

SPECIAL POSTER FEATURE

AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES (AASLD): THE LIVER MEETING® 2016 COVERAGE

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MEETING SUMMARY

The Liver Meeting®, the official meeting of the American Association for the Study of Liver Diseases (AASLD), held in Boston, Massachusetts, USA, supported the presentation of recent clinical and basic research in liver disease by renowned experts, to target the diverse needs of hepatology professionals. A summary of posters presented on viral hepatitis and orthotopic liver transplantation (LT) and oral presentations discussing chronic hepatitis infection were given.

VIRAL HEPATITIS AND ORTHOTOPIC LIVER TRANSPLANTATION POSTER SESSION

Hepatitis B virus (HBV) and hepatitis C virus (HCV) infection are among the most common causes of cirrhosis and hepatocellular carcinoma (HCC), with cirrhosis secondary to chronic HCV the leading indication for LT globally.¹ The Viral Hepatitis and Orthotopic Liver Transplantation poster session at The Liver Meeting® covered important topics related to LT including whether HCV antibody (Ab) positive livers can safely be transplanted into HCV Ab⁻ recipients and whether regional differences exist in the characteristics of patients with HCV-related LT. Outcomes for chronic HCV have improved with the introduction of interferon (IFN)-free direct-acting antiviral (DAA) regimens,^{1,2} and studies presented in this poster session largely relate to the safety and efficacy of DAAs, some of which were conducted in special patient populations such as HIV-HCV co-infected individuals.

Late breaking abstracts of large clinical studies and high-impact translational studies, which featured the most current research, were presented at The Liver Meeting 2016.

The Use of Hepatitis C Virus-Positive Donors in Hepatitis C Virus-Negative Liver Transplant Recipients

There has been an increasing emphasis on using HCV Ab⁺ donor livers in HCV Ab⁻ LT candidates with the introduction of DAAs; however, data are lacking to support these potential donor-expanding policies.

Dr George Cholankeril, University of Tennessee, Memphis, Tennessee, USA, presented a study that evaluated post-LT survival rates in HCV Ab⁺ donor/HCV Ab⁺ recipient (+/+) and HCV⁺ donor/HCV Ab⁻ recipient (+/-) populations, using the United Network for Organ Sharing (UNOS) Database (2003-2014).³ Survival was also compared in the HCV Ab⁺ donor cohorts with the HCV Ab⁻ donor/HCV Ab⁻ recipient populations (-/-).

Of 1,953 HCV Ab⁺ donor livers, 1,883 (96.4%) were allocated to HCV Ab⁺ LT recipients (+/+)

and 70 (3.6%) to HCV Ab⁻ LT recipients (+/-). Compared with the HCV Ab (+/+) group, the HCV Ab (+/-) group contained both older donors (43.5 versus 41.5 years; $p < 0.01$) and younger recipients (52.0 versus 54.6 years; $p < 0.01$).

HCV Ab (+/-) LT recipients had a lower 1-year and 5-year post-LT survival rate compared with HCV Ab (-/-) and HCV Ab (+/+) recipients ($p < 0.001$). The 1-year and 5-year survival rates post-LT were, respectively, 90.1% and 81.7% for HCV Ab (-/-), 89.9% and 77.1% for HCV Ab (+/+), and 85.7% and 65.7% for HCV Ab (+/-).

A subanalysis of findings from the years 2013–2014 (era of DAA) was performed. During this 2-year period, 32 of the 70 (45.7%) HCV Ab (+/-) LT surgeries occurred. The subanalysis found that the 1-year survival rate post-LT in the HCV (+/-) group was 90.6%, comparable to both the HCV Ab (-/-) and HCV Ab (+/+) groups (91.7% and 92.5%, respectively).

The investigators of this study demonstrated a worse survival rate post-LT in HCV Ab⁻ recipients who received livers from HCV Ab⁺ donors. However, during the era of DAA therapy, an improvement was noted in the 1-year survival rate post-LT, raising the possibility that the donor pool may be safely expanded in the future.

Peritransplant Treatment with Direct Acting Antivirals of HIV-Hepatitis C Virus Co-Infected Patients

New DAAs have significantly improved sustained viral response (SVR) rates in the treatment of HCV, including special patient populations, such as HIV-HCV co-infected individuals and LT recipients. However, there are limited efficacy and safety data for DAAs in HIV-HCV co-infected patients in the peritransplant setting.

