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# Radiopaque marker colonic transit study in the pediatric population BSPGHAN Motility Working Group consensus statement

M. Papadopoulos[1] | M. Mutalib[1] | K. Nikaki[2] | E. Volonaki[3] | A. Rybak[2] | N. Thapar[4,5,6,7] | K. Lindley[2] | O. Borrelli[2] | A. Das[8] | D. Crespi[9] | S. Cleeve[9] | E. Athanasakos[9]

[1]Department of Paediatric Gastroenterology, Evelina London Children's Hospital, St Thomas' Hospital, London, UK

[2]Gastroenterology Department, Great Ormond Street Hospital, London, UK

[3]Department of Paediatric Gastroenterology, University Hospitals Bristol NHS Foundation Trust, Bristol, UK

[4]Gastroenterology, Hepatology and Liver Transplant, Queensland Children's Hospital, Brisbane, Queensland, Australia

[5]Faculty of Medicine, University of Queensland, Brisbane, Queensland, Australia

[6]Centre for Child Nutrition Research, Queensland University of Technology, Brisbane, Queensland, Australia

[7]Stem Cells and Regenerative Medicine, UCL Institute of Child Health, London, UK

[8]Paediatric Department, Broomfield Hospital, Broomfield, UK

[9]Department of Paediatric Surgery, The Royal London Hospital, Barts Health NHS, London, UK

**Correspondence**
Dr M. Papadopoulos, Department of Paediatric Gastroenterology, Evelina London Children's Hospital, St Thomas' Hospital, Westminster Bridge Road, London SE1 7EH, UK.
Email: michalis.papadopoulos@gstt.nhs.uk

## Abstract

Functional constipation (FC) is a common condition in childhood in the United Kingdom and worldwide. Various radiological approaches have been established for diagnostic purposes. The radiopaque marker study (ROMS) is universally accepted and used to assess colonic transit time (CTT) in children with FC. Despite being widely used, there is a lack of standardization with various technical protocols, reproducibility of different populations, the purpose for using investigation, variance in the number of markers used, the amount of study days and calculations, the need to empty the colon before performing the test, and whether to perform on medication or off, or the use of specific diets. As part of the British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN) motility working group (MWG), we decided to explore further into the evidence, in order to provide guidance regarding the use of ROMS in dealing with FC in the pediatric population.

**KEYWORDS**
colonic manometry, colonic transit time (CTT), constipation, pediatrics, radiopaque marker study (ROMS), scintigraphy

## 1 | INTRODUCTION

Functional constipation (FC) is an emerging public health problem. In the United Kingdom, 5%–30% of children are suffering with FC[1] and 0.7%–29.6% worldwide.[2–5] FC is frequently related with infrequent and/or painful defecation, fecal incontinence (FI), and abdominal pain. It has significant distress to the child and family and has a considerable impact on healthcare cost. The etiology of FC is variable, yet most children have no underlying structural or medical causes, responsible for their symptoms.[6]

Living with FC, is a debilitating condition, having profound psychosocial impact on both the patient and families, including feelings

  

of shame, anxiety, poor self-esteem, worry, communication difficulties, and family dysfunction.[3,7–10] The majority of patients adhere to conservative treatment modalities recommended (e.g., laxatives, rich fiber diet, and sufficient fluid intake), however, in approximately one-third of children, symptoms become debilitating and there is refractoriness to conservative management.[6,11]

Despite FC being common, there is variability in patient awareness and definition, which implies the need for objective criteria for diagnosis. Patients who have failed conservative measures and their symptoms have become chronic, early referral to a specialized service is vital; to investigate the underlying pathophysiological mechanisms involved and eventually tailor effective treatment.[11,12]

The most widely used diagnostic tool in patients with FC, to gain information about their colorectal function, is the radiopaque marker study (ROMS). This is followed by an x-ray, which was first described by Hinton et al[13] and has been widely been used since.[14–18] ROMS is noninvasive, simple, one-visit, and a cost-effective investigation to perform in children.[15,18,19] The investigation involves an abdominal x-ray after ingestion of radiopaque capsules and colonic transit time (CTT), which is calculated based on the amount of remaining intra-abdominal markers.[14–17,20]

Despite ROMS being widely accepted and utilized, there are current challenges involved including[14–18,21]:

1. lack of standardization with different technical protocols,
2. reproducibility of various populations,
3. the purpose for using investigation,
4. the need to clear out the bowel before proceeding with the study,
5. variance in the number of markers used,
6. the amount of study days and calculations, and
7. whether to perform on medication or off or the use of specific diets.

