Title: STRICTuring Crohn's disease assessment using advanced Ultrasound and magnetic REsonance imaging techniques for evaluation of inflammation and fibrosis (STRICTURE)

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Background & Aim

Bowel stricturing is a frequent complication in Crohn's disease (CD). Recent studies have elucidated multiple phenotypes for CD strictures. Whereas inflammatory strictures might benefit from anti-inflammatory therapy, fibrotic strictures often need a surgical approach. However, current imaging biomarkers are unable to adequately determine stricture composition. Intestinal ultrasound (IUS) is frequently used in the evaluation of disease activity. Previous studies showed that contrast-enhanced ultrasound (CEUS) and elastography are promising tools in stricture characterization. However, data is scarce and limited studies have evaluated both techniques with histopathological inflammation and fibrosis in the resection specimen. Furthermore, there is no data on response to anti-inflammatory treatment in stricturing CD. Therefore, we will evaluate state-of-the-art cross-sectional IUS parameters to define stricture composition as defined by the histopathological degree of inflammation and fibrosis in the resection specimen. In addition, we prospectively follow-up response to anti-inflammatory treatment with advanced IUS techniques.

Methods

42 patients will be included with 32 receiving a small bowel resection for stricturing CD. Before surgery patients receive CEUS, elastography and small intestinal contrast ultrasound (SICUS). Location-matched histology will be evaluated according to a histopathological score for inflammation and fibrosis. Patients treated with anti-inflammatory medication will be followed up and IUS examinations are repeated after 26 weeks of treatment to determine response.

Impact of the study

The identification of IUS parameters indicating predominant inflammation or fibrosis might help in treatment decision making. In addition, cross-sectional imaging might become an important endpoint in future clinical trials with anti-fibrotic medication. IUS is a potential technique to determine treatment effect in these clinical trials.

Timeline

We have started inclusion in December 2019 and up to date 30 patients have been recruited (medical arm: 8/surgical arm: 22). We aim to include the last patient in summer 2021 and present results in early 2022.