

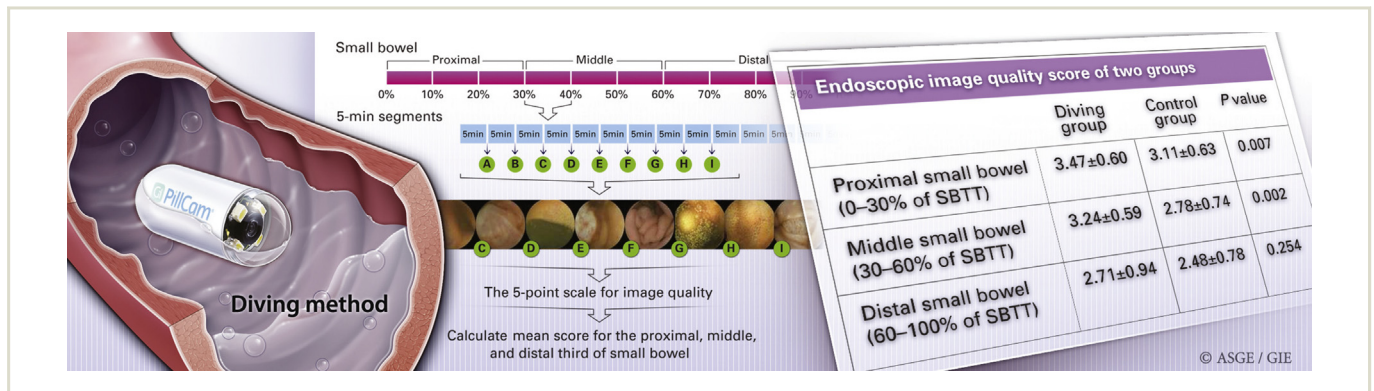


Value of the diving method for capsule endoscopy in the examination of small-intestinal disease: a prospective randomized controlled trial

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GRAPHICAL ABSTRACT



Background and Aims: Video capsule endoscopy (VCE) is limited by poor image quality and incomplete small-bowel transit. This study was designed to evaluate the diving method for VCE in the examination of small-intestinal disease.

Methods: From July 2017 to September 2017, eligible patients were randomly assigned to 2 groups, the diving group and the control group. For the diving group, 500 mL of water was administered every hour when the capsule reached the small bowel. The primary outcomes were image quality and positive findings. Secondary outcomes were the completion rate of examination, gastric transit time (GTT), small-bowel transit time (SBTT), lesion detection rate, adverse events, and patient satisfaction.

Results: One hundred forty patients were included. The scores of endoscopic images in the proximal third and middle third of the small bowel in the diving group were significantly higher than that in the control group ($3.47 \pm .60$ vs $3.11 \pm .63$ [$P = .007$] and $3.24 \pm .59$ vs $2.78 \pm .74$ [$P = .002$], respectively). The positive findings in the distal third of the small bowel were significantly different between the 2 groups ($P = .005$). The completion rate in the diving group was significantly higher (92.19% vs 76.32%, respectively; $P = .012$). The GTT, SBTT, and lesion detection rate were similar in 2 groups ($P = .282$, $.067$, and $.577$, respectively). No discomfort or adverse events were reported except for a few cases of frequent urination.

Conclusions: The diving method for VCE examination effectively improves the endoscopic view in the proximal and middle thirds of the small bowel and the positive findings in the distal small intestine and increases the completion rate. (Clinical trial registration number: ChiCTR-RDR-17011823.) (Gastrointest Endosc 2021;94:795-802.)

(footnotes appear on last page of article)

Wireless video capsule endoscopy (VCE) is now widely available for detecting lesions of the entire small bowel, particularly for obscure GI bleeding (OGIB). The diagnostic yield of VCE largely depends on the quality of the endoscopic views, which may be obscured by bile, bubbles, debris, and other particles; it may also be limited by a lower completion rate because of delayed gastric transit time (GTT) and small-bowel transit time (SBTT).¹⁻³ Although the device's manufacturer proposed a preparation regimen of 12 hours of clear liquid intake and/or fasting overnight and did not recommend the use of purgative solutions before the procedure,⁴ the American Society for Gastrointestinal Endoscopy and the European Society of Gastrointestinal Endoscopy advocated the use of 2 L of polyethylene glycol (PEG) before small-bowel VCE.⁵⁻⁷

