CACVS 2017

Aggressive endovascular management of ilio-femoral DVT is the "key" in preventing post thrombotic syndrome

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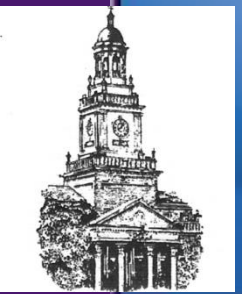


The Reading Hospital and Medical Center

READING VASCULAR SPECIALISTS

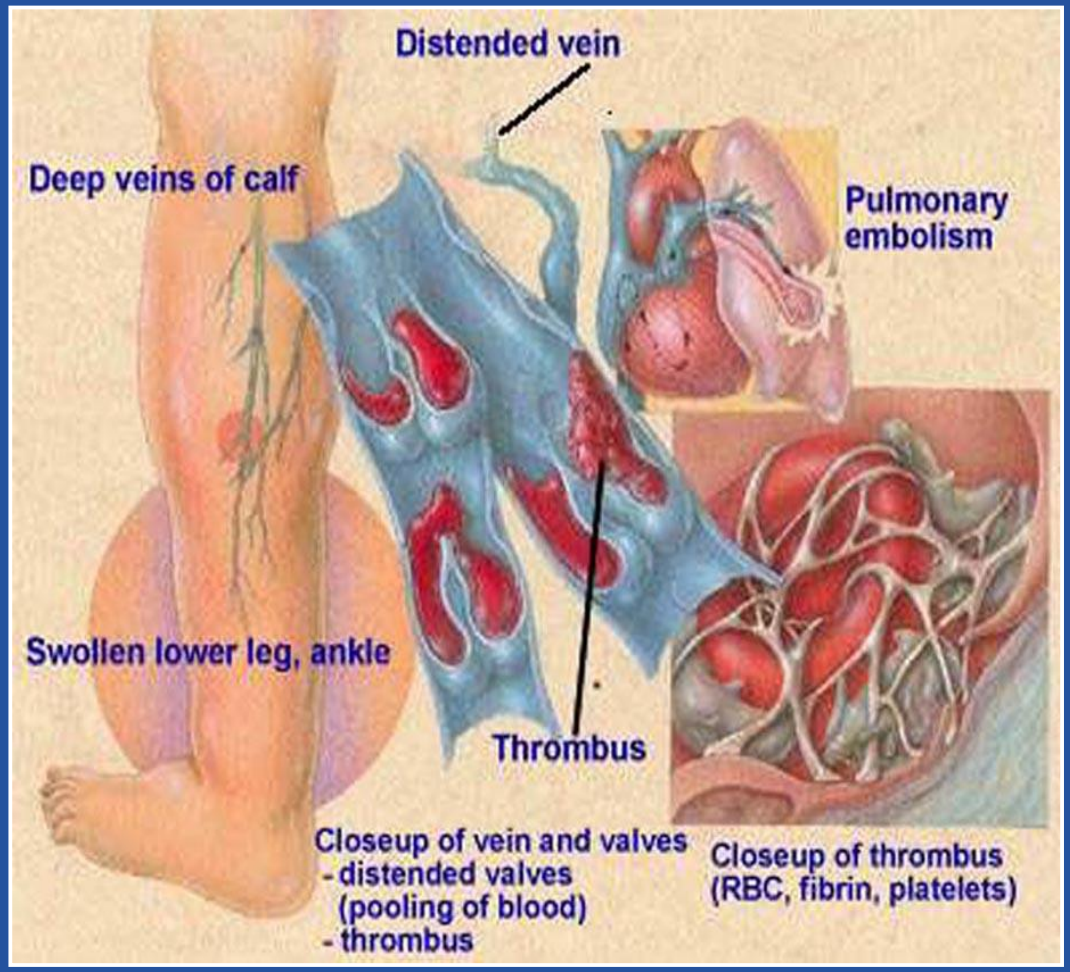
Faculty Disclosure

- Consultant Medtronic, Boston Scientific, Cardinal Health,

Venous Thromboembolism (DVT & PE)

- >2 million Deep vein thrombosis
- >200,000 deaths from pulmonary embolism
- Even after 6 months of anticoagulation following first VTE event, risk of subsequent VTE is increased by 5-12% annually.

Pathophysiology



http://www.uspharmacist.com/NewLook/Ce/deepvein/lesson.htm. Accessed February 2000.
Originally published in *US Pharmacist* with permission of the artist Kevin A. Sommerville. May not be reproduced without permission of the artist.

Deep Vein Thrombosis

- **Hematologist:**

  view DVT as a disorder of hematology and biology.

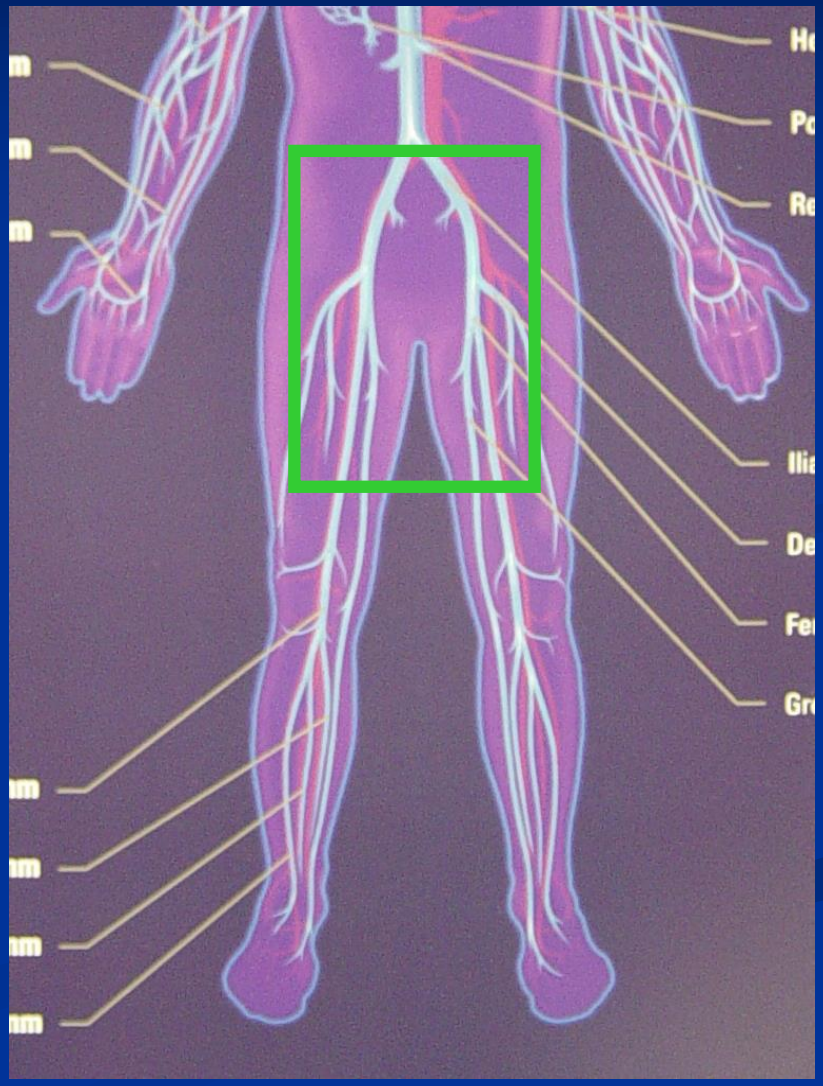
- **Vascular Surgeon and Interventional Radiologist:**

  view DVT from an Anatomical and Functional perspective.

Ilio-Femoral DVT

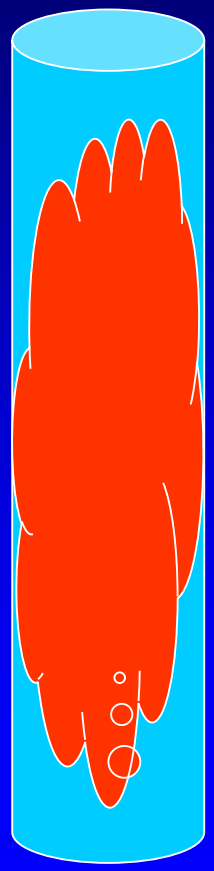
Endovascular Specialists:

- View ilio-femoral DVT as fundamentally different from physiologic considerations as well as more severe disease manifestation
- BUT it is rarely distinguished from other forms of DVT by other physicians.