As part of the British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN) motility working group (MWG), we decided to further explore into the evidence and discuss as a specialized group. This process involved a voting consensus platform within the group, in order to provide guidance regarding the use of ROMS testing in the pediatric population.

## 2 | METHODS

We conducted non-systematic literature search using the following search engines:

1. PubMed
2. Google Scholar
3. Science Direct
4. Cochrane Library, and
5. MEDLINE

This was for all available literature published in English (up to July 2023) using the combinations of the following words: *transit*, *colonic*, *radiopaque*, *paediatric*, *pediatric*, *child*, *constipation*, *functional constipation*, *and marker*.

In order to make our recommendations we held 10 meetings among members of the MWG from the BSPGHAN between the period 2020 and 2022. The team comprised of multidisciplinary professionals (pediatric gastroenterologist, pediatricians, clinical scientist, clinical nurse specialist, and other allied health professionals) from the United Kingdom who are the leading experts within the field. The working group met on at least two occasions initially, which provided the platform for discussions about the topic and development of the questions to address. Various methods used for ROMS and current practice were compared, with the emphasis on their strengths and limitations. Discussion about the main issues with the current use of CTT was heavily focused on. The following eight questions were developed using the literature and the MWG expertise:

1. Do we recommend performing ROMS as an initial investigation for FC?
2. Is ROMS useful to confirm non-retentive fecal incontinence?
3. Can ROMS be used to indicate type of constipation?
4. ROMS may be used in patients with FC to assist with management (including investigations—along with further testing and multidisciplinary team (MDT) discussions).
5. Do we recommend one particular ROMS protocol over another?
6. Do we recommend a specific diet when performing ROMS?
7. Do we recommend performing ROMS off medication?
8. Do we recommend performing a clear out prior to ROMS?

Studies that were included were those who reported on any aspect of ROMS in children relevant to the working group's aim and purpose. Studies were screened using the principle of the GRADE[22] strength of evidence and grouped into high, moderate, low, and very low qualities. Overall the evidence was in low- and very low-quality groups. The working group consensus was reached after evaluating the available literature, which was gained by personal qualitative opinions of the individual members of the MWG and combined with current pediatric practice (as represented by the members of the MWG) and expert opinion.

We voted on each position using a 1–9 scale, with 1 being strongly disagree and 9 strongly agree. We agreed that consensus was reached if >75% of the group members voted 6, 7, 8, or 9 in favor of the recommendation.

### 2.1 | Position 1: Do we recommend performing ROMS as an initial investigation for FC?

There are no specific tests or biomarkers to help with diagnosing FC, thus the diagnosis relies heavily on symptoms and clinical examination. The recently updated Rome IV standards provide the criteria,

which are divided into two age groups for children toilet- and non-toilet-trained.[23] As such, there is no need for unnecessary and costly investigations. There are of course other definitions for FC which are however less validated.[24] Moreover, there are concerns regarding radiation exposure from abdominal x-rays. The average dose of radiation has been calculated around 0.46 mSv,[25] which is more than 35 times higher than that required for a chest x-ray −0.013 mSv.

**Recommendation 1: We do not recommend performing ROMS as an initial investigation for FC**

**Voting: 9, 9, 9, 9, 9, 9, 8, 9, 9, 9**

Various studies have evaluated the efficacy of ROMS to diagnose FC, yet few have been performed in pediatric patients. Although all of the studies have concluded that CTT is delayed in children with FC, they were all case controls, hence very likely over reporting the accuracy of CTT.[26–29] The 2010 NICE guidelines (updated in 2017) have suggested, to not use of CTT to make a diagnosis of FC.[1] Additionally NASPGHAN/ESPGHAN (2014) recommendations also concluded that evidence does not support the routine use of CTT to diagnose FC. However, the group added that ROMS can be used in situations in which the diagnosis cannot be made based on the ROME IV Criteria, for example when history is unreliable or a clinical examination is not possible.[6] Thus, conflicting evidence remains on the recommendations needed to perform ROMS in children, as an initial diagnostic tool for FC.

