

Assessment of the Efficacy of Certolizumab Pegol for the Treatment of Crohn's Disease at a Single North American Center

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Purpose: While there have been multiple prospective clinical trials evaluating the efficacy of certolizumab pegol (CZP) for the treatment of Crohn's Disease (CD), the most recently approved anti-TNF biologic, there is limited published data evaluating the efficacy of CZP in clinical practice. We evaluated the efficacy of CZP in a single site practice. In addition, we evaluated the efficacy of split dose modification (200 mg every 2 weeks) in those patients who were having a flare of symptoms despite remaining on a standard maintenance dose of CZP (400mg once monthly).

Methods: Study Design: This study was a retrospective chart review of CZP treated CD patients seen at the University of Washington's Inflammatory Bowel Diseases Clinic (IBD) between April 1, 2008 and August 1, 2009. Efficacy Evaluation: Patients seen in the IBD clinic are uniformly evaluated with the Harvey-Bradshaw Index (HBI) and the Short Inflammatory Bowel Disease Questionnaire (SIBDQ). We defined response as any decrease in the HBI within 12 weeks of the first induction dose. Remission was defined as an HBI of ≤ 5 . The same outcome measures were evaluated for both standard dosing as well as for split dosing.

Results: Sixty nine patients (36 women, 33 men) were included in the standard dosing analysis; 43.5% met the definition of response and 34.8% either achieved or maintained a clinical remission. Among responders the mean change in HBI was -4.8 ($p < 0.001$). Thirty one patients who lost response to the 400 mg once monthly dose (14 women, 17 men) were included in the split dosing analysis; 55.8% met the definition of response and 35.6% either achieved or maintained a clinical remission. Among responders the mean change in HBI was -3.11 ($p < 0.001$).

Conclusion: At a single North American site, certolizumab pegol induced a clinical response, as measured by the HBI, in 43.5% of Crohn's Disease patients with standard dosing of 400 mg administered subcutaneously once per month. In addition, 34.8% of patients either achieved clinical remission or maintained a clinical remission with the traditional dosing strategy. Further, CZP induced a clinical response in 55.8% of patients who lost response to the 400 mg once monthly dose and were transitioned to split dosing of 200 mg every 2 weeks. Remission was achieved or maintained in 35.6% of CD patients following dose modification. Although the sample size was limited in this analysis, these results support the effectiveness of CZP in clinical

practice and warrant further investigation into dosing options for CZP for the treatment of Crohn's Disease.

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