Not All Clots Are Created Equal

Venous Thrombosis



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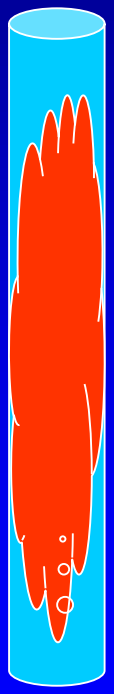
Peripheral Arterial Thrombosis



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Coronary Artery Thrombosis

Post thrombotic syndrome

- Most physicians treat all cases of proximal DVT the same.
- MUST differentiate between iliofemoral DVT and infrainguinal DVT.
- Iliofemoral DVT → Virulent post-thrombotic morbidity.

20 -60% of Pts with DVT
800,000/Yr cases of Post-Thrombotic Syndrome

Incidence and cost burden of post-thrombotic syndrome.
AU
Ashrani AA, Heit JA
J Thromb Thrombolysis. 2009 Nov;28(4):465-76.

Post Thrombotic Syndrome

- Chronic leg heaviness
- Leg aching
- Venous claudication
- Edema
- Venous varicosities
- Chronic skin changes
- Ulceration

Iliofemoral DVT

Natural History

Associated with Severe Postthrombotic Morbidity!

O'Donnell T J Surg Res. 1977	Mavor GE Br J Surg 1969	Beyth RJ Arch Int Med 1995

Ilio-Femoral DVT
Long Term Clinical Status and QOL

- ***Conclusions***
- Venous claudication developed in almost 50%
- Limited ambulation in 15%
- Marked hemodynamic impairment
- Markedly reduced QOL

Delis KT et al
Ann Surg 2004;239(1):118

Ilio-Femoral DVT Treatment Objectives

- Minimize or eliminate the Embolic potential of the existing Thrombus
- Prevent further Thrombosis

- Restore Venous Patency (remove obstruction)
- Preserve Venous Valvular function

Anticoagulation

DOES

- Minimize or eliminate the Embolic potential of the existing Thrombus
- Prevent further Thrombosis

DOES NOT

- Restore Venous Patency (remove obstruction)
- Preserve Venous Valvular function

Post Thrombotic Syndrome (PTS)

- Venous Hypertension
- Venous Capacitance is reduced
- Calf pump ejection fraction is reduced

Ambulatory Venous Hypertension

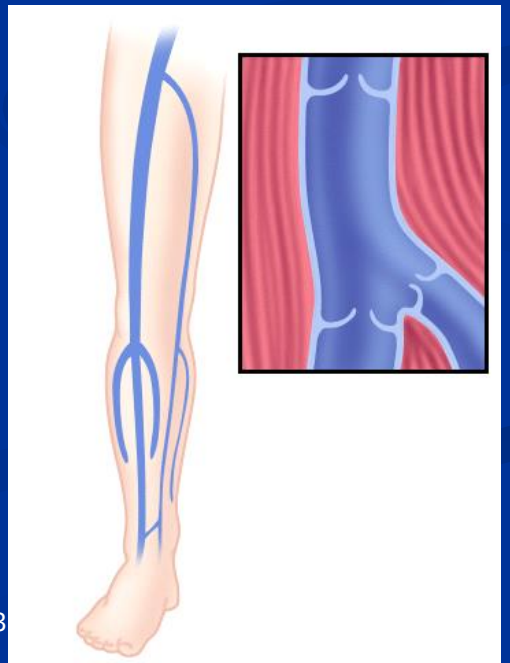
Components

- Obstruction
- Valve incompetence

Ambulatory Venous Hypertension

Combination of Obstruction + Valvular Incompetence

Highest Venous Pressure and most severe morbidity



Indications for Endovascular Therapy

- Functional patient with ilio-femoral DVT
- No Major risk factors for the use of thrombolytic
- “But” can use Mechanical Thrombectomy
- Need to be anticoagulated with Heparin and Coumadin
- Phlegmasia Cerulea Dolens

Ilio-Femoral DVT
Improved Outcome with Early Resolution

Randomized Trial: Iliofemoral DVT

Venous Thrombectomy vs. Anticoagulation

(Follow-up @ 6 mos, 5 yrs, 10 yrs)

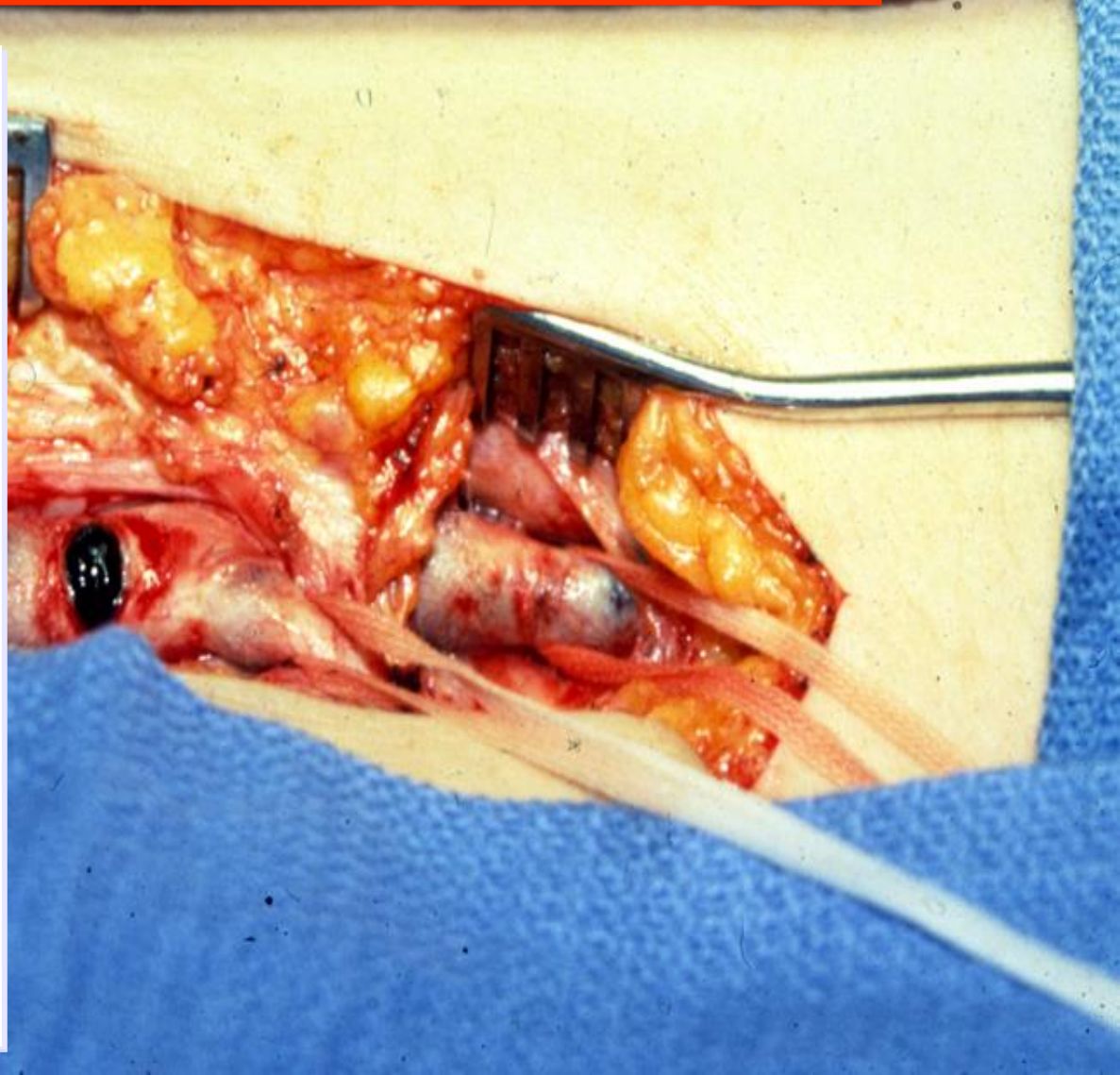
- **Patients randomized to thrombectomy showed:**
  1. Improved patency $P < 0.05$
  2. Lower venous pressures $P < 0.05$
  3. Less leg swelling $P < 0.05$
  4. Fewer post-thrombotic symptoms $P < 0.05$

