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All Oral Interferon-Free Antivirals for Hepatitis C Virus Cryoglobulinemia Vasculitis: A Long Term Follow up Multicenter International Study

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SESSION INFORMATION

Date: Sunday, November 5, 2017

Session Title: Vasculitis I: Clinical Trials and Outcomes

Session Type: ACR Concurrent Abstract Session

Session Time: 2:30PM-4:00PM

Background/Purpose: Interferon (IFN) containing regimens used for hepatitis C virus (HCV)-cryoglobulinemia vasculitis (CryoVas) are poorly effective and associated with important side effects. In small-size and short term studies, direct antiviral agents (DAAs) have been reported to have a better response rate and tolerance. To evaluate effectiveness and tolerance of all oral IFN-free regimen in a real life – long term follow up – large cohort of symptomatic HCV-CryoVas patients.

Methods: 145 patients (57 years, 55% F) presenting symptomatic HCV-CryoVas who received DAAs, i.e. Sofosbuvir (SOF) plus Ribavirin (n=50), SOF plus Daclatasvir (n=49), SOF plus Ledipasvir (n=23), SOF plus Simeprevir (n=18), or other DAAs (n=5), for 12 or 24 weeks. Primary efficacy end point was a complete clinical response of CryoVas 12 weeks after stopping antivirals. Secondary endpoints: (i) sustained virological response (SVR12), (ii) tolerance of antivirals, and (iii) complete clinical response of CryoVas at the end of follow up.

Results: Baseline HCV-CryoVas features included arthralgia (64%), purpura (57%), neuropathy (58%), and glomerulonephritis (17%). Forty six (36%) patients had cirrhosis and 70 (48.3%) were naïve of antivirals. At 12 weeks post-DAAs, 103 (72%) showed a complete clinical response, 33 (23.1%) a partial response and 7 (4.9%) no response of CryoVas symptoms. Cryoglobulinemia disappeared in 53.1%. SVR12 was obtained in 97.1%. Premature DAAs withdrawal due to side effects was noted in 6 (4.1%). Main differences between patients with a complete response of the vasculitis (n=103) vs. partial/no response (n=40) were a severe form of CryoVas (65.1% vs 85%), arterial hypertension (22.3% vs. 45%), type 3 mixed cryoglobulinemia (31.3% vs. 9.1%), and use of immunosuppressant/plasma exchange (36.1% vs. 13.7%). The only factor that remained independently associated with a poor response was a severe form of CryoVas [OR 0.26, CI95% 0.07-0.98; P=0.04]. After a median follow-up of 15.3 months, 4 (2.8%) patients died. The 12-months survival rate was 97% [CI95% 94,100]. At the end of follow up, rates of CryoVas manifestations clearance were skin ulcers (98%), purpura (98%), renal involvement (92%), arthralgia (87%), neuropathy (78%) and cryoglobulinemia (54%). Rates of CryoVas complete remission at week12 post-treatment and at the end of follow up were for SOF plus Ribavirin 62% and 70%, SOF plus Simeprevir 67% and 72%, SOF plus Daclatasvir 78% and 88%, and SOF plus Ledipasvir 87% and 87%, respectively.

Conclusion: Sofosbuvir-based IFN-free DAAs combinations are highly effective in HCV-CryoVas patients in short term and long term, with a very good tolerance profile.

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