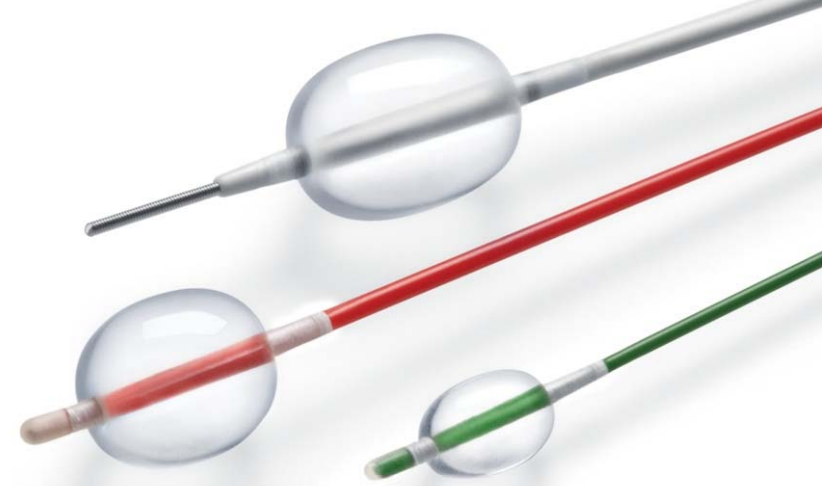


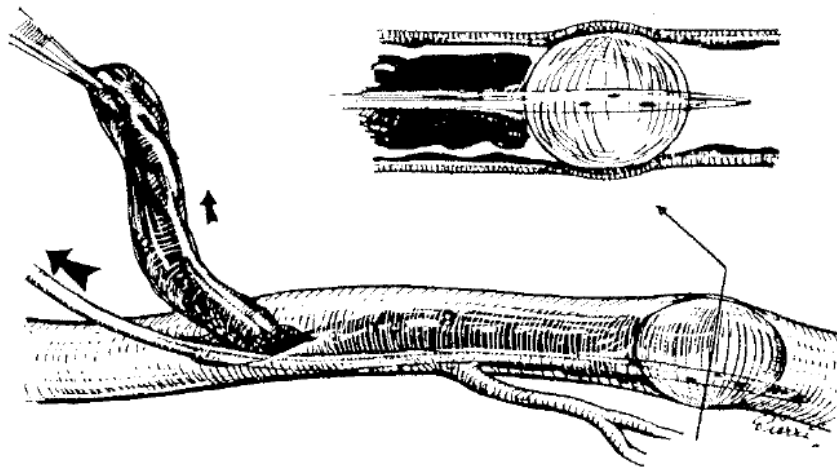


Embolectomy and OTW Embolectomy Catheters

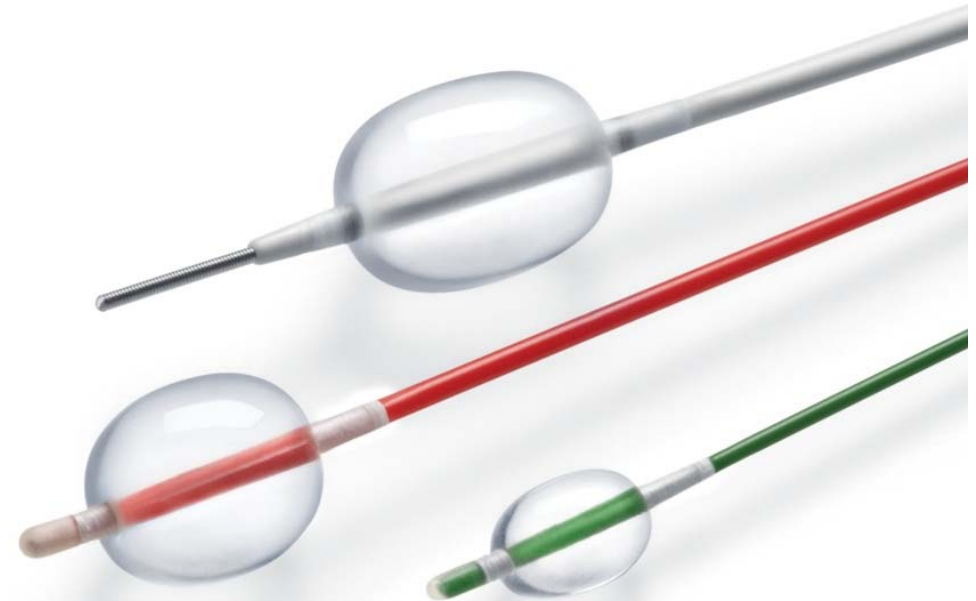
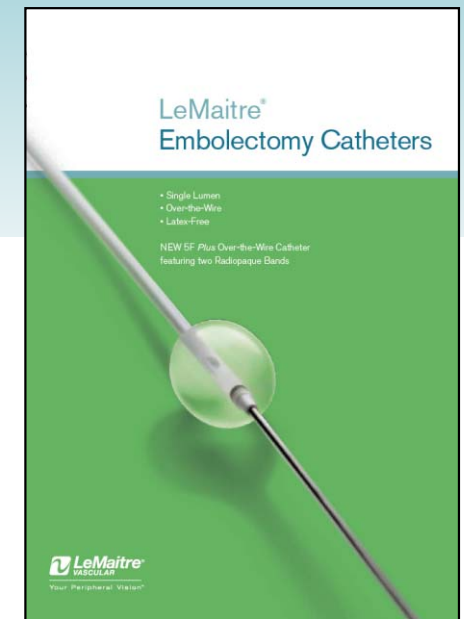
Wolfgang Meichelboeck
VP Marketing Int.
Jan 12, 2012

Embolectomy Catheter

● **Reliable high
quality
Embolectomy
catheters**



a



The PROBLEM = Arterial circulatory disturbances

acute

acute limb ischemia

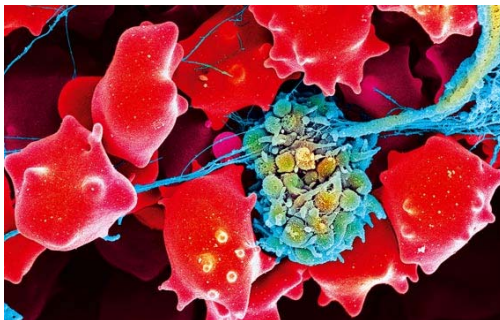
ALI



chronic

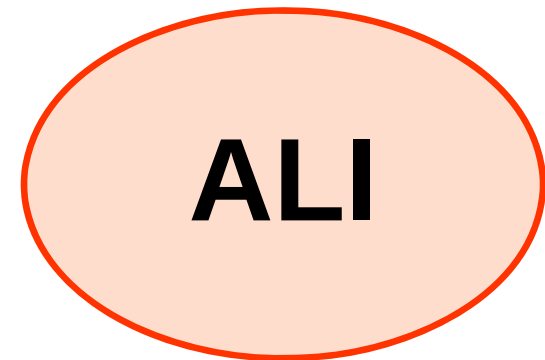
arterial occlusive disease

pAOD / PAD



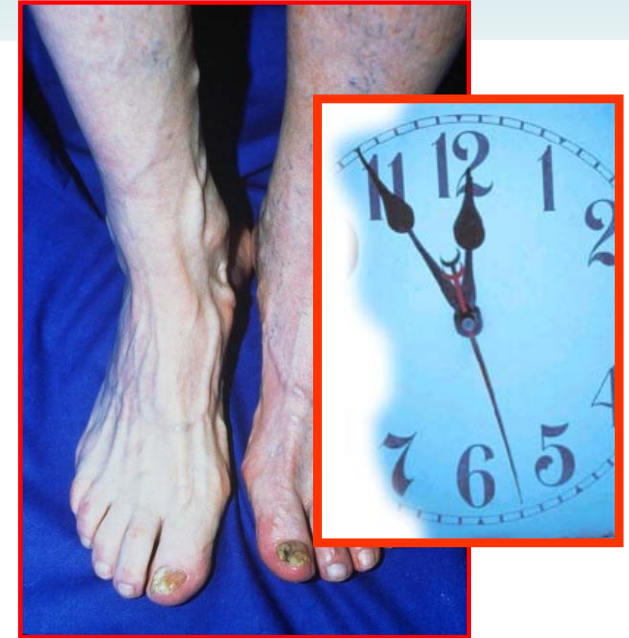
Acute Limb Ischemia (ALI) - Definition

- **Sudden decrease of limb perfusion**
causing a potential threat to limb viability
- Acute = event or symptoms less than 14 days
 - o Hyper acute = < 24h
 - o Acute A < 7 days
 - o Acute B < 14 days
 - o Subacute = 15 days to 3 month
 - o Chronic after 3 month



Embolectomy Catheters – disease (1)

 **Acute ischemia**
(Thrombosis / Embolism)
of
peripheral arteries
(limbs or arms)



White ischaemia



"trash foot" syndrome



Gangrene

Pictures: courtesy PD. Dr. Gunnar Riepe, Koblenz Germany

Causes of acute limb ischemia

➤ *Conditions mimicking acute limb ischemia*

- o Heart failure (especially if associated with chronic occlusive disease)
- o Acute DVT
- o Acute compressive neuropathy

➤ *Nonatherosclerotic causes of acute limb ischemia*

- o Arterial trauma (especially iatrogenic)
- o Aortic/arterial dissection
- o Arteritis with thrombosis (eg, giant cell arteritis, thromboangiitis obliterans)
- o Spontaneous thrombosis associated with a hypercoagulable state
- o Popliteal cyst with thrombosis
- o Popliteal entrapment with thrombosis
- o Vasospasm with thrombosis (eg, ergotism)

➤ *Causes of acute limb ischemia in atherosclerotic patients*

- o Thrombosis of an atherosclerotic stenosed artery
- o Thrombosis of an arterial bypass graft
- o Embolism from heart, aneurysm, plaque, or critical stenosis upstream (including cholesterol or atherothrombotic emboli secondary to endovascular procedures)
- o Thrombosed aneurysm (especially popliteal aneurysm)

Causes of acute limb ischemia – diff. diagnosis

➤ *Causes of acute limb ischemia in atherosclerotic patients*

- **Thrombosis** of an atherosclerotic stenosed artery
- **Thrombosis** of an arterial bypass graft
- **Embolism** from the heart, aneurysm, plaque, or critical stenosis upstream
 - including cholesterol or atherothrombotic emboli secondary to endovascular procedures)
- **Thrombosed aneurysm**
(especially popliteal aneurysm)

Embolitic & Thrombotic Occlusion

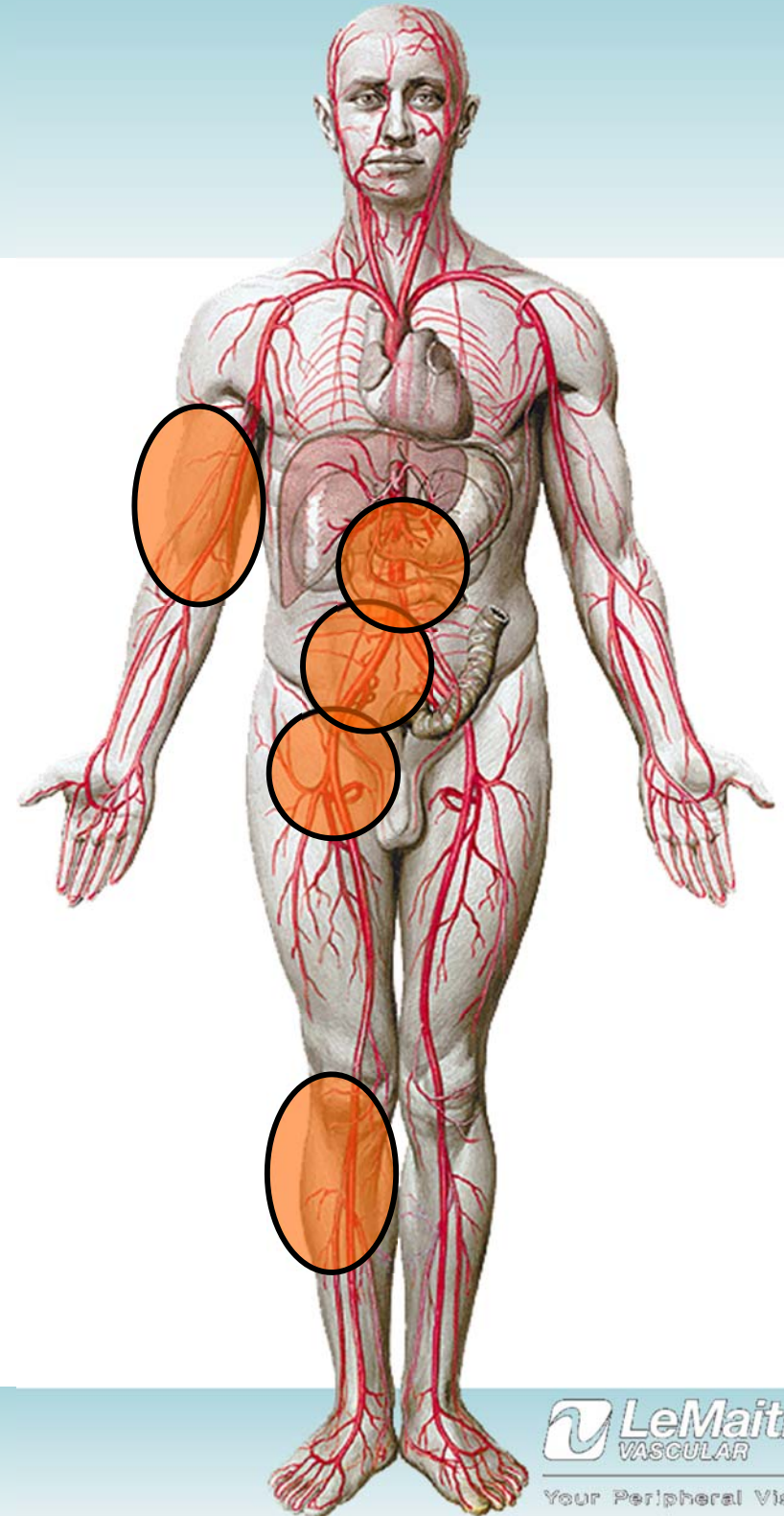
- **Arterial thrombosis** makes **85%** of the occlusions
- **Embolitic** events are responsible for **15% of ALI**
 - o 90% of the emboli are of cardiac origin