Compared to anticoagulation

Plate G, et al. *JVS*; 1984
Plate G, et al. *Eur J Vasc Surg*; 1990
Plate G, et al. *Eur J Vas Endovasc Surg*; 1997

Venous Thrombectomy

Femoral Vein Exposure



Mangagment of Ilio-Femoral DVT

Anticoagulation

↓

Surgical Thrombectomy

↓

Catheter Directed Thrombolysis

↓

PharmacoMechanical Thrombectomy

Combination of Mechanical Thrombectomy and Thrombolysis

- Combination therapy is even more Powerful
- Initially reduces more thrombus burden
- Exposes a greater area of the thrombus surface to lytic agent
- Decrease Dose and Infusion time for thrombolytic drugs
- One Retrospective study, PMT greatly reduced both time of lysis (40% reduction) and Lytic drug dose (60% reduction).

Endovascular Intervention

1. Access
2. Device/Techniques

Access

- Popliteal Vein
- Small Saphenous vein
- Post Tibial Vein
- Contralateral Femoral vein
- IJ Vein

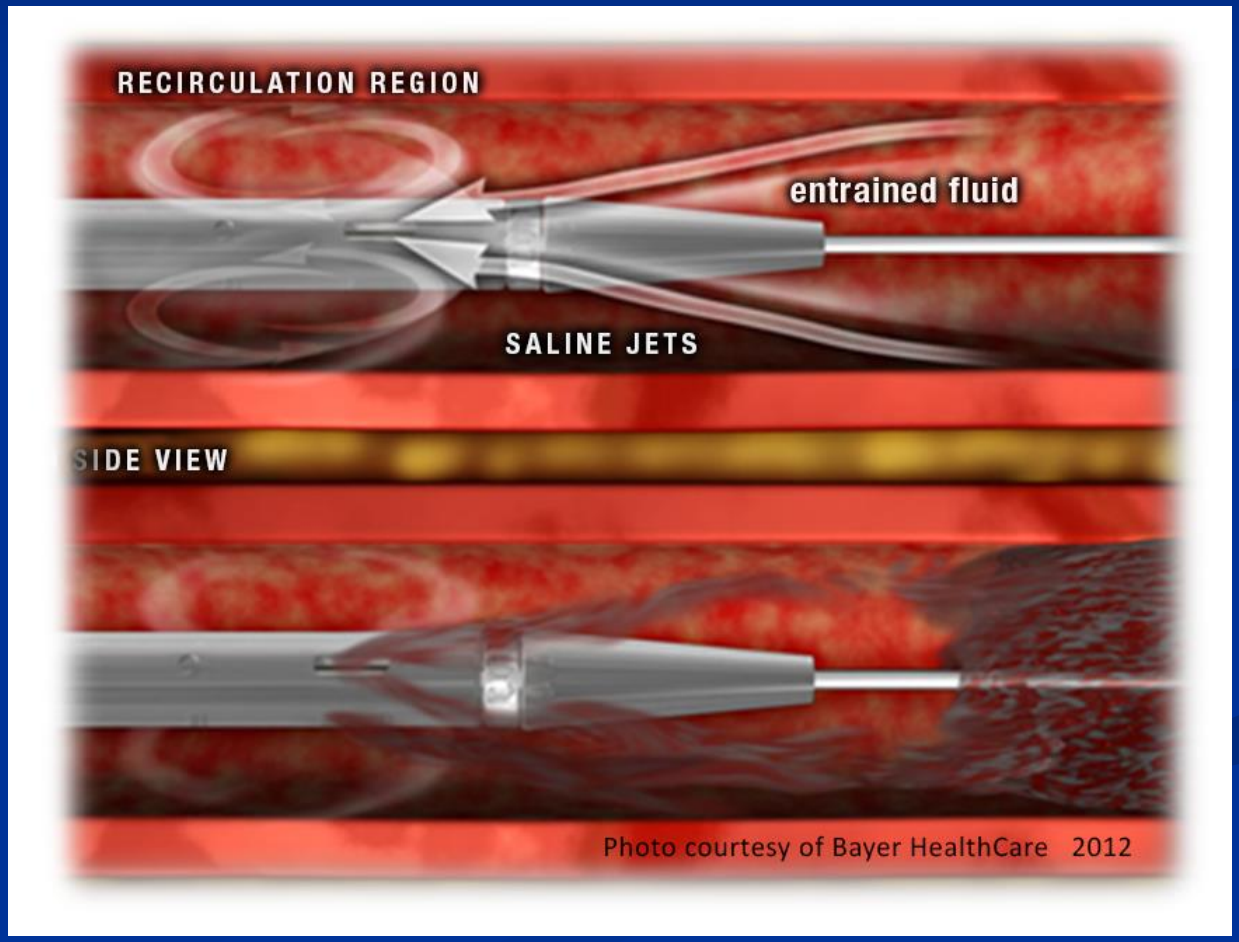
Popliteal Vein

Small Saphenous Vein

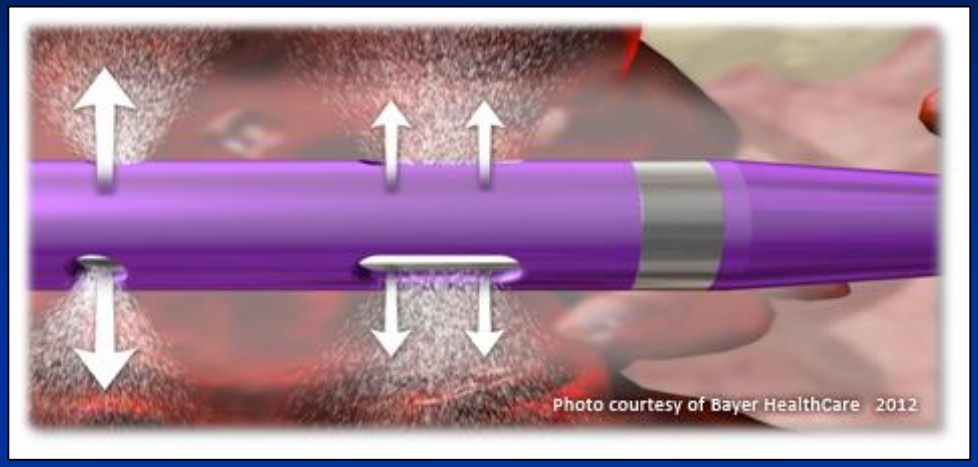
PT Vein Access

Device/ Techniques

Treating DVT with AngioJet



AngioJet® Power Pulse® Delivery System



Power Pulse® Delivery

- Power-infuse lytic solution directly into the clot
- Combination of chemical and mechanical thrombolysis

Solent™ Family
AngioJet® Catheters for Peripheral Vessels

SOLENT Proxi - 90 cm length

SOLENT Omni - 120 cm length

- Thrombectomy power similar to DVX®
- Compatible with 6FR sheath and 0.035" guidewire
- Guidewire swapability
- Contrast injection port
- Power Pulse® Delivery enabled

