The feasibility of wireless capsule endoscopy in detecting small intestinal pathology in children under the age of 8 years: a multicentre European study

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The feasibility of wireless capsule endoscopy in detecting small intestinal pathology in children under the age of 8 years: a multicentre European study

A Fritscher-Ravens,1 P Scherbakov,2 P Butler,3 F Torroni,4 T Ruuska,5 H Nuutinen,6 M Thomson,7 M Tabbers,8 P Milla9

ABSTRACT
Objective: To systematically evaluate the feasibility and methodology to carry out wireless capsule endoscopy (WCE) in children <8 years to define small intestinal pathology.

Design: Prospective European multicentre study with negative prior investigation.

Patients and interventions: 83 children aged 1.5–7.9 years were recruited. Initially, all were offered “swallowing” (Group 1) for capsule introduction. If this failed endoscopic placement (Group 2) was used and the Roth net, Advance or custom-made introducers were compared.

Outcome measures: Primary endpoint: to determine pathology; secondary endpoint: comparison of capsule introduction methods.

Results: Capsule introduction: 20 (24%) children aged 4.0–7.9 years (mean, 6.9 years; 14 male) comprising Group 1 were older (p < 0.025) than 63 (76%) aged 1.5–7.9 years (mean, 5.25 years; 30 male) forming Group 2. Complications: Roth net mucosal trauma in 50%; no others occurred. The available recording apparatus was inappropriate for those <3 years. Indications: gastrointestinal bleeding: n = 30 (16 positive findings: four ulcerative jejunitis, four polyps, two angiodyplasia, two blue rubber blebs, two Meckel’s diverticula, one anastomotic ulcer, one reduplication); suspected Crohn’s disease: n = 20 (11 had Crohn’s disease); abdominal pain: n = 12 (six positive findings: three Crohn’s disease, two lymphonodular hyperplasia, one blue rubber bleb); protein loss: n = 9 (four lymphangectasia); malabsorption: n = 12 (seven positive findings: six enteropathy, one ascans). No abnormalities overall: 45%.

Conclusion: WCE is feasible and safe down to the age of 1.5 years. 20 children >4 years swallowed the capsule. The Advance introducer proved superior for endoscopic placement. The pathologies encountered showed age specificity and, unlike in adolescents, obscure gastrointestinal bleeding was the commonest indication.

Investigations in small children always require special consideration compared to adults, as paediatric patients have limited understanding of procedures, and a great fear of a foreign environment. In addition, some agents, such as x rays, are potentially damaging, and devices and instruments are often not suitable. This is particularly evident when the small bowel requires examination. As in adults, radiological tests are mostly insensitive and double balloon enteroscopy is unsuitable for the younger child.1–4

As a consequence understanding of mucosal pathology and the ability to diagnose lesions of the jejunum and upper ileum is limited. There is thus a clinical need for improved methods of examining the small bowel in the young child.

The introduction of wireless capsule endoscopy (WCE) has made available a new, powerful, noninvasive imaging modality. Since the United States Food and Drug Administration (FDA) approved the use of WCE in patients >10 years in 2001 the technique has been shown to be a safe with no pain and few complications.5–14 The knowledge obtained since its introduction has provided new insights into a variety of diseases15–32 and has altered the management of patients with small intestinal diseases previously investigated with little success by a variety of endoscopic and radiological techniques.5–15

Several case reports, some studies and reviews of WCE in older children and adolescents have now been published, in whom it has been shown to be a safe and effective means of detecting small intestinal pathology. They are also able to swallow the capsule and carry the necessary equipment. Systematic studies of children <3 years are not available but anecdotal evidence in case reports and papers reporting 19 children show WCE to be feasible in this age group.22–26

There is, however, a need for robust and systematically obtained data of WCE in young children, as to date the indications are unclear, the most suitable method of introduction into the small bowel, if the capsule cannot be swallowed, not analysed and possible complications unknown. In this paper we describe a European multicentre study of children under the age of 8 years, systematically enrolled for WCE of the small bowel when routine endoscopy and radiological tests failed to define pathology which explained their symptoms. A secondary goal was to compare different means of introducing the capsule into the bowel in those children who could not swallow it.

PATIENTS AND METHODS
Patients
Eighty-three children aged 1.5–7.9 years (57 male, 45 female) were recruited by nine paediatric centres throughout Europe. Their age distribution is shown in table 1.

Children with occult gastrointestinal bleeding, suspected Crohn’s disease, abdominal pain of unknown aetiology, protein-losing enteropathy and malabsorptive disorders were enrolled into...
and fasted for 12 h overnight prior to the study. Further on their cots.

