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
Telaprevir 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 Telaprevir, Peg Interferon and Ribavirin for CHC-C. 45/52 (86%), with 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-recital manometry.

Results

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

Conclusion
Results: Rectalgia resolved in 3/17 (17%), 8/17 (47%) and 17/18 (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.

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 Telaprevir, with SOC for 24 weeks in treatment experienced patients.

Methods
60 (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 Telaprevir 750 mg three times daily for 12 weeks. Viral load was obtained at day 0, 7th day, 14th day, 4th week, 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%), Thrombocytopenia 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%) Eletrombopeg 5/50 (10%).

Results

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<th></th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undetectable</td>
<td>9/12 (75%)</td>
<td>10/12 (83%)</td>
<td>16/26 (62%)</td>
</tr>
<tr>
<td>NR</td>
<td>1/12 (8%)</td>
<td>2/12 (16%)</td>
<td>4/26 (15%)</td>
</tr>
<tr>
<td>PR</td>
<td>1/12 (8%)</td>
<td>12/12 (100%)</td>
<td>3/26 (11%)</td>
</tr>
<tr>
<td>AVR</td>
<td>11/12 (92%)</td>
<td>12/12 (100%)</td>
<td>20/26 (77%)</td>
</tr>
<tr>
<td>VRV</td>
<td>11/12 (92%)</td>
<td>10/12 (83%)</td>
<td>22/26 (84%)</td>
</tr>
<tr>
<td>RVR</td>
<td>9/12 (75%)</td>
<td>10/12 (83%)</td>
<td>18/26 (70%)</td>
</tr>
<tr>
<td>EVR</td>
<td>9/12 (75%)</td>
<td>10/12 (83%)</td>
<td>16/26 (62%)</td>
</tr>
<tr>
<td>ETVR</td>
<td>9/12 (75%)</td>
<td>10/12 (83%)</td>
<td>16/26 (62%)</td>
</tr>
</tbody>
</table>

Conclusion
This quadruple truncated regimen has excelled the RV, 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.

PREVALENCE OF HEPATITIS E IN NEW YORK AMONG HIV NEGATIVE CHRONIC LIVER DISEASE POPULATION “IS IT AN INNOCENT BYSTANDER”

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Prevalence of hepatitis E in New York among HIV negative chronic liver disease population “Is it an Innocent Bystander”

Epidemiology of viral hepatitis E virus (HEV) is expanding. A recent Rotterdam study reported a prevalence of 4.5% in chronic liver disease population in the Netherlands. In the United States, there are no similar studies. The aim of this study was to evaluate prevalence of HEV in chronic liver disease population seen at a tertiary care center in New York.

Methods
A total of 865 patients suffering from chronic liver disease were enrolled in the study. An HEV screening was performed with HEV IgM and IgG ELISA. Patients positive for IgM were tested for HEV RNA. The study was approved by Institutional Review Board (IRB). The study population included patients with chronic hepatitis C, non-alcoholic steatohepatitis (NASH), autoimmune hepatitis (AIH) and primary sclerosing cholangitis.

Results
Of the 865 patients enrolled in the study, 6% were positive for HEV IgM. 3.5% were positive for HEV RNA. 6.8% were positive for anti-HEV IgM and 4.6% for anti-HEV IgG.

Conclusion
We report a higher prevalence of HEV in chronic liver disease population in New York than previously reported. Further studies are needed to elucidate pathogenesis in chronic liver disease patients.
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Introduction Hepatitis E is essentially an oral fecal infection with high prevalence in developing countries. There is limited data available on its prevalence in Urban US. The study evaluates the prevalence of hepatitis E antibody IgG and IgM in New York in patients with chronic liver disease.

Methods 440 (n=440) were divided into two groups: group A; control 140 patients without any stigmata of liver disease. Group B, 300 patients with history of liver disease including hepatitis B 125/300 (41%), Chronic hepatitis C 60/300 (20%), fatty liver 70/300 (23%), Alcoholic liver disease 29/300 (10%), HBV HCV co infection 9/300 (3%), auto immune hepatitis 2/300 (0.6%), PBC /PSC 5/300 (2%).

Results The prevalence of HEV IgG was 40.6% (122/300) including 3.7% (4/122) of subjects having both IgM and IgG positive. The prevalence of HEV IgG was significantly higher in Group B, 60/69 (87%) in hepatitis C, 60/69 (87%) in hepatitis B, 26/30 (87%) in fatty liver, 18/30 (60%) in alcoholic liver disease.

Conclusion Results: Group A) HEV IgG positive 13% (18/140), Group B HEV IgG positive 40.6% (122/300) including 3.7% (4/122) having both IgM and IgG positive. The prevalence of HEV IgG was 54% (12/22) in the liver transplant recipient group and 33% (2/6) of kidney transplant recipient group. The study demonstrates the prevalence of hepatitis E infection in New York and HEV antibody in CLD. Including transplant donors and recipients. Questions remain the impact and progression of acute or chronic liver disease with concomitant HEV in pre, peri, and post liver transplant recipient. Larger study needs to validate.

Competing interests None declared.