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Dark lumen MR colonography based on fecal tagging for detection of colorectal masses: accuracy and patient acceptance

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Abstract

Background: Magnetic resonance colonography (MRC) with fecal tagging has recently been investigated in clinical studies for the detection of polyps. We assessed fecal tagging MRC in a field trial.

Methods: Forty-two patients in a private gastroenterologic practice underwent MRC with barium-based fecal tagging (150 mL of 100% barium at each of 6 main meals before MRC) and conventional colonoscopy. Diagnostic accuracy of MRC and patient acceptance were assessed and compared with the respective results of conventional colonoscopy.

Results: Eighteen percent of all MRC examinations showed a remaining high stool signal in the colon that impeded a reliable inclusion or exclusion of polyps. On a lesion-by-lesion basis, sensitivities for polyp detection were 100% for polyps larger than 2 cm ($n = 1$), 40% for polyps between 10 and 19 mm, 16.7% for polyps between 6 and 9 mm, and 9.1% for polyps smaller than 6 mm. The main reason for the low acceptance of MRC was the barium preparation, which was rated worse than the bowel cleaning procedure with conventional colonoscopy.

Conclusion: MRC with fecal tagging must be further optimized. The large amount of barium resulted in poor patient acceptance, and barium according to this protocol did not provide sufficient stool darkening. Other strategies, such as increasing the hydration of stool, must be developed.

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Key words: Magnetic resonance colonography—Barium—Fecal tagging—Patient acceptance—Diagnostic accuracy

Colorectal cancer (CRC) is an excellent candidate for screening: it has a high prevalence and incidence (~6% of the general population will develop CRC during their lifetimes) [1], lethal if detected late, and curable if diagnosed early. In view of these "ideal" characteristics, CRC has been the focus of many screening efforts for quite some time. Despite these efforts, the incidence of CRC continues to increase, with more than 130,000 newly diagnosed patients and 50,000 deaths annually in the United States alone [2].

Up to 90% of all cases of CRC are thought to originate from benign adenomas through a series of genetic alterations called the adenoma-carcinoma sequence. The biology of CRC, with its evolution from a precancerous colonic polyp to carcinoma over a considerable time span [3], has elevated colorectal polyp screening, with subsequent endoscopic polypectomy, to one of the most promising preventive measures in medicine [4].

Conventional colonoscopy (CC) constitutes the gold standard in the detection of colorectal disease [4]. CC offers the possibility to biopsy and remove focal colonic lesions within the same setting. However, poor patient acceptance due to procedural pain and discomfort and the need for bowel cleaning have limited the effect of colonic screening [5].

Other screening modalities of colorectal diseases have demonstrated insufficient diagnostic accuracy (occult fecal blood tests) [6–11]) or are used with ionizing radiation (double-contrast barium enema).

Virtual colonography, which is based on spiral computed tomographic or three-dimensional (3D) magnetic resonance (MR) datasets, has been found to be highly sensitive for detecting clinically relevant colorectal polyps larger than 8 mm [12–14]. Although computed tomographic colonography has some advantages with regard to spatial resolution, examination cost, scanner availability, lack of harmful side effects including ionizing radiation, and unsurpassed soft tissue contrast render MR imaging an attractive alternative imaging modality for colorectal screening.

The diagnostic accuracy of MR colonography (MRC) has been assessed in several studies [14, 15] by using CC as the standard of reference. Although most mass lesions smaller than 5 mm in size were missed [14], almost all lesions larger than 10 mm were correctly identified. In a study by Pappalardo et al. [13], MRC detected an even larger total number of polyps larger than 10 mm compared with CC because MRC identified additional polyps in regions of the colon not reached by CC. Most authorities believe that polyps smaller than 10 mm present a lower risk to patients than do polyps 10 mm or larger [16]. Therefore, MRC according to some investigators is considered as reliable as CC with regard to the assessment of colonic lesions at risk for malignant degeneration. Further, the costs of MRC are comparable to those of CC [15, 16]. Moreover, there are advantages of MRC over CC. MRC has the ability to simultaneously detect extraintestinal lesions that affect the parenchymal abdominal organs, representing a considerable advantage over CC [17]. Further, MRC can be combined with fecal tagging, a technique based on modulating the signal intensity of fecal material by adding contrast compounds to regular meals. Because 75% of patients who undergo bowel preparation complain of symptoms ranging from ''feeling unwell'' to an ''inability to sleep'' [18], eliminating the need for bowel cleaning might dramatically enhance patient acceptance of colonic screening with MR imaging.

