Feasibility of full-spectrum endoscopy: Korea’s first full-spectrum endoscopy colonoscopic trial

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Abstract

AIM: To evaluate the full-spectrum endoscopy (FUSE) colonoscopy system as the first report on the utility thereof in a Korean population.

METHODS: We explored the efficacy of the FUSE colonoscopy in a retrospective, single-center feasibility study performed between February 1 and July 20, 2015. A total of 262 subjects (age range: 22-80) underwent the FUSE colonoscopy for colorectal cancer screening, polyp surveillance, or diagnostic evaluation. The cecal intubation success rate, the polyp detection rate (PDR), the adenoma detection rate (ADR), and the diverticulum detection rate (DDR), were calculated. The endoscopists and nurses involved considered that the full-spectrum colonoscope improved navigation and orientation within the colon.

RESULTS: All patients completed the study and the success rates of cecal and terminal ileal intubation were 100% with the FUSE colonoscope; we found 313 polyps in 142 patients and 173 adenomas in 95. The overall PDR, ADR and DDR were 54.2%, 36.3%, and 25.2%, respectively, and were higher in males, and increased with age. The endoscopists and nurses involved considered that the full-spectrum colonoscope improved navigation and orientation within the colon.
No colonoscopy was aborted because of colonoscope malfunction.

CONCLUSION: The FUSE colonoscopy yielded a higher PDR, ADR, DDR than did traditional colonoscopy, without therapeutic failure or complications, showing feasible, effective, and safe in this first Korean trial.

Key words: Colonoscopy; Colonoscopes; Feasibility studies; Colonic polyps

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Core tip: Although many efforts have been made to improve visualization and reduce blind spots in the colonic mucosa, about 10% of the colonic surface remains unobserved during traditional standard forward-view (SFV) colonoscopy. In contrast to the maximum field of view (170°) of SFV colonoscopes, the full-spectrum endoscopy (FUSE) colonoscopy platform affords the endoscopist a high-resolution, 330° "full spectrum" view of the colorectal mucosa. In this first Korean trial, the FUSE colonoscopy yielded a higher polyp, adenoma, diverticulum detection rate without therapeutic failure or complications, to be feasible, effective, and safe.

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INTRODUCTION
Although it is widely accepted that screening colonoscopy is most effective for early detection of colorectal cancer (CRC), CRC remains a leading cause of cancer-related mortality worldwide[1]. Simple colonoscopic polypectomy can prevent CRC and reduce mortality. However, several studies have highlighted the miss rates of adenomatous polyps during colonoscopy[2,3]. The overall adenoma miss rate is approximately 20% during traditional colonoscopy, ranging from 6%-48%[4,5]. As such missed adenomas can trigger interval CRC, improving adenoma detection during colonoscopy is important to enhance screening efficiency. Other than inadequate colon preparation, incomplete colonoscopy (thus not examining the cecum), short withdrawal times (less than 6 min), and patient-related factors, the principal problem is that it is relatively difficult to visualize polyps on the proximal sides of haustral folds, in the internal curves of flexures, and in the area around the ileocecal valve[6]. These anatomical sites tend to be hidden from the traditional, standard forward-view (SFV) colonoscope (with a 140°-170° angle of view) and are often only accessible if a skillful endoscopist manipulates the colonoscope, flattening folds and straightening flexures, with prolonged retroflexion of the colonoscope per se[7-9]. Such maneuvers may not always be performed, or may be performed suboptimally, because they require additional time, more skill, and are associated with (limited) risks to the patient. However, today, most endoscopists still employ colonoscopic technology that has been used for the past 40 years[10]. In recent times, efforts have been made to enhance the imaging and endoscopic technologies used during colonoscopy beyond employment of standard-definition white-light (SDWL) and the traditional SFV angle[4,11-13]. Of these, the recently developed Full-Spectrum Endoscopy® (FUSE®, EndoChoice, Alpharetta, GA, United States) colonoscope is a new platform with imagers not only on the forward tip of the colonoscope, but also on both sides of that tip[14,15]. The three imagers cover a 330° angle of view displayed on three side-by-side video monitors, affording a comprehensive picture of the entire colonic lumen, including the traditional blind spots at flexures or the proximal edges of mucosal folds. In an in vitro model of the colon, a significant increase in polyp detection was evident when the FUSE colonoscope was used; 85.7% versus 52.9% using a conventional scope (P < 0.0001). The FUSE colonoscopy was particularly valuable to detect polyps in flexures behind folds[14]. Further, in the first-ever pilot feasibility study in 50 subjects, the cecal intubation rate was 100% and the device was ranked highly by both patients and endoscopists; no adverse event was noted[15]. In a randomized, multicenter, back-to-back study on same-day FUSE and SFV colonoscopies in 185 patients, the adenoma miss rate with the FUSE colonoscopy was considerably less than that with SFV (7.5% vs 40.8%, P < 0.001)[16]. We thus sought to establish the feasibility, safety, and utility of the FUSE colonoscopy in terms of polyp detection rate (PDR), adenoma detection rate (ADR), and diverticulum detection rate (DDR), in Korea. We were the first to use the FUSE system in Korea; this is thus the first report in a Korean population.

