Femoropopliteal Report:
Current Endovascular Outcomes and Expectations

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Background

- Peripheral arterial disease (PAD) affects a large segment of the adult population (4-15%), and endovascular therapy is generally preferred as the first choice for symptomatic patients with PAD.

  - Selvin E et al, Circulation 2004
  - Hirsch AT et al, JAMA 2001
  - Hunink MG et al, JAMA 1995

- Unlike most other vascular beds, where stenting is the preferred modality of endovascular revascularization, the optimal therapy for femoropopliteal arterial (FPA) disease remains unknown.

Meta Analysis (I)

- To estimate the patency results of percutaneous transluminal angiography (PTA) and bypass surgery in the treatment of FPA disease.
  - Adjusted 5-year primary patency after angioplasty varied from 12% to 68%, the best results being for patients with claudication and stenotic lesions.
  - Adjusted 5-year primary patency after surgery varied from 33% to 80%, the best results being for saphenous vein bypass performed for claudication.
- Stenting results of the femoropopliteal segment were **not** included.

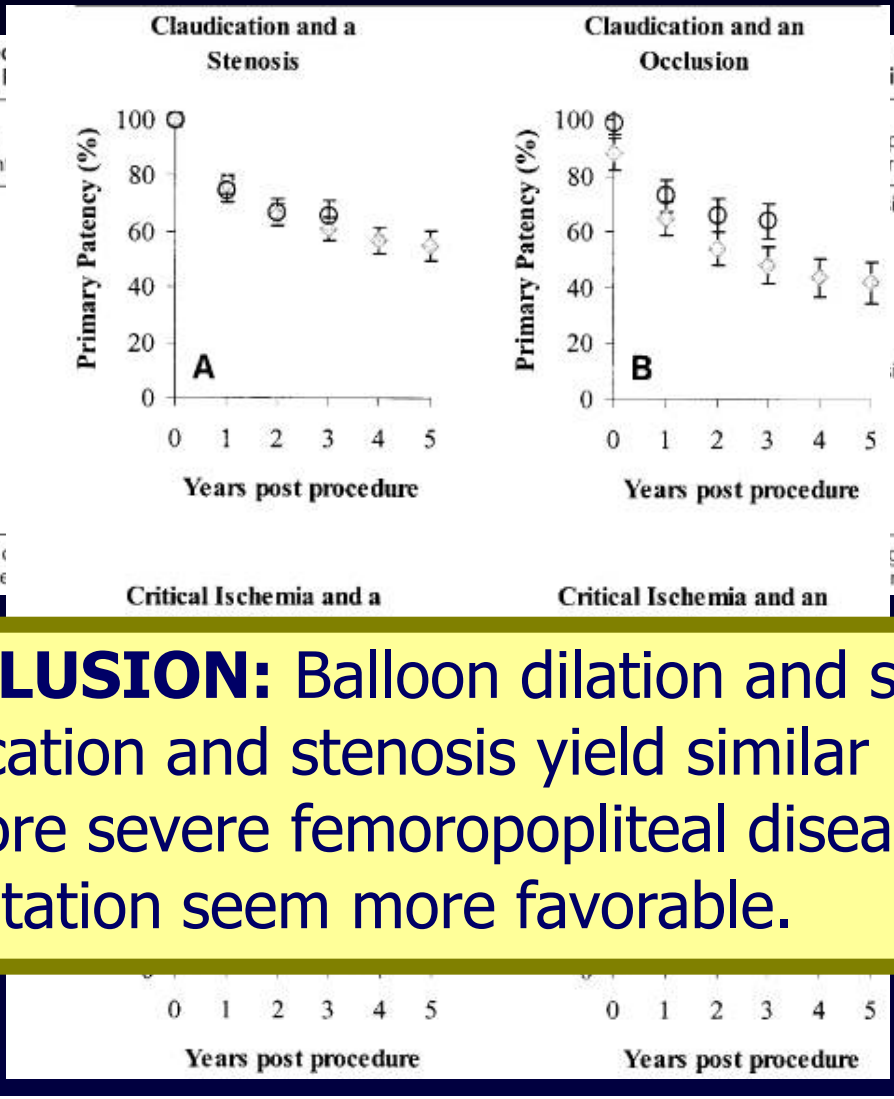
- Hunink MG et al, Med Decis Making 1994

Meta Analysis (II)

