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Original Article

MR Enterography Scores Correlate with Degree of Mucosal Healing in Pediatric Crohn's Disease: A Pilot Study

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Abstract

Objectives: MR enterography (MRE) Index of Activity (MaRIA) and Clermont are validated scores that correlate with Crohn's disease (CD) activity; however, the Clermont score has not been validated to correlate with the degree of change in mucosal inflammation post induction treatment in children. This pilot study evaluated if MaRIA and Clermont scores can serve as surrogates to ileocolonoscopy for assessing interval change in mucosal inflammation in pediatric CD post-induction treatment.

Methods: Children with known or newly diagnosed ileocolonic CD starting or changing therapy underwent ileocolonoscopy, scored with simple endoscopic score for Crohn's disease (SES-CD), and MRE on the same day at two time points (Week 0 and 12). Accuracy of global MaRIA and Clermont indices relative to ileocolonoscopy in detecting degree of post-treatment interval change in mucosal inflammation was assessed through correlational coefficients (r). Inter-reader agreement was calculated for imaging scores through intraclass correlation (ICC).

Results: Sixteen children (mean age 11.5 ± 2.8) were evaluated. Global MaRIA/Clermont correlated with SES-CD in detecting the degree of change in mucosal inflammation ($r = 0.676$ and $r = 0.677$, $P < 0.005$, respectively). Correlation for pooled timepoint assessments between SES-CD and global MaRIA/Clermont was moderate ($r = 0.546$, $P < 0.001$ and $r = 0.582$, $P < 0.001$, respectively). Inter-rater reliability for global MaRIA and Clermont was good (ICC = 0.809 and ICC = 0.768, respectively, $P < 0.001$).

Conclusions: MRE-based global scores correlate with endoscopic indices and may be used to monitor disease changes in children with CD undergoing induction treatment, which can advise the physician if treatment changes should be made.

INTRODUCTION

Pediatric Crohn's disease (CD) rates are rising worldwide, particularly in the youngest children (1). Meanwhile, more effective medications—particularly biologics—are increasingly used, necessitating accurate methods of assessing clinical prognosis (2). Mucosal healing (MH) following treatment is currently the best therapeutic endpoint in CD, and endoscopy is the gold standard for assessment (3). However, repeated endoscopies in children are invasive and require sedation (4).

Magnetic resonance enterography (MRE) poses a non-invasive alternative to endoscopy (5). It accurately differentiates active from inactive disease and detects disease of the small bowel in areas that are impossible to reach with traditional endoscopy (6–10). Two validated MR indices have shown high diagnostic accuracy for assessing CD activity in adults: the MR Index of Activity (MaRIA) and the Clermont score (4,11–15). The Clermont is based on MaRIA but utilizes apparent diffusion coefficient (ADC) values acquired from diffusion-weighted imaging (DWI) instead of contrast-enhancing values, which mitigates the use of gadolinium-chelated contrast (15). To the best of our knowledge, there are no longitudinal prospective studies that evaluate the correlation of MaRIA and Clermont scores with the degree of interval change of mucosal inflammation following 12-week induction therapy in children with CD.

The aims of this study were (1) to evaluate the performance of MaRIA and Clermont scores for assessing interval change in bowel inflammation following induction therapy in children; and (2) to assess inter-observer variation of MaRIA and Clermont scores.

MATERIALS AND METHODS

Study Design and Population

This prospective pilot study was conducted at a tertiary care pediatric hospital between June 2012 and July 2013. Inclusion criteria were children (<18 years old) with known diagnosis of ileal and/or colonic CD who were undergoing endoscopy and changing biologic therapy, and children with newly diagnosed CD who were starting induction therapy. Exclusion criteria were isolated proximal small bowel and/or upper gastrointestinal disease, fibrostenotic disease causing significant stricturing of the TI, or contra-indication to MRI.