MATERIALS AND METHODS

Study design and patients
This was a retrospective, single-center feasibility study conducted between February 1 and July 20, 2015, at Division of Gastroenterology, Department of Internal Medicine at LCT Hospital, Suwon, Korea. Gastroenterologists experienced in colonoscopy evaluated the feasibility, utility, and safety of the FUSE colonoscope in 272 patients referred for colorectal cancer screening, polyp surveillance, or diagnostic evaluation. We excluded individuals with a history of colonic resection (n = 2), inflammatory bowel disease (n = 1), polyposis syndrome or a suspected colonic stricture caused by prior abdominal surgery (n = 5),
suspected acute diverticulitis \( (n = 2) \)\(^{[15]} \). Neither of the participating endoscopists had prior clinical experience of the FUSE colonoscopy system.

**FUSE colonoscopy system**

The FUSE colonoscopy platform features a video colonoscope and a processor. The colonoscope is a standard adult device (168 cm in working length, outer diameter 12.8 mm) that is flexible, re-usable, re-processable, and appropriate for repeated clinical use (for diagnostic visualization and/or therapeutic interventions). The device has a high-resolution 330° field of view with maintenance of all standard colonoscopic capabilities. The technical features are identical to those of current SFV colonoscopes in terms of maneuverability [including full tip deflection (up or down 180° and left or right 160°)]; working channel diameter (3.8 mm); the availability of air or \( \text{CO}_2 \) insufflation options; a suction feature; and forward water jet irrigation. The FUSE colonoscopy features three imagers and light-emitting diode groups positioned at the front and on the sides of the distal tip of the colonoscope. Figure 1 shows the fields of view of the SFV and the FUSE gastrosopes and colonoscopes displayed on two or three contiguous video monitors. The left, center, and right monitors show colonic images transmitted from the left-facing, forward-facing, and right-facing lenses, respectively (Figure 2)\(^{[14-16]} \).

**Colonoscopy**

All subjects underwent standard colonoscopy preparation using either a polyethylene-glycol-based solution or a sodium picosulfate preparation; these solutions are commercially available and are approved for use in colonoscopy preparation in Korea. The choice of preparative method was at the discretion of the endoscopist. The mode of conscious sedation was chosen by the endoscopist and featured the use of either midazolam or propofol, or a combination thereof. All colonoscopy examinations were performed under white light only; no electronic imaging technology was employed. The intention was to attain and intubate the cecum. Intubation of the terminal ileum was optional, thus at the discretion of the endoscopist. The endoscopists were instructed to use their usual withdrawal techniques but to spend a minimum of 6 min withdrawing and examining the colon\(^{[13]} \). Insertion, withdrawal, and total procedure times were derived from times printed on colonoscopic images, all of which were recorded. A polyp or diverticulum located proximal to the splenic flexure was a priori defined as being in the right colon; all more distal polyps or diverticula were regarded as being located in the left colon\(^{[4,5]} \). Retroflexion of the colonoscope within the rectum was performed in each subject. Biopsies and/or polypectomies, and even endoscopic submucosal dissections (ESDs), were performed as needed. All polyps detected were completely removed and sent to the pathology department. Histological results were reported to the attending gastroenterologist and the study coordinator. Polyps were categorized as adenomatous, hyperplastic, or other. If a polyp was adenomatous on the basis of pathology, the adenoma subtype was also recorded (i.e., tubular, tubulovillous, villous, or serrated). We also histologically analyzed low- and high-grade dysplasias within adenomas\(^{[15,16]} \).

