A comparative study of two kinds of small bowel cleaning score system for capsule endoscopy

H.-b. Chen[1], Y. Huang[1], S.-y. Chen[2], D.-y. Deng[1], L.-h. Gao[1], J.-t. Xie[1], L.-n. Yang[1], C. Huang[1], S. He[3], X.-l. Li[4]

(1) Department of Gastroenterology, Sanming First Affiliated Hospital of Fujian Medical University, Sanming 365000, China ; (2) Department of Digestive Endoscopy, Fujian Provincial Tumor Hospital, FuZhou 350000, China ; (3) Department of Gastroenterology, the 2nd Affiliated Hospital of Chongqing Medical University, Chongqing 400010, China ; (4) Department of Cardiology, Fu wai hospital of Chinese Academy of Medical Sciences of Peking Union Medical College, Peking 100037, China.

Abstract

Aim : **The study is aim to compare two kinds of cleaning score system for capsule endoscopy, with a view of these two cleaning score system can help to evaluate small bowel cleanliness.**

Methods : **Three readers evaluated these two cleaning score system by assessing the inter-observer, intra-patient, and intra-observer agreement.**

Results : **The assessment of the reliability and concordance, inter-observer agreement and intra-patient agreement of System1 and System2 was excellent with the intraclass correlation coefficient (ICC) values of 0.873, 0.821, 0.863 and 0.772. The data regarding the assessment on intra-observer agreement and intra-patient agreement of System1 and System2 were available and the results were also excellent with ICC values of 0.887, 0.846, 0.870 and 0.809. The overall adequacy assessment of System1 and System2, there was no significant difference among the three readers of inter-observer agreement (X2 = 0.051, P = 0.822, X2 = 0.085, P = 0.081, X2 = 0.048, P = 0.827) and intra- patient agreement (X2 = 0.196, P = 0.658, X2 = 0.208, P = 0.648, X2 = 0.054, P = 0.817), neither was intra-observer agreement (X2 = 0.208, P = 0.648, X2 = 0.223, P = 0.637, X2 = 0.484, P = 0.487) and intra-patient agreement (X2 = 0.054, P = 0.817, X2 = 0.054, P = 0.817, X2 = 0519, P = 0.471).**

Conclusion : **The two system both are simple, operable, and can be used in clinical practice.** (Acta gastroenterol. belg., **2012**, 75, **342-348**).

Key words : capsule endoscopy ; small bowel cleaning score system.

Abbreviation

CE : capsule endoscopy
OAA : Overall adequacy assessment
ICC : intraclass correlation coefficient.

Introduction

Out of the whole gastrointestinal tract, the small intestine is the part that is the most difficult to examine. It is far away from both the mouth and the anus ; it is not only long but also unattached inside the peritoneum ; and it is tied to the mesentery, forming complex multiple intestinal loops. All these factors place considerable limits on the use of conventional inspection techniques. The introduction of capsule endoscopy (1) (CE), for the first time, made non-invasive, visualized examination of the small intestine possible. It has become one of the most important methods for examining the small intestine (2-5). The procedure is safe, generally well tolerated, noninvasive, convenient and enjoys widespread acceptance. Nevertheless, the procedure is not without limitations. One is that the diagnostic yield of the procedure is partly dependent upon the level of visibility of the intestinal mucosa. Many published studies have reported that poor bowel preparation may reduce the visibility by the presence of fluid, debris, air bubbles and bile/chyme staining (6-7). The other limitation is that, unlike gastrointestinal endoscopic examination, during which air and water can be fed into the gastrointestinal tract followed by suction to wash out debris□there is no possibility of suctioning or washing of the small bowel mucosa. Therefore, some parts of the lumen can not be visualized, leaving examiners unable to observe the entire small bowel mucosa thoroughly. This indicates that an optimal method of cleansing the small bowel is critical for a successful CE. However, up until now it has remained unclear how best to assess small bowel cleansing techniques. Although several grading scores for the preparation small bowel cleanliness have been suggested (7-20), none has yet been incorporated routinely into reports of CE results. There is also no prior published study of any protocol for the uniform assessment of any such cleansing score system, The reliability and efficacy of these grading systems have rarely been evaluated (18). For this reason, we designed a visually reproducible form small bowel cleanliness assessment. We evaluated and compared its clinical efficacy to our previously reported cleansing grading system (19).