## 2.2 | Position 2: Is ROMS useful to confirm non-retentive fecal incontinence (NRFI)?

Fecal incontinence (FI) is defined as the passage of a stool without control (usually in a socially inappropriate place) after 4 years of age, at least once a month over a 3-month period.[1–5,30–38] When first presented, FI may be associated with FC, which causes misguided management. Yet, studies have shown that over 80% of children with FC also suffer from FI[35–37] and thus their coexistence is now universally accepted. FI has an estimated worldwide prevalence in children of up to 8%,[37] with the majority of children having it secondary to FC.[38]

Although FI is usually secondary to FC, in a minority of cases it can be seen without it; this is called non-retentive fecal incontinence (NRFI). The term NRFI is used to describe the passage of normal bowel movement in the underwear. NRFI can be subdivided into a primary (or continuous) form (FI with no evidence of FC occurring in children who have not been toilet trained successfully) and secondary (or discontinuous) NRFI (occurring in children who were completely toilet-trained and subsequently regressed to incontinence).[39–41]

Although ROMS is not routinely recommended for differentiating FC from NRFI, it has a more prominent role than in FC. The Rome Foundation supports that "the diagnosis of NRFI should be based on clinical symptoms, such as normal defecation frequency and absence of abdominal or rectal palpable mass, in combination with normal transit marker studies." In the 2014 constipation guidelines, NASPGHAN/ESPGAHN committee stated that "demonstration of a normal CTT with the prompt passage of markers suggests either NRFI (a condition in which children have faecal incontinence without having FC) or an unreliable medical history." Finally, according to the International Children's Continence Society "determining the CTT can be a valuable tool in the workup of a child suspected of NRFI." And that "in inconclusive cases, CTT can help to differentiate between FC and FNRFI."

**Recommendation 2: ROMS may be used to confirm non-retentive fecal incontinence**

**Voting: 9, 8, 9, 9, 9, 9, 9, 9, 8, 8**

Benninga et al (1994) demonstrated that children with NRFI form a different group of patients than the typical FC one.[41] Not only from a clinical point of view (i.e., via history and examination), but also from investigations. Of the 111 children with FC, almost half of them had normal CTT. Of the FI group, nearly 90% were within normal limits. Pensabene et al[42] conquers with this, in a retrospective review of abdominal x-rays which demonstrated abnormal CTT in about 40% of children with FC and 23% in NRFI. NRFI is typically challenging to treat and often laxatives have no role, unless there is a degree of FC. Education and rigid toileting program are vital,[43] alongside psychological input, including a daily bowel diary and a reward system. Special attention should be paid to psychosocial or behavioral problems, as these frequently occur in affected children. Functional NRFI is often difficult to treat, requiring prolonged therapies with incremental improvement on treatment and frequent relapse.[44]

## 2.3 | Position 3: Can ROMS be used to indicate type of constipation?

Based on CTT, constipation can be divided into (i) normal transit constipation (NTC); (ii) slow transit constipation (STC); and (iii) rectal outlet obstruction (ROO) or also known as rectal evacuatory disorder (RED).[17,45,46] Wagener et al[47] confirmed normative data for total and segmental CTT in children from six studies using various capsule protocols. It was found that the CTT and segmental transit times in children, to be similar to adult values, although this could be secondary to the fact that adolescents were overrepresented in the studies and all age groups were described as pediatric. There is only one study in which children were subdivided in three groups. Velde[21] in 2013 compared segmental and total CTT in children aged 3–6, 7–12, and 13–18 and found the median total CTT to be 36 h (<2.4–86.4 h). There is no significant difference between age categories (toddlers 31.2 h (<2.4–74.4 h), elementary school 36 h (2.4–79.2 h), and adolescents 43.2 h (14.4–86.4 h)). There was no statistical significance for sex either.

Southwell's et al[18] review clarifies the subdivisions as followed. NTC defined as a CTT < 32 h (upper 95th centile: 54 h). STC has been described when there is slowing of the markers through all colonic segments[48,49] and/or the markers remain in the proximal and transverse colon, at 48-h scans.[49] STC is mostly found in older children, and recognized as intractable constipation that is not responsive to

diets, laxatives or lifestyle changes.[50] When the delay occurs and over 50% of the markers are held up in the rectosigmoid colon, children are labeled as having ROO.[18] ROO has been described when the radioisotope has passed the transverse colon at 30 h after the study, but persists in the rectosigmoid region up to 48 h.[48–50] Studies have shown that most children have either NTC or outlet obstruction, and only about one in five have STC.

