All patients were treated with AngioJet Thrombectomy

Patient history, procedural information, adjunctive treatments, outcomes and adverse events were collected

Patients were analyzed in arterial, venous & dialysis access indications

Determine efficacy of thrombus removal from baseline to final angiogram/venogram

Evaluate clinical outcomes of treated patients at defined intervals of 3, 6 & 12 months

Characterize clinical events

Characterize treatment options used with the AngioJet System

Estimate rate of AngioJet Thrombectomy-related adverse events

PEARL I
Followed patients for 3 months with documentation of symptomatic improvement after AngioJet™ thrombectomy (with mid-length catheters).

PEARL II
Followed patient outcomes through 12 months after AngioJet thrombectomy with any AngioJet catheter

OBJECTIVES:

- Determine efficacy of thrombus removal from baseline to final angiogram/venogram
- Evaluate clinical outcomes of treated patients at defined intervals of 3, 6 & 12 months
- Characterize clinical events
- Characterize treatment options used with the AngioJet System
- Estimate rate of AngioJet Thrombectomy-related adverse events

ENROLLMENT

952 patients 34 enrolling sites; 4 Countries

145 (15%) Hemodialysis Access (HA)

371 (39%) Deep Venous Thrombosis (DVT)

410 (43%) Limb Ischemia (LI)

26 (3%) Other

Complete >90% occlusion
Substantial 50-90% occlusion OR <50% occlusion and >3 cm in length
Partial <50% occlusion AND <3 cm in length
Normal/Patient Without viable thrombus or occlusion

Baseline and final angiographic/venographic degree of occlusions were determined by the treating physician based on the criteria shown.
PEARL DVT  I  N=371 patients

SUMMARY:

- 34% of patients treated in single session; 87% of patients had 2 or less lab sessions
- 38% of procedures treated in ≤ 6 hours; 75% completed in ≤ 24 hours
- Less total lytic use when delivered utilizing AngioJet™ (Power Pulse™ and/or Rapid Lysis) than if CDT were included in treatment with final venographic results comparable across all technique subgroups
- 1295 venous vessels treated with 97% showing improvement, 3% unchanged, <1% worse

DVT LOCATION  I  Upper Extremity (UE): 11%   Lower Extremity (LE): 89%

<table>
<thead>
<tr>
<th>DVT Segments (LE Only)</th>
<th>% of Patients</th>
<th>DVT Segments</th>
<th>% of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iliac Femoral Popliteal</td>
<td>31%</td>
<td>Iliac only</td>
<td>7%</td>
</tr>
<tr>
<td>Iliac Femoral</td>
<td>27%</td>
<td>Femoral only</td>
<td>6%</td>
</tr>
<tr>
<td>Femoral Popliteal</td>
<td>25%</td>
<td>Popliteal</td>
<td>2%</td>
</tr>
</tbody>
</table>

DVT TECHNIQUE SUBGROUPS

<table>
<thead>
<tr>
<th>Treatment (LE Only)</th>
<th>Frequency</th>
<th>Median Time in Hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>AngioJet Thrombectomy (no lytic)</td>
<td>13 (4%)</td>
<td>1.4</td>
</tr>
<tr>
<td>AngioJet + Lytic by AngioJet “PMT”</td>
<td>115 (35%)</td>
<td>2</td>
</tr>
<tr>
<td>AngioJet Thrombectomy + CDT</td>
<td>29 (9%)</td>
<td>41</td>
</tr>
<tr>
<td>AngioJet “PMT” + CDT</td>
<td>172 (52%)</td>
<td>22</td>
</tr>
</tbody>
</table>

No CDT needed in 39% of patients
Overall: 36% completed in ≤ 6 Hrs 73% completed in ≤ 24 Hrs

LYTIC USE

<table>
<thead>
<tr>
<th>Total Lytic</th>
<th>DVT Mean ± SD (Median)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alteplase (mg)</td>
<td>24.4 ± 19.5 (21.7) N=217</td>
</tr>
<tr>
<td>Retaplace (units)</td>
<td>29.9 ± 59.4 (15.8) N=17</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Lytic by Lytic Treatment Group</th>
<th>Alteplase Only (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lytic delivered by AJ only (Powerpulse and/or Rapid Lysis)</td>
<td>12.8 ± 15.1 (10.0) N=53</td>
</tr>
<tr>
<td>Lytic delivered by CDT only</td>
<td>37.7 ± 21.4 (37.1) N=18</td>
</tr>
<tr>
<td>Lytic delivered by AJ (PPS and/or RL) and CDT</td>
<td>27.2 ± 18.8 (26.2) N=145</td>
</tr>
</tbody>
</table>

Predominate Physician Prescribed Fluid: Activase
Predominate Activase Dose: 10 mg
Total Activase given per patient by PPS
(mean/median): 12.8 mg/ 10.0 mg
Dwell Times (mean/median): 35 minutes/25 minutes

The total lytic dose for treating DVT was lower when using PPS/RL (with/without CDT) versus CDT without PPS/RL.
N = patients with recorded lytic doses
88% of cases utilized Power Pulse and/or Rapid Lysis.

RESULTS

Venographic Results by Technique Subgroups
(p<0.0001)  N=1295 vessels treated

Amongst the 4 treatment groups there wasn’t any statistical difference in baseline occlusion, final occlusion or in the change of occlusion.
The difference seems to be in the treating physician's preference to treatment.

