

943c ACCELERATED STEP-CARE THERAPY WITH EARLY AZATHIOPRINE (AZA) VS. CONVENTIONAL STEP-CARE THERAPY IN CROHN'S DISEASE. A RANDOMIZED STUDY.

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BACKGROUND/AIM: In early Crohn's disease (CD) patients at risk for disabling disease, two possible treatment strategies are considered as potentially highly effective : accelerated step-care (steroids + AZA) or early combined immunosuppression (anti-TNF + AZA). However the accelerated step-care strategy (early AZA) has been poorly explored. The aim of this randomized, openlabel, controlled trial was to compare an early AZA approach with conventional step-care therapy in early CD.

METHODS: patients with a diagnosis of CD of less than 6mos, naive to immunosuppressors and biologics, with no previous history of surgery and having at least two predictors of disabling disease were randomized to receive AZA 2.5mg/kg at inclusion (e-AZA) or on demand according to guidelines (Controls). Predictors of disabling CD included an age < 40 years, active perianal disease within the first 6 mos and need for oral steroids within the first 3 mos¹. Patients were included in 24 GETAID centres between 2005, July, and 2010, December. The primary endpoint was the proportion of trimesters spent in steroid-free and anti-TNF-free remission during the first 3 years after inclusion. Data were compared between e-AZA and Control groups using non-parametric tests.

RESULTS: 147 patients were randomized to e-AZA or to Controls. Five patients were excluded just after inclusion, leaving 142 patients (71 e-AZA, 71 Controls) with a median (IQR) follow-up of 35 mos (15-36) at the reference date of on-going follow-up (2011, October 1). They were 71 M and 71 F with median age (IQR) of 27 yrs (22-29) and a median disease duration of 2.5 months (1-3.7). 42 Controls (62%) required immunosuppressors during follow-up after a median time of 5.6 months (3.2-9.6). The proportion of trimesters in remission (median, IQR) was 61% (12-83) in e-AZA patients, vs. 50% (30-72) in Controls (NS). Additionally, 19 e-AZA patients (29%) required anti-TNF vs. 18 Controls (26%, NS), 2 (3%) had unplanned surgical perianal procedures vs. 9 Controls (13%, p 0.055), and 7 (11%) had intestinal surgery vs. 14 Controls (21%, p 0.11). Median values of mean CDAI and C-reactive protein did not differ between the 2 groups.

CONCLUSION: in patients at risk for disabling CD, early AZA was not associated with a significantly increased clinical remission rate during the first years of CD. More than one third of control patients had a mild-to-moderate course not requiring immunosuppressors at a 3 year follow-up. These data do not support the widespread use of an accelerated stepcare strategy compared to conventional step-care.

REFERENCES: 1 Beaugerie et al. Gastroenterology 2006; 130: 650-6