

## Small caliber overtube-assisted colonoscopy

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Received: June 18, 2007 Revised: August 15, 2007

### Abstract

**AIM:** To combine the benefits of a new thin flexible scope with elimination of excessive looping through the use of an overtube.

**METHODS:** Three separate retrospective series. Series 1: 25 consecutive male patients undergoing unsedated colonoscopy using the new device at a Veteran's hospital in the United States. Series 2: 75 male patients undergoing routine colonoscopy using an adult colonoscope, pediatric colonoscope, or the new device. Series 3: 35 patients who had incomplete colonoscopies using standard instruments.

**RESULTS:** Complete colonoscopy was achieved in all 25 patients in the unsedated series with a median cecal intubation time of 6 min and a median maximal pain score of 3 on a 0-10 scale. In the 75 routine cases, there was significantly less pain with the thin scope compared to standard adult and pediatric colonoscopes. Of the 35 patients in the previously incomplete colonoscopy series, 33 were completed with the new system.

**CONCLUSION:** Small caliber overtube-assisted colonoscopy is less painful than colonoscopy with standard adult and pediatric colonoscopes. Male patients could undergo unsedated colonoscopy with the new system with relatively little pain. The new device is also useful for most patients in whom colonoscopy cannot be completed with standard instruments.

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**Key words:** Colonoscopy; Endoscopy; Colon Cancer; Colon cancer screening

Friedland S, Soetikno RM. Small caliber overtube-assisted colonoscopy. *World J Gastroenterol* 2007; 13(44): 5933-5937

<http://www.wjgnet.com/1007-9327/13/5933.asp>

### INTRODUCTION

Colonoscopy is typically performed using relatively large-diameter (11-13 mm) pediatric and adult instruments with enough rigidity to permit advancement of the instrument despite multiple turns within the bowel<sup>[1-3]</sup>. With these instruments, looping of the endoscope is a common difficulty that results in pain for the patient and hinders advancement of the endoscope<sup>[4,5]</sup>. In an effort to overcome looping, which is particularly common in the sigmoid colon, some practitioners have used stiffening overtubes that are preloaded on the back end of the scope and advanced over the colonoscope after negotiation of the sigmoid colon<sup>[6-8]</sup>. With the tube in place, further advancement of the instrument can be attained with minimal looping in the sigmoid; the overtube facilitates transmission of force from the endoscopist's pushing hand to the proximal end of the overtube. However, the overtubes employed for colonoscopy in the past have been relatively bulky and rigid devices that accommodate the large diameter of standard colonoscopes.

It is sometimes possible to perform colonoscopy using relatively thin and flexible upper endoscopes<sup>[9]</sup>. Thinner, more flexible scopes are often more easily advanced through the left colon<sup>[10]</sup>; this is perhaps the major reason why many endoscopists prefer pediatric colonoscopes over standard adult colonoscopes in female patients and in patients with sigmoid adhesions<sup>[2]</sup>. However, even pediatric colonoscopes are often associated with more difficulty in advancement through the proximal colon due to excessive looping<sup>[2]</sup>. These observations suggest that a very thin and flexible scope might facilitate insertion through the distal colon, but a mechanism to prevent excessive looping is important for optimal advancement through the proximal colon. One alternative to conventional colonoscopy that employs this strategy is to perform the procedure using a double balloon enteroscope<sup>[11-13]</sup>. The double balloon system also employs a very thin scope and an overtube, with the addition of balloons on the scope tip and overtube tip that can be inflated to secure the position by pressing against the bowel wall<sup>[14-16]</sup>. The double balloon system is used increasingly in patients who have failed conventional colonoscopy, but a major limitation is that the procedure is laborious and time consuming<sup>[17-19]</sup>. We surmised that by using a standard 160 cm length of scope, rather than the 200 cm long double balloon enteroscope, and a short 60 cm overtube, rather than a 140 cm long double balloon overtube, the procedure would be more efficient.

## MATERIALS AND METHODS

The new colonoscopy system consists of a thin 9 mm scope, 170 cm in length, together with a 13 mm diameter 60 cm long overtube. The new 9 mm endoscope has the same outer diameter and instrument channel diameter (2.8 mm) as diagnostic upper endoscopes, but a 170 cm length that is similar to that of standard colonoscopes. The new scope has already received regulatory approval by the U.S. Food and Drug Administration for routine clinical use. The endoscope was provided by the Olympus corporation (Olympus America, Melville, New York, USA). The overtube (TS-13140, Fujinon Corporation, Wayne, New Jersey, USA) has a proprietary coating that reduces friction with the scope when the system is exposed to water; it is available commercially and is widely used in double balloon endoscopy. Because the overtube was too long, we cut off the proximal (near the hub) 100 cm and moved the plastic handle from its original position to the proximal end of the shortened tube (Figure 1). We also removed the inflatable latex balloon at the tip of the overtube because our earlier experience suggested that it is not generally helpful. Prior to each procedure, the overtube was temporarily filled with water to activate the lubrication system inherent in the tube and then back-loaded to the hub of the endoscope, leaving the distal 110 cm of the endoscope free for performing the initial portion of the examination without the overtube in place. After reaching the transverse colon, the scope was reduced, and the overtube was advanced over the scope until the handle on its proximal end was near the buttocks. An assistant then held the handle on the end of the overtube and the scope was advanced to the cecum.