**Recommendation 3: ROMS may be used to indicate type of constipation**

**Voting: 8, 9, 8, 9, 7, 9, 9, 8, 8, 7**

## 2.4 | Position 4: ROMS may be used in patients with FC, to assist with management (including investigations, MDT discussions, discuss treatment modalities, and other safeguarding areas)

Diagnostic methods such as ROMS are required to distinguish causes and tailor management for the patient. The MWG believe that ROMS can assist the clinician, for deciding the next plan of action when managing the patient with FC. This could be investigations (such as anorectal manometry [ARM], colonic manometry [CM]), MDT discussions, and furthermore various treatment modalities. As a group, we believe that FC is multifactorial in nature, thus it is no surprise that when it comes to diagnosis and treatment, a multimodal approach needs to be applied.

Studies have suggested that distinguishing the types of constipation, might benefit from different treatment modalities.[28,47,51] The use of objective evidence of CTT can be useful to the clinician, patient, and family, to understand the type of constipation their child has. Using ROMS can also be helpful in patients who have NTC, who may benefit from further management such as ARM or biofeedback or identify rare cases potentially fictitious.[52] From the MWG of expertise, we believe that from our clinical experience and vast exposure to such patients, CTT in conjunction with clinical history, presenting history and compliance, the patient may benefit first from MDT discussion and the likelihood of a behavioral or psychosocial input.

Withholding behavior for example, will result in increased number of markers in the rectosigmoid and distal rectum, as will ROO disorders, like dyssynergia. This evidence allows the clinician to tailor management for the patient, by using other allied investigations (such as anorectal manometry) to differentiate types of constipation such as dyssynergia. By withholding behavior we refer to the reluctance of a child to open bowels, following a negative experience such as a hard, painful, or frightening bowel motions. This can occur, due to the child being preoccupied with other activities (e.g., school and playing) and therefore postpone defecation and lead to fecal impaction, overflow, and FI.[53,54]

Dyssynergia on the other hand, has been used to describe constipation associated with anorectal dysfunction, these include the terms "anismus," "pelvic floor dyssynergia," "obstructive defecation," "paradoxical puborectalis contraction," "pelvic outlet obstruction," and "spastic pelvic floor syndrome".[53] The term dyssynergic defecation is used to describe the inability to coordinate the abdominal and pelvic floor muscles to evacuate stools due to paradoxical anal contraction or inadequate anal relaxation. Dyssynergic defecation can only be described after ARM or a balloon expulsion test.[53–55]

Various treatment modalities have been suggested for children with STC. Initially, maintaining the use of regular oral laxatives is suggested, yet more invasive therapeutic approaches such as surgical treatment have been proposed (e.g., antegrade continence enema [ACE] or transcutaneous electrical stimulation [TES]).[49,55–57] A delay in CTT may predict the presence of a more simplified modification, such prokinetic drugs or using biofeedback techniques that involve ARM, to assist children in understanding and to recover their normal defecatory mechanisms.[27]

Currently, there is a lack of published studies investigating the diagnostic value of CTT in the follow-up of children who have completed treatment for FC. One study has explored the relationship between symptoms and CTT and the significance of symptoms and CTT in predicting outcome of FC.[6] It was concluded that, measuring CTT in children with FC has limited value as a diagnostic measurement or in predicting successful clinical outcome. However, it is evident from the literature that ROMS is often used in conjunction with our tools (such as medical history, patient compliance, family expectations and other investigations) and often compliments the decision.

ROMS has proved to be helpful in establishing the diagnosis of FC in children in cases of clinical uncertainty and might be of value to direct what other gastrointestinal motility tests may be needed to compliment and guide treatment. Confirming the CTT may help identify subgroups of patients with different pathophysiological mechanisms including the differentiation between dyssynergia or other causes of ROO (e.g., aganglionosis and rectocele).

Gutierrez et al. (2002) compared findings on ROMS studies with ARM[25] and found that 37% of the children with FC showed delayed transit in the left colon and rectosigmoid colon, suggesting ROO. The results of the study supported the hypothesis because up to 64% of the children with delayed transit times showed dyssynergia when attempting to defecate, using ARM. Koletzko et al.[58] found that children with paradoxical contraction showed significantly longer total colonic transit times (110.6 ± 32.8 h) than those with normal defecation, yet no mention is made of the segmental transit times. Park et al.[59] verified that regional CTT (i.e., the measurement of transit in specific colonic segments) could not be used to exclude evacuation disorders in adults with FC. It was suggested, that further investigations such as the balloon expulsion test or ARM are recommended. Park et al,[59] hypothesized that fecal impaction could delay colonic motility; thus, making it difficult to differentiate between STC and an ROO.[6]