At diagnosis or decision to initiate biologic therapy (Week 0), patients underwent laboratory investigations (C-reactive protein [CRP]), clinical disease activity measured using the Pediatric Crohn's Disease Activity Index (PCDAI), endoscopy and MRE. Twelve weeks following initial endoscopy (Week 12), patients underwent repeated endoscopy and MRE. At both timepoints, endoscopy and MRE were performed on the same day. Patients who were lost to follow-up or withdrew from the study before Week 12 were excluded.

Ethics

The CHEO Research Ethics Board approved the study. Informed consent/assent was obtained prior to assessments. This study conforms to the relevant STROBE AND STARD guidelines (16,17).

Endoscopic Assessment

Children followed a bowel cleaning protocol with oral ingestion of Pico-Salax® as previously described (18). Endoscopy was performed under general anesthesia following MRE. Two endoscopists (7 and >20-year experience) completed the Simple Endoscopic Score for Crohn's Disease (SES-CD) immediately following colonoscopy, which is a validated score of endoscopic CD severity (19). Its components were scored in the TI and four colonic segments. A global SES-CD was calculated for each patient using the sum of scores for five ileocolonic segments.

Radiologic Assessment

MRE was performed in a 1.5 Tesla magnet (Sigma HD, General Electric Healthcare Technologies, Waukesha, WI). MRE was completed after bowel cleansing (see above) and enteric contrast administration (Sorbitol 3%, 20 cc/kg), which was administered as follows: 10 cc/kg 1 h before the examination, 5 cc/kg 30 min before the examination, and 5 cc/kg immediately before the examination.

As part of the protocol, a SSFSE sequence with 5-mm thickness was acquired on coronal plane to confirm adequate contrast progression into the TI and appropriate bowel distension. The following sequences were subsequently acquired: (1) SSFSE with 5-mm thickness on sagittal and axial planes; (2) 2D FIESTA with 5-mm thickness in the axial plane; (3) cine multiphase 2D FIESTA with 5-mm thickness on the coronal plane for 5 min; and (4) DWI with 5-mm thickness and two b-values (b = 50 and b = 1000) on coronal and axial planes.

Before gadolinium-chelated contrast administration, 0.2 mg of intravenous (IV) glucagon was administered, followed by a 5% dextrose flush. After glucagon administration and before gadolinium administration, a 3D FSPGR-LAVA fat-saturated sequence was acquired on coronal and axial planes.

Disease Measurement Using MRE and DWI

Two pediatric radiologists (4- and 8-year experience) who were blinded to endoscopy results evaluated each MRE study independently. The radiologists were trained to assess the MaRIA and Clermont score components by reading five index cases together that were not part of the study. The radiologists were instructed to perform measurements in areas of more dense disease; however, the region of interest (ROI) was independently chosen. The studies were evaluated on a rolling basis as patients enrolled; Week 0 and Week 12 evaluations were not performed in the same sitting and radiologists were blinded to the study timepoint and results of other studies.

For image analysis, the bowel was divided into five segments: TI, right colon, transverse colon, left colon, and rectum. Quantitative measurements were obtained from the area of greatest thickness within each segment. Relative contrast enhancement (RCE) was calculated as previously described (Table, Supplemental Digital Content [SDC] 1) (12). Quantitative assessment of bowel thickening was measured in millimetres (mm).

ADC values of DWI images were calculated using FUNTOOL GE software, on the ADC map, in the area that corresponds with the highest signal on the b = 1000 sequence in each of the referred segments.

MaRIA and Clermont scores were calculated as previously described (Table, SDC 1) (12,14) at Week 0 and 12 using the formula function in spreadsheet software. Radiologists entered values for MaRIA/Clermont components into the spreadsheet as they interpreted images, and the score was automatically generated. Radiologists were blinded to score results. A global MaRIA index was calculated in the spreadsheet by adding MaRIA scores from five ileocolonic segments described above. A global Clermont index was similarly determined.