For fecal tagging, a highly concentrated, barium sulfate-containing contrast agent (Micropaque, Guerbet, Sulzbach, Germany; 1 mg barium sulfate/mL) is administered orally in a volume of 200 mL, with each of four principal meals beginning 36 h before MRC [19]. This has been shown to decrease the signal intensity of stool in T1-weighted images [20]. ''Barium-based'' fecal tagging is combined with dark lumen MRC; the colon is distended with a rectally applied water enema, and paramagnetic contrast is administered intravenously to enhance the colonic wall and adherent colorectal mass lesions, which appear bright.

Fecal tagging plus MRC was reported to detect all polyps larger than 8 mm in a small population of 24 patients who had known or suspected colorectal tumors [20]. Overall sensitivity of MRC amounted to 89.3% for the detection of colorectal masses, and specificity was 100%. This pilot study reported a high patient acceptance.

We investigated the following problems: Does MRC retain its diagnostic accuracy if tested in a field study, which differs from previous studies by a lower prevalence for colonic lesions? How do the single different factors in MRC and CC influence patient acceptance? Is patient acceptance higher for MRC than for CC?

Materials and methods

Subjects

Over a 3-month period, all patients who were scheduled for CC in a private gastroenterologic practice were asked if they would be interested in this study. After a short series of questions to exclude patients who had contraindications to MR, interested patients received a two-page description that explained the study and MRC. Forty-two patients participated in the study. Patients were not paid for participation.

Patient preparation for MRC

After informed consent had been obtained for MRC and CC, a detailed information sheet was mailed with instructions and materials concerning bowel preparation necessary for MRC. Patients were asked to ingest a highly concentrated, barium sulfate-containing contrast agent (Micropaque; 1 mg barium sulfate/mL) in a volume of 150 mL with each of six principal meals beginning 36 h before MRC [19]. In addition, they were instructed to avoid intake of all fiber-rich foods and foods with a high concentration of manganese such as nuts, chocolate, and fruit. Manganese was thought to potentially increase the signal of the stool due to its paramagnetic features, and fibers would increase the amount of colonic stool. Otherwise, subjects were free to choose their diet, and there were no restrictions on fluid intake; rather, patients were asked to drink a minimum of 2 L/day to minimize constipation effects from barium.

MR imaging

MR examinations were performed on a 1.5-T MR system (Magnetom Sonata, Siemens Medical Solutions, Erlangen, Germany) with the patient in the prone position. Imaging in the prone position decreases breathing artifacts. A combination of two surface coils was used in conjunction with the built-in spine array coil for signal reception to permit coverage of the entire colon. To minimize bowel peristalsis, 40 mg of scopolamine (Buscopan, Boehringer Ingelheim, Ingelheim, Germany) was injected intravenously before the enema. No patient had contraindications for scopolamine. After placement of a rectal enema tube (E-Z-Em, Westbury, NY, USA), the colon was filled with approximately 2000 to 2500 mL of