The signal was stored on a portable recorder, which was carried on a belt around the patient’s waist, in a custom-made rucksack as shown in fig 1 or, in the smallest children, placed beside them in a custom-made acorn-like device. The choice of the insertion device was left to the endoscopist, but any complications directly attributable to the endoscopic introduction and the ease or difficulty in carrying it out were noted and the methods and devices were compared.

Two hours after introduction of the capsule the patients were allowed to drink clear fluids and after 4 h to have a light meal. Patients or their parents were asked to note when the capsule was passed in the child’s stools and to recover the capsule. Any complications encountered were noted.

The video observers were asked to assess any macroscopic pathological lesions, the number of lesions, and to attempt to define their approximate position in the small bowel.

### Statistical analysis

The patient demography and observations were entered into a Microsoft Excel spreadsheet by the different recruiting centres, collated and then subjected to statistical analysis. The Student t test and a χ² test were used for normally distributed populations. Data are expressed as range and mean. All p values <0.05 were considered statistically significant.

### Ethics

A unified ethical proposal was provided for the study participants as a template for individual applications for approval by the appropriate ethics board of each centre. Approval for the study was obtained for each of the participating centres after additional requests from some centres’ ethical review boards were complied with. Three ethical review boards feared that capsule retention would occur in such young children. One requested that preliminary x ray studies should only be done if there was a suspicion of obstructive symptoms. A further board requested a small number of post-mortem investigations to prove that the capsule would traverse the ileo-caecal valve in infants as young as 1 year of age. These preliminary additional studies using dummy capsules were carried out at the Ludwig–Maximilian University, Munich, Germany, showed that a normal-sized capsule could traverse the ileo-caecal valve in infants down to age 6 months and through the pylorus down to 1 year and 10 kg body weight. These results were in accordance with at least one previous report demonstrating that there was no correlation between body size and capsule retention.

### RESULTS

Eighty-five studies were carried out in the 83 children aged 1.5–7.9 years (44 male). Four (4.7%) studies in three children were incomplete. In two children battery failure at 2.3 and 3.5 h, respectively, was noted but, in both, relevant diagnostic information was obtained. In another child the capsule failed to exit the stomach on two different occasions. Subsequently, it was introduced into the duodenum endoscopically.

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;3</td>
<td>9</td>
</tr>
<tr>
<td>3–4</td>
<td>14</td>
</tr>
<tr>
<td>5–6</td>
<td>14</td>
</tr>
<tr>
<td>6–7</td>
<td>15</td>
</tr>
<tr>
<td>7–8</td>
<td>15</td>
</tr>
</tbody>
</table>

*The ages of six patients who were <3 years were 1.5, 1.7, 1.8, 2.1, 2.5 and 2.7 years.

Figure 1  A custom-made rucksack for the batteries and recorder in small children.

### Table 1  Age distribution of the patients

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;3</td>
<td>6</td>
</tr>
<tr>
<td>3–4</td>
<td>14</td>
</tr>
<tr>
<td>5–6</td>
<td>14</td>
</tr>
<tr>
<td>6–7</td>
<td>16</td>
</tr>
<tr>
<td>7–8</td>
<td>18</td>
</tr>
</tbody>
</table>
Twenty (24%) children aged 4.0–7.9 years (mean, 6.9 years; 14 male) were able to swallow the capsule (Group 1), while 65 (76%) aged 1.5–7.9 years (mean, 5.25 years; 30 male) were unable to swallow it (Group 2), as shown in table 3.

The children in Group 1 were significantly older than those in Group 2 (Group 1, 4.0–7.9 years, mean 6.9 years; Group 2, 1.5–7.9 years, mean 5.25 years; p<0.025). The youngest child to swallow the capsule was a boy of 4 years of age. More than twice the number of boys (n = 14) were willing to swallow the capsule compared to girls (n = 6). In Group 2 it was possible to introduce the capsule endoscopically into the duodenum in all infants (n = 65) from 1.5 years of age and 10 kg weight. Unlike patients in Group 1 there was no difference in sex distribution (30 male) in Group 2.

**Adverse events**
Significant mucosal trauma occurred in the pharynx (n = 2) at the upper oesophageal sphincter (n = 3) and the pylorus (n = 1) in 4/8 patients in whom the Roth net was used. No further complication was noted and specifically no capsule retention occurred.

