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ORIGINAL ARTICLE

Gastroenterology: Inflammatory Bowel Disease

Point-of-care ultrasound provides useful information in children with Crohn's disease visiting the outpatient clinic

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Abstract

Objectives: Point-of-care ultrasound (POCUS) is increasingly used in clinical practice. However, it's additional value next to conventional markers of disease activity has not been studied in paediatric Crohn's disease (CD). This study aimed to assess the clinical added value of POCUS in children with CD.

Methods: Consecutive children with CD visiting the outpatient clinic were prospectively enrolled and underwent POCUS in addition to faecal calprotectin (FC) test and mucosal inflammation noninvasive index for paediatric Crohn's disease (MINI-index) assessment. Both tests were categorised into normal, uncertain and abnormal. Paediatric gastroenterologists decided on clinical management before and after POCUS disclosure. Predictive value of POCUS for clinical flares within 4 months was assessed. Outcomes were the proportion (95% CI) of patients where POCUS result was discordant from FC and MINI-index, proportion of patients where POCUS changed clinical management, and predictive values of POCUS for clinical disease flares.

Results: We included 76 patients (median age: 16 years, 34 (45%) female, median disease duration: 2 years). In 7 (9% (4%–18%)), and 2 (3% (0%–9%)) patients, the POCUS resulted in a less severe classification and in 43 (57% (45%–70%)), and 44 (58% (46%–69%)), in a more severe classification of disease severity compared to FC and MINI-index, respectively. Clinical management was adjusted in 46 (58%) cases after POCUS result disclosure. The positive and negative predictive value for clinical flares within 4 months of an abnormal POCUS were 71 (57%–82)% and 74 (64%–83)%, respectively.

Conclusions: POCUS seems a valuable noninvasive monitoring tool for children with CD. Our results support the application of POCUS in the clinical management of these children.

KEYWORDS

bedside ultrasound, disease monitoring, intestinal ultrasound, pediatric Crohn's disease

1 | INTRODUCTION

Crohn's disease (CD) is a chronic inflammatory condition that can affect the entire gastrointestinal tract. The incidence of childhood onset CD is 9–10 per 100,000.[1] Due to the relapsing and remitting disease course, monitoring of disease activity is crucial for prevention and early detection of clinical flares and disease complications. CD activity in children is predominantly monitored non-invasively, using markers in stools (i.e., faecal calprotectin [FC]) and in blood (e.g., C-reactive protein [CRP], and erythrocyte sedimentation rate [ESR]). However, these markers are not informative on disease localisation and extent. Moreover, FC levels might be less accurate in children compared to adults,[2] and specificity of FC seems to be lower, for example, in patients with ileal disease compared to colonic disease,[3] while the ileum is one of the most frequent disease localisations of CD, whether or not combined with colonic disease.[4]

Intestinal ultrasound strongly correlates with endoscopic disease activity[5] and is increasingly used as point-of-care tool to improve noninvasive detection of disease activity. However, there is a lack of data on the information point-of-care ultrasound (POCUS) provides in clinical practice, in addition to conventional monitoring tools. To determine whether noninvasive monitoring of children with CD can be improved with POCUS, this study assessed the proportion of patients in clinical practice in whom the POCUS result is discordant with conventional noninvasive markers. Secondary outcomes were the proportion of patients in whom POCUS changed the clinical management, the predictive value of POCUS for clinical disease flares and patient's discomfort and acceptance of POCUS.

What is Known

- In children, Crohn's disease activity is mainly monitored non-invasively.
- Point-of-care ultrasound (POCUS) is increasingly used for this purpose, however, data on the added value in clinical practice are missing.

What is New

- In our study, POCUS resulted in a different classification of disease severity compared to biochemical biomarkers in the majority of children with CD.
- POCUS contributed to clinical management decisions in 58% of cases.
- Lastly, the prediction of a disease flare within 4 months could be improved with the use of POCUS.

2 | METHODS

2.1 | Participants

This was a prospective longitudinal study carried out at the Amsterdam University Medical Centre, location AMC, in the Netherlands. This centre had integrated POCUS into care for 2 years previously to starting this study. Consecutive patients with CD visiting the outpatient clinic were requested to participate between May 2020 and May 2021. Inclusion criteria were: diagnosis of CD according to the Porto criteria,[6] with a disease duration of at least 4 months, visiting the outpatient department (either for check-up, or for intravenous administration of medication) and aged 3–17 years. Exclusion criteria were: ulcerative colitis, IBD-U, ongoing infectious gastroenteritis, or pregnancy.

