## **Intervention For**

## **Acute Limb Ischemia**

#### Jae-Hwan Lee, MD, PhD

Cardiovascular Center in Chungnam National University Hospital

## Catheter-Based Thrombectomy (CBT)

## <u>Arterial</u>

- Acute limb ischemia
- STEMI
- Ischemic stroke

### <u>Venous</u>

- Deep vein thrombosis
- Pulmonary embolism
- AV fistula occlusion

# **Rutherford Classification of ALI**

#### Table 1. Stages of Acute Limb Ischemia.\*

Stage	Description and Prognosis	Findings	
		Sensory Loss	Muscle Weakness
1	Limb viable, not immediately threatened	None	None
П	Limb threatened		
lla	Marginally threatened, salvageable if promptly treated	Minimal (toes) or none	None
IIb	Immediately threatened, salvageable with immediate revascularization	More than toes, associated with pain at rest	Mild or moderate
111	Limb irreversibly damaged, major tissue loss or permanent nerve damage inevitable	Profound, anesthetic	Profound, paralysis (rigor)
* Data a	re from the Society for Vascular Surgery standa	ards. <sup>4</sup>	

N Engl J Med 2012;366:2198-206

## **Diagnosis and Treatment Algorithm**

#### A Diagnosis



# Indication of CBT

- Mild-to-moderate limb ischemia (stage I & IIA)
  - viable or marginally threatened limb
- Recent occlusion ≤ 2 weeks
- Thrombosis of a synthetic graft
- Acute stent occlusion
- At least one identifiable distal runoff
- Not accessible to embolectomy
- Popliteal artery aneurysm where all run-off vessels are also thrombosed
- When surgery deemed too high a risk

N Engl J Med 2012;366:2198-206 J Vasc Surg. 2007;45(1 Suppl):S5-S67

# CBT; UK vs. tPA?

- tPA; (half-life 5 min) Bolus injection of 5-10 mg t-PA →Continuous infusion of 0.5-1.5 mg/hr
  UK; (half-life 20 min) Bolus injection of a 250,000 U
  → Followed by 4000 U/min for 4 hours
  → Followed by 2000 U/min for up to 32 hours
- in a volume >100 ml/hr
- coupled with peripheral or intrasheath IV heparin at 600-800 U/h

Tech Vasc Interventional Rad 2009;12:117-29

 My center; keeping UK 1,000,000 U in the cath lab
 200,000 U for intralesional injection during the procedure
 → Overnight UK infusion, 800,000 – 1,000,000 U in 1 L N/S mix IV for the next 10-15 hrs, 70-100 cc/hr speed, UK dose ≅ 60,000~80,000 U/hr

## ALI; Endovascular Thrombus Management

### <u>Thrombolysis</u>

Catheter-directed thrombolysis (CDT)

#### <u>Mechanical Adjuncts</u>

- Manual aspiration thrombectomy (MAT) Sheath / Catheter
- Mechanical fragmentation Rotarex, Jetstream
- Rheolytic thrombectomy Angiojet
- Aspiration thrombectomy

- Aspirex, ThromCat, Indigo, Megavac

Ultrasonic / Laser

## Manual vs. Mechanical Thrombectomy

Catheter Aspiration Thrombectomy: Syringe suction used to aspirate the debris



#### Mechanical Thrombectomy: Saline jets or rotating catheter head to breakup thrombus before its aspiration



Manual Devices include: Diver<sup>™</sup>, Diver<sup>™</sup> CE, Export<sup>®</sup>, Pronto<sup>™</sup>, QuickCat, Rescue<sup>™</sup>, Thrombuster<sup>®</sup>, and TransVascular Aspiration Catheter<sup>®</sup>. Mechanical devices include: AngioJet<sup>®</sup> (and X-Sizer<sup>®</sup>.)

