Conclusions: The majority of strictures in CD patients treated by surgery are consistent with a mixed type inflammation (acute inflammation plus fibrosis). The presence of stratified BS pattern shows a significantly higher degree of fibrosis while the evidence of high mural signal intensity on T2-weighted fat-saturated images on MRI reflects histological features of acute inflammation. Even if the ideal definition of the type of the strictures in CD still remains significantly far to be obtained, the combined use of BS and MRI can offer useful information in a sub-group of patients needing surgery for complicating CD.

DOP030 Feasibility, precision and reproducibility of MR enterography for detection of inflammation in Crohn’s Disease in a multicenter clinical trial

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Background: 1) To test the feasibility of MR enterography (MRE) for objective assessment of inflammation in patients with Crohn’s Disease (CD) in a global multicenter study; 2) To evaluate test–retest reproducibility of a quantitative MRE-based inflammation score in small bowel (SB); and 3) To assess feasibility and tolerability of MRE with and without a colonic distention enema.

Methods: In total, 19 CD patients gave informed consent to participate in this multicenter (3 USA sites/3 European sites) MRE–MRIA–IC approved study. With 14 days, each patient underwent 1 ileocolonoscopy (IC) followed by 2 consecutive MREs with or without colonic distention with water enema. The MRE protocol was developed in consensus with the participating sites: sequences included T2-weighted Fast Spin Echo, balanced Gradient Recalled Echo, and T1-weighted series pre- and post-Gd contrast. Tolerability questionnaire was completed following each MRE examination. All MRE images were read centrally as a MaRIA score [1] was assigned for each of 9 bowel segments (4 SB, and 5 colon) as well as a global MaRIA score incorporating all bowel segments. In the study, 332 series across 37 MRE examinations were assessed for quality and a 5-grade quality assessment (QA) score was assigned to each MRE sequence and artifacts annotated. IC videos were centrally read and scored. Precision of QA score was assessed from the paired repeated measures in 4 SB segments per patient. Overall feasibility of MRE was assessed comparing protocol and QA. MRE and IC concordance was assessed using correlation analysis. Impact of colonic distension was evaluated by assessing agreement of MRE quantification of active disease using IC as the standard reference.

Results: The compliance to the predefined MRE protocol was 97%; 86% of series scored good to excellent in quality and 97% scored fair or better in quality. Test–retest MRE scores in SB segments showed an intra-class correlation of 0.96. Analysis of variance confirmed between site variability accounted for less than 1% of the overall variability between the two MRE measurements. The two sets of MaRIA scores from the colon segments, with and without colonic contrast, show significant correlations with CDEIS (r = 0.57, p = 0.018 and r = 0.59, p = 0.013 respectively), but not with CDAI (r = 0.30, p = 0.24 and r = 0.29, p = 0.26 respectively). The correlation of CDAI with CDEIS was r = 0.14 (p = 0.57). Tolerability of MRE was comparable to IC, with patients slightly favoring MRE without enema.

Conclusions: High quality MRE data can be acquired from a uniform MRI scanning protocol in a global multicenter setting. MRE is tolerable and inflammation scores are highly reproducible in SB.

Reference(s)

DOP031 A multicenter study to evaluate magnetic resonance enterography (MRE) for selection of Crohn’s disease patients for inclusion into a therapeutic clinical trial

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Background: The current approvable endpoint for Crohn’s Disease (CD) clinical trials is the Crohn’s Disease Activity Index (CDAI). There is supportive evidence that the inaccuracy of the CDAI in identifying active inflammatory CD may have led to inconclusive or erroneous activity assessment of anti inflammatory therapies [1] or novel therapies in development [2]. Magnetic resonance enterography (MRE) has shown potential to assess CD activity and complications in single center studies. The purpose of this study was to evaluate MRE as a tool to select patients for CD clinical trials in a multicenter setting.

Methods: Patients were recruited from 6 centers (3 US, 3 European) globally based on their pre-specified levels of disease according to a prospectively conducted CDAI (Remission: <150, mild: 150 < CDAI < 225, and moderate-severe: CDAI >225, respectively). Within a 2 week period each patient underwent an ileocolonoscopy and a pair of MREs with and without colonic distention with each procedure separated by at least 24 hours. MRE scans and ileocolonoscopy videos were scored by central
readers using the MaRIA index and CDEIS, respectively. A MaRIA subsegment score >11 and CDEIS >8 were used as selection criteria demonstrating active disease for inclusion into a study of moderate to severely active CD.