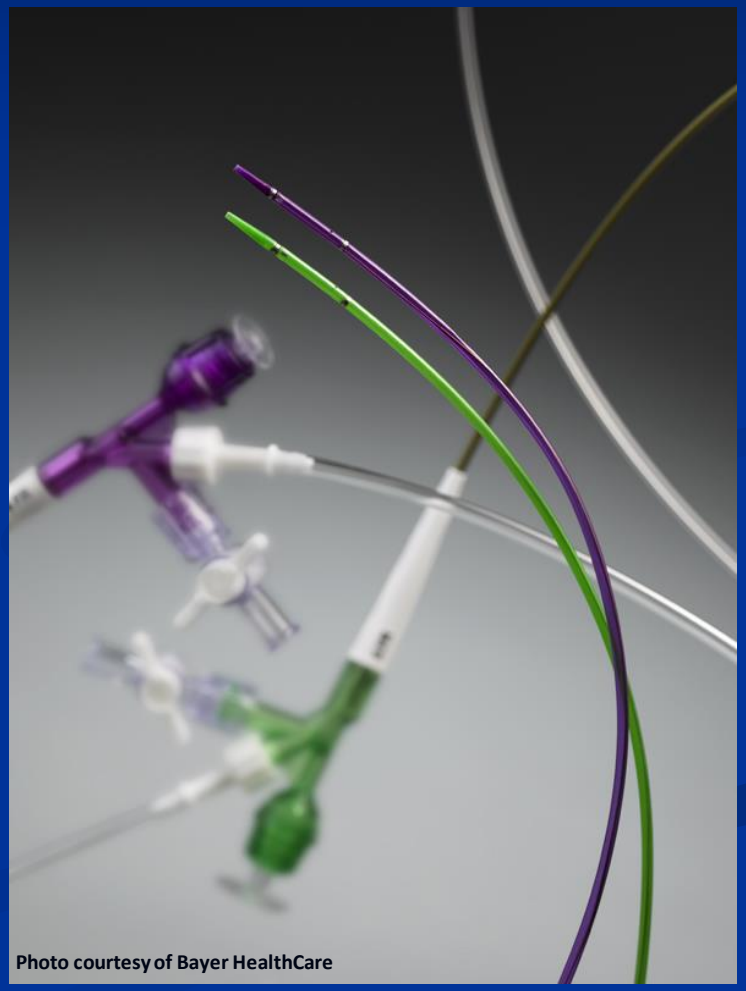
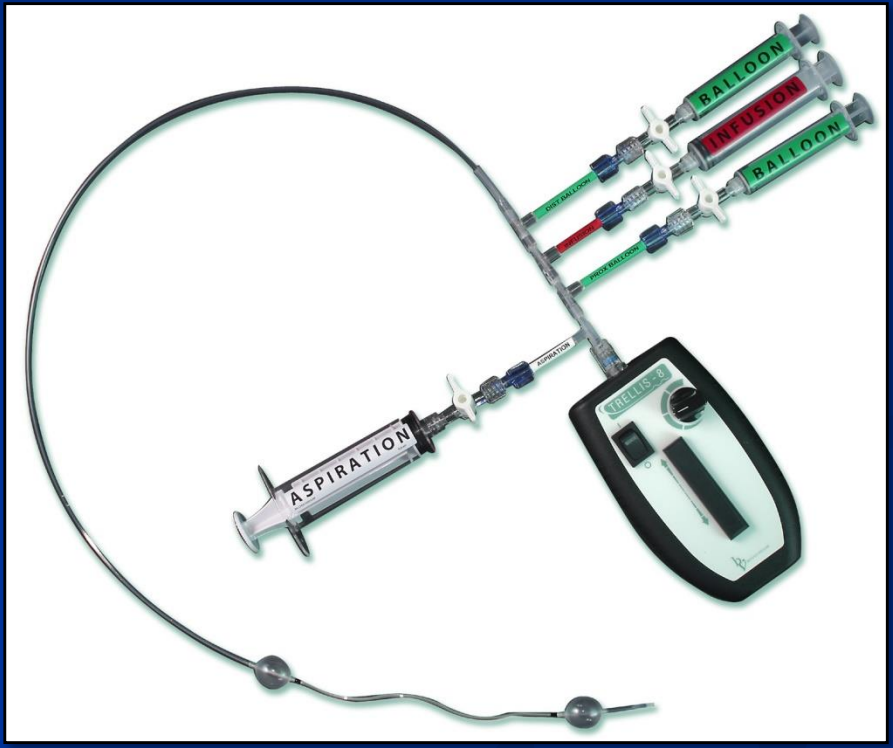


Photo courtesy of Bayer HealthCare

Treating DVT: Meet the Players

Trellis- PMT System

- Thrombus isolated between 2 occluding balloons, reducing embolization risk
- Local delivery of lytic allows minimal dose needed to achieve high concentration
- Sinusoidal wire disperses lytic, mechanically disrupts thrombus
- Aspiration following treatment
- Often requires only single treatment setting

