PTH-058

ADVERSE EVENTS ASSOCIATED WITH INFLIXIMAB THERAPY IN A LARGE SINGLE CENTRE UK COHORT

doi:10.1136/gut.2011.239301.459

M Sprakes,[1,*] P J Hamlin,[1] L Warren,[1] D Greer,[1] A C Ford[1] [1]*Gastroenterology, Leeds General Infirmary, Leeds, UK*

Introduction Long term safety data for biologic therapies in Crohn's disease (CD) is still emerging. A recent study has suggested that serious adverse events occur in 15% of patients receiving infliximab (IFX) therapy for CD, and more frequently in patients on concomitant immunosuppression. However, the TREAT registry observed no increased risk of adverse events with IFX, compared to other therapies. The authors assessed adverse events in patients who have received IFX therapy for CD at their referral centre.

Methods All patients who receive IFX therapy for CD in our referral centre for CD were included on a prospective database. Data stored included sex, age at diagnosis, duration of disease, previous surgical history, smoking history and Montreal classification. Response and remission data are also prospectively recorded. Adverse events to infliximab are documented each time a patient attends for an infusion, or at the following clinic visit. Patients who were not receiving concomitant immunosuppression were premedicated with hydrocortisone at each infusion.

Results In total, 3165 IFX infusions were administered to 210 patients (median of 24 (IQR 7–48) months), mean Harvey-Bradshaw index of 9. In total, 59 (28.1%) patients experienced adverse events to IFX. 23 patients had a reaction during the infusion, with 9 discontinuing therapy. 12 patients

had hypersensitivity reactions and discontinued IFX. Seven patients discontinued IFX due to psoriatiform rashes. There were 14 (6.7%) opportunistic infections (including seven episodes of Varicella zoster reactivation, and one diagnosis of pulmonary tuberculosis in a Caucasian male who had received 3 years of maintenance therapy and had a normal chest x-ray pre-IFX), 3 infections required permanent discontinuation of IFX. There were 3 malignancies (1.4%) all discontinuing IFX. One was an adenocarcinoma in a peri-anal fistula tract. Examination under anaesthesia (EUA) and biopsy pre-IFX had been non-diagnostic, but EUA was repeated after non-response to IFX. One older diabetic patient developed a fatal spindle-cell tumour, and one patient in remission had an incidental finding of a renal cell carcinoma when disease was being reassessed by imaging prior to withdrawal of IFX. Overall, 34 (16.2%) patients discontinued IFX due to adverse events. 21 (35.6%) patients were receiving concomitant immunomodulator therapy at the time of the adverse event. There was no significant difference in adverse events when comparing episodic versus maintenance therapy (p=0.62).

Conclusion IFX is safe and well tolerated with low numbers of adverse events, malignancies and mortality in our large single centre cohort of patients with severe active CD. Careful patient selection, pre-IFX screening and monitoring during therapy can optimise the risk benefit ratio.

Competing interests None.

Keywords adverse events, infliximab.