Pathogenesis

● Predispositioned Locations

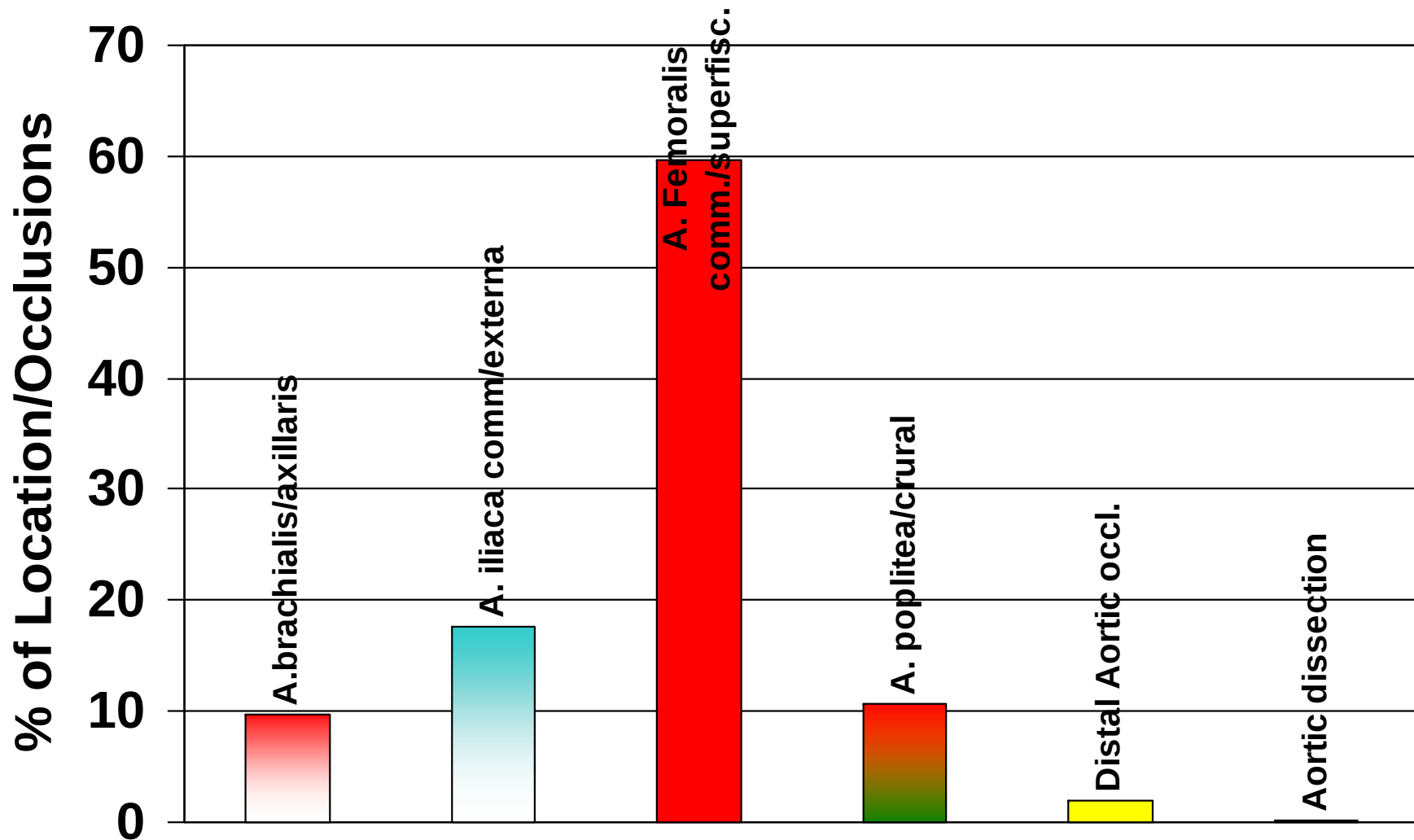
Femoral junction	60%
Iliac junction	18%
Popliteal artery	11%
Brachial artery	10%
Aortic	2%

from: % Kopp R, Chirurg 2003



Localization of acute occlusion – Location (n=1537)

Jan 1991- June 2003



Kopp R, et al. Acute limb ischemia from the general surgeon's point of view. How much knowledge of vascular surgery is necessary? Chirurg 2003 · 74:1090–1102

Incidence of arterial occlusion by location - literature review -

Table 3. Relative incidence of arterial occlusion by location in embolism and acute thrombosis

Studija	Aorta (%)	Iliac artery (%)	Femoral artery (%)	Popliteal artery (%)	Tibial artery (%)
Embolism					
J. Horton et al.	17	21	46	10	4
W. A. Dale	7.1	7.1	50	28.6	7.2
D. Raithel	16	17.7	52	14.3	–
A. Enjalbert et al.	19.6	29.6	50.8	–	–
Average incidence	14.9	18.8	51.9	17.6	5.6
KUMH	–	15.8	32.9	44.7	7
Acute thrombosis					
J. Horton et al.	10	14	55	18	1
W. A. Dale	–	25	32.1	28.6	14.3
D. Raithel	10	35.9	42.9	11.2	–
A. Enjalbert et al.	2.5	33.6	60.6	3.3	–
Average incidence	7.5	27.1	47.7	15.3	7.6
KUMH	–	22.7	37.9	24.2	2

Antušėvas A, Aleksynas N. The surgical treatment of the lower limb acute ischemia.

MEDICINA (2003) Vol. 39, No.7 - <http://medicina.kmu.lt>

Major amputation rate - literature review

Table 4. Major amputation rate of patients with embolism and acute thrombosis in lower limbs

Authors	Reason of ischemia	Major amputation rate (%)
F. Pellegrino (11)	thrombosis embolism	16 11
J. P. Becquenim (12)	embolism	23
G. Illuminati (14)	thrombosis embolism	37.7 17.2
P. Kuukasjarvi (15)	thrombosis embolism	26 10
D. F. Neuzil (16)	embolism	7.4
Vilnius University (22)	embolism	10
KUMH	thrombosis embolism	7.6 2.6

3 to 40 %

Antušėvas A, Aleksynas N. The surgical treatment of the lower limb acute ischemia.
MEDICINA (2003) Vol. 39, No.7 - <http://medicina.kmu.lt>

Thrombus versus Embolus

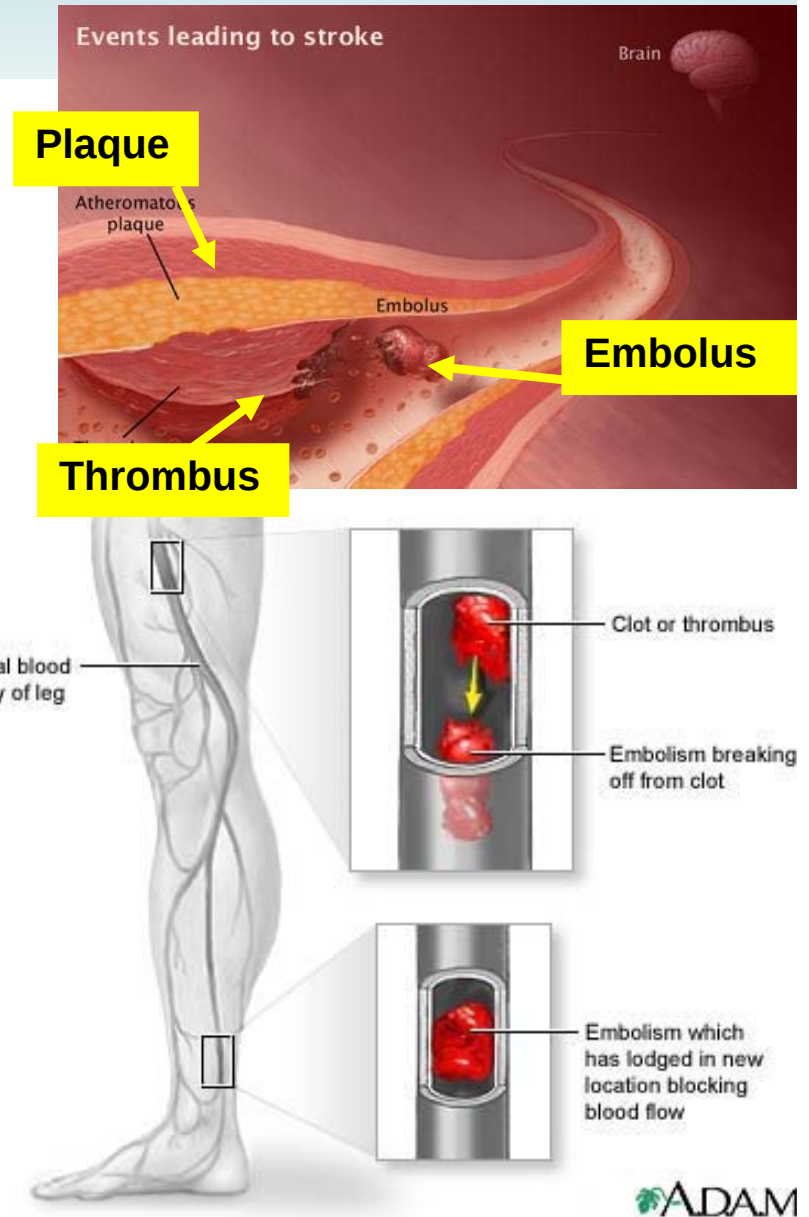
- **Blockages of arteries**
- A blood clot can block a blood vessel.
Thrombus or **Embolus**.

► **Thrombus:**

- a clot which builds up and blocks a blood vessel

► **Embolus:**

- a clot which forms, then breaks off and travels along a blood vessel until it gets stuck.



Standards ? - TASC

TASC

Management of
Peripheral Arterial Disease (PAD)
TransAtlantic Inter-Society Consensus (TASC)

Section A: Introduction

Section B: Intermittent Claudication

Section C: Acute Limb Ischemia

Section D: Critical Limb Ischemia

- TASC, J Vasc Surg 2000 Vol.31 (1), Section C

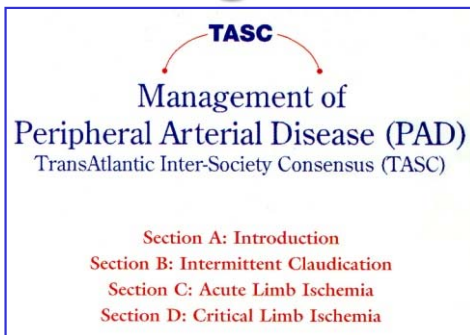
Clinical categories of acute limb ischemia

			Findings		Doppler signals	
Category		Description/prognosis	Sensory loss	Muscle weakness	Arterial	Venous
I	Extremity Viable	Not immediately threatened	None	None	Audible	Audible
IIa	Extremity Marginally threatened	Salvageable if promptly treated	Minimal (toes) or none	None	(Often) inaudible	Audible
IIb	Extremity Immediately threatened	Salvageable with immediate revascularization	More than toes, associated with rest pain	Mild, moderate	(Usually) inaudible	Audible
III	Irreversible changes*	Major tissue loss or permanent nerve damage inevitable	Profound, anesthetic	Profound, paralysis (rigor)	Inaudible	Inaudible

*When presenting early, the differentiation between class IIb and III acute limb ischemia may be difficult.