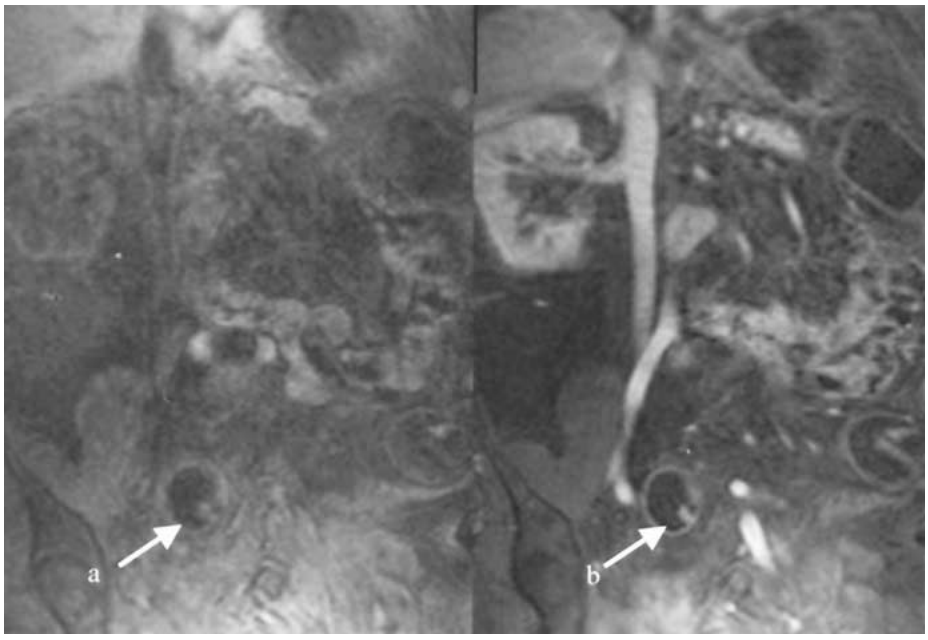

Fig. 1. Small polyp in the sigmoid colon (*arrows*) in native (**a**) and contrast-enhanced (**b**) T1-weighted 3D gradient echo sequences. The polyp is vividly enhanced.

warm tap water. Water was used because air insufflation would have required a dedicated apparatus; however, water can be administered only by use of the water pressure column. This enema was performed without fluoroscopic control because the maximum amount of water that can be administered depends only on the patient's subjective feeling; further, according to our experience, the cecum is dilated in every case after this regime. After bowel distention, a T1-weighted 3D gradient echo dataset was collected in the coronal plane. Sequence parameters included a repetition time of 1.64 ms, an echo time of 0.6 ms, a flip angle of 15 degrees, a field of view of 450×450 mm, a matrix of 512×460, and an effective slice thickness of 1.5 to 2.0 mm, depending on the patient's size. The 3D data were collected during a breath-hold of 22 s. Subsequently, paramagnetic contrast (Gd-BOPTA, Multihance, Bracco, Italy) was administered intravenously at a dosage of 0.2 mmol/kg and a flow rate of 3.5 mL/s. After delays of 75 and 120 s, respectively, second and third 3D datasets were acquired with identical parameters. These parameters were found to produce optimal results in our previous studies. After MRC, the enema water was drained back into the enema bag.

Patient preparation for video coloscopy

Patients underwent CC 7 to 21 days after fecal tagging plus MRC. Seven days before CC, patients were asked to consume a diet low in fiber and grain content. All patients underwent a standardized bowel cleaning procedure with 4 L of a polyethylene glycol solution (GoLYTELY; 1.46 g of sodium chloride, 1.68 g of sodium hydrogen carbonate, 5.68 g of sodium sulfate, 0.75 g of potassium chloride, and 59 g of polyethylene glycol 4000 dissolved in 1 L of water); 3 L was ingested the night before CC and 1 L was ingested the morning of the examination.

CC procedure

CC was performed with standard equipment (Pentax). The attending gastroenterologist was unaware of the MR findings. Only relevant side findings in organs other than the colon or terminal ileum were reported to the gastroenterologist before CC. All patients received sedatives (2.5 to 5 mg of midazolam; Dormicum, Roche, Germany) or, when necessary, a small dose of analgesics (1% disoprivan). Location and size of colorectal masses were recorded. All polyps were removed. Suspicious cancers and inflammatory lesions were biopsied. All polyps and biopsy materials were analyzed by histopathology.

Patient acceptance

After MRC and CC, all patients were asked to fill in a questionnaire regarding their impressions concerning noise, introduction of the rectal tube, needle puncture, enema, breathing commands (MRC), sedation, abdominal pain, bowel cleaning (CC), and overall examination (both techniques). Ratings were "yes" or "no" for dichotomous answers or a scale of 1 (no complaint) to 10 (unbearable).

