



## Posters

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## A Case of Pleural Effusion in IBD: extraintestinal presentation, treatment complication, or something else?

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### Introduction

Inflammatory bowel disease (IBD) is systemic disease that manifest not only in the gastrointestinal tract but also in the extraintestinal organs ( mostly involving the skin, eyes, joints, hepatobiliary system and rarely the pulmonary, cardiac and nervous system).

### Case presentation

A 58-year-old male is being followed up in our IBD outpatient clinic due to ulcerative colitis.

He was diagnosed with ulcerative proctosigmoiditis at the age of 42 and was treated intermittently with mesalazine.

At the age of 40, he was also diagnosed with sarcoidosis, for which he was treated with systemic corticosteroids and methotrexate.

In 2024, he was hospitalized in our hospital due to an acute flare of ulcerative pancolitis. At the same time, pulmonologists ruled out latent tuberculosis and active sarcoidosis. Treatment with systemic corticosteroids in tapering doses was initiated, followed by biological therapy with infliximab, after which the symptoms of ulcerative colitis subsided.

During follow-up visits, the patient began reporting progressive dyspnea and chest pain. A CT angiography of the pulmonary arteries was performed, which ruled out pulmonary embolism. A small left-sided pleural effusion was seen, along with enlarged lymph nodes and infiltrates in the apical regions of the lungs.

He was re-hospitalized in the pulmonary department, where cytological analysis confirmed a lymphocytic pleural effusion and tuberculosis was excluded.

During further outpatient follow-up, the patient reported additional symptoms: fatigue, dizziness, more frequent bowel movements, pain in small joints, and a facial rash. Laboratory results showed worsening kidney function, mildly elevated CRP, abnormal liver function tests consistent with hepatocellular damage, a marked increase in fecal calprotectin, and low infliximab levels. On follow-up colonoscopy, erythema of the rectal mucosa, scarring from previous inflammation, and pseudopolyps were observed.

The patient was re-discussed at the IBD multidisciplinary team meeting due to ineffective treatment. A switch to a JAK inhibitor was recommended. Due to the newly described symptoms, serological testing for SLE and a rheumatology consultation were also advised. Diagnostics are ongoing...



Figure 1: A CT scan showing left side pleural effusion

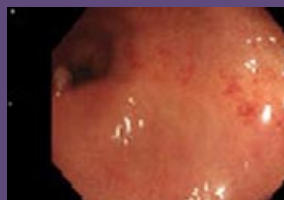


Figure 2: endoscopy showing active proctitis

Figure 3: Laboratory results in last visit

### The literature review

The pulmonary complications include inflammation of small and large airways, pulmonary parenchymal disease, serositis and pulmonary embolism and are usually associated with the ongoing inflammation of the underlying IBD, which is not a prerequisite [1,2].

Lymphocytic pleural effusion is an exudate with predominance of lymphocytes among white blood cells (more than 50%). The main causes of most lymphocytic effusions are malignomas and tuberculosis. The other common causes are virus or mycotic infections, sarcoidosis, autoimmune (rheumatoid arthritis, systemic lupus erythematosus... ) and systemic disease (congestive heart failure, renal disease, liver cirrhosis...), drug related (chemotherapeutics, mesalazine...), after trauma or operative procedures [3].

### Conclusion

It is imperative for clinicians to maintain a high index of suspicion for the development of pulmonary disease in the setting of IBD in order to recognise and institute prompt and appropriate treatment early with avoiding further complications and morbidity.

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# A rare case of primary true enterolithiasis presenting with large bowel obstruction in a patient with prior bowel resection and newly confirmed Crohn's disease

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## BACKGROUND

Enterolithiasis refers to hard, dense masses within the bowel that may lead to obstruction. Enteroliths are classified as primary or secondary. Secondary enteroliths originate outside the gastrointestinal tract and migrate into the bowel, most commonly as gallstones. Primary enteroliths are subdivided into true and false types. True primary enteroliths form within the bowel from luminal substances in areas of anatomical alteration and stasis. Their composition varies by location: proximal small intestine stones are typically composed of cholic acid, while distal small intestine stones often contain calcium phosphate, calcium oxalate, or calcium carbonate. Enteroliths are most frequently observed in post-surgical patients, particularly at side-to-side or end-to-side anastomoses. Stenosing Crohn's disease is a recognized risk factor, with stones commonly forming in aneurysmal, saccular, or dilated segments. Rarely, enteroliths can cause acute bowel obstruction.



Figure 1: Abdominal X-ray with a stone in the projection of pelvis



Figure 2-3: Abdominal CT showing two calcified enteroliths



Figure 4: Mucosal inflammation in terminal ileum at endoscopy

## CASE PRESENTATION

A 58-year-old female was admitted to our ward with subacute diarrhea and signs of bowel obstruction. Her history included a partial large bowel resection with a caeco-sigmoid anastomosis due to acute bowel obstruction caused by multiple intramucosal lipomas. Five years prior, she underwent balloon dilatation of the anastomosis for symptomatic stenosis. On admission, she reported diarrhea lasting nearly four weeks, associated with nausea, and on the day of admission she experienced fever (38.5°C) and chills. Physical examination revealed a febrile patient with a distended, diffusely tender abdomen and hyperactive bowel sounds. A plain abdominal X-ray demonstrated a 6 cm-wide colonic loop in the right lower quadrant, borderline dilated small bowel loops, and a ~40 mm calcified mass in the pelvic cavity. Subsequent abdominal CT revealed obstruction of the cecum and an additional 20 mm calcified lesion in the pelvis, with no signs of perforation. Given a presumed diagnosis of anastomotic stenosis, a colonoscopy with possible balloon dilatation was planned. Endoscopic examination revealed a narrowed anastomosis with a lumen of approximately 8 mm; dilation was performed using a TTS balloon up to 12 mm. Upon passing the anastomosis with a therapeutic gastroscope, a large enterolith was visualized. Ulcerations were observed at the Bauchin valve and in the small bowel, from which biopsies were taken. The large enterolith was considered the likely cause of obstruction, and lithotripsy was attempted. The stone was extremely hard, and each attempt at partial fragmentation, although successful, resulted in damage to the lithotripter. The second calcified lesion was not identified during the procedure. Post-procedure, the patient's symptoms rapidly resolved, and she was discharged four days later. Stone analysis confirmed a calcium phosphate composition, and histology of the ileum revealed features consistent with Crohn's disease. Three weeks later, the patient remained asymptomatic, and a second colonoscopy was performed to fragment the remaining stone.



Figure 5: Endoscopic balloon dilatation of postoperative large bowel stenosis



Figures 6-9: Endoscopic lithotripsy of enteroliths in the large bowel

## CONCLUSION

Enterolithiasis is a rare but important cause of bowel obstruction, particularly in patients with prior bowel surgery or anatomical alterations. In our case, the obstruction was successfully managed endoscopically, avoiding the need for surgery. However, due to the patient's underlying Crohn's disease and anatomical predisposition, she remains at risk for recurrence. Careful follow-up and monitoring are therefore essential to promptly identify and manage any future episodes. This case highlights that with timely endoscopic intervention, even large and hard enteroliths can be treated non-surgically.

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## CLINICAL DECISION SUPPORT TOOL FOR VEDOLIZUMAB CAN PREDICT TREATMENT PERSISTENCE IN CROHN'S DISEASE BUT NOT IN ULCERATIVE COLITIS

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### Background:

Vedolizumab (VDZ) has displayed up to 82.9% treatment persistence as a first-line biologic for ulcerative colitis (UC) and ranked third in the second line. It ranked fourth in treatment persistence as the first or second-line biological therapy in Crohn's disease (CD) (1,2). Factors most commonly associated with treatment outcomes have been indicators of more aggressive disease, like refractoriness to corticosteroids and tumour necrosis factor (TNF) alpha inhibitors, elevated baseline patient-related outcomes (PROs), comorbidities in CD and faecal calprotectin (2,3). Pre-treatment prediction of response and long-term persistence could help optimise treatment in an individual patient.