This study consists of 3 retrospective series of patients undergoing colonoscopy at the Veterans Affairs Palo Alto Health Care System. Informed consent was obtained from all patients. The study was approved by the institutional review board of our hospital. All of the procedures were done by a single endoscopist with 8 years of experience performing approximately 1000 colonoscopies per year. The first series consisted of 25 consecutive male patients who were scheduled for unsedated colonoscopy (no medications given for the procedure); the patients were scheduled for unsedated procedures because of patient preference, medical contraindications to sedation, or lack of a driver to take them home after the procedure. The second series consisted of 75 consecutive male patients undergoing routine colonoscopy (3 female patients, 3 patients with previous partial colectomy and 1 patient with inflammatory bowel disease who necessitated a high-resolution magnification scope were not included in the series). An adult (Olympus CF-Q160AL), pediatric (Olympus PCF-Q180AL) and the thin scope/overtube were used in alternating cases. Patients were pre-medicated with lorazepam 2 mg sublingually (1 mg for patients over age 80) 15 min before the procedure. Patients were instructed by the nursing staff to request additional medication if they experienced pain or discomfort. Intravenous fentanyl was administered if the patient requested further sedation. The third series consisted of



**Figure 1** The new 9 mm scope is shown alongside the 60 cm-long overtube.

35 patients who had incomplete colonoscopies in our endoscopy unit (the cecum was not reached) using any combination of standard adult (Olympus CF-Q160AL) and/or pediatric (Olympus PCF-160AL or PCF-Q180AL) endoscopes. The incomplete colonoscopies were performed by one of eight experienced attending endoscopists who work in our department.

### Statistical analysis

Statistical comparison calculations were performed with two-tailed unequal-variance student's *t*-test<sup>[20]</sup>. Odds ratios and confidence intervals were calculated with the Newscombe-Wilson method without continuity correction<sup>[21]</sup>.

## RESULTS

In the first series, unsedated colonoscopy was successful in 25 consecutive patients at the Veterans Affairs Palo Alto Health Care System using the new device. None of the patients received any medication for the procedure. The indication for colonoscopy was a previous history of adenoma in 14 patients, positive stool occult blood in 3, screening in 2, family history of colon cancer in 2, hematochezia in 2, anemia in 1 and constipation in 1. Patients underwent unsedated colonoscopy for one of three reasons: patient preference (10 patients), inordinately high sedation risk (6) or unavailability of a driver to take them home after receiving sedation (9). All of the patients were male veterans. The age of the patients ranged between 53 and 94, with an average age of 68.1 and a median of 70.

Cecal intubation was achieved in all 25 patients, in a median time of 6 (average 6.4, range 2.5-15) min. Patients rated their maximal pain level during the procedure on a 0-10 scale. The median maximal pain level was 3 (average 2.9, range 0-6.5). Six patients had a maximal pain of 4 or higher. The entire procedure lasted a median time of 13 (average 13.6, range 7-28) min, including at least one snare polypectomy in 8 patients and forceps biopsy in another 2 patients. Small (< 10 mm) areas of mild erythema from passage of the overtube were seen occasionally on withdrawal, but no mucosal disruptions or other signs of trauma were observed. There was one complication:

bleeding one week after endoscopic mucosal resection of a 1.5 cm flat adenoma. The patient underwent urgent colonoscopy with successful clipping of an actively bleeding vessel at the resection site. He did not require blood transfusion or hospitalization.

The second series consisted of 75 male patients undergoing routine screening or surveillance colonoscopy. A standard adult colonoscope, pediatric colonoscope, and the thin scope/overtube system were used alternately; 25 procedures were performed with each type of scope. The median age of the thin scope group was  $70 \pm 10$ , compared to  $69 \pm 9$  in the adult scope group ( $P = \text{NS}$ ). The median age of the pediatric scope group was  $65 \pm 8$ , which was significantly younger than the thin scope group ( $P = 0.03$ ).