Estimated Poole
Implantation in

Lesion Type and Year after Treatmen
Stenosis
0
1
2
3
4
5
Occlusion
0
1
2
3
4
5

Note.—Ranges are
* Number in pare



Pooled Primary Patency Rates after Balloon Dilation and Stent
ion in Patients with Critical Ischemia

pe and reatment	Balloon Dilation		Stent Implantation	
	Patency (%)*	Range (%)	Patency (%)*	Range (%)
is				
	83 (3.7)	69–88	100 (3.3)	94–100
	60 (4.0)	46–63	74 (3.8)	68–80
	49 (4.0)	35–54	66 (3.9)	59–72
	43 (4.1)	30–51	65 (4.1)	58–71
	40 (4.3)	26–46	NA	NA
	38 (4.5)	24–44	NA	NA
ion				
	70 (3.5)	62–75	98 (3.2)	94–100
	47 (3.5)	41–51	73 (3.6)	68–75
	36 (3.6)	28–41	65 (3.7)	60–68
	30 (3.7)	20–37	63 (3.9)	58–68
	27 (3.9)	16–34	NA	NA
	25 (4.1)	13–32	NA	NA

ges are derived from sensitivity analyses. NA = not available.
r in parentheses is the standard error.

CONCLUSION: Balloon dilation and stent implantation for claudication and stenosis yield similar long-term patency rates. For more severe femoropopliteal disease, the results of stent implantation seem more favorable.

- Muradin GS et al, Radiology 2001

ACC/AHA TASC Consensus

- PTA as the initial preferred option for endovascular treatment of symptomatic femoropopliteal arterial lesions, reserving provisional stenting for salvage therapy after a suboptimal or failed result from balloon dilation.

Debates for Stenting

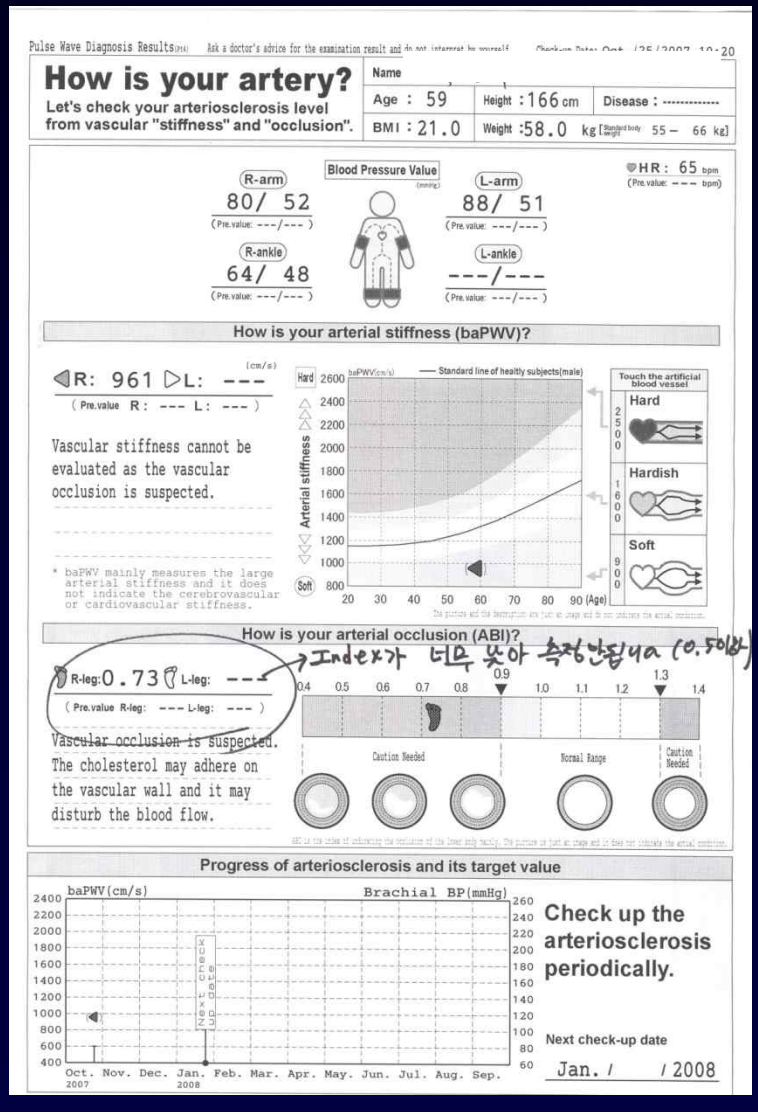
- Endovascular stenting avoids the problems of early elastic recoil, residual stenosis, and flow-limiting dissection after balloon angioplasty and can thus be used for the treatment of long and calcified lesions.
- In contrast, FPA is subject to longitudinal stretching, external compression, torsion, and flexion, which may lead to stent fractures and eventually to restenosis.
- Although evolution in stent material and design have overcome some of these limitations, the clinical impact remains unclear.