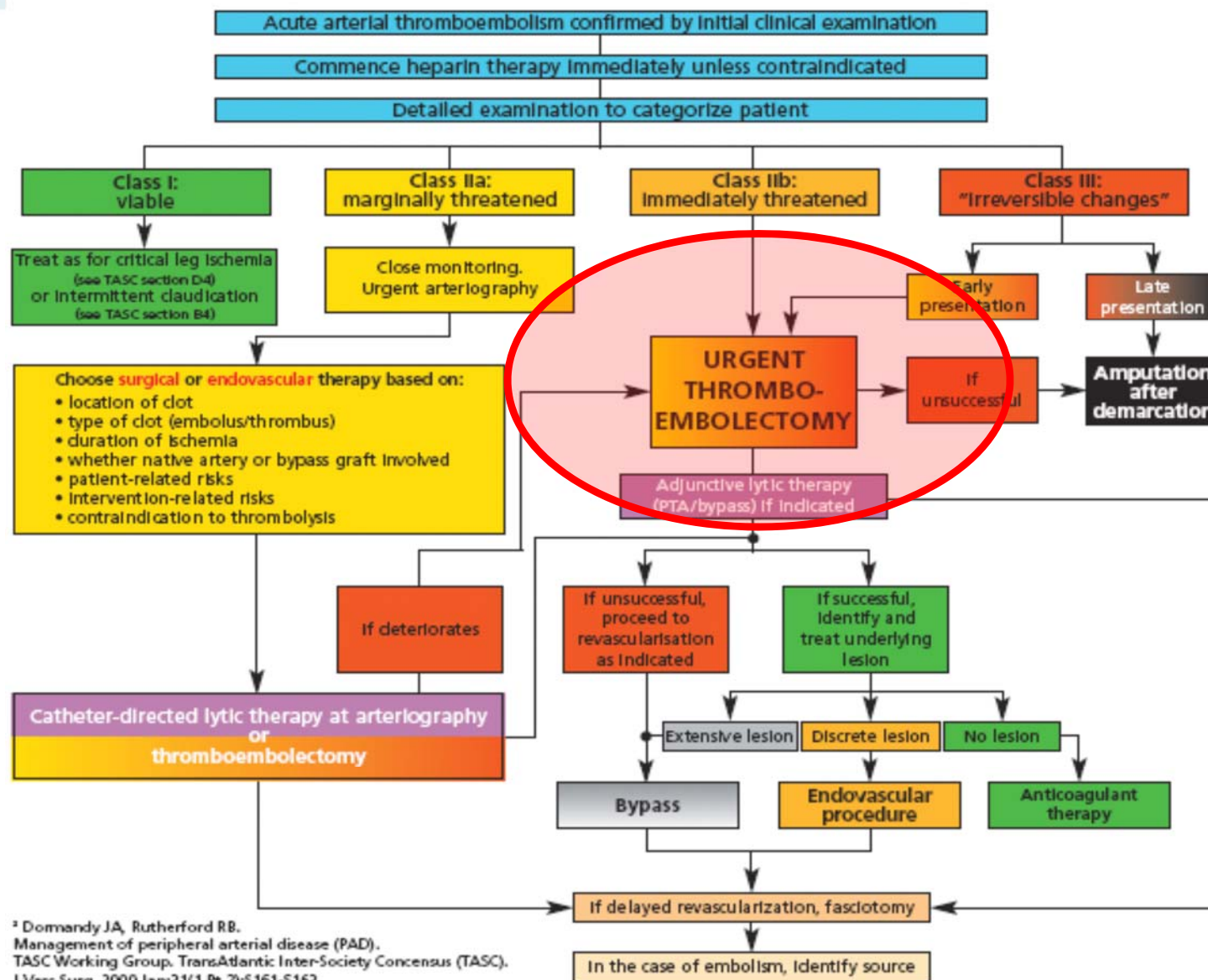
Source: TASC JVascSurg 2000; 31(1) Part2 page 142

TASC Algorithm



Category	Description/ prognosis	Findings		Doppler signals (at pedal level)	
		Sensory loss	Muscle weakness	Arterial	Venous
I	Extremity viable	Not immediately threatened	None	Audible	Audible
IIa	Extremity marginally threatened	Salvageable if promptly treated	Transient or minimal limited to the toes, or none	(Often) inaudible	Audible
IIb	Extremity immediately threatened	Salvageable with immediate revascularisation	More than toes, associated with persistent rest pain	Mild, moderate	(Usually) inaudible
III	Irreversible changes*	Major tissue loss or permanent nerve damage inevitable	Profound, anesthetic	Profound, paralysis (muscle rigor or skin mottling)	Inaudible

Ideal Management Algorithm for the Treatment of Acute Limb Ischemia acc. to TASC²



² Domandy JA, Rutherford RB. Management of peripheral arterial disease (PAD). TASC Working Group. TransAtlantic Inter-Society Consensus (TASC). J.Vasc.Surg. 2000 Jan;31(1 Pt 2):S161-S163.

TASC Algorithm

Ideal Management Algorithm for the Treatment of Acute Limb Ischemia acc. to TASC²

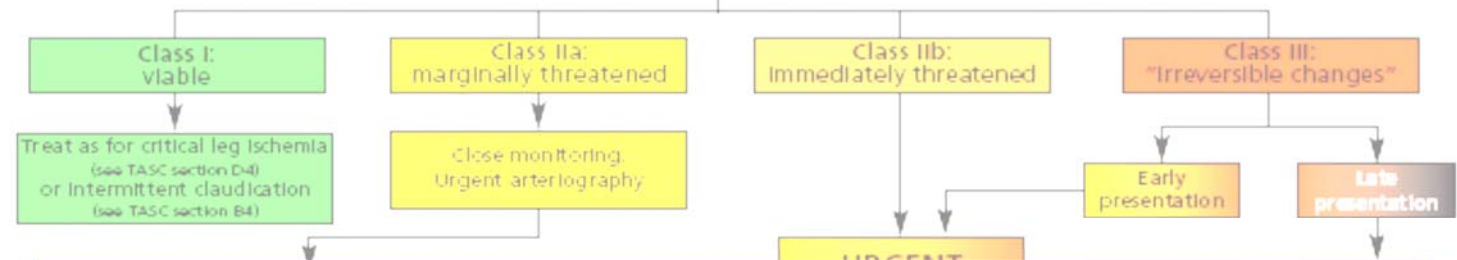
Acute arterial thromboembolism confirmed by initial clinical examination

Clinical examination – Heparin admin. - Categorization

TASC
Management of
Peripheral Arterial Disease (PAD)
TransAtlantic Inter-Society Consensus (TASC)

Section A: Introduction
Section B: Intermittent Claudication
Section C: Acute Limb Ischemia
Section D: Critical Limb Ischemia

Category	Description / prognosis	Findings		Doppler signals (at pedal level)	
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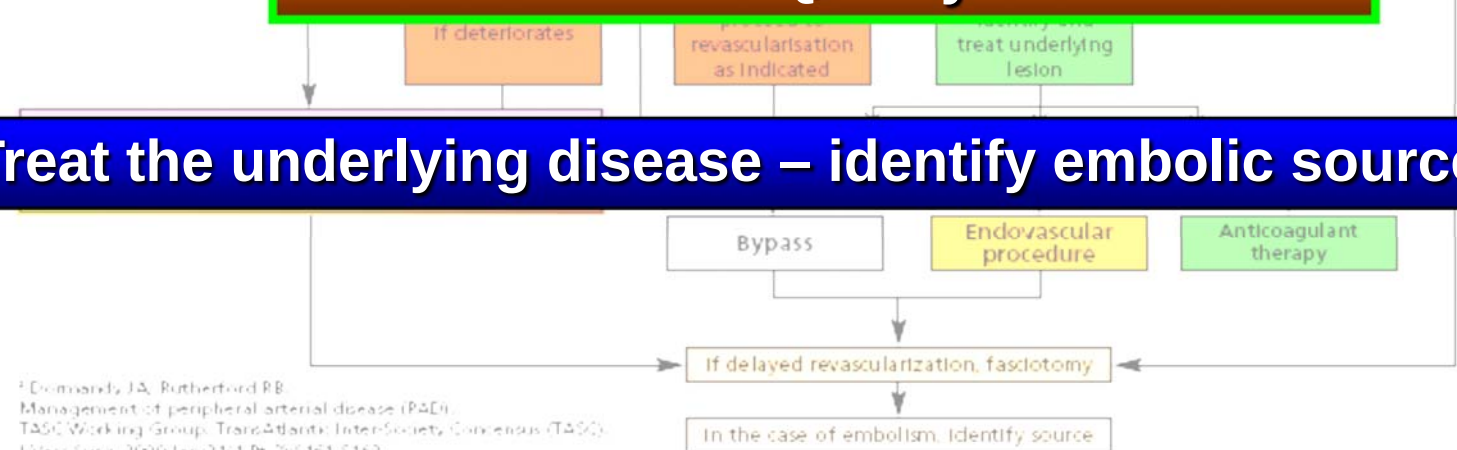


Removal of emboli / thrombi with adequate tools

- duration of ischemia
- whether native artery or bypass graft involved
- patient-related risks
- intervention-related risks
- contraindication to thrombolysis

ANGIOGRAPHIC Quality CONTROL !!!

Treat the underlying disease – identify embolic source

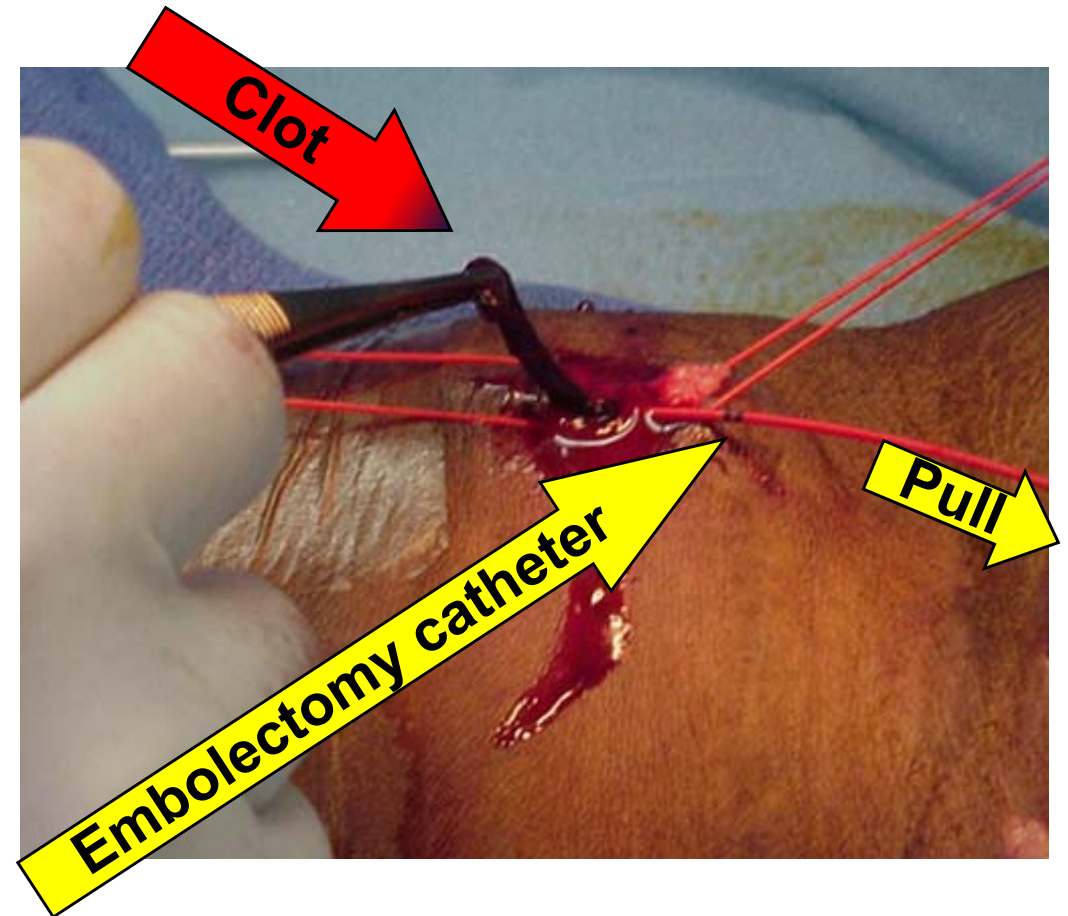


² Dormandy JA, Rutherford RB.
Management of peripheral arterial disease (PAD).
TASC Working Group. TransAtlantic Inter-Society Consensus (TASC).
J Vasc Med Biol. 2000 Jan 31;12 Pt 2:S161-S163.