**Clinical indications**
WCE was undertaken for occult GI bleeding (n = 30), suspected Crohn’s disease (n = 20), abdominal pain of unknown aetiology (n = 12), protein-losing enteropathy (n = 9) and malabsorption (n = 12) in children in whom standard investigations had failed to yield the cause of their symptoms. Patients with obscure GI bleeding, protein-losing enteropathy and malabsorption were significantly younger than those suspected of having Crohn’s disease or recurrent abdominal pain, as shown in table 4.

**Obscure gastrointestinal bleeding**
WCE identified a source of bleeding in 16/30 (age 1.5–7 years, mean 4.5 years) patients with obscure GI bleeding and/or chronic anaemia, six of whom were blood transfusion dependent. These included four children with an ulcerative jejunitis, three of whom were non-steroidal anti-inflammatory drug related. All of these children suffered from juvenile rheumatoid arthritis. Four children had polyps, two with Peutz–Jegher’s syndrome and two nonsyndromic juvenile polyps (fig 2A), two angiodysplasia (fig 2B), two “blue rubber bleb”-type haemangiomas, two Meckel’s diverticulae, one astomotic ulcer (fig 2C) and one reduplication of the intestine. In 14/30 children the source of bleeding could not be found by WCE. In two patients, lesions which were not bleeding were found: one lymphonodular hyperplasia and one patchy partial villous atrophy. In 12 patients, no lesions were found by WCE, two of whom were non-symptomatic at the time of the study.

**Suspected Crohn’s disease**
Twenty children (age 5–8 years, mean 7.35 years) were suspected of suffering from small intestinal Crohn’s disease but in whom upper and lower intestinal endoscopy failed to provide a diagnosis. In 11/20 evidence of small intestinal Crohn’s disease was found which varied from diffuse aphthous ulcerations (fig 2D) throughout the small bowel to deeper ulceration and fissuring with (fig 2E) terminal ileitis. All 11 of the patients had evidence of acute active disease. In three, additional colonic lesions (fig 2C) and one reduplication of the intestine. In 14/30 children the source of bleeding could not be found by WCE. In two patients, lesions which were not bleeding were found: one lymphonodular hyperplasia and one patchy partial villous atrophy. In 12 patients, no lesions were found by WCE, two of whom were non-symptomatic at the time of the study.

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**Table 2** Bowel preparations used in the participating centres

<table>
<thead>
<tr>
<th>Bowel preparation</th>
<th>Centres, n</th>
<th>Patients %</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear fluids only</td>
<td>3</td>
<td>40</td>
<td>Mucosa satisfactorily seen, but some food residues</td>
</tr>
<tr>
<td>+Senna &amp; picolax</td>
<td>1</td>
<td>8</td>
<td>3 patients vomited during preparation. Mucosa partially obscured but positive diagnoses made</td>
</tr>
<tr>
<td>+Klean Prep</td>
<td>5</td>
<td>52</td>
<td>Good preparation but bubbles in some. Mucosa well seen</td>
</tr>
</tbody>
</table>

**Table 3** Method of introducing the capsule into the duodenum of children in Groups 1 and 2

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Sex</th>
<th>Method</th>
<th>n</th>
<th>Compl*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>Range</td>
<td>Mean</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>1</td>
<td>4.0–7.9</td>
<td>6.9</td>
<td>14</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>1.5–7.5</td>
<td>5.25</td>
<td>30</td>
<td>33</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Difference in age range group 1 vs group 2: p<0.05.

Compl*: complications.
Abdominal pain
Six of 12 patients (age 4.5–8.0 years, mean 6.3 years) with recurrent abdominal pain were found to have significant pathology. Three patients had small intestinal Crohn’s disease (fig 2D,E), which accounted for the complaints, one had a “blue rubber bleb”, and two had lymphonodular hyperplasia, one of whom had juvenile rheumatoid arthritis. The other six children had completely normal studies. In two of those a final diagnosis of non-ulcer dyspepsia was made on further investigation.

Protein-losing enteropathy
Nine children (2.5–7.5 years, mean 4.1 years) had protein loss from the bowel for which no cause had been found. Despite normal duodenal biopsies, four had lymphangectasia and two had lymphonodular hyperplasia on WCE. The remaining three children had no detectable abnormality of their small intestine.

Malabsorption
Of the 12 patients (3.0–7.5 years, mean 4.8 years) with malabsorption and suspected enteropathy in six, all of whom had normal duodenal histology at prior endoscopy, varying degrees of villous atrophy were detected on WCE. Two of those had subtotal and four patchy partial villous atrophy. In none of the six patients was the final diagnosis coeliac disease. In the remaining six children no abnormality of the small intestine was detected. One had sucrose intolerance and two were food allergic but in three no cause was found for their failure to thrive at the time of this study, although in one patient there was an infestation with Ascaris lumbricoides (fig 2F).