Case #1

M/61

- C.C: Claudication of left leg
- D: 5 years
- PHx: HTN (+), DM (-), Smoking (+): 45PY
  CAOD (+): Stent insertion at LAD (2004)
- P/Ex: BP 140/90 mmHg, HR 72
- Lab: BUN/Cr 13.8/0.9 mg/dL

ABI (2007-10-25)



Pulse Wave Diagnosis Results(PH1) Ask a doctor's advice for the examination result and do not interpret by yourself. Check-up Date: Oct. /25/2007 10:20

How is your artery?

Let's check your arteriosclerosis level from vascular "stiffness" and "occlusion".

Name			
Age : 59	Height : 166 cm	Disease : ----------	
BMI : 21.0	Weight : 58.0 kg [Standard body weight 55 – 66 kg]		

Blood Pressure Value (mmHg)

R-arm 80/ 52 (Pre.value: ---/---)

L-arm 88/ 51 (Pre.value: ---/---)

R-ankle 64/ 48 (Pre.value: ---/---)

L-ankle ---/--- (Pre.value: ---/---)

HR : 65 bpm (Pre.value: --- bpm)

How is your arterial stiffness (baPWV)?

(cm/s) R: 961 L: --- (Pre.value R: --- L: ---)

Vascular stiffness cannot be evaluated as the vascular occlusion is suspected.

* baPWV mainly measures the large arterial stiffness and it does not indicate the cerebrovascular or cardiovascular stiffness.

baPWV(cm/s) — Standard line of healthy subjects(male)

Arterial stiffness: Hard 2600, 2400, 2200, 2000, 1800, 1600, 1400, 1200, 1000, Soft 800

20 30 40 50 60 70 80 90 (Age)

Touch the artificial blood vessel: Hard (2500), Hardish (1600), Soft (900)

How is your arterial occlusion (ABI)?

R-leg: 0.73 L-leg: --- (Pre.value R-leg: --- L-leg: ---)

Index가 너무 못아 측정안됨 (0.50대)

Vascular occlusion is suspected. The cholesterol may adhere on the vascular wall and it may disturb the blood flow.

0.4 0.5 0.6 0.7 0.8 0.9 1.0 1.1 1.2 1.3 1.4

Caution Needed | Normal Range | Caution Needed

ABI is the index of estimating the occlusion of the lower body vessels. The picture is just an image and it does not indicate the actual condition.

