. Likewise, pulling the capsule up and down caused no or mild discomfort in all patients. Pulling the capsule out of the esophagus caused no or minimal discomfort in 82.8% (24/29), and moderate discomfort in 17.2% (5/29) (Table 3).

When patients were asked as to which endoscopic method (string-capsule *vs* EGD) they would prefer if they had the choice for a repeat study of their esophagi, 3 (10%) preferred EGD, 2 (6.9%) had no preference of one method over the other whereas the remaining 25 (83.3%) patients preferred the string-capsule endoscopy over EGD.

Regarding the diagnostic accuracy of the pictures obtained with the string-capsule endoscopy; there was a complete diagnostic agreement for absence/presence of esophageal varices in 29/30 patients (96.7%). The only patient where there was a disagreement was diagnosed of having grade I varices on EGD and no varices on string-capsule endoscopy. All 5 patients with large varices on string-capsule endoscopy had corresponding large varices on conventional EGD. Likewise, all 5 patients found to have no varices on string-capsule endoscopy had no varices on conventional EGD (all these patients had their procedures for screening purposes). Of the remaining 20 patients with small-medium size varices on conventional EGD, there were 3 (15%) that string-capsule endoscopy either underestimated (one patient) or overestimated their variceal size (two patients). The sensitivity of string-capsule endoscopy for detecting esophageal varices when compared to the gold standard conventional EGD was 96% (24/25) with a 100% positive predictive value, a specificity of 100% (5/5), and a negative predictive value of 83.3% (5/6). Figure 2 shows some representative thumbnail pictures of patients with different grades of esophageal varices.

The mean recording time per patient was 5.8 min (range: 2.9–8.7 min).

Table 2. Demographic and Clinical Characteristics of Patients Undergoing String Wireless Capsule Endoscopy

	Screening (n = 11)	Surveillance (n = 19)	Total (n = 30)
Mean age (yr)	54.2	54.6	54.4
Etiology			
HCV	7		14
Alcohol	3	7	8
HCV + alcohol	1	5	7
Cryptogenic		6	1
Mean MELD score	11.1	13.3	12.5
Mean Child-Pugh score	6.2	6.3	6.3

HCV = hepatitis C virus.

DISCUSSION

We have presented data to support string-capsule endoscopy as a feasible, accurate, and safe alternative method to conventional esophagoscopy for the diagnosis of esophageal varices. Wireless capsule endoscopy is a major technological advance in the diagnosis of small bowel mucosal conditions (9–13). The U.S. Food and Drug Administration approved it for clinical use in 2001. The device currently available (Given M2A, Given Imaging Ltd., Yoqneam, Israel) is a 26 mm long by

Table 3. Discomfort Scores Associated with String Wireless Capsule Endoscopy

Score	0: n (%)	1: n (%)	2: n (%)	3: n (%)	Mean Score
Swallowing capsule	12 (41.4)	11 (37.9)	5 (17.2)	1 (3.5)	0.83
Strings: throat discomfort	20 (69)	9 (31)			0.31
Strings: gagging	23 (79.3)	6 (20.7)			0.21
Pulling up and down	25 (86.2)	4 (13.8)			0.14
Capsule retrieval	11 (37.9)	13 (44.9)	5 (17.2)		0.79

0 = none; 1 = mild; 2 = moderate; and 3 = severe.