DISCUSSION
WCE is an endoscopic technique that offers an extremely safe approach to the investigation of small bowel pathology in adults and is potentially applicable in children where the alternatives are invasive, uncomfortable or require ionising radiation. To our knowledge only few capsule examinations in children of <8 years have been reported in the literature. The inability to swallow the capsule, a fear of capsule retention and a lack of FDA approval in this age group in the US, accompanied by the smaller number of patients requiring evaluation of the small bowel, have severely restricted systematic evaluation. The paucity of previous studies resulted in this multicentre approach in order to recruit sufficient children to systematically evaluate WCE in small children.

A major concern of both investigators and ethical review boards was the fear of capsule retention, which has been shown to be the most frequent complication of 1–2%. As a consequence preliminary post-mortem studies were performed in one centre, which successfully proved the ability of the capsule to traverse the pylorus and ileo-caecal valve in infants of 1 year of age. There were no instances of capsule retention in the 85 examinations of our group with the smallest child weighing just 10 kg. This might occur, however, if a larger group of infants was examined even if care was taken to exclude obstructive conditions. But it seems that there is no higher incidence to be feared when compared to adults.

Failure of the capsule to exit the stomach may be experienced as the first choice rather than swallowing in these children. If this occurred, it might be worthwhile to use endoscopic insertion of the capsule to the pylorus and ileo-caecal valve in infants of this age range under general anaesthesia.

Table 4
Indications and findings of positive capsule studies and their distribution among the groups overall

<table>
<thead>
<tr>
<th>Findings</th>
<th>Age range, years (mean)</th>
<th>Positive studies, n</th>
<th>Patients, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal bleeding</td>
<td>1.5–7.0 (4.5)</td>
<td>30</td>
<td>16</td>
</tr>
<tr>
<td>Crohn’s disease</td>
<td>5.0–7.9 (7.35)</td>
<td>20</td>
<td>11</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>4.5–7.9 (6.3)</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>Protein loss</td>
<td>1.5–7.5 (4.1)</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Malabsorption</td>
<td>3.0–7.5 (4.8)</td>
<td>12</td>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Findings</th>
<th>n</th>
<th>No pathology, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ulcerative jejunitis</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>Polyposis</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Angiodysplasia</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Blue rubber bleb</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Meckel’s diverticulum</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Anastomotic ulcer</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Reduplication</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Small intestinal Crohn’s disease</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Crohn’s colitis</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Small intestinal Crohn’s disease</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Lymphonodular hyperplasia</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Blue rubber bleb</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Lymphangectasia</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Lymphonodular hyperplasia</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Non-coeliac</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Enteropathy</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Ascaris</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Difference in age range: gastrointestinal bleeding vs Crohn’s disease, p < 0.01; gastrointestinal bleeding vs abdominal pain, p < 0.05; protein-losing enteropathy vs Crohn’s disease, p < 0.01; protein-losing enteropathy vs abdominal pain, p < 0.05; malabsorption vs Crohn’s disease, p < 0.01; and malabsorption vs abdominal pain, p < 0.05.
In a previous review it was stated that children under the age of 9 years would be unable to swallow the capsule due to its large size. In this study 24% of the recruited children swallowed it without undue difficulty, the youngest being just 4 years of age. Various factors accounted for the fact that a child could or would swallow the device. These included the child’s personality, acceptance by the parent(s) that the capsule could be swallowed and the skill of the investigator in challenging the child’s ability. In this study boys were significantly more likely to swallow it than girls (14 boys vs 6 girls; p = 0.025). The ability of the investigator to turn the investigation into an interactive game was a major factor, which proved more helpful than previous suggestions of training with candies.

However, endoscopic introduction into the duodenum was necessary in the majority of children (76%). The use of the Roth net resulted in mucosal trauma in 50% of the patients and was cumbersome to use even if an end-cap was added. It was thus abandoned, especially when the purpose-made Advance introducer proved to be easier to handle and non-traumatic. But the loaded capsule increases the overall diameter and it was previously thought to be unsuitable for use in infants. These concerns proved unjustified in our study.

To the best of our knowledge, there have been no studies of bowel preparation in young children and its necessity is controversial. We left the mode of preparation to the single centres, as each of them reported good experience with “their” certain method. Although we did not carry out a formal study the results seen after using three different methods amongst the participating centres as described in table 2 show that clear fluids 24 h prior to WCE and Klean Prep as used for colonoscopy was the most successful regimen and this would be our recommendation.