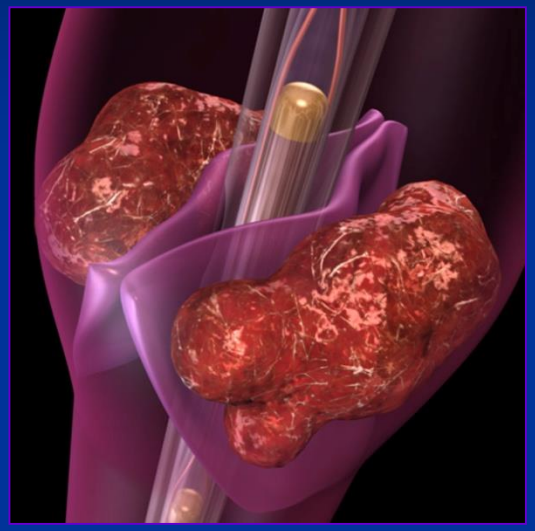


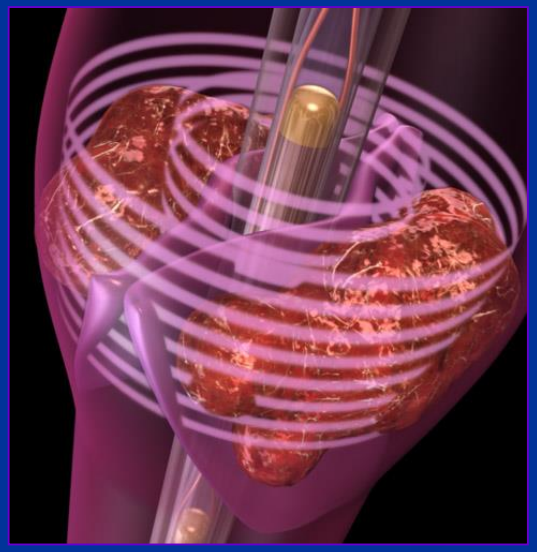
Treating DVT: Meet the Players

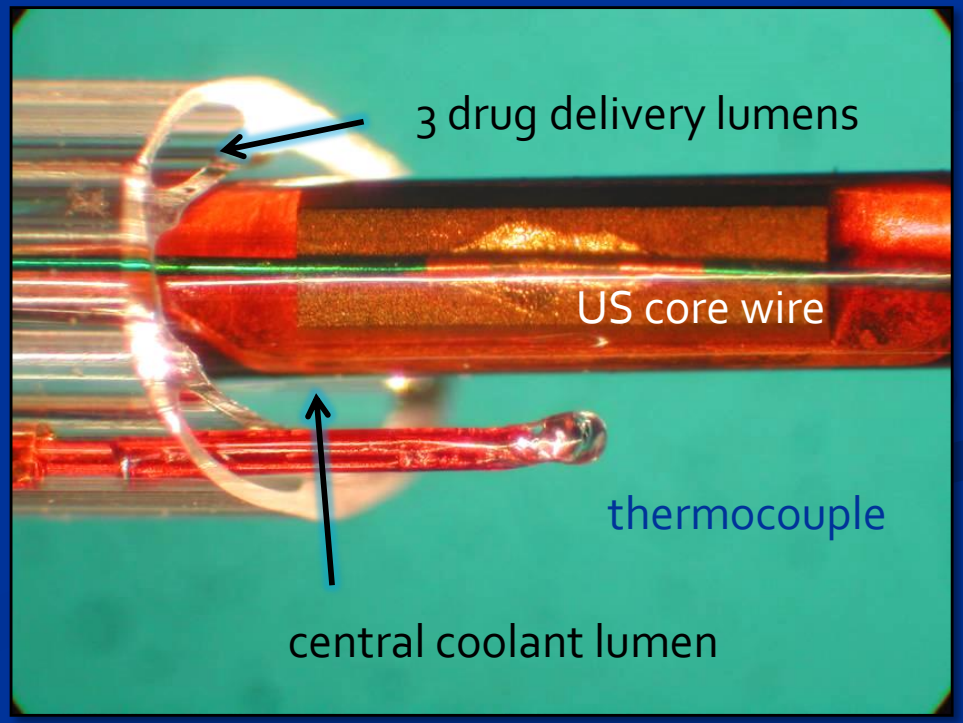
EKOS Lysis System

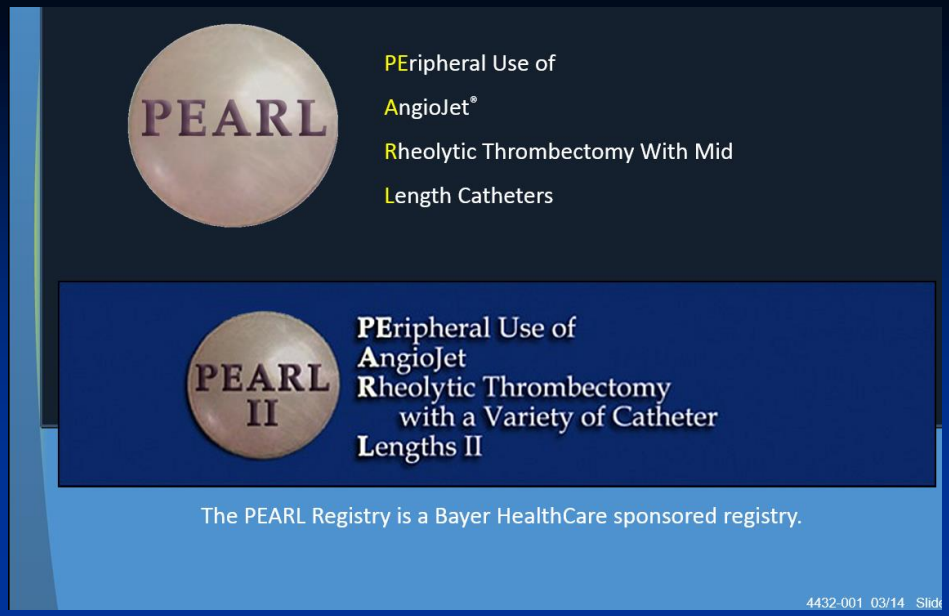
EKOS US-Assisted CDT

>99 % of US energy passes through valves









CLINICAL STUDY

Endovascular Management of Deep Vein Thrombosis with Rheolytic Thrombectomy: Final Report of the Prospective Multicenter PEARL (Peripheral Use of AngioJet Rheolytic Thrombectomy with a Variety of Catheter Lengths) Registry

Mark J. Garcia, MD, MS, Robert Lookstein, MD, Rahul Malhotra, MD, Ali Amin, MD, RVT, Lawrence R. Blitz, MD, Daniel A. Leung, MD, Eugene J. Simoni, MD, and Peter A. Soukas, MD

PEARL Registry

- Prospective, multi-center registry collecting patient history, procedural information, adjunctive treatments, outcomes and adverse events. All pts treated with AngioJet® Thrombectomy catheters.
- Pts divided into arterial, venous & dialysis access
- PEARL I *(January 2007 thru April 2010)*: Followed patients for 3 months with documentation of symptomatic improvement after rheolytic thrombectomy (with mid-length catheters).
- PEARL II *(March 2010 thru June 2013)*: Followed patients outcomes through 12 months after thrombectomy using any AngioJet® Catheter

Registry Objectives

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

DVT Age

From Signs/Symptoms Onset

Acute	≤ 24 Hours	18 (5%)	256/371 (69%)
	> 24 Hours and ≤ 7 Days	158 (43%)	
	> 7 Days and ≤ 14 Days	80 (22%)	
Sub Acute	> 14 Days and ≤ 30 Days	68 (18%)	68/371 (18%)
Chronic	> 30 days and ≤ 3 Months	33 (9%)	47/371 (13%)
	> 3 Months and ≤ 6 Months	8 (2%)	
	> 6 Months	6 (1%)	

69% of patients report symptom onset of < 14 days

PEARL Results

Duration of treatment

Time Period	Frequency
</= 6 Hrs	133 (38%)
> 6 Hrs & </= 12 Hrs	37 (10%)
> 12 Hrs & </= 24 Hrs	97 (27%)
>24 Hrs	88 (25%)

(355/371 had times recorded)

38% completed in ≤ 6 hrs
75% completed in ≤ 24 hrs

PEARL Results

of sessions

# of Sessions	N(%)
1	**123 (34%)**
2	**189 (53%)**
3	40 (11%)
>3	7 (2%)

(359/371 had # sessions recorded)

87% had 2 or less sessions

PEARL Results

Lab Test Comparisons

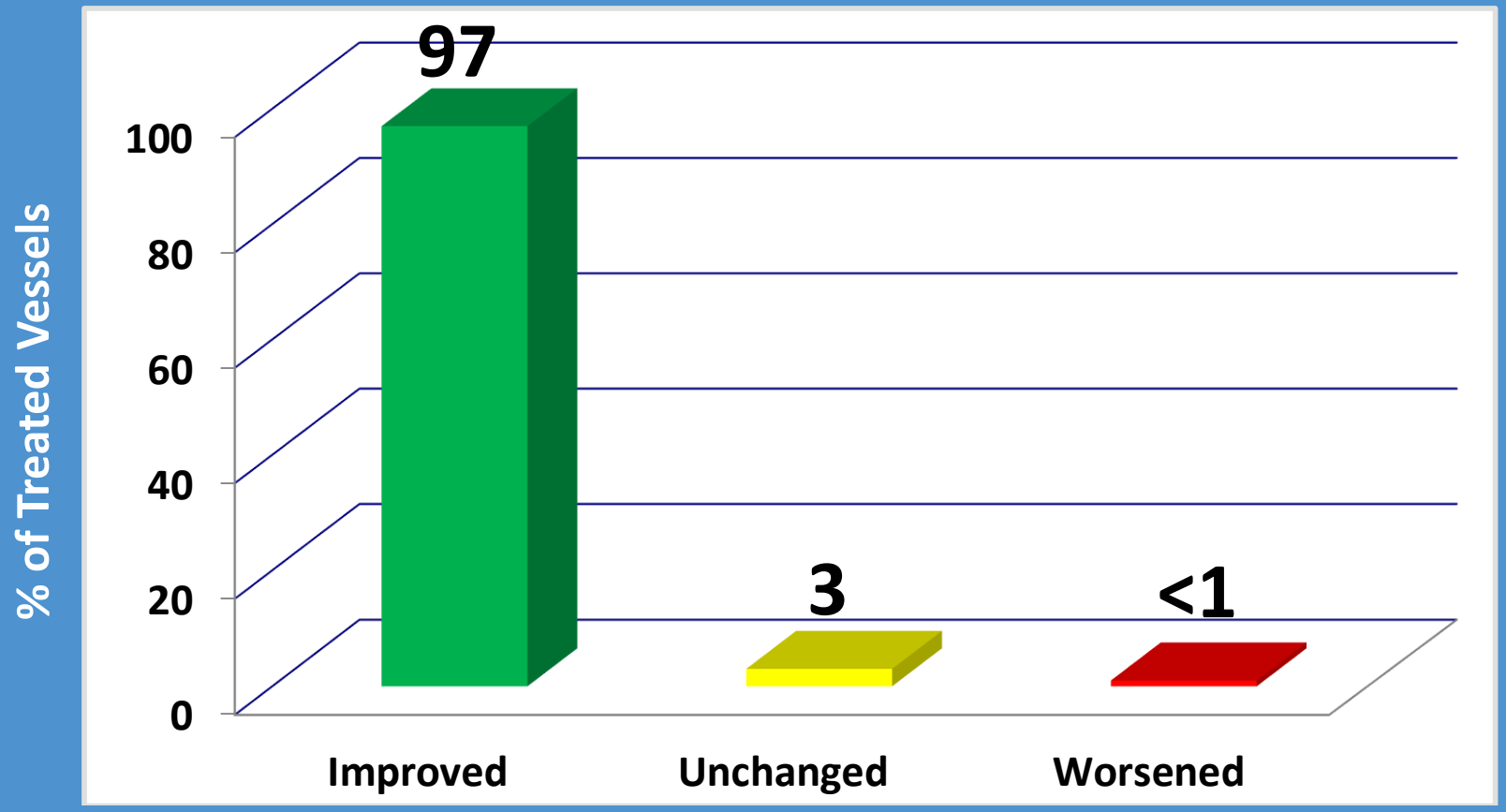
Analyte	Pre-procedure Mean	Post-procedure Mean	Mean Difference*	P Value
Hemoglobin (N=266)	12.4	11.2	-1.3	<0.0001
BUN (N=235)	16.8	16.4	-0.4	0.1030
Creatinine (N=239)	1.1	1.2	0.1	0.0848