Embolectomy Catheters – disease (2)

- **Thrombosed Vascular Access for Haemodialysis**

- AV Fistulas
- Shunts

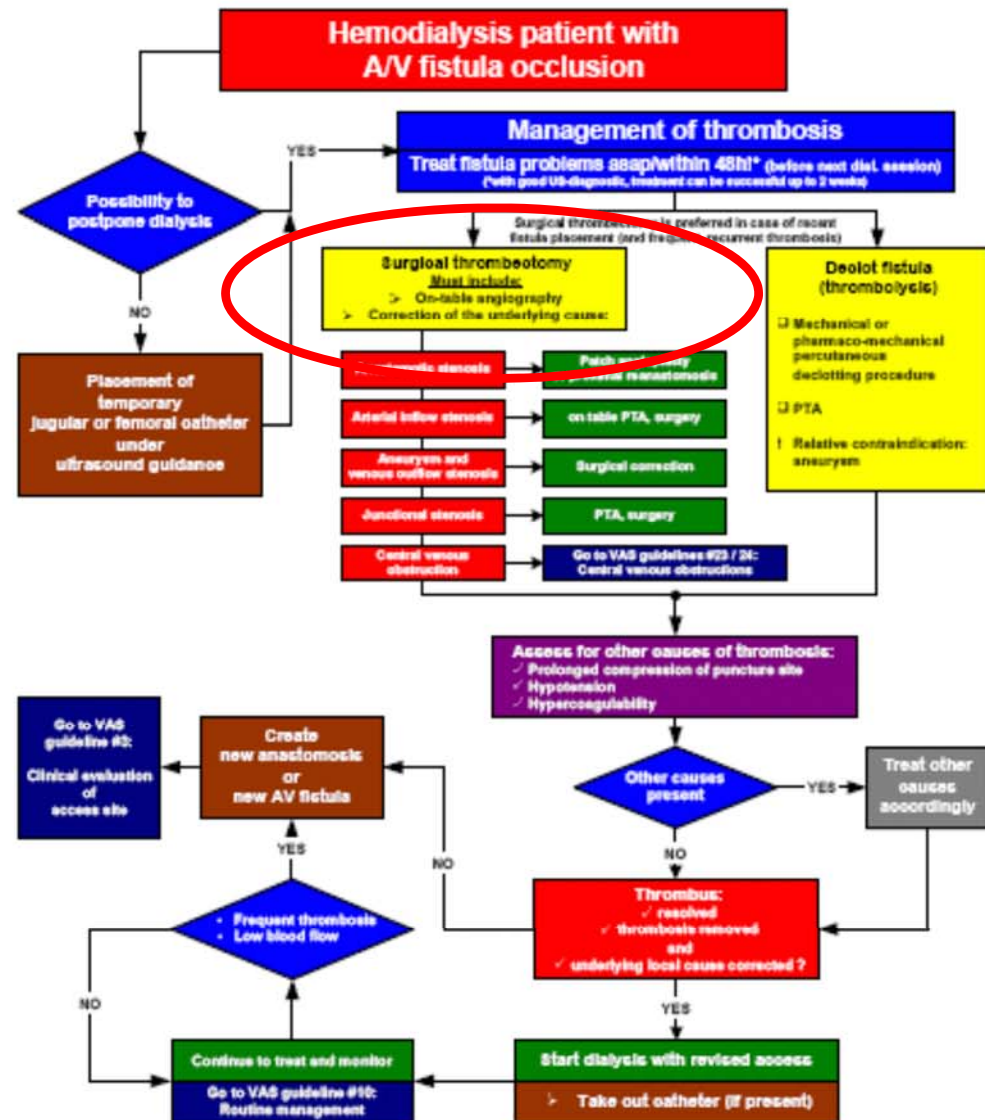


Vascular Access - AV-Fistula Thrombosis

➤ Guidelines of the

Vascular Access Society

www.vascularaccesssociety

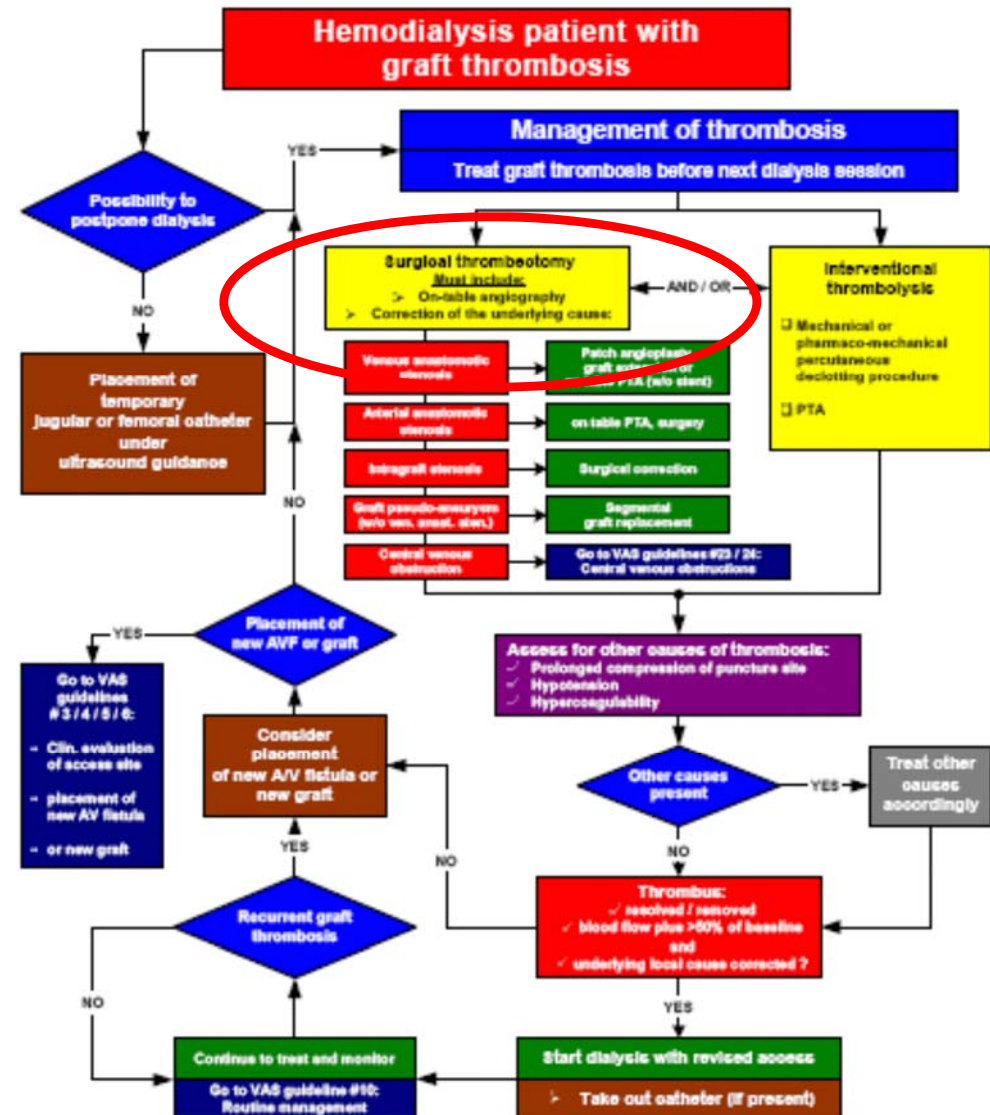


Vascular Access - Graft Thrombosis

➤ Guidelines of the

Vascular Access Society

www.vascularaccesssociety



Treatment methods of Acute ischemia

- **Surgical revascularisation** (SR): (= The STANDARD)
 - **Thrombo-Embolectomy with the “Fogarty type balloon catheter”**
- **Endovascular Procedures:**
 - CDT – Catheter Directed Lysis (Thrombolysis)
 - Intraoperative Thrombolysis
 - PAT – Percutaneous Aspiration Thromboembolectomy
 - PMT – Percutaneous Mechanical Thromboembolectomy
- **Adjuvant treatments:**
 - PTA / Stent
 - **Bypass (PTFE or Polyester)**
 - Antiocoagulants
 - Fasciotomy

The original Fogarty Catheter - 1963

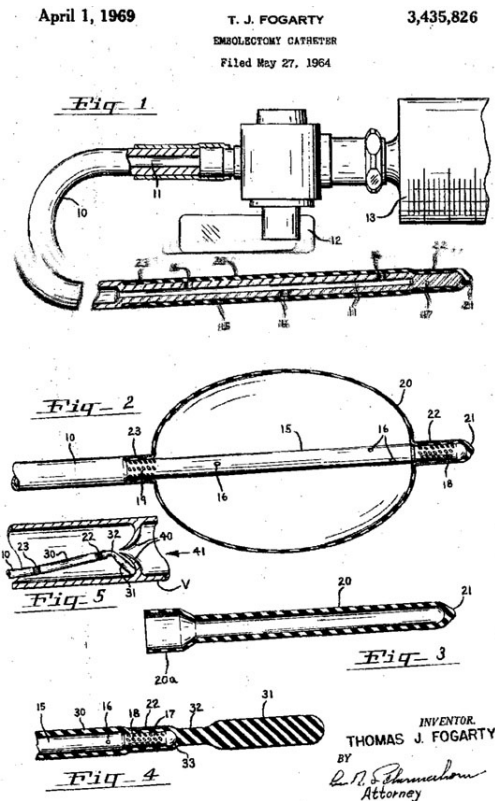
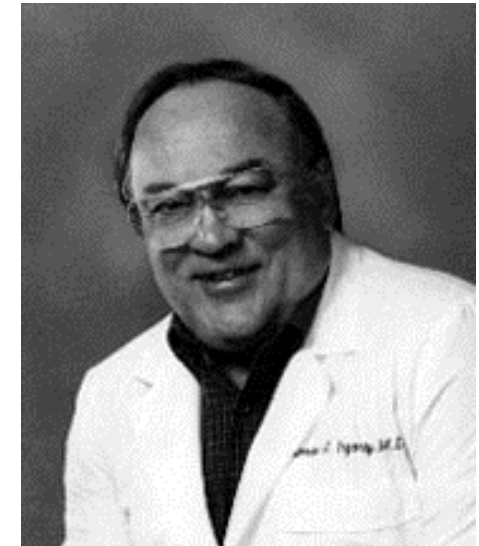
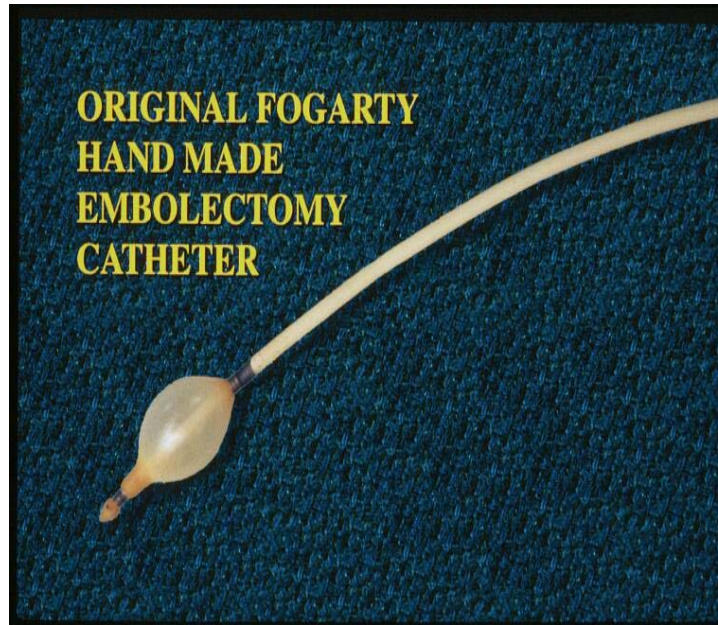