2.2 | Procedures

A POCUS was performed on the same day as the routine outpatient clinic visit. As part of regular care, patients were requested to collect a stool sample for FC measurement, and blood was routinely drawn to measure CRP, ESR, albumin, thrombocytes and haematocrit. A maximum of 2 weeks, without change in medication, was allowed between the POCUS and the FC and blood sample. The paediatric Crohn's disease activity index (PCDAI)[7] was assessed as well. Treating physicians were not informed of the POCUS result, unless a complication (i.e., stenosis, abscess or fistula) was found, or unless the physician judged the POCUS result was needed for clinical care. After 4 months, the electronic medical charts of the participants were checked for the occurrence of clinical flares (defined as a PCDAI > 10 combined with FC > 250 mg/kg, or FC > 500 mg/kg or need for medication escalation).

2.3 | POCUS

The POCUS was performed by one trained physician (EW), who performed > 200 ultrasound examinations before start of the study. She was blinded for all clinical disease activity parameters. During the POCUS, jejunum, ileum, terminal ileum (TI), and all colon segments were scanned systematically for disease activity. The paediatric Crohn's disease ultrasound (PCD-US) score was used to define disease activity. This score is designed with endoscopy as reference standard. This endoscopy based score showed moderate to good accuracy to define disease activity, and it is the only currently published ultrasound score for children with

CD[8]; in the TI POCUS was defined as uncertain when bowel wall thickness (BWT) was 3.0–3.7 mm and as abnormal when BWT was > 3.7 mm, reflecting the higher normal values for BWT in children compared to adults.[8,9] In the colon, POCUS was defined as uncertain when BWT was 1.6–2.0 mm combined with mesenteric fat proliferation, or when BWT was 2.0–2.7 mm. POCUS was defined as abnormal when BWT was > 2.0 with mesenteric fat proliferation, or when BWT was > 2.7 mm. In the inception cohort[8]; an uncertain PCD-US score had a specificity of 73%–77%, and an abnormal score a specificity of 88%–92%, compared to endoscopy, indicating that an abnormal PCD-US score is likely to represent disease activity (i.e., low false positive rate). Duration of the POCUS examination was measured as well.

2.4 | Impact on clinical management

After the outpatient department visit, patient details were noted on two cards. Patient details included: age, gender, Paris classification, medical history (including IBD medication switches), baseline PCDAI, baseline laboratory results (CRP, blood count and FC) and the most recent previous laboratory result. POCUS results were only displayed on the second card. Two experienced paediatric gastroenterologists (AK and TM), who were not involved in the care of the included patients, were presented the two cards of all included patient in a random sequence, and were instructed to decide on medical management. The paediatric gastroenterologists did not have experience in POCUS themselves. The trained physician (EW) reported the interpretation of the POCUS results. Options for medical management were:

a) Continue treatment as before (including dose optimisations)
b) Change treatment:
    1. De-escalate treatment
    2. Start local medical therapy (defined as: budesonide tablets or an enema/suppository)
    3. Surgical therapy
    4. Escalate therapy (defined as: starting an immunomodulator, or starting a remission induction therapy, such as (enteral) nutrition therapy, prednisone, biological)
c) Perform invasive/burdensome diagnostic procedure (defined as: endoscopy, magnetic resonance imaging (MRI)).
d) Perform standard of care US by radiologist

Medical management choice of both raters, with and without the POCUS result, were noted. In case of disagreement between the two raters, cases were discussed among them to achieve consensus for all cases. The choice of medical management in this study did not impact the real life medical management.

2.5 | Acceptability of POCUS

After POCUS, participants filled out the Discomfort During Research Procedures questionnaire (DISCO-RC).[10] This questionnaire was developed to assess the child's reported discomfort after different types of research procedures and consists of six multiple choice questions, reflecting different forms of discomfort (i.e. nervousness, annoyance, pain, fright, boredom and tiredness). Each is scored using a 5-point Likert scale and answers range from 'not discomforting' (=0 points) to 'extremely discomforting' (=4 points), hence the total score ranges from 0 to 24 points. In addition children were asked if they would be willing to undergo a POCUS more frequently during an outpatient clinic visit. Answers to this score were also scored on a 5-point Likert scale (0 = would not mind at all, 5 = would mind a lot).