Statistical Analysis

Repeated-measures analysis of variance (ANOVA) was performed to assess the association of SES-CD (independent variable) with MaRIA or Clermont in the most affected segment (dependent variable). Using pooled cross-sectional data from Week 0 and 12, Spearman coefficient was used to calculate the correlation between SES-CD and MaRIA/Clermont indices of the most affected area for Reader 1, Reader 2, and their average. The performance of MaRIA and Clermont to evaluate treatment response was assessed through correlational analysis (Spearman) using interval change in SES-CD and MRE between Week 0 and 12.

Agreement between radiologists was assessed using Bland and Altman 95% limits of agreement and intraclass correlation coefficients (ICC), using Shrout and Fleiss' two-way random ANOVA model ± 95% confidence interval (CI) for continuous variables.

As this was a pilot study, post-hoc power analysis was calculated in IBM SPSS Statistics Version 19 (IBM Corporations,

Somers, NY) based on the sample size and Spearman coefficient between interval change of MRE scores and SES-CD. A value of $P < 0.05$ was considered statistically significant. Statistical analyses were conducted using SAS version 9.2 (SAS Institute, Inc., Cary, NC) and IMB SPSS Statistics Version 19.

RESULTS

A total of 36 children aged 6–16 years were enrolled and completed the initial endoscopy and MRE. Four patients were lost to follow up and 16 patients withdrew from the study (13 patients refused repeat endoscopy, 3 patients did not initiate treatment). This yielded a final sample of 16 patients (mean age 11.2 ± 3.2 years) (Figure, SDC 2). Demographic and clinical characteristics of the patient sample are summarized in **Table 1**. The TI was not intubated in two of 16 patients at Week 0 (12.5%); however, the global SES-CD score in these patients was 9 and 25 at Week 0, and 1 and 12 at Week 12. Treatment for each patient between Weeks 0 and 12 is summarized in Table, SDC 3. SES-CD distribution at Week 0 and Week 12 is found in Figure, SDC 4.

Table 1. Demographic and clinical characteristics of the study group at Week 0

		***n* = 16**
Male		9 (56%)
Age at diagnosis (years)		12 (9–14)
Age at enrollment (years)		12 (10–14)
New diagnosis		11 (69%)
Time from scope to treatment (days)		4 (1–14.5)
PCDAI		37.5 (27.5–42.5)
CRP (mg/L)		33.1 (10.8–51.8)
Baseline SES-CD		16.7 (4.0–28.0)
Perianal disease		7 (44%)
Paris Classification		
Age at diagnosis	<10 years	3 (19%)
	10–17 years	13 (81%)
	17–40 years	0
Disease location	L1	5 (31%)
	L2	2 (13%)
	L3	8 (50%)
	Isolated L4	1 (6%)
Upper disease location	No upper GI	10 (63%)
	L4a	5 (31%)
	L4b	1 (6%)
Disease behaviour	B1	15 (94%)
	B2	1 (6%)
	B3	0
	B2B3	0
Growth	G_0	11 (69%)
	G_1	5 (31%)

Data are presented as either *n* (%) or median (IQR).
CRP = C-reactive protein; PCDAI = pediatric Crohn disease activity index.

Correlation of MaRIA and Clermont Scores with SES-CD

A moderate correlation emerged between global MaRIA and SES-CD for pooled Week 0 and 12 assessments ($r = 0.546$, 95% CI 0.46 to 0.62, $P < 0.001$). For evaluating interval change in bowel inflammation, a moderate-strong correlation between global MaRIA and SES-CD was noted ($r = 0.676$, 95% CI 0.27 to 0.88, $P < 0.005$).

When comparing the global Clermont and SES-CD for pooled Week 0 and 12 assessments, a moderate correlation was found ($r = 0.582$,95% CI 0.49 to 0.67, $P < 0.001$). The coefficient for interval change in bowel inflammation between global Clermont and SES-CD was 0.677 (95% CI 0.27 to 0.88, $P < 0.005$).

