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P-59

Clinical features of patients with new onset of autoimmune hepatitis following SARS-CoV-2 vaccination

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Introduction: Autoimmune hepatitis (AIH) is a relatively rare chronic immune-mediated liver disease, which develops in genetically predisposed individuals following an environmental trigger. A few cases of AIH have been recently reported after the SARS-CoV-2 vaccination.
Aims: The aim of this study was to describe clinical-epidemiological profile of a series of adult patients who experienced AIH onset following SARS-CoV-2 vaccination.
Materials and Methods: This multicentric observational study collected clinical data of adult patients who had received SARS-CoV-2 vaccination and thereafter were diagnosed with AIH between 03/2021 and 10/2021 in Italy, using an online survey among members of the Italian Association for the study of the Liver (AISF).
Results: Among the 12 patients included: 50% were females, median age 62 years (range 32-80), 6 (50%) had preexisting extra-hepatic autoimmune disease (3 thyroiditis, 2 rheumatoid arthritis, 1 systemic lupus erythematosus), 7 patients have received Comirnaty (BioNTech/Pfizer) vaccine, 2 Spikevax (Moderna Biotech) and 3 Vaxzevria (AstraZeneca). Ten patients (83%) had acute onset of AIH with transaminase levels $\geq$10 times the upper limit of normal (ULN, range 13-77 x ULN), 8 (67%) with jaundice (total bilirubin 3.5-18.6 x ULN). At AIH diagnosis (median time from first and second vaccine dose: 48 and 10 days, respectively) median AST was 18 x ULN (range 5-85), ALT 23.8 x ULN (range 7-83), total bilirubin 3.8 x ULN (range 0.6-18.6), alkaline phosphatase 1.3 x ULN (range 0.8-7.1), immunoglobulin G 1.2 x ULN (median 0.8-1.5). Eight (67%) patients had autoantibodies: 6 ANA, 1 SMA, 1 LKM-1. Liver biopsy was typical for AIH in 8 and compatible in 3 patients. After 3 months 58% achieved complete biochemical response to standard immunosuppressive treatment.
Conclusion: While intensive vaccination against SARS-CoV-2 continues, the diagnosis of AIH secondary to vaccines should be included in the differential diagnosis in cases of acute hepatitis of unexplained aetiology.

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P-60

Biomarkers, imaging and safety in resmetirom 52 week non-cirrhotic NASH phase 3 clinical trial, completed open-label arm of maestro-NAFLD-1

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Background: MAESTRO-NASH (NCT03900429) and MAESTRO-NAFLD-1 (NCT04197479) are 52-week Phase 3 registrational double-blind placebo controlled clinical trials to study the effect of resmetirom, a selective thyroid receptor beta (THR-β) agonist in NASH patients. A goal of MAESTRO-NAFLD-1, a 1200 patient "real life" NASH study is to identify non-invasive markers that correlate with patient response to resmetirom treatment. The 171 patient 100 mg open label arm completed the 52-week study in July 2021.
Methods: Eligibility required at least 3 metabolic risk factors, transient elastography (TE) measured in kPa consistent with $\geq$F1, and MRI-PDFF $\geq$8%. The primary and key secondary endpoints of MAESTRO-NAFLD-1 include safety, relative percent reduction of MRI-PDFF (week 16) and LDL-C, Apolipoprotein-B, triglycerides (week 24).
Results: Statistically significant ($p<0.0001$) reduction of MRI-PDFF -53% (3.3 (SE)) at week 52. Liver volume (LV) was elevated at baseline (2202 cm3 (535)) by ~50% relative to normal controls and ~15% after correction for BMI. Resmetirom reduced LV by -21% (1.0), -23% (1.0) respectively, at weeks 16 and 52 ($p<0.0001$). LV reduction was greater than predicted by % reduction in MRI-PDFF; LV-corrected mean MRI-PDFF reduction at Week 52 was -61% (2.4). At week 52, MRE (-0.34, $p=0.03$); CAP (-39 (4.6)) and TE (-1.87, $p<0.0001$) were reduced relative to baseline. LDL-C (-21% (1.9)), apolipoprotein-B (-22% (1.6)) and triglycerides (-22% (2.6)) were statistically significantly reduced ($p<0.0001$). No safety flags were identified; BP (systolic, diastolic) was reduced by ~2-4 mmHg, bone mineral density (DEXA) was unchanged at 52 weeks.
Conclusion: Noninvasively identified patients with NASH treated with 100 mg per day of resmetirom for up to 52 weeks demonstrated rapid and sustained reduction in 1-hepatic fat and LV; 2-fibrosis, assessed by biomarkers, MRE and TE; 3- LDL and atherogenic lipids; 4-liver enzymes and inflammatory biomarkers, supporting the use of non-invasive tests to monitor NASH patient response to resmetirom.

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P-61

Arterial hypertension in cirrhotic patients is associated with older age and protects against liver decompensation independently of the etiology of the liver disease

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