Fig 1. Fogarty embolectomy catheter

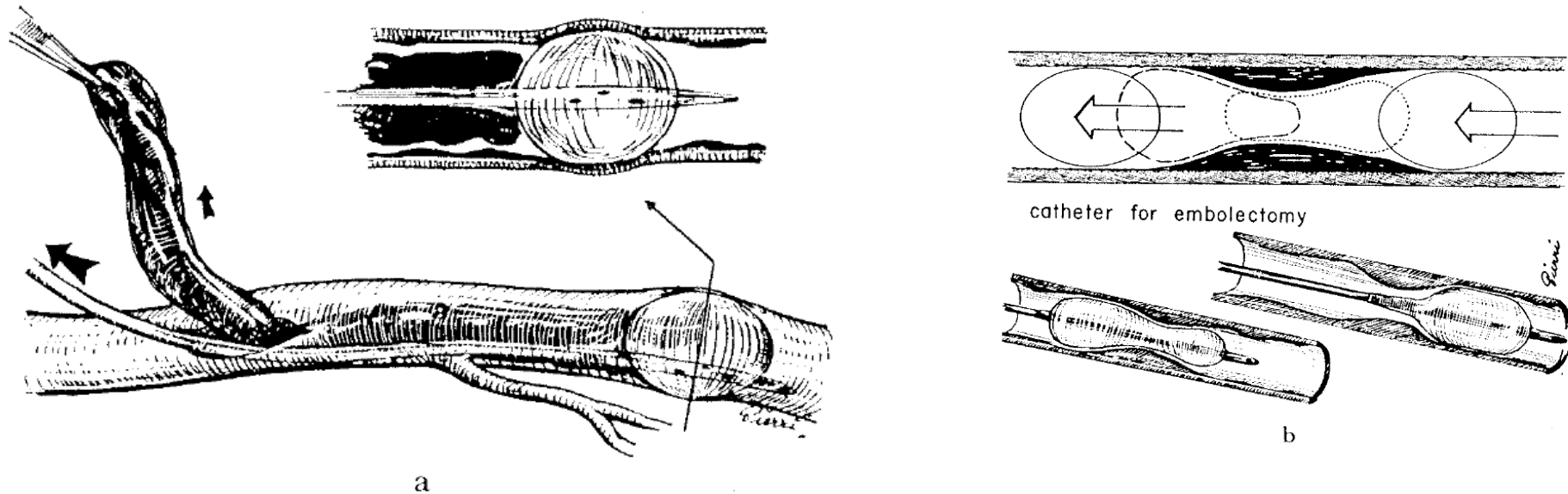


Prof. Thomas
Fogarty

Fogarty TJ, Cranley JJ, Krause RJ, Strasser ES, Hafner CD.
A method for extraction of arterial emboli and thrombi.
Surg Gynecol Obstet 1963 Feb;116:241-4.

Embolectomy Procedure

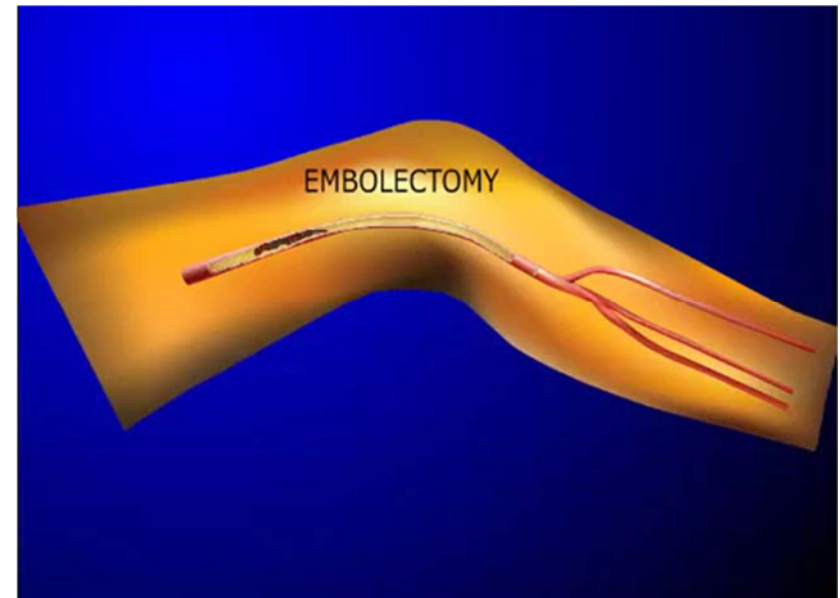
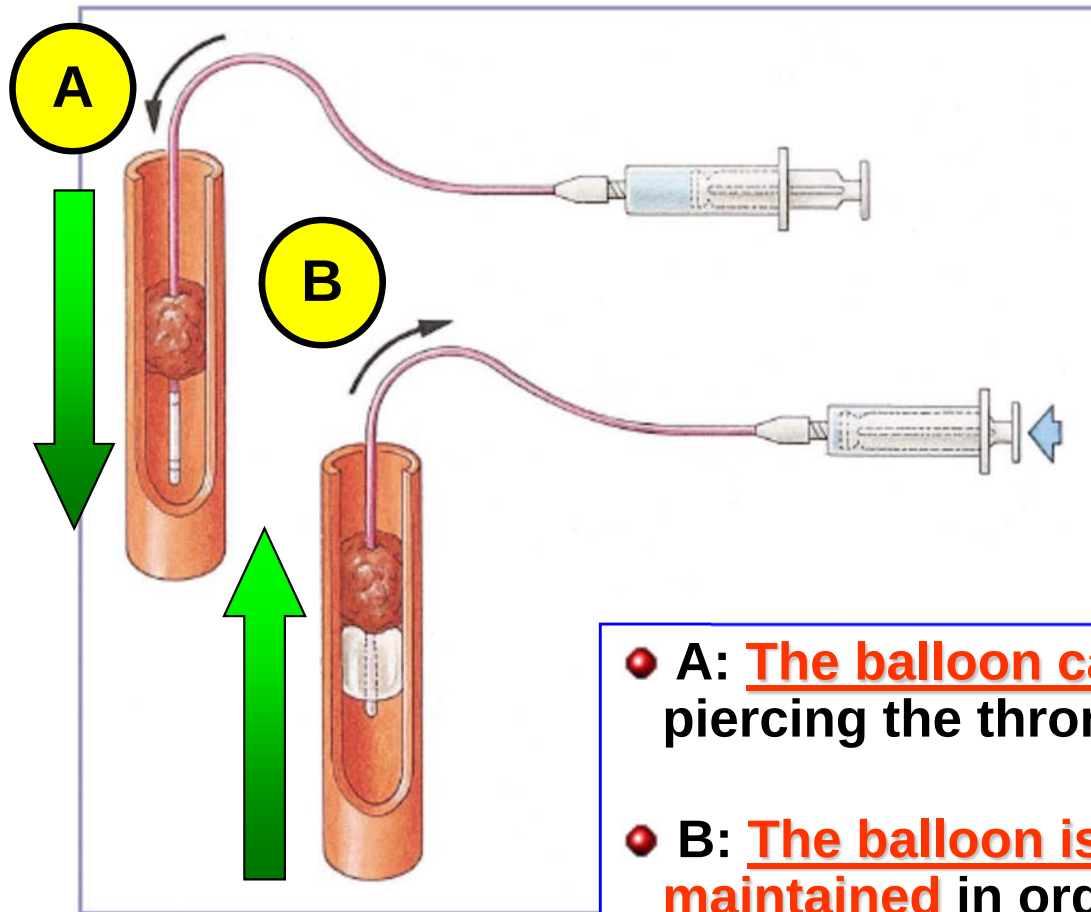
- **Surgical removal** of thrombus or emboli causing the acute ischemia **with a balloon catheter**



Pictures from:

Fogarty TJ et al. A method for extraction of arterial emboli and thrombi. Surg Gynecol Obstet (1963)116:241-4

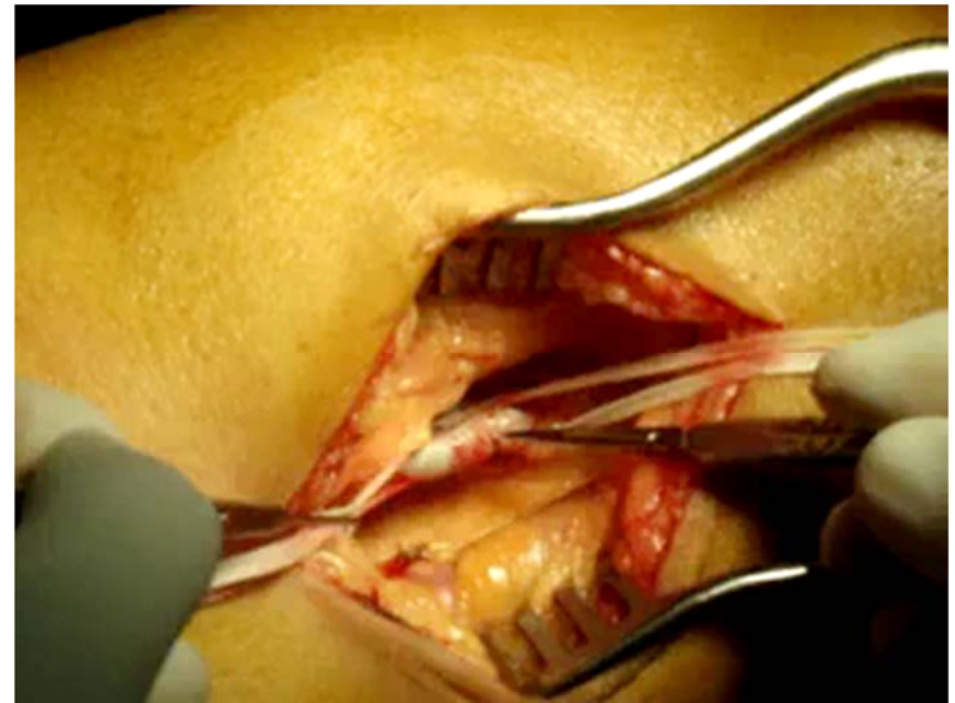
The “Fogarty” principal (1)



- A: The balloon catheter is pushed distally, piercing the thrombus in the process.
- B: The balloon is inflated, a constant pressure is maintained in order for the balloon to remain in contact with the arterial wall irrespective of its caliber; the thrombus can thus be withdrawn.

Popliteal Embolectomy with a 4F catheter

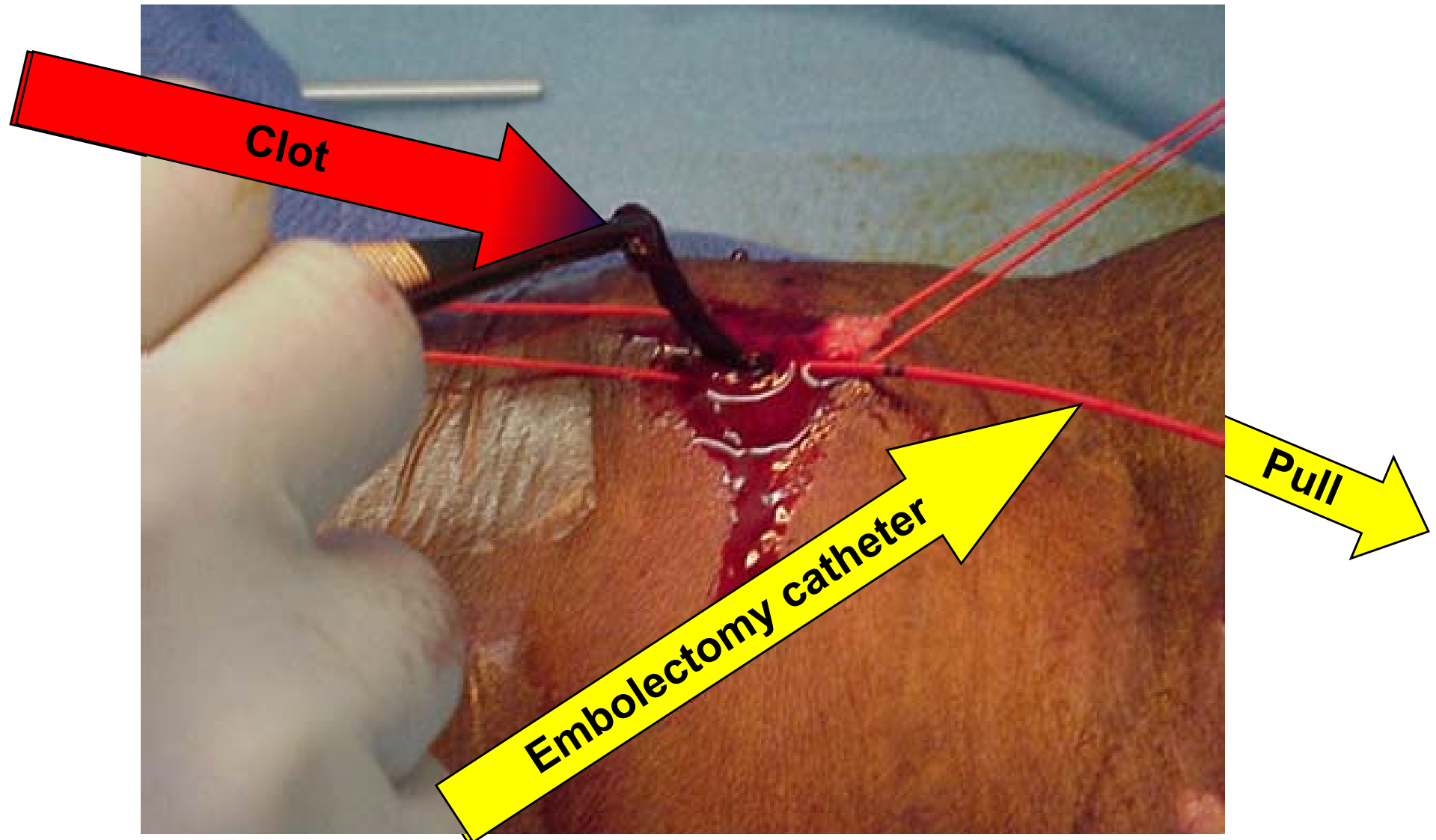
- Incision
- Test the Balloon catheter
- Insert and advance the catheter
 - o Manually or with forceps
- Advance the catheter behind the clot
 - o Length markers
- Block the catheter
- Retract the catheter to remove the embolus / thrombus