### Methods:

We performed a retrospective single-centre cohort study based on the UR-CARE registry. Data for 129 patients treated with VDZ from July 2016 until April 2023 were analysed. A validated clinical decision support tool (CDST) for CD and UC was used to stratify patients according to the probability of response to VDZ (4,5). We used Kaplan-Meier survival curves to analyse treatment persistence at week 52, depending on the CDST group for CD and UC. The association between the CDST group and the optimisation of VDZ therapy was evaluated using the  $\chi^2$  test.

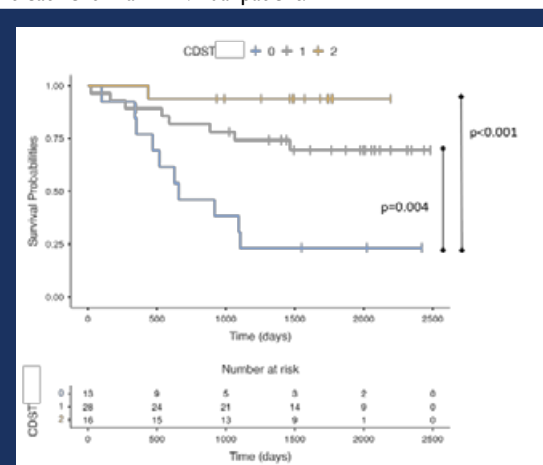


Figure 1: Treatment persistence in Crohn's disease

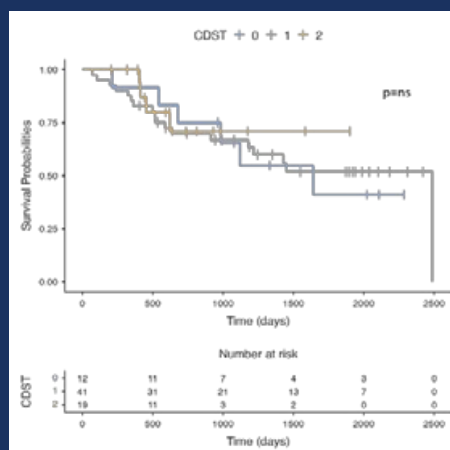


Figure 2: Treatment persistence in ulcerative colitis

### Results:

The study included 57 CD patients (median age 34 years, 38.6% male), and 72 UC patients (median age 32.1 years, 59.7% male). Patients with CD had longer disease duration (4.1 years) than UC patients (2.6 years). 33.3% of CD patients had ileo-colonic disease, 24.6% had upper GI involvement, 33.3% had fistulising disease, and 56.1% had prior surgery. 63.9% of patients with UC had pancolitis, and 34.7% had concomitant corticosteroids at baseline. Before VDZ, more than half of patients were exposed to TNF alpha inhibitors in both CD and UC (57.9% and 52.8%, respectively). We found significantly higher **treatment persistence in CD** patients stratified into groups with intermediate (group 1) and high (group 2) probability of response, according to CDST compared to the group with low (group 0) probability of response. The VDZ therapy was discontinued in 76.9%, 28.6% and 6.3% of patients within CDST groups 0, 1, and 2, respectively. The association was statistically significant ( $p < 0.001$ ) (figure 1).

We could not confirm any significant difference in **treatment persistence in UC** between CDST groups. The VDZ therapy was discontinued in 50.0%, 34.9%, and 21.9% in groups 0, 1, and 2, respectively. While the trend between discontinuation of VDZ and CDST groups can be observed, the association was not statistically significant ( $p = 0.165$ ) (figure 2).

### Conclusions:

In our study, treatment persistence for VDZ could be predicted using CDST for CD, but not for UC.

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## CLINICAL DECISION SUPPORT TOOL FOR VEDOLIZUMAB COULD NOT PREDICT OUTCOME IN ULCERATIVE COLITIS PATIENTS – A RETROSPECTIVE REAL-LIFE SINGLE-CENTRE COHORT STUDY

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### Background:

Early intervention with biologics can slow the progression of ulcerative colitis (UC), thus improving long-term outcomes (1). As treatment options in UC expand, the positioning of advanced therapies is becoming more important. The ability to identify patients with UC who are more likely to respond well to a specific drug before initiation of treatment could help physicians navigate within the proposed treatment algorithm. Dulai *et al.* derived and validated a clinical decision support tool (CDST) for the prediction of response to vedolizumab (VDZ) in UC (2).

### Methods:

We performed a retrospective single-centre cohort study based on UR-CARE registry data. Data for 72 UC patients treated with VDZ from July 2016 until April 2023 were analysed. CDST for UC was calculated using four variables: absence of exposure to a tumour necrosis factor (TNF) alpha inhibitor, disease duration of  $\geq 2$  years, moderate baseline endoscopic activity and baseline albumin concentration. Patients were then stratified into three probability groups: group 0 with low ( $\leq 26$  points), group 1 with intermediate (27 to  $\leq 32$  points) and group 2 with high ( $> 32$  points) probability of response (2). To test the association between CDST, clinical remission (CR) (defined as PRO2  $\leq 1$  with rectal bleeding score 0), corticosteroid-free remission (CSFR) and endoscopic activity (defined as no change in endoscopic activity, endoscopic improvement (EI) (change of endoscopic Mayo of  $\geq 1$ ), or endoscopic remission (ER) (endoscopic Mayo  $\leq 1$ ))  $\chi^2$  test was used. The difference in fecal calprotectin (FC) depending on whether VDZ was continued or not was tested by the Mann-Whitney U test.

Table 1: Demographic data and disease characteristics

	UC (n=72)
Gender	
• male; n (%)	43 (59.7%)
• female; n (%)	29 (40.3%)
Age at diagnosis (years)	median=32.1 (34.8 $\pm$ 16.0)
Disease duration (years)	median=2.6 (2.9 $\pm$ 1.9)
Disease location (Montreal classification)	E1: n=0 (0%) E2: n=26 (36.1%) E3: n=46 (63.9%)
Prior surgery	2 (2.8%)
Concomitant CS therapy (n, %)	25 (34.7%)
Previous exposure to anti-TNF therapy (n, %)	38 (52.8%)
Baseline CRP (mg/L)	median=5 (10.3 $\pm$ 12.9)
Baseline albumin (g/L)	median=38.2 (38.0 $\pm$ 4.62)
Probability of response to vedolizumab	
Low (n, %) (CDST group = 0)	n=12; 16.7%
Medium (n, %) (CDST group = 1)	n=41; 56.9%
High (n, %) (CDST group = 2)	n=19; 26.4%
Duration of follow-up (months)	median=9.9 (11.5 $\pm$ 8.7)

UC = ulcerative colitis, CS = corticosteroid, CRP = C-reactive protein, CDST = clinical decision support tool

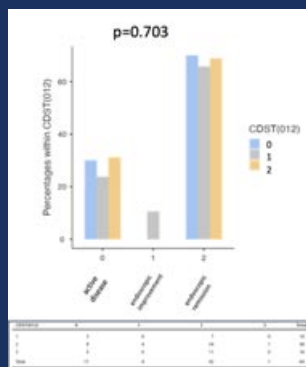


Figure 1: CDST groups according to endoscopic activity

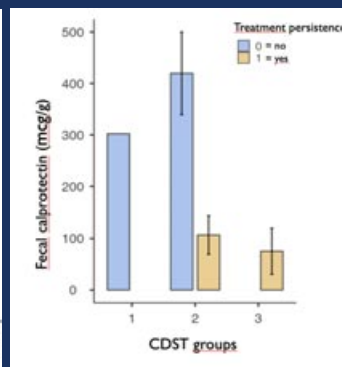


Figure 2: Fecal calprotectin according to CDST groups

### Results:

We found no statistically significant association between the CDST group and CR or CSFR at weeks 14 and 52 nor endoscopic activity at follow-up endoscopy. All patients in group 2 responded with lowering of FC 3-6 months after initiating VDZ and continued treatment. Also, patients in CDST group 1 who experienced lowering of FC continued VDZ therapy. In contrast, all patients in CDST group 0 and patients in group 1 who had persistently elevated FC eventually failed VDZ regardless of optimisation. The difference in FC between those who discontinued VDZ and those who did not was statistically significant ( $p=0.004$ ).