Correspondence to : Hong-bin Chen, Department of Gastroenterology, Sanming First Hospital Affiliated to Fujian Medical University, Sanming 365000, China.
E-mail : smchb2008@qq.com

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Materials and methods

Patients and methods

A retrospective study was performed on 60 patients who had undergone CE at Sanming First Affiliated Hospital of Fujian Medical University between May 2010 and August 2011, Exclusion criteria included intestinal obstruction, pregnancy, suspicious impaired intestinal motility, and history of gastrointestinal surgery. Bowel preparation with 250 mL 20% mannitol and 1L 0.9% saline were taken orally at 20:00 hours on the day before the procedure and at 05:00 hours on the day of procedure. In addition, 20 mL oral simethicone (Espumisan ; Berlin-Chemie, Germany, containing 40 mg simethicone in 1mL emulsion) and 200 mL water were drank 30 minutes before capsule ingestion (19). One senior gastroenterologist with imaging-reviewing experience of more than 200 cases and two physicians with no CE reading experience who separately evaluated 60 CE cases of small bowel cleansing with two cleansing grading systems. All of them were unaware of the patient's medical history. The recorder data were analyzed and scored by Chongqing Jinshan Image Processing Software (version 4.64). The study was approved by the local ethics committee.

Scoring system

Image quality score of a single frame

System 1

The whole visualization of each selected photograph was equally divided into 8 radial sections, which was subdivided into 3 regions by two virtual concentric circles with a 1/3 and 2/3 radius of the round respectively. Thus every frame was divided into 24 subfields, and each sub-field was scored using a 9-point scale (1 means minimal impairment as shown in figure 1A, 3 means moderate impairment as in figure 1B and 5 means severe impairment as in figure 1C.). The total score of a single frame was obtained by summing the scores of 24 subfields, with a maximum possible score of 72 points. Based on the total scores, the quality of each frame was graded as excellent (scoring 0-17 points), good (scoring 18-35 points), fair (scoring 36-53 points) and poor (scoring 54-72 points).

System 2

Our previously published cleansing grading system simply described as follows. First the whole visibility of the small bowel mucosa in each frame of the video was evaluated by an image processing software, image-pro plus version 6.0 (Media Cybernetics). After the selected single frame was open in the window, the area of part of the invisible mucosa was outlined, calculated and summed, irrespective of brightness or obstructing elements defined by Brotz (7) including fluid, debris, bubbles and bile/chyme staining, followed by a total area of each frame counted in the same way. Finally the ratio of the area of unmasked mucosal divided by the total area of a single frame scored using a modified 4-grade scale based on criteria set by Dai (10) (3 points were given if ratio was 76-100%, 2, 1 and 0 point meaned 51-75%, 26-50% and 0-25%, respectively) with a maximum possible score of 3. Based on the score, the view quality of a single frame was graded as excellent (scoring 3 points), good (scoring 2 points), fair (scoring 1 point) and poor (scoring 0 point).

Assessment of small-bowel cleansing

Visibility of each frame at equal interval of 3 min of the playback was estimated. Each independent score of a single frame and the total number of observations were recorded for grading small-bowel cleansing. The sum of scores was finally divided by the total number of observations (which would be the sum of scores, in the case of an ideal preparation). Based on the total scores, small-bowel cleansing of System1 and System2 were separately graded as excellent (scoring 0-17.9 points, 3-2.26 points), good (scoring 18-35.9 points, 2.25-1.51 points), fair (scoring 36-53.9 points, 1.50-0.76 points) and poor (scoring 54-72 points, 0.75-0 points).

Overall adequacy assessment (OAA) of small-bowel cleansing

Overall adequacy assessment (OAA) of small-bowel cleansing is divided into “adequate” and “inadequate” according to the small-bowel cleansing coefficient (17). Small-bowel cleansing coefficient of System1 was equal to the sum of the single image scores which was divided by the total number of observations multiplied by 72. Small-bowel cleansing coefficient of System2 was equal to the sum of the single image scores which was divided by the total number of observations multiplied by 6. Small-bowel cleansing coefficient ranged from 0.00 (indicating the worst preparation) to 1.00 (indicating the ideal preparation).

In view an overall adequacy assessment (OAA), small-bowel cleansing for System1 and System2 was separately graded, which was considered “adequate” when the cleansing coefficient more than 0.513 (for System1) and 0.333 (for System2), and “inadequate” when the cleansing coefficient less than or equal to 0.513 (for System1) and 0.333 (for System2) (appendix).

