THU0385
SAFETY OF TOFACITINIB THERAPY IN HBsAg CARRIERS WITH ANKYLOSING SPONDYLITIS: A PROSPECTIVE STUDY

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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 needs more concern. Rare data from a prospective study focus on the use of ts-DMARDs in patients with concurrent ankylosing spondylitis (AS) and HBV infection were available by now.

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

Methods: In this 52 weeks observation, HBsAg carriers with active AS (BASDAI ≥ 4) despite failed treatment with at least two NSAIDs and sulfasalazine (for patients with persistent peripheral arthritis) were studied. Patients must be positive for HBsAg and have a normal liver function prior to study.

All patients received therapy with tofacitinib (5mg twice daily). Entecavir were prescribed preventively regardless of individual viral load. Pre-existing NSAIDs and sulfasalazine were allowed. 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: Eleven patients (9 male) were recruited. Eight patients had a baseline viral load >2000 copy/ml (group 1), and the other 3 patients had a viral load ≤ 2000 copy/ml (group 2). 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.

One patient (male, 26 years old) from group 1 underwent a mild increase of both AST and ALT (67 and 56 UI/L respectively) at week 16, but no elevated viral load (2.1e3 copies/ml, baseline 2.8e3) or a HBV YMDD mutation was found. The tofacitinib treatment continued. After prescription of polyene phosphatidylcholine, the liver enzyme of this patient decreased to normal range in 4 weeks and remained normal throughout the study.

No reactivation of hepatitis B was observed in patients from group 2.

Conclusion: Tofacitinib treatment may be a safe and effective option for HBsAg carriers with AS refractory to traditional treatment. Prophylaxis strategy with effective anti-viral drugs is recommended.

References:

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PREDICTORS OF MAINTENANCE OF SECUKINUMAB TREATMENT IN A MULTICENTER COHORT OF 561 SPONDYLARTHITIS

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Objectives: Secukinumab (SEC) is an interleukin-17 inhibitor used to treat patients with axial spondyloarthritis (axSpA) and psoriatic arthritis (PsA). Drug maintenance is often used as a proxy for treatment effectiveness and safety in real life settings. We aim to assess SEC maintenance in routine clinical practice and to identify survival predictors associated.

Methods: We conducted a retrospective, longitudinal, observational, multi-center study including all patients (pts) with axSpA or PsA who received at least 1 injection of SEC between July 2016 and October 2019. We collected patient’s demographics and clinic characteristics, SEC date of initiation and dosage and dosage modification of SEC, previous biologic Disease-modifying antirheumatic drugs (bDMARDs) and concomitant treatments. Date and reasons of discontinuation – i.e., lack of efficacy, safety issue, sustained remission or others – were collected. Several potential maintenance predictors were tested: age, gender, disease (axSpA or PsA), smoking status, bDMARDs history and concomitant treatment. Among patients with non-radiographic axSpA (nr-axSpA), evidence of MRI sacroiliitis or elevated CRP were also assessed as potential maintenance predictors. Drug maintenance was analyzed by the Kaplan-Meier method and adjusted for baseline factors were estimated by log rank analysis.

Results: The main characteristics of the 561 pts included were the following: 363 (64.7%) axSpA, 198 (35.3%) PsA, 329 (58.6%) female, mean age 45.6 +/- 12 years, 221 (39.4%) smokers, 175 (32.1%) radiographic sacroiliitis, 259 (46.2%) MRI sacroiliitis, 198 (35.3%) elevated CRP, 247 (44.0%) HLA B27 positive, mean BASDAI 48.3 +/- 26.8%. SEC was associated to methotrexate (MTX) in 139 pts (24.8%) and was the first line bDMARD in 55 pts (9.8%). The median drug maintenance (MDM) of SEC was 79 weeks (wk) [73-84]. At 52 wk, 245 pts (60%) SpA were still treated with SEC. During the 3-year follow-up, 264 pts discontinued SEC; 180 (68.2%) pts for lack of effectiveness; 47 (17.8%) for adverse events, 14 (5.3%) for others and 23 (8.7%). SEC prescription as first line bDMARD was associated with longer survival versus second line or more: 111 wk [83-138] vs. 69 wk [57-80] (p=0.017) (figure 1). MDM was not significantly different depending on gender, MTX combo, elevated CRP, axSpA vs PsA and smoking status. Among the nr-axSpA pts, MRI sacroiliitis or elevated CRP did not modify SEC maintenance (p=0.68) (figure 2).

Conclusion: In routine clinical practice, SEC median maintenance was 79 weeks. Fist line administration was the only independent factor associated with improved SEC retention. Lack of effectiveness was the most common reason of discontinuation.

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Figure 1. Secukinumab maintenance according to therapeutic line

**Figure 2. Secukinumab maintenance in nr-axSpA population**
Background: Biological disease-modifying antirheumatic drugs (bDMARD) have a role in spondyloarthritis (SpA) patients who do not respond to other treatments. There is a lack of studies comparing the effects of different bDMARDs on spinal mobility.

Objectives: To compare the effects of different bDMARDs on spinal mobility in a cohort of SpA patients.

Methods: A cohort of 137 SpA patients treated with bDMARDs were included. Baseline disease activity scores (BASMI) and spinal mobility were assessed. Follow-up visits were done at 6 and 12 months. The primary outcome was the change in BASMI at 12 months, and the secondary outcomes were the change in BASMI at 6 months.

Results: The mean age of patients was 42 years old [34, 50], 92 (51.7%) were males with a median disease duration of 4.9 [1.0, 10.3] years. One hundred and sixty-six patients (70.8%) had axSpA, 51 (25.9%) had nr-axSpA, and 4 (2.1%) had PsA. The mean BASMI at baseline was 8.0 [6.5, 10.7] and the mean change in BASMI at 6 months was -1.6 [−3.1, −0.1] and at 12 months was -2.9 [−4.1, −1.6].

Conclusions: Different bDMARDs have a significant effect on spinal mobility in SpA patients. Secukinumab had the most significant effect on spinal mobility, followed by infliximab and adalimumab. Further studies are needed to determine the long-term effects of different bDMARDs on spinal mobility in SpA patients.

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