RESULTS

Naïve and 71 White DAA tablet manipulation may impact drug absorption and treatment outcome.

F0

3 Experienced

No patients experienced severe adverse effects.

1a

White

F0

N/A

3

Oberoi RK, Zhao W, Sidhu DS, et al. A phase 1 study to evaluate the effect of crushing, crushed and N/A

Black

1a

White


41

White

F0

No patients experienced severe adverse effects.

1a

N/A

Black

Adult patients receiving DAA therapy with

F4

1a

61

This case series provides evidence for safety and effectiveness with HCV DAA tablet manipulation.

METHOD

Background

Direct Acting Antivirals (DAAs) can produce sustained virologic response (SVR) rates >90%.

There is limited data regarding the use of DAAs in patients unable to swallow tablets.

DAA tablet manipulation may impact drug absorption and treatment outcome.

Objective

Describe the safety and effectiveness outcomes of real-world cases requiring DAA tablet manipulation.

Design

Multi-site, retrospective case series

Sample

Adult patients receiving DAA therapy with tablet manipulation at three academic health systems

Study period

January 2013 to December 2019

Outcomes

Achievement of SVR at least 16 weeks after therapy completion, reasons for tablet manipulation, adverse effects and adherence

Figure 1: Practice Sites

Vanderbilt University Medical Center, Nashville, TN

Prisma Health-USC Medical Center, Columbia, SC

Temple University Health System, Philadelphia, PA

Physicians 1 and 2

Nurse Practitioners 3

Pharmacists 1

Pharmacists 2

CPA, collaborative practice agreement

REFERENCES


Figure 2: Reasons for Tablet Manipulation

- Difficulty swallowing due to history of head and neck cancer
- Difficulty swallowing large tablets
- Short gut syndrome requiring enteral feeding
- Impatient intubation post multi-organ transplant
- No patients experienced severe adverse effects.
- Unpleasant taste was reported.

Figure 3: HCV RNA Lab Monitoring

*Defined as reaching an undetectable HCV RNA while on treatment

**3 patients lost to follow up after end of treatment

CONCLUSION

- All patients with available data achieved an SVR12.
- This case series provides evidence for safety and effectiveness with HCV DAA tablet manipulation.

DISCLOSURES

- David E. Koren is an independent consultant for Gilead and AbbVie.
- Other authors report no disclosures or conflicts of interests.

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Table 1: Summary of Cases of HCV Treatment Requiring DAA Manipulation

<table>
<thead>
<tr>
<th>Gender</th>
<th>Race</th>
<th>Age</th>
<th>Pertinent Medical History</th>
<th>Non-Viral DAA RX Burden</th>
<th>GT</th>
<th>Fibrosis Stage</th>
<th>Previous HCV Treatment</th>
<th>Drug Regimen</th>
<th>Potential Drug Interactions with DAA</th>
<th>Method of Administration</th>
<th>Patient-Reported Adherence</th>
<th>Treatment Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>White</td>
<td>67</td>
<td>NAT+ heart/kidney transplant, HTN, HLD, DM, GI bleed</td>
<td>28</td>
<td>1a</td>
<td>NA</td>
<td>Naive</td>
<td>GLE/PIB</td>
<td>atorvastatin, quetiapine, tacrolimus, omeprazole</td>
<td>Crushed and taken by PEG tube</td>
<td>No missed doses</td>
<td>SVR12 achieved</td>
</tr>
<tr>
<td>Male</td>
<td>Black</td>
<td>71</td>
<td>Short gut syndrome, ischemic colitis requiring colectomy</td>
<td>8</td>
<td>1a</td>
<td>F2/F3</td>
<td>Naive</td>
<td>LDV/SOF</td>
<td>N/A</td>
<td>Halved and taken by mouth</td>
<td>No missed doses</td>
<td>SVR12 achieved</td>
</tr>
<tr>
<td>Male</td>
<td>Black</td>
<td>61</td>
<td>H/o squamous cell carcinoma of larynx, HTN, DM, HLD</td>
<td>7</td>
<td>1a</td>
<td>F0</td>
<td>Experienced (IFN)</td>
<td>LDV/SOF</td>
<td>magnesium</td>
<td>Crushed and taken with small amount of orange juice</td>
<td>No missed doses</td>
<td>Lost to follow up</td>
</tr>
<tr>
<td>Male</td>
<td>White</td>
<td>54</td>
<td>H/o laryngeal cancer</td>
<td>3</td>
<td>1a</td>
<td>F0/F1</td>
<td>Naive</td>
<td>LDV/SOF</td>
<td>N/A</td>
<td>Crushed and taken by mouth</td>
<td>Several missed doses</td>
<td>Lost to follow up</td>
</tr>
<tr>
<td>Male</td>
<td>Black</td>
<td>60</td>
<td>H/o carcinoma of tonsil, HCC, GERD, HTN</td>
<td>8</td>
<td>3</td>
<td>F2/F3</td>
<td>Naive</td>
<td>SOF/VEL</td>
<td>N/A</td>
<td>Crushed and taken by PEG tube</td>
<td>1 missed dose</td>
<td>SVR12 achieved</td>
</tr>
<tr>
<td>Female</td>
<td>White</td>
<td>41</td>
<td>H/o malignant neoplasm of supraglottis</td>
<td>3</td>
<td>3</td>
<td>F2</td>
<td>Naive</td>
<td>SOF/VEL</td>
<td>N/A</td>
<td>Cruised and taken by mouth</td>
<td>No missed doses</td>
<td>SVR12 achieved</td>
</tr>
<tr>
<td>Female</td>
<td>Black</td>
<td>60</td>
<td>H/o squamous cell carcinoma of larynx, GERD, HTN, CAD</td>
<td>0</td>
<td>3</td>
<td>F0</td>
<td>Naive</td>
<td>SOF/VEL</td>
<td>N/A</td>
<td>Not available</td>
<td>No missed doses</td>
<td>SVR12 achieved</td>
</tr>
<tr>
<td>Female</td>
<td>Black</td>
<td>50</td>
<td>Decompensated cirrhosis, h/o submandibular malignant mass</td>
<td>11</td>
<td>1a</td>
<td>F0</td>
<td>Experienced (SMV + SOF)</td>
<td>SOF/VEL</td>
<td>N/A</td>
<td>Crushed and taken on applesauce</td>
<td>3 missed doses</td>
<td>SVR12 achieved</td>
</tr>
<tr>
<td>Female</td>
<td>White</td>
<td>50</td>
<td>Decompensated cirrhosis, h/o submandibular malignant mass</td>
<td>12</td>
<td>3</td>
<td>F4</td>
<td>Experienced (IFN)</td>
<td>SOF/VEL + RBV</td>
<td>calcium carbonate, ranitidine</td>
<td>Quartered and taken by mouth</td>
<td>4 missed doses</td>
<td>SVR12 achieved</td>
</tr>
</tbody>
</table>