Introduction

- Hepatitis C Virus (HCV) has a global prevalence of 71 million cases with 75% coming from low-and-middle-income countries (LMIC).
- Access to direct-acting antiviral (DAA) medications continues to increase globally, but the availability of diagnostics remains a barrier, especially in LMIC.
- The gold standard to determine HCV cure is the demonstration of SVR with quantitative HCV RNA levels via polymerase chain reaction (PCR) at least 12 weeks after completion of treatment.
- Confirmatory HCV-PCR assays are expensive; in Mumbai, the price for liver function tests is 550 Rupees while the prices for HCV-PCR assays are 2000 Rupees.
- Our aim was to determine if change in ALT can serve as a surrogate marker for SVR.

Methods

- Retrospective cohort study of 149 patients in Mumbai, India.
- Received treatment between 2015-2021.
- All patients treated with DAA approved by FDA equivalent in India, brought back for follow-up 12 weeks after completion of treatment.

Results

- 149 patients included in the study, 128 achieved SVR (86%) and 21 (14%) did not.
- Genotype 3 was most common in the cohort.
- No significant differences in SVR across genotypes, diabetes status, hyperlipidemia, or thyroid disease.
- The change in ALT between initiation and completion of therapy was significantly different based on SVR (p < 0.01).
- Secondary analysis showed that the greater the change in ALT, the higher the positive predictive value of achieving SVR.
- Additional analysis showed that a lower absolute value of ALT after completion of treatment showed higher positive predictive value.

Discussion

- LMIC with high HCV burden face barriers to diagnose SVR via HCV-PCR, and can benefit using ALT as a surrogate marker.
- This is a novel finding and opens new opportunities for monitoring SVR.
- This finding can help in the treatment of HCV in LMIC where liver function tests are cheaper.
- Given that this study was conducted in India, it is limited in its generalizability across different ethnicities and genotypes.
- Further research is needed, especially since this population was ethnically homogeneous.
- Future projects should be conducted in sub-Saharan Africa.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall (n=149)</th>
<th>SVR (n=128)</th>
<th>No SVR (n=21)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in ALT (mean ± SD)</td>
<td>41.8 ± 55</td>
<td>46.7 ± 55.9</td>
<td>11.5 ± 51</td>
<td>&lt;0.01</td>
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</tbody>
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</tr>
</thead>
<tbody>
<tr>
<td>Patients with change in ALT &gt; 10 (n, %)</td>
<td>87 (58.4)</td>
<td>80 (62.5)</td>
<td>7 (33.3)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ALT Values after completing treatment</th>
<th>No SVR (n=16)</th>
<th>SVR (n=108)</th>
<th>PPV</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20</td>
<td>1 (6.2)</td>
<td>42 (38.9)</td>
<td>97.7</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>20-40</td>
<td>6 (37.5)</td>
<td>47 (43.5)</td>
<td>88.7</td>
<td></td>
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<tr>
<td>&gt;40</td>
<td>9 (56.3)</td>
<td>19 (17.6)</td>
<td>67.9</td>
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