**Outcomes**

The primary endpoint was cecal intubation. Additional endpoints included the extent of success of diagnostic and therapeutic interventions, and the number of adverse events. We calculated the PDR, ADR, and DDR. We defined an adenoma 10 mm or greater in diameter as advanced if villous histology, or high-grade dysplasia, or cancer was evident\(^{[2]} \).

**Statistical analysis**

All variables and derived parameters were compared using descriptive statistics. The data summary tables include sample sizes; means; standard deviations; and the medians, minima, and maxima of the means of continuous variables. The paired \( t \)-test was used to explore the significance of differences between the two view modes in terms of the numbers and percentages of polyps, adenomas, and diverticula detected. We calculated 95%CI where appropriate, using the binomial proportion for one-way tables. All tests were two-tailed, and a \( P \) value \( \leq 0.05 \) was considered to indicate statistical significance. All data were analyzed using SAS version 9.1 for Windows (SAS Institute, Cary, NC, United States).

**RESULTS**

The success rates of cecal and terminal ileal intubation were both 100% using the FUSE colonoscopy. A total of 262 subjects completed the study and we found 313 polyps in 142, 173 adenomas in 95, and 26 cases of colitis. The gender ratio (M:F) was 50.4:49.6 and the mean age was 48.9 ± 11.8 (range 22-80) years. The overall PDR, ADR, and DDR were 54.2%, 36.3%, and 25.2%, respectively (Table 1). The right side: left side ratios (in %) of all polyps, adenomas, and diverticula detected. We calculated \( 95\% \text{CI} \) where appropriate, using the binomial proportion for one-way tables. All tests were two-tailed, and a \( P \) value \( \leq 0.05 \) was considered to indicate statistical significance. All data were analyzed using SAS version 9.1 for Windows (SAS Institute, Cary, NC, United States).
of the adenomas (13.3%) had advanced histologies (e.g., high-grade dysplasia, or a villous component, or cancer). All diagnostic and therapeutic interventions were performed with the FUSE colonoscope and successful. No acute or delayed adverse event was noted. The endoscopists and nurses considered that the FUSE colonoscope improved navigation and orientation within the colon. Insertion of endoscopic accessories through the working channel, followed by guidance to the desired location, was convenient. No colonoscopy was aborted because of equipment malfunction or failure.

**DISCUSSION**

The principal advantage of colonoscopy compared to non-endoscopic screening is that the former technique facilitates therapy, or at least allows biopsy of colorectal...
lesions prior to subsequent therapy. Therefore, colonoscopy is regarded as the gold standard when screening for CRC and the precursor lesions thereof, colorectal adenomas. Although many efforts have been made to improve visualization and reduce blind spots in the colonic mucosa, and to increase the PDR and ADR, about 10% of the colonic surface remains unobserved during SFV colonoscopy even after good bowel preparation\cite{12,17}. Even more importantly, the quality of colonoscopy is a major determinant of the risk of incident interval CRC; substantial adenoma miss rates [approximately 20% for any adenoma and 2%-6% for large adenomas (\( \geq 10 \text{ mm in diameter} \))] have been reported in many studies\cite{3,4,7,11,14}. The ADR is inversely associated with the risks of interval colorectal cancer, advanced-stage interval cancer, and fatal interval cancer. Importantly, each 1% increase in the ADR was associated with a 3% decrease in the risk of colorectal cancer\cite{3}. In addition, other than the quality of bowel preparation and the skills of the endoscopist, growing evidence suggests that it is important to reduce the adenoma miss rate of traditional SFV colonoscopy by improving current colonoscopic techniques, and removing current limitations of visualization and

