

# 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

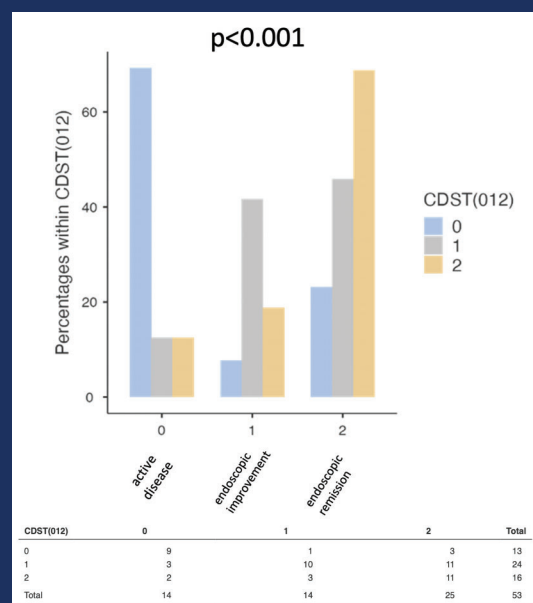


Figure 1: CDST groups according to endoscopic activity

## Literature:

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