SWITCHING TO ANTI-IL-6 BIOLOGICS AFTER ANTI-TNF THERAPY IN CHILDREN WITH JIA

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Background: Development of biologics gives rise to novel classes of drugs, offering more options for treating children with primary or secondary failure of anti-TNF therapy. However, the question of whether or not previous exposure to biologic therapy and the number of previously administered biologics influence the efficacy of current treatment still needs to be solved.

Objectives: To compare tocilizumab efficacy in biologics-naive and biologics-switched patients with JIA.

Methods: Comparative analysis involved patients who had initiated TOC treatment at the National Medical Research Centre of Children’s Health (Moscow) and EOL Labs Ltd, Department of Biostatistics; Institute of Computational Mathematics and Mathematical Geophysics SB RAS, Novosibirsk, Russian Federation.

Results: Thirty-two patients were biologics-naive and 43 patients switched to TOC were previously treated with ETA (n=10), ADA (n=34), certolizumab (n=2), and infliximab (n=1). Children in the biologics-naive group differed from the switchers in a number of important baseline parameters: shorter disease duration (2.13 [1.25:5.34] and 7.42 [3.10:7.5] years, respectively; p<0.001) and lower arthritis severity indices (the number of joints affected, the CHAQ and JADAS scores). Therapy with TOC in children was found very effective. The CHAQ and JADAS disease activity scores, the CRP and ESR laboratory values, morning stiffness duration, and the VAS score (assessed by both patient and physician), and the number of affected joints (swollen or painful joints, joints with the limited range of motion and with active arthritis) significantly decreased after 4 week therapy in all patients (p<0.01). The percentages of biologics-naive patients and switchers who achieved ACR90 after the first 12 months of therapy were 31.25% and 25.6%, respectively (p=0.613). A smaller percentage of children achieved stable remission – 4.65% of switchers and 6.25% of biologics-naive patients (p=0.999).

Conclusions: Tocilizumab therapy is highly efficient both as the first and subsequent biologic agent. Children with history of therapy with at least one biologic agent have lower chances for achieving remission during the first 12 months of therapy. However, this difference is most likely caused by the longer and more severe arthritis course in children allocated to the group of biologics-switched patients compared to biologics-naive ones. Further matched large-cohort study is needed to identify predictors of response to therapy.

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EFFICACY AND RETENTION RATE OF CERTOLIZUMAB PEGOL IN RHEUMATOID ARTHRITIS: DATA FROM A LARGE REAL-LIFE MULTICENTRE RETROSPECTIVE COHORT

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Background: Effective treatment improvement and remission rates were similar in first- and second-line patients (66% vs 60.7% [p=0.65] and 39.6% vs 32.1% [p=0.52], respectively). The overall 5 year retention rate was 42.5%, with no difference between first- and second-line therapy (43.5% vs 40.5%, respectively; p=0.98), but with a clear trend in favour of childhood subpopulation versus older children (62.8% vs 32.3%, respectively; p=0.07). Concomitant MTX was a predictor of CZP persistence (Hazard Ratio [HR] 1.79, 95% confidence interval [95% CI] 1.08–2.95; p=0.02), whereas sex (HR 1.35, 95% CI 0.71–2.54, p=0.35), age (HR 1.01, 95% CI 0.99–1.03; p=0.14), mean disease duration (HR 0.99, 95% CI 0.97–1.02; p=0.87), and baseline DAS28-ESR (HR 1.15, 95% CI 0.96–1.38; p=0.12) were not associated with CZP retention rate. The most frequent reason for discontinuation was inefficacy (60%), whereas only 21% of patients stopped the drug because of adverse events.

Conclusions: In our real-life experience, CZP showed a very good clinical response, with more than one third of patients achieving 2 year clinical remission and more than 40% persisting on treatment after 5 years. Unexpectedly, no significant difference was found between first and second line of treatment. The use of CZP in childhood patients seems to be associated with a higher retention rate. Disclosure of Interest: None declared.


INDIRECT STANDARDISED ASSESSMENT OF INJECTION SITE PAIN FOLLOWING SUBCUTANEOUS ADMINISTRATION OF CITRATE-FREE FORMULATION OF ADALIMUMAB AND ITS BIOSIMILAR ABP 501


Background: In randomised double-blind studies in patients with rheumatoid arthritis (RA) and psoriasis (PsO), ABP 501, an approved adalimumab biosimilar, had significantly lower injection site pain (ISP) perception compared with the citrate-containing formulation (CCF) of adalimumab reference product (RP) (40 mg/0.8 mL); however, there have been no direct or indirect comparisons of ISP perception between ABP 501 and the CFF of the RP (40 mg/0.4 mL).

Objective: To demonstrate that pain perception after injection of both the ABP 501 formulation and the CFF-RP formulation was lower than after CFF-RP.

Methods: We analysed ISP perception data after injection from two ABP 501 phase 3 studies, one in patients with RA (NCT01970475) and another in patients with PsO (NCT01970488) and 2 citrate-free RP formulation studies (NCT01561313, NCT01502423) where the “control” group received the CCF-RP. In all studies, patients were equally randomised between the 2 treatment arms. Patients were asked to rate the ISP perception on a visual analogue scale (VAS) on which the current pain level was marked from 0 cm (no pain) to 10 cm (worst possible pain). We calculated Cohen’s d-statistic for difference in ISP perception with ABP 501 compared with CCF-RP for the 2 ABP 501 studies. Similar comparisons were performed between the ISP perception associated with CFF-RF and CCF-RF. These measures were subsequently compared in a descriptive manner.

Results: Both ABP 501 and CFF-RF were associated with lower ISP perception after injection with maximum reduction observed immediately post-injection. The 95% confidence intervals of relative reduction in ISP perception for ABP 501 formulation and the CFF-RP (table 1) were provided descriptively.

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