Figure 2  Demonstration of full-spectrum endoscopy. The full-spectrum endoscopy (FUSE) reveals “hidden” colon polyps of several types not detected by traditional standard forward-view colonoscopy.
lesions in high-risk populations, such as those with inflammatory bowel disease or hereditary syndromes associated with development of colonic polyps\cite{23}. In a large randomized trial comparing CE-plus-HDWL with HDWL alone, only marginal increases in the ADR and the number of adenomas detected per patient were evident\cite{24}. In contrast to optical CE, several virtual CE systems enhance images using light of specific wavelengths; these include the Narrow Band Imaging system (Olympus Medical Systems), Fujinon Intelligence Chromoendoscopy (FICE), Storz Professional Image Enhancement System (SPIES, Karl Storz), and the i-Scan (Pentax). Selection of specific wavelengths creates a colored image resembling that of an image derived using CE\cite{25,26}. However, overall, studies on virtual CE have yielded conflicting results, or have found that CE was of limited utility compared to HDWL in terms of improving the ADR\cite{27,28,29}. To enhance visualization during mucosal resection, mucosal folds have been flattened by fitting a 4-mm-diameter clear cap to the end of the colonoscope. However, randomized trials of CAC versus conventional colonoscopy have yielded conflicting results in terms of improving the ADR\cite{10,11}. The Third Eye technologies, the acronyms for which are TER and TEP, are auxiliary, through-the-scope (TER) or fitted-onto-scope (TEP) techniques developed to detect polyps located on proximal folds and at anatomical flexures of the colon; they afford 135° retrograde views\cite{12}. Several studies have evaluated additional diagnostic yields afforded by the TER technology; increases in the PDR and ADR were evident\cite{13,14}. Despite such increases, the TER system has several limitations that mitigate against widespread adoption. The TER is more expensive than conventional colonoscopy (because the device is disposable), and the auxiliary scope must be removed from the working channel if any other item, such as forceps or a snare, is required for polyp removal. This may prolong withdrawal time and limit the utility of the system in daily practice\cite{15,16}. The NaviAid G-EYE balloon scope uses a standard endoscope in which a permanently integrated, inflatable reusable, reprocessable balloon is incorporated at the distal flexible tip. Mechanical flattening and straightening of hastral folds using the inflated balloon allows visualization of hidden anatomical areas, thus increasing adenoma detection. The EC is similar in concept to balloon-assisted colonoscopy. This is a 2-cm-long flexible cuff with two rows of small flexible hinged wings that help to flatten large mucosal folds during withdrawal of the instrument, permitting visualization of hidden anatomical areas, thus increasing the ADR\cite{17,18}. Although relatively few studies have been performed, increased ADRs have been reported using NaviAid G-EYE and the EC system; further evaluation is required\cite{19,20}. The Extra-Wide-Angle-View colonoscope has a projecting convex lens affording a lateral-backward (144°-232°) view, in
addition to a forward-view (140°) lens at the tip of the scope, and blends simultaneous views from either lens into a single endoscopic image. However, the ADRs of several studies have differed [37]. In contrast to the maximum field of view (170°) of SFV colonoscopes, the FUSE colonoscopy platform affords the endoscopist a high-resolution, 330° ‘full spectrum’ view of the colorectal mucosa, with maintenance of all standard colonoscopic capabilities. Following in vitro testing, a successful pilot study in humans, and an international multicenter, randomized, back-to-back comparative study, Hassan et al. reported that the FUSE colonoscopy appeared to be more cost-effective in terms of colon cancer screening and surveillance than was standard colonoscopy [12,16,38].

In our present study, the PDR, ADR, and DDR using the FUSE colonoscopy were higher than those of other studies using traditional colonoscopy ranging 18%-37.5%, 17%-25%, and 1.3%-11.5%, respectively. Very recently, Choi et al. [39] reported the PDR, ADR of 1937 Korean individuals in a multicenter, randomized, back-to-back comparative study. Hassan et al. reported the PDR, ADR, and DDR than did traditional colonoscopy, combined with the FUSE system.