Optimal visualization of the small bowel by VCE requires bowel preparation. Numerous methods of bowel preparation have been used for VCE, including a clear liquid-only diet, purgative agents (eg, PEG, sodium phosphate, magnesium citrate, and mannitol), simethicone, metoclopramide, linaclotide, lubiprostone, erythromycin, coffee enema, and chewing gum.^{1,8-12} Purgative bowel preparation with PEG has been shown to improve mucosal visualization and diagnostic yield more effectively than fasting or a clear liquid diet alone in many studies,¹³⁻²⁴ but other investigations have failed to show its superiority.^{1,2,25-33} Therefore, the optimal method for bowel preparation before VCE examination has not been established.

Ito et al¹⁵ reported that the ingestion of PEG solution after swallowing the capsule significantly improved VCE image quality but did not enhance the completion rate to the cecum. Previously, our study showed that instructing patients to drink clear water intermittently during, rather than before, VCE examination improved the image quality, completion rate, and lesion detection rate without significantly increasing patient discomfort.³⁴ We named this protocol the "diving method." Clean water was the medium used through which the capsule endoscope dived into the intestinal cavity. Intestinal peristalsis and continuous water flow contributed to clearer observations of the small-bowel mucosa. We aimed to corroborate our previous results by a randomized controlled trial with larger samples to evaluate whether the diving method for VCE examination results in a better image quality and a higher lesion detection rate.

METHODS

This study was a single-center, prospective, randomized, controlled trial approved by the Ethics Committee on Biomedical Research, West China Hospital of Sichuan University and registered in the Chinese Clinical Trial Registry (<http://www.chictr.org.cn>; Registration number: ChiCTR-RDR-17011823). Informed consent was obtained from all patients enrolled in this study.

Patients

Consecutive patients with indication for VCE were prospectively enrolled. The following indications for VCE were included: OGIB, iron deficiency anemia (IDA), diarrhea, malabsorption, small-bowel tumor, inflammatory bowel disease, celiac disease, and so on. Exclusion criteria were age <18 years or >80 years, pregnancy, previous gastric or intestinal surgery, GI stricture or fistula, history of intestinal obstruction, GI motility disorders, intake of medications affecting GI movement within 1 week, history of implanted medical electronic device, or refusal of informed consent.

Randomization and blinding

Eligible patients were randomly divided into 2 groups, the diving group and the control group, by consecutive assignment using a computer-generated list of random numbers. All patients fasted for 12 hours, followed by the ingestion of 10 mL of simethicone 10 minutes before swallowing the capsule. The control group received 1 L of PEG solution the evening before the examination and 1 L of PEG solution in the morning 4 hours before the examination.³⁵ In the diving group, the preparation before the examination was the same as the control group. Further, 500 mL of water was administered when the capsule reached the small bowel, as ascertained by a real-time viewer. Next, 500 mL of water was administered every hour until the capsule ran out of power or had gone into the colon. Inpatients drank water under the supervision of doctors or nurses, whereas outpatients filled out a record form and took pictures to send back to us as they drank. Although blinding of the patients and endoscopists was impossible, reviewing physicians were blinded to the group allocation status of the patients.

Video capsule endoscopy

VCE was performed using the OMOM capsule endoscopy system (Jinshan Science and Technology Group Co, Ltd, Chongqing, China). The main technical details of this capsule are listed in Table 1. A light meal was permitted 4 hours after the ingestion of the capsule. The recording apparatus was removed when the power of the battery was exhausted or the capsule was excreted.