### Conclusions:

Our results did not confirm the predictive value of existing CDST for VDZ in UC patients. Novel prediction tools in UC are needed.

### Literature:

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# CLINICAL DECISION SUPPORT TOOL FOR VEDOLIZUMAB IS USEFUL IN PREDICTING ENDOSCOPIC REMISSION IN CROHN'S DISEASE – A RETROSPECTIVE REAL-LIFE SINGLE-CENTRE COHORT STUDY

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## Background:

Early control of inflammation could modify the disease course and improve outcomes in patients with Crohn's disease (CD). Positioning of advanced therapies is becoming more important as treatment options expand (1). Dulai *et al.* derived and externally validated a clinical decision support tool (CDST) for predicting response to vedolizumab (VDZ). They noticed that the high probability group, according to CDST, has the highest probability of achieving clinical remission (CR), corticosteroid-free remission (CSFR) and mucosal healing. In contrast, low and intermediate-probability groups are more likely to need surgery (2,3).

## Methods:

We performed a retrospective single-centre cohort study based on the UR-CARE registry. Data for 57 CD patients treated with VDZ from July 2016 until April 2023 were analysed. We stratified patients according to CDST for CD into three response probability groups: group 0 with low ( $\leq 13$  points), group 1 with intermediate (14-19 points) and group 2 with high ( $> 19$  points) probability of response to VDZ. CDST was calculated using five variables: no prior bowel surgery, no prior tumour necrosis factor (TNF) alpha antagonist exposure, no prior fistulising disease, baseline albumin and baseline C-reactive protein (CRP) (2). For analysis of the association between CDST, CR (defined as PRO2  $\leq 4$  (abdominal pain  $\leq 1$  and stool frequency  $\leq 3$ )), CSFR and endoscopic activity (defined as no change in endoscopic activity, endoscopic improvement (EI) (improvement of at least 50%), or endoscopic remission (ER) (no ulcers))  $\chi^2$  test was used.

## Results:

We found a significant association between the CDST group and endoscopic activity at follow-up endoscopy but no statistically significant association between the CDST group and CR nor CSFR at weeks 14 and 52. The majority (69.2%) of patients stratified into CDST group 0 had endoscopically active disease, while in contrast, 68.8% of patients in CDST group 2 achieved ER. In group 1, EI was found in 45.8% and ER in 41.7% of patients.

## Conclusions:

In our retrospective study, CDST for VDZ predicted ER and EI in our cohort of patients with CD. We could not confirm the association between CDST and CR or CSFR, probably due to the definition used in a retrospective design, namely PRO2, which does not correlate well with endoscopic activity in CD (4).

Table 1: Demographic data and disease characteristics

	CD (n=57)
Gender	22 (38.6%)
• male; n (%)	35 (61.4%)
• female; n (%)	
Age at diagnosis (years)	median=34 (36.0 $\pm$ 15.8)
Disease duration (years)	median=4.1 (3.7 $\pm$ 1.9)
Disease location (Montreal)	L1; n=11 (19.3%) L2; n=13 (22.8%) L3; n=19 (33.3%) +L4; n=14 (24.6%)
Fistulizing disease (n, %)	19 (33.3%)
Prior surgery	32 (56.1%)
Concomitant CS therapy (n, %)	8 (14%)
Previous exposure to anti-TNF therapy (n, %)	33 (57.9%)
Baseline CRP (mg/L)	median=6 (12.8 $\pm$ 15.8)
Baseline albumin (g/L)	36.8 $\pm$ 4.66 (median=37.0)
Probability of response to vedolizumab	
Low (n, %) (CDST group = 0)	n=13; 22.8%
Medium (n, %) (CDST group = 1)	n=28; 49.1%
High (n, %) (CDST group = 2)	n=16; 28.1%
Duration of follow-up (months)	27.4 $\pm$ 19.5 (median=24.2)

CD = Crohn's disease, CS = corticosteroid, CRP = C-reactive protein, CDST = clinical decision support tool

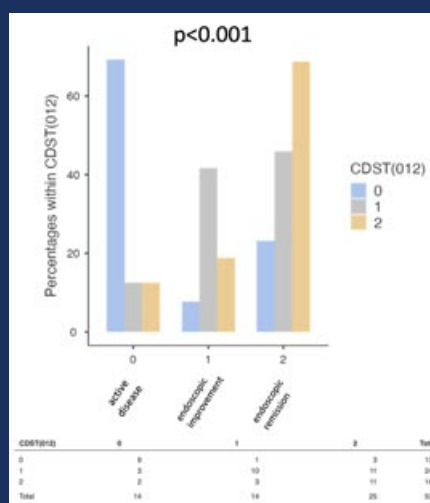


Figure 1: CDST groups according to endoscopic activity

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# COMPARISON OF PATIENTS IN ROUTINE CLINICAL PRACTICE AND PATIENTS INCLUDED IN RANDOMIZED TRIALS OF DRUGS FOR INFLAMMATORY BOWEL DISEASE: DISEASE COURSE AND TREATMENT OUTCOMES

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**BACKGROUND:** New advanced drugs for the treatment of chronic inflammatory bowel disease (IBD) are being tested in randomized clinical trials. Previous Slovenian studies have shown that only one-third of IBD patients in everyday clinical practice are eligible for inclusion in randomized clinical trials. This calls into question the transferability of clinical trial results to clinical practice.

**AIM:** Determine differences between trial eligible and ineligible patients.

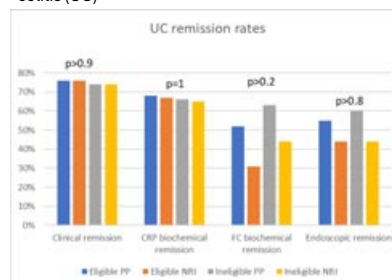
**METHODS:** The clinical study is retrospective and comparative. The sample consisted of adult patients who were treated at the chronic inflammatory bowel disease consortium in Ljubljana in 2022. We obtained data on demographic and clinical characteristics, target therapy replacement, surgeries, hospitalizations, glucocorticoid initiation, and deaths within one year after the consortium, as well as data on remission of different types one year after the council. We compared the data of patients suitable for inclusion with the data of those unsuitable.

**RESULTS:** We analyzed data from 111 patients with ulcerative colitis (UC) and 142 patients with Crohn's disease (CD). No significant demographic or clinical differences were found. Analysis of treatment outcomes is shown in graphs 1 and 2, for UC and CD respectively.