In conclusion, the FUSE colonoscopy yielded a higher PDR, ADR, and DDR than did traditional colonoscopy, without therapeutic failure or complications. In this first Korean trial, the FUSE colonoscopy was feasible, effective, and safe; further larger comparative studies are required.

**Table 2** Age and gender differences in terms of polyp detection rate, adenoma detection rate, and diverticulum detection rate

| Age          | Gender (n) | PDR: % (95/262) | ADR: % (23/130) | DDR: % (21/85) |
|--------------|------------|-----------------|-----------------|---------------|
| All patients | Overall    | 54.2% (142/262) | 36.3% (95/262)  | 25.2% (66/262) |
|              | M (132)    | 68.2% (90/132)  | 47.0% (62/132)  | 26.5% (35/132) |
|              | F (130)    | 40.0% (52/130)  | 25.4% (33/130)  | 23.8% (31/130) |
| Under 40 yr  | Overall    | 45.5% (26/58)   | 17.7% (11/62)   | 14.5% (9/62)   |
|              | M (41)     | 51.2% (21/41)   | 26.8% (11/41)   | 14.6% (6/41)   |
|              | F (21)     | 4.8% (1/21)     | 0% (0/21)       | 14.3% (3/21)   |
| 41-60 yr     | Overall    | 58.1% (93/160)  | 38.1% (61/160)  | 22.5% (36/160) |
|              | M (75)     | 73.3% (55/75)   | 52.0% (39/75)   | 24.0% (18/75)  |
|              | F (85)     | 44.7% (38/85)   | 25.9% (22/85)   | 21.2% (18/85)  |
| Over 61 yr   | Overall    | 67.5% (27/40)   | 57.5% (23/40)   | 52.5% (21/40)  |
|              | M (16)     | 87.5% (14/16)   | 75.0% (12/16)   | 68.8% (11/16)  |
|              | F (24)     | 54.2% (13/24)   | 45.8% (11/24)   | 41.7% (10/24)  |

COMMENTS

**Background**

Although it is widely accepted that screening colonoscopy is most effective for early detection of colorectal cancer (CRC), CRC remains a leading cause of cancer-related mortality worldwide. Simple colonoscopic polypectomy can prevent CRC and reduce mortality. However, several studies have highlighted the miss rates of adenomatous polyps during colonoscopy. In recent times, many efforts have been made to enhance the imaging and endoscopic technologies used during colonoscopy beyond the traditional SFV angle. Of these, recently developed the Full-Spectrum Endoscopy® (FUSE, EndoChoice, Alpharetta, GA, United States) colonoscopy platform is expected to improve the detection of colorectal lesions because the field of view (330°) is much wider than that of traditional colonoscopy (170°). An international, multicenter, randomized, back-to-back comparative study showed that the adenoma detection rate was significantly higher and the miss rate lower when the FUSE...
rather than standard colonoscopy was employed.

Research frontiers
As no other Korean center currently employed the FUSE technology, the author of this study explored the efficacy of the FUSE system for the first time in Korea; this is thus the first report on a Korean population.

Innovations and breakthroughs
In this study, the polyp detection rate (PDR), adenoma detection rate (ADR), and diverticulum detection rate (DDR) using the FUSE colonoscopy (54.2%, 36.5%, and 25.2%, respectively) were higher than those of other studies using traditional colonoscopy at 18%-37.5%, 17%-25%, and 1.3%-11.5%, respectively. The authors used only the FUSE colonoscope for all diagnostic and therapeutic interventions including ESDs, and they encountered no therapeutic failure or complications.

Applications
This study shows that FUSE colonoscopy is feasible, effective, and safe; further larger comparative studies are required.

Peer-review
The author of this paper showed that the FUSE colonoscopy yielded a higher PDR, ADR, and DDR than did traditional colonoscopy, without therapeutic failure or complications. In this first Korean trial, the FUSE colonoscopy was feasible, effective, and safe; further larger comparative studies are required.

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