Outcome measurement

The primary outcomes were the quality of VCE images and positive findings. All VCE images were read by 2 independent reviewers. The quality of the VCE images was assessed only in cases in which the capsule reached the colon. No standardized or validated scoring system for the quality of small-bowel cleanliness was available for application. We used a 5-point scale (0-4 points), as described by Hosono et al.¹⁷ The scoring system of the image quality was based on the percentage of unobscured area of the VCE image (Fig. 1). A score of 0 was assigned if the image showed the mucosa or lumen of the small intestine almost covered with bile, bubbles, debris, and other particles; a score of 4 was assigned if there was nearly no

TABLE 1. Main technical details of OMOM capsule endoscopy system

Items	Parameters
Size, mm, length × diameter	27.9 × 13.0
Weight, g	6
Battery life, h	6-8 or longer
Resolution	640 × 480
Frame per seconds	2
Field of view, degrees	140
Communication	Radiofrequency

obscuration. The reviewing physicians were trained to use this scoring system in our pre-experiment. Positive findings included ulcers, erosions, angioectasia, bleeding point, hyperemia/erythema, polyps, and parasites.

Secondary outcomes were the completion rate of the endoscopic examination, GTT, SBTT, the detection rate of lesions, adverse events, and patient satisfaction. The time when the capsule entered the duodenum was denoted as 0% SBTT, whereas that of the capsule entry into the colon through the ileocecal valve represented 100% SBTT. The average score of 5-minute segments was evaluated from the first duodenal image (0% SBTT) to the final image (100% SBTT). The SBTT was then divided into 10 equal parts. Cleanliness was assessed in the proximal third (0%-30% SBTT), middle third (30%-60% SBTT), and distal third (60%-100% SBTT) of the small bowel, based on the mean 5-minute segments scores (Fig. 2). The detection rate of the lesions was defined as the ratio of the number of cases with lesions to the total number of cases. The number of lesions was also counted. Adverse events included capsule retention, aspiration, capsule-induced bleeding or perforation, and pancreatitis according to the guideline from the European Society of Gastrointestinal Endoscopy.⁶ In terms of patient satisfaction, any discomfort, such as nausea, abdominal pain, and bloating, were recorded throughout the trial. Only the cases that completed the examination were included in the calculation of SBTT and the detection rate of lesions.

Sample size calculation and statistical analysis

Based on our pre-experiment results (15 cases in each of the diving group and the control group), we obtained scores in the diving group and control group that were $3.5 \pm .7$ and $3.1 \pm .7$, respectively. With a Type I error of .05 (2-sided) and a power of .80, a minimum of 100 patients (50 in each group) were required.

Continuous variables are expressed as means with standard deviation or medians with interquartile ranges. Categorical data are presented as a frequency and percentage. Continuous data with a normal distribution were compared using the Student *t* test. Categorical data were analyzed using the χ^2 test. A level of significance of *P* <

.05 was used for all inferential testing. The interobserver agreement of image quality was assessed by Kendall's Concordance Coefficient *W* test. The analyses were performed using SPSS 25.0 (IBM Corp, Armonk, NY, USA).

RESULTS

Patient data

From July 2017 to September 2017, 185 patients were screened for eligibility. Of them, 45 were excluded because of age >80 years or <18 years (*n* = 17), previous gastric or intestinal surgery (*n* = 8), history of intestinal obstruction (*n* = 4), GI motility disorders (*n* = 3), intake of medications affecting GI movement within 1 week (*n* = 8), or patients who declined to undergo VCE or to participate in the study (*n* = 5). Finally, 140 patients, including 63 women, with a median age of 61.00 years (range, 52.00-67.00) were enrolled in the study. Sixty-four patients were randomized to the diving group and 76 patients were randomized to the control group (Fig. 3).

Patient characteristics and indications for VCE are presented in Table 2. The most frequent indication for VCE was OGIB/IDA. No significant differences in age (*P* = .364), body mass index (*P* = .738), and indication for VCE (*P* = .322) were found between the 2 groups. However, a significant difference was observed in the sex ratio (*P* = .014). All capsules were ingested without being endoscopically placed. The mean amount of water consumed by patients in the diving group was 2446.10 ± 1037.50 mL.

Image quality

The visualization scores of the proximal, middle, and distal thirds of the small bowel of the 2 groups are listed in Table 3. The scores of the proximal small bowel in the diving and control groups were $3.47 \pm .60$ and $3.11 \pm .63$, respectively (*P* = .007) and in the middle-third segment were $3.24 \pm .59$ versus $2.78 \pm .74$ (*P* = .002). The image quality was significantly better in the proximal and middle small-bowel segments of the diving group. However, no significant difference was established between the 2 groups in the quality of the images of the distal small bowel. The scores in the diving and control groups were $2.71 \pm .94$ and $2.48 \pm .78$, respectively (*P* = .254). The Kendall's Concordance Coefficient *W* test showed a good level of consistency for mucosal visualization with a value of .81.