Data analysis

For each subject, native and contrast-enhanced 3D datasets were made available on a postprocessing workstation (Virtuoso, Siemens Medical Solutions). For potentially better evaluation, two sets of subtraction

Table 1. Reasons for nonparticipation in the study

Reasons	
Fear	8
Not interested	5
No time	11
Other	20
Claustrophobia	2
No. of patients who underwent MRC	46
No. of CCs performed	42
Patients who completed study examinations	42

CC, conventional colonoscopy; MRC, magnetic resonance colonography

Table 2. Indications for colonoscopy

Screening	16
Abdominal complaints	12
Fecal blood	5
Care after colorectal cancer	4
Changes in stool composition	2
Care after colorectal adenoma	2
Rectoscopic suspicion of polyps	1

Table 3. Polyp detection

Polyp size (mm)	Total no. of polyps	True-positive finding with MRC	False-positive finding with MRC	False-negative finding with MRC
>20	1	1	0	0
10–20	5	2	0	3
6–10	12	2	0	10
<6	11	1	2	10
Total	29	6	2	23

MRC, magnetic resonance colonography

images were calculated by subtracting the native dataset from the first postcontrast image and from the second postcontrast image. The 3D MRC datasets were assessed interactively in multiplanar reformation mode by two experienced radiologists (who had more than 4 years of experience in abdominal MR imaging) who had no knowledge of coloscopic findings and reached conclusions by consensus. The signal of the colonic stool was judged according to a 3-point scale (dark, good diagnostic quality; medium dark; too bright for a conclusive diagnosis). Lesions with contrast uptake were considered "certain" (Fig. 1). In case bright lesions without identifiable contrast uptake moved across the three scans, they were regarded as stool. In equivocal cases, the potential diagnosis of a polyp was made.

Statistical analysis

MRC and CC findings were compared by a paired McNemar test (in the case of dichotomous answers) or a Wilcoxon rank test (for all other answers). A $p < 0.05$ was considered statistically significant.

All MRC findings were compared with those obtained with conventional endoscopy, and the sensitivity, specificity, positive predictive value, and negative predictive value were calculated for MRC by using CC and histopathology as gold standard references.

Results

Patients

Ninety-two patients from a private practice who had planned CC volunteered for the study. However, 46 patients did not participate, and reasons for nonparticipation are listed in Table 1. Two of these patients could not be examined with MR due to claustrophobia. Four patients did not take part in CC, which was performed after MRC in all patients. Despite an explanation by the radiologist that CC would follow MRC, these patients believed that MRC alone was sufficient. Thus, for final assessment of diagnostic accuracy, only 42 patients (18 men and 24 women, ages 23 to 75 years) were evaluated. In all 42 patients, the cecum could be reached by CC. No patient had contraindications for CC or MRC or for administration of additional medication such as scopolamine. The indications for CC are listed in Table 2.

CC findings and histology

Twenty-nine polyps were diagnosed in 17 patients. Polyps were found to be tubular adenomas ($n = 20$ lesions), tubular adenomas with epithelial dysplasia ($n = 2$ lesions), inflammatory polyps ($n = 2$ lesions), and hyperplastic polyps ($n = 3$ lesions); histology was not available in two patients (two 5-mm polyps). The sizes of these polyps are listed in Table 3.

Diagnostic accuracy of MRC

The only polyp larger than 20 mm was detected with MRC; two additional polyps were larger than 10 mm. On a lesion-by-lesion basis (Table 3), this resulted in sensitivities of 100% for polyps larger than 20 mm, 50% for polyps larger than 10 mm, and 20.7% for all polyps detected with MRC.

Table 4. Findings on a polyp-by-polyps basis

Polyp size	No. of patients with polyps on CC	No. of patients without polyps on CC	Total
Positive finding on MRC	5	2	7
Negative finding on MRC	12	23	35
Total	17	25	42

