961 Infliximab Discontinuation in Crohn's Disease Patients in Stable Remission On Combined Therapy with Immunosuppressors: A Prospective Ongoing Cohort Study

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INTRODUCTION: Infliximab (IFX) is an effective maintenance therapy in Crohn's disease (CD). The question of whether this treatment can be safely interrupted after a period of prolonged remission is of great interest to patients and physicians. Objectives: To asses the risk of relapse after IFX discontinuation in patients on combined maintenance therapy with immunosuppressors (IS) and to identify factors of relapse. A secondary objective was to assess response and tolerance to IFX re-treatment in relapsers.
METHODS: Luminal CD patients treated for at least one year with combined IFX + IS and in stable remission without steroids for at least 6 months were prospectively recruited. Data recorded at baseline were: blood cell counts, CDAI, ileocolonoscopy with CDEIS, centralized USCRP, fecal calprotectin, ATI and IFX through level. Patients were followed up every two months with IS kept at a stable dose. Relapse was defined by a CDAI >250 or a CDAI between 150 and 250 with a 70 pts increase during two consecutive weeks. Association between demographic, clinical and biological factors and time-to-relapse was assesed through log-rank method. Hazard ratios (HR) were estimated through Cox model. Relapsers were retreated with IFX and both efficacy and tolerance were evaluated.
RESULTS: 115 patients were recruited in 20 GETAID centres. Median duration of IFX and IS treatments were 2.2 years and 2.8 years. At inclusion, median CDAI and CDEIS were 37 and 0.7; median USCRP, fecal calprotectin and IFX trough levels were 2.0 mg/l, 51 microg/g and 3.8 microg/ml. After a median follow-up time of 12 months, 45 relapses have been observed. In univariate analysis, current smoking, previous steroid treatm ent,lower haemoglobin, higher CDAI, CDEIS, USCRP and fecal calprotectin were associated with the risk of relapse. In multivariate analysis, a model based on CDEIS (≥2, HR=3.0, P<0.001) USCRP (≥5 mg/l, HR=3.8, P<0.001), haemoglobin (≤14.5g/dl, HR=4.7, P=0.002) and IFX trough levels (≥2microg/ml, HR=2.9, P=0.006) identified 4 subgroups of patients
with increasing risk of relapse. Thirty seven relapsers are currently evaluable 4 weeks after IFX re-infusion for response to IFX retreatment: 36/37 were in remission and none experienced acute or delayed reaction.
CONCLUSION: after a stable remission under combined IFX + IS therapy for at least one year, more than half of patients have not relapsed one year after IFX discontinuation. In relapsers, IFX re-treatment was well tolerated and induced remission in the short term. A subgroup of patients with very low risk of relapse could be identified through a combination of biological and endoscopic markers.