Positive findings

The total lesion numbers of the diving and control groups in the proximal, middle, and distal thirds of the small bowel were 56 versus 41 (*P* = .585), 21 versus 25 (*P* = .144), and 85 versus 64 (*P* = .582), respectively (Table 4). The positive findings of the diving and control groups in the proximal, middle, and distal thirds of the small bowel were 48 versus 31 (*P* = .565), 23 versus 20

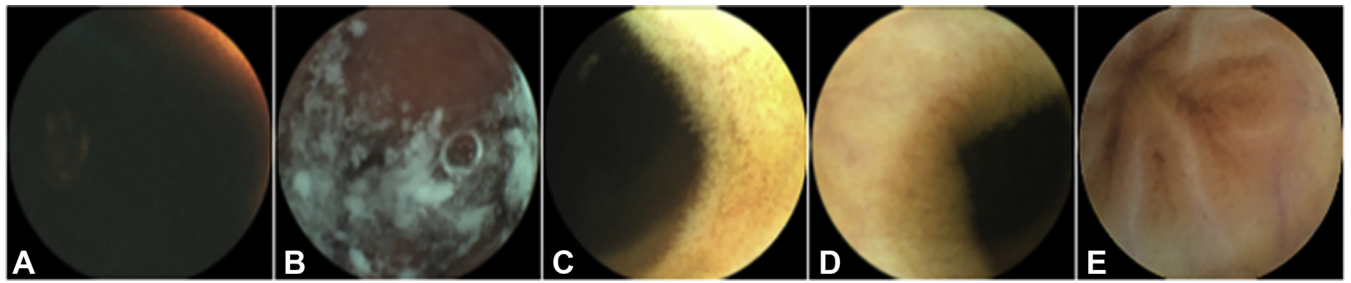


Figure 1. The 5-point scale for image quality, based on the percentage of unobscured area of video capsule endoscopy images. **A**, 0 points, 0% to 20%; **B**, 1 point, 20% to 40%; **C**, 2 points, 40% to 60%; **D**, 3 points, 60% to 80%; **E**, 4 points, 80% to 100%.