The per-segment correlations of SES-CD with MaRIA and Clermont scores are summarized in **Table 2** with graphic distribution in Figure, SDC 5(a-e) and 6(a-e). Notably, the correlation between SES-CD and MaRIA or Clermont for the rectum was poor ($r = 0.175$, 95% CI –0.18 to 0.49, $P = 0.338$; $r = 0.033$, 95% CI –0.32 to 0.38, $P = 0.858$, respectively). Global MaRIA and global Clermont score distributions at Week 0 and Week 12 can be found in Figure, SDC 7(a-b) and 8(a-b).

Correlation of MaRIA and Clermont

When comparing global MaRIA with global Clermont for disease activity detection in pooled Week 0 and 12 assessments, a very strong emerged ($r = 0.985$, 95% CI 0.97 to 0.99, $P < 0.001$). The per-segment correlation between MaRIA and Clermont for pooled assessments was also very strong (TI $r = 0.985$, 95% CI 0.97 to 0.99; RC $r = 0.989$, 95% CI 0.98 to 1.0; TC $r = 0.950$, 95% CI 0.90 to 0.98; LC $r = 0.994$, 95% CI 0.99 to 1.0; rectum $r = 0.934$, 95% CI 0.87 to 0.97; all $P < 0.001$). Similarly, a very strong correlation was seen between global MaRIA and Clermont for identifying interval change in bowel inflammation between Week 0 and 12 ($r = 0.992$, 95% CI 0.98 to 1.0, $P < 0.001$).

Inter-observer Agreement

Inter-observer agreement in pooled Week 0 and 12 assessments was good for global MaRIA (ICC 0.809, 95% CI 0.61 to 0.91, $P < 0.001$) and global Clermont (ICC 0.768, 95% CI 0.52 to 0.89, $P < 0.001$). The per-segment ICCs for MaRIA and Clermont are shown in Table 3.

Power Analysis

Post-hoc power analysis demonstrated 75% power using a sample of 16 individuals, *r* coefficient of 0.67, and α of 0.05.

DISCUSSION

In children with CD, quantitative assessment of disease activity is necessary to assess response to therapy, especially during the induction period as it can guide further management and change of treatment, if required (20). MRE is rapidly becoming part of routine care for IBD and has been shown to correlate with endoscopic IBD evaluation (6,21). However, little is known about the correlation of interval change in MRE-based MaRIA and Clermont scores and endoscopy to assess mucosal inflammation following induction treatment in children.

Table 2. Per-segment and global correlations between endoscopy and MR scores

Site	TI	RC	TC	LC	Rectum	Global
Pooled Week 0 and Week 12 assessments						
MaRIA (Average R1 + R2)	0.597 (0.30–0.79) $P < 0.001$	0.655 (0.39–0.82) $P < 0.001$	0.672 (0.42–0.83) $P < 0.001$	0.467 (0.14–0.70) $P < 0.01$	0.175 (–0.18–0.49) $P = 0.338$	0.546 (0.46–0.62) $P < 0.001$
Clermont (Average R1 + R2)	0.605 (0.31–0.79) $P < 0.001$	0.680 (0.42–0.84) $P < 0.001$	0.676 (0.43–0.83) $P < 0.001$	0.450 (0.12–0.69) $P < 0.01$	0.033 (–0.32–0.38) $P = 0.858$	0.582 (0.49–0.67) $P < 0.001$
Change between Week 0 and Week 12 assessments						
MaRIA (Average R1 + R2)	0.783 (0.43–0.93) $P < 0.001$	0.812 (0.49–0.94) $P < 0.001$	0.615 (0.17–0.85) $P = 0.01$	0.568 (0.10–0.83) $P = 0.02$	0.262 (–0.27–0.67) $P = 0.327$	0.676 (0.27–0.88) $P < 0.005$
Clermont (Average R1 + R2)	0.756 (0.38–0.92) $P < 0.005$	0.820 (0.51–0.94) $P < 0.001$	0.657 (0.24–0.87) $P < 0.01$	0.523 (0.04–0.81) $P = 0.04$	0.178 (–0.35–0.62) $P = 0.510$	0.677 (0.27–0.88) $P < 0.005$

LC = left colon = descending colon + sigmoid colon; RC = right colon = ascending colon; TC = transverse colon; TI = terminal ileum.