## **Mechanical Devices for Thrombus Removal**

# Now available in Korea



Jetstream, BSC

**Rotarex, Straub Medical** 

Angiojet, BSC

## Most Simple & Cheap Way; Thrombosuction by a sheath



## Most Simple & Cheap Way; Thrombosuction by a sheath



## Ipsilateral approach; My Aspiration Devices Ansel sheath + Sheath dilator + 0.014" Command ES GW

For thrombusuction

**Tuohy-borst type** 

Short Y connector



Contralateral approach; Shuttle sheath + 0.035" compatible Dilator + 0.035" Amplatzer extrastiff GW

## **My Personal Aspiration Devices**

#### <u>lliac</u>

- Ipsilateral or Contralrateral
- 7 Fr Ansel sheath + Sheath dilator + 0.014" Command ES GW
   <u>Femoral</u>
- Ipsilateral; 7 Fr Ansel sheath + Sheath dilator + 0.014" Command ES GW
- Contralateral; 6-7 Fr Shuttle sheath + Sheath dilator

+ 0.014" Command ES GW  $\rightarrow$  for soft aortoiliac anatomy

+ 0.035" Amplatzer extrastiff GW → for difficult aortoiliac anatomy <u>Proximal BTK</u>; 5 Fr Heartrail through the Ansel / Shuttle sheath <u>Foot level</u>; Thrombuster or Export catheter

# **Representative Cases**

#### Case

- Image: 61 / F, ALI Rutherford I
- Slowly progressing dyspnea, NYHA Fc 3
- Right leg pain, coldness and numbress for 2 weeks
- ECG; Afib
- TTE; Severe MS, MVA 0.9 cm<sup>2</sup>, LAA thrombi



#### Right popliteal embolic occlusion



#### Baseline

Aspiration with 7Fr sheath

Angiogram using suction catheter

#### Thrombectomy using both sheath and suction catheter



#### Sheath aspiration for P3

#### Final angiogram of the 1<sup>st</sup> procedure

### Thrombus on the table



### After overnight UK infusion, 100,000U/hr



Next day angiogram

## Final angiogram





- 41 / F, Antiphospholipid syndrome with arm embolism
- Smoker
- Right hand color change, coldness and pain for 3 weeks
- Poor right ulnar and radial pulsation
- Normal left U/E and both L/E angiogram

 $\rightarrow$  Ruled out Buerger's disease

Lupus anticoagulant Ab (+)

#### **Brachial artery embolic occlusion**



Femoral approach 5 Fr 110 cm long Shuttle sheath 0.014" Command GW Thrombuster catheter

#### After overnight UK infusion



Kissing balloon angioplasty

#### Case

- 75 / M, ALI, Rutherford IIa
- H/O CHF with pulmonary edema, 2010
  - severe LV dysfunction, EF 28% with LAA thrombi
  - $\rightarrow$  F/U Lost
  - $\rightarrow$  Right lower leg pain for 5 days
- Atrial fibrillation