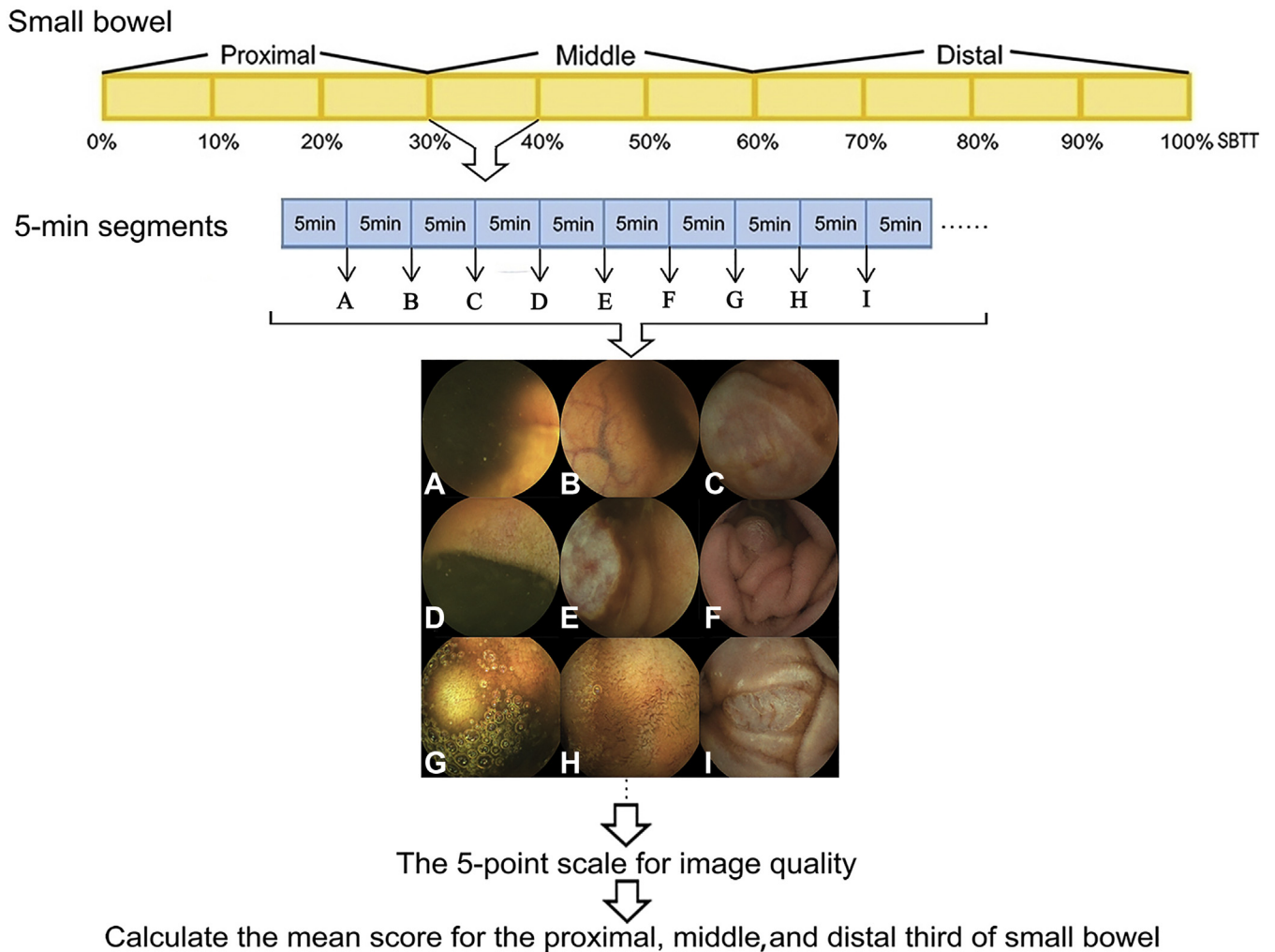


Figure 2. Process of the mean 5-minute segments scores. SBTT, Small-bowel transit time.

($P = 1.000$), and 84 versus 55 ($P = .005$), respectively. Details are shown in [Table 5](#).

Completion rate, GTT, SBTT, adverse events, and patient satisfaction

The small-bowel examination was completed in 59 patients of the diving group (92.19%) and 58 patients of

the control group (76.32%; $P = .012$). The GTT was 43.72 minutes (range, 13.75-98.50) in the diving group and 52.51 minutes (range, 30.78-98.59) in the control group ($P = .282$). The SBTT of the diving and control groups were 261.14 ± 124.72 minutes and 299.34 ± 96.40 minutes, respectively ($P = .067$). Lesions were detected in 41 of 59 patients (69.49%) in the diving group

