INTRODUCTION

• Ascites is the most common complication of decompensated cirrhosis and occurs in 10% of all cirrhotic patients at any one time
• The presence of ascites is associated with further complications including early satiety and eventual malnutrition, and the risk for developing spontaneous bacterial peritonitis, hepaticorenal syndrome, and abdominal hernias
• The presence of large ascites also requires many hospital visits for paracentesis.
• Thus, patients with ascites have poor quality of life
• The Automated Low Flow Ascites pump (alfa pump)(Sequana Medical AG) is a subcutaneous implantable rechargeable device that automatically transfers the ascitic fluid from the peritoneal cavity into the bladder. The ascites is then discharged as urine
• The alfa pump carries out a continuous low-rate paracentesis for approximately 16 hours per day and therefore keeps the ascites under control

AIM

• To determine the efficacy and safety of the alfa pump system in the management of recurrent large ascites in cirrhotic patients
• To evaluate the quality of life (QoL) and large volume paracentesis (LVP) requirement at 3 months after alfa pump implantation

MATERIALS & METHODS

• Prospective, open label, single arm multi-center study
• Cirrhotic patients with recurrent large ascites requiring LVP for symptom relief ≥ once/month, and not eligible for TIPS.
• Safety: evaluated by incidence & severity of device and procedure related serious adverse events & survival
• Efficacy: evaluated by assessing LVP requirement and QoL after insertion of alfa pump
• QoL: Evaluated using Ascites-Q questionnaire, an instrument used to measure quality of life in patients with ascites. Ascites-Q has been modified from the Polycystic Liver Disease questionnaire.

RESULTS

Table 1: Patient demographics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>30</td>
</tr>
<tr>
<td>Age (years)</td>
<td>63 (32-72)</td>
</tr>
<tr>
<td>M : F</td>
<td>17 : 13</td>
</tr>
<tr>
<td>Etiology of cirrhosis</td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>9 (30%)</td>
</tr>
<tr>
<td>NASH</td>
<td>9 (30%)</td>
</tr>
<tr>
<td>Viral hepatitis</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Alcohol/Viral</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Alcohol/NASH</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Cholestatic</td>
<td>2 (6.7%)</td>
</tr>
<tr>
<td>Others</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>MELD at enrollment</td>
<td>15.1 ± 5.1</td>
</tr>
</tbody>
</table>

Figure 1: Patient Disposition

Figure 3: Serious Adverse Events

Figure 4: Quality of Life Changes

Figure 2: Change in Large Volume Paracentesis Requirement

Figure 5: Patient Outcomes

DISCLOSURES

FW: Consultant for Gore, Inc. and Mallinckrodt Pharmaceuticals; grant/research support from Sequana Medical AG, Mallinckrodt Pharmaceutical & Grifols.
RTF: Grant/research support to CPMC Institution from Sequana Medical AG
ZH: Consultant for W.L. Gore and Associates, C.R. Bard, Boston Scientific; grant/research support: Sequana Medical AG
JC: Sequana Medical AG employee
PK: Consultant for Sequana Medical AG

CONCLUSIONS

• In this North American study, the implantation of an alfa pump resulted in improvement of ascites control
• Clinically relevant changes in QoL, as measured by CLDQ and Ascites-Q, improved significantly as early as 1 month after alfa pump implantation and continued through 3 months
• Mortality rate was less than what is expected in a population of patients with refractory ascites
• The need for explantation of the pump, renal dysfunction including electrolyte abnormalities and infections remain concerns
• Future studies should include refinement of patient selection criteria, revised pump and catheter design, and procedural and post-procedural care algorithms including the mandated use of albumin