A prospective study comparing water only with positive oral contrast in patients undergoing abdominal CT scan

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Consecutive adults scheduled to undergo abdominal CT with oral contrast were asked to choose between 1000 ml water only or positive oral contrast (50 ml Télébrix-Gastro diluted in 950 ml water). Two abdominal radiologists independently reviewed each scan for image quality of the abdomen, the diagnostic confidence per system (gastrointestinal system/organ/peritoneum/retroperitoneum/lymph nodes) and overall diagnostic confidence to address the clinical question (not able/partially able/fully able). Radiation exposure was extracted from dose reports. Differences between both groups were evaluated by Student’s t-test, Mann-Whitney-U-test or chi-square-test. Of the 320 participants, 233 chose water only. All baseline characteristics, image quality of the abdomen and the diagnostic confidence of the organs were comparable between groups and both observers. Diagnostic confidence in the water only group was more commonly scored as less than good by observer 1. The results were as follows: the gastrointestinal system (18/233 vs 1/87; p = 0.031), peritoneum (21/233 vs 1/87; p = 0.012), retroperitoneum (11/233 vs 0/87; p = 0.040) and lymph nodes (11/233 vs 0/87; p = 0.040). These structures were scored as comparable between both groups by observer 2. The diagnostic confidence to address the clinical question could be partially addressed in 6/233 vs 0/87 patients (p = 0.259). The water only group showed a tendency towards less radiation exposure. In summary, most scan ratings were comparable between positive contrast and water only, but slightly favored positive oral contrast for one reader for some abdominal structures. Therefore, water only can replace positive oral contrast in the majority of the outpatients scheduled to undergo an abdominal CT.

Background. CT protocols vary by institution, equipment, setting and clinical question. However, the default abdominal CT protocol for outpatients regularly includes both oral contrast (either positive or negative) and an intravenous contrast administration. The use of positive oral contrast in the outpatient setting has several direct and indirect effects, such as increased costs, decreased practice efficiency and patient inconvenience/discomfort. The latter has been shown by Harieaswar et al.; patients rated oral contrast significantly worse than intravenous cannulation and injection 1. The question arose whether oral contrast can be eliminated. The justification of omitting oral contrast for emergency department patients has been questioned and extensively studied, leading to withholding oral contrast in these patients 2–5. However, it is not clear whether the advantages of withholding oral contrast in the emergency department can be extrapolated to the outpatient setting, as they have different clinical questions and patient spectrum. There are no sufficient data on withholding oral contrast in this patient population 6–9 and the available data are also equivocal.

Positive and Negative Oral Contrast. However several studies 7–10 evaluated the role of “negative oral contrast” with water only and showed that the use of water only had similar image quality in follow-up abdominopelvic CT for general oncological indications 7–9 and even better delineation 8,10 and/or diagnosis compared to “positive oral contrast”. Although limited data is available, it seems that positive oral contrast can be replaced by water only, without losing image quality and the confidence of the diagnosis.
Radiation Exposure. Another issue associated with positive oral contrast, is the radiation exposure. One study by Wang et al. showed higher radiation exposure for scans performed with positive oral contrast than those with negative oral contrast in phantoms, respectively 8.7 ± 0.1 mGy, and 8.2 ± 0.2 mGy (6.1% higher than in water only, p = 0.02). In patients these values were respectively 13.1 mGy and 11.8 mGy (11.0% higher than in water only p = 0.003)11.

However, all the aforementioned data7–11 were retrospectively obtained and it is known that retrospective studies have several limitations, such as selection bias, missing data and potential confounders. This makes the implementation of the findings of these studies in routine practice difficult.

Pilot Study. In the Netherlands many hospitals still use Télébrix Gastro as oral contrast agent for general oncological/hematological indications.

Oral contrast has a predominant role in the evaluation of the gastrointestinal mucosa or bowel distension. However, the focus for most outpatient scans is not the gastrointestinal mucosa and/or bowel distension, but on the evaluation of visceral or metastatic disease. Therefore, intravenous contrast is necessary12,13. This is the reason we previously performed a single-centre, prospective pilot study14 including 50 consecutive adult outpatients (25 in each arm) undergoing a contrast-enhanced abdominal CT scan. In the pilot study we randomised positive (50 ml Télébrix Gastro in 950 ml water) and water only as oral contrast (1000 ml water only). Two radiologists independently rated scan quality and diagnostic confidence by a validated 5-point scale system. Almost all quality and diagnostic confidence scores were comparable between both observers and between both groups. One observer scored the diagnostic confidence of the gastrointestinal system as less than good in 10 of the patients receiving water only as oral contrast. Patients’ discomfort in this pilot study was assessed by a questionnaire. The pilot study showed that oral preparation with water only was just as sufficient and safe as positive oral contrast preparation with Télébrix Gastro diluted in water. To validate the hypothesis that water only as oral contrast is non-inferior to positive oral contrast preparation in abdominal CT, we performed a larger prospective study.