**Results**: A total of 19 patients were enrolled across the six centers. Using ileocolonoscopy as the standard reference, MRE without enema identified deep ulcers in the colon with 58% sensitivity, 73% specificity; MRE with enema had similar sensitivity, 58% but better specificity, 80%. For enrolment into a trial for moderate to severely active CD, the CDAI identified 6 patients. Of these, only 3 patients had active disease confirmed by either MRE or ileocolonoscopy. One of these three patients had an abscess identified by MRE. The remaining three patients had no objective evidence of disease by MRE or ileocolonoscopy. Using MRE, 12 subjects were identified for inclusion into a trial of which 3 would have been excluded from a clinical trial due to presence of an abscess or abdominal extramural radiopacity. Two of the remaining 9 subjects did not have identifiable disease on ileocolonoscopy. Using ileocolonoscopy, 6 subjects were identified of whom 2 patients would have been excluded by MRE due to an abscess. Overall, MRE selected 7 patients with active disease compared with 4 and 2 patients by CDEIS and CDAI who would be appropriate to include in a CD clinical trial.

**Conclusions**: In comparison to endoscopy and the CDAI, MRE better enriches for patients with more appropriate levels of disease for inclusion in a clinical trial with therapeutic intervention.

**Reference(s)**


**DOP032**

Clinical impact and safety of capsule endoscopy in patients with established Crohn’s disease – a multicenter cross-sectional study

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**Background**: Videocapsule endoscopy (VCE) enables noninvasive visualization of the entire small bowel (SB) mucosa. Multiple studies have established the exceptional accuracy of VCE for the diagnosis of small bowel Crohn’s disease (CD). VCE is also useful in patients with an established diagnosis of CD. However little data is available on the therapeutic impact of VCE findings in patients with established CD.

**Aims**: To examine the impact and safety of VCE on the management of patients with established CD.

**Methods**: Retrospective multicenter cross-sectional study. The study cohort included consecutive patients with established CD who underwent VCE in 4 academic referral centers (1 Canada, 1 Sweden, 2 UK) from November 2008 to October 2013. Patients were excluded if VCE was performed as a part of the initial diagnosis of CD. The presence of small bowel mucosal inflammation on VCE was quantified using the Lewis score (LS). Normal VCE was defined as LS < 135, mild to moderate inflammation as 135 ≤ LS < 790, and moderate to severe as LS ≥ 790. Fecal calprotectin (FCP) was determined either by ELISA (positive > 200 μg/g) or a rapid semi-quantitative test (positive > 100 μg/g).

**Results**: The characteristics of the 133 patients included in the study included: mean age 31 (14–70) years, mean age at onset = 23 (7–68) years, male 39.5%; disease location: ileal 41.3%, ileocolic 34.2%, colonic 25.5%. VCE was normal in 28%, mild to moderate in 43.2%, and moderate to severe inflammation in 28.8% of the patients, with mean LS of 1194 ± 1573. Management was changed as a result of VCE findings in 49.9% of the patients (including initiating or intensification of an immunomodulator/biologic, initiation of a corticosteroid, referral to surgery). CRP was elevated in 42.1%, and FCP in 63% of the available patients. Elevated FCP had a sensitivity of 69%, specificity of 40%, positive predictive value (PPV) of 48.9%, negative predictive value (NPV) of 61.5% for LS above 790, while elevated CRP had a sensitivity of 60.4%, specificity of 68%, PPV of 61.9 and NPV of 66.7% for LS above 790. If VCE was limited to patients with positive inflammatory markers only, significant SB inflammation would have been missed in 33–38% of the patients. Symptomatic capsule retention occurred transiently in 1 patient (0.7%), with spontaneous resolution. Conclusions: VCE findings had a significant impact on the management of patients with established Crohn’s disease. VCE should not be limited to patients with positive inflammatory markers as their predictive value for significant SB inflammation is moderate at best. Capsule retention was very rare and did not require invasive intervention.

**DOP033**

Evaluation of site versus central assessment of endoscopies in Crohn’s disease: Comparison using data from EXTEND


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**Background**: Interobserver variation in the endoscopic assessment of disease activity has been reported for ulcerative colitis clinical trials [1]. We performed a post hoc analysis to compare the agreement between site and central readings of endoscopies from the adalimumab Crohn’s disease clinical trial EXTEND [2].

**Methods**: All randomised patients (pts) from EXTEND who had endoscopies reviewed by one central reviewer and by site reviewers were included in this analysis. Endoscopies were performed at baseline (BL), week (wk) 12, and 52 and scored using SES-CD at all 19 sites and CDEIS at six sites. Agreement between site and central reading was determined by calculating the kappa (κ) coefficient for categorical variables and the Pearson (r) coefficient for continuous variables.

**Results**: Of the 129 randomized pts in EXTEND, 52 pts at BL, 49 at wk 12, and 34 at wk 52 had CDEIS scored endoscopies by both the one central reviewer and the site reviewer, whereas 129, 122, and 84 pts, respectively, had SES-CD scored endoscopies by both reviewers. A high degree of agreement on total CDEIS score or total SES-CD score occurred between central and site