Progress of arteriosclerosis and its target value

baPWV(cm/s) 2400 2200 2000 1800 1600 1400 1200 1000 800 600 400

Brachial BP(mmHg) 260 240 220 200 180 160 140 120 100 80 60

Next check up date

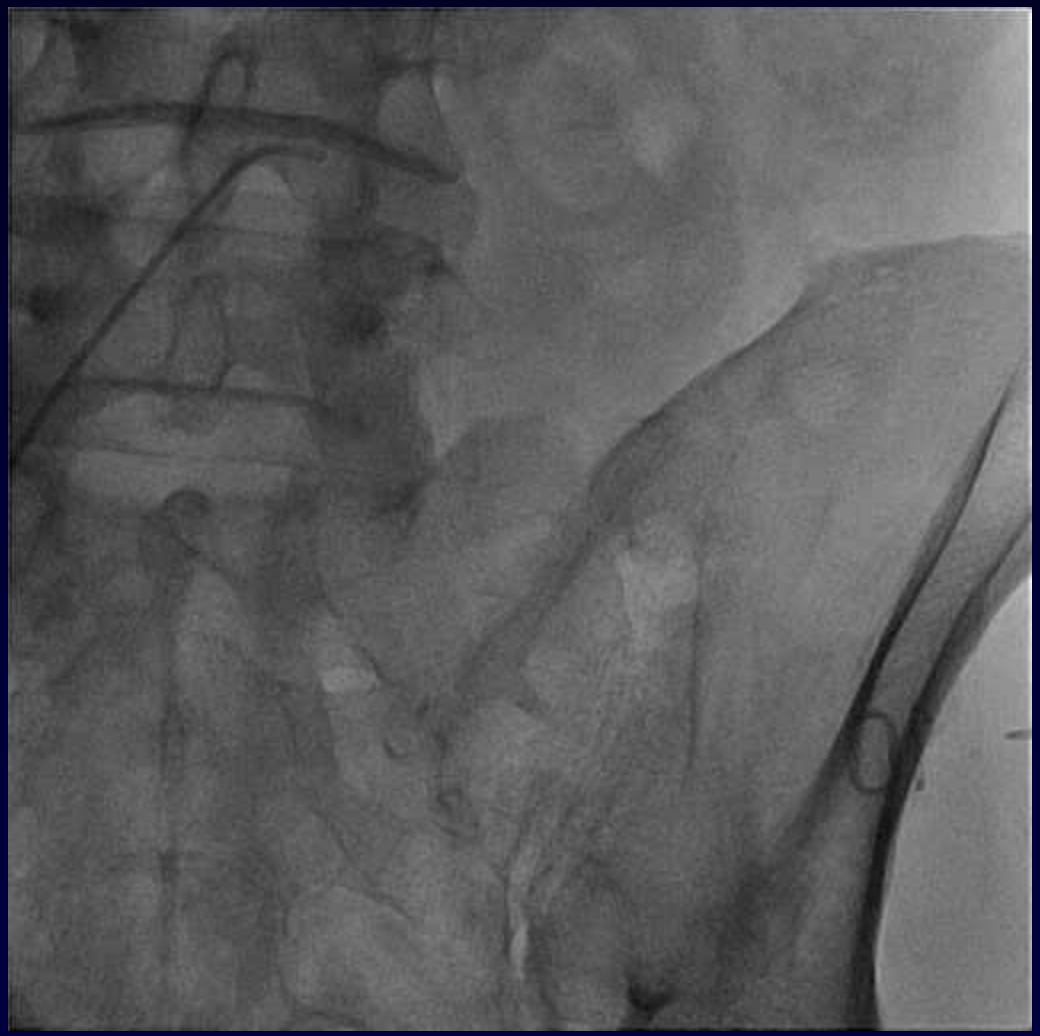
Oct. 2007 Nov. Dec. Jan. 2008 Feb. Mar. Apr. May. Jun. Jul. Aug. Sep.

Check up the arteriosclerosis periodically.