Results Patient population and selection. Four hundred five (405) outpatients (age ≥18 years) were scheduled to undergo an abdominal CT scan with oral and intravenous contrast. Sixty (60) patients were excluded due to various reasons (Fig. 1). 345 patients were asked to participate, of whom 24 did not want to participate. One patient was excluded due to technical problems. Finally, 320 patients were included and 233 (72.8%) chose water only as oral contrast. The remaining 87 patients (27.2%) chose positive oral contrast.

Patients and CT characteristics. All patient baseline characteristics (Table 1) were comparable between both groups (all p-values > 0.05), except the height, which was p = 0.049. The same accounts for the CT characteristics (p > 0.05).
| Sex distribution (male: female) | 130:103 | 40:47 | 0.117 |
| Age in years* (mean ± SD) | 62.7 ± 12.7 | 62.9 ± 13.7 | 0.895 |
| Height in cm* (mean ± SD) | 174.3 ± 9.8 | 171.8 ± 9.6 | 0.049 |
| Weight in kg* (mean ± SD) | 78.0 ± 16.7 | 75.2 ± 14.9 | 0.178 |

*Due to the low number of patients scanned on the 128 and 2*192 slice scanners, these data were combined.

**Baseline patients and CT characteristics.**

### Table 1

| Region scanned | Water only as oral contrast:1000 ml water (n = 199)* | Positive oral contrast: 50 ml Télébrix Gastro diluted in 950 ml water (n = 79)* | p-values |
|----------------|---------------------------------------------------|-----------------------------------------------------------------|---------|
| Abdomen: n = 43 (18.5%) | Neck/Chest/Abdomen: n = 43 (18.5%) | Neck/Chest/Abdomen: n = 43 (18.5%) | 0.994 |
| Chest: n = 147 (63.0%) | Chest: n = 147 (63.0%) | Chest: n = 147 (63.0%) | 0.877 |
| Neck: n = 37 | Neck: n = 37 | Neck: n = 37 | 0.703 |
| Abdomen: n = 43 (18.5%) | Abdomen: n = 43 (18.5%) | Abdomen: n = 43 (18.5%) | 0.815 |

**Radiation exposure.** Although not significant, all medians (except CTDIvol in the chest/abdomen region) were higher in the positive oral contrast group scanned by 64 slice scanners (Table 2). The medians of the total DLP and CTDIvol of the different regions scanned by the 128 and 2*192 slice scanners seem comparable between the two oral contrast groups (Table 3), but this might be explained by the low number of patients.

**Image quality of the abdomen.** The agreement between the observers was 86.9% (53/61). There was no difference between the water only and positive contrast for both observer 1 and observer 2 (p-values were respectively 0.574 and 0.310) (Figs. 2 and 3).

**Diagnostic confidence per structure of abdomen.**

*Gastrointestinal system.* The agreement between the observers for the evaluation of the diagnostic confidence was 90.3% (289/320). Observer 1 scored significantly more scans as less than good in the water only group compared to the positive contrast group (18/233 vs 1/87); p = 0.031. Observer 2 scored comparable diagnostic confidence of the gastrointestinal system between water only and the positive contrast groups (p = 0.634) (Fig. 4a).

*Organs.* The agreement between the observers for the evaluation of the diagnostic confidence was 97.5% (312/320). The diagnostic confidence was comparable between the water only and positive contrast groups, as assessed by observer 1 (p = 1.000) and observer 2 (p = 0.063) respectively (Fig. 4b).

*Peritoneum.* The agreement between the observers for the evaluation of the diagnostic confidence was 90.9% (291/320). Observer 1 scored significant more scans as less than good in the water only group compared to the positive contrast group (21/233 vs 1/87); p = 0.012. Observer 2 scored comparable diagnostic confidence of the gastrointestinal system between water only and the positive contrast groups (p = 1.000) (Fig. 4c).
Retroperitoneum. The agreement between the observers for the evaluation of the diagnostic confidence was 96.3% (308/321). Observer 1 scored significantly more scans as less than good in the water only group compared to the positive contrast group (11/233 vs 1/87); $p = 0.040$. Observer 2 scored comparable diagnostic confidence of the gastrointestinal system between water only and the positive contrast groups ($p = 0.272$) (Fig. 4d).