Colonic manometry (CM) remains at its infancy, regarding clinical use within pediatrics. However, Rybak et al.[60] review has described CM as a gold standard for assessing colonic neuromuscular function in children with FC.[16,60] Case series have shown that CM can be useful in (i) predicting the outcome after having an ACE; (ii) recognize patients with an ACE who may be able to be weaned from the

washouts; and (iii) can detect specific segments of colonic dysfunction that may be amenable for surgery.[61,62] Tipnis et al[63] evaluated oroanal transit time (OTT) measured by ROM with CM findings in children with FC. The study demonstrated that all of the children with normal OTT had normal CM studies; however, only children with slow OTT had an abnormal CM study. Therefore, although sensitive, the OTT study was not specific for predicting whether the whole colon or a segment of the colon was affected by either a neuropathic or myopathic disease process.[63] Pensabene et al[64] demonstrated the value of using CM in identifying the cause of FC in children. It was found that 62% of the children with FC and medical management had abnormal colon motility which included: distal colonic low-amplitude simultaneous contractions in 45%, proximal colon motility abnormality in 1%, and pancolonic abnormality in 16%. It was proposed that 24-h CM studies, may further allow us to understand the cause of STC in children. King et al,[65] found in children with STC, to have fewer numbers of antegrade propagating contractions compared with children with NTS and normal adults.[65] Overall CM, although only available to a few centers for children in the world, is a test that can potentially provide further insight in challenging cases of STC.[66]

Scintigraphy can measure the entire gut transit or can be solely on that of the colon, using radiolabeled material and tracked with a gamma camera. It is able to assess, motor function of the colon and distinguish between whole colonic delayed transit, localized colonic dysmotility and ROO with the hold-up of the radionuclide in the rectosigmoid colon.[67] Cook et al[68] underwent scintigraphy in 101 children with FC and demonstrated the advantages of assessing gastric and small bowel transit in the same study, as it could identify children with previously unrecognized pan-intestinal motility disorders. Despite the fact, that scintigraphy is noninvasive and provides more detail it is currently less widely implemented than in adults. This is due to various reasons including: limited availability, more expensive than ROM, multiple image acquisition over consecutive days and lack of pediatric normative values.[10,69] Southwell et al[18] reported pediatric normative values for scintigraphy evaluation of CTT in both adults and children and compared these results with the ROMS. There was evidence of good reliability of these techniques in adult patients; however, comparison of scintigraphy and ROMS for the evaluation in children has not been finalized.

Evidence based recommendations from ESPGHAN/NASPGHAN in 2011, concluded that there are no studies (263 studies searched) that have demonstrated the diagnostic value of scintigraphy in children with CC and based on their expert opinion, do not recommend routine use of it, in children with FC.[6] Furthermore, it has been suggested that abnormal scintigraphy suggestive of colonic inertia should be confirmed in other investigations (e.g., CM) before any medical or surgical treatment is planned.[70]

**Recommendation 4: ROMS may be used in patients with FC, to assist with management (including investigations, multidisciplinary team discussions, discuss treatment modalities, and other safeguarding areas)**

**Voting: 7, 9, 8, 8, 9, 7, 9, 8, 9, 9**

## 2.5 | Position 5: Do we recommend one particular ROMS protocol over another?

CTT has progressed from 1969, when Hinton[13] first described the technique which involved the rate of marker expulsion using radiographing and fecal collection to record the appearance or an abdominal x-ray to confirm disappearance of the barium-labeled pellet.[13] Calculation of the CTT was from the time taken to pass the first pellet, to passing 80% of the pellets. Since first described by Hinton, ROMS has been widely used[14–18] and subsequently, over 10 protocol variations have been developed[13,15–18,71–77] (Table 1).

Protocol approaches of ROMS, ranges from a single or multiple capsule ingestion followed by single or multiple abdominal x-rays including at specific times (4th day or 4th and 7th day).[15,28,73–75] The most commonly used protocols are

(i) Abrahamsson method[73] (ingestion of three sets of distinctive pellets on three consecutive days followed by an x-ray on Day 7). Note others use same method[21,27,47,73,75] OR.
(ii) Metcalf method[16] (x-ray on Day 4). Note others use same method.[15,16,70,78] Rao et al[79] uses a single capsule containing 24 markers followed by a single x-ray on Day 5.