- Video by Dr. Zan Mitrev – from “You Tube”, Skopje Macedonia

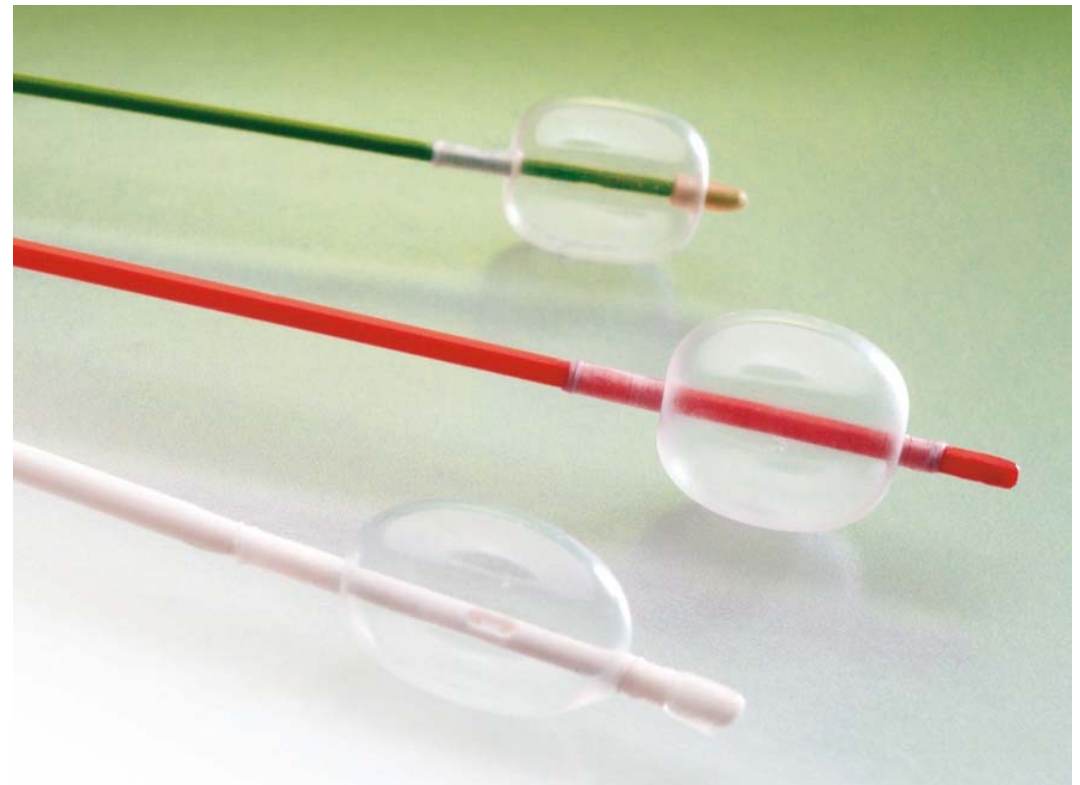
80 sec. - video downloaded from “You Tube”

The “Fogarty Manuever” in Vascular Access



LeMaitre Single Lumen Embolectomy Balloon Catheters

- **High quality**
- **Strong latex balloon**
- **No flexible tip**
- **Radiopaque**
- **Highly centric**
- **Progressive inflation**



The MUST know - major advantages of LeMaitre SL embolectomy catheter are:

1. High quality extra strong balloon

- **Less ruptures** of balloon during the procedure
- More calcified arteries are seen due to the progression of the atherosclerotic disease

2. Latex balloon

- Good grip, **good removal of thrombotic or embolic material**

3. Pebax shaft material (no PVC) (PEBA Poly- Ether-Block-Amide)

- Extra strong plastic, **high pull strength** (no rupture)
- **Radiopaque in all sizes**, visibility under fluoroscopy (X-ray)

The MUST know - major advantages of LeMaitre SL embolectomy catheter are:

4. Strong catheter tip in 2F and 3F (no flexible tip)

- properly penetrates the clot

5. High quality packing, good handling, good markings, etc.

6. Extended Shelf Life (Sterility)

- 4 years shelf life for Latex balloons (EW 27 month)
- 5 years latex free

LeMaitre Single Lumen Embolectomy Catheter

- Product Range -



Size (French / F) & color code	Length [cm]	Balloon Diameter [mm]	Balloon Volume	REF
2	40	4.5	0.05 ml	1601-24
2	60	4.5	0.05 ml	1601-26
2	80	4.5	0.05 ml	1601-28
3	40	8.0	0.20 ml	1601-34
3	80	8.0	0.20 ml	1601-38
4	40	10.5	0.75 ml	1601-44
4	80	10.5	0.75 ml	1601-48
5	80	13.0	1.50 ml	1601-58
6	80	13.5	1.60 ml	1601-68
7	80	14.0	1.75 ml	1601-78

Novasil Latex Free Emb Catheters

- **When
Latex free
embolectomy catheters
are needed**

Latex Free



Latex Allergy ?

Latex Free

- Latex free Catheters ?
- The allergy mainly from gloves !



- Approx. 1% of catheter sales
 - o except UK,
here higher “latex free sensitivity”



LeMaitre - Novasil - Latex free Embolectomy Catheter



Latex Free



➤ Balloon from silicon

- o Less grip

➤ Catheter from Pebax

- o same material as standard EMB catheter
- o High pull force

➤ Suggestion:

- o Keep some Latex Free catheters in inventory for patients with latex allergy
- o **Latex catheters** are the **much better option for a good performance** in clot removal

LeMaitre – Novasil – Latex free Embolectomy Catheter

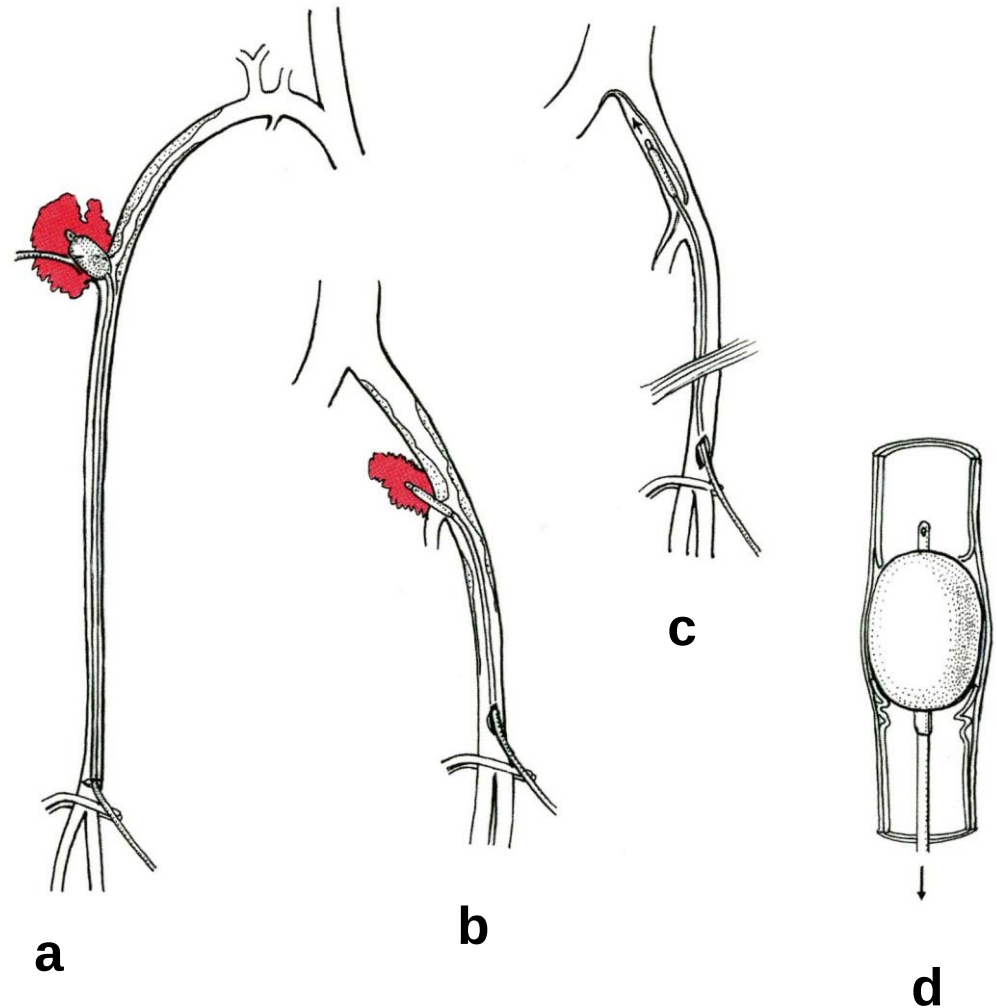


Size (French / F) & Colour Code	Length [cm]	Max. volume (fluid) [ml]	Ballon Diameter (inflated) [mm]	Tube Pack REF
2F	40	0,05	4	1801-24
2F	60	0,05	4	1801-26
3F	40	0,10	6	1801-34
3F	80	0,10	6	1801-38
4F	40	0,50	9	1801-44
4F	80	0,50	9	1801-48
5F	80	0,75	11	1801-58
6F	80	1,60	13	1801-68
7F	80	1,75	14	1801-78

Fogarty maneuver

– typical/possible complications

- a) Perforation due a wrong guided Fogarty catheter (e.g. circumflexa humeri lateralis)
- b) Perforation prestenotic with presence of atherosclerotic lesion
- c) Vessel wall dissection
- d) Damage of intima due to balloon overinflation (Can cause reocclusion)



Fogarty maneuver – typical complications



perforation iliac



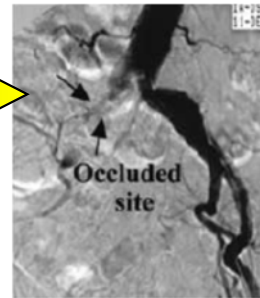
perforation trunc. tib-fib.



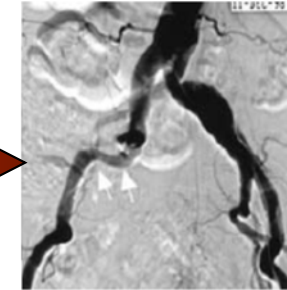
dissection femoral

Standard, "blind embolectomy" is suboptimal...

- It may not be possible to **pass the balloon catheter**
 - o through tortuous, diseased arteries



?



- It is **difficult to assess the adequacy of thrombectomy**



? enough

- **Underlying lesions**
 - o responsible for the thrombosis **can be missed**



- Traction of an **overinflated balloon catheter**
 - o can damage arterial segments

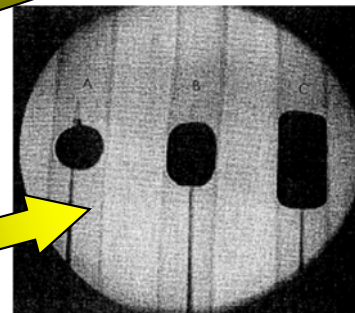
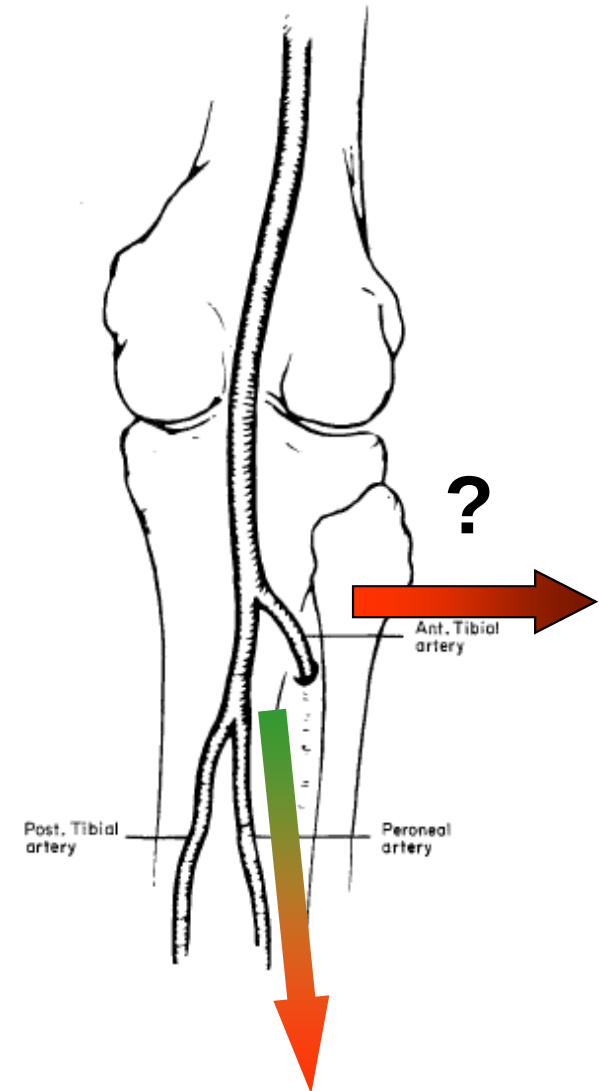


FIG. 6 A - Fig. 6 A. Peri-operative completion arteriography showing severe lesions of the crural arteries distal to a thrombectomy of a femoropopliteal bypass. B - Completion angiography after dilation.

