Monitoring Response to anti-TNF Therapy in Ulcerative Colitis Patients by Gastrointestinal Ultrasound

Sub-analysis from TRUST&UC
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Disclosure

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Introduction

- Gastrointestinal ultrasound (GIUS) is a non-invasive diagnostic modality providing objective parameters of ulcerative colitis (UC) activity.
- Disease management concepts (Treat-to-Target (T2T), Tight Control) integrate objective and clinical parameters for guiding treatment optimization resulting in improved outcomes.
- Hence, GIUS parameters such as bowel wall thickening (BWT) could serve as adjunctive objective parameters for treatment optimization.
- Here, we assessed the utility of GIUS for monitoring response to anti-TNF therapy in ulcerative colitis patients.
**Methods – Study design**

TRUST & UC was a prospective, observational multicentre study in N=224 patients with active UC and at 42 centres in Germany

**Inclusion criteria:**

- Patients ≥ 18 years
- Patients with diagnosis of left-sided colitis or pancolitis and currently in relapse (SCCAI ≥ 5)
- Signed patient consent declaration

**Primary objective:** prospective evaluation of GIUS in disease course control of UC patients in routine medical practice.

**US parameters:** increased bowel wall thickness (BWT), loss of bowel wall stratification, loss of haustration, mesenteric fibro-fatty proliferation and/or masses, mesenteric lymphadenopathy, ascites, and vascularity within the affected bowel wall areas are qualitatively assessed by duplex US.

**Laboratory and clinical parameters:** CRP, FC, white blood cell count (WBC), platelets, change in UC-specific medication and SCCAI are measured.

N=253 patients with UC and SCCAI ≥ 5

*patients without a BWT at T0/baseline were documented, but excluded from the study for further documentation.
Results – Baseline

- **29.0 % (65/224) received** an anti-TNF therapy (adalimumab, golimumab or infliximab) **at least at one time point** during study.

- All patients (65/65) had a bowel wall thickening in the sigmoid colon or descending colon.

Patient demographics and characteristics at baseline (N=65)

<table>
<thead>
<tr>
<th>Age [years, mean ± SD]</th>
<th>37.3 ± 12.9</th>
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<tbody>
<tr>
<td>Male [%]</td>
<td>56.9</td>
</tr>
<tr>
<td>Time till diagnosis [months, mean ± SD]</td>
<td>7.56 ± 8.39</td>
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<tr>
<td>SCCAI</td>
<td>9.52 ± 2.62</td>
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<tr>
<td>CRP [mg/dL, mean ± SD]</td>
<td>3.91 ± 6.07</td>
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<tr>
<td>FC [µg/g, mean ± SD]</td>
<td>1,609 ± 1,721.7</td>
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Results – Change in GIUS parameters over the study period

- **Loss of haustration**: ***p<0.001, #p=0.001; Chochran-Q-test**
- **Loss of bowel wall stratification**: p=0.060
- **BWT**: **Baseline N=65**, **T1 (6 weeks) N=61**, **T2 (12 weeks) N=55**

***p<0.001, #p=0.001; Chochran-Q-test**

BWT, bowel wall thickening
Results – Change in BWT over the study period

- Normalisation of BWT: N=61
- Reduced BWT
- Increasesd BWT
- No change in BWT

BWT, bowel wall thickening
Results – Change in SCCAI during study period

![Graph showing change in SCCAI over time]

- **All patients**
  - Baseline: N=224
  - T1 (6 weeks): 189
  - T2 (12 weeks): 179

- **Anti-TNF treated patients**
  - Baseline: N=65
  - T1 (6 weeks): 61
  - T2 (12 weeks): 55
Results – Correlation of SCCAI and vascularisation

Vascularisation

No vascularisation

Baseline

T1 (6 weeks)

T2 (12 weeks)

SCCAI

N= 43

N= 22

N= 18

N= 47

N= 13

N= 52

*Outlier value: 1.5 – 3 fold box length

*Extreme value: > 3.0 fold box length
Conclusion

We demonstrated that anti-TNF treatment results in normalisation/reduction of BWT in a majority of UC patients as early as 6 weeks after start of anti-TNF therapy

GIUS is useful in early monitoring of therapy response to anti-TNF therapy in UC patients enabling a non-invasive, easy and repeatable mean of tight control in daily practice