There are specific formulas that allow the calculation of total CTT by counting the number of markers remaining in the colon. It is also possible to calculate the segmental transit time by dividing the x-ray of the large bowel, to right colon based on bony landmarks easily recognizable in the x-ray. CTT can be calculated by

(i) Total: counting the total number of markers on the plain x-ray or
(ii) Segmental: based on the number of retained markers in three colonic segments: right colon, left colon, and rectosigmoid region.[15] The modified Metcalf formula is used to calculate segmental transit time.[16,77] The number of markers per segment is multiplied by 1.2, a constant representing the ratio between the period during which the test is performed (72 h) and the number of markers ingested ($n = 60$, expressed in hours).

Patients are categorized as STC when there is a delay in transit with the markers spread throughout the colon. When the delay occurs in the rectosigmoid, with more than 50% of the markers lying in this area, children are categorized as having ROO. Normal transit time has been defined as a CTT less than 36 h.[70] Rao et al[79] scores if ≥5 markers retain this is considered to be abnormal.

Using the single-radiograph protocol has its advantages including: (i) significant reduction in radiation exposure and (ii) offers strong correlation with other protocols requiring daily radiographs, it is now acknowledged as the most suitable for children.[28] However, in cases where colonic transit diagnosis is unclear or exceptional circumstances (e.g., safeguarding concerns, fabrication of illness, over/under medicating, eating disorders, incomplete medical history, or physical examination), multiple x-rays may be

**TABLE 1** Protocol variations for measuring CTT.

| Author (Reference) | Year | Markers ingested | Day of x-ray |
|---|---|---|---|
| Hinton[13] | 1969 | 20 markers on Day 1<br>20 markers on Day 1 | 3, 5<br>Every 24 h until no maker is seen |
| Arhan[15] | 1981 | Twenty-four markers of similar or different shapes are ingested daily consecutively for 3–6 days | Daily |
| Metcalf[16] | 1987 | 20 markers of different shapes each day for three consecutive days | 4 and 7 (delayed film) |
| Abrahamsson[73] | 1988 | 10 ring-shaped markers daily for 6 days and an additional 20 rod-shaped on Days 4, 5, 6 | 7 (24 h after last marker ingestion) |
| Chaussade[72] | 1989 | 22 markers each day for three consecutive days | 4, 7 (at the same time as marker ingestion time) and Day 10 if markers still present at Day 7 |
| Bouchoucha[17] | 1992 | 20 markers on Day 1 | 5 |
| Bautista[70] | 1991 | | 4 |
| Benninga[29] | 1995 | 20 markers each day for three consecutive days | 4, 7+ days 10, 13, 16 if >20% remaining |
| Zaslavsky[28] | 1998 | 20 markers on three consecutive days | 4 |
| Gutiérrez[27] | 2002 | 10 at 9:00 AM on each of six consecutive days. The capsules were numbered and contained the following marker forms: Capsule 1, 10 rods; Capsule 2, 10 spheres; Capsule 3, 10 large rings; Capsule 4, 10 cubes; Capsule 5, 10 small rings; Capsule 6, 10 rods | 7 |
| Sadiq[19] | 2003 | 10 markers every AM for five consecutive days. On Day 6: 5 markers in the AM and 5 at 8 PM. Fluoroscopy guidance for 8 h to follow markers | 7 |
| Wagener[47] | 2004 | 10 radiopaque markers at the same time daily for 6 days. A | 7 |
| Park[78] | 2004 | 20 markers of different shapes each day for three consecutive days | 4 and 7 (delayed film) |
| Pomerri[89] | 2007 | Two groups- 1st group: 10 markers daily for 10 days, 2nd group: 10 markers daily for 10 days and barium paste given orally on Day 9 | 11 |
| Rao[79] | 2009 | Single capsule (24 markers) | 5 |
| Vande Velde[21] | 2016 | 10 ring-shaped markers daily for 6 days | 7 (24 h after last marker ingestion) |

beneficial. Additionally, compliance to swallow one single capsule rather than multiple is another advantage for patients with cognitive disabilities, hospital anxiety, socioeconomic difficulties for family, compliance issues, or simply to avoid multiple visits to the hospital. Most pediatric hospitals in the United Kingdom have a standard protocol they use and there has been no significant evidence to choose one protocol over another. Thus, it is not unusual that there was disparity among the MWG and voting. However, this has been mentioned in an international review from ESPHGAN[60] which reports that one need to value that the measurement of ROMS does not give a direct measurement of colonic neuromuscular function, thus, a single study to assess colonic motor function may not be possibly adequate. It was suggested that clinicians need to consider this, subject to the severity of the condition and interpret them within a clinical context. Refer to Table 1 for summary.

