Capsule Endoscopy

Is There a Role for Nurses as Physician Extenders?

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Capsule endoscopy is a novel technique for examining the small bowel; however, data interpretation is time consuming and requires expertise. This study aimed to compare the interpretation of capsule endoscopy between an experienced gastroenterologist and a nurse. A total of 50 consecutive videos were viewed independently by a nurse and a physician, both blinded to the referral indications. The nurse had no prior experience with capsule endoscopy. Possible pathology was graded in a pre-agreed standardized manner, with findings described as "relevant," "uncertain," or "irrelevant." Another gastroenterologist, who had knowledge of all the cases including follow-up data and clinical outcomes, independently arbitrated. Findings showed no difference in the number of relevant or uncertain pathologies identified. The nurse reader was more likely to record irrelevant findings (4.7 vs. 2.0 lesions; $p < .01$) and required more time to read the videos than the physician (mean = 73 vs. 58 min; $p < .01$). This study shows that a nurse capsule endoscopy reader is as capable as an experienced physician in identifying small bowel mucosal abnormalities on capsule endoscopy. Capsule endoscopy is an area in which nurses could develop as physician extenders.

Capsule endoscopy, a novel wireless method for investigating the small bowel, has revolutionized the field of endoscopy. The capsule, a remote instrument that can be swallowed, is propelled through the gastrointestinal tract by the action of peristalsis (Iddan, Meron, Glukhovsky, & Swain, 2000).

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Historically, the small bowel was considered a technically difficult area to examine because of its length (3 to 5 m), location, and tortuosity (Ginsberg et al., 2002). Push enteroscopy allows examination only 120 cm beyond the duodenojejunal flexure, whereas barium follow-through (small bowel meal) and enteroclysis (double-contrast small-bowel follow-through) have proved to have a low diagnostic yield, particularly for subtle mucosal changes such as angiodysplasia (Costamagna et al., 2002; Nolan & Traill, 1997).

Background

Capsule endoscopy currently has an established role in obscure gastrointestinal bleeding and is increasingly used for the diagnosis of Crohn's disease where other methods have failed (Lewis, Eisen, & Friedman, 2005). A single video produces more than 50,000 images of the small bowel (Iddan et al., 2000). Reviewing and interpreting a video requires

30 to 120 min. This time-consuming step also involves a level of expertise.

There is limited published data comparing the reading and interpretation of capsule endoscopy videos between novice readers and experienced physicians (Chen et al., 2006). A few previous studies have compared the interobserver variability between an experienced gastroenterology or endoscopy nurse and a physician (Bossa, Cocomazzi, Valvano, Andriulli, & Annese, 2006; Levinthal, Burke, & Santisi, 2003; Niv & Niv, 2005). Other investigators also have made comparisons between physicians with different levels of experience (endoscopy fellows or junior endoscopists vs. experienced physicians; Adler, Knipschield, & Gostout, 2004; De Leusse et al., 2005). However, a comparison of capsule endoscopy interpretation between a nurse without any gastroenterologic or endoscopic experience and a physician has never been evaluated. We tested the hypothesis that, like other areas of gastroenterology, the role of nurses could be potentially extended to capsule endoscopy interpretation.

Methods

The "Capsule"

The PillCam SB Capsule Endoscope (Given Imaging Ltd., Yoqneam, Israel) measures 26 × 11 mm and weighs 3.7 g. It contains a complementary metal oxide semiconductor imaging chip video camera (Iddan et al., 2000), six white LED illumination sources, two silver oxide batteries, and a radio telemetry transmitter. The image field of view is 140°, and the magnification is 1:8 (Iddan et al., 2000). The small bowel images are transmitted by radiofrequency at a rate of two frames per second to a sensor array in a belt placed around the patient's abdomen (Iddan et al., 2000; Iddan & Swain, 2004). The patient wears a digital data recorder around his or her waist for the duration of the battery life (~8 hr).

Procedure

The study enrolled 50 consecutive patients who underwent capsule endoscopy in routine clinical practice. The patients fasted overnight for 12 hr after ingesting two sachets of polyethylene glycol solution (Kleen-Prep, Norgine) as per protocol in our unit. Written informed consent was obtained from all the patients. The patients were allowed to drink 2 hr after ingestion of the capsule and to eat a light snack after another 2 hr. The sensor array and recorder pack were disconnected after 8 hr, and images were downloaded to a workstation.