2.6 | Statistical analyses and sample size calculation

Baseline characteristics were calculated using descriptive statistics. To assess the proportion of patients in which the POCUS and conventional markers were discordant, we calculated the proportion and 95% confidence interval (CI) of patients in whom POCUS led to a more, and less severe classification of disease activity than FC, the proportion of patients in whom POCUS led to a more and less severe classification of disease activity than all currently used inflammatory markers combined. FC results were categorised into low (0–250 mg/kg) uncertain (250–500 mg/kg) or high (>500 mg/kg), based on guidelines for monitoring IBD patients.[11] To combine different inflammatory markers, we used the mucosal inflammation noninvasive index for paediatric Crohn's disease (MINI-index),[12] which combines presence of liquid or bloody stools, FC, ESR and CRP into a score (range –3 to 25). A cut-off of ≥8 was used to define disease activity. The proportion of patients in whom POCUS altered choice for therapy due to knowledge of disease localisation and extension were calculated. The positive and negative predictive values of the POCUS for prediction of having a clinical relapse (definition described above) within 4 months was calculated to assess the predictive value of the POCUS.

Since no previous studies have been performed we based the sample size calculation on the assumption that POCUS would lead to a more severe classification of disease activity in 15% of patients, resulting (alpha 0.05, Power 0.8) in a required

sample size of 76 patients. All analyses were done using SPSS v.25 and p-values < 0.05 were considered statistically significant.

3 | RESULTS

3.1 | Patient population

A total of 76 paediatric CD patients were included. The baseline characteristics are displayed in Table 1. The median disease duration of included patients was 2 years and 42 (55%) received anti-tumour necrosis factor-alpha as maintenance treatment. Six patients did not hand in their stool sample within 2 weeks of the POCUS, thus FC level could not be assessed.

3.2 | POCUS

The mean duration of the POCUS was 15 min (standard deviation: 3 min). The image quality was good in 60 (79%) cases and moderate in 16 (21%) cases. The POCUS results per segment are displayed in Table 2. The POCUS result was disclosed in 9 (12%) patients; three times because of a stricture, and six times because the treating physician requested the results to substantiate the choice for clinical management, for example, in case a patient reported severe symptoms, but biochemical markers were normal. These patients were excluded from the analysis on the predictive value of the POCUS.

3.3 | Discordance of POCUS and other noninvasive markers of disease activity

The discordance between FC and POCUS results are displayed in Table 3a. In 7 (9%, 95%CI: 4%–18%) patients, the POCUS resulted in a less severe classification of disease severity and in 43 (57%, 95%CI: 45%–70%) patients, the POCUS resulted in a more severe classification of disease severity than FC.

The discordance between the MINI-index and POCUS results are displayed in Table 3b. In 2 (3% 95%CI: 0%–9%) patients, the POCUS resulted in a less severe classification of disease severity and in 44 (58%, 95% CI: 46%–69%) patients, the POCUS resulted in a more severe classification of disease severity than the MINI index.

3.4 | Impact of POCUS on clinical management

The decisions on clinical management with and without obtaining the POCUS results are displayed in Figure 1.

TABLE 1 Baseline characteristics.

	***N* = 76**
Age (median [IQR])	16 [14–17] years
Gender	34 (45%) female
BMI (mean (SD))	22 (4)
Disease duration (median [IQR])	2 [1–4] years
Paris classification (n (%))	
A1a- diagnosis before age of 10 years	23 (30%)
A1b – diagnosis after age of 10 years	53 (70%)
L1 – ileo-caecal disease	16 (21%)
L2 – colonic disease	18 (24%)
L3 – ileo-colonic disease	39 (51%)
L4a – upper gastro-intestinal disease	33 (43%)
L4b – distal small bowel disease	6 (8%)
B1– uncomplicated disease behaviour	64 (84%)
B2– structuring disease behaviour	10 (13%)
B3– penetrating disease behaviour	0
B2,3 – both B2 and B3	2 (3%)
P– peri-anal disease	23 30%)
G1– growth delay	14 (18%)
Clinical markers of disease activity	
CRP (n = 75) (median [IQR]), mg/L	1 [0.4–6.2]
ESR (n = 68) (median [IQR]), mm/h	9 [3–17]
Faecal calprotectin (n = 70) (median [IQR]), mg/kg	205 [39–601]
PCDAI (n = 66) (median [IQR])	4 [0–15]
MINI index (n = 70) (median [IQR])	5 [0–9]
Number (%) of patients with PCDAI > 10	19 (25%)
Maintenance treatment (n (%))	
None	2 (3%)
Immunomodulators only	21 (28%)
Nutrition therapy only	6 (8%)
Anti-TNF-alpha	42 (55%)
Vedolizumab	1 (1%)
Other	1 (5-ASA) (1%)

Abbreviations: BMI, body mass index; CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; PCDAI. paediatric Crohn's disease activity index; TNF-alpha, tumour necrosis factor-α.