Dr Carmen Vinaixa, Hospital Universitari i Politècnic La Fe, Valencia, Spain, presented an observational case-controlled study that investigated the efficacy, safety, and drug-drug interactions with DAA treatment in HIV-HCV co-infected patients in the pre-transplant setting (wait list) and post-transplant setting.⁴ The HIV-HCV co-infected patients were compared to HCV mono-infected patients by matching each co-infected patient with two mono-infected patients by HCV genotype, fibrosis stage, antiviral treatment regimen, and by Model of End-Stage Liver Disease (MELD) and Child-Pugh scores if cirrhosis was present.

In the pre-transplant setting, data were collected for nine HIV-HCV co-infected patients and 18 HCV mono-infected patients. The most common treatment regimen in co-infected patients was sofosbuvir (SOF)+daclatasvir (DCV)±ribavirin (RBV) (70%), and in mono-infected patients was SOF/ledipasvir (LDV)±RBV (43%). A rapid virological response occurred in 67% of co-infected and 73% of mono-infected patients. At Week 4, a SVR occurred in 67% of co-infected and 89% of mono-infected patients, and these rates were unchanged at 12 weeks. There were two non-responses in the HIV-HCV (genotype 4) co-infected patients treated with the suboptimal regimen SOF-RBV, and one relapse occurred in a single HCV mono-infected patient.

In the post-transplant setting, data were collected for 15 HIV-HCV co-infected patients and 30 mono-infected patients. The most common treatment regimen was SOF/LDV±RBV in co-infected patients (67%) and mono-infected patients (64%). The rapid virological response rate was 57% in co-infected and 80% in mono-infected patients; the SVR rates at Week 4 and Week 12 were 93% in co-infected and 97% in mono-infected patients. One relapse occurred in a HIV-HCV co-infected patient. Compared with mono-infected patients, co-infected patients had higher rates of anaemia (57% versus 50%), use of erythropoietin (EPO; 33% versus 17%), and transfusions (33% versus 10%).

The investigators concluded that antiviral treatment with DAAs in HIV-HCV co-infected patients in the pre and post-transplant setting is effective, safe, and easily applicable, even when co-administered with HIV antiviral drugs. In the co-infected group in the pre-transplant setting, there was a higher incidence of infections, whereas more anaemia, use of erythropoietin (EPO), and transfusions were evident in the post-transplant setting. The investigators recommend closer on-treatment monitoring in HCV-HIV co-infected patients in the peritransplant setting.

Hepatitis E Virus Infection and Hepatic Graft Versus Host Disease In Allogenic Hematopoietic Stem Cell Transplantation Recipients

In immunocompromised patients, such as those with allogenic haematopoietic stem cell transplantation (alloHSCT), hepatitis E virus (HEV) genotype 3 infection can lead to the development of chronic HEV infection and liver cirrhosis.^{5,6} Increased alanine

aminotransferase (ALT) levels occur in most patients with HEV infection and at least one episode of elevated transaminase levels is experienced by most alloHSCT patients post-transplantation.⁷ Elevated ALT levels are usually ascribed to drug toxicity, graft versus host disease (GvHD), or iron deposition.⁸

Dr Donna Bezuur, Academic Medical Center, Amsterdam, Netherlands, presented a retrospective cohort analysis on the prevalence of HEV infection in patients with elevated ALT levels following alloHSCT between 2005 and 2015.⁹ Of the 130 alloHSCT patients, 123 had ≥ 1 episodes of elevated ALT levels (defined as ALT >50 U/L for ≥ 4 consecutive weeks), recurrent elevated ALT levels (>50 U/L for a shorter period of time with normal ALT levels in between), or an episode of peaking ALT levels (>100 U/L during a period of <4 weeks). To confirm an active viral presence at the time of ALT elevation, HEV RNA was isolated and identified using real-time quantitative PCR.

Of the 123 patients with ALT elevations, 5 (4%) had HEV infection; their age ranged from 37–70 years, 2 were female, and the underlying diseases were chronic lymphoid leukaemia (n=2), acute lymphatic leukaemia (n=1), chronic myeloid leukaemia (n=1), or Hodgkin lymphoma (n=1). In the entire cohort of 130 alloHSCT recipients, 19 were diagnosed with GvHD. Three of the five HEV positive patients had signs of concomitant GvHD, and in two of these patients, RBV treatment led to rapid clearance of the virus and resolution of the GvHD.

The investigators concluded that HEV infection was prevalent among alloHSCT recipients and may be related to the presence of GvHD. Additionally, the investigators hypothesised that HEV could provoke or sustain hepatic GvHD. While further study in larger patient cohorts is required to confirm these findings and test this hypothesis, the results suggest that all alloHSCT patients with persistently elevated ALT levels should be considered for HEV infection, particularly in patients with signs of hepatic GvHD.

