Efficacy and safety of certolizumab pegol in an unselected Crohn's disease population: 26-week data of the FACTS II survey

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BACKGROUND:: Certolizumab pegol (Cimzia, CZP) was approved for the treatment of Crohn's disease (CD) patients in 2007 in Switzerland as the first country worldwide. This prospective phase IV study aimed to evaluate the efficacy and safety of CZP over 26 weeks in a multicenter cohort of practice-based patients.

METHODS:: Evaluation questionnaires at baseline, week 6, and week 26 were completed by gastroenterologists in hospitals and private practices. Adverse events were evaluated according to World Health Organization (WHO) guidelines.

RESULTS:: Sixty patients (38F/22M) were included; 53% had complicated disease (stricturing or penetrating), 45% had undergone prior CD-related surgery. All patients had prior exposure to systemic steroids, 96% to immunomodulators, 73% to infliximab, and 43% to adalimumab. A significant decrease of the Harvey-Bradshaw Index (HBI) was observed under CZP therapy (12.2 ± 4.9 at week 0 versus 6.3 ± 4.7 at week 6 and 6.7 ± 5.3 at week 26, both P < 0.001). Response and remission rates were 70% and 40% (week 6) and 67% and 36%, respectively (week 26). The complete perianal fistula closure rate was 36% at week 6 and 55% at week 26. The frequency of adverse drug reactions attributed to CZP was 5%. CZP was continued in 88% of patients beyond week 6 and in 67% beyond week 26.

CONCLUSIONS:: In a population of CD patients with predominantly complicated disease behavior, CZP proved to be effective in induction and maintenance of response and remission. This series provides the first evidence of CZP's effectiveness in perianal fistulizing CD in clinical practice. (Inflamm Bowel Dis 2011;).

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