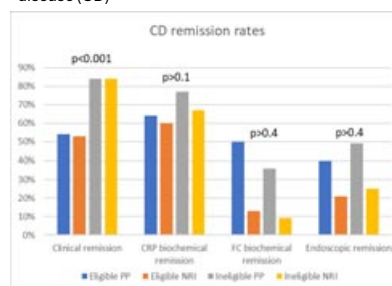
Similar analysis was performed for disease course and is shown in graphs 3 and 4.

**CONCLUSIONS:** Trial eligible and trial ineligible patients with IBD don't differ in clinical and demographic characteristics. Real world use of biologics does not show inferior efficacy, with only minor differences in safety between trial eligible and ineligible.

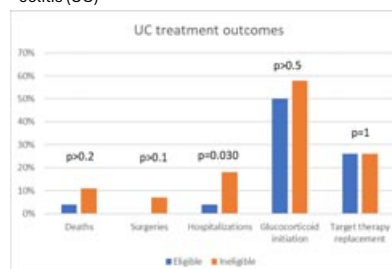
Graph 1: Comparison of remission rates in ulcerative colitis (UC)



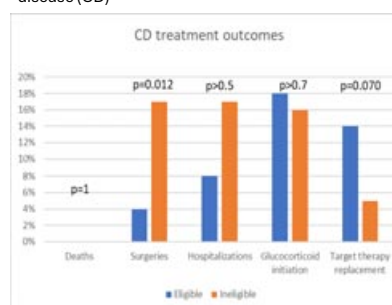
Graph 2: Comparison of remission rates in Crohn's disease (CD)



Graph 3: Comparison of outcomes in ulcerative colitis (UC)



Graph 4: Comparison of outcomes in Crohn's disease (CD)



# Determining the Success of the Treatment of Inflammatory Bowel Disease with Ustekinumab as a First-Line Advanced Therapy

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University Medical Centre Ljubljana

## Background

In recent years, there have been several new treatment options for inflammatory bowel disease (IBD). Tumour necrosis factor  $\alpha$  (TNF- $\alpha$ ) inhibitors have been joined by novel advanced therapies, including ustekinumab (UST). These drugs are mostly used as second-line treatment after TNF- $\alpha$  inhibitors, with subsequent lower efficacy. There are few data available on the efficacy of treatment with UST in biologically naïve patients. We aimed to assess the efficacy of UST in biologically naïve patients in a retrospective cross-sectional study at a tertiary referral IBD centre (University Medical Centre Ljubljana, Slovenia).

## Methods

- Retrospective cross-sectional study
- 71 biologically naïve patients who started first-line treatment with UST were included (60 patients with Crohn's disease (CD), 11 patients with ulcerative colitis (UC))
- Determining treatment persistence
- Determining treatment efficacy based on clinical, biochemical and endoscopic parameters (three timelines)
- Determining the correlation between serum concentration of UST and remission

## Results

- One-year treatment persistence: 88% (92% for CD, 82% for UC)
- Two-year treatment persistence: 72% (74% for CD, 68.5% for UC)

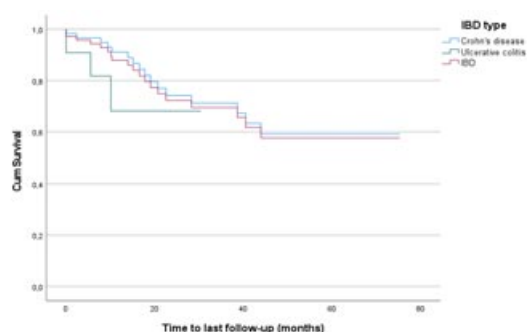


Figure 1. Kaplan-Meier curve of UST treatment persistence.

Table 1. Percentage of patients who achieved remission. All data refer to the last follow-up. IBD – inflammatory bowel disease, CD – Crohn's disease, UC – ulcerative colitis, CRP – C-reactive protein, FC – faecal calprotectin.

Clinical remission for CD: absence of abdominal pain and liquid stools

Clinical remission for UC: pMayo score  $\leq 1$

Biochemical remission: CRP  $\leq 5$  mg/l or FC  $< 100$  mg/kg

Endoscopic remission for CD: absence of ulcers at endoscopy

Endoscopic remission for UC: Mayo score  $\leq 1$

Type of remission	IBD (%)	CD (%)	UC (%)
Clinical	44.3	41.2	90.9
Biochemical (CRP)	77.6	75.4	90.0
Biochemical (FC)	71.1	71.4	70.0
Endoscopic	58.3	58.1	60.0

- No significant difference between the median serum concentrations of UST in the group of patients who achieved remission and who did not achieve remission

Table 2. Comparison of median UST serum concentration in the group of patients who achieved remission and who did not achieve remission. Me – median, UST – ustekinumab, CRP – C-reactive protein, FC – faecal calprotectin.

Type of remission	Me UST serum concentration in group of patients who achieved remission ( $\mu\text{g/ml}$ )	Me UST serum concentration in group of patients who did not achieve remission ( $\mu\text{g/ml}$ )	p-value
Clinical	5.86	5.31	0.689
Biochemical (CRP)	5.93	3.25	0.476
Biochemical (FC)	5.63	4.47	0.412
Endoscopic	7.14	4.64	0.439

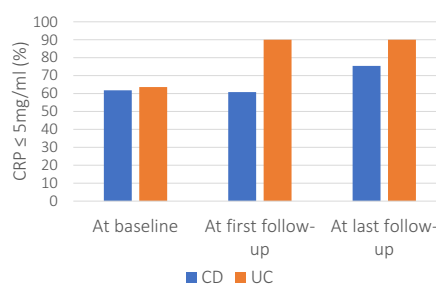


Figure 2. Percentage of patients who achieved biochemical remission according to C-reactive protein (CRP) levels at baseline, at first and last follow-up. CD – Crohn's disease, UC – ulcerative colitis.

First follow-up: median 3.7 months (IQR 3.5–3.9 months).

Last follow-up: median 16.8 months (IQR 7.8–38.0 months).

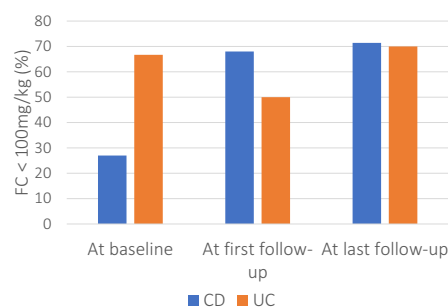


Figure 3. Percentage of patients who achieved biochemical remission according to faecal calprotectin (FC) levels at baseline, at first and last follow-up. CD – Crohn's disease, UC – ulcerative colitis.

First follow-up: median 3.7 months (IQR 3.7–3.8 months).

Last follow-up: median 17.0 months (IQR 6.2–29.6 months).

## Conclusions

- The persistence of UST treatment in biologically naïve patients is high. Compared to the data in literature, it's higher than the persistence in second- or third-line treatment.
- With the use of UST as the first-line treatment, high rates of clinical, biochemical and endoscopic remission are achieved.

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The authors have no potential conflict of interest to disclose.

