Prediction Tools for Vedolizumab Drug Exposure and Efficacy for Ulcerative Colitis and Crohn's disease

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BACKGROUND

Vedolizumab (VDZ) is an effective therapy for the management of patients with moderately to severely active ulcerative colitis (UC) or Crohn's disease (CD) who have failed conventional therapy with aminosalicylates, corticosteroids, and thiopurines, as well as biologic therapy with tumor necrosis factor (TNF) antagonists. Several studies have identified potential predictors of treatment outcomes; however, the optimal approach to integrating predictors into routine practice is uncertain.

No prior decision support tools exist to predict VDZ drug exposure in UC and CD and link this back to differences in effectiveness or response to VDZ dose escalation. By having a tool that can predict at baseline prior to start of therapy whether VDZ will be effective and what a patients drug exposure profile will be with VDZ, the provider can 1) determine if VDZ is an appropriate therapy to begin, 2) proactively monitor those patients deemed high risk for treatment failure with VDZ, and 3) proactively measure drug concentrations for VDZ to then increase the dose or the interval at which VDZ is administered to improve outcomes.

TECHNOLOGY DESCRIPTION

Researchers at UC San Diego have addressed this gap by deriving multivariable logistic regression prediction models and clinical design support tools (CDST) using the GEMINI clinical trial data sets for the outcomes of corticosteroid-free clinical and endoscopic remission. The correlation between variability in VDZ exposure and differences in efficacy across predicted probability groups was explored in the derivation set, and the CDST was subsequently validated in an external cohort of UC and CD patients treated with VDZ in routine practice. The intent was to create a CDST that will help clinicians optimize VDZ therapy for individual patients.

APPLICATIONS

The models give a score and thus predicts how an UC or CD patient will respond to VDZ, how quickly they will respond, and it predicts what the individual patient's drug exposure profile will be during therapy and whether they would benefit from VDZ dose or interval changes.

ADVANTAGES

The scores put the patients into a high, intermediate, or low probability of response to VDZ category. Patients in the high probability group are predicted to have higher drug exposure and can be monitored less frequently with no drug concentration testing. Patients in the intermediate or low probability group will have incrementally lower drug exposure and efficacy. In these patients providers can have the patient return for follow-up sooner, check drug concentrations, and increase the dose of VDZ or the interval of VDZ administration until they achieve a concentration consistent with the concentrations achieved in the high probability of response group.

STATE OF DEVELOPMENT

The models performance in clinical practice was confirmed through an external validation in a large multi-center cohort of VDZ treated UC and CD patients.

INTELLECTUAL PROPERTY INFO

This technology is patent pending and available for licensing and/or research sponsorship.

RELATED MATERIALS

▶ Dulai PS, Boland BS, Singh S, Chaudrey K, Koliani-Pace JL, Kochhar, G, Parikh MP, Shmidt E, Hartke J, Chilukuri P, Meserve J, Whitehead D, Hirten R, Winters AC, Katta LG, Peerani F, Narula, N, Sultan K, Swaminath A, Bohm M, Lukin D, Hudesman D, Chang JT, Rivera-Nieves J, Jairath V, Zou GY, Feagan BG, Shen, B, Siegel CA, Loftus EV Jr, Kane S, Sands BE, Colombel JF, Sandborn WJ, Lasch K, Cao C. Development and Validation of a Scoring System to Predict Outcomes of Vedolizumab Treatment in Patients With Crohn's Disease. Gastroenterology. 2018 Sep;155(3):687-695.e10. doi: 10.1053/j.gastro.2018.05.039.Epub 2018 May 30. - 05/30/2018

PATENT STATUS

Patent Pending

CONTACT
University of California, San Diego
Office of Innovation and Commercialization
innovation@ucsd.edu
tel: 858.534.5815.

OTHER INFORMATION

KEYWORDS

Biomarker, prediction model, therapeutic drug monitoring, ulcerative colitis, vedolizumab

CATEGORIZED AS

- ▶ **Medical**
  - ▶ Disease: Digestive System
  - ▶ Screening

RELATED CASES

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University of California, San Diego
Office of Innovation and Commercialization
9500 Gilman Drive, MC 0910, ,
La Jolla,CA 92093-0910

Tel: 858.534.5815
innovation@ucsd.edu
https://innovation.ucsd.edu
Fax: 858.534.7345