When reading and interpreting the recorded images, any investigator can highlight the perceived abnormal areas. This is done by creating "thumbnails," which then can be reviewed at a later date without observing the whole capsule endoscopy–recorded sequence. This allows other investigators to interpret and correlate the identified pathology with clinical findings, but in a less time-consuming manner. All videos were analyzed by an experienced consultant gastroenterologist (physician) and a staff nurse who had no prior capsule endoscopy experience. The physician, a certified gastroenterologist of 8 years with vast endoscopic experience, had viewed 50 videos before this study. The nurse was 5 years beyond qualification but had no experience in gastroenterology, endoscopy, or capsule endoscopy. Both readers were blinded to the indication for capsule endoscopy and the findings of each other.

The time taken to read each video was recorded. Possible pathology was graded as "relevant" (ulcers, erosions, angioectasia, blood), "uncertain" (erythema, red dots, edema), or "irrelevant" (lymphangiectasia, prominent vessels, lymphoid follicles). These images then were saved as "thumbnails." Lesions observed were reported in a similar fashion to the Capsule Endoscopy Structured Terminology (CEST) subsequently described and published in 2005 by Korman et al. A third gastroenterologist arbitrated these findings, but with full clinical knowledge and the follow-up outcome for all the patients (unblinded). This approach ensured that the images were appropriately graded. Statistical analysis was done using a Student's *t* test for paired samples.

Results

Both readers interpreted 50 consecutive small bowel examinations ($n = 27$ women; mean age = 48 years). The indications for capsule endoscopy included iron deficiency anemia ($n = 16$), suspected Crohn's disease ($n = 15$), overt bleeding ($n = 12$), suspected functional bowel disorders ($n = 4$), and a "miscellaneous" group ($n = 3$). Comparisons between the two readers, specifically considering identified pathology, showed no difference in the mean number of relevant or uncertain pathologies identified per case: "relevant" (3.8 [nurse] vs. 5.2 [physician]) and "uncertain" (2.4 vs. 2.2). The nurse reader was more likely to record "irrelevant" findings (4.7 vs. 2 lesions per case; $p < .01$).

There was a significant difference in the average time required to read the videos between the gastroenterologist (58 min) and the nurse (73 min; $p < .001$). The gastroenterologist did miss one small pedunculated terminal ileal polyp in a patient with anemia. Otherwise, no important pathology was missed by either reader.

Discussion

The findings of this study show that a nurse capsule endoscopy reader is as capable as an experienced physician in identifying small bowel abnormalities on a capsule endoscopy in all clinically relevant cases. This suggests that capsule endoscopy is an area in which nurses could develop as physician extenders. Over the past decade, the role of nurses has expanded rapidly, particularly in the United Kingdom, where nurses are now undertaking independent endoscopy (*A report of the working party,* 2005).

Our findings also suggest that a nurse without any prior capsule endoscopy experience can interpret capsule endoscopy images and identify pathology in all clinically relevant cases. This finding was not significantly different from that for an experienced physician ($p < .1$).

There has been no published literature to date on the reading of capsule endoscopy by a novice nurse reader. Other studies have evaluated the role of nurses in the reading of capsule endoscopy videos, but the subjects had prior gastroenterologic or endoscopic experience (Table 1) (Bossa et al., 2006; Levinthal et al., 2003; Niv & Niv, 2005). In a study using medical students as novice readers, Chen et al. (2006) advocated similar findings in support of our data. Further studies with more than one novice nurse reader and

TABLE 1

Studies Evaluating the Role of Nurses in Reading Capsule Endoscopy

Country	Author	Type of Nurse Reader	No. of Patients	Findings
Italy	Bossa et al. (2006)	Experienced endoscopy nurse	39	Agreement excellent for all selected lesions (mean kappa > 0.85)
Israel	Niv & Niv (2005)	Experienced gastroenterology nurse	50	Complete agreement between two readers in 96.9%
United States	Levinthal et al. (2003)	Experienced endoscopy nurse	20	93% sensitivity for significant lesions detected by the nurse

an evaluation of the interobserver variability between them would strengthen the findings of this study.