There was disagreement in 20 (26%) of cases that did not include the POCUS result, and in 26 (34%) cases that did include the POCUS results. Consensus was achieved in all these cases. The decision on clinical management changed in 46 (58%) cases after

obtaining the POCUS result: in 5 (7%) patients the physicians changed their management from continue as before to either escalating therapy ($n = 2$, 3%) or to perform endoscopy, MRI or CT ($n = 3$, 4%). In 39 (51%) patients physicians changed their management from requesting a regular US to either continue treatment as before ($n = 12$, 16%), start local therapy ($n = 4$, 5%), escalating therapy ($n = 15$, 20%) or perform either endoscopy, MRI or CT ($n = 8$, 11%).

3.5 | Predictive value of POCUS on clinical disease activity

In 67 (88%) patients, complete 4 month follow up data were available: 27 (42%) patients had a clinical relapse. The positive predictive value (PPV) of an abnormal POCUS was 71% (57%–82%) and the negative predictive value (NPV) was 74% (64%–83%). In the 45 patients with a normal FC result at baseline, the PPV of an abnormal POCUS was 91% (80%–96%), and the NPV 42% (23%–63%). In the 20 patients with an abnormal FC, the PPV was 93% (76%–98%), and the NPV was 20% (5%–56%). In the 51 patients with a normal MINI-index at baseline, the PPV was 79% (68%–87%), and the NPV 56% (37%–74%). In the 19 patients with an abnormal MINI-index, the PPV was 92% (68%–98%), and the NPV 33% (14%–61%).

TABLE 2 POCUS result per segment.

	POCUS normal	Uncertain POCUS result	Abnormal POCUS result
Terminal ileum	32 (42%)	27 (36%)	16 (21%)
Caecum	47 (62%)	18 (24%)	7 (9%)
Ascending colon	51 (67%)	18 (24%)	6 (8%)
Transverse colon	54 (71%)	15 (20%)	5 (7%)
Descending colon	46 (61%)	20 (26%)	7 (9%)
Sigmoid colon	48 (63%)	18 (24%)	8 (11%)

Abbreviation: POCUS, point-of-care ultrasound.

3.6 | Acceptability of POCUS

Majority of children ($n = 59$, 78%) reported they would not mind to undergo a POCUS at future outpatient clinic visits. The other patients reported they would mind a little ($n = 12$, 16%), would mind somewhat ($n = 2$, 3%) or would mind a lot ($n = 2$ (3%). One patient did not answer the question. The median total DISCO score was low: 1 (IQR: 1–3) out of 24. The most frequently scored item of the DISCO-RC was boredom (median score 1, IQR 0–1).

4 | DISCUSSION

In our cohort of children with known CD visiting the outpatient clinic, the POCUS results gave a more severe classification of disease activity than conventional markers of inflammation in 58% of children. Moreover, physicians adjusted their management in 58% of the real life patients' scenarios when the POCUS result was included.

To our knowledge, this is the first study investigating the additional diagnostic value of POCUS compared with conventional diagnostic markers and its impact on clinical decision making in paediatric CD outpatient care. Our results strongly suggest that disease activity in children is missed in the majority of patients when monitoring based on clinical symptoms and inflammatory markers like FC and CRP only. The PPV of 71% for a relapse within 4 months indicates that not all positive POCUS findings resulted in a flare as defined in this study. However, absence of a flare after 4 months does not preclude that mild disease activity was present during POCUS. The relevance of the abnormal POCUS findings is underlined by previous cross-sectional studies on the diagnostic accuracy of POCUS demonstrating a high specificity—and thus low false positive rate—of POCUS, compared to endoscopy.[5,13] Remarkably, in

TABLE 3 a: Discordance between POCUS and FC results.