SLOVENSKO ZDRUŽENJE  
ZA GASTROENTEROLOGIJO  
IN HEPATOLOGIJO

# EFFICACY AND CONSUMPTION OF GOLIMUMAB IS SIMILAR WITH EUROPEAN AND AMERICAN DOSING REGIMENS IN ULCERATIVE COLITIS: RESULTS OF A PROSPECTIVE STUDY

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## BACKGROUND AND AIM:

- ▶ Golimumab maintenance dose for patients weighing  $\leq 80$  kg differs in European Union (EU) (= 50 mg every 4 weeks) and United states of America (US) (= 100 mg every 4 weeks).
- ▶ But is efficacy, safety and drug consumption **the same after 1 year of treatment?**

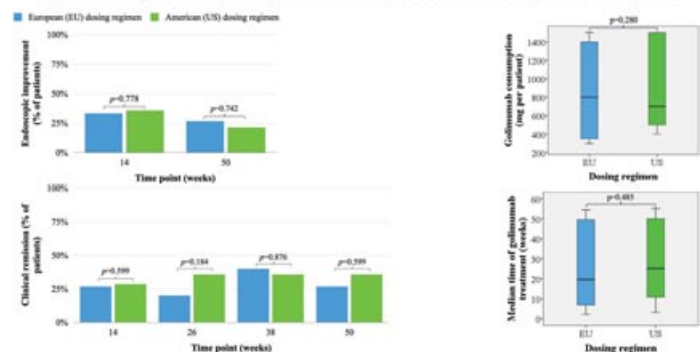
## MATERIAL AND METHODS:

- ▶ Prospective multicenter study of 29 patients  $\leq 80$  kg with ulcerative colitis.
- ▶ The same induction of golimumab and different 1 year maintenance regimen:
  - ▶ US (52 %): 100 mg every 4 weeks,
  - ▶ EU (48 %): 50 mg every 4 weeks:
    - ▶ Inadequate or loss of response in EU patients increase to 100 mg every 4 weeks.
- ▶ Co-primary endpoints: **endoscopic improvement and clinical remission.**

	European (EU) dosing regimen*	American (US) dosing regimen**	All patients	p-value
Number of patients	14	15	29	/
Sex, patient number (%)				
Male	4 (28.6)	5 (33.3)	9 (31.0)	/
Female	10 (71.4)	10 (66.7)	20 (67)	/
Age at diagnosis (years, median with range)	25 (14 – 53)	36 (17 – 66)	31 (14 – 66)	0.012
Maurot disease extent, number of patients (% per group)				
E1 (proctitis)	2 (13.3)	6 (40)	8 (27.6)	/
E2 (left-sided)	10 (66.6)	4 (26.7)	14 (48.3)	/
E3 (extensive)	2 (13.3)	5 (33.3)	7 (24.1)	/
Age at the start of golimumab treatment, median in years (range)	34 (18 – 58)	47 (19 – 71)	40 (19 – 71)	0.007
Treatment at the start of golimumab, number of patients (% per group)				
Aminosalicylates	11 (78.6)	10 (66.6)	21 (72.4)	0.474
Systemic steroids	6 (42.9)	4 (26.7)	10 (34.4)	0.359
Local steroids	1 (7.1)	2 (13.3)	3 (10.3)	0.584
Azathioprine	0 (0)	3 (20)	3 (10.3)	0.077

\* EU: 50 mg of golimumab every 4 weeks with option of reactive dose escalation to 100 mg in case of inappropriate response  
 \*\*US: 100 mg of golimumab every 4 weeks

Figure 1: Efficacy and consumption of golimumab in European vs. American dosing maintenance regimens



## RESULTS:

- ▶ Patient demographic data (Table 1).
- ▶ Endoscopic improvement and clinical remission rates were similar in EU and USA maintenance regimens (Figure 1).
- ▶ 8/14 (57%) of patients in EU regimen needed dose escalation to 100 mg due to inadequate response.
- ▶ Drug persistence and drug consumption were similar in both maintenance regimens (Figure 1).
- ▶ In the US regimen 3 potentially drug-related side effects occurred, none in the EU regimen.

## CONCLUSIONS:

- ▶ EU and US golimumab maintenance regimens resulted in **similar endoscopic improvement and clinical remission rates** in UC with body weight  $\leq 80$  kg
- ▶ Due to high dose escalation rates in EU regimen **dose consumption was similar** in both maintenance regimens.

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# Experiences in the Management of Pregnancy and Pregnancy Outcomes of Women with IBD on Biologic Therapies

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## 1 Introduction

The diagnosis of IBD raises many questions; these include concerns about sexuality, disease heritability, and the impact of medications and disease activity on fertility, pregnancy outcomes, and lactation. Uncertainty about the health of the offspring may influence patients' choices in family planning. Therefore, the management of patients who wish to conceive or who are pregnant requires specialized counseling and appropriate management. (1) In our center, we currently manage 399 patients undergoing advanced therapies. This study provides an overview of the management of pregnant women with IBD in our center, with a focus on pregnancy outcomes.

## 2 Objectives

The objective of this study was to collect and analyze data on women with IBD who conceived while receiving biologic therapy or were treated with it during pregnancy. We aimed to evaluate:

- pregnancy outcomes, including mode of conception,
- disease activity during pregnancy,
- treatment strategies,
- mode of delivery,
- neonatal outcomes and breastfeeding practices.

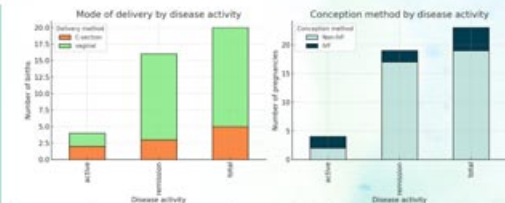
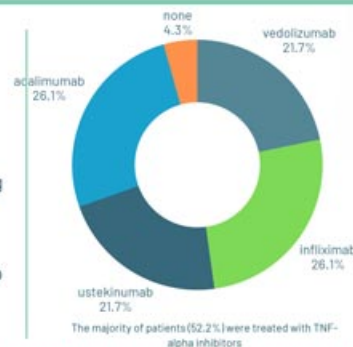
## 3 Methodology

We performed a retrospective, single-center study, including women with IBD who conceived while receiving biologic therapies or were treated with them from 2017 to 2025.

Clinical data were collected from patient records or additional interviews and included maternal age, disease activity at conception and during pregnancy, and type of biologic therapy. Pregnancy-related variables comprised mode of conception, type of delivery, gestational age at delivery, and pregnancy complications. Neonatal outcomes included sex, birth weight, and complications after birth. Breastfeeding practices after delivery were also recorded. Data were analyzed using appropriate statistical tests.

## 3 Results

- 7 women conceived and carried their pregnancies.
- A total of 20 children have been born to date, and one pregnancy was electively terminated following the prenatal diagnosis of a genetic abnormality.
- 11 women had one child, one woman gave birth to twins, and two women have three children.
- 3 women are currently pregnant.



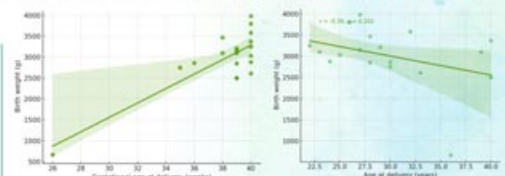
Cesarean section was more frequent in women with active disease compared to those in remission (50% vs. 19%), although the difference did not reach statistical significance ( $p = 0.25$ ). Regarding conception, 4 pregnancies occurred after IVF and 19 were spontaneous or natural.

Women with active disease were more likely to require IVF compared to those in remission (50% vs. 11%), but again, this difference was not statistically significant ( $p = 0.12$ ).

The majority of patients (15/23, 65%) were during pregnancy followed in a specialized high-risk pregnancy clinic, while 26% were not, and data were unavailable for 9%. Breastfeeding was reported in 75% of women, while 25% did not breastfeed (data available for 20 out of 23 pregnancies).

Biologic therapy was discontinued following established protocols, except for two patients who independently discontinued treatment during the second trimester, deviating from the recommended regimen.