Lipsitz EC, Veith FJ: Semin Vasc Surg 2001; 14: 100-6

Standard, "blind embolectomy" is suboptimal...

- The route taken by the catheter in the arteries below the knee is uncontrolled
- 90 % of Embolectomy catheters introduced transfemorally for below knee embolectomy pass into the peroneal artery



Gwynn BR, et al. Eur J Vasc Surg 1987;1:129-32

Completion angio is essential....

- Identifies residual thrombosis and
- underlying lesions
- Leads to an extension of the operation in up to 58 % with
 - o subsequently **improved outcome**

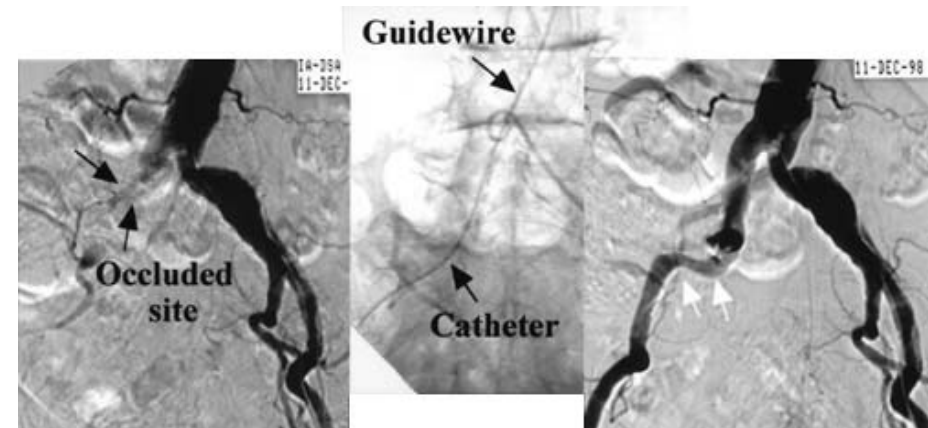
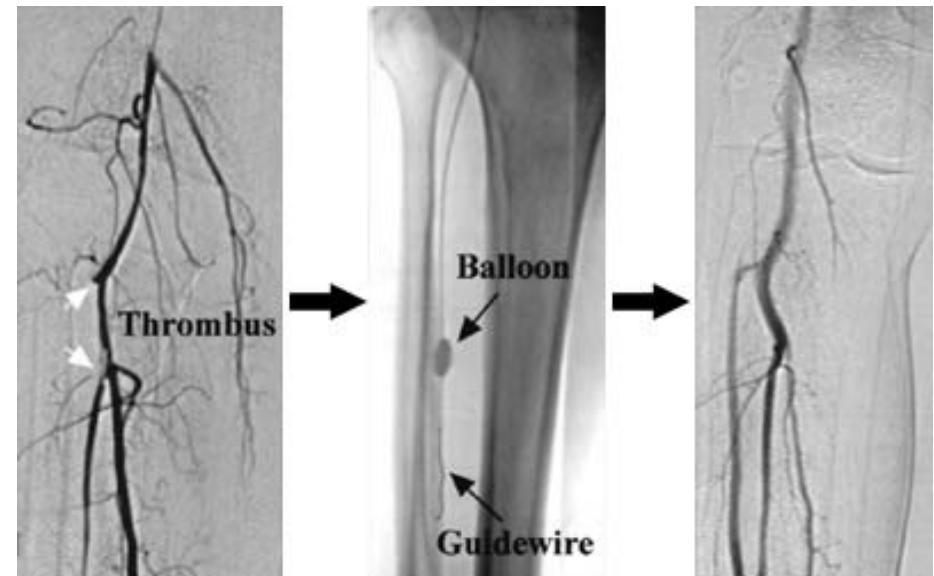
Bosma HW, Jörning PJG. Eur J Vasc Surg 1990; 4: 469-72
Parsons RE, et al. Ann Vasc Surg 1996; 10: 201-10



LeMaitre® OTW - Embolectomy Catheters

Over-The-Wire Emb. Catheters

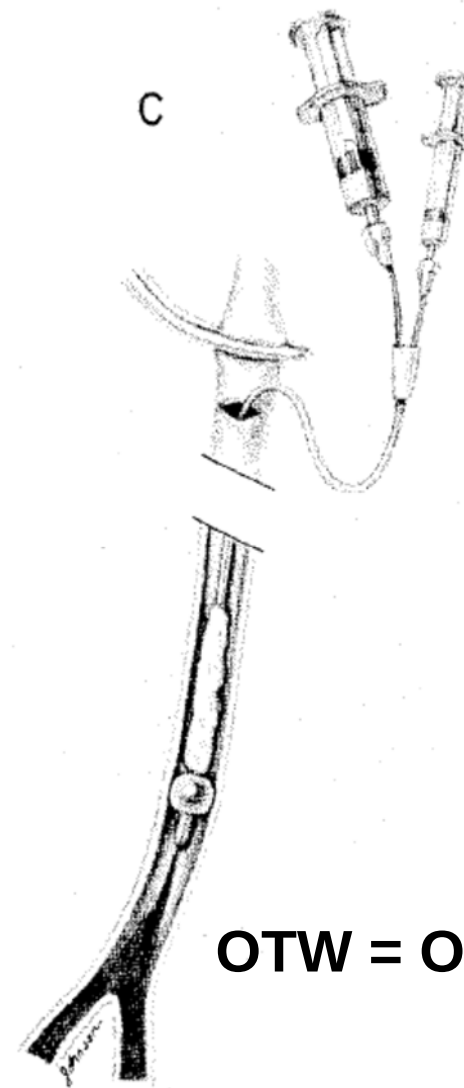
- **Solution for clot removal
under
fluoroscopic guidance**



Pictures: Hasegawa, Y. Jpn. J. Vasc. Surg., 12:71-75, 2003

OTW Embolectomy Technique

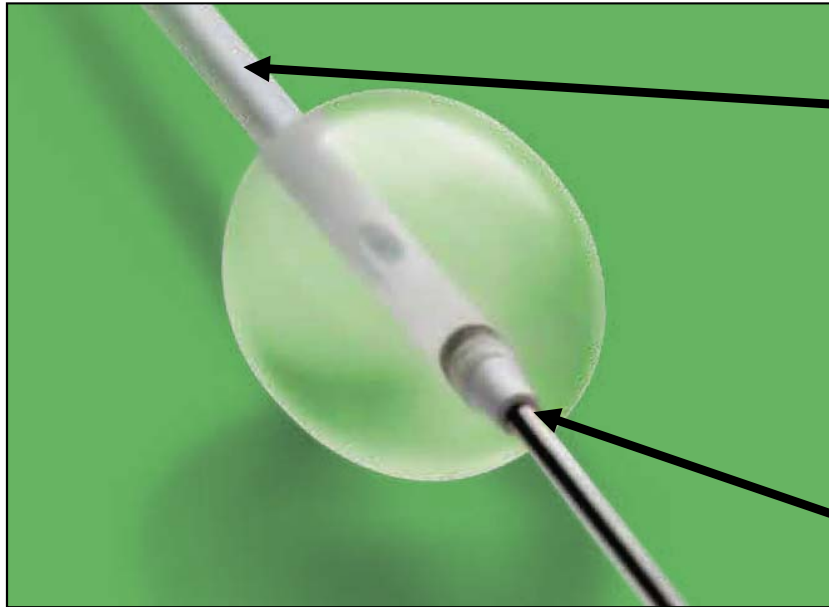
- « Dye-enhanced flouroscopy-directed catheter embolectomy »
- The idea was published in already 1984



OTW = Over The Wire

Robicsek F. Surgery 1984; 95: 622-4

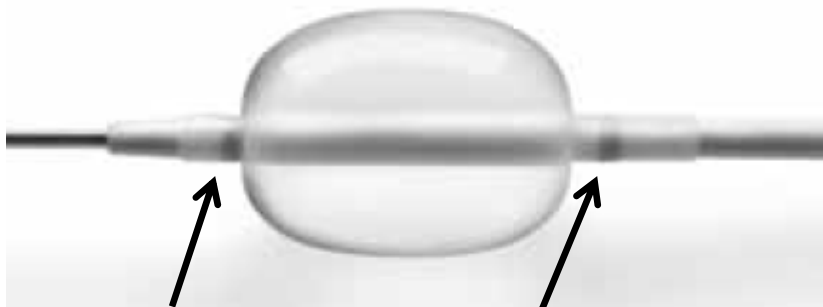
LeMaitre® OTW - Embolectomy Catheters



➤ Radiopaque catheter body

➤ Dual lumen for;

- Guidewire
- And/or fluid delivery (irrigation)



➤ Packed incl. syringe

➤ 5F Plus additional radiopaque markers

Advantage – selective embolectomy no exposition of the poplitea (PIII)

- Selective embolectomy of the crural arteries
- No surgical exposition of the below knee popliteal segment



Selective embolectomy of the occluded anterior tib. art.

OTW - ADVANTAGE

- **Selective embolectomy to crural arteries**
 - o no need to expose the distal popliteal artery
- **Selective control angio**
 - o with less contrast media (e.g. Diabetics or ESRD patients)

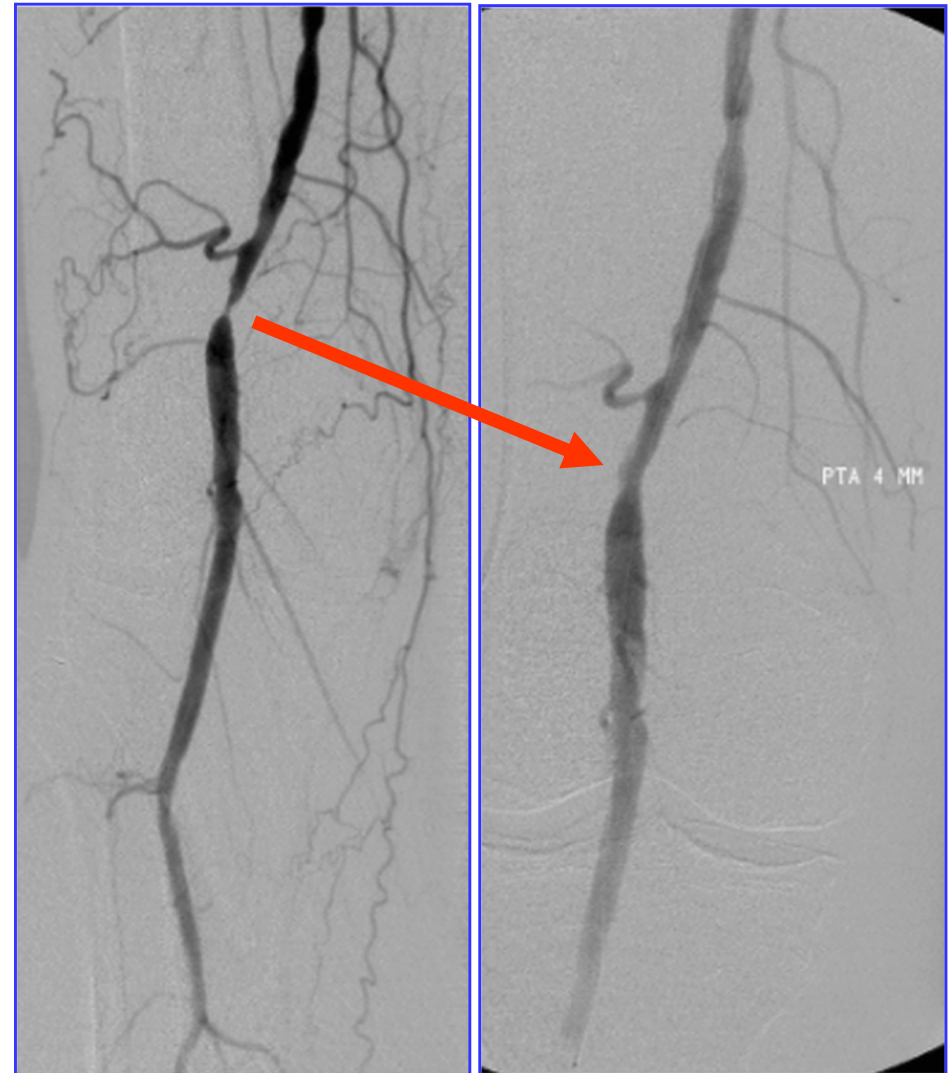


OTW - ADVANTAGE

➤ With the guidewire already in place,

- o PTA,
- o stenting or
- o Thrombolysis

may be performed to
treat the underlying
disease



OTW: Example

- A)
Remaining thrombotic material in the distal popliteal artery after thrombectomy of the native artery
- B)
Result after thrombo-aspiration
(still remaining stenotic lesions in the peroneal art.);
 now (PTA!)