	POCUS normal	POCUS uncertain	POCUS abnormal
FC < 250 mg/kg ($n = 45$)	7 (16%)	26 (58%)	12 (27%)
FC 250-500 mg/kg ($n = 12$)	2 (18%)	4 (36%)	5 (45%)
FC > 500 mg/kg ($n = 20$)	1 (5%)	4 (20%)	15 (75%)
b **Discordance between POCUS and MINI-index results**			
MINI-index negative ($n = 51$)	7 (14%)	28 (55%)	16 (31%)
MINI-index positive ($n = 19$)	2 (11%)	4 (21%)	13 (68%)

Abbreviations: FC, faecal calprotectin; MINI-index, mucosal inflammation noninvasive index for paediatric Crohn's disease; POCUS, point-of-care ultrasound.

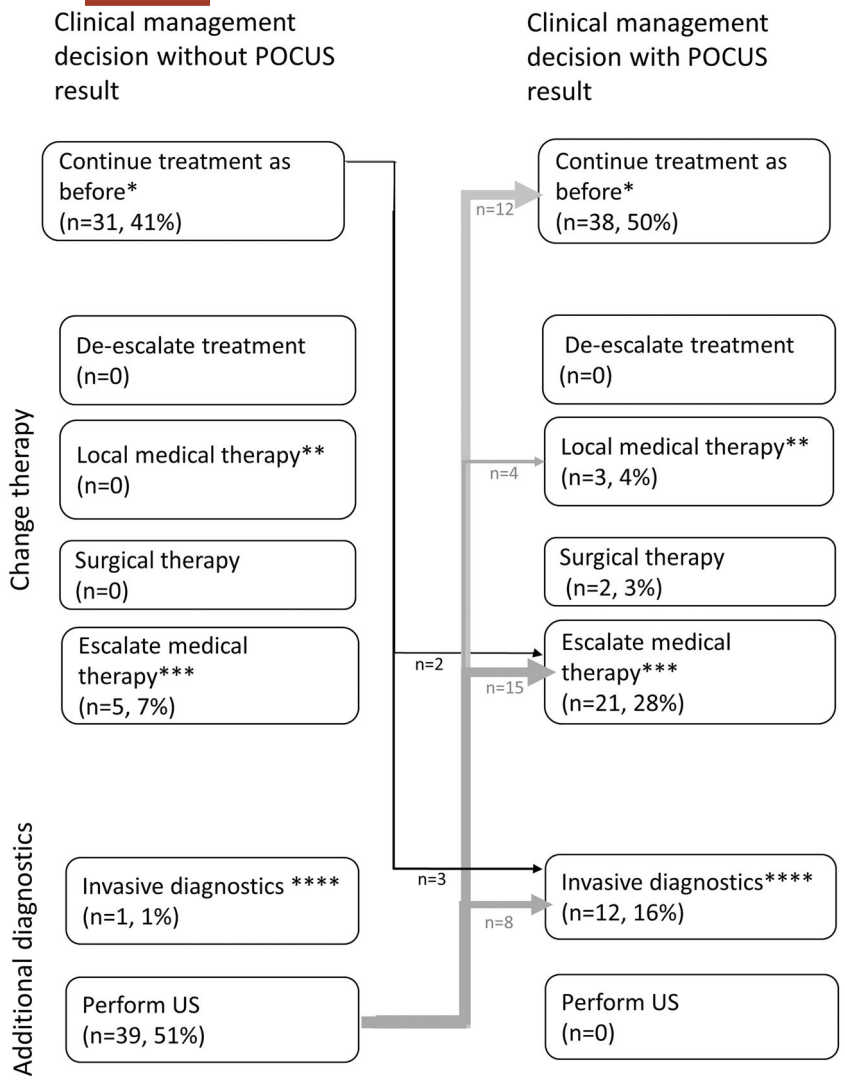

FIGURE 1 Impact of POCUS on clinical management. The arrows depict the change in clinical management before and after obtaining the Point-of-Care ultrasound (POCUS) result. The arrow size depicts the number of times this change occurred. *including dose optimisations, ** defined as: budesonide or enema/suppository, *** defined as: start an immunomodulator, or start a remission induction therapy, such as (enteral) nutrition therapy, prednisone, biological, ****invasive and\or burdensome diagnostics, defined as: endoscopy, magnetic resonance imaging (MRI).

the subset of those with a low baseline FC and abnormal POCUS result in our study, the PPV was even higher (91%) compared to the whole study group, further supporting the value of POCUS in addition to conventional markers.

