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SAT0140

SAFETY OF TOFACITINIB THERAPY IN HBsAg CARRIERS WITH RHEUMATOID ARTHRITIS: A PROSPECTIVE STUDY

L. Fang¹, Z. Lin¹, Z. Liao¹, O. Jin¹, Y. Pan¹, J. Gu¹. ¹The Third Affiliated Hospital of Sun Yat-sen University, Guangzhou, China

Background: Targeted synthetic DMARDs (ts-DMARDs) are becoming more available and affordable in developing countries, where the prevalence of hepatitis B virus (HBV) infection is still an important public health issue. The safety of ts-DMARDs therapy in terms of the reactivation of hepatitis B virus (HBV) infection need more concern. Rare data from a prospective study focus on the use of ts-DMARDs in patients with concurrent rheumatoid arthritis (RA) and HBV infection were available by now.

Objectives: To evaluate the influence of tofacitinib on reactivation of HBV infection in HBsAg carriers with RA.

Methods: In this 52 weeks observation, HBsAg carriers with active RA (DAS28>5.1) despite failed combined treatment with MTX and other non-biological DMARDs were enrolled. Patients must have normal liver function prior to study. All patients received therapy with tofacitinib (5mg twice daily) and concomitant MTX (10-12.5mg/w). Entecavir was prescribed preventively for patients who had a baseline HBV load >2000 copy/ml (group 1), and Lamivudine for patients with HBV load ≤ 2000 copy/ml (group 2). Liver enzymes (AST/ALT) and HBV viral load were monitored every 4 weeks. Increased viral load and abnormal liver function were managed according to expert opinion.

Results: Thirteen patients (10 female) were recruited. Nine patients had a baseline viral load >2000 copy/ml (group 1, with preventive Entecavir), and the other 4 patients had a viral load ≤ 2000 copy/ml (group 2, with preventive Lamivudine). Two patients from group 1 discontinued tofacitinib at week 12 due to ineffectiveness, and both continued taking Entecavir for another 3 months after the discontinuation of tofacitinib.

No reactivation of hepatitis B was observed in patients from group 1. One patient (female, 54 years old) from group 2 underwent a mild increase of both ALT and AST (67 and 56 IU/L, respectively) at week 16. An elevated viral load (4.9e6 copies/ml, baseline 1.4e3) and a HBV YMDD mutant was also found. The tofacitinib treatment continued. After prescription of Adefovir (combined with the pre-existing Lamivudine), both liver enzyme and viral load decreased to normal range in 8 weeks and remained normal throughout the study.

Conclusion: An aggressive Tofacitinib + MTX therapy may be a safe option for HBsAg carriers with cs-DMARDs refractory RA. More active and effective prophylaxis strategy may be recommended to reduce the risk of HBV reactivation during the treatment.

References:

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SAT0141

LONG-TERM EFFECTIVENESS OF TOFACITINIB IN CONVENTIONAL DMARDs NON-RESPONDERS WITH RHEUMATOID ARTHRITIS: RESULTS OF RUSSIAN NATIONAL REGISTER

I. Gaydukova¹, V. Mazurov¹, A. Lila², A. Baranov³, G. Lukina⁴, E. Zhilyaev⁵, E. Koltsova⁶, E. Shmidt⁷, O. Fomina⁸, I. Bondareva⁹, O. Anoshenkova¹⁰, A. Vasilenko¹¹, E. Vasilenko¹, N. Yudina¹², L. Knyazeva¹³, V. Poncratov¹³, E. Gaydukova¹⁴, E. Nasonov². ¹North-Western State Medical University named after I. I. Mechnikov, St. Petersburg, Russian Federation; ²Nasonova Research Institute of Rheumatology, Moscow, Russian Federation; ³Yaroslavl State Medical University, Yaroslavl, Russian Federation; ⁴Moscow Clinical Scientific and Practical Centre named after Loginov AS, Moscow, Russian Federation; ⁵Russian Medical Academy of Post Graduate Education, Moscow, Russian Federation; ⁶Scientific and Research Institute of Health Care Organization, Moscow, Russian Federation; ⁷Municipal Clinical Hospital # 1 named after NI Pirogov, Moscow, Russian Federation; ⁸Amur Regional Hospital, Blagoveshchensk, Russian Federation; ⁹Kemerovo Regional Clinical Hospital, Kemerovo, Russian Federation; ¹⁰Siberian State Medical University, Tomsk, Russian Federation; ¹¹Regional Clinical Hospital, V. Novgorod, Russian Federation; ¹²Republican Hospital No 1 of the Republic of Tuva, Kyzyl, Russian Federation; ¹³Kursk State Medical University, Kursk, Russian Federation; ¹⁴Clinical Rheumatological Hospital No 25, St. Petersburg, Russian Federation

Background: Tofacitinib is an oral Janus Kinase inhibitor for the treatment of rheumatoid arthritis (RA).

Objectives: To evaluate the three-year effectiveness of tofacitinib in RA conventional synthetic (cs) DMARDs non-responders.

Methods: Data from 374 patients from Russian national register OREL of patients with RA treated with tofacitinib not less than 3 years after failure of conventional DMARDs were included in the statistical analysis. Clinical and laboratory data from 4 consecutive visits with an interval of 12 months between the visits (± 28 days) were analyzed. Treatment with any biologics ever was an exclusion criteria. Demographic (age, sex) and disease-related characteristics of RA (symptoms duration, RF- and ACCP positivity, presence of joint erosions, DAS28, CDAI, number of tender and swollen joints (NTJ, NSJ), erythrocytes sedimentation rate (ESR), C-reactive protein (CRP)) collected. Statistical analysis performed with statistical programs SPSS2017 and GraphPadPrizm. p-value < 0.05 considered as significant.

Results: Baseline characteristics of RA patients, involved in the analysis are presented in table 1.

Table 1. Baseline characteristics of the patients with RA (n=374).

Parameter	Characteristics
Male, n (%)	92 (24.5)
Age, years (mean±SD)	53.4±13.38
Symptoms duration, month (mean±SD)	140±137
Positive rheumatoid factor (RF), n (%)	123(32.8)
Positive antibodies to cyclic citrullinated peptide (ACCP), n (%)	329(87.9)
Erosions of hand joints (X-rays), n (%)	372 (99.4)
BMI, kg/m ² (mean ±SD)	26.8 ± 6.14
Smokers (current and in the past), n (%)	54 (14.4)

Changes in the diseases activity parameters in patients with RA, treated with tofacitinib not less than 3 years after cs DMARD failure are presented in table 2, figure 1, and figure 2.

Figure 1. DAS28 of patients with RA, treated with tofacitinib (n=374) – 3-years follow-up (time-points are presented in years ± 28 days).

Figure 2. DAS28 of patients with RA, treated with tofacitinib (n=374) – 3-years follow-up (time-points are presented in years ± 28 days).