Presented by Dr. Mark Garcia at CIRSE 2013; Final PEARL Data Aug 2013
**Summary:**

- 947 arterial vessels treated with 93% showing improvement, 6% unchanged, <1% worse
- 89% limb salvage rate (185/207). 207 ALI patients had a baseline Rutherford Classification of Ila, Iib and III
- 56% of patients treated in single session; 86% of patients had 2 or less lab sessions
- 58% of procedures treated in < 6 hours; 80% completed in < 24 hours

**LI RESULTS BY LOCATION**

![Angiographic Results by Location](image)

**LI TECHNIQUE SUBGROUPS**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Frequency</th>
<th>Median Time in Hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>AngioJet Thrombectomy (no lytic)</td>
<td>77 (19%)</td>
<td>1.6</td>
</tr>
<tr>
<td>AngioJet + Lytic by AngioJet “PMT”</td>
<td>151 (37%)</td>
<td>1.9</td>
</tr>
<tr>
<td>AngioJet Thrombectomy + CDT</td>
<td>116 (28%)</td>
<td>24.1</td>
</tr>
<tr>
<td>AngioJet “PMT” + CDT</td>
<td>66 (16%)</td>
<td>22.5</td>
</tr>
</tbody>
</table>

Overall: 58% completed in <6 Hrs
80% completed in <24 Hrs

**LYTIC USE**

<table>
<thead>
<tr>
<th>Lytic Use</th>
<th>Limb Ischemia Mean ± SD (Median)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alteplase (mg)</td>
<td>19.4 ± 16.1 (12.7) N=209</td>
</tr>
<tr>
<td>Retaplase (units)</td>
<td>8.2 ± 6.2 (8.2) N=17</td>
</tr>
</tbody>
</table>

**Predominate Physician Prescribed Fluid:** Activase
**Predominate Activase Dose:** 10 mg
**Total Activase given per patient by PPS (mean/median):** 12.0 mg/10.0 mg
**Dwell Times (mean/median):** 23 minutes/20 minutes

- Lytic delivered by AJ only (Powerpulse and/or Rapid Lysis) 10.4 ± 11.0 (8.9) N=75
- Lytic delivered by CDT only 21.6 ± 15.3 (18.7) N=45
- Lytic delivered by AJ (PPS and/or RL) and CDT 27.4 ± 16.3 (26.2) N=83
**PEARL AV Access**  |  N=145 patients

**SUMMARY:**
- Hemodialysis Access Overall Patency: 78% patency at 3 months; KDOQI minimum goal is 40% at 3 months
- 76% graft/fistula survival at 1 year

**TREATMENTS UTILIZED & SUBGROUPS**
- Total 145 patients (65% grafts / 35% fistulas); 186 treated vessels
- 86% (125/145) of patients treated with AngioJet Thrombectomy without thrombolytics

**RESULTS**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Frequency (patients treated)</th>
<th>Median Time in Hrs</th>
<th>Angiographic results</th>
</tr>
</thead>
<tbody>
<tr>
<td>AngioJet Thrombectomy (no lytic)</td>
<td>125 (86%)</td>
<td>1.25</td>
<td>98% improved; 2% Unchanged</td>
</tr>
<tr>
<td>AngioJet + Lytic by AngioJet “PMT”</td>
<td>19 (13%)</td>
<td>1.41</td>
<td>100% Improved</td>
</tr>
<tr>
<td>AngioJet Thrombectomy + CDT</td>
<td>1 (1%)</td>
<td>14.0</td>
<td>100% Improved</td>
</tr>
</tbody>
</table>

Higher % of Substantial lysis were achieved in the groups with PMT.

There was a difference (p=0.0003) in the mean baseline thrombus between the 4 groups. With the PMT + CDT group having a greater occlusion initial score than the other groups.

**KDOQI:** minimum goal for percutaneous thrombectomy is 40% unassisted patency and functionality at 3 months
THE PEARL REGISTRY IS A BOSTON SCIENTIFIC SPONSORED STUDY

ANGIOJET ULTRA CONSOLE

CAUTION: Federal law restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions. INTENDED USE/INDICATIONS

FOR USE: The Console is intended for use only in conjunction with an AngioJet Ultra Thrombectomy Set. Refer to the individual Thrombectomy Set Information for Use manual for specific clinical applications. CONTRAINDICATIONS: Refer to the individual Thrombectomy Set Information for Use manual for specific contraindications. WARNINGS AND PRECAUTIONS: Use the AngioJet Ultra Console only with an AngioJet Ultra Thrombectomy Set. This Console will not operate with a previous model pump set and catheter. • Do not attempt to bypass any of the Console safety features. • If the catheter is removed from the patient and/or is inoperative, the waste tubing lumen, guide catheter, and sheath should be flushed with sterile, heparinized solution to avoid thrombus formation and maintain lumen patency. Reprime the catheter by submerging the tip in sterile, heparinized solution and operating it for at least 20 seconds before reintroduction to the patient. • Refer to the individual AngioJet Ultra Thrombectomy Set Information for Use manual for specific warnings and precautions. • Do not move the collection bag during catheter operation as this may cause a collection bag error. • Monitor thrombotic debris/liquid flow exiting the catheter through the waste tubing during use. If blood is not visible during console activation, the catheter may be occlusive within the vessel or the outflow lumen may be blocked. • Ensure adequate patient anticoagulation to prevent thrombus formation in outflow lumen. • Refer to individual AngioJet Ultra Thrombectomy Set Instructions for Use manual for specific instructions regarding heparinization of the Thrombectomy Set. • The Console contains no user-serviceable parts. Refer service to qualified personnel.

ADVERSE EVENTS:

Refer to the individual Thrombectomy Set Information for specific observed and/or potential adverse events.

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