Following premedication with lorazepam, 24/25 procedures with the thin scope were completed without additional sedation medication, compared to 9/25 with the adult scope (odds ratio 43,  $P < 0.005$ ) and 14/25 with the pediatric scope (odds ratio 19,  $P < 0.01$ ). The mean dose of fentanyl ( $\mu\text{g}$ ) used was  $12 \pm 60$  with the thin scope, compared to  $51 \pm 53$  with the adult scope ( $P < 0.05$ ) and  $39 \pm 53$  ( $P = \text{NS}$ ) with the pediatric scope. The median maximal pain during the procedure on a 0-10 scale was  $3.5 \pm 2$  in the thin scope group, compared to  $8 \pm 2$  in the adult colonoscope group ( $P < 0.001$ ), and  $7.5 \pm 2.5$  in the pediatric colonoscope group ( $P < 0.001$ ). The cecum was reached in all patients, but the adult colonoscope was exchanged for a smaller diameter scope in 2 patients due to acute angulation in the sigmoid, and the pediatric colonoscope was exchanged for another scope in 2 patients due to excessive looping. The median time in minutes to reach the cecum was  $5.5 \pm 2.5$  in the thin scope group, compared to  $6.0 \pm 2.1$  in the adult colonoscope group ( $P = \text{NS}$ ), and  $4.0 \pm 1.9$  min in the pediatric colonoscope group ( $P = 0.004$ ).

In the third series, 35 patients who had previously undergone unsuccessful colonoscopy (with inability to reach the cecum) had the procedure repeated using the new device. The reasons given by the endoscopist for the inability to reach the cecum were: excessive looping (22 patients), acute sigmoid angulation (11 patients) and acute angulation at the splenic flexure (2 patients). 28 of the patients were male and 7 were female. The age ranged between 33 and 90, with a median age of 65 and a standard deviation of 13. The procedure was successful in 33; the cecum could not be reached in 2 male patients due to excessive looping and double balloon colonoscopy was successfully performed in both of these cases. The median time to reach the cecum in the 33 successful cases was 7 (standard deviation 3.9) min. The median total colonoscopy time, including snare polypectomies in 8 patients and forceps biopsies in 3 patients, was 15 (standard deviation 8.4) min. There were no complications.

## DISCUSSION

Sedation practices for colonoscopy vary widely across the world; unsedated colonoscopy is commonly performed in Asia and Finland<sup>[2]</sup>, whereas it is generally very poorly accepted in the United States<sup>[22-25]</sup>. A major reason is pain

due to looping of the endoscope. Small caliber overtube-assisted colonoscopy can potentially decrease looping and pain enough to make unsedated colonoscopy feasible in the general population. The small caliber scope used in this study was easily and rapidly advanced through the distal colon with minimal pain. After reduction of the scope, the thin low-friction overtube was advanced into position without significant resistance. With the overtube in place, it was generally possible to directly advance the endoscope to the cecum with relatively little attention to subsequent loop formation or paradoxical backward motion of the tip upon insertion. Our study suggests that this colonoscopy system could potentially make colonoscopy without intravenous sedation feasible a significant number of patients. The thin scope/overtube system was significantly less painful than conventional adult or pediatric colonoscopes. The 25 patients who required unsedated colonoscopy for a variety of indications all had successful procedures, and only 6 had a maximal pain level of 4 or higher on a 10 point scale. In the second patient series, when routine colonoscopy was performed after premedication with sublingual lorazepam, only 1 of 25 patients in the thin scope/overtube group requested additional sedation, compared to 11 of the patients with the pediatric colonoscope and 16 with the adult colonoscope. This suggests that most male patients undergoing routine screening or surveillance colonoscopy do not require intravenous conscious sedation and would be satisfied with a mild sedative that can be administered by mouth without an intravenous line. This could potentially result in a substantial cost savings by eliminating the need for extensive monitoring of patients receiving conscious sedation, and potentially make colonoscopy feasible for many patients in an office setting.

The thin scope/overtube system offers several benefits compared to standard colonoscopes. The thin scope is generally easily advanced through the sigmoid colon, as demonstrated by the successful performance of colonoscopy in 11 patients in the third series in whom previous colonoscopy was unsuccessful due to acute sigmoid angulations. Once the scope has been advanced through the left colon and reduction of loops has been performed, the overtube is advanced into position and subsequent looping of the scope during advancement through the right colon should theoretically be minimized. We did not specifically measure looping in the procedures we performed, but in our experience once the overtube was in place the scope was easily advanced through the right colon with little effort or attention required to prevent or reduce loops. The median time required to reach the cecum was 6 min in the unsedated group and 5.5 min in the lorazepam premedication group. This suggests that despite the additional step of positioning the overtube, reaching the cecum with the system can still be in an acceptable period of time. The median overall procedure time was 13 and 13.5 min in the unsedated and lorazepam groups, including at least one snare polypectomy in approximately 1/3 of the patients, demonstrating that withdrawal and polypectomy can also be performed efficiently.

