

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 ≥ 2 years, moderate baseline endoscopic activity and baseline albumin concentration. Patients were then stratified into three probability groups: group 0 with low (≤ 26 points), group 1 with intermediate (27 to ≤ 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 ≤ 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 ≥ 1), or endoscopic remission (ER) (endoscopic Mayo ≤ 1)) χ^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)	mediana=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

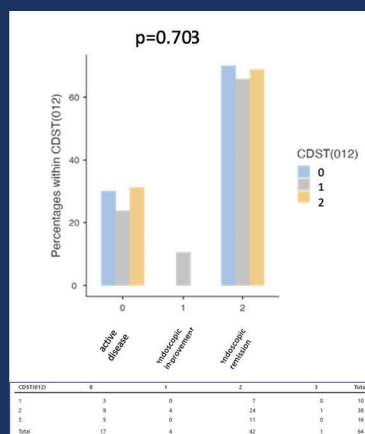


Figure 1: CDST groups according to endoscopic activity

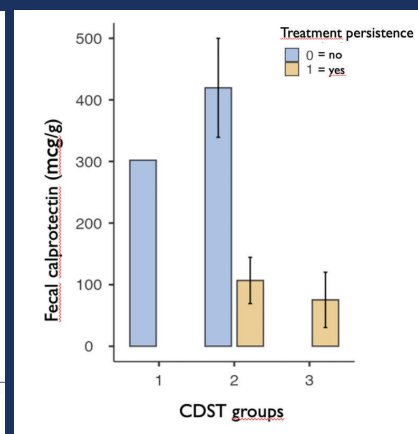


Figure 2: Fecal calprotectin according to CDST groups

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:

1. V D'Amico F, Zacharopoulou E, Peyrin-Biroulet L, Danese S. Early Intervention in Ulcerative Colitis: Ready for Prime Time? J Clin Med. 2020;9(8):2446.
2. Dulai PS, Singh S, Castele N, Vande, Meserve J, Winters A, Chablany S, et al. Development and Validation of Clinical Scoring Tool to Predict Outcomes of Treatment With Vedolizumab in Patients With Ulcerative Colitis. Clin Gastroenterol Hepatol. 2020;18(13):295