- The mean gestational age at the time of the last biologic administration was  $31.9 \pm 7.5$  weeks (median 36, IQR 32–36; range 15–38;  $n = 17$ ).
- The mean gestational age at delivery was  $38.3 \pm 3.3$  weeks (median 39, IQR 38.5–40; range 26–40;  $n = 19$ ).
- The mean birth weight was  $2982 \pm 693$  g (range 670–3980 g). The median was 3100 g (IQR 2800–3310 g). After exclusion of one extreme outlier (670 g), the mean birth weight was  $3111 \pm 420$  g, with a median of 3100 g (IQR 2853–3340 g; range 2500–3980 g).



The correlation between gestational age at delivery and neonate birth weight

The correlation between neonate birth weight and mother age

The mean maternal age at delivery was  $30.4 \pm 5.6$  years (range 22–40). Maternal age showed a non-significant negative correlation with birth weight ( $r = -0.39$ ,  $p = 0.10$ ) and gestational age at delivery ( $r = -0.25$ ,  $p = 0.30$ ).

These findings suggest a trend towards lower birth weight and slightly earlier delivery in older mothers, although not statistically significant in this cohort.

### THE MAIN EVENTS RECORDED:

- 1 patient, aged 36 years, on VDZ, conceived twins via IVF. Prenatal testing revealed trisomy 21 in one fetus, and the pregnancy was electively terminated. Two weeks after the procedure, spontaneous preterm delivery occurred at 26 weeks of gestation.
- In addition, 1 newborn was diagnosed with a patent foramen ovale; the mother had been treated with VDZ during pregnancy, while her disease remained in remission.
- Biologic therapy was initiated due to disease flare during 1 pregnancy, while 2 additional pregnancies occurred during active disease. 1 patient required methylprednisolone.

## 4 Conclusion

In this retrospective single-center analysis, women with IBD who conceived while on advanced therapy were overall well managed, with the majority maintaining disease remission throughout pregnancy. Most patients adhered to treatment recommendations. Pregnancy and neonatal outcomes were comparable to those reported in the general population, with no clinically significant deviations observed. However, the relatively small cohort size represents a limitation and introduces potential bias; larger studies will be required to confirm these findings.

### Related literature

1 Torres J, et al. European Crohn's and Colitis Guidelines on Sexuality, Fertility, Pregnancy, and Lactation. *J Crohns Colitis*. 2023;17:1-27

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# IMPACT OF FREE CHOICE OF IBD CENTER ON THE WORKLOAD OF NURSES IN A TERTIARY CARE CENTER

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## BACKGROUND:

Inflammatory bowel disease (IBD) is on the rise worldwide, including Slovenia, where approximately 9,000 patients live with the condition and about 100 new cases are diagnosed each year (1). Twelve IBD centers operate in Slovenia, with the tertiary center at the University Medical Centre Ljubljana (UMC Ljubljana) managing the largest patient load. Due to patients' free choice of treatment center, the workload of nurses at the tertiary center exceeds recommended standards, raising concerns about quality and sustainability of care.

## METHODS:

A cross-sectional survey was conducted between June and August 2025 among 356 patients from other regions who sought care at UMC Ljubljana. Data were collected on patients' experiences with regional centers, motives for choosing the tertiary center, and values they prioritize in healthcare.

## RESULTS:

Nearly 40% of patients treated at UMC Ljubljana come from outside the central Slovenian region (Figure 1). Among them, 74% had never visited their regional center. Of those who had, two-thirds rated the regional center as worse, one-third as equivalent, and none as better than the tertiary center. The main reasons for choosing the tertiary center were belief in broader and better treatment (33%) and higher trust (30%) (Table 1). Patients identified professionalism, communication, timeliness, empathy, and continuity of staff as the most important aspects of care (Table 2).

## CONCLUSION:

The voluntary influx of patients into the tertiary center exceeds the international staffing standard (1 nurse per 500 patients)(2), increasing the risk of reduced quality of care and nurse burnout. This highlights a key challenge for the Slovenian healthcare system: strengthening visibility, accessibility, and professional standards of regional centers to ensure high-quality care closer to patients' homes. Adjustments to staffing policies and enhancing the reputation of regional centers could help balance workloads and support sustainable care delivery.

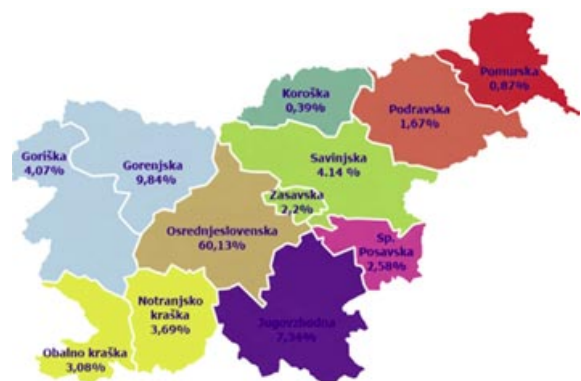


Figure 1: Regional Origin of Patients Treated at the IBD Outpatient Clinic, University Medical Centre Ljubljana (as of 31 August 2025)

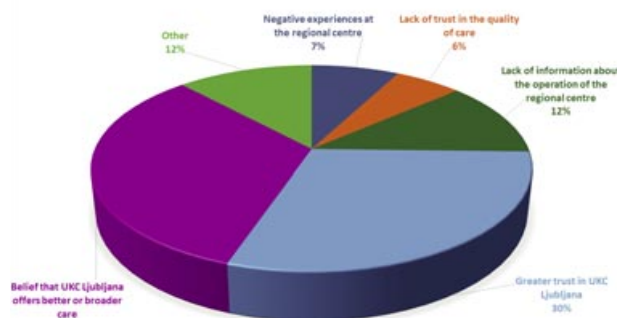


Table 1: Reasons for Choosing a Tertiary IBD Centre Over a Regional Centre

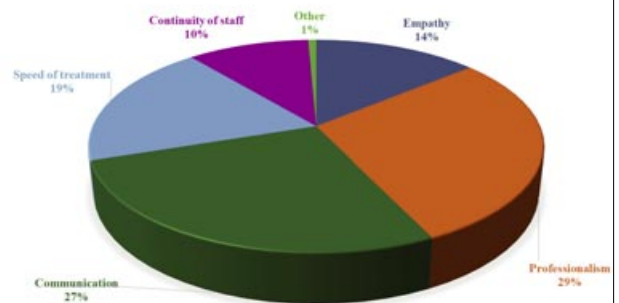


Table 2: What is most important in healthcare?

## REFERENCE:

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2. Leary A, Punshon G. Modelling Caseload Standards for IBD Specialist Nurses in the UK. Crohn's & Colitis UK; 2017. Available from: <https://ibregistry.org.uk/wp-content/uploads/2021/11/Modelling-Caseload-for-IBD-CNS-CCUK-report-2017.pdf>

# Maintenance of IBD remission after switching from IV to SC administration of infliximab



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**Introduction:** Infliximab (IFX) was the first TNF alpha inhibitor approved for treatment of inflammatory bowel disease (IBD). Despite new advanced therapies IFX is still mainstay of treatment in perianal Crohn's disease (CD), acute severe ulcerative colitis (UC) and extraintestinal manifestations. Since 2013 biosimilars of IFX and since 2023 sc formulation of IFX have been available which contributed to cost reduction and potential relief of infusion centers.

**Methods:** We performed a prospective, observational, single center, cohort study in IBD patients treated with IFX. Serum IFX levels were measured with fluorescence immunoassay; ez-Trecker, Theradiag, France.