Table 3. Inter-rater reliability for MaRIA and Clermont scores

	MaRIA	Clermont
TI	0.696 (0.38–0.85) $P < 0.001$	0.724 (0.43–0.86) $P < 0.001$
RC	0.614 (0.21–0.81) $P < 0.005$	0.527 0.03–0.77) $P < 0.05$
TC	0.909 (0.81–0.95) $P < 0.001$	0.957 (0.91–0.98) $P < 0.001$
LC	0.851 (0.69–0.93) $P < 0.001$	0.827 (0.64–0.91) $P < 0.001$
RE	0.608 (0.20–0.81) $P < 0.01$	0.572 (0.12–0.80) $P < 0.01$
Global	0.809 (0.61–0.91) $P < 0.001$	0.768 (0.52–0.89) $P < 0.001$

LC = left colon = descending colon + sigmoid colon; RC = right colon = ascending colon; TC = transverse colon; TI = terminal ileum.

Our principal finding is that MaRIA and Clermont scores correlate with the degree of change in intestinal inflammation as assessed by endoscopy ($r = 0.676$ and $r = 0.677$, $P < 0.005$, respectively) and may be useful to monitor changes in disease activity following induction therapy in children with CD. In adult CD, Ordàs et al. demonstrated that the degree of change in MaRIA moderately correlated with those in endoscopic scores assessed by CDEIS following 12-week treatment ($r = 0.51$, $P < 0.001$) (22) The per-segment correlations were not available in this study. In another retrospective study of 24 adults, degree of change in MaRIA scores was shown to predict endoscopic MH in the terminal ileum following anti-TNF treatment (23).

Some studies have correlated MaRIA and Clermont scores with endoscopy in patients with CD. We found a moderate correlation between endoscopy and the global Clermont and MaRIA ($r = 0.582$ and 0.546, respectively) for pooled Week 0 and 12 assessments. The recent study by the ImageKids group only provided the correlation value for MaRIA and SES-CD in the terminal ileum ($r = 0.418$) which is below our correlation values ($r = 0.597$) (24). The remaining segments in the ImageKids study were scored using the MRE-VAS (visual analogue scale), which did not allow for a direct comparison with our study. The correlation between MRE-VAS and global correlational values of endoscopy was $r = 0.658$ in the ImageKids study (24). In adults, Coimbra (25) described a correlation coefficient of 0.63 for MaRIA and CDEIS, and a correlation of 0.64 and 0.71 for Reader 1 and 2 for MaRIA and SES-CD. The major difference between our study and Coimbra's study is that in our study, global MaRIA scoring and SES-CD were calculated by adding the values of five bowel segments (TI, RC, TC, LC and rectum), while Coimbra's study calculated MaRIA scoring by adding six segments on MRE (TI, AC, TC, DC, SC, rectum) and comparing them with five segments on the endoscopic score (TI, RC, TC, LC and rectum) (25). Furthermore, patients in Coimbra's study underwent endoscopy and two MREs (with and without colonic contrast) within a 2-week period, with no bowel cleanout prior to MRE. In our study, however, endoscopy was performed on the same day as MRE and MRE measurements were done on clean and distended colon, which likely allowed for a better assessment of the distended bowel. The rectum shows poor histological and endoscopic correlation with MRE, which will also act as a factor when we have five measurements on MR rather than six as done in the other publications, including Moira's study (25,26).