11 mm in diameter sealed outer plastic capsule that is resistant to breakdown within the gut. The size and shape allow easy ingestion and convenient passive passage through the gut. A complementary metal oxide silicone chip camera that has lower power and illumination needs than conventional endoscopes is responsible for the generation of images. Four pulsing white, light-emitting diodes generate the necessary illumination. In addition, there are two silver oxide batteries behind the light source followed by an ultrahigh frequency band radio telemetry transmitter. The image generated has a 140° viewing field and a 1:8 magnification of objects from 1 to 30 mm depth of view. It transmits two frames per second over a total time of 7– 8 h. Images are transmitted to an antenna array over the abdomen that in turn is connected to a portable hard drive and power source worn on a belt. After recording is completed, usually in 8 h, the recorded images are downloaded into a customized personal computer workstation and then reviewed and interpreted in the form of a video or individual frames. The device is usually eliminated with the normal passage of stools. Due to its rapid transit time, the wireless capsule endoscopy device has been unable to provide adequate information regarding esophageal mucosal details. Manometrically, a peristaltic contraction reaches the LES 5–6 s after swallowing (14); after determining that the average upright esophageal transit time for the wireless endoscopy capsule was 2.2 min in 57 patients undergoing the study for standard indications, it was not recommended for examination of the esophagus (15). In another study (16) the median exposure time of capsule endoscopy in the esophagus was found to be 2 s (range 0–217 s) with a median of only four images generated (range:0–434) and again it was concluded that distal esophageal assessment by capsule endoscopy for screening purposes was not feasible. In a study of 210 patients undergoing standard capsule endoscopy, the esophagus was visualized in 159 patients (75.7%) and of these, 86% (156 patients) had less than 10 s of esophageal images, and 11% had between 10 and 300 s of images (17). In those with esophageal images, the Z-line was at least partially visible in only 29% of cases. Again, in all these studies the crucial limiting factor was the transit time of the device through the esophagus. The attachment of a string to the capsule allows a longer transit time that is basically operator dependent and not physiologically dependent and provides more esophageal images for study. Initial experience utilizing this concept in a group of four volunteers although the visibility of the Z-line was better, the procedure was deemed so unpleasant that no more subjects were enrolled (15). In another study, the capsule secured by a string was used in two volunteers. In one, the capsule could not be swallowed because of intense gagging and in the other images of the gastroesophageal junction were obtained but the retrieval of the capsule was hampered by spasm of the UES (17). We have recently been able to successfully use the technique in 50 patients with Barrett's esophagus with a mean recording time of 7.9 min providing enough pictures to confidently make an endoscopic diagnosis (7). The study had high accuracy and was safe and very well tolerated by patients. In addition, we were able to show that the technique was the preferred method when compared to conventional EGD.

The safety data from our present study revealed that the attachment of the strings to the capsule was well preserved with no evidence of rupture, movement, or interference with imaging and without loss of the capsule in any of the exams. By allowing the capsule's retrieval, the risk of capsule retention that has been reported in up to 5% of patients with unsuspected gastrointestinal strictures (18) has been practically eliminated. In addition, previous negative microbiological data supported the adequacy of high-level disinfection with currently available techniques, glutaraldehyde in particular, allowing for the capsule's safe reuse (7).

The string-capsule endoscopy was well tolerated by our patients with no or only minimal discomfort caused by the strings. The most difficult part of the procedure from the patient's perspective was swallowing the capsule (moderate or very difficult to swallow in 20.6%) and the final retrieval of the capsule (moderate discomfort in 17.2% patients). The high tolerability of the procedure in general we believe is related to both the thickness and material of the string used and, the method used to attach the strings to the capsule allowing only its longitudinal passage, particularly across the esophageal sphincters. The patient's acceptance of the method was further reflected by their choice of the string-capsule endoscopy over conventional EGD in the great majority of patients (83.3%).

The sensitivity for the visual diagnosis obtained with the string-capsule endoscopy was 96% when compared to the gold standard, EGD. These results are indeed encouraging since they would render the string-wireless capsule endoscopy technique as an accurate, safe, comfortable, and rapid alternative for screening for esophageal varices without the need for conscious sedation and its associated costs. This may ultimately prove to be a cost-effective alternative to

