The Tablo® Hemodialysis System ("Tablo") obtained FDA clearance for home hemodialysis (HHD) in March 2020. Approval was based on a prospective, crossover trial, where 30 patients were followed for 8 weeks during each study phase (in-center and home). Tablo met all safety and effectiveness endpoints, reported high rates of treatment adherence, patient retention, and included a diverse patient population (Home IDE; NCT02460263).

METHODS

Utilizing the same eligibility criteria as the Tablo IDE:
- Incident and prevalent patients were initiated on Tablo at participating study sites.
- Treatment data were obtained wirelessly via the Tablo data platform.
- All other data were reported by site staff into the study database.
- Data collected from the first 30 patients on the HOME Registry over the first 8 weeks was compared to the 30 patients who participated in the IDE.

RESULTS

- Mean patient age was 55.2 years, with the majority being male (66.7%), white (73.3%) and with an AV fistula (60.0%).
- Mean prescribed treatment time was 3.3 hours, with a mean prescribed frequency of 3.8 treatments per week.
- Treatment adherence was 95%, with 92% of treatments completing at least 90% of prescribed time.
- The mean number of clinically significant alarms per treatment was 1.3 (±2.9), with an average time to resolution of 10.8 (±23.1) seconds.
- The mean weekly standard Kt/V at the 4-week visit was 2.3±0.5.
- Patient retention was 100%, with no patients opting out of HHD with Tablo.
- One serious adverse event (SAE) was reported, a seizure and subsequent hospitalization, that was deemed not related to Tablo or to the HD treatment by the site investigator.

CONCLUSION

- Tablo achieves standard adequacy goals and provides more flexibility in dialysis schedules than current HHD options.
- Results from the Tablo IDE are reproducible with high treatment adherence, patient retention, and low rates of alarms and SAEs.

BACKGROUND

- The Tablo® Hemodialysis System ("Tablo") obtained FDA clearance for home hemodialysis (HHD) in March 2020.
- Approval was based on a prospective, crossover trial, where 30 patients were followed for 8 weeks during each study phase (in-center and home).
- Tablo met all safety and effectiveness endpoints, reported high rates of treatment adherence, patient retention, and included a diverse patient population (Home IDE; NCT02460263).

OBJECTIVE

To report on the first 30 patients in the HOME Registry (NCT04526301), which is an ongoing study of real-world patients utilizing Tablo for HHD.

Table 1. Comparison of Patient Demographics: IDE & Registry

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>IDE (n=30)</th>
<th>Registry (N=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>52.3±11.6</td>
<td>55.2±16.3</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>93.8±17.0</td>
<td>90.4±34.3</td>
</tr>
<tr>
<td>Race White</td>
<td>57% (17)</td>
<td>73% (22)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>43% (13)</td>
<td>17% (5)</td>
</tr>
<tr>
<td>Asian</td>
<td>-</td>
<td>7% (2)</td>
</tr>
<tr>
<td>Not Reported</td>
<td>-</td>
<td>3% (1)</td>
</tr>
<tr>
<td>Ethnicity Hispanic or Latino</td>
<td>27% (8)</td>
<td>13% (4)</td>
</tr>
<tr>
<td>No Hispanic or Latino</td>
<td>73% (22)</td>
<td>87% (26)</td>
</tr>
<tr>
<td>Vascular Access Type Fistula</td>
<td>77% (23)</td>
<td>60% (18)</td>
</tr>
<tr>
<td>Catheter</td>
<td>13% (4)</td>
<td>30% (9)</td>
</tr>
<tr>
<td>Graft</td>
<td>10% (3)</td>
<td>10% (3)</td>
</tr>
</tbody>
</table>

Table 2. Comparison of Treatment Parameters: IDE & Registry

<table>
<thead>
<tr>
<th>Parameter</th>
<th>IDE</th>
<th>Registry</th>
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</thead>
<tbody>
<tr>
<td>Prescribed treatment time (min)</td>
<td>207±24</td>
<td>195.9±35.3</td>
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<tr>
<td>Actual treatment time (min)</td>
<td>203±31</td>
<td>190.0±45.2</td>
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<tr>
<td>Prescribed UF volume (ml/tx)</td>
<td>2232±1118</td>
<td>1250.8±987.7</td>
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<tr>
<td>Actual UF volume (ml/tx)</td>
<td>2223±1119</td>
<td>1088.8±1064.9</td>
</tr>
<tr>
<td>Prescribed UF rate (ml/min)</td>
<td>10.6±4.8</td>
<td>6.5±5.1</td>
</tr>
<tr>
<td>Actual UF rate (ml/min)</td>
<td>10.7±4.9</td>
<td>6.7±9.7</td>
</tr>
<tr>
<td>Avg Standard Weekly Kt/V</td>
<td>2.8±0.3</td>
<td>2.3±0.5</td>
</tr>
<tr>
<td>Avg Clinically Significant Alarms (tx)</td>
<td>1.3±3.0</td>
<td>1.3±2.9</td>
</tr>
<tr>
<td>Avg time to Alarm Resolution (s)</td>
<td>11.7±28.5</td>
<td>10.8±23.1</td>
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