Lymph nodes. The agreement between the observers for the evaluation of the diagnostic confidence was 96.3% (308/321). Observer 1 scored significantly more scans as less than good in the water only group compared to the positive contrast group (11/233 vs 1/87); $p = 0.040$. Observer 2 scored comparable diagnostic confidence of the gastrointestinal system between water only and the positive contrast groups ($p = 0.272$) (Fig. 4e).

Overall diagnostic confidence to address the clinical question. The agreement between the two observers for the evaluation of the overall diagnostic confidence was 96.3% (308/321; 307 fully addressing the clinical question and 1 partially addressing the clinical question). There were no scans where the clinical question could not be addressed. Observer 1 scored 8 scans as partially addressing the clinical question in patients with water only. Observer 2 scored 6 scans, 4 scans of patients with water only and 2 patients with positive oral contrast agent, as partially addressing the clinical question. In total, 13 patients, 11 with water only and 2 with positive oral contrast were rechecked by observer 3 (Table 4).

In 7 patients (5 with water only and 2 patients with positive oral contrast), the clinical question could be answered by observer 3. The remaining 6 scans were also scored as partially addressed by observer 3. A total of 6/233 vs 0/87 were scored as partially addressed ($p = 0.259$). Scans that partially addressed the clinical questions, were due to; 1) difficulties in evaluating peritoneal and/or omental depositions; 2) fistulas and liquid collections; and 3) difficulties in performing mass measurement if located close to or merged with the intestine.

Discussions

Summary. We found that outpatients undergoing abdominal CT scan preferred water only as oral contrast above the positive oral contrast. This does not influence image quality. One observer experienced slightly less confidence in the evaluation of the GI tract, peritoneum, retroperitoneum and lymph nodes; this might be explained by the lower experience of the observer.

In addition, the clinical question could be fully addressed in the majority of patients. Only 6/233 in the water only group vs 0/87 in the positive oral contrast group were scored as partially addressed. In none of the patients, could the clinical questions not be addressed. Scans that only partially addressed the clinical questions were due to the difficulties in evaluating peritoneal and/or omental depositions; fistulas and liquid collections; and mass

| Water only as oral contrast: 1000 ml water (n = 31) | Positive oral contrast: 50 ml Télébrix Gastro diluted in 950 ml water (n = 7) | p-values |
|---|---|---|
| Total DLP in milligray*centimeters (median + range) | Neck/Chest/Abdomen (n = 6) 575.6 (367.0–652.5) | Neck/Chest/Abdomen (n = 1) 533.1* |
| Chest/abdomen (n = 20) 422.3 (214.7–755.1) | Chest/abdomen (n = 5) 415.0 (242.1–566.6) | 1.000 |
| Abdomen (n = 5) 278.2 (213.2–462.7) | Abdomen (n = 1) 266.2* | 0.530 |
| CTDIvol in milligray (median + range) | Neck/Chest/Abdomen (n = 6) 7.02 (4.58–8.43) | Neck/Chest/Abdomen (n = 1) 6.13* |
| Chest/abdomen (n = 20) 6.12 (4.36–11.88) | Chest/abdomen (n = 5) 6.70 (3.66–8.10) | 0.857 |
| Abdomen (n = 5) 6.33 (4.96–8.37) | Abdomen (n = 1) 5.30* | 0.921 |

Table 3. Radiation exposure in patients per region scanned by 128 and 2*192 slice scanners. All data were non-normally distributed and therefore Mann-Whitney test was performed to compare the distribution between the two arms. *n = 1, therefore no range can be given.

Figure 2. The quality of the scans assessed by observer 1 and observer 2.
denum (p = 0.02), and slightly worse distention in the ileum (P = 0.003). In our previous study14, the mean total DLP was 719.3 ± 245.7 mGy·cm² and 686.0 ± 206.9 mGy·cm² (p = 0.62) in the Télébrix Gastro and water only respectively. The mean CTDIvol was 11.1 ± 3.7 mGy and 9.8 ± 2.6 mGy respectively (p = 0.20). In this study, although not significant, there was also a trend towards higher values in the positive oral contrast group. The findings of this study concerning the image quality, diagnostic confidence and the diagnostic reliability (clinical question) and radiation exposure were in line with the results of all the above mentioned studies7–11.

