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PEARL REGISTRY

STUDY DESIGN:

TWO-PHASE, PROSPECTIVE, NON-RANDOMIZED MULTI-CENTER REGISTRY

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

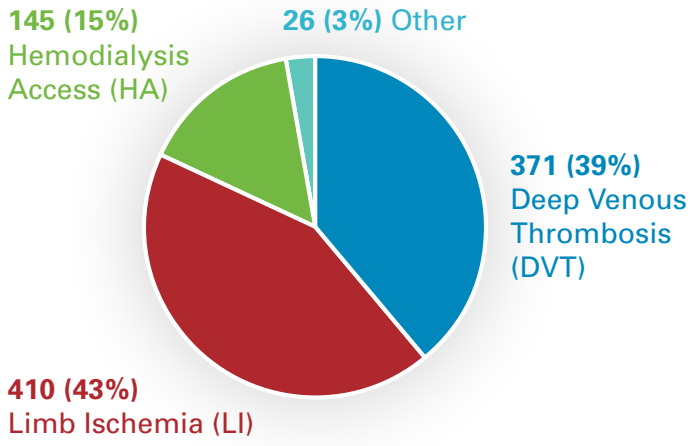
PEARL II
Followed patient outcomes through 12 months after AngioJet thrombectomy with any AngioJet catheter

- 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

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



Complete	>90% occlusion
Substantial	50-90% occlusion OR <50% occulusion and >3 cm in length
Partial	<50% occlusion AND <3cm 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 | 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 | Upper Extremity (UE): 11% Lower Extremity (LE): 89%

DVT Segments (LE Only)	% of Patients	DVT Segments	% of Patients
Iliac Femoral Popliteal	31%	Iliac only	7%
Iliac Femoral	27%	Femoral only	6%
Femoral Popliteal	25%	Popliteal only	2%

DVT TECHNIQUE SUBGROUPS

Treatment (LE Only)	Frequency	Median Time in Hrs
AngioJet Thrombectomy (no lytic)	13 (4%)	1.4
AngioJet + Lytic by AngioJet "PMT"	115 (35%)	2
AngioJet Thrombectomy + CDT	29 (9%)	41
AngioJet "PMT" + CDT	172 (52%)	22

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

LYTIC USE

Total Lytic	DVT Mean ± SD (Median)
Alteplase (mg)	24.4 ± 19.5 (21.7) N=217
Retaplase (units)	29.9 ± 59.4 (15.8) N=17

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

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

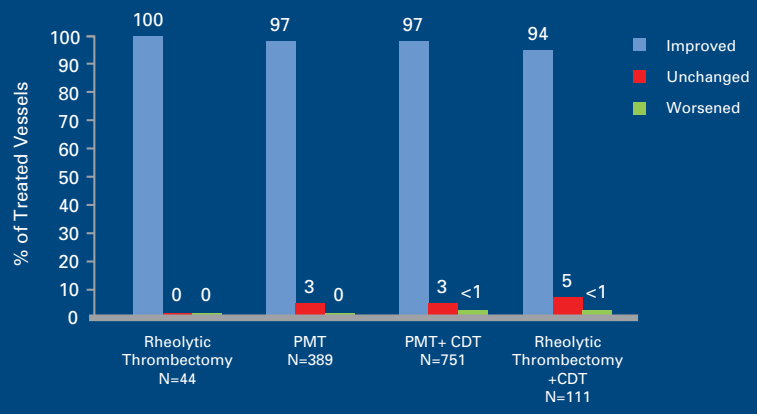
The total lytic dose for treating DVT was lower when using PPS/RL (with/without CDT) versus CDT without PPS/RL.

N = patients with recorded lytic doses

86% of cases utilized Power Pulse and/or Rapid Lysis.

RESULTS

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



CDT, catheter-directed thrombolysis
PMT, pharmacomechanical thrombolysis
Presented by Dr. Mark Garcia at CIRSE 2013; Final PEARL Data Aug 2013

Amongst the 4 treatment groups there wasn't any statistical difference in baseline occlusion, final occlusion or in the change of occlusion.

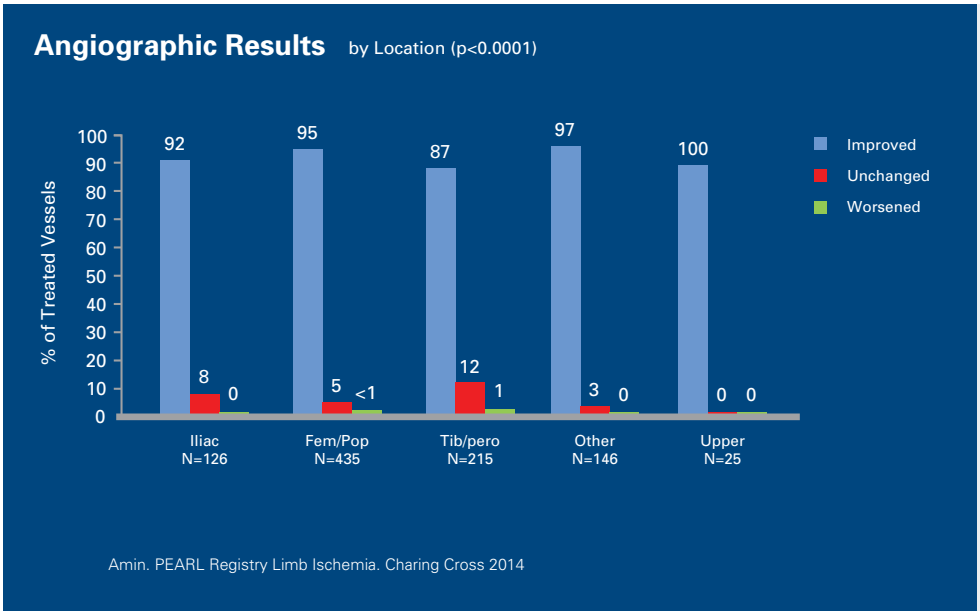
The difference seems to be in the treating physician's preference to treatment.