Daclatasvir in Combination with Other Direct Acting Antivirals Achieves a High Rate of Virological Clearance with an Excellent Safety Profile in Liver Transplanted Patients for Hepatitis C Virus

Prior to the new DAA era, outcomes were poor for patients who underwent LT for HCV. Based on the availability of DAA combinations, the Italian Named Patient Programme (NPP) was started (2013–2014).

The NPP was granted access to LT recipients who had advanced disease and a life expectancy <12 months due to severe HCV recurrence or cholestatic hepatitis.

Dr Rafaella Lionetti, IRCCS Lazzaro Spallanzani, Rome, Italy, presented a real-world study that evaluated the efficacy and safety of DAAs.¹⁰ Italian patients in the NPP that underwent LT for HCV and who were treated with DCV+SOF or simeprevir (SMV) were included in the analysis. Of the 94 patients, the majority were infected by HCV genotype 1 (84.1%) and 79.2% of patients were cirrhotics. The treatment used was DCV+SOF \pm RBV in 88 patients and DCV+SMV in 6 patients, with all patients treated for 24 weeks. The addition of RBV to dual DAAs was by physician choice. HCV RNA was undetectable in 50% of patients at Week 4, 75% at Week 8, and 97% at Week 12. Of the 87 evaluable patients, the SVR at Week 12 was 88.2% and remained unchanged at Week 24. Virological breakthrough after achieving viral undetectability occurred in three patients in the DCV+SMV group without RBV, and two patients on DCV+SOF without RBV relapsed after end of treatment (EOT). Overall, RBV was administered in 53 patients (57%); all but 1 patient experienced SVR; therefore, RBV use was associated with SVR benefit (odds ratio [OR]: 15.1; $p=0.012$).

A significant improvement from baseline in bilirubin ($p<0.001$) and albumin ($p<0.0001$) levels was found at the EOT and at Week 12 and 24 follow-ups. Creatinine increased significantly from baseline to EOT (1.14 versus 1.2 mg/dL; $p<0.004$), which indicated a worsening in renal function; creatinine levels at the Week 12 follow-up (1.17 mg/dL) and Week 24 follow-up (1.19 mg/dL) were no longer significantly higher than baseline, suggesting a return to normal function. RBV was stopped in 13 patients due to anaemia (n=11), rash (n=1), or diarrhoea (n=1).

Findings from the study found that the combination of DAAs with DCV was efficacious and had an excellent safety profile in this real-world Italian study of LT HCV patients. The addition of RBV to DAAs appeared to improve SVR. Liver function improved during therapy and persisted during follow-up, whereas a mild and transient worsening in renal function occurred during treatment.

Variation in Demographics and Comorbidities in Hepatitis C Virus Liver Transplant Recipients within United Network for Organ Sharing Regions

HCV is the leading indication for LT in the USA. Dr George Cholankeril presented an analysis of regional characteristics of HCV-related LT recipients within the USA.¹¹ The UNOS database was used to determine differences in HCV-related LT within the 11 UNOS regions of the USA from 2003–2014. A subanalysis then compared the two UNOS regions with the highest number of HCV-related LTs. Analysis included the evaluation of demographics, diabetes, ascites, hepatic encephalopathy, HCC, and post-transplant survival.

Overall, 20,778 HCV-related LTs were performed in the USA from 2003–2014. Region 3 (n=3,415; 16.4%) and Region 5 (n=3,150; 15.2%) were the two UNOS regions with the highest proportion (31.6%) of HCV-related LTs. Compared with all other HCV-related LTs in the USA, Region 3 and Region 5 had slightly improved 5-year post-transplant survival with 75.6% for other regions, 76.9% for Region 3 (p<0.01 versus other regions), and 78.1% for Region 5 (p<0.01 versus other regions).

When comparing characteristics between regions, Region 5 had a higher proportion of Asians (8.3% in Region 5, 1.5% in Region 3, and 2.6% in other regions; p<0.01), which constituted 38.7% of all HCV-related LTs within the Asian cohort. Another notable difference was the prevalence of HCC, which was 32.1% in Region 5, 22.7% in Region 3, and 29.9% in other regions (p<0.01). Regional differences in demographics and comorbidities of HCV-related LT recipients within the USA are considerable, though this likely represents a regional disparity in wait list time to LT. Understanding these differences in HCV-LT recipients may help identify geographical subpopulations at risk for decompensated liver disease due to HCV.

