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Early Local Western Australian Experience with Ombitasvir, Paritaprevir, Ritonavir, Dasabuvir +/- Ribavirin in Genotype 1 Hepatitis C Patients and its Impact on Liver Fibrosis and Liver Inflammation

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Background and Aims

A new wave of direct acting antivirals against Hepatitis C virus (HCV) were approved in 2016 in Australia by the Pharmaceutical Benefits Scheme (PBS). We aimed to evaluate the success of ombitasvir, paritaprevir, ritonavir, and dasabuvir with or without ribavirin not only on viral clearance but also its impact on liver fibrosis using transient elastography and liver inflammation using ALT in a local cohort of Western Australian HCV genotype 1 patients who obtained treatment via compassionate access in the preceding 18 months.

Methods

We retrospectively analysed 27 genotype 1 HCV patients (17 with genotype 1a, 8 with genotype 1b, and 2 with unspecified genotype 1 subtype) who obtained treatment via compassionate access and were treated as per the treatment guidelines in Table 1. We collected data on the patients' fibrosis status and previous treatment attempts, in addition to pre-treatment and post-treatment HCV viral load, ALT, and liver stiffness measurement using transient elastography. We recorded their sustained virological response, defined as an undetected viral load 3 months (SVR12) and 6 months (SVR24) after treatment completion.

Results

Sustained Virological Response (either SVR12 or SVR24) was achieved in 26/27 (96.3%) patients who completed treatment. 3 months after treatment completion, transient elastography was performed on 16 patients, and 10/16 patients demonstrated a statistically significant improvement in liver stiffness measurement on average by 37%. 3 patients did not demonstrate an improvement in their liver stiffness measurement, and a further 3 patients' liver stiffness measurement deteriorated despite achieving sustained virological response. All 27 patients demonstrated a statistically significant improvement in their ALT (including the patient who did not achieve SVR12). The ALT normalised rapidly after treatment commenced, with 20/27 patients achieving a normal ALT on average in 24 days after commencing treatment. The ALT level improved on average by 2.3% per day, or 15.9% per week over the first 4 weeks since commencing treatment.

SVR by Genotype subtype, cirrhosis and prior treatment

Genotype 1a	SVR12 or SVR24
Noncirrhotic, Treatment Naïve	4/4 (100%)
Noncirrhotic, Treatment experienced	6/6 (100%)
Cirrhotic, Treatment Naïve	3/4 (75%)
Cirrhotic, Treatment experienced	3/3 (100%)

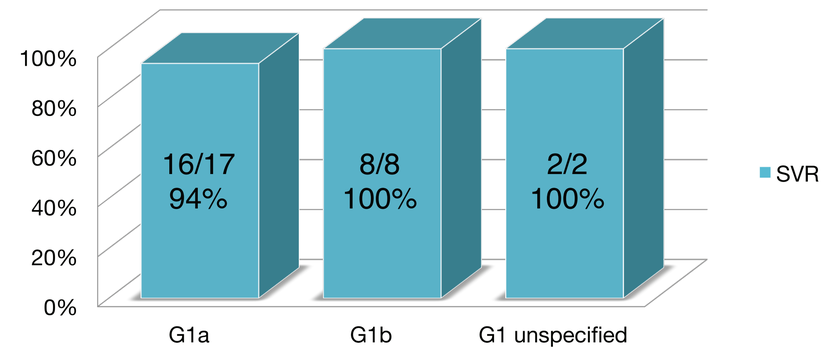
Genotype 1b	SVR12 or SVR24
Noncirrhotic, Treatment Naïve	2/2 (100%)
Noncirrhotic, Treatment experienced	3/3 (100%)
Cirrhotic, Treatment Naïve	2/2 (100%)
Cirrhotic, Treatment experienced	1/1(100%)

Genotype	SVR12 or SVR24
All G1a	16/17 (93%)
All G1b	8/8 (100%)
All G1 unspecified subtype	2/2 (100%)
Total	26/27 (96.3%)