Other studies comparing nurses and gastroenterologists in endoscopic procedures such as flexible sigmoidoscopy have shown that nurse endoscopists can carry out this role competently and safely (Duthie et al., 1998; Goodfellow, Fretwell, & Simms, 2003; Schoenfeld et al., 1999; Shapero, Alexander, Hoover, Burgis, & Schabas, 2001). In the United Kingdom, the British Society of Gastroenterology has developed clear guidelines for the training of nurse endoscopists (*A report of the working party,* 2005) to support their role as physician extenders.

Capsule endoscopy has become an important method in the pathway for investigating small bowel disorders. Currently, most reading of capsule endoscopy videos is done by physicians at a considerable expenditure of time (due to the number of images each capsule produces). Expanding the role of nurses into areas traditionally dominated by doctors is a potentially cost-effective measure. This practice would provide a more timely report for patients and thus increase patient satisfaction. In addition, it represents an opportunity for nurses to develop an interest in a specialized area of gastroenterology.

Conclusion

Nurse capsule endoscopy readers are as capable as experienced physicians in the interpretation of capsule endoscopy. Nurses with a special interest in capsule endoscopy should be encouraged to expand their role as physician extenders, allowing the service to cater to increased demand. Further studies with more than one novice nurse reader and an evaluation of the interobserver variability between nurse and physician would strengthen the findings of this study, as would additional studies reporting patient outcomes as a result of nurse-read capsule endoscopy videos.

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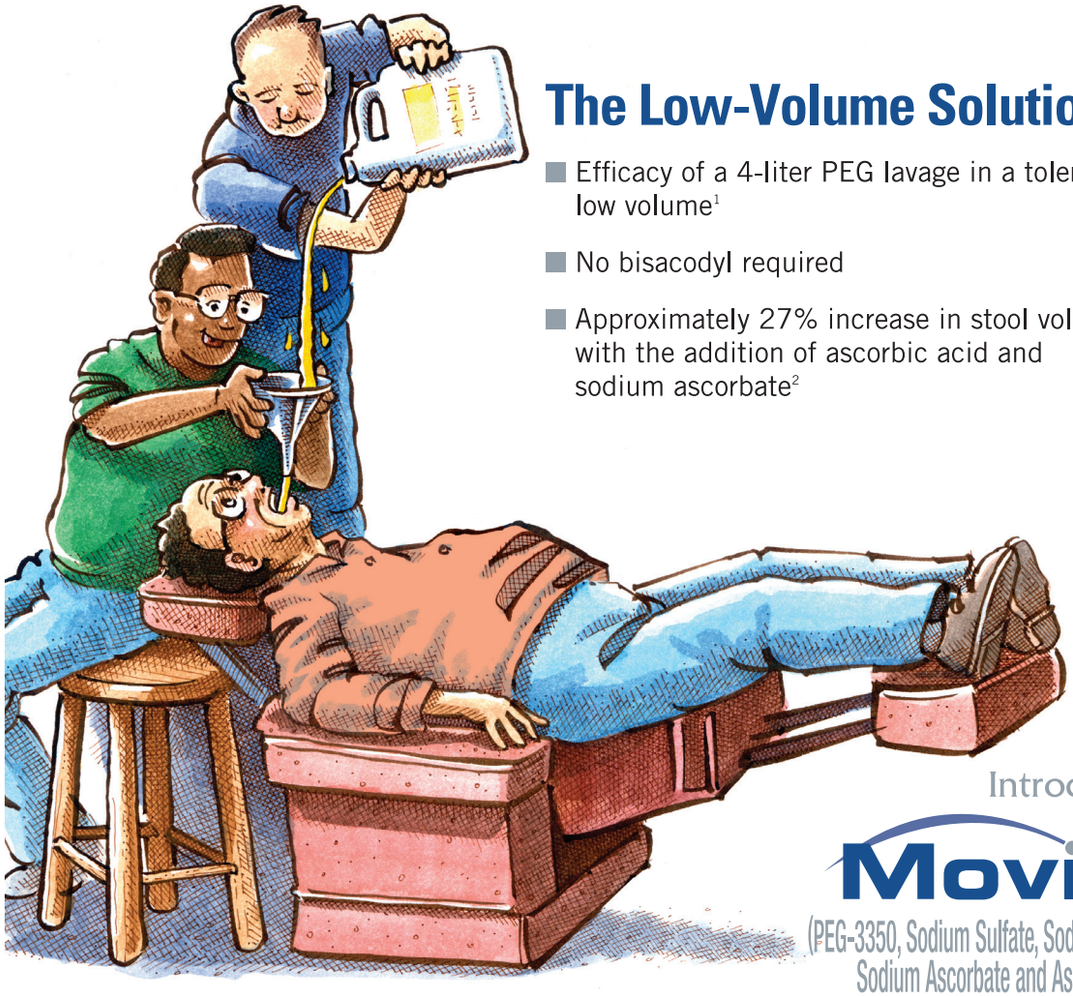