## Angiogram





#### Thrombus aspiration from Popliteal, ATA and PTA



**Ipsilateral antegrade 7 Fr Ansel sheath** 

#### Overnight intralesional UK infusion → Followed by adjunctive balloon angioplasty



# **Case of Mechanical Thrombectomy**

#### ALI case with toe gangrene - subacute course

#### 46/M

Polycythemia vera

Hb 20.5g/dL, WBC 20,500/uL, PLT 512K/uL

Right calf pain, coldness and 1st toe gangrene for 1 month







Jetstream thrombectomy



#### DEB 6.0x120 mm

## 74/F, ALI stage IIa, 10 days ago onset



## 74/F, ALI stage IIa, 10 days ago onset



## 74/F, ALI stage IIa, 10 days ago onset





6 months later, asymptomatic, but

### **ALI CBT Data From Our Center - Baseline**

	Total (n=57)	Manual Aspiration (n=38)	Jetstream (n=19)	P-value
Age	72.4±13.6	68.1±12.9	81.2±10.5	<0.001
Sex(male)	40(70.2%)	28(73.7%)	12(63.2%)	0.407
DM	27(47.4%)	20(52.6%)	7(36.8%)	0.260
IHD	28(49.1%)	21(55.3%)	7(36.8%)	0.190
Previous Cl	12(21.1%)	9(23.7%)	3(15.8%)	0.491
CKD	14(24.6%)	6(15.8%)	8(42.1%)	0.030
HTN	38(66.7%)	25(65.8%)	13(68.4%)	0.843
Dyslipidemia	9(15.8%)	8(21.1%)	1(5.3%)	0.123
AF	20(35.1%)	13(34.2%)	7(36.8%)	0.844
Cancer	11(19.3%)	7(18.4%)	4(21.1%)	0.812
Smoking	17(25.5%)	12(31.6%)	5(26.3%)	0.682

### **ALI CBT Data From Our Center – Presentation & Lesion**

	Total (n=57)	Manual Aspiration (n=38)	Jetstream (n=19)	P-value
Sx duration (day)	22.4±28.2	25.4±32.4	16.3±16.4	0.257
Onset of Sx				
Acute (<14day)	36(63.2%)	25(65.8%)	11(57.9%)	0.560
Subacute (>2wk)	21(36.8%)	13(34.2%)	8(42.1%)	0.560
Rutherford grade				
	34(59.6%)	25(65.8%)	9(47.4%)	0.181
lla	11(19.3%)	8(21.1%)	3(15.8%)	0.635
llb	12(21.1%)	5(13.2%)	7(36.8%)	0.039
Proximal extent				
lliac	10(17.5%)	7(18.4%)	3(15.8%)	0.805
Femoral	29(50.9%)	13(34.2%)	16(84.2%)	<0.001
Popliteal	11(19.3%)	11(28.9%)	0(0.0%)	0.009
Tibial	7(12.3%)	7(18.4%)	0(0.0%)	0.046

#### **ALI Data From Our Center – Procedural Characteristics**

	Total (n=57)	Manual Aspiration (n=38)	Jetstream (n=19)	P-value
Sheath diameter(Fr)	6.28±0.84	5.92±0.82	7.00±0.0	<0.001
Lesion length(mm)	156.2±85.4	132.7±77.7	203.3±82.4	0.002
Calcification				
No/mild	43(75.4%)	28(73.7%)	15(78.9%)	0.663
Moderate	13(22.8%)	9(23.7%)	4(21.1%)	0.823
Severe	1(1.8%)	1(2.6%)	0(0.0%)	0.476
Intervention feature				
De novo lesion	47(82.5%)	21(81.6%)	16(84.2%)	0.805
Previous PTA lesion	19(17.5%)	7(18.4%)	3(15.8%)	0.805

### **ALI Data From Our Center – Procedural Characteristics**

	Total (n=57)	Manual Aspiration (n=38)	Jetstream (n=19)	P-value
UK use	47(82.5%)	32(84.2%)	15(78.9%)	0.622
UK dose(10thousand)	53.2±39.1	56.3±39.6	46.8±38.2	0.393
UK duration(hour)	6.2±5.1	6.6±4.8	5.3±5.6	0.389
Initial procedure time(min)	97.5±39.3	87.8±38.7	118.8±32.2	0.003
Initial radiation time min)	39.8±20.2	32.9±16.4	53.7±20.2	<0.001
Initial contrast dose(cc)	160.8±64.9	147.9±67.6	186.6±51.3	0.032
Stage procedure	22(38.6%)	19(50.0%)	3(15.8%)	0.012
Stage procedure time(min)	32.8±53.3	38.7±49.9	21.1±59.1	0.242
Stage radiation time(min)	13.7±18.5	17.1±19.0	7.0±16.1	0.052
Stage contrast dose(cc)	53.1±65.9	64.5±69.1	30.4±53.7	0.065
Total procedure time(min)	128.7±67.8	123.1±69.0	139.9±65.9	0.382
Total radiation time(min)	53.5±24.5	50.0±24.1	60.7±24.2	0.120
Total contrast dose(cc)	213.4±81.9	211.6±89.1	217.0±67.5	0.817
Costs (1,000 won)	10578.0±5366.8	10605.7±5632.7	10552.6±4938.3	0.972
Hospital stay(day)	22.6±39.6	30.4±46.5	7.05±6.1	0.034