We found an almost perfect correlation between MaRIA and Clermont in detecting MH at singular timepoints ($r = 0.985$) and degree of change following therapy ($r = 0.992$). This is consistent with the findings by Kopylov et al. ($r = 0.99$) (27). This is not surprising as Clermont and MaRIA scores are largely similar and only differ in the use of ADC instead of the RCE. This finding is reassuring as the limitations of contrast-enhanced MRE are particularly important in children. The lengthy time required of patients to lie still while images are acquired affects its feasibility in young patients (28). Additionally, studies require the administration of gadolinium to differentiate active from inactive disease, which requires intravenous access and may be uncomfortable for children (29). Furthermore, glucagon—which is given following contrast administration to diminish bowel peristalsis and acquire good quality images—can cause nausea and vomiting (30). Therefore, using DWI imaging and the Clermont score may mitigate some of these challenges and encourage more use of MR for disease monitoring.

Our analysis revealed a poor correlation between SES-CD and MaRIA or Clermont for the rectum. This finding was

indirectly observed by Pomerri et al., who reported a sensitivity of 28% for detecting active disease in the rectum versus more than 50% in other segments (87.5% in TI) (31). Similarly, Kang et al. reported a poor correlation between SES-CD and MaRIA in the rectum of children with CD on treatment (r = 0.29, P < 0.096) (32). While previous studies attributed this poor correlation to inadequate rectal distension, the patients in this study had a well-distended bowel (31,32). It has been shown that MRE displays a higher incidence of rectal involvement in children with CD compared to adults (33). The rectum in children shows more extensive histological than endoscopic disease, which is understandable given that endoscopy is limited to mucosa while CD affects the entire bowel wall thickness (26). Therefore, we postulate that MRE was able to detect more rectal disease compared to endoscopy, as observed in SDC 5 and 6, where SES-CD = 0 showed moderate–high values in Clermont and MaRIA scores, which consequently decreases the correlation between rectal SES-CD and MR indices.

In clinical practice, MRE offers several advantages over performing colonoscopy alone including (1) concurrent small bowel assessment; (2) potential to evaluate entire bowel wall thickness, which reflects CD pathogenesis; and (3) its non-invasive nature (34). Overall, it is a well-tolerated procedure in children, though our study had a high rate of dropouts following the Week 0 endoscopy and MRE. This was largely because performing MRE and endoscopy on the same day was difficult to endure for children and thus likely contributed to reduced acceptance of recurrent examinations during Week 12.

There are several limitations to our study. First, the small sample size introduces variability in the data and reduces the power of the study. Second, the ROI was not explicitly established by radiologists, though an agreement to analyze the most disease-affected area was reached prior to interpretation. Third, all MRE examinations were performed under the bowel preparation protocol, which is not a common practice in radiology departments and may not be reflective of MRE and DWI assessments that occur in regular practice.

In conclusion, this study demonstrates that the degree of change MaRIA and Clermont MRE scores correlate with those in endoscopic scores following 12-week induction treatment. This suggests that they may be used to make decisions about effectiveness of the child's induction regimen and advise the physician if changes should be made. MRE with DWI in particular may represent a favourable alternative to colonoscopy and contrast-enhanced MRE in children due to its greater tolerability. A bowel cleanout protocol should also be considered prior to MRE for optimization of image interpretation to reduce the need for a colonoscopy in children. Larger prospective studies should be conducted to further validate this correlation.

SUPPLEMENTARY DATA

Supplementary data are available at *Journal of the Canadian Association of Gastroenterology* online.

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AUTHOR CONTRIBUTIONS

M.G. wrote the first draft of the manuscript. E.B., D.M., E.M., and J.D. were responsible for study design. E.B. and D.M. were involved in subject recruitment, endoscopic scoring and clinical assessment. J.D. and K.H. were involved in image interpretation and MR score calculations. N.M. and J.D. carried out the data statistical analyses. E.B., D.M., E.M., J.D. performed a critical review of the manuscript. All authors reviewed and approved the manuscript in its final form.

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CONFLICT OF INTEREST

E.B. is the Editor-in-Chief of the Journal of the Canadian Association of Gastroenterology.

DATA AVAILABILITY

The data underlying this article cannot be shared publicly due to the privacy of patients enrolled in the study. The data can be shared on a reasonable request to the corresponding author.

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