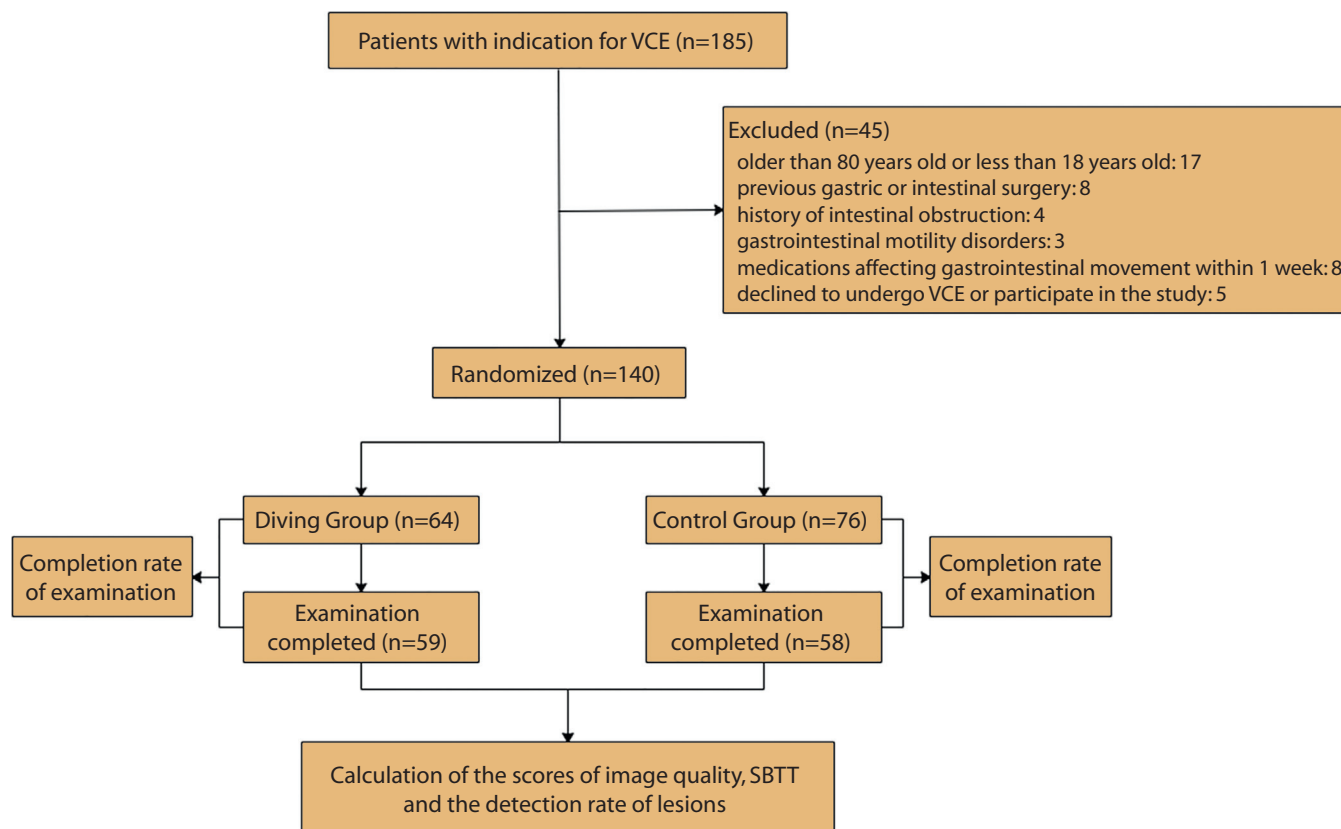


Figure 3. Flowchart of patients involved in the trial. VCE, Video capsule endoscopy; SBTT, small-bowel transit time.

TABLE 2. Patient characteristics and indication for video capsule endoscopy

	Diving group (n = 64)	Control group (n = 76)	P value
Age, y	50.95 ± 15.56	47.70 ± 16.71	.364
Sex, male/female	28/36	49/27	.014
Body mass index, kg/m ²	22.10 ± 3.32	21.95 ± 3.74	.738
Indication			.322
Obscure GI bleeding/iron deficiency anemia	30 (46.9)	44 (57.9)	
Abdominal pain	29 (45.3)	25 (32.9)	
Other*	5 (7.8)	7 (9.2)	
Amount of water consumed, mL	2446.10 ± 1037.50		

Values are mean ± standard deviation, n/N, or n (%).

*Diarrhea, malabsorption, and inflammatory bowel disease.

and in 43 of 58 patients (74.14%) in the control group ($P = .577$). No adverse events were reported during the entire trial. No discomfort was recorded except the complaints of frequent urination of 5 patients.

DISCUSSION

The diagnostic yield of VCE depends mainly on the visibility of the bowel mucosa. Different protocols for bowel preparation before VCE have been published but with controversial results. Almost all previous studies were

focused on the bowel preparation before the VCE examination. From a new perspective, the protocols of some studies were performed while VCE was working. For example, Ito et al¹⁵ instructed their patients to ingest a small amount of PEG solution (500 mL) within a 2-hour period starting 30 minutes after swallowing the capsule, which significantly improved the image quality but failed to show completion-enhancing effects. Meanwhile, some studies have actually suggested that a longer SBTT is associated with enhanced diagnostic yield.^{36,37} The underlying hypothesis is that image acquisition is improved during a

TABLE 3. Endoscopic image quality score of 2 groups

	Diving group	Control group	P value
Proximal small bowel (0%-30% of SBTT)	3.47 ± .60	3.11 ± .63	.007
Middle small bowel (30%-60% of SBTT)	3.24 ± .59	2.78 ± .74	.002
Distal small bowel (60%-100% of SBTT)	2.71 ± .94	2.48 ± .78	.254

SBTT, Small-bowel transit time.