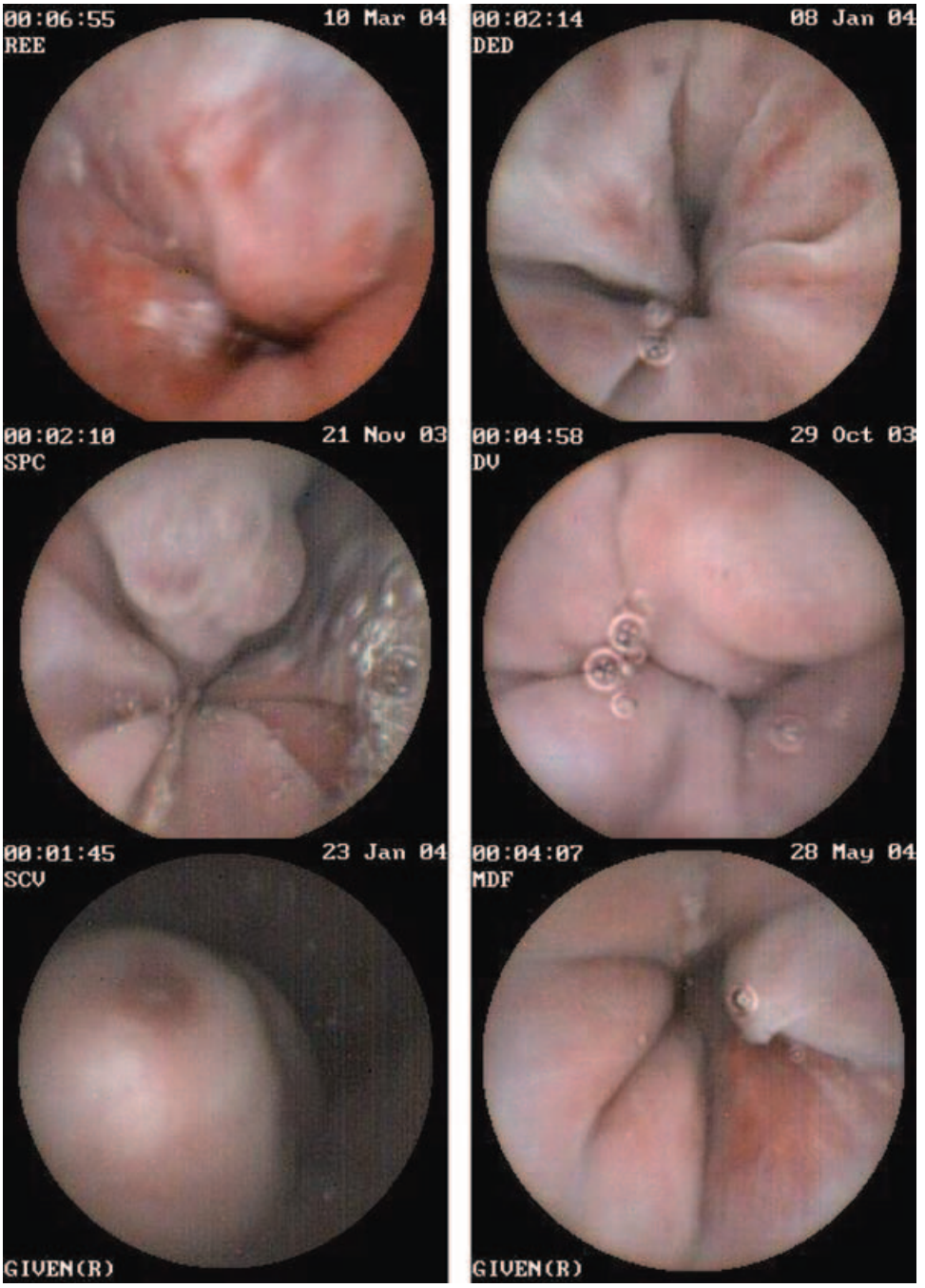

Figure 2. Set of thumbnail pictures from patients with esophageal varices.

conventional EGD. In order to justify prophylactic intervention (beta-blockers or band ligation) a firm diagnosis of moderate or large varices (19, 3) is first needed but in order to be cost effective, the screening EGD would need to decrease by two-thirds to $281 (20), and this could only be possibly achieved if the costs from conscious sedation are eliminated and endoscopic devices would be reused. Our proposed method with string-capsule endoscopy could allow for this. The use of ultrathin endoscopes has been evaluated as an alternative to conventional endoscopy avoiding the use of conscious sedation. The procedure in general has been found to be feasible, accurate, and with comparable levels of patient's acceptance to conventional EGD (4, 5, 21, 22). Ultrathin endoscopes have also been used to assess their utility in the diagnosis of esophageal varices. Unsedated endoscopy using these instruments have yielded accurate results for both detecting and grading esophageal varices and the procedures have been deemed safe and well tolerated by patients (23, 24). Major limitations for the use of ultrathin endoscopes with screening purposes (*i.e.,* Barrett's esophagus, esophageal varices) include evidence that the patient acceptance may still be limited (6), the adequacy of esophageal