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MoviPrep contains a maximum of 2.33 mg of phenylalanine per treatment.

Please see accompanying brief summary of Prescribing Information for MoviPrep.

References: 1. MoviPrep [package insert]. Morrisville, NC: Salix Pharmaceuticals, Inc; 2006. **2.** Data on file, Salix Pharmaceuticals, Inc.

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INDICATIONS AND USAGE

MoviPrep® is indicated for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age or older.

CONTRAINDICATIONS

MoviPrep® is contraindicated in patients who have had a severe hypersensitivity reaction to any of its components.

WARNINGS

There have been rare reports of generalized tonic-clonic seizures associated with use of polyethylene glycol colon preparation products in patients with no prior history of seizures. The seizure cases were associated with electrolyte abnormalities (e.g., hyponatremia, hypokalemia). The neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities. Therefore, MoviPrep® should be used with caution in patients using concomitant medications that increase the risk of electrolyte abnormalities [such as diuretics or angiotensin converting enzyme (ACE)-inhibitors] or in patients with known or suspected hyponatremia. Consider performing baseline and post-colonoscopy laboratory tests (sodium, potassium, calcium, creatinine, and BUN) in these patients.

MoviPrep® should be used with caution in patients with severe ulcerative colitis, ileus, gastrointestinal obstruction or perforation, gastric retention, toxic colitis, or toxic megacolon.

PRECAUTIONS

General:

Patients with impaired gag reflex and patients prone to regurgitation or aspiration should be observed during the administration of MoviPrep®. If a patient experiences severe bloating, abdominal distention, or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms abate. If gastrointestinal obstruction or perforation is suspected, appropriate tests should be performed to rule out these conditions before administration of MoviPrep®.

Phenylketonurics: MoviPrep® contains phenylalanine – a maximum of 2.33 mg of phenylalanine per treatment.

No additional ingredients (e.g., flavorings) should be added to the MoviPrep® solution.

Since MoviPrep® contains sodium ascorbate and ascorbic acid, MoviPrep® should be used with caution in patients with glucose-6-phosphate dehydrogenase (G-6-PD) deficiency especially G-6-PD deficiency patients with an active infection, with a history of hemolysis, or taking concomitant medications known to precipitate hemolytic reactions.

Information for patients:

MoviPrep® produces a watery stool which cleanses the colon before colonoscopy. It is recommended that patients receiving MoviPrep® be advised to adequately hydrate before, during, and after the use of MoviPrep®. Patients may have clear soup and/or plain yogurt for dinner, finishing the meal at least one hour prior to the start of MoviPrep® treatment. No solid food should be taken from the start of MoviPrep® treatment until after the colonoscopy.

The first bowel movement may occur approximately 1 hour after the start of MoviPrep® administration. Abdominal bloating and distention may occur before the first bowel movement. If severe abdominal discomfort or distention occurs, stop drinking temporarily or drink each portion at longer intervals until these symptoms disappear.

Drug Interactions:

Oral medication administered within 1 hour of the start of administration of MoviPrep® may be flushed from the gastrointestinal tract and the medication may not be absorbed.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term studies in animals to evaluate the carcinogenic potential have not been performed with MoviPrep®. Studies to evaluate potential for impairment of fertility or mutagenic potential have not been performed with MoviPrep®.

Pregnancy: Teratogenic Effects:

Pregnancy Category C. Animal reproduction studies have not been performed with MoviPrep®. It is also not known if MoviPrep® can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. MoviPrep® should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

Because many drugs are excreted in human milk, caution should be exercised when MoviPrep® is administered to a nursing woman.