Of the 35 patients who had previously failed colonoscopy using standard instruments, 33 had a



successful procedure with the thin scope/overtube system. The median time to reach the cecum in those 33 patients was only  $7 \pm 3.9$  min. Although these cases were subjectively more difficult than routine cases, the patients received conscious sedation, which may facilitate rapid advancement, resulting in a similar overall time to cecum as in unsedated routine cases. This compares very favorably to our prior published experience of using a double balloon enteroscope to successfully complete 19 of 20 patients with previously incomplete colonoscopies, where the median time to reach the cecum was  $28 \pm 20$  min<sup>[26]</sup>. Based largely on this difference in time, our preference is currently to use the thin scope/overtube system in all cases after failed colonoscopy with standard instruments, and reserve the double balloon enteroscope for those situations when the thin scope/overtube system is unsuccessful.

There are clear limitations to the current study: the retrospective design, the relatively small number of patients in each of the series, the overwhelmingly male patient population, the previously documented tolerance of male American veterans to unsedated colonoscopy<sup>[2,27]</sup>, and the single-center design. Since the study was retrospective, the routine screening colonoscopy patients were not randomized to the new scope or a standard adult or pediatric scope, but rather the scopes were alternated. There were no complications attributable to the thin scope/overtube system in our study (the lone complication in the 3 retrospective series was a post-polypectomy bleed in one of the unsedated patients), but all of the procedures were performed by one experienced endoscopist and it remains to be demonstrated that the system is safe when used by practitioners of varying experience. Given the substantial differences across different institutions and different countries in the performance of unsedated colonoscopy, it is difficult to predict what effect this system could have on colonoscopy practice, but our study does demonstrate the potential for making colonoscopy less painful and better tolerated without dramatically increasing procedure time or complexity.

There are several disadvantages to the small caliber endoscope and overtube system used in this study. The overtube is marketed for single-use and is expensive in its current form (approximately US\$200 at our institution); shortening the tube is also cumbersome. It is conceivable that a more reasonably priced short tube could be manufactured or that a reusable version could be developed. The 9-mm scope has a relatively small 2.8-mm channel which is adequate for typical maneuvers such as snare polypectomy and clip placement, but can limit suctioning of stool residue and resected polyps. A water jet port for efficient lavage is not available. The field of view, lighting and optical resolution may be slightly compromised compared to the latest generation of high-resolution adult colonoscopes. However, the potential for reducing pain may outweigh any of these disadvantages. Further studies will also need to address whether some colonoscopies are more difficult with this system, whether there is any increase in the rate of missed lesions, and whether certain therapeutic cases would be better served by using a standard colonoscope. The ultimate goal of reducing

pain during colonoscopy enough to make unsedated colonoscopy better tolerated, thereby eliminating both complications due to sedation as well as an estimated 40% of the cost of the procedure<sup>[2]</sup>, is particularly important given the current widespread screening practices in many countries. Additional adjunctive measures, such as using carbon dioxide instead of air for insufflation<sup>[28,29]</sup>, may also play a role in achieving this goal.

## COMMENTS

### Background

Colonoscopy using standard instruments is often relatively painful and most procedures are done using intravenous sedation. Reduction of pain is a major focus of research because the potential for eliminating conscious sedation may make the procedure safer and less expensive.

### Research frontiers

The development of new types of scopes for performance of colonoscopy with less pain and less sedation is a major area of research. Thinner scopes can potentially cause less pain during colonoscopy, but they can also result in more loop formation which can hamper the procedure.

### Innovations and breakthroughs

In this article we describe our experience using a new thin scope in combination with an overtube designed to minimize loop formation. We demonstrate that the new system is less painful than standard colonoscopes.

### Applications

This study suggests that the combination of a thin scope and an overtube can be useful for unsedated, routine and difficult colonoscopies.

### Terminology

Looping: the process where the scope tip does not progress forward when the endoscopist pushes the scope into the patient, but rather the mid-section of the scope bows out, resulting in stretching of the colon.

### Peer review

This is an important and well written contribution. Through retrospective comparative study, the authors concluded that small caliber overtube-assisted colonoscopy is less painful than colonoscopy with standard adult and pediatric colonoscopes. Male patients can undergo unsedated colonoscopy with the system with relatively little pain. The new device is also useful for most patients in whom colonoscopy cannot be completed with standard instruments.

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S- Editor Zhu LH L- Editor Lutze M E- Editor Ma WH