**Strengths.** To our knowledge this is the first large prospective study performed on this topic. The advice of oral contrast preparation dates back to the year 200015. We did not only evaluate the image quality and diagnostic confidence, but also the overall diagnostic confidence and the radiation exposure. Two abdominal radiologists with different levels of experience reviewed all of the scans independently.
Limitations. There were some limitations in the present study. This study is not a randomised controlled trial but a prospective case-control study. This design was selected, as both types of contrast agents were used to a different extent in the general practice and we also aimed to study the preference of patients. Although patients were free to choose between water only and Télébrix Gastro as oral contrast, we do not think this generated a high risk of bias, as baseline characteristics were comparable. We excluded patients with a primary gastro-intestinal indication. It is known that opacification of the gastrointestinal (GI) system by water only effects the diagnosis of the GI system\textsuperscript{12,13}. However, the patient population in our study consist of mainly oncological patients where the focus lies on metastases and not on the GI tract. For the specific interpretation of GI systems (for e.g. polyps or Crohn's disease), regular CT scans are not sufficient and more specific imaging is needed, such as CT enterography or

Figure 4. The diagnostic confidence of the different regions by observer 1 and observer 2.
drink this volume in 45 minutes. The patients who chose positive oral contrast (50 ml Télébrix Gastro for the use of data was obtained before the CT scan started. Patients who chose water only were instructed to drink within 60 minutes as standard protocol. No adjustments were made concerning intravenous administration of the contrast agent. The intravenous scan protocol for the SOMATOM Force contains 80 ml Iomeron. The two 64 slice systems (SOMATOM Sensation, Siemens Healthcare, Erlangen, Germany) and one dual source 192 slice system (SOMATOM Force, Siemens Healthcare, Erlangen, Germany) were used. Iomeron (300 mg I/ml, Bracco UK limited, High Wycombe, UK) was used as intravenous contrast agent. The intravenous scan protocol for the SOMATOM Force contains 80 ml Iomeron.

**Materials and Methods**
This study was conducted according to the principles of the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013) and a waiver concerning the Medical Research Involving Human Subjects Act (WMO) regulation was obtained. This study is reported according to Strobe (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

**Population.** Consecutive adult outpatients that were scheduled to undergo an abdominal CT scan with oral and intravenous contrast at the department of Radiology and Nuclear Medicine between June 2018 and September 2018 were included. The indications for abdominal CT scan with oral contrast were: follow-up oncology, chronic pancreatitis, pseudocyst, follow-up hepatopancreatobiliary (HPB) surgery and hematology. Inclusion criteria were: (1) patients scheduled to undergo an abdominal CT scan (with or without neck and chest scan) with oral and intravenous contrast; (2) outpatients and (3) age ≥18 years. Exclusion criteria were: (1) patients undergoing CT for research purposes; (2) patients who were not able to drink; and (3) patients requiring positive oral contrast for evaluation of the gastrointestinal/intraluminal tract (primary staging and response evaluation of colonic adenocarcinoma, follow-up hepatopancreatobiliary surgery and hematology) and patients with complex problems (cause unknown).

**Procedure.** Patients scheduled to undergo contrast-enhanced abdominal CT scan and fulfilling inclusion criteria received a letter 5–8 days before the scheduled CT scan. Patients were asked to choose between water only as oral contrast (1000 ml water) or positive oral contrast (50 ml Télébrix Gastro (Guerbet, Villepinte, France) diluted in 950 ml water), as both methods are general accepted methods in The Netherlands. Written informed consent for the use of data was obtained before the CT scan started. Patients who chose water only were instructed to drink this volume in 45 minutes. The patients who chose positive oral contrast (50 ml Télébrix Gastro + 950 ml water) were instructed to drink within 60 minutes as standard protocol. No adjustments were made concerning intravenous administration of the contrast agent.

**CT acquisition.** CT scans were performed according to our routine protocol, using 4 different CT systems. Two 64 slice systems (SOMATOM Sensation, Siemens Healthcare, Erlangen, Germany and Philips Brilliance, Philips Medical Systems, Best, The Netherlands), one 128 slice system (SOMATOM Definition AS+, Siemens Healthcare, Erlangen, Germany) and one dual source 192 slice system (SOMATOM Force, Siemens Healthcare, Erlangen, Germany) were used. Iomeron (300 mg I/ml, Bracco UK limited, High Wycombe, UK) was used as intravenous contrast agent. The intravenous scan protocol for the SOMATOM Force contains 80 ml Iomeron. The other three scanners (Sensation, Definition AS+, and Brilliance) used 100 ml Iomeron.