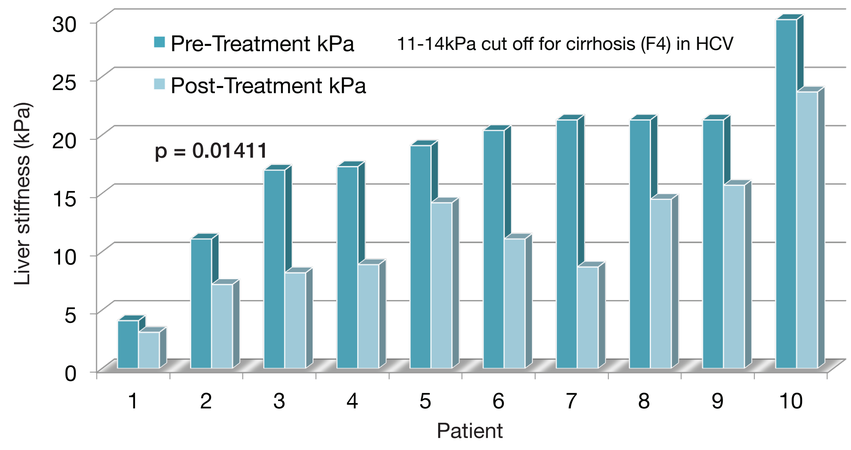
Patient population	Treatment	Duration
Genotype 1a, without cirrhosis	Ombitasvir/paritaprevir/ritonavir plus dasabuvir + ribavirin	12 weeks
Genotype 1a, compensated cirrhosis	Ombitasvir/paritaprevir/ritonavir plus dasabuvir + ribavirin	24 weeks
Genotype 1b, without cirrhosis	Ombitasvir/paritaprevir/ritonavir plus dasabuvir	12 weeks
Genotype 1b, compensated cirrhosis	Ombitasvir/paritaprevir/ritonavir plus dasabuvir + ribavirin	12 weeks

Table 1. Treatment of GT1 HCV guidelines using ombitasvir, paritaprevir, ritonavir, dasabuvir +/- ribavirin

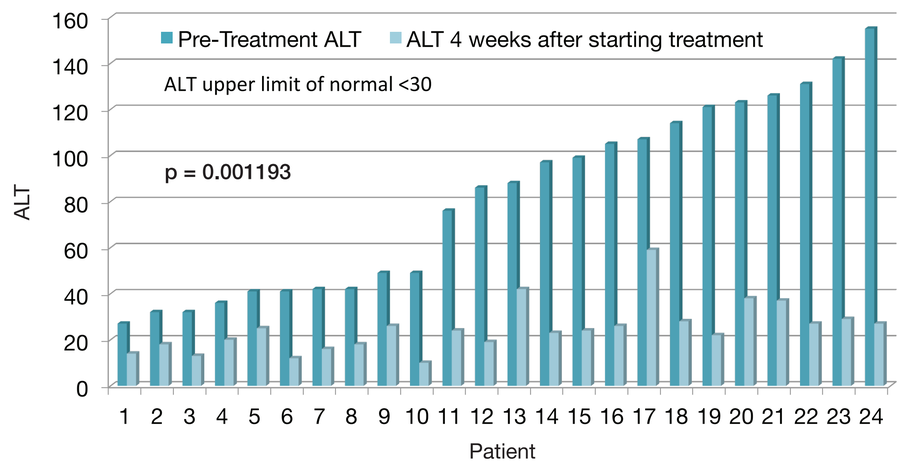
Sustained Virological Response by Genotype subtype



Pre and post treatment liver stiffness measurement



Pre and post treatment liver inflammation (ALT)



Conclusion

The regimen of ombitasvir, paritaprevir, ritonavir and dasabuvir with or without ribavirin is effective in our local cohort of Western Australian HCV genotype 1 patients. We achieved not only similar SVR rates compared to larger international randomised controlled trials, but also statistically significant improvements in liver inflammation measured with ALT and liver stiffness measurement using transient elastography after treatment.

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