Efficacy evaluation

60 CE cases were reviewed and frames were selected twice according to the aforementioned two grading systems, then the selected images were graded and the difference between the two grading systems was analyzed.

The reliability of the two grading system was evaluated by assessing the inter-observer, intra-patient, and intra-observer agreement (18). For the assessment on inter-observer agreement (1st week), three examiners

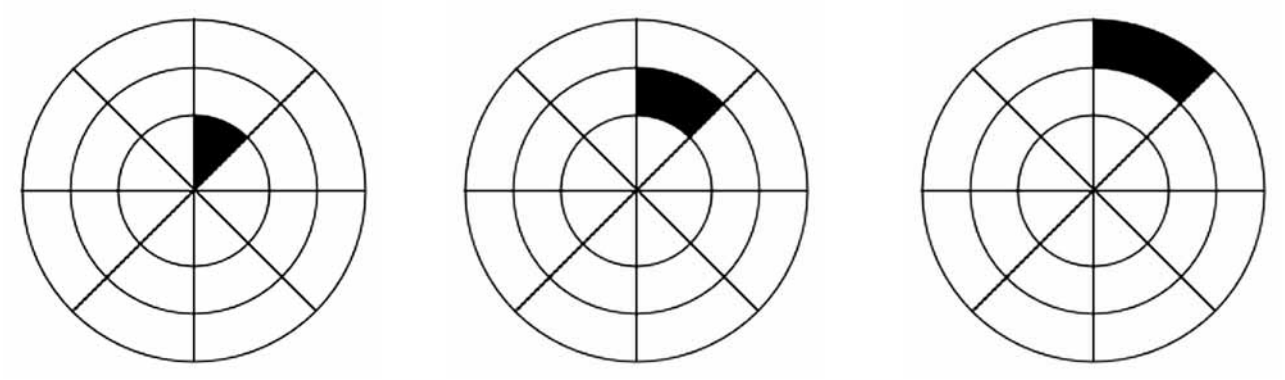

Fig. 1. — According to the effect of the bubbles, bile, opaque mucus, fecal residues, food residues and brightness et al on the quality of image, a single frame was scored, 1point was scored as shown in A, 2 points as in B and 3 points as in C.

each separately scored the same selected frames which from the first duodenal frame was captured to the moment of capsule arrived at the ileocecal valve at 3-min intervals and then compared theirs score of a single frame, small-bowel cleanliness and small-bowel cleansing coefficient between System1 and System2. For the evaluation of intra-patient agreement (1st week), each examiner reviewed the same case after choosing their own starting frame (reader1, reader2 and reader3 were respectively within the first 1 min, 2 min and 3 min, of the capsule's entrance into the duodenum), from where the ensuing frames were picked up at 3-min intervals and scored accordingly. For the analysis on intra-observer agreement (inter-observer agreement 4th week and intra-patient agreement 4th week), the same frames from the same cases were scored once again after four weeks and scores were compared with the previous results.

Statistical analysis

Concordance between the quantitative variables was assessed by intraclass correlation coefficient (ICC). An ICC value less than 0.40 was considered poor, between 0.40 and 0.75 was considered fair to good, and greater than 0.75 was considered excellent (18,21). Differences in means were assessed by analysis of variance for normally distributed vaiables and Kruskal-Wallis test for non-normally distributed variables. Differences for categorical variables were assessed by the X^2 test or Fisher exact test (when expected count was < 5) and Pearson X^2 test. Differences in constituent proportions were evaluated by the one-sample goodness-of-fit test. Differences between groups were evaluated by paired-samples t test for categorical variables. A two-tailed P-value less than 0.05 was considered statistically significant. SPSS (version 19.0) was used for statistical analysis.

Results

A total of 60 patients referred for CE owing to suspected small bowel disease were enrolled in the study. Among them, 48 were outpatients and 12 were inpatients, with 26 women (43.3%) and 34 men (56.7%).The overall average age was 53.6 ± 12.3 years (range from 18 to 79 y). The indication for CE was obscure gastrointestinal bleeding (29 of 60, 48.3%), unexplained abdominal pain (14 of 60, 23.3%), and chronic diarrhea (17 of 60, 28.3%). The average time for each reader to complete the reviewing during 1st week and 4th week was 10.7 days, with a median time of 10 .2 days (range from 7 to 19 days).