imaging may be dependent on instrument size (25), need for additional training if transnasal insertion is chosen (26), costs and the possibility of requiring an additional processor. Although string-capsule endoscopy was able to grade correctly the size of varices in 88% of cases (22 out of 25 patients with varices), the disagreement was in the small varices group. All patients with definitive large varices and the presence of red signs, *i.e*., those who would require therapeutic intervention (primary or secondary prophylaxis) were not missed. The study to evaluate cost-effectiveness of string-capsule endoscopy in the screening and surveillance of esophageal varices is underway in our unit.

There are currently several limitations of string-capsule endoscopy. These include: (i) the large size of the capsule that may be difficult to swallow by some patients; (ii) the presence of bubbles (from saliva and/or air swallowed with water) and secretions may somewhat interfere with the pictures obtained by the capsule endoscopy. We used sterile water in all patients in order to minimize these interferences. The transit time of the capsule through the esophagus again is crucial so more frames can be assessed. Although the transit time across the esophagus may be artificially delayed by altering the patient's position (*i.e.*, supine position), the transit is still unpredictable and the number of frames and their adequacy particularly the lower part of the esophagus may be insufficient when the conventional capsule endoscopy device is used. Although the addition of another lens ("dual chamber" capsule: back and front) doubles the number of images taken, the unpredictability of the transit time across the esophagus (*i.e.*, physiology) may still hamper the adequate visualization of the entire esophagus and does not prevent the possibility of capsule retention. The addition of the strings to the capsule eliminates this physiologically dependent factor and makes it more operator-dependent instead. Another limitation with the current capsule design is the depth of visualization (up to 30 mm) not allowing bright, clear, and accurate pictures from farther distances in the esophagus. We found that the best pictures were obtained when the capsule was in close contact with the mucosa, during swallow-induced peristalsis. This again stresses the need for a longer transit time between the capsule and the esophagus and this could only be provided by an operator-controlled movement up and down the esophagus through the use of a string. Increasing the capsule's power of illumination might allow for better pictures taken from the distance. Another and perhaps more important limitation is the inability to display "live" or "real-time" pictures. All these limitations are amenable to improvement in the future.

In conclusion, the modification of the conventional wireless capsule endoscopy by attaching strings to it and converting it into a string-capsule endoscopy device is feasible, safe, well tolerated, and accurate for the diagnosis of esophageal varices. Its accuracy and the ability to reuse the capsule after proper disinfection/sterilization may prove to be a cost-effective alternative to standard esophagoscopy in the evaluation of esophageal varices.

APPENDIX: String-capsule endoscopy-associated discomfort and preference survey. Please rate the following items.

STRING-CAPSULE
Swallowing. The capsule was: 0: easy to swallow and no different from other pills 1: mildly difficult to swallow 2: moderately difficult to swallow 3: very difficult to swallow
Strings. The strings attached to the capsule: 0: were minimally perceived and caused no throat discomfort 1: caused mild throat discomfort 2: caused moderate throat discomfort 3: caused severe throat discomfort 0: caused no gagging 1: caused minimal gagging 2: caused moderate gagging 3: caused severe gagging
Pulling the string-capsule up and down: 0: caused no discomfort 1: caused minimal discomfort 2: caused moderate discomfort 3: caused severe discomfort
Pulling the capsule out: 0: caused no discomfort 1: caused mild discomfort 2: caused moderate discomfort 3: was very uncomfortable

After your experience with the string-capsule endoscopy and compared to conventional endoscopy (EGD): Would you rather have the string capsule endoscopy instead of EGD if a look in your esophagus is needed again:

1. Yes
2. No

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