Next check-up date

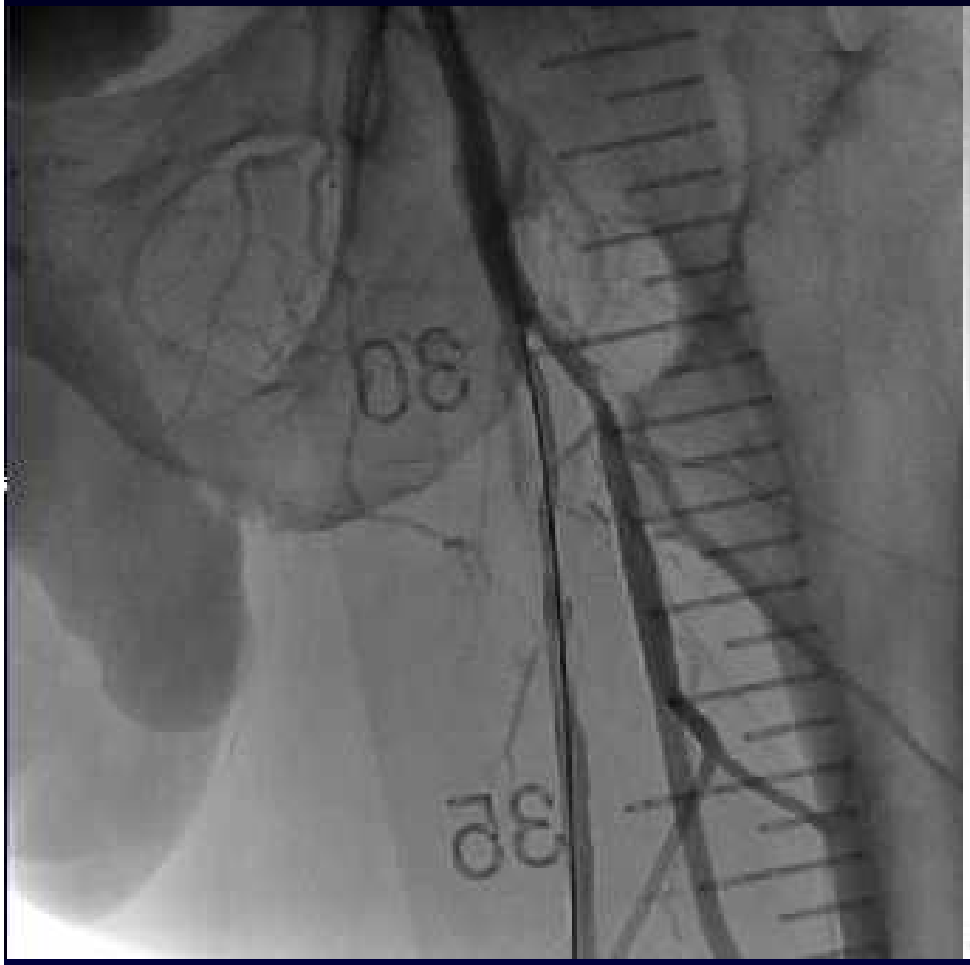
Jan. / / 2008

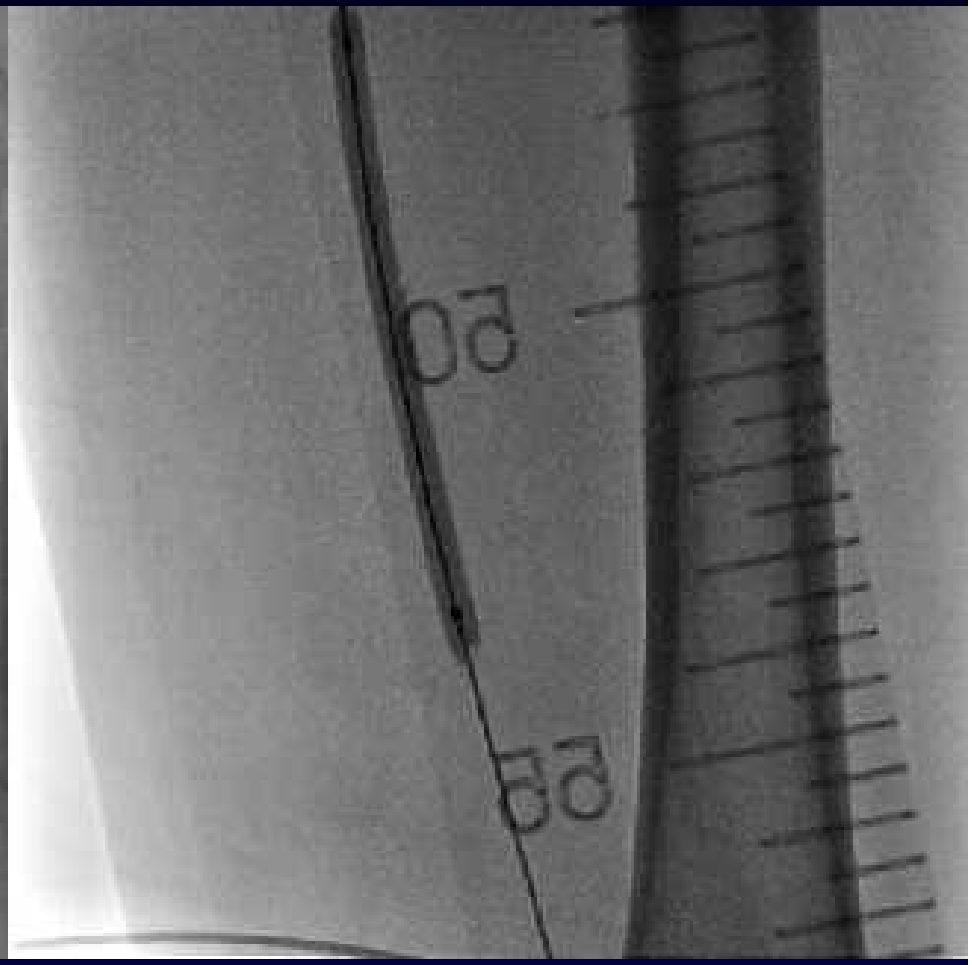
Lt. EIA & SFA stenoses (2007-11-27)