**Recommendation 5: We do not recommend one particular ROMS protocol over another, however we do suggest the single-radiograph protocol to minimize radiation exposure**

**Voting: 8, 2, 6, 9, 6, 3, 7, 7, 8, 8**

## 2.6 | Position 6: Do we recommend a specific diet when performing ROMS?

Most clinicians would agree that children continue their usual activities and diet while undertaking ROMS. There have been some discussions whether supplementation with fiber (e.g., psyllium) should be used. There is no protocol in the pediatric gastroenterology units in the United Kingdom that advice a specific diet or supplementation with fiber before performing or during the ROMS study that we are aware of.

**Recommendation 6: We do not recommend a specific diet when performing ROMS**

**Voting: 9, 9, 7, 9, 7, 9, 9, 8, 9, 8**

However, there have been two randomized control studies which have investigated the effect fiber has on ROM test. Weber et al[80] found no statistical difference in the CTT between a group of children with controlled FC who had a mixture of fiber and the placebo group. Castillejo et al[81] on the other hand did, found a statistical difference between children who received cocoa husk supplement compared to placebo. The reduction in CTT observed was greater in children who had a basal prolonged CTT. Of note, there are some differences in ROM studies when comparing CTTs in children participating in studies from other continents. For example, there is evidence from a study in India that CTT in children is shorter compared to children from Western Europe and this is felt to be secondary to dietary fiber.[82]

## 2.7 | Position 7: Do we recommend performing ROMS off medication?

The answer to the question will depend on the clinical question. Clearly if we need to diagnose FC/type of constipation, then the test should be performed while off medications. ROMS might be helpful in children with FI on intensive and invasive treatments and still have complaints of infrequent defecation and/or FI. If we want to assess efficacy of treatment, then patient should continue with laxatives. There are no published pediatric studies that look into the effect of laxatives on ROM or even investigating the diagnostic value of CTT in the follow-up of children who have completed treatment for defecation disorders. However, as this will almost certainly have an impact on the CTT, it would be prudent to stop medications that might affect colonic motility at least 24–48 h before the test is done (there is no consensus regarding the timing laxatives should be stopped). Furthermore, the American Gastroenterology Association in 2013 in the algorithm for constipation suggested performing a CTT off medication and then repeating the study while on treatment if there is no improvement.[83] This can be summarized from the professionals from the MWG as below:

1. Do ROMS off medication to see type of FC (i.e., NTS, ROO, and STC).
2. Do ROMS on medication to assess efficacy of treatments (e.g., laxatives, ACE, TES, and safeguarding concerns).
3. Do a clear out prior to ROMS post disimpaction or when is it needed for procedures such as ARM or anal irrigation.
4. Do ROMS when there is safeguarding concern (over medicating/under medicating and fabrication of illness).

**Recommendation 7: ROMS is recommended to be performed off medication, unless it is done in order to assess the efficacy of the laxative regime**

**Voting: 8, 9, 9, 7, 9, 3, 9, 8, 8, 8**

The MWG has discussed this recommendation in great detail, in the presence of national experts. It is the group experience that discontinuing laxatives for the purposes of the CTT can be extremely disruptive to the patient and their family. Patients have been advised in a clinical setting to discontinue laxatives prior to and for the duration of the transit study—a period of at least a week. Once the study was completed there was exacerbation of symptoms and some were impacted. This needs to be considered by the clinician when making this decision.

## 2.8 | Position 8: Do we recommend performing a bowel clear out prior to ROMS?

The question of: "whether the colon should be emptied/cleaned before studying CTT and if so how and when?" has been discussed in the literature. It has been suggested, that ROMS studies should preferably be undertaken after colon disimpaction as fecal impaction is known to prolong colon transit time,[27,84–86] yet this can be challenging in clinical practice where staff and room/bed availability need to be utilized to accommodate this, with unclear idea of the length of time needed to ensure bowel is clean. The experience from the MWG is that disimpaction needs to be carefully decided, if required following the CTT further, potentially unnecessary disruption to the patient and families, with many needing more time off school. Reestablishing the correct maintenance dose of laxatives is often not straightforward and requires significant clinical time and support in some cases.