**Table 4.** Patients with partially assessed overall diagnostic confidence by either observer.

| Patient number | Water only or positive contrast | Patient Spectrum | Age in years | Sex (male or female) | Observer 1 | Observer 2 | Observer 3 |
|----------------|--------------------------------|------------------|--------------|----------------------|------------|------------|------------|
| 1              | Water only                     | Oncology         | 79.3         | Female               | Partially addressed | Fully addressed | Fully addressed |
| 2              | Water only                     | Oncology         | 77.6         | Male                 | Partially addressed | Fully addressed | Partially addressed |
| 3              | Water only                     | Oncology         | 63.7         | Male                 | Partially addressed | Fully addressed | Partially addressed |
| 4              | Water only                     | Other            | 66.5         | Male                 | Fully addressed   | Partially addressed | Partially addressed |
| 5              | Water only                     | Oncology         | 64.8         | Female               | Fully addressed   | Partially addressed | Partially addressed |
| 6              | Water only                     | Oncology         | 65.9         | Male                 | Partially addressed | Partially addressed | Partially addressed |
| 7              | Water only                     | Other            | 71.7         | Female               | Partially addressed | Fully addressed | Fully addressed |
| 8              | Water only                     | Oncology         | 65.9         | Female               | Partially addressed | Fully addressed | Fully addressed |
| 9              | Water only                     | Oncology         | 81.5         | Female               | Fully addressed   | Partially addressed | Fully addressed |
| 10             | Water only                     | Oncology         | 72.3         | Female               | Partially addressed | Fully addressed | Fully addressed |
| 11             | Water only                     | Other            | 68.9         | Male                 | Partially addressed | Fully addressed | Fully addressed |
| 12             | Positive oral contrast         | Other            | 49.7         | Female               | Fully addressed   | Partially addressed | Fully addressed |
| 13             | Positive oral contrast         | Oncology         | 78.4         | Female               | Fully addressed   | Partially addressed | Fully addressed |

8 of 13 partially addressed
6 of 13 partially addressed
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colography. Finally, later emerging contra-indications like diarrhea, nausea or vomiting were not taken into consideration in this study. The current study focuses only on subjective grading of image quality and diagnostic confidence, and does not test miss-rates for disease. Ultimately, the miss-rate of bowel and peritoneal disease is the most important end point, and will require larger numbers of scans and appropriate follow-up studies in the future.

**Conclusions**
We found that abdominal CT with water only has comparable diagnostic confidence as abdominal CT with positive oral contrast in the majority of outpatients. Therefore, water only can replace positive oral contrast in the standard CT protocol for the majority of outpatients scheduled to undergo an abdominal CT.

**Table 4.** Patients with partially assessed overall diagnostic confidence by either observer.

| Patient number | Water only or positive contrast | Patient Spectrum | Age in years | Sex (male or female) | Observer 1 | Observer 2 | Observer 3 |
|----------------|--------------------------------|------------------|--------------|----------------------|------------|------------|------------|
| 1              | Water only                     | Oncology         | 79.3         | Female               | Partially addressed | Fully addressed | Fully addressed |
| 2              | Water only                     | Oncology         | 77.6         | Male                 | Partially addressed | Fully addressed | Partially addressed |
| 3              | Water only                     | Oncology         | 63.7         | Male                 | Partially addressed | Fully addressed | Partially addressed |
| 4              | Water only                     | Other            | 66.5         | Male                 | Fully addressed   | Partially addressed | Partially addressed |
| 5              | Water only                     | Oncology         | 64.8         | Female               | Fully addressed   | Partially addressed | Partially addressed |
| 6              | Water only                     | Oncology         | 65.9         | Male                 | Partially addressed | Partially addressed | Partially addressed |
| 7              | Water only                     | Other            | 71.7         | Female               | Partially addressed | Fully addressed | Fully addressed |
| 8              | Water only                     | Oncology         | 65.9         | Female               | Partially addressed | Fully addressed | Fully addressed |
| 9              | Water only                     | Oncology         | 81.5         | Female               | Fully addressed   | Partially addressed | Fully addressed |
| 10             | Water only                     | Oncology         | 72.3         | Female               | Partially addressed | Fully addressed | Fully addressed |
| 11             | Water only                     | Other            | 68.9         | Male                 | Partially addressed | Fully addressed | Fully addressed |
| 12             | Positive oral contrast         | Other            | 49.7         | Female               | Fully addressed   | Partially addressed | Fully addressed |
| 13             | Positive oral contrast         | Oncology         | 78.4         | Female               | Fully addressed   | Partially addressed | Fully addressed |