100% Virological Response With 3D Regimen and Significant Short-Term Liver Stiffness Improvement in Patients with Recurrent Hepatitis C Virus Following Liver Transplantation

The DAA regimen of ombitasvir/paritaprevir/ritonavir, dasabuvir, and RBV (3D+R) was approved by the US Food and Drug Administration (FDA) in December 2014 for LT recipients with genotype 1 recurrent HCV, although drug interactions may be a concern. Treatment with 3D+R is a cost-

effective and outcome-improving regimen for this difficult-to-treat population of LT patients with recurrent HCV.¹²

Dr Speranta Iacob, Fundeni Clinical Institute, Bucharest, Romania, presented results from a cohort of 72 patients with recurrent HCV after LT who were treated with 3D+R for 24 weeks.¹³ Liver stiffness can be used to assess inflammation and fibrosis in LT recipients and to follow these patients after HCV eradication. Liver stiffness was assessed by non-invasive Fibroscan® before therapy, at EOT, and at the time of SVR12 evaluation. FibroMAX was performed before therapy to provide a measure of baseline inflammation, fibrosis, and steatosis.

Of the 72 patients, 40 were male, the mean age was 55.2 years, and the median time since LT was 26.6 months. By Week 8 of treatment, HCV RNA was undetectable in 100% of patients, and this persisted up to 12 weeks after EOT. Liver stiffness assessed by FibroMAX at baseline differed significantly by activity grade (p=0.0008) and fibrosis stage (p<0.0001). Furthermore, liver stiffness assessed by Fibroscan significantly improved from baseline to EOT (p=0.0016) and further improved from EOT to SVR12 (p=0.007).

The study found that virological response with 3D+R in LT patients with recurrent HCV reached 100% at EOT and up to 12 weeks after. Liver stiffness significantly decreased after EOT and SVR12 and suggests improvement in liver damage with 3D+R.

Treatment of Hepatitis C Virus with Ledipasvir, Sofosbuvir, with or without Ribavirin in Post-Liver Transplant Patients in an Academic Centre

Recurrence of HCV is challenging in the LT population, particularly with accelerated rates of fibrosis, lower SVR rates, and decreased tolerability to traditional therapies. Dr Nikolaos Pyrsopoulos, Rutgers, The State University of New Jersey, New Brunswick, New Jersey, USA, presented results of a study of 63 LT patients with HCV who were treated with SOF and LDV with or without low-dose RBV and immunosuppressive therapy.¹⁴

Patients included in the analysis were at least 3 months post-LT with documented recurrent HCV of genotype 1a, 1b, 3, 4, 5a, or 6, and were treated with SOF/LDV with concurrent immunosuppressive therapy (cyclosporine, tacrolimus, everolimus, or sirolimus). Pre-treatment dosing of

immunosuppressive therapy was maintained, and patients were evaluated for SVR12 and side effects of therapy.

Of the 63 patients, 48 (76%) were male and the median age was 61 years. Treatment with SOF/LDV+RBV was completed by 60 patients (genotype 1a, n=39; genotype 1b, n=14; genotype 3, n=1; genotype 4, n=3; genotype 5, n=1; genotype 6, n=2). RBV was commonly dosed at 200 mg twice daily and titrated as tolerated. Of the three patients treated with SOF/LDV, two (genotype 1a) completed the 24 weeks of treatment, and one completed only 8 weeks due to severe allograft dysfunction. All 63 patients were evaluable for efficacy, and the SVR12 was 100%. Adverse effects were reported in 23 patients and included fatigue/weakness (n=15), anaemia (n=4), headache (n=3), diarrhoea (n=2), nausea/vomiting (n=1), pruritus (n=1), and arthralgia (n=1). The four patients with anaemia received EPO alpha and three of these received blood transfusions. These findings suggest that SOF/LDV with or without low-dose RBV may be a viable treatment option for LT patients with HCV.

Hepatitis B Reactivation Associated with Direct Acting Antiviral Therapy for Hepatitis C Virus: A Review of Spontaneous Post-Marketing Cases

Treatment for HCV with new DAAs allows for >90% chance of SVR, which is an improvement over older regimens. HBV co-infection with HCV is common in particular geographical areas where both infections are endemic and in populations at high risk of acquiring both infections due to common routes of transmission. HBV reactivation (HBV-R) can occur spontaneously but is usually triggered by immunosuppressive therapy, immunodeficiency due to HIV, autoimmune disease, or organ transplantation. HBV-R has also been reported in HBV-HCV co-infected patients treated with IFN-based therapy.