TABLE 4. Completion rate, detection rate, number of lesions, GTT, and SBTT

	Diving group	Control group	P value
Completion rate, %	92.19 (59/64)	76.32 (58/76)	.012
Detection rate, %	69.49 (41/59)	74.14 (43/58)	.577
No. of lesions			
Proximal third	56	41	.585
Middle third	21	25	.144
Distal third	85	64	.582
GTT	43.72 (13.75-98.50)	52.51 (30.78-98.59)	.282
SBTT	261.14 ± 124.72	299.34 ± 96.40	.067

Values are % (n/N), median (interquartile range), and mean ± standard deviation unless otherwise defined.

GTT, Gastric transit time; SBTT, small-bowel transit time.

TABLE 5. Positive findings of detected lesions

Types of lesion	Proximal third		Middle third		Distal third	
	D	C	D	C	D	C
Ulcer	2	0	4	1	18	0
Erosion	3	4	0	0	2	1
Angioectasia	3	1	1	0	1	1
Bleeding point	10	1	1	4	5	3
Hyperemia/erythema	10	10	2	3	3	4
Polyp	19	13	12	15	55	46
Parasites	1	2	0	0	0	0
Total, n (%)	48 (85.7)	31 (75.6)	20 (95.2)	23 (92.0)	84 (98.8)	55 (85.9)
P value	.206		1.000		.005	

D, Diving group; C, control group.

slower study, and it may not be wise to use prokinetics that speed up the SBTT but may be wise to use an agent that shortens GTT without influencing SBTT. In our diving method, 500 mL of water was given every hour after we confirmed the capsule had reached the small bowel. The GTTs in the diving group and control group of the current study were similar ($P = .282$), as were the SBTTs ($P = .067$). Therefore, the water proved not to prolong the GGT and SBTT.

Flowing clean water fills in the intestinal tract, reduces the formation of air bubbles, flushes debris, and dilutes the digestive juice, which diminishes the contamination of the VCE lens. The image quality scores showed significantly improved mucosal visualiza-

tion in the proximal and middle small-intestinal segments. The completion rate was also significantly higher. We also noticed that the image quality of the distal small bowel did not significantly improve, and the mean SBTT of the diving group was shorter than that of the control group despite the lack of a statistically significant difference. Although we required the patients to drink 500 mL of water per hour, some loss occurred on the way because the clear water and VCE needed to run a long distance to reach the distal part of the small bowel, and the intestinal mucosa absorbed the ingested water.

The improved endoscopic view increased the diagnostic yield in our study. More lesions were detected in the

proximal and distal thirds of the small-bowel segments. The positive findings in the distal small intestine were significantly increased ($P = .005$). Interestingly, the quality of the images was not statistically different between the 2 groups in the distal small bowel ($P = .254$). Image quality was graded and scored according to the percentage of unobscured area. Some images had more than 50% of obscured area (0, 1, or 2 point), but positive lesions happened to be present in the unobscured portion of these images (Supplementary Fig. 1, available online at www.giejournal.org), perhaps causing such a result. In addition, good image quality may increase the ease of detecting lesions but does not necessarily mean that more lesions can be detected.

Differences in the detection rate did not reach statistical significance between the 2 groups and among each segment of small bowel. In real clinical practice, some lesions might be ignored because of the location of lesions and the inherent defects of capsule endoscopy. However, these kinds of factors could equally affect the results of both groups in the current randomized designed study. Moreover, detection rate was a secondary outcome, and the sample size was calculated based on the scores of image quality. Therefore, it may be difficult to clearly explain this negative result.