PEARL Limb Ischemia | N=410 patients

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 IIa, 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



LI TECHNIQUE SUBGROUPS

Treatment	Frequency	Median Time in Hrs
AngioJet Thrombectomy (no lytic)	77 (19%)	1.6
AngioJet + Lytic by AngioJet "PMT"	151 (37%)	1.9
AngioJet Thrombectomy + CDT	116 (28%)	24.1
AngioJet "PMT" + CDT	66 (16%)	22.5

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

LYTIC USE

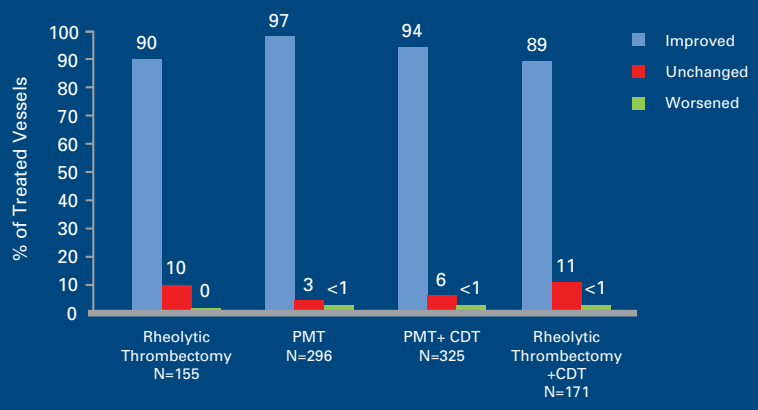
Total Lytic	Limb Ischemia Mean ± SD (Median)
Alteplase (mg)	19.4 ± 16.1 (12.7) N=209
Retaplase (units)	8.2 ± 6.2 (8.2) N=17

Total Lytic by Lytic Treatment Group	Alteplase Only (mg)
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

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

RESULTS

Angiographic Results by Technique Subgroups (p<0.0001)



CDT, catheter-directed thrombolysis
PMT, pharmacomechanical thrombolysis

Presented by Dr. Ali Amin at Charing Cross 2014; Final PEARL Data Aug 2013

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.

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

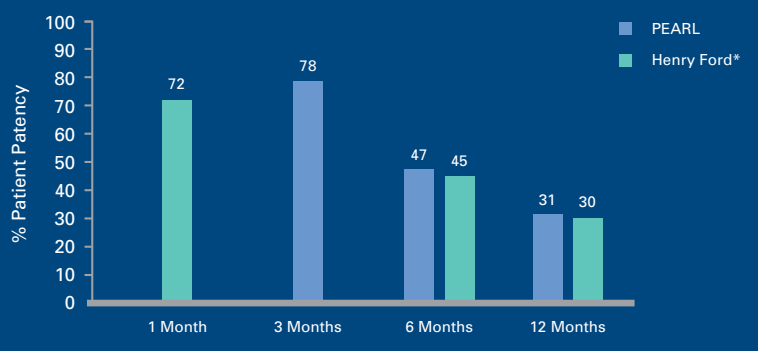
TREATMENTS UTILIZED & SUBGROUPS

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

Treatment	Frequency (patients treated)	Median Time in Hrs	Angiographic results
AngioJet Thrombectomy (no lytic)	125 (86%)	1.25	98% improved; 2% Unchanged
AngioJet + Lytic by AngioJet "PMT"	19 (13%)	1.41	100% Improved
AngioJet Thrombectomy + CDT	1 (1%)	14.0	100% Improved

RESULTS

Hemodialysis Access Overall Patency



*Kakkos SK, Haddad GK, Haddad J, Scully MM. J Endovasc Ther. 2008;15(1):91-102.
Simoni. PEARL Registry Hemodialysis Access. VEITH 2013.
National Kidney Foundation Clinical Practice Guidelines and Recommendations; 2006.
KDOQI, Kidney Disease Outcomes Quality Initiative

Presented by Dr. Eugene Simoni at VEITH 2013; Final PEARL Data Aug 2013

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 (USA) 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/fluid 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 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. • Removal of outer covers may result in electrical shock. • This device may cause electromagnetic interference with other devices when in use. Do not place Console near sensitive equipment when operating. • Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide. • To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. • Where the "Trapping Zone Hazard for Fingers" symbol is displayed on the console, there exists a risk of trapping or pinching fingers during operation and care must be exercised to avoid injury. • Do not reposition or push the console from any point other than the handle designed for that purpose. A condition of overbalance or tipping may ensue. • The AngioJet Ultra Console should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the AngioJet Ultra Console should be observed to verify normal operation in the configuration in which it will be used. • Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT. • The use of accessories and cables other than those specified, with the exception of accessories and cables sold by Bayer HealthCare as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Ultra Console. • MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding Electro-Magnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the tables provided in the IFU. **ADVERSE EVENTS:** Refer to the individual Thrombectomy Set Information for Use manual for specific observed and/or potential adverse events.

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