Wilcoxon Signed Rank Test
*Paired analysis

PEARL Results

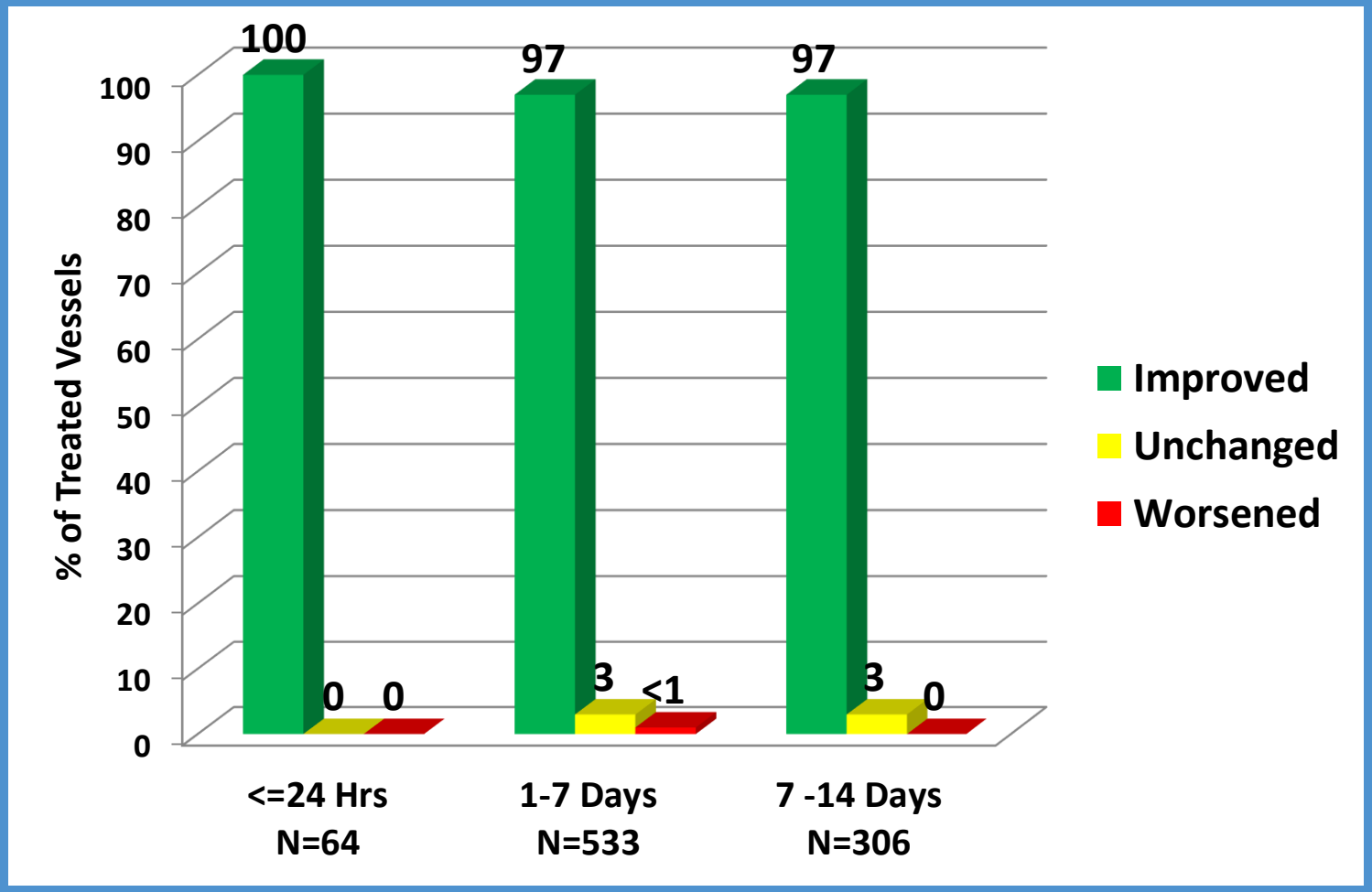
Venographic Results

N = 1295 vessels treated (p<0.0001)



Venographic Results

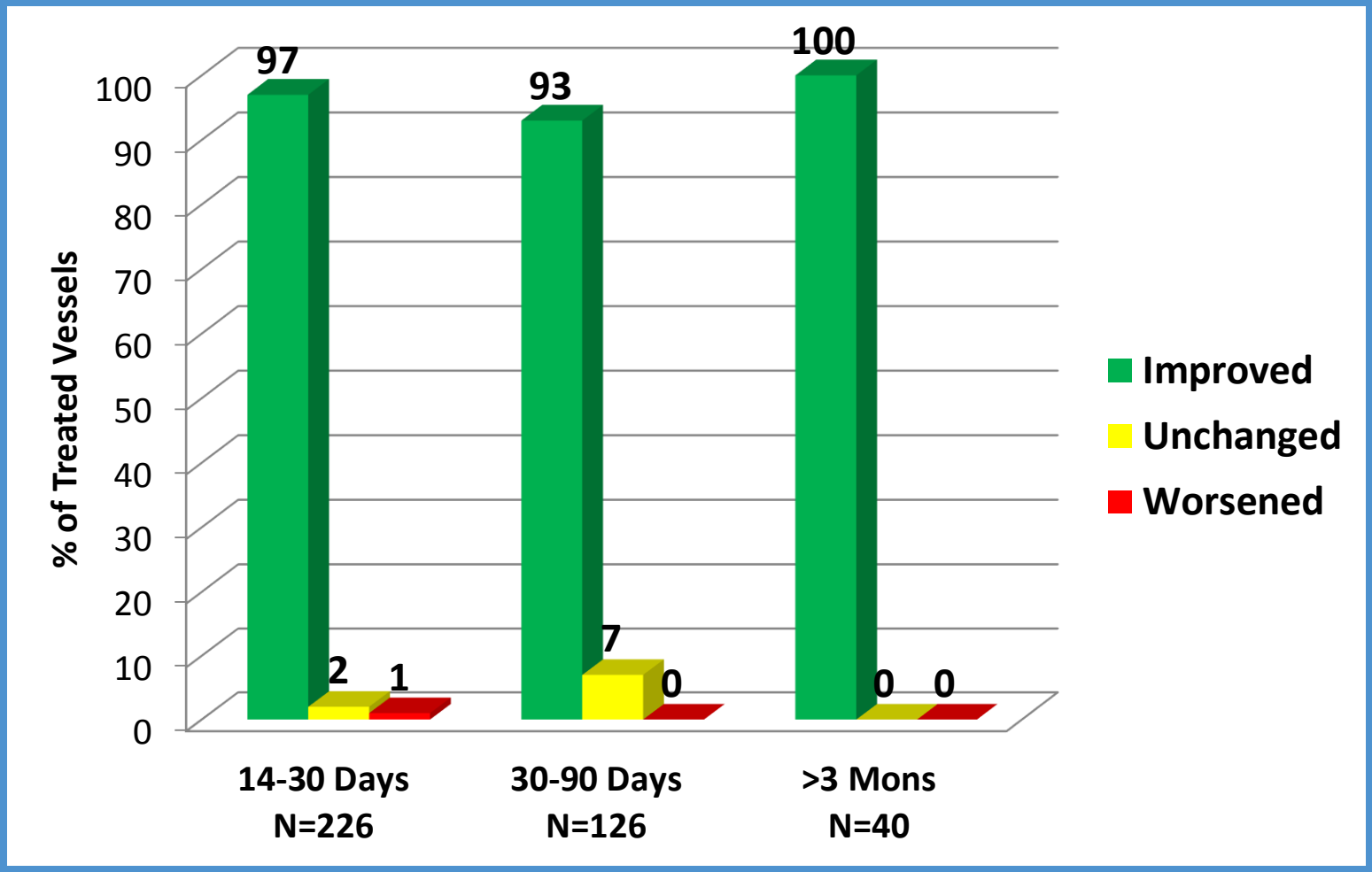
clot age by Sx Onset (p<0.0001)