Apart from which method of analysis to use, there is still no clear standardized consensus regarding the need for a clear out before performing the test. Based on the limited studies and in expert opinion, most centers would perform a clear out initially, especially if there is high suspicion for the presence of a fecaloma, even though this might prove to be challenging in few cases. Quitadamo et al[84] investigated CTT of 24 children with FC and compared before and after bowel cleansing. Not only was CTT reduced, but the type of constipation also was affected, with less children being diagnosed with STC following the clear out. Bekkali et al[85] found a significant decrease in CTT following clear out of the bowel with enema or laxatives. Interestingly, the decrease was similar in both groups, indicating that the way the bowel was cleared did not affect the end result.

In adults there are two relevant studies to mention. Sloots et al in 2002[87] showed that in constipated patients, CTT decreased from a median 70 h (range 10 ± 130 h) to 48 h (5 ± 94 h) in the cleansed state ($p < 0.001$) and a decrease overall in all segments of the bowel. However, there was no difference in overall distribution from pre to post clear out. There is also the study of Berger and Read[88] in adults which did not demonstrate a change in CTT, but difference in subtype from STC and ROO.

**Recommendation 8: We recommend performing a clear out prior to ROMS?**

**Voting: 9, 9, 9, 9, 9, 9, 9, 9, 6, 1**

## 2.9 | Other considerations

Age is not a limiting factor for performing the test, as long as the child can ingest the markers, either as tablets or dispersed in another medium, for example, yogurt and consumed roughly at the same time.

Generally, CTT does not seem to be significantly affected by age, although it tends to be shorter in younger children.[15,21,27,28,44,70,78,86]

It might be worth mentioning the 2004 De Lorijn et al[76] study which looked into identifying factors that would predict successful outcome for constipated children in 1 year. The factors that were considered were gender, defecation frequency, presence of FI and frequency, large stools, night-time incontinence, palpable abdominal mass, and palpable rectal mass and CTT by ROM. Prolonged CTT was defined as >62 h and it was not related to not successful treatment, unless it was >100 h. Measurement of CTT did not predict outcome if less than 100 h. In contrast, a CTT above 100 h predicted a poor outcome at 1 year. Clinicians might consider a more aggressive initial treatment plan for patients who have prolonged CTT.

## 3 | CONCLUSION

FC in children is common and an emerging public health condition. Specialized centers across the United Kingdom are using established diagnostic tools from traditional to more advanced tests, to gain pathophysiological understanding in these patients. This consensus allowed an experienced group of clinicians to discuss and investigate the current scientific indications, protocols, and practice of various approaches to CTT.

Despite great efforts, there remains significant variability, which in some cases might lead to conflicting results and discussions among clinicians. Therefore, it is important that we not only merge the various approaches in clinical practice, but also imperative to not rely on a sole investigation to confirm diagnosis and etiology of a multifactorial condition. It is essential for clinical professionals managing these patients to:

(i) Be clear about the clinical question they are asking prior to investigations (e.g., when using CTT).
(ii) Recognize and appreciate that ROMS does not provide a direct measurement or understanding of all the pathophysiological mechanisms involved in FC.
(iii) Use a multimodal approach (i.e., using various diagnostic tools and modalities), depending on the severity of the problem and interpret them in the clinical context.
(iv) Discuss these patients at a MDT to ensure all professional are involved when managing these patients.

### AUTHOR CONTRIBUTIONS

M. Papadopoulos: Designed and conducted the literature search, lead voting and group discussions, wrote the paper, involved in editing paper and submission. M. Mutalib: Involved in voting and discussions and offering edition suggestions. K. Nikaki: Involved in voting and discussions and offering edition suggestions. E. Volonaki: Involved in voting and discussions and offering edition suggestions. A. Rybak: Involved in voting and discussions and offering edition suggestions. N. Thapar: Involved in voting and discussions and offering edition suggestions. K. Lindley: Involved in voting and discussions and offering edition suggestions. O. Borrelli: Involved in voting and discussions and offering edition suggestions. A. Das: Involved in voting and discussions and offering edition suggestions. D. Crespi: Involved in voting and discussions and offering edition suggestions. S. Cleeve: Involved in voting and discussions and offering edition suggestions. E. Athanasakos: Lead and coordinate group discussions, wrote the paper, involved in editing paper and submission.

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The authors have no competing interests to disclose.

### DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

### ORCID

*O. Borrelli* https://orcid.org/0000-0003-0241-0508
*E. Athanasakos* https://orcid.org/0000-0001-9207-7379

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