### **ALI Data From Our Center – Procedural Complications**

	Total (n=57)	Manual Aspiration (n=38)	Jetstream (n=19)	P-value
Transient embolism	42(72.3%)	26(68.4%)	16(84.2%)	0.202
Embolism	7(12.3%)	3(7.9%)	4(21.1%)	0.154
Hematoma	3(5.3%)	3(7.9%)	0(0.0%)	0.208
Bleeding	4(7.0%)	4(10.5%)	0(0.0%)	0.142
Respiratory distress	1(1.8%)	1(2.6%)	0(0.0%)	0.476
Dissection or perforation	2(3.5%)	0(0.0%)	2(10.5%)	0.042
Deep vein thrombus	0(0.0%)	0(0.0%)	0(0.0%)	1.000
Pseudoaneurysm	1(1.8%)	1(2.6%)	0(0.0%)	0.476
Acute renal failure	2(3.5%)	2(5.3%)	0(0.0%)	0.309
Infection	1(1.8%)	1(2.6%)	0(0.0%)	0.476
Mortality	3(5.3%)	3(7.9%)	0(0.0%)	0.208

### ALI Data From Our Center – Clinical Outcomes

	Total (n=57)	Manual Aspiration (n=38)	Jetstream (n=19)	P-value
Procedure failure	3(5.3%)	3(7.9%)	0(0.0%)	0.208
Pre TIMI	0.11±0.36	0.16±0.44	$0.0 \pm 0.00$	0.122
Post TIMI	2.56±0.68	2.53±0.73	2.63±0.60	0.587
Intervention treatment				
Balloon angioplasty	52(91.2%)	34(89.5%)	18(94.7%)	0.508
Stent implantation	6(10.5%)	5(13.2%)	1(5.3%)	0.360
30 day primary patency	49(86.0%)	32(84.2%)	17(89.5%)	0.590
1 year primary patency	42(73.7%)	28(73.7%)	14(73.7%)	1.000
<b>Re-intervention</b>	9(15.8%)	5(13.2%)	4(21.1%)	0.370
Time to 1 <sup>st</sup> re-intervention	10.7±33.6	8.5±31.7	15.0±37.7	0.441
Amputation	6(10.6%)	5(13.2%)	1(5.3%)	0.360
Limb salvage	53(93.0%)	35(92.1%)	18(94.7%)	0.714

### Manual Aspiration vs. Mechanical Thrombectomy

	Manual Aspiration Thrombectomy	Mechanical Thrombecomy		
Pros	Less invasive, Cheaper No special device needed Smaller catheter applicable Less time consuming Smaller radiation & contrast dose	<ul> <li>More efficient thrombus removal</li> <li>→ reduce duration and amount of thrombolytic agents</li> <li>Rapid reperfusion</li> <li>More effective on organized thrombi or combined atherosclerosis</li> </ul>		
Cons	Less effective thrombus removal More thrombolytic agent needed - longer duration, larger amount - pt's inconvenience, more bleeding risk Repetitive session may be needed	Specialized device should always be prepared in the cath lab → \$2,000 More embolization risk Filter device sometimes needed Potential risk of vessel damage		
	No rendemized comparison. No large outcome data			

No randomized comparison, No large outcome data
 → Clinical outcome difference not defined yet
 Economic burden difference? No answer

?

#### Manual Aspiration vs. Mechanical Thrombectomy

- We definitely need more data.
- Routine use of mechanical device is not desirable.
- We must establish an appropriate treatment strategy based on the patient and the condition of the lesion.



## ALI Thrombus - Mechanical vs. Manual?

# We must compare the gain and the yarn

## For Making Good Footprints

100

100

Thanks for the Time

## ALI Thrombus - Mechanical vs. Manual?

# We must compare the gain and the yarn