**Results:** We included 40 patients, demographic data are presented in table 1, disease characteristics in table 2 and prior and baseline treatment in table 3. Persistence of clinical remission at week 24, target serum IFX levels are presented in figures 1-3 and patients' satisfaction and QoL in figure 4.

**Objective:** To switch patients from maintenance IV to SC infliximab at fixed time interval of 4 weeks between last IV and first SC injection.

Table 1: Demographic data

	CD [n=28]	UC [n=12]
Gender, female, n [%]	9 [32.14%]	3 [25%]
Age, mean [SD]	42.5 [11.9]	42.5 [18.3]
Age at diagnosis, mean [SD]	27.04 [10.9]	27.58 [12.4]
Disease duration, years, median [Q1-Q3]	13.5 [0-28]	14.5 [2-28]

Table 2: Disease characteristics

	CD [n=28]	UC [n=12]
Disease localization in CD, n [%]:		
- Ileal [L1]	4 [14.29]	
- Colonic [L2]	5 [17.86]	
- Ileo-colonic [L3]	19 [67.86]	
- Upper GI [L4]	3 [10.71]	
Behaviour classification in CD, n [%]:		
- nonstricturing, nonpenetrating [B1]	4 [14.29]	
- stricturing [B2]	10 [35.71]	
- penetrating [B3]	14 [50]	
Disease extent in UC, n [%]:		
- Proctitis [E1]		0 [0]
- Left-sided [E2]		2 [16.67]
- Pancolitis [E3]		10 [83.33]
Perianal disease, n [%]:	14 [50]	1 [8.33]

Approach to switching in patients on maintenance iv IFX:

IBD patients in remission, including stable perianal disease

Time interval between i.v. and s.c. = 4 weeks

- Independent of IFX type (originator or biosimilar)
- Independent of iv dosing regime (switch to 120 mg or 240 mg sc)

Observed outcomes:

- Clinical disease activity (HBI, p-Mayo)
- Serum IFX levels
- Patient's satisfaction (TSQM-9)
- QoL (Short-IBDQ)

Table 3: Prior and baseline treatment

	CD [n=28]	UC [n=12]
Surgery, n [%]	16 [57.14]	0 [0]
Concomitant immunomodulator, n [%]	25 [89.29]	7 [58.33]
Line of therapy, n [%]		
- first	20 [71.43]	11 [91.67]
- second	6 [21.43]	1 [8.33]
- ≥ 3	2 [7.14]	0 [0]
Prior TNF-α therapy, n [%]	7 [25]	0 [0]
Optimized iv IFX therapy, n [%]	10 [35.71]	6 [50]
Time till starting IFX, months, median [IQR]	83.5 [2-316]	53.5 [2-220]
IFX therapy duration, months, median [IQR]	60 [4-228]	71 [14-179]



Figure 1: Persistence of clinical remission (HBI) in CD

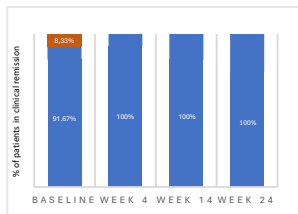


Figure 2: Persistence of clinical remission (pMayo) in UC

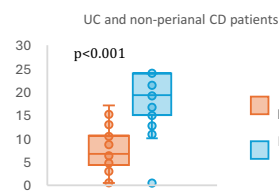
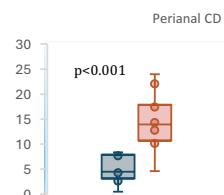


Figure 3: Target serum IFX levels in mg/L

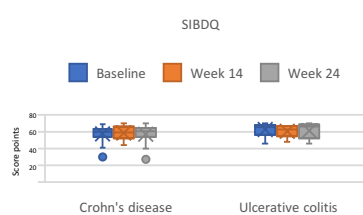
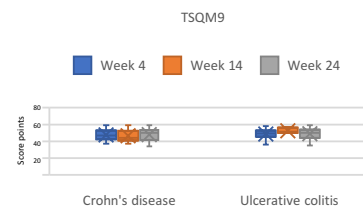


Figure 4: Patients' satisfaction and QoL

**Conclusions:** Time interval 4 weeks between iv and sc IFX administration was appropriate. Target IFX conc. were reached in high number of patients at week 24. In perianal CD treatment persistence after switch to sc IFX was high at week 24. QoL and patients' satisfaction on sc was not inferior to iv administration at week 24.

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# Safe Use of Biologic Therapy in IBD - The Nurse's Perspective



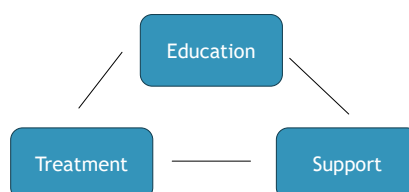
Tamara Zečevič dipl.m.s.

## Role of the Nurse



- Patient education on medication and its effects.
- Teaching proper administration technique (intravenous, subcutaneous).
- Monitoring adherence and potential issues.

## Patient Monitoring



- Baselines tests (tuberculosis, hepatitis).
- Monitoring during treatment: regular blood count, skin, lipids.
- Recognizing signs of infection and act promptly.

## Medication Administration



- IV administration: safe preparation and monitoring during infusion.
- SC administration: Correct injection/pen technique, site rotation.
- Emphasize aseptic technique and safe handling.

## Lifestyle and Self-Care



- Avoid risk foods in individualized diet.
- Moderate regular physical activity.
- Plan rest and relaxation techniques.
- Avoid smoking, alcohol and sun exposure.

## Medication Storage (Cold Chain)



- Storage at 2-8 °C. Always in original packaging, protected from light.
- Transport in cooler bag.

## Nurse's Role in Patient Support

Plays a key role in the safe use of biologic therapies, in monitoring and supporting patients and their families, and in promoting a healthy lifestyle, thereby significantly contributing to a better quality of life for patients with IBD.

# Tracing Transmural Healing in Crohn's Disease with MRI: correlation between MR enterography, laboratory findings and endoscopy

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## Introduction

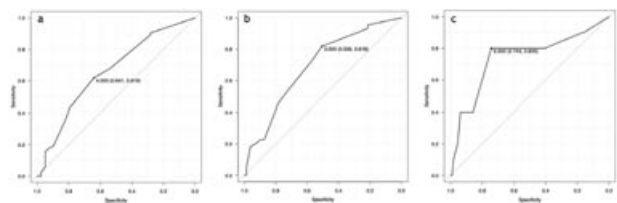
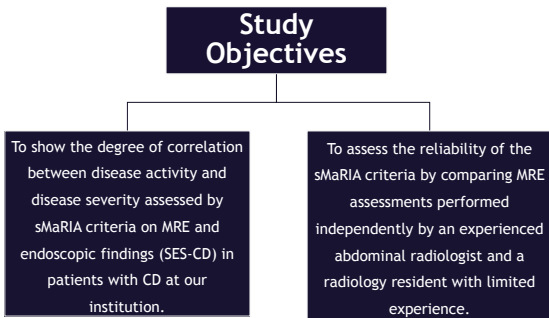
- Crohn's disease (CD) is a chronic inflammatory condition of the gastrointestinal tract, characterized by a relapsing and remitting course. It is a progressive disorder that leads to cumulative bowel damage and long-term disability.
- Magnetic resonance enterography (MRE) is an important tool for diagnosis and management of patients with CD. Several radiological scoring systems are used to assess CD on MRE, primarily to quantify inflammation, guide treatment and monitor disease. Magnetic Resonance Index of Activity (MaRIA) and its simplified form sMaRIA being the most widely used and validated systems.