ACUTE DVT

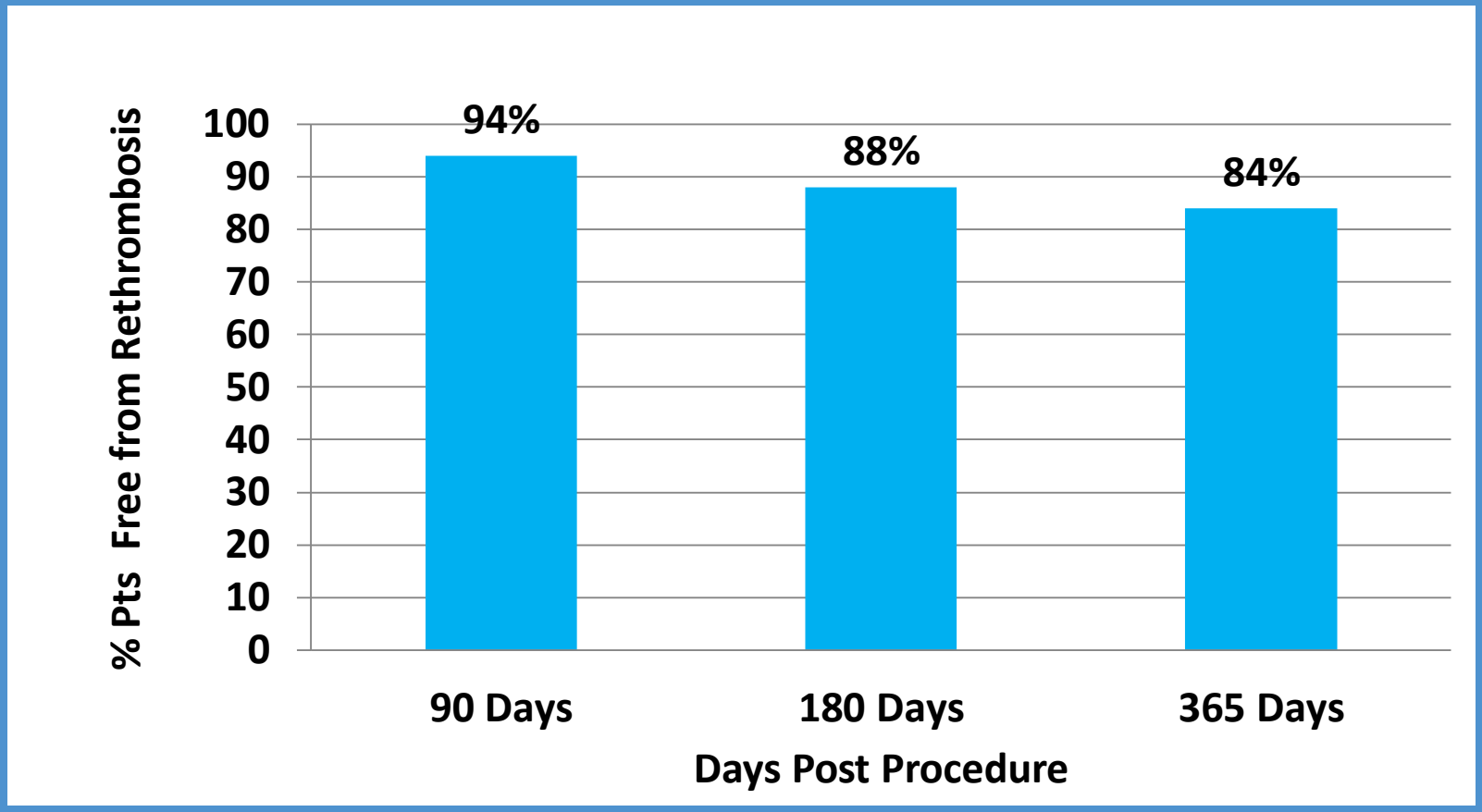
Venographic Results

clot age by Sx Onset (p<0.0001)