Besides persistent low grade inflammation, part of false positive findings in predicting a flare after 4 months might be explained by a lag of BWT recovery after a flare compared to other clinical markers, as was also suggested by the longitudinal "Transabdominal Ultrasonography of the bowel in subjects with iBD To monitor disease activity" (TRUST) studies. These studies demonstrated normalisation of BWT in around 50% of patients with colonic lesions, and 25% of patients with ileal lesions 3 months after initiation of treatment.[14,15] To assess the full potential of POCUS as monitoring tool for children with CD, a longitudinal study to replicate the findings of the TRUST studies in a paediatric cohort is needed.

Clinical management of CD is not a matter of reacting just to one laboratory or cross-sectional finding. To put our POCUS results in conjunction with other findings, we imitated the outpatient clinic setting by presenting cases with patients' history, clinical- and other laboratory findings to experienced paediatric IBD physicians. The fact that in 21 (28%) patients, the physicians decided to escalate therapy or to start local medical therapy after disclosure of the POCUS result, and that in 39 (51%) cases without the POCUS result the physicians requested a US, further confirms that in many cases conventional markers are not conclusive and that in these cases POCUS provides relevant additional information to guide management. Whether long term outcome of patients improves when adding POCUS as noninvasive monitoring tool remains to be investigated.

Our results are in line with a study in 49 adult CD patients, where signs of active disease on POCUS were found in 52% of patients in clinical remission. In that study, clinical decisions were adjusted after POCUS disclosure in 60%. These results may have been biased by the fact that the physicians were not blinded

to the study objectives, and thus might have been more inclined to change clinical decisions based on the POCUS result. To overcome this bias, the physicians in the current study decided on clinical management based on the cards in a random sequence, and did not assess the card with the POCUS result directly after the card without POCUS result. In a recent study in 259 adult IBD patients visiting the outpatient clinic, POCUS was requested in 73 patients and clinicians changed their interpretation of disease activity in 22% hereafter.[16] In another recent retrospective study in 301 adult IBD patients, POCUS had impact on medical management in 60% of patients.[17] These studies together confirm that POCUS provides valuable information on disease activity in an important part of patients. In addition, acceptability of POCUS was high in our cohort, and children reported little discomfort after the POCUS examination, making it a suitable alternative for other imaging techniques such as MRI and endoscopy from the patient perspective.

Our study has several strengths. First of all, we tried to avoid bias in our results by analysing the clinical value of POCUS in three different ways, by including a consecutive sample of children, regardless of their clinical symptoms, and by blinding the ultrasonographer to the clinical symptoms and laboratory findings. Second, the physicians rating the clinical cases were not the treating physician and were unaware of which patients they were rating, making our results more generalisable. Limitations of our study are the absence of a reference standard, such as endoscopy or MRI, to compare our findings to. However, as we aimed to represent the real-live clinical outpatient care, it was ethically unacceptable to perform these reference standards. Another limitation is the use of the recently developed PCD-US. This score was internally validated, however, external validation has not yet been done. Also, in some studies a lower cut-off value for BWT is used.[18–20] However, our cut-off is based on endoscopy comparison,[8] and reflects the higher normal values in children for BWT, especially in TI.[9] In addition, a higher cut-off level of BWT increases the specificity, and strengthens the conclusions of this study. Lastly, we did not perform separate analyses for small and large bowel, as our study was not powered for this and more importantly, there is currently no validated score for intestinal ultrasound in small bowel in children.[21]

5 | CONCLUSIONS

In conclusion, based on our results routine use of POCUS in outpatient care impacts clinical decision making in the majority of children with CD, predicts clinical flares, and has high patient reported acceptability. In all, our results support the application of routine POCUS in the clinical management of children with CD. Future research with larger sample and longer follow-up time should investigate the effect of routine POCUS on long term outcome of patients.

CONFERENCE PRESENTATION

Part of this study was presented at the World Congress of Paediatric Gastroenterology Hepatology and Nutrition (WCPGHAN) 2021 (G-eP-402), Apart from this the manuscript, including related data, figures and tables has not been previously published and the manuscript is not under consideration elsewhere.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data underlying this article will be shared on reasonable request to the corresponding author.

ETHICS STATEMENT

All participants and/or parents gave written informed consent before entering the study. This study was approved by the institutional review board of the Amsterdam UMC.

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