Pediatric Use:

The safety and effectiveness of MoviPrep® in pediatric patients has not been established.

Geriatric Use:

Of the 413 patients in clinical studies receiving MoviPrep®, 91 (22%) patients were aged 65 or older, while 25 (6%) patients were over 75 years of age. No overall differences in safety or effectiveness were observed between geriatric patients and younger patients, and other reported clinical experience has not identified differences in responses between geriatric patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

In the MoviPrep® trials, abdominal distention, anal discomfort, thirst, nausea, and abdominal pain were some of the most common adverse reactions to MoviPrep® administration. Since diarrhea was considered as a part of the efficacy of MoviPrep®, diarrhea was not defined as an adverse reaction in the clinical studies. Tables 3 and 4 display the most common drug-related adverse reactions of MoviPrep® and its comparator in the controlled MoviPrep® trials.

Table 3: The Most Common Drug-Related Adverse Reactions[1] (≥ 2%) in the Study of MoviPrep® vs. 4 liter Polyethylene Glycol plus Electrolytes Solution

	MoviPrep® (split dose) N=180	4 L PEG + E[2] N=179
	n (%=n/N)	n (%=n/N)
Malaise	35 (19.4)	32 (17.9)
Nausea	26 (14.4)	36 (20.1)
Abdominal pain	24 (13.3)	27 (15.1)
Vomiting	14 (7.8)	23 (12.8)
Upper abdominal pain	10 (5.6)	11 (6.1)
Dyspepsia	5 (2.8)	2 (1.1)

[1] Drug-related adverse reactions were adverse events that were possibly, probably, or definitely related to the study drug.

[2] 4 L PEG + E is 4 liter Polyethylene Glycol plus Electrolytes Solution.

Table 4: The Most Common Drug-Related Adverse Reactions[1] (≥ 5%) in the Study of MoviPrep® vs. 90 mL Oral Sodium Phosphate Solution

	MoviPrep® (evening-only) (full dose) N=169	90 mL OSPS[2] N=171
	n (%=n/N)	n (%=n/N)
Abdominal distention	101 (59.8)	70 (40.9)
Anal discomfort	87 (51.5)	89 (52.0)
Thirst	80 (47.3)	112 (65.5)
Nausea	80 (47.3)	80 (46.8)
Abdominal pain	66 (39.1)	55 (32.2)
Sleep disorder	59 (34.9)	49 (28.7)
Rigors	57 (33.7)	51 (29.8)
Hunger	51 (30.2)	121 (70.8)
Malaise	45 (26.6)	90 (52.6)
Vomiting	12 (7.1)	14 (8.2)
Dizziness	11 (6.5)	31 (18.1)
Headache	3 (1.8)	9 (5.3)
Hypokalemia	0 (0)	10 (5.8)
Hyperphosphatemia	0 (0)	10 (5.8)

[1] Drug-related adverse reactions were adverse events that were possibly, probably, or definitely related to the study drug. In addition to the recording of spontaneous adverse events, patients were also specifically asked about the occurrence of the following symptoms: shivering, anal irritations, abdominal bloating or fullness, sleep loss, nausea, vomiting, weakness, hunger sensation, abdominal cramps or pain, thirst sensation, and dizziness.

[2] OSPS is Oral Sodium Phosphate Solution.

Isolated cases of urticaria, rhinorrhea, dermatitis, and anaphylactic reaction have been reported with PEG-based products and may represent allergic reactions.

Published literature contains isolated reports of serious adverse events following the administration of PEG-based products in patients over 60 years of age. These adverse events included upper gastrointestinal bleeding from a Mallory-Weiss tear, esophageal perforation, asystole, and acute pulmonary edema after aspirating the PEG-based preparation.

OVERDOSAGE

There have been no reported cases of overdose with MoviPrep®. Purposeful or gross accidental ingestion of more than the recommended dose of MoviPrep® might be expected to lead to severe electrolyte disturbances, including hyponatremia and/or hypokalemia, as well as dehydration and hypovolemia, with signs and symptoms of these disturbances. The patient who has taken an overdose should be monitored carefully, and treated symptomatically for complications until stable.

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