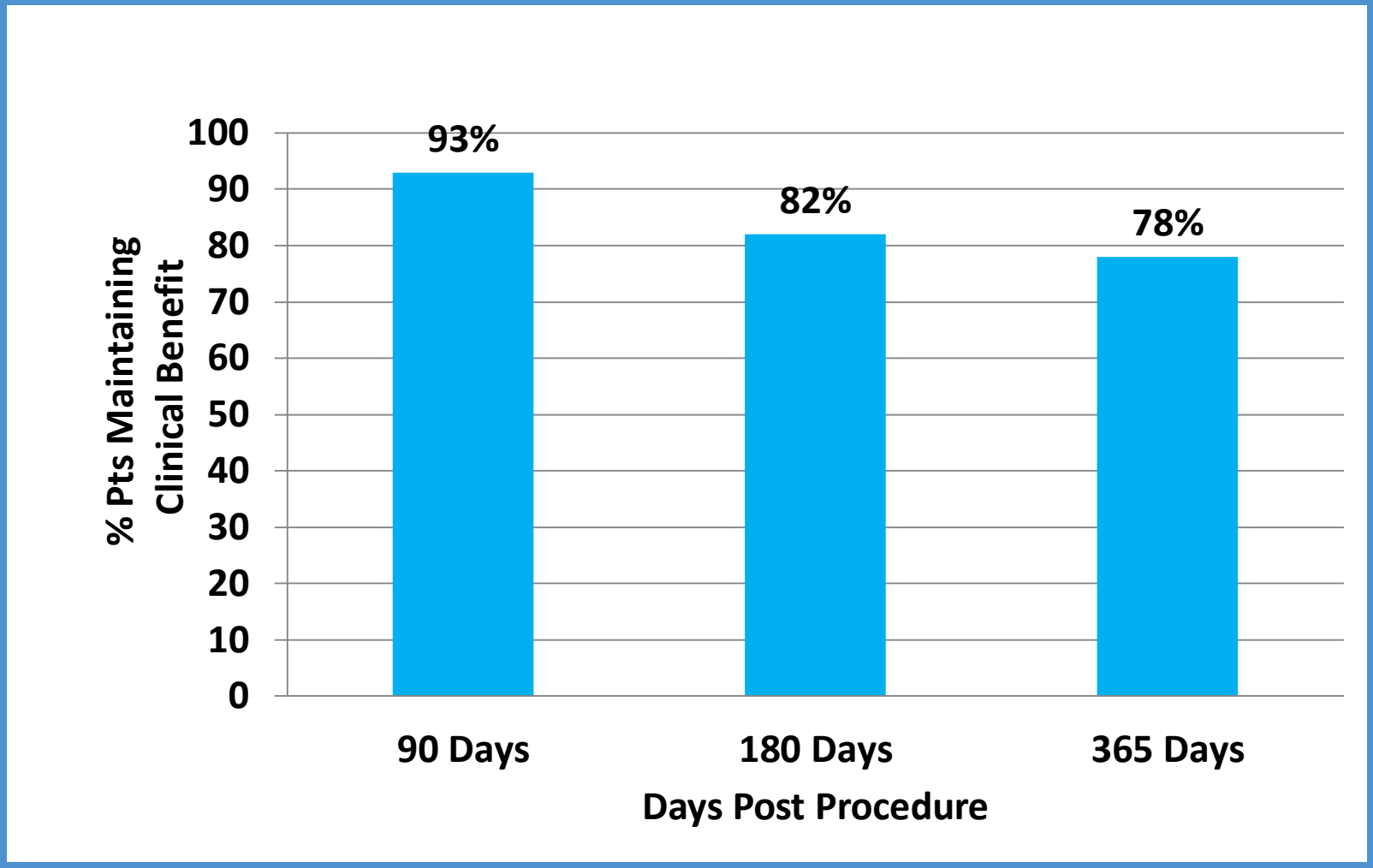
SUBACUTE CHRONIC

Freedom from Rethrombosis*



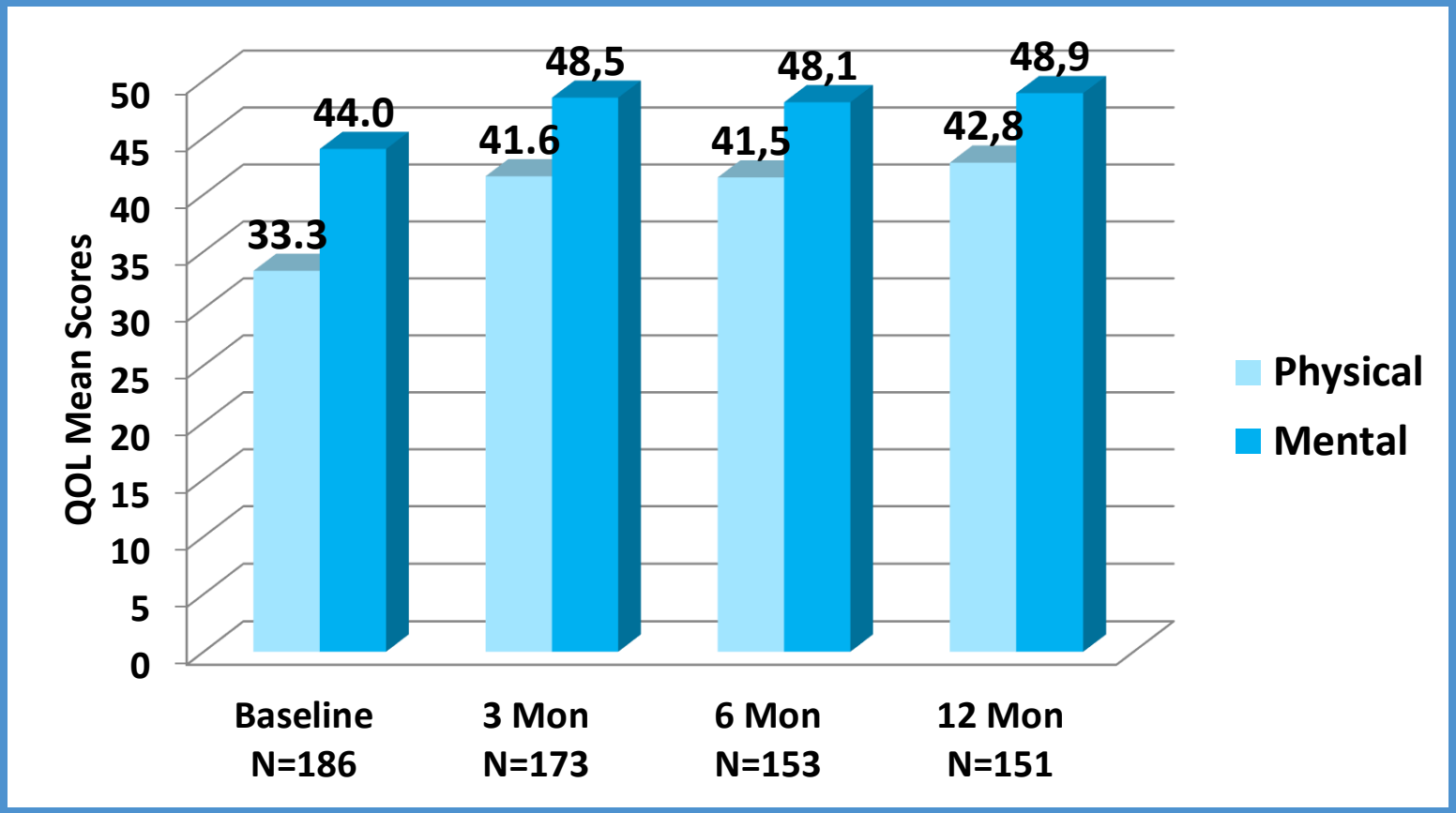
* Estimated by Kaplan Meier

Maintained Clinical Benefit*



* Estimated by Kaplan Meier

SF 12 QOL (PII Only)



There are statistically significant improvements measured by the physical ($p<0.0001$) and mental ($p<0.0001$) components.
The pretreatment physical scores differ significantly from the 3, 6 & 12 month follow ups

PEARL Comparison

Treatment of LE DVT

	PEARL	Venous Registry*	CaVenT**	
			CDT	STD
# of Patients	329	287	90	99
# of Sites	35	63	20	
Prior DVT	40%	31%	10%	9%
Primary Treatment	AngioJet Thrombectomy With or Without PPS/RL	CDT	CDT	LMWH
Stent Placement	35%	33%	17%	NA
Primary access	Popliteal	Popliteal	Popliteal	NA
Gender	Male=57%; Female=43%	Male= 48%; Female=52%	Male=64%; Female=36%	Male=62%; Female=38%
Age *(mean)*	52.2 yrs	47.5 yrs	53.3 yrs	50.0 yrs
Treatment Location	Iliofemoral – femoral pop	Iliofemoral – femoral pop	CFV or iliofemoral	
Limbs Involved	Left=62%; Right=38%	Left=61%; Right=39%	Left=60%; Right=40%	Left=62%; Right=38%

*Mewissen MW, Seabrook GR. Radiology 1999:211:39-49
**Enden , Haig Y. . Lancet 2012:379:31-38

PEARL Comparison

Treatment of LE DVT

		PEARL	Venous Registry*	CaVenT**	
				CDT	STD
Onset of DVT Symptoms	Acute	67% (≤14 days)	66% (≤10 Days)	100% ≤21 days	
	Chronic	33% (>14 days)	16% (>10 Days)	NA	
	Acute & Chronic	NA	19%	NA	
Primary Lytic		TPA	Urokinase	TPA	NA
CDT Drip Times *(mean)*		17 hrs	48 hrs	57.6 hrs (2.4 days)	NA
Procedure Times	CDT (N=29)	40.9 hrs	NA	NA	NA
	CDT+PPS/RL (N=172)	22.0 hrs	NA	NA	NA
	PPS/RL (N=115)	2.0 hrs	NA	NA	NA
Bleeding Complications		5% (major & minor combined)	11% (major); 16% (minor)	22% (major & minor combined)	0%

*Mewissen MW, Seabrook GR. Radiology 1999:211:39-49
**Enden , Haig Y. . Lancet 2012:379:31-38

PEARL Comparison

Treatment of LE DVT

		PEARL	Venous Registry*	CaVenT**	
				CDT	STD
Overall % Thrombus Removal		96%	83%	89%	NA
By Lytic Groups: % thrombus Removal	CDT (N=28)	93%	NA	NA	
	CDT+PPS/RL (N=167)	97%	NA	NA	
	PPS/RL (N=113)	95%	NA	NA	
Acute: % Thrombus Removal		97%	86%	89%	
Chronic: % Thrombus Removal		95%	68%	NA	
Acute & Chronic: % Thrombus Removal		NA	76%	NA	
Primary Patency		NA	6 Mon=65%; 12 Mon=60%	6 Mon = 65.9%	6 Mon = 47.4%
Freedom from Rethrombosis		6 Mon= 87%; 12 Mon=83%	NA	NA	NA

*Mewissen MW, Seabrook GR. Radiology 1999:211:39-49
**Enden , Haig Y. . Lancet 2012:379:31-38

Summary: Acute Ilio-Femoral DVT

- Medical management is associated with higher PTS compare to endovascular management
- There is increasing evidence that early thrombus resolution with endovascular intervention is associated with improved outcome
- Pharmacomechanical decreases procedure time, decrease amount of thrombolytic used

“Pull out, Betty! Pull out!...You’ve hit an artery!”