## Results

SES-CD and sMaRIA score	Spearman's rho	p value	Interpretation
Total	0.344	<0.001	Moderate, statistically significant positive correlation
Terminal ileum	0.476	<0.001	Moderate, statistically significant positive correlation
Ascending colon	0.180	0.061	No statistically significant correlation
Transverse colon	0.485	<0.001	Moderate, statistically significant positive correlation
Left colon and sigmoid	0.479	<0.001	Moderate, statistically significant positive correlation
Rectum	0.234	0.01	Weak, statistically significant positive correlation

### Correlation of endoscopic SES-CD score with radiological MRE sMaRIA score

- Strongest segmental correlations in
  - Terminal ileum
  - Transverse colon
  - Left colon/sigmoid colon
- Rectal segment
  - Weak but significant
- Ascending colon
  - Weak, non-significant



### sMaRIA score prediction of the activity/severity of disease based on the global SES-CD score - sMaRIA showed:

- substantial discriminative ability to distinguish between active and inactive endoscopic activity
- substantial discriminative ability to distinguish between mild and moderate-to-severe endoscopic activity
- moderate discriminative ability to distinguish between severe and non-severe endoscopic activity

## Methods

- We retrospectively evaluated 121 patients with a confirmed diagnosis of CD who underwent both MRE and endoscopy at our institution less than six months apart.
- Patients were selected from our institutional database based on the availability of complete clinical, endoscopic, and radiologic records.
- MREs were independently scored by an abdominal radiologist and a radiology resident using the sMaRIA score for each intestinal segment, while endoscopic findings were reviewed and evaluated using the SES-CD.

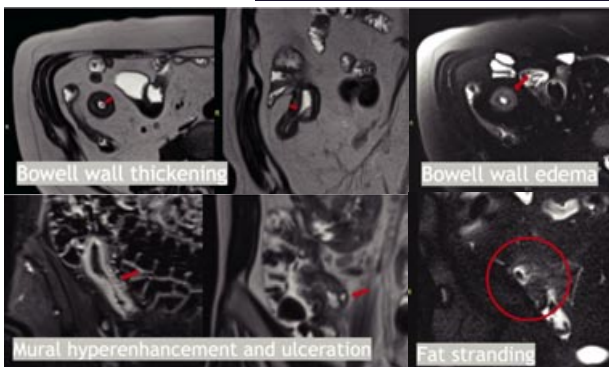
### Interobserver variability of the sMaRIA between a radiology specialist and resident

sMaRIA	Kappa statistics, p=0.001		ICC, p<0.001	
	Kappa value	Interpretation	ICC value, 95% CI	Interpretation
Total	0.738	Statistically significant; almost perfect agreement	0.881-0.921	Strong interobserver correlation

Interobserver variability revealed consistently strong agreement between the radiology specialist and the resident across all intestinal segments.

## Signs of disease activity on MRE

Simplified MaRIA (sMaRIA)			
Bowel wall thickness	Bowel wall edema	Fat stranding	Ulcerations



## Conclusion

- With transmural healing being an emerging treatment target in Crohn's disease → greater importance of cross-sectional imaging
- Endoscopy only assesses mucosal healing; MRE and intestinal ultrasound capture full bowel wall and complications
- Non-invasive imaging is gaining importance for monitoring deep disease activity
- There's a need for simple, reliable MRE scoring systems like sMaRIA for routine clinical use

Our study demonstrated moderate to substantial sMaRIA ability to accurately predict CD activity using SES-CD as a reference. The interrater reliability between a radiology resident and an expert was excellent, supporting sMaRIA as a suitable clinical practice instrument.

# Ustekinumab biosimilar for Crohn's disease – patients' perspective



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**Introduction:** Since august 2024 ustekinumab (UST) biosimilars have become available for treatment of Crohn's disease (CD) in Slovenia. We performed a prospective single centre cohort study on patient's willingness to switch from originator to biosimilar UST and factors influencing the choice of sc applicator type.

**Results:** 43 CD patients treated with UST were included. 22 (51.2%) were female, median age 52 (range 23-79) years, median duration of CD was 16 (range 2-40) years. Lines of therapy with UST are shown in figure 1. 11 (25.6%) patients were anti-TNF naïve. In 26 (60.5%) patients UST dosing was optimised, and 18 (39,5%) patients were treated with standard UST dose.

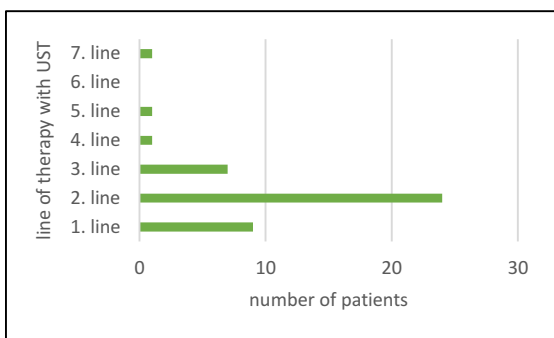


Figure 1: Line of therapy with UST

When offered biosimilar 15 (34.9%) patients agreed to switch and 28 (65.1%) wanted to continue treatment with originator drug. Regarding payment, only 12 (27.9%) patients were willing to pay a possible surcharge to continue treatment with originator UST. Patients were asked which aspects of sc application were most important to them when deciding on sc applicator form, answers are shown in table 1.

31 (73.8%) patients found application with the pen more suitable, 8 (19.1%) preferred the syringe, 3 (7.1%) had no preference (figure 2).

When asked which applicator would they wish to use in the future, 29 (67.4%) patients opted for the pen, 2 (4.7%) for the syringe and 12 (27.9%) did not mind either way (figure 3).

**Methods:** All patients with CD treated with originator UST were offered a switch to biosimilar for subcutaneous (sc) application. Data on comparable effectiveness and safety of biosimilars was explained to patients in written form in accordance with EMA statement and opinion of The Health Insurance Institute of Slovenia. Patients completed a survey questionnaire regarding sc application, factors influencing the choice of sc applicator type and their decision regarding switching to biosimilar.

Table 1: Factors influencing the choice of applicator type (multiple answers were possible)

Factor	n (%)
Needle is not visible	12 (27.9%)
Easy preparation	22 (51.2%)
Drug solution is clearly visible during application	6 (13.9%)
Easy handling	30 (69.8%)
Sound signal	14 (32.6%)
Safe disposal	14 (32.6%)
Less painful application	20 (46.5%)
Price	1 (2.3%)
Other factors: Effectiveness	2 (4.6%)
Smaller volume of solution	1 (2.3%)

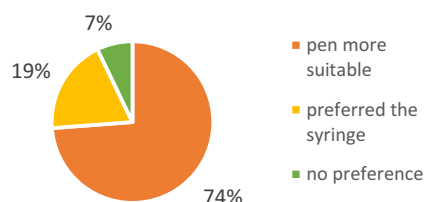


Figure 2: Patients' preferences regarding applicator type

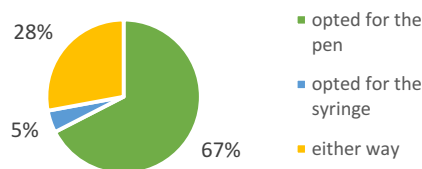


Figure 3: Patients' decision on future applicator use

**Conclusions:** Almost 2/3 of our CD patients treated with UST did not agree to switch from originator to biosimilar, despite the recommendations of healthcare agencies and expected financial savings. Most patients chose the pen, the lack of which is the leading drawback of currently available biosimilars. Top three factors influencing patients' choice of applicator type were easy handling, easy preparation and less painful application. Additional efforts must be invested in informing patients of the efficacy, safety and expected benefits of biosimilars.

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