CC, conventional colonoscopy; MRC, magnetic resonance colonography

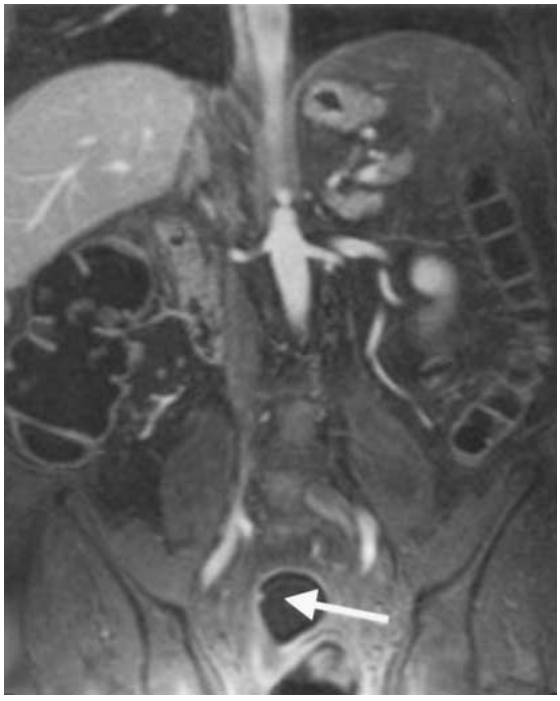

Fig. 2. Contrast-enhanced coronal MRC image. A small polyp (*arrow*) in the rectum is detected due to high uptake of contrast material. The liver can be assessed in addition to the colon.

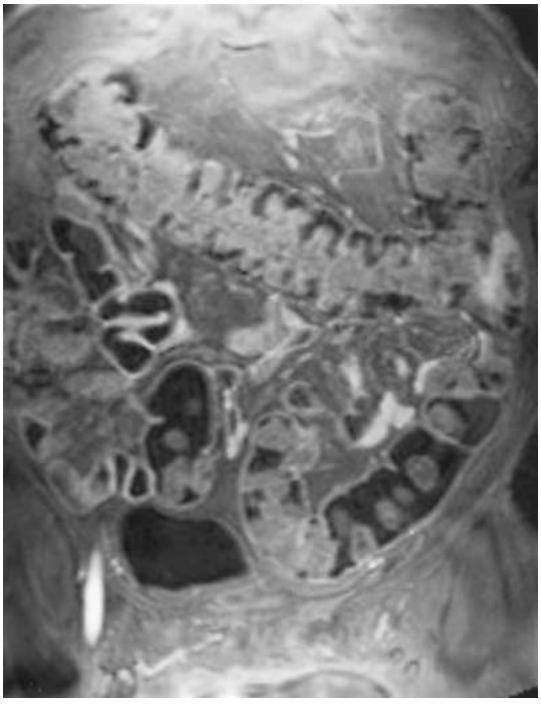

Fig. 3. Bright stool is visible in the entire colon. Even after administration of contrast material, polyps are difficult diagnose due to the bright stool signal in this patient.

On a patient-by-patient basis, the following values were calculated for polyps of any size: 29.4% sensitivity for patients with polyps, 92% specificity, 71.4% positive predictive value, and 65.7% negative predictive value (Table 4).

MR performance

Eighteen percent of all MRC examinations showed a high stool signal in the colon that impeded a reliable inclusion or exclusion of polyps (Fig. 2); 22% had a sufficiently low stool signal for assessment of the colon (Fig. 3). The contrast-to-noise-ratio between colonic wall and stool in the contrast-enhanced images varied drastically across subjects; 49% had a higher stool signal than wall signal (on enhanced images). In many patients there was a tendency for darker stool in the proximal colon, whereas the distal colon had brighter stool, which visually seemed more compact (Fig. 4).

With knowledge of the CC results, four potential lesions could be found with MRC when assessed retrospectively at a second time point; they had been previously missed mainly because of their small size and not because of adjacent bright stool.

Patient acceptance

Ingestion of barium was the most disturbing single factor with MRC; the mean grade was 3.7, and four patients (8.7%) reported high scores (8 to 10) for inconvenience of barium preparation. The second most inconvenient factor in MRC was the length of the breath-hold commands for MR data acquisition (Fig. 5). All other single factors were graded below 2.52, resulting in a discomfort factor of 3.05 for the overall MRC examination. The explanations made by the technicians were regarded as very helpful, with a score of 1.25.

