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POSTER PRESENTATION Open Access

PReS-FINAL-2088: Risk of severe adverse events in juvenile idiopathic arthritis and pediatric-onset inflammatory bowel disease, treated with anti-tnf drugs

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Introduction

Severe adverse events have been described in children affected by Juvenile Idiopathic Arthritis (JIA) and Inflammatory Bowel Disease (IBD) treated with anti-tnf drugs.

Objectives

To define the risk of severe adverse events in patients with JIA and IBD treated with anti-tnf drugs.

Methods

This is a retrospective cohort study. All patients with JIA and IBD attending the "IRCCS Burlo Garofolo" of Trieste from 2000 to 2012 were enrolled. They were divided into 2 groups on the basis of the presence or absence of anti-tnf exposure.

Severe adverse events were considered the followings: a) infections needing anti-tnf permanent suspension and/or hospitalization; b) autoimmune diseases with present or potential organ damage, except for hepatitis and cholangitis during IBD; c) anaphylaxis; d) malignancies.

Univariate analysis testing the effect of anti-tnf exposure on adverse events appearance was realized.

Results

323 patients were enrolled (159 with JIA and 164 with IBD). 120 patients were exposed to anti-tnf and 203 were not. Infliximab was the most used anti-tnf (73 patients), followed by etanercept (56 patients) and adalimumab (21 patients). Mean total duration of anti-tnf therapy was 26 months (min.1, max.127). The two cohorts were comparable for sex, age, diagnosis and other therapies assumed.

Severe adverse events occurred in 38 anti-tnf-exposed patients (31.7%) and 22 of the not-exposed group (10.8%), with a statistically significant difference ($p = 0.000$) and a relative risk (RR) of 2.9 (95% confidence interval, CI, 1.8 to 4.7). Anaphylaxis occured in 11 patients (9.2% of the anti-tnf-treated), all assuming infliximab; in the not-treated group none presented reactions ($p = 0.000$). Infection rate was 6.7% in the anti-tnf-treated group (8 patients) and 3.5% in the not-exposed group (7 patients) ($p = 0.273$, RR = 1.9, 95% CI: 0.7 to 5.2). Incidence rate of autoimmune diseases in patients treated with anti-tnf was 18.3% (22 patients) vs 7.9% in not-exposed cohort ($p = 0.007$, RR = 2.3, 95% CI: 1.3 to 4.2). Uveitis was the most frequent autoimmune disease. Both uveitis and lupus-like syndrome were more likely in the subgroup of patients treated with anti-tnf ($p = 0.005$, RR = 2.5, 95% CI: 1.1 to 6.0 for uveitis and $p = 0.050$ for lupus-like syndrome). No patients developed malignancies. The outcome of severe anti-tnf drug reactions was as follows: 2 out of 3 uveitis, all anaphylactic reactions, severe infections and lupus-like syndromes healed without organ damage, whereas the other autoimmune complications have been still treating with a good clinical outcome.

Conclusion

The patients with JIA or IBD treated with anti-tnf have a higher risk of severe adverse events, like anaphylaxis and autoimmune diseases (in particular uveitis and lupus-like syndrome), whereas it seems that this risk does not exist for severe infections. No malignancies were observed during follow up.

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Our data suggest that, although the risk of severe adverse reactions to anti-tnf therapy is significant, the occurrence of a permanent damage results very low.

Disclosure of interest

None declared.

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