Assessment of the reliability

To assess the reliability, inter-observer agreement (1st week) of System1 and System2 was excellent with ICC values of 0.873 (95% CI : 0.813-0.917) and 0.821 (95% CI : 0.742-0.882), respectively, and the intra-patient agreement (1st week) of System1 and System2 was also excellent with ICC values of 0.863(95% CI : 0.800-0.911) and 0.772(95% CI : 0.676-0.848), respectively. The data regarding the assessment on intra-observer agreement (4th week) and intra-patient agreement (4th week) of System1 and System2 were available from three examiners and the results were also excellent with ICC values of 0.887 (95% CI : 0.833-0.927), 0.846 (95% CI : 0.775-0.899), 0.870 (95% CI : 0.810-0.916) and 0.809 (95% CI : 0.725-0.874), respectively.

Assessment the score of small-bowel cleansing

The score of inter-observer agreement and intra-patient agreement (1st week) of System1 and System2 were 28.16 ± 13.31, 27.68 ± 15.59 and 1.84 ± 0.58, 1.78 ± 0.55 in read1, 29.04 ± 12.36, 27.14 ± 14.68 and 1.82 ± 0.59, 1.80 ± 0.57 in read2, 28.02 ± 13.49, 26.82 ± 15.81 and 1.82 ± 0.53, 1.80 ± 0.54 in read3, which did not differ significantly among the readers (F = 0.107, P = 0.899 ; F = 0.048, P = 0.953 and F = 0.025, P = 0.975 ; F = 0.030, P = 0.971, respectively). Similarly, the score of inter-observer agreement and intra-patient agreement (4th week) of System1 and System2 did not differ significantly among the readers : 27.38 ± 15.31, 27.31 ± 14.77 and 1.83 ± 0.55, 1.80 ± 0.51 in read1, 28.22 ± 15.18, 26.42 ± 15.00 and 1.80 ± 0.55, 1.82 ± 0.54 in read2, 27.67 ±

Table 1. — **Overall adequacy assessment (OAA) of inter-observer agreement and intra- patient agreement (1st week) of System1 and System2**

Reader	System1		System2		*X*	*P*
	Adequate	Inadequate	Adequate	Inadequate		
Reader1*	80.0%(48/60)	20.0%(12/60)	78.3%(47/60)	21.7%(13/60)	0.051	0.822
Reader2*	81.7%(49/60)	18.3%(11/60)	83.3%(50/60)	16.7%(10/60)	0.058	0.810
Reader3*	78.3%(47/60)	21.7%(13/60)	76.7%(46/60)	23.3%(14/60)	0.048	0.827
Reader1+	80.0%(48/60)	20.0%(12/60)	76.7%(46/60)	23.3%(14/60)	0.196	0.658
Reader2+	81.7%(49/60)	18.3%(11/60)	78.3%(47/60)	21.7%(13/60)	0.208	0.648
Reader3+	81.7%(49/60)	18.3% (11/60)	80.0%(48/60)	20.0%(12/60)	0.054	0.817

* : inter-observer agreement, + : intra-patient agreement.

Table 2. — **Overall adequacy assessment (OAA) of inter-observer agreement and intra- patient agreement (4th week) of System1 and System2**

Reader	System1		System2		*X*	*P*
	Adequate	Inadequate	Adequate	Inadequate		
Reader1*	78.3%(47/60)	21.7%(13/60)	81.7%(49/60)	18.3%(11/60)	0.208	0.648
Reader2*	80.0%(48/60)	20.0%(12/60)	83.3%(50/60)	16.7%(10/60)	0.223	0.637
Reader3*	83.3%(50/60)	16.7%(10/60)	78.3%(47/60)	21.7%(13/60)	0.484	0.487
Reader1+	80.0%(48/60)	20.0%(12/60)	81.7%(49/60)	18.3%(11/60)	0.054	0.817
Reader2+	81.7%(49/60)	18.3%(11/60)	80.0%(48/60)	20.0%(12/60)	0.054	0.817
Reader3+	80.0%(48/60)	20.0%(12/60)	85.0%(51/60)	15.0%(9/60)	0.519	0.471

* : inter-observer agreement, + : intra-patient agreement.

14.06, 26.91 ± 15.20 and 1.75 ± 0.55, 1.89 ± 0.53 in read3 (F = 0.050, *P* = 0.952 ; F = 0.053, *P* = 0.948 and F = 0.311, *P* = 0.733 ; F = 0.487, *P* = 0.615, respectively).