Fasting before CC was regarded as slightly less problematic than the barium preparation ($p = 0.05$; Fig. 6). No difference was found between barium intake

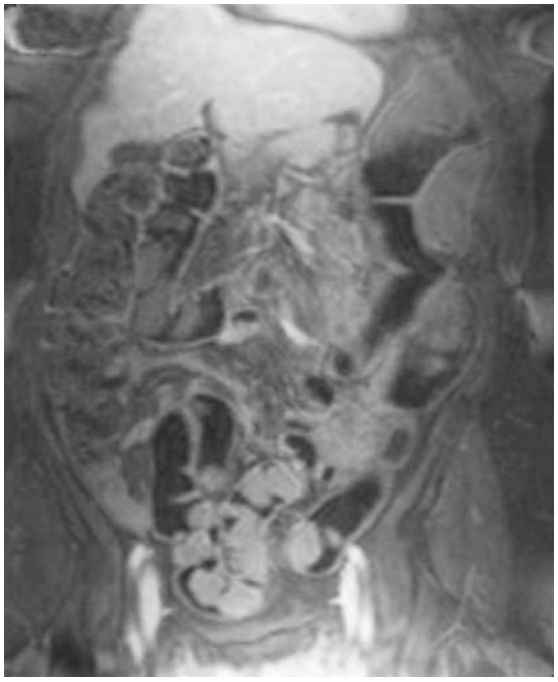

Fig. 4. Coronal image of 3D T1-weighted dataset 60 s after injection of contrast material. A relatively dark stool signal is observed in the ascending colon, whereas the stool signal in the distal colon seems more dehydrated (visual impression) and hyperintense.

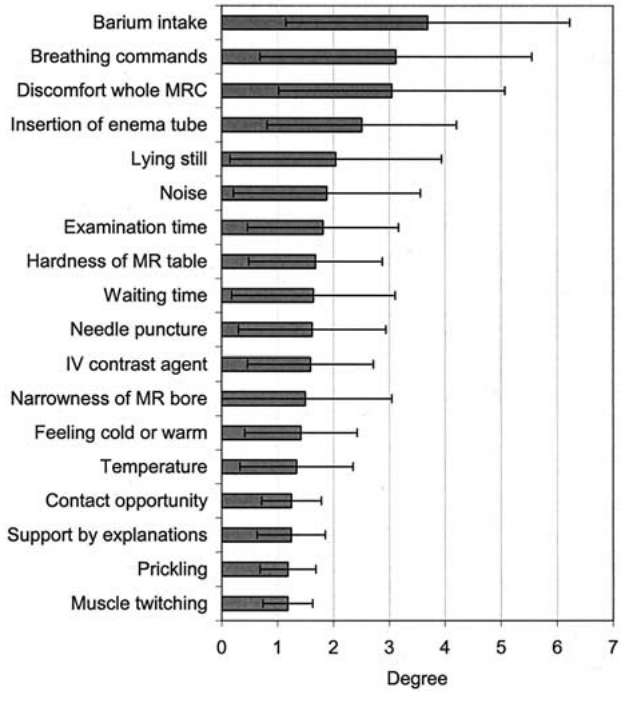

Fig. 5. Grades of discomfort during MRC show that preparation with barium is the most disturbing factor.

and bowel cleaning, with bowel cleaning being highly and significantly more problematic than fasting.

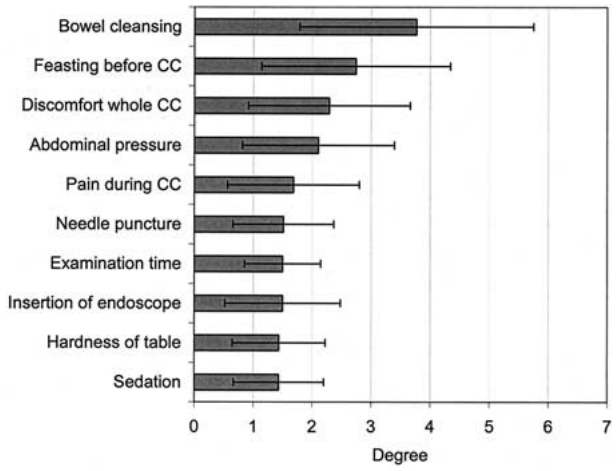

Fig. 6. Grades of discomfort during CC indicate that bowel cleaning is the single most disturbing factor.