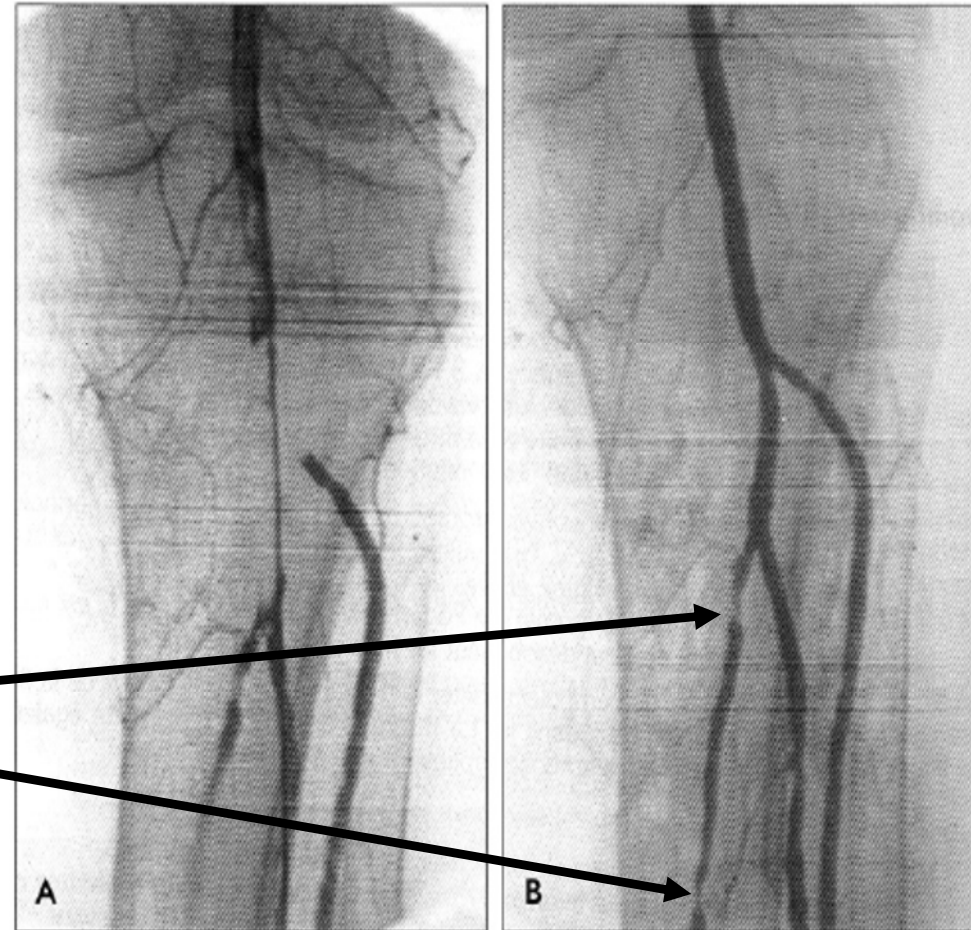


FIG. 3 A - Residual thrombus in the distal popliteal artery after thrombectomy of the native artery.
B - Result after thrombo-aspiration.

Valerio,N.; Blankensteijn,J.;

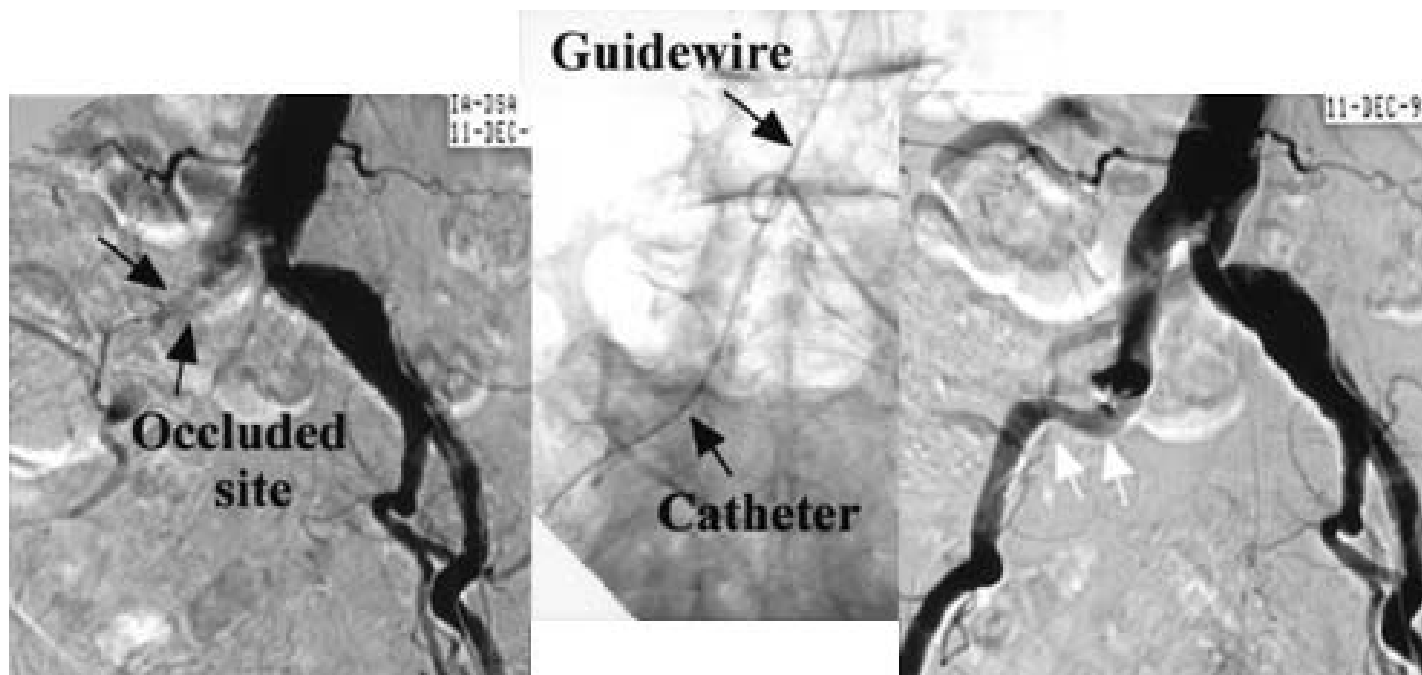
Assisted Thromectomy for Acute Lower Limb Ischemia

In: Branchereau,A.; Jacobs, M. EVC 2004

OTW: Example

Jpn. J. Vasc. Surg., 12: 71-75, 2003

- Even in a **severely tortuous lesion** (white arrow), the over-the-wire technique is enable to **pass the catheter safely through the occluded artery** (here iliac) and enables total removal of thrombotic material



Modern Clotmanagement in „Over-the-Wire“ technique

OTW Catheter = A excellent good multifunctional tool to:

- **Remove the clot in OTW technique using fluroscopic control**
 - ▶ Pass through tortuous, diseased arteries and clot with a guide-wire
 - ▶ Full control of EMB catheter (less risk of arterial damage)
 - ▶ Further applications:
 - ▶ contrast media injection, local lysis, hearin application, etc. (2nd lumen)
 - ▶ Temporary, controlled Balloon blockage
- **Combination** with therapy of the underlying disease **with endovascular methods** (PTA/Stent).



Modern Clotmanagement in „Over-the-Wire“ technique

OTW Catheter = A good multifunctional tool to:

- **Remove the clot in OTW technique using fluroscopic control**

- ▶ **Further applications:**

- ▶ contrast media injection, local lysis, hearin application, etc. (2nd lumen)
- ▶ Temporary controlled Balloon blockage



- **REMEMBER:**

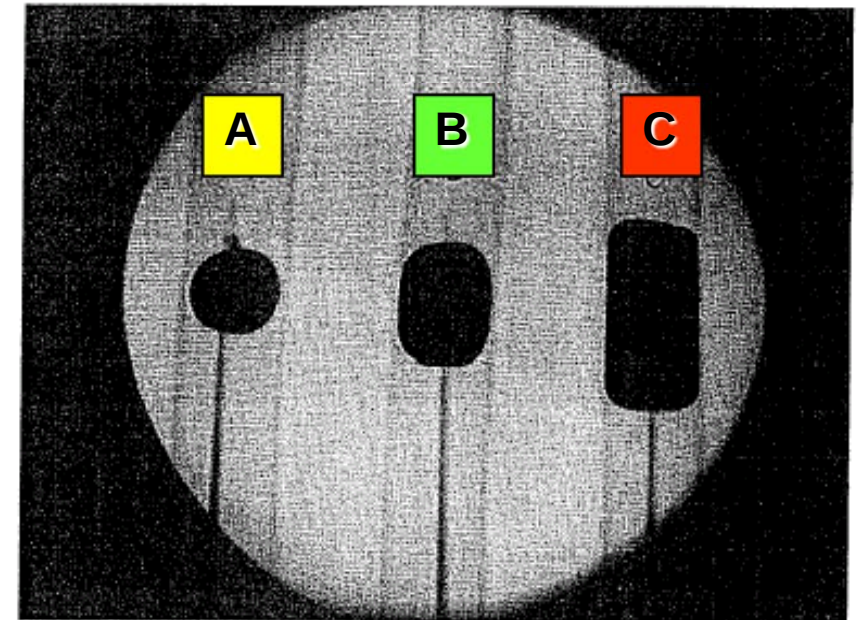
- ▶ **A PTA-catheter is NOT the adequate tool to remove a thrombus**
- ▶ **PTA catheters are NON COMPLIANT**



OTW and CM - ADVANTAGE

- Usage of embolectomy catheter with contrast media (approx. 10-25% of CM)

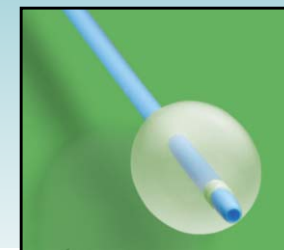
- A. Minimal inflation:
almost no contact to the vessel lumen
- B. Appropriate inflation:
close apposition to the vessel wall
- C. Overinflation:
significant radial force on the vessel wall.



Parsons RE, Marin ML, Veith FJ, Sanchez LA, Lyon RT, Suggs WD, et al. Fluoroscopically assisted thromboembolectomy: an improved method for treating acute arterial occlusions. Ann Vasc Surg 1996 May;10(3):201-10.

LeMaitre OTW Embolectomy Catheter

- Product Range -



Size (French / F) & color code	Length [cm]	Balloon Diameter [mm]	Balloon Volume	Guidewire [inch]	REF
3	40	6.0	0.20 ml	0.018"	1651-34
3	80	6.0	0.20 ml	0.018"	1651-38
4	40	10.0	0.75 ml	0.025"	1651-44
4	80	10.0	0.75 ml	0.025"	1651-48
5 Plus	40	12.0	1.50 ml	0.035"	1651-84
5 Plus	80	12.0	1.50 ml	0.035"	1651-88
6	40	13.0	1.60 ml	0.035"	1651-64
6	80	13.0	1.60 ml	0.035"	1651-68
7	40	14.0	1.75 ml	0.038"	1651-74
7	80	14.0	1.75 ml	0.038"	1651-78

Summary

- We do have a very good offering with **high quality Embolectomy catheters**
 - o Single Lumen Latex and Latex Free
 - o Over-The Wire Catheters
- Over-the-Wire Catheters have additional benefits due to the second lumen for modern management
- Bundling options