8 of 13 partially addressed
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Sample size calculation. In the pilot study, the percentage of overall diagnostic confidence was rated as good in 98.4% and 94.4% of patients with respectively positive oral contrast and water only. Based on these findings and a non-inferiority design, we had to include at least 210 patients (water only group) with a power of 90% (90% sure) and an upper limit of one-sided 95% confidence interval to exclude a difference in favour of the standard group of more than 4%.

Data-extraction. Age, sex, height, weight, patient spectrum (oncological, haematological or other), scanned regions and CT scanner system were extracted/reported.

Radiation exposure measures such as CTDIvol (volume CT dose index) and DLP (Dosis Length Product) were extracted from radiation exposure reports of each scanner. In our institution, a dose report is electronically captured for all CT exams with CTDIvol and DLP.

Data evaluation. Two abdominal radiologists, with respectively 6 years (observer 1) and 19 years (observer 2) experience in evaluating abdominal scans, reviewed each image set independently. Images were presented in a random order and blinding of the images was not necessary as high attenuation images with positive oral contrast were being compared to images with water only as oral contrast and this could not be concealed. They rated the image quality of the abdomen, the diagnostic confidence per structure in the abdomen and finally an overall diagnostic confidence to address the clinical question.

Image quality of the abdomen. Image quality of the abdomen was assessed according to an ordinal rating scale of five response categories; (1) very poor; (2) poor; (3) less than good; (4) good and; (5) very good, adapted from Båth and Månsson.

Diagnostic confidence per structure in the abdomen. The diagnostic confidence per system was also rated according to the same 5-point scale. The following five systems were rated;(1) gastrointestinal system (stomach, duodenum, jejunum, ileum, colon and appendix); (2) organs (liver, spleen, pancreas, adrenals, gallbladder, kidneys including ureters, bladder, ovaries, uterus or prostate); (3) peritoneum; (4) retroperitoneum; and (5) lymph nodes.

Overall diagnostic confidence to address the clinical question. An overall diagnostic confidence was assessed using a 3-point scale; 1) not able; 2) partially able; and 3) fully able to address the clinical question. Any scan scored as partially able to address the clinical question by one of the two radiologists was checked independently by a third abdominal radiologist (observer 3) with experience in abdominal CT reporting of 7 years. The abdominal radiologist had to score the scans by choosing; 1) partially able; and 2) fully able to address the clinical question.

Statistical analysis. Patients and CT characteristics. Baseline data was summarized using descriptive statistics. Both groups were compared using the Student’s t-test statistic (normal distributed continuous data), Mann-Whitney U-test (non-normal distributed continuous data) or chi-squared test for categorical data. And the medians and ranges of the total DLP and CTDIvol of the different regions between the two groups were compared by using the Mann-Whitney test.

Study parameters. The results of image quality and diagnostic confidence per structure between the two groups were expressed as proportion and corresponding 95% confidence intervals. These data were categorised in three categories (1 and 2, 3, 4 and 5) and null hypothesis of no difference was evaluated by chi-squared test for trend, due to the ordinal character of the data. Agreement between observers was expressed as percentages.

The results on overall diagnostic confidence (not able, partially able or fully able to address the clinical question) were expressed as proportion of corresponding 95% confidence interval and evaluated by chi-squared test. Agreement between the observers was expressed as percentages.

Data availability

The datasets used and/or analysed in this study are available from the corresponding author on reasonable request.

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Author contributions
P.A.M.d.W., J.A.W.T., P.R.v.D., I.O.A., L.F.M.B. and S.B. were responsible for the study design and concept. P.A.M. d.W., J.A.W.T., L.F.M.B. and S.B. collected all data. P.A.M.d.W. and S.B. performed the data-analysis (statistical analysis). P.A.M.d.W., J.A.W.T., P.R.v.D., I.O.A., L.F.M.B. and S.B. did the interpretation of data. P.A.M.d.W. and S.B. performed the manuscript preparation. P.A.M.d.W., J.A.W.T., P.R.v.D., I.O.A., L.F.M.B. and S.B. performed the manuscript edition and approved the final version of the manuscript for submission.

Competing interests
The authors declare no competing interests.

Additional information
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