High grades (toward worse acceptance) were reported for introducing the coloscope or the rectal enema tube, with insertion of the rectal enema tube being graded as more painful ($p < 0.007$).

No statistically significant differences existed between MRC and CC when needle puncture and all other comparable factors were assessed. No significant difference was found across grades for total examination time, comfort of the examination table, or the fear of negative results in both examinations.

No correlation was found between age and total grading of the examinations.

Figures 5 and 6 show the mean grades of all factors related to MRC and CC.

The entire MRC examination was regarded as more disturbing than the CC examination ($p < 0.01$). Thirty patients (65%) patients states they would undergo MRC as a screening method, and 37 (76%) would also undergo CC. Eighteen patients would prefer, whereas 14 would not prefer, MRC as a screening tool. Twenty-four percent declared that fear about the results would hinder them from accepting either method for screening purposes.

The main reason for the low acceptance of MRC was the barium preparation, whereas the most disturbing factor in CC was the bowel cleaning procedure.

MR side findings

In six patients MRC correctly diagnosed a diverticulosis in one patient who had signs of diverticulitis. In another patient, a colitis was correctly diagnosed (Fig. 7). In another patient, MRC diagnosed a diverticulitis without a CC correlate. Among the side findings in other abdominal organs (Table 5), no malignancy was found.

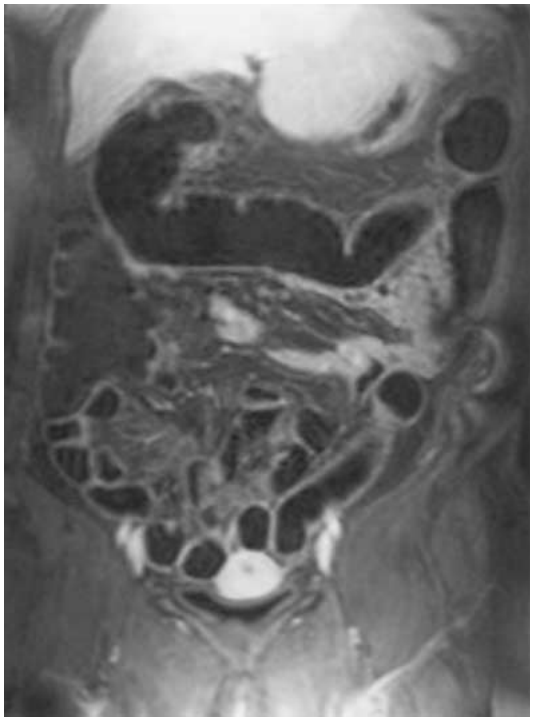

Fig. 7. Patient with pancolitis. Colonic haustrae are decreased, and the stool signal is hypointense due to diarrhea and resultant high water content.

Table 5. Findings on a patient-by-patient basis

Findings[a]	No. of patients	Further diagnostic workup necessary
Hepatic cysts	8	
Renal cysts	15	
Uterus myoma	10	5
Prostata changes	4	3
Osteochondrosis	6	1
Disk prostrusion	1	1
Pancreatic lipomastasis	1	

[a]Patients can have more than one finding.

Side effects

Orally administered barium led to unpleasant feeling of fullness in 33% of patients; further, the resulting stool was noticeable thickened and led to painful constipation. Other complaints that were not part of the questionnaire concerned blocking the toilet, which was most unpleasant for a patient on external duty. Inspection of the MR site toilet showed cement-like consistency of the stool after MRC in many patients.

Complications due to sedation, the technique, or therapeutic interventions (polypectomy) were not noted.

Discussion

Despite the initially promising studies with barium-based fecal tagging for dark lumen MRC, this field trial resulted in less positive results. The study sample remained small because we had to stop including patients due to the poor performance of barium-based fecal tagging with MRC.

Colonic cancer is an ideal disease for screening, but the low acceptance of CC decreases the screening benefit for CRC, leading to an increased incidence of disease [2]. According to some studies, the most unpleasant factor in CC is the procedure of bowel preparation [5]. New MR techniques allow for accurate detection of colonic polyps larger than 10 mm. The recent barium-based fecal tagging technique was introduced to decrease patients' complaints related to bowel cleaning, and the initial results in highly selected and small patient groups seemed to render positive results [19]. Sensitivity for detection of polyps larger than 10 mm was almost as high as with standard dark lumen techniques. However, the patient groups in these studies had a very high prevalence of colorectal lesions, a circumstance that does not mirror the standard population. Further, a standardized questionnaire that compared discomfort with both modalities was not filled out.