Overall adequacy assessment (OAA)

In overall adequacy assessment (OAA) of inter-observer agreement (1st week) of System1 and System2, there was no significant difference among the three readers (X^2 = 0.051, *P* = 0.822, X^2 = 0.085, *P* = 0.081, X^2 = 0.048, *P* = 0.827, respectively, Table 1), nor was in intra-patient agreement (1st week) (X^2 = 0.196, *P* = 0.658, X^2 = 0.208, *P* = 0.648, X^2 = 0.054, *P* = 0.817, respectively, Table 1). The data regarding the assessment on OAA of intra-observer agreement (4th week) and intra-patient agreement (4th week) of System1 and System2 were available from three examiners and the results were also no significant difference among the readers (X^2 = 0.208, *P* = 0.648, X^2 = 0.223, *P* = 0.637, X^2 = 0.484, *P* = 0.487, respectively, Table 2, X^2 = 0.054, *P* = 0.817, X^2 = 0.054, *P* = 0.817, X^2 = 0519, *P* = 0.471, respectively, Table 2).

Assessment the paired scoring

The paired scoring of inter-observer agreement in the first week and the fourth week of System1 were 28.16 ± 13.31 and 27.38 ± 15.31 in read1, 29.04 ± 12.36 and 28.22 ± 15.18 in read2, 28.02 ± 13.49 and 27.67 ± 14.06 in read3, which did not differ significantly among the readers (t = 0.758, *P* = 0.452, t = 0.922 *P* = 0.415, t = 0.360, *P* = 0.680, respectively, Table 3) and the paired correlation was 0.854, 0.896 and 0.884, respectively. Similarly, The paired scoring of inter-observer agreement 1st week and 4th week of system2 did not differ significantly among the readers : 1.84 ± 0.58 and 1.83 ± 0.55 in read1, 1.82 ± 0.59 and 1.80 ± 0.55 in read2, 1.82 ± 0.53 and 1.75 ± 0.55 in read3 (t = 0.396, *P* = 0.694, t = 0.486, *P* = 0.629, t = 1.779, *P* = 0.080 respectively, Table 3) and the paired correlation was 0.932, 0.806 and 0.836, respectively (Table 3). There was also no significant difference among the three readers in paired scoring of intra-patient agreement 1st week and 4th week of System1 (127.68 ± 15.59 and 27.31 ± 14.77 in reader1, t = 0.348, *P* = 0.729, 27.14 ± 14.68 and 26.42 ± 15.00 in reader2, t = 0.776, *P* = 0.441, 26.82 ± 15.80 and 26.91 ± 15.20 in reader3, t = -0.090, *P* = 0.929, respectively, Table 3) and paired scoring of intra-patient agreement 1st week and 4th week of System2 (1.78 ± 0.55 and 1.80 ± 0.51 in reader1, t = 0.-0.415, *P* = 0.680, 1.80 ± 0.57 and1.82 ± 0.54 in reader2, t = -0.413, *P* = 0.681, 1.80 ± 0.54 and 1.89 ± 0.53 in reader3, t = -1.911, *P* = 0.061 respectively, Table 3). Paired correlation of the two systems was 0.856, 0.884, 0.880, respectively, in System1 and 0.802, 0.795, 0.794, respectively, in System2 (Table 3).

Table 3. — **Paired scoring of small-bowel cleanliness of the two grading systems of inter-observer agreement and intra-patient agreement**

Reader	System1					System2				
	1st week	4th week	t	p	correlation	1st week	4th week	t	p	correlation
Reader1*	28.16 ± 13.31	27.38 ± 15.31	0.758	0.452	0.854	1.84 ± 0.58	1.83 ± 0.55	0.396	0.694	0.932
Reader2*	29.04 ± 12.36	28.22 ± 15.18	0.922	0.360	0.896	1.82 ± 0.59	1.80 ± 0.55	0.486	0.629	0.806
Reader3*	28.02 ± 13.49	27.67 ± 14.06	0.415	0.680	0.884	1.82 ± 0.53	1.75 ± 0.55	1.779	0.080	0.836
Reader1+	27.68 ± 15.59	27.31 ± 14.77	0.348	0.729	0.856	1.78 ± 0.55	1.80 ± 0.51	-0.415	0.680	0.802
Reader2+	27.14 ± 14.68	26.42 ± 15.00	0.776	0.441	0.884	1.80 ± 0.57	1.82 ± 0.54	-0.413	0.681	0.795
Reader3+	26.82 ± 15.80	26.91 ± 15.20	-0.090	0.929	0.880	1.80 ± 0.54	1.89 ± 0.53	-1.911	0.061	0.794

* : inter-observer agreement, + : intra- patient agreement.