Since its introduction WCE has provided clinically useful information in the management of a wide variety of well-known different bowel disorders, as shown in table 5 which shows that it is used most commonly for differing indications at different ages.

For example, in adult practice the third commonest indication is for coeliac disease despite the sensitivity of WCE being far from 100% for more subtle grades of villous atrophy. In childhood there are many different causes of enteropathy often with patchy mild changes for which the sensitivity of WCE is low. Consequently, malabsorption as an indication for WCE should be the last resort.

Table 5  Indication for wireless capsule endoscopy in different age groups

<table>
<thead>
<tr>
<th>Indication</th>
<th>Adults</th>
<th>Children, 10–18 years</th>
<th>Children, 1–8 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obscure gastrointestinal bleeding</td>
<td>48</td>
<td>45</td>
<td>37</td>
</tr>
<tr>
<td>Suspected Crohn’s disease</td>
<td>25</td>
<td>23</td>
<td>24</td>
</tr>
<tr>
<td>Coeliac disease</td>
<td>20</td>
<td>22</td>
<td>Abdominal pain 14</td>
</tr>
<tr>
<td>Polyposis</td>
<td>2</td>
<td>Protein loss 3</td>
<td>Malabsorption 14</td>
</tr>
<tr>
<td>Protein loss</td>
<td>2</td>
<td>Malabsorption 3</td>
<td>Protein loss 10</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>2</td>
<td>Polyposis 3</td>
<td></td>
</tr>
</tbody>
</table>

Information concerning adults is taken from Mazzarolo and Brady, Gay and Delvaux, Waterman and Elakim and Delvaux and Gay. Information regarding children of 10–18 years is taken from Sant’Anna et al, Antao et al, Arguilles-Arias et al, Thomson et al and Moy and Levine. Information regarding children of 1–8 years is from the present study.
More recently, new roles have been suggested including the diagnosis of small intestinal neoplasms,\(^\text{14}\) the evolution of inflammatory bowel disease\(^\text{2}\) and in graft versus host disease.\(^\text{2}\)

To date the few studies that have been carried out in children >10 years show that WCE has particularly a role in the diagnosis of small intestinal Crohn’s disease, obscure GI bleeding, and polyposis syndromes.\(^\text{2 10 12 14 16–26}\) Our data in younger children suggest that obscure GI bleeding is the commonest indication as in adults (see table 4), being 35% of those studied. This is at variance with older children, in whom it accounted for only 15–24%.\(^\text{10 12 16 18 27}\) Overall, another marked difference is represented by the underlying aetiology of the haemorrhage. In our study 6/16 of the bleeding lesions were associated with congenital and genetically determined disorders including Meckel’s diverticula, reduplication cysts, and Peutz–Jegher syndrome, whilst in older children and adults this was rare.

Suspicion of Crohn’s disease was the second most frequent indication, accounting for 24% in our study. In three of these cases evidence of additional Crohn’s disease in the colon was found on WCE despite previous negative colonoscopy, which makes falsely negative endoscopy an important cause of undetected disease. In contrast, in studies of older children, Crohn’s disease accounted for 40–66%.\(^\text{10 12 16 18 22}\) The difference in indication is due to the age of peak presentation.\(^\text{28}\) Overall, the indications for WCE in this study of small children were similar to older children and adults, but they were differently distributed. The underlying diseases especially those causing GI bleeding were also different and congenital or genetically determined conditions were frequently present.

Furthermore, in the case of bleeding, protein loss, and malabsorption with no other abnormal findings it is clear that WCE might be helpful. However, our data also shows that 25% of those who were investigated for recurrent abdominal pain were suffering from Crohn’s disease. As at least one study has shown that WCE has a higher sensitivity for small bowel disease in paediatric patients with a suspicion of Crohn’s disease. Endoscopy 2004; 36:869–73\(^\text{29}\)

Acknowledgements: We gratefully acknowledge the preliminary post-mortem studies carried out by Professor R Penning, Institut für Rechtsmedizin, Ludwig–Maximilian University, Munich, Germany. We thank Professor S Kołekzień, Ludwig–Maximilian University, Dr K.L. Kolho, Children’s Hospital, Helsinki, Finland, and Dr L Dal’Oslo, Bambino Gesù Hospital, Rome, Italy, for helpful discussions, the recruitment of patients and comments on the manuscript. We are grateful for the technical support provided by Given Imaging, Hamburg, Germany.

Competing interests: None.

Ethics approval: Approval was obtained from the appropriate Ethics Review Board for each of the participating centres.

Provenance and peer review: Not commissioned; externally peer reviewed.

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