Before a new diagnostic method can be introduced to the public, theoretical extrapolations from a pilot study or field trials must be performed to do justice to the different compositions of either study group. Thus, this study assessed diagnostic accuracy and patient acceptance of MRC in comparison with the gold standard of CC in a field trial. The 40.5% prevalence of patients with colonic polyps in the study group matches the prevalence in a normal population of this age group. All patients were recruited consecutively from a private practice, which represents the common population more closely than a group of patients from a university gastroenterologic institute, as in previous studies.

The results of this study were unexpectedly poor for MRC. The signal of the colonic stool remained relatively high, and many lesions were missed by MRC; of lesions larger than 10 mm, only 50% were detected by MRC. This low sensitivity is not acceptable. Barium intake was rated slightly more problematic than bowel cleaning and more disturbing than all other potential sources of complaints.

Oral ingestion of barium itself was not pleasant, but even more disturbing to patients was the feeling of constipation and abdominal pain in addition "side effects" such as toilet blocking. We believe that questioning patients about acceptance should be more prominent in any clinical study, especially in screening studies, because a potentially low compliance can be deduced before larger studies are performed.

Before fecal tagging can be used for future screening purposes, the procedure of tagging has to be improved in two ways: first, more reliable tagging of the stool must be achieved for higher accuracy in polyp detection, second the oral substances used must provide a significantly higher patient acceptance.

As a recent study showed [21], meal composition does not influence the stool signal in a predictive way; thus, fecal tagging techniques can be performed without restriction in diet days before the MRC examination. The main point around which tagging revolves remains the nature and magnetic features of the substance that will mix with colonic stool. This substance has to provide a low T1 signal by itself because no substance can increase the T1 time of another substance. Thus, barium is not required. It is sufficient to achieve a homogenization of the stool by adding water or water-like substances. The problem with water, and this was the motivation for introducing the nonresorbable barium, is that most of it will be taken up by the intestinal mucosa on its way through the digestive tract. This uptake theoretically could be overcome by adding highly osmotic substances to water as an attractive alternative to barium.

Another reason for discomfort that has not be eliminated in MRC or any other imaging technique is introduction of the rectal tube. The diameter or size of the rectal tube certainly can not be decreased to any great extent because the inflated balloon has to bear the pressure of the 2000-mL enema, but the radiologist may have a certain influence on a patient's experience with the examination. A patient can be provided with thorough instruction and information before and during the examination and the tube can be gently inserted. The influence of how technicians and radiologists prepare the patient and perform the examinations is supported by our results; the quality and influence of their instructions constituted the most relieving factor of MRC.

There certainly are some caveats in interpreting these results. The patient's opinion regarding CC details might be biased by the application of sedatives; the questionnaire was filled out while the patient rested after CC. However, some of the questions were invented to test potential bias: procedures that are almost similar in CC and MRC, e.g., needle puncture, showed no difference between modalities.

Performance of MRC strongly depends on optimal darkening of the stool signal; poor patient compliance with respect to barium intake might have led to the poor results for fecal tagging in our study. However, because the quality of a test depends on the weakest link in the chain, a patient's compliance must be assessed. In addition, in some patients the MRC preparation time with ingestion of barium for only 36 h before MRC might not be sufficiently long; this was underscored by out finding that in some patients stool in the proximal colon was darker than stool in the distal parts (Fig. 4). However, this effect was also observed in unprepared patients with "native" colonic stool (our observations), so that the different stool signals might be explained by an increasing dehydration of the stool on its way through the colon.

In conclusion, the technique of fecal tagging is not ready for use in a clinical setting. This study has provided not only performance data concerning the detection of colonic lesions but also a detailed insight into patients' experience with the CC and MRC procedures and the specific potentially disturbing factors of both modalities. Until now, neither method (CC or MRC) fulfills the requirement of sufficient patient acceptance, which is necessary for a successful screening technique.

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