Discussion

CE is a well-accepted technology used to evaluate the small bowel mucosa, but sometimes physicians refuse to adopt it. This is usually because of its time-consuming viewing process and the difficulty of viewing the entire small bowel due to the presence of the intestinal contents (3,22-23). To date, the issue of the ideal scheme of small bowel preparation for CE is still questionable and the studies evaluating bowel cleansing are extremely heterogeneous. This is because of the lack of truly standard criteria (24,25) and because of the absence of a validated scale for accurate qualitatively and quantitative assessment of intestinal cleansing. This had led to controversy in the literature and made it impossible to compare diagnostic yield between different studies. Therefore, it is important to assess the cleanliness of the intestinal tract to ensure the accuracy of the small intestine capsule during endoscopic examination.

In our study, the capsule slid in the small intestine, and the images were taken at 2 frames/sec. The average amount of time that the capsule spent in the small intestine was 4-6 hours (6,10,14-17,19,25), so the total number of images taken in the small intestine is about 30,000-40,000. Some of these images were clear, and some were of poor quality, which made the assessment of the cleanliness of the small bowel difficult. For this reason, many researchers worldwide have conducted studies on the influence of bowel preparation on the quality of capsule images. The results of these studies have varied quite a lot (26-29), and most used different evaluation standards, so there has not yet been any common agreement. This is mainly because the number of capsule images required to assess the cleanliness of the small intestine is huge. Reading all these images is not only time consuming and difficult but also impractical in clinical applications. Therefore we established a quality grading standard to correctly assess the image quality of a single frame and sampled every 3 min based on these scores. In this way, we only needed to assess about 80-120 individual images when evaluating the cleanliness of each patient's small intestine. Our method was relatively quick and easy to perform in clinical settings.

To make our system of evaluating the small bowel cleanliness more objective and appropriate for practical use by all medical workers and to avoid the influence of individual errors to the grading system, we compared the evaluation results produced by one expert with rich experience in reading capsule images to those produced by two clinical doctors who had never read capsule images before. The expert graded each image strictly and assessed the overall cleanliness of the small intestine using her specialized skills. The two clinical doctors did not receive any training beforehand, so we expected their grading to be more mechanical and objective. Our results revealed that the assessments of small intestine cleanliness by the three image readers using System1 and System2 showed high intraclass correlation coefficients ; the consistency and reliability were highly correlated. With these two systems, graders offered almost the same scores both immediately after the images were taken and upon reexamining the images 1 or 4 weeks later.

When we used System1 and System2 to assess small intestine cleanliness, we found that System2 was more accurate in grading the image quality of a single frame, and System1 was more convenient for use in clinical settings. Although both of the two systems showed advantages and disadvantages, the final assessments of small intestine cleanliness with the two systems were about the same.

Conclusion

Our study showed that the two systems here used to assess the cleanliness of the small intestine exhibited highly correlated intraclass correlation coefficients with respect to inter-observer, intra-patient and intra-observer agreement. Grading System1 was found to be as reliable and accurate in evaluating the cleanliness of small intestine images as the system previously published by our group. Both System1 and System2 were found to be uncomplicated, practical, and operable, and could be used in clinical settings. These two assessment systems were highly repeatable and could be used as reference standards for qualitative and quantitative assessments of the quality of bowel preparation to objectively evaluate

the accuracy of the results of capsule endoscopic examinations. These two systems could also be used to evaluate the efficacy of different methods of bowel preparation.

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Appendix

Small-bowel scoring sheet

Investigator : _____ Date : _____

Name : _____ Number :_____

1. **Image quality score of a single frame**

System1

□ Excellent (0-17 points) □ Good (18-35 points)

□ Fair (36-53 points) □ Poor (54-72 points)

System2

□ Excellent (3 points) □ Good (2 points)

□ Fair (1 point) □ Poor (0 point)

2.Scoring of small-bowel cleanliness

System1

□ Excellent (0-17.9 points) □ Good (18-35.9 points)

□ Fair (36-53.9 points) □ Poor (54-72 points)

System2

□ Excellent (3-2.25 points) □ Good (2.25-1.51 points)

□ Fair (1.50-0.76 points) □ Poor (0.75-0 points)

3. The overall quality of the small bowel prep was :

Score of the small bowel cleansing coefficient (0.00-1.00) [ ]

System1

□ Adequate □ Not adequate

System2

□ Adequate □ Not adequate