Efficacy and safety of certolizumab pegol induction therapy in an unselected Crohn's disease population: Results of the FACTS survey

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BACKGROUND:: Switzerland was the first country to approve certolizumab pegol (Cimzia, CZP) for the treatment of patients with moderate to severe Crohn's disease (CD) in September 2007. This phase IV study aimed to evaluate the efficacy and safety of CZP in a Swiss multicenter cohort of practice-based patients.

METHODS:: Baseline and Week 6 evaluation questionnaires were sent to all Swiss gastroenterologists in hospitals and private practices. Disease activity was assessed with the Harvey-Bradshaw Index (HBI) and adverse events were evaluated according to WHO guidelines.

RESULTS:: Fifty patients (31 women, 19 men) were included; 56% had complicated disease (stricture or fistula) and 52% had undergone prior CD-related surgery. All patients had prior exposure to systemic steroids, 96% to immunomodulators, 78% to infliximab, and 50% to adalimumab. A significant decrease in HBI was observed at Week 6 (versus Week 0) following induction therapy with CZP 400 mg subcutaneously at Weeks 0, 2, and 4 (12.6 +/- 4.7 Week 0 versus 6.2 +/- 4.4 Week 6, P < 0.001). Response and remission rates at Week 6 were 54% and 40%, respectively. We identified 8/11 CD patients undergoing a 50% fistula response (P = 0.021). The frequency of adverse drug reactions attributed to CZP was 6%. CZP was continued in 80% of patients beyond Week 6.

CONCLUSIONS:: In a population of CD patients with complicated disease behavior, CZP induced a response and remission in 54% and 40% of patients, respectively. This series provides the first evidence of the effectiveness of CZP in perianal fistulizing CD. Inflamm Bowel Dis 2010.