No discomfort and adverse events were observed in the present study except for few cases of frequent urination. It is noteworthy that many patients reported poorly tolerated purgative preparation before VCE.^{8,22,30,32} Clean water seemed to be better accepted by the patients than a purgative. Nonetheless, this study lacked a numerical scale to evaluate the degree of patient discomfort.

Because of the inherent error of using computer-generated random numbers and the relatively small sample size, the number of patients assigned in the control group was slightly higher than that of the diving group. However, the number of patients in each group reached the statistical standard of sample size. There was a significant difference in the sex ratio of recruited patients in this study. However, the completion rate and the image quality of VCE seemed to not have been affected by gender, based on our clinical experience; furthermore, no previous study has reported such a difference.

There are some limitations to this study. First, because of the potentially long time of the VCE examination, the mean volume of water needed to be drunk was more than 2 L. Drinking high quantities of water could increase the risk of patients with heart failure and renal dysfunction and cause frequent urination. Therefore, the dosage of clear water may need to be adjusted. Second, patients younger than 18 and older than 80 years were excluded. However, unexplained GI bleeding, IDA, unexplained chronic abdominal pain, and diarrhea are not uncommon in elderly and young patients. In addition, the change to an isotonic purgative agent that is not absorbed by the intestinal mucosa may improve the quality of the distal small-bowel examination and reduce the volume of the intake of solution.

In conclusion, the diving method for VCE examination effectively improves the endoscopic view in the proximal and middle third of the small bowel. It also contributed to positive findings in distal small intestine and increases the completion of VCE.

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Abbreviations: GTT, gastric transit time; IDA, iron deficiency anemia; OGB, obscure GI bleeding; PEG, polyethylene glycol; SBTT, small-bowel transit time; VCE, video capsule endoscopy.

DISCLOSURE: All authors disclosed no financial relationships. Research support for this study (Bing Hu) was provided by the 1·3·5 project for disciplines of excellence—Clinical Research Incubation Project, West China Hospital, Sichuan University (20HXFH016).

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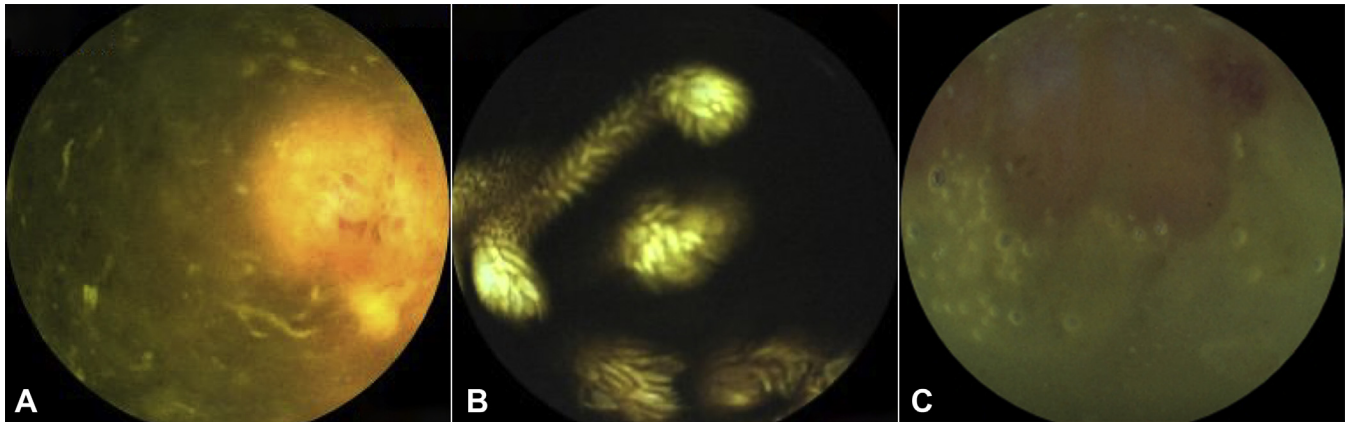
<https://doi.org/10.1016/j.gie.2021.04.018>

Received February 26, 2021. Accepted April 18, 2021.

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Supplementary Figure 1. Positive findings present in the unobscured portion of images scored 0 (A), 1 (B), and 2 (C).