Dr Susan Bersoff-Matcha, FDA, Silver Spring, Maryland, USA, presented an analysis of the FDA's Adverse Event Reporting System (FAERS) database to identify reports of HBV-R associated with second-generation HCV DAAs and determine whether HBV-R is a safety concern with DAAs.¹⁵ Reports of HBV-R cases among patients receiving all currently approved second-generation DAAs from 22nd November 2013 (the date of USA SMV approval) to 15th October 2016 were included.

There were 29 cases of HBV-R identified among patients receiving currently approved second-generation DAAs: 19 were reported in Japan, 5 in the USA, and 5 in other countries. All cases were temporally related to DAA initiation and the mean time from DAA to HBV-R was 53 days (range: 14–196 days). Of the 3 patients who developed decompensated liver failure, 2 died and 1 required LT. In the 16 patients treated for HBV, treatment was delayed in at least 7 cases (44%) and 1 of these patients died. Most patients had improvement in HBV DNA with treatment, as well as accompanying signs and symptoms such as elevated transaminases and malaise/fatigue. In 18 patients with a confirmed HCV genotype, 16 patients (89%) had genotype 1. A range of DAAs were received, suggesting that HBV-R is associated with the class of drug and not one particular DAA. The data should be interpreted with caution as FAERS is a voluntary reporting system and data may be incomplete, of variable quality, and subject to reporting bias and under-reporting.

The investigators concluded that HBV-R is a safety concern in patients previously infected with HBV who take DAAs. However, the benefit of a high HCV cure rate with DAAs continues to outweigh the risks, even in patients who may be at risk of HBV-R. Patients with a history of HBV require careful monitoring while on DAA therapy and further studies are required to determine the monitoring frequency and risk factors for HBV-R to identify patients who may benefit from HBV prophylaxis and treatment.

Reduction in Liver Transplantation Wait List in the Era of Direct Acting Antiviral Therapy

DAA therapy in patients with HCV and decompensated cirrhosis can improve hepatic function and may allow the avoidance of LT. Dr Jennifer Flemming, Queen's University, Kingston, Ontario, Canada, presented a retrospective population-based cohort analysis of trends in LT wait lists to explore the potential impact of effective therapy on wait list registration.¹⁶

Adult patients listed for first LT for HCV, HBV, or non-alcoholic steatohepatitis (NASH) were identified from the Scientific Registry of Transplant Recipients (SRTR) database from 2003–2015. The indication for waitlisting was either decompensated cirrhosis if their biochemical MELD score was ≥ 15 , or HCC. The era of wait list was defined as 'IFN' (2003–2010), 'protease inhibitor' (2011–

2013), or 'DAA' (2014–2015). Annual standardised incidence rates for LT wait list addition were analysed using modified Poisson regression.

Of 47,591 LT wait list registrants identified, 61% were listed for decompensated cirrhosis and 39% for HCC. Compared to the IFN era, the LT wait list rate for decompensated cirrhosis in HCV patients decreased by 4.8% in the protease inhibitor era ($p=0.004$) and by 31.9% in the DAA era ($p<0.001$). The LT wait list rate for decompensated cirrhosis in HBV patients also decreased in the protease inhibitor era (17%, $p=0.002$) and the DAA era (24.1%, $p<0.001$) compared with the IFN era. Conversely, LT wait list rates for decompensated cirrhosis in patients with NASH increased by 41.2% in the protease inhibitor era ($p<0.001$) and by 80.8% in the DAA era ($p<0.001$) compared with the IFN era. In 2015, the LT wait list rate for decompensated cirrhosis in NASH was equal to HCV. Wait list rates for HCC in both HCV and NASH patients increased in both the protease inhibitor and DAA eras ($p<0.001$), while wait list rates for HCC in HBV patients did not change significantly. This analysis found that LT wait list registrations have

decreased more than 30% for decompensated HCV disease during the DAA therapy era in the USA. The ongoing efforts to increase HCV screening and linkage to care and improved access to DAAs will likely eliminate HCV as the leading cause for LT in the USA.

CONCLUSION

The Viral Hepatitis and Orthotopic Liver Transplant poster session largely consisted of real-world studies that confirmed the efficacy and safety of DAA therapy in HCV patients. Of note, an FDA analysis concluded that HBV-R is a safety concern in patients previously infected with HBV who take DAAs; however, the benefit of DAAs for HCV outweigh the risks even for patients who may be at risk for HBV-R.¹⁵ Furthermore, a large USA study found that LT wait list registrations for decompensated cirrhosis from HCV decreased >30% in the DAA therapy era compared with the IFN era.¹⁶ Investigators are hopeful that increased HCV screening, linkage to care, and access to DAA therapy will eliminate HCV as the leading cause for LT in the USA.¹⁷

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