nurse specialists. Proformas identifying treatment centre, patient characteristics, viral response, treatment compliance and outcome were completed and entered into a database for further analysis. Viral data from genotype 1 HCV patients identified those who relapsed, had viral breakthrough or were non-responders. Non-responders were further categorised into partial and null responders.
Results 361 patients from five centres (Plymouth, Exeter, Truro, Torbay and Barnstaple) were identified. 164/361 patients (45.4%) had genotype 1, of which 11.6% (n=19) were cirrhotic. 40.8% (n=67) achieved SVR, 15.9% (n=26) relapsed and 4.3% (n=7) had viral breakthrough. Of 33 (20.1%) non-responders, 20 were null responders, 11 partial responders and 2 had insufficient viral load data. 9.1% (n=15) stopped treatment early, 7.9% (n=13) were lost to follow-up and 1.8% (n=3) had no post-treatment viral load data available. 17 genotype 1 patients were treated in prison, of which, 11.7% (n=2) stopped treatment early and 41.1% (n=7) were lost to follow-up. Of the 97 (59.2%) genotype 1 cases who did not achieve SVR, at least 44/164 (26.8%) would have a very clear benefit from re-treatment with PIs.
Conclusion A significant number (26.8%) of genotype 1 treatment-experienced patients treated in the South West would benefit from re-treatment, with addition of a PI to their HCV treatment. Adherence with treatment and reliable follow-up of patients are crucial for safe treatment with PIs. Despite the provision of a good HCV service, a significant number of cases did not attend for prearranged reviews. At present, 7.9% of cases treated were lost to follow-up, with prisoners disproportionately unlikely to attend planned clinics.

Competing interests M Saunders: None declared, C Sieberhagen: None declared, L Taylor: None declared, F Fry: None declared, M McKenna: None declared, S Needs: None declared, R Chimakurthi: None declared, M Cramp grant/research support from: Unrestricted educational grants from Roche, MSD and Janssen, Conflict with: Served on advisory boards for Janssen, Roche, MSD and Gilead.

REFERENCE

1. **Ghany M,** *et al.* An Update on Treatment of Genotype 1 Chronic Hepatitis C Virus Infection: 2011 Practice Guideline by the American Association for the Study of Liver Diseases. *Hepatology* 2011;**54**:1433–44.

PM0-166 EARLY EXPERIENCE WITH TELAPREVIR FOR PATIENTS WITH ADVANCED FIBROSIS OR CIRRHOSIS

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Introduction The direct-acting HCV protease inhibitor telaprevir has recently been licensed for treatment of chronic genotype 1 HCV infection, and promises significant improvements in sustained virological response for these patients. However the patients who may benefit most from novel HCV therapies, namely those with advanced fibrosis or cirrhosis who have previously failed to respond to pegylated interferon (pegIFN) and ribavirin treatment, are relatively poorly represented in the telaprevir clinical trials. Efficacy, safety and tolerability were assessed in patients with genotype 1 HCV and advanced fibrosis/cirrhosis who have received telaprevir-containing treatment at the Royal London Hospital.
Methods Laboratory results and case notes were reviewed for all patients treated with pegIFN, ribavirin and telaprevir at the Royal London Hospital between September 2011 and January 2012.
Results Eight patients with genotype 1 HCV had commenced telaprevir-containing treatment. All had advanced fibrosis/cirrhosis (median Ishak score 5, range 4–6). One was treatment-naïve, three had previously failed to respond to pegIFN/ribavirin and four had relapsed after therapy. All patients had completed at least 4 weeks of telaprevir-containing therapy. With one exception, all patients achieved undetectable HCV RNA at week 4 of treatment; the patient who did not had a viral load of 168 IU/ml at week 4 and undetectable HCV RNA at week 8. One patient had completed 12 weeks of therapy, with undetectable HCV RNA. The most common side effects were fatigue (8/8), pruritis (4/8), rash (3/8), anal pain (3/8), depression (3/8), nausea (3/8), gastrointestinal disturbance (2/8) and oral candidiasis (2/8). Most side effects were successfully managed, although telaprevir was stopped in two patients at week 8 due to worsening rash and one patient withdrew from all therapy at week 4 due to tolerability. The most common laboratory abnormality was an early, transient rise in bilirubin (3/8). Significant anaemia (Hb).
Conclusion Telaprevir in combination with pegIFN and ribavirin appears efficacious in patients with advanced fibrosis or cirrhosis, who have previously failed treatment with pegIFN and ribavirin alone. However, the incidence of significant side effects in this subgroup of patients is high and necessitates frequent follow-up with medical support. Side effects, particularly rash, may limit duration of telaprevir treatment. Whether this impacts on sustained virological response remains to be seen.

Competing interests M Cunningham: None declared, J Schulz: None declared, L Payaniandy: None declared, Y Kallis: None declared, P Kennedy: None declared, P Kooner: None declared, R Marley: None declared, G Foster grant/research Support from: Roche, Janssen, Tibotec, Novartis, Consultant for: Abbott, BI, BMS, Chughai, Janssen, Merck, Novartis, Roche, Tibotec.

PM0-167 PRESENCE OF VIABLE HCV RNA IN MONOCYTES AT THE END OF TREATMENT PREDICTS RELAPSE IN GENOTYPE 3 HCV INFECTION

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Introduction Although genotype (G)3 HCV is generally regarded as "easy to treat", based on clinical trial data showing response rates of up to 80%, real world studies have shown substantially lower rates of treatment response (45%), particularly in patients with advanced fibrosis or cirrhosis. Most patients who fail treatment for G3 HCV initially respond to antiviral therapy, but relapse after the end of treatment. HCV RNA has been demonstrated in peripheral blood mononuclear cells from patients with chronic HCV, but whether viral replication occurs in these cells remains controversial. This study tests the hypothesis that viable HCV in monocytes at the end of treatment predicts relapse in patients with G3 HCV.
Methods CD14 (+) monocytes from patients at the end of treatment for G3 HCV were isolated and fused with HuH7 cells. The fused cells were maintained in tissue culture for up to 5 days, before extraction of HCV RNA and quantification by PCR. p Values were derived using the Mann–Whitney U test for comparison of non-parametric data. Results are expressed as mean ± SEM.
Results HCV RNA increased up to fivefold in fused compared to unfused monocytes. Viral protein production was demonstrated in fused cells by indirect immunofluorescence, confirming that viral replication occurs in the fused cells. Fused monocytes from patients who relapsed after treatment showed a significantly greater increase in HCV RNA than those from patients with a sustained virological response (246.8±103.9%, compared to 5±33.9%, p=0.02).
Conclusion These data demonstrate that the presence of replication-competent HCV in monocytes at the end of treatment predicts

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relapse in patients with G3 HCV. Monocytes may act as a sanctuary site for HCV virions during interferon-based treatment, facilitating relapse after withdrawal of therapy.

Competing interests M Cunningham: None declared, A Javaid: None declared, J Waters: None declared, G Foster Grant/Research Support from: Roche, Janssen, Tibotec, Novartis, Consultant for: Abbott, BI, BMS, Chughai, Janssen, Merck, Novartis, Roche, Tibotec.

PMO-168 EFFECTS OF LIDOCAINE 3% GEL DELIVERED RECTALLY IN ANORECTAL DYSFUNCTION (ARD) INDUCED BY TELAPRAVIR THERAPY IN CHRONIC HEPATITIS C (CHC-C) A RANDOMISED PLACEBO CONTROL STUDY

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Introduction Telapravir is a Potent Protease Inhibitor, which causes anorectal dysfunction (ARD) comprising Proctalgia, Rectal Ulcers, Hemorrhoids and rectal bleeding. Conventional therapy is suboptimal causing treatment Failure. This study evaluates 3% Topical Lidocaine gel rectal delivery to abate the drug related ARD to avoid treatment failure.

Methods 52 Patients (mean age 51) were recruited undergoing therapy with Telapravir, Peg Interferon and Ribaviran for CHC-C. 45/52 (86%), with Rectalgia, 8/52 (15%) rectal ulcers, Hemorrhoids 19/52 (36%) with bleeding 6/19 (31%) without Bleeding 13/19 (68%). Group A (n=17) placebo Group B (n=17) hydrocortisone 2.5% Cream and Group C (n=18) Lidocaine 3% Gel foam per rectally twice daily. All underwent Pre and post Proctoscopic evaluation and Ano-rectal manometry.

Results

	Group A	Group B	Group C
Rectalgia	3/17 (17%)	8/17 (47%)	17/18 (94%)
Rectal ulcers	0/2 (0%)	1/3 (33%)	2/3 (66%)
Hemorrhoids resolved w/o bleed	1/6 (16%)	2/6 (33%)	5/7 (71%)
Proctocopic examination showing normalisation of mucosa post therapy	4/17 (23%)	7/17 (41%)	17/18 (94%)

Conclusion Results: Rectalgia resolved in 3/17 (17%), 8/17 (47%) and 7/18 (94%) for Group A, B and C respectively. Rectal ulcers healed in 0/2 (0%), 1/3 (33%) and 2/3 (66%) for all the above groups. Hemorrhoids resolved in 1/6 (16%), 2/6 (33%) and 5/7 (71%) in all groups. Pre/Post Proctoscopy revealed normal mucosal integrity 4/17 (23%), 7/17 (41%) and 17/18 (94%) above groups. Results of Pre/Post Rx mean scores for pain, Itching and Burning shown on (Abstract PMO-168 table 3). AR Manometry results showed Pre/Post treatment high sphincter tone >4 mm in Group A 2/15 (8%) and no differences in pre and post treatment, Group B 7/15 (41%), 4/15 (22%) and Group C 5/15 (20%), 2/15 (10%) respectively (Abstract PMO-168 table 4). Side events; Numbness, 4/17 (23%) in lidocaine. Conclusion: Rectally delivered Lidocaine 3% gel is efficacious, tolerable compared to the SOC and placebo for ARD causing treatment failure, retention and SVR. Larger trial needs to validate this finding.

Competing interests None declared.

PMO-169 PEGYLATED INTERFERON α, NITAZOXANIDE, TELAPRAVIR, RIBAVIRIN, IN GENOTYPE 1 UNDERGOING PRIOR EXPERIENCED CHRONIC HEPATITIS C PATIENTS: A RANDOMISED PLACEBO CONTROL CLINICAL PILOT TRIAL (I N T R I G U E C) INTERIM

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Introduction Chronic hepatitis C is a global challenge with end stage liver disease and rising Hepatocellular Carcinoma. Peg Interferon α and Ribavirin was the backbone of therapy. Recently introduced Directly Acting Antivirals -protease inhibitor has a promising role in escalating Sustained Viral Response in Response guided therapy in non-responders, partial and relapses. This study utilised Nitazoxanide (NTZ) and Telapravir, with SOC for 24 weeks in treatment experienced patients.

Methods 50 (n=50) patients were divided into Group A (n=12) NTZ 500 mg three times for 12 weeks, Group B (n=12) NTZ 500 mg twice daily for 24 weeks Group C (n=26) control. All received Peg Interferon α 2a 180 μg SQ QOW with fixed dose of Ribavirin 1200 mg daily for 24 weeks with Telapravir 750 mg three times daily for 12 weeks. Viral load was obtained at day 0, 7th day, 14th day, 4 weeks, 12th week and 24 weeks. Viral kinetics was analysed. In Group A: 5/12 (42%) Non-Responder, 6/12 (50%) partial responder, 2/12 (16%) relapsers. In Group B: 5/12 (42%) Non-responders, 6/12 (50%) partial responder, 1/12 relapsers (8%). In Group C: 10/26 (38%) non-responder, 10/26 (38%) partial responder, 4/26 (15%) relapsers, 2/26 (8%) unknown. Exclusion: Decompensated Cirrhotic, HCC, poor DM, Haemolytic Anaemia, Severe Coronary artery disease, major depression, renal failure, Prior severe skin rash, active drug and alcohol abuse. Side Effects: Anaemia 28/50 (56%), Neutropenia 14/50 (28%), Thrombocytopaenia 8/50 (16%), Fatigue 34/50 (68%), Depression 10/50 (20%), Mild skin rash 22/50 (44%), Severe skin rash 1/50 (2%). Use of Growth factors: Epogen 12/50 (24%) Neupogen 8/50 (16%) Elthrombopag 5/50 (10%).

Results

Results	Group A	Group B	Group C
Undetectable	9/12 (75%)	10/12 (83%)	16/26 (62%)
NR	1/12 (8%)	2/12 (16%)	4/26 (15%)
PR	1/12 (8%)	12/12 (100%)	3/26 (11%)
AVR	11/12 (92%)	12/12 (100%)	20/26 (77%)
VRVR	11/12 (92%)	10/12 (83%)	22/26 (84%)
RVR	9/12 (75%)	10/12 (83%)	18/26 (70%)
EVR	9/12 (75%)	10/12 (83%)	16/26 (62%)
ETVR	9/12 (75%)	10/12 (83%)	16/26 (62%)

Conclusion This quadruple truncated regimen has excelled the RVR, ETVR over SOC with Directly Acting Antivirals over 13%, without any difference between 24 weeks of NTZ over 12. Needs a larger trial for validation.

Competing interests None declared.

PMO-170 PREVALENCE OF HEPATITIS E IN NEW YORK AMONG HIV NEGATIVE CHRONIC LIVER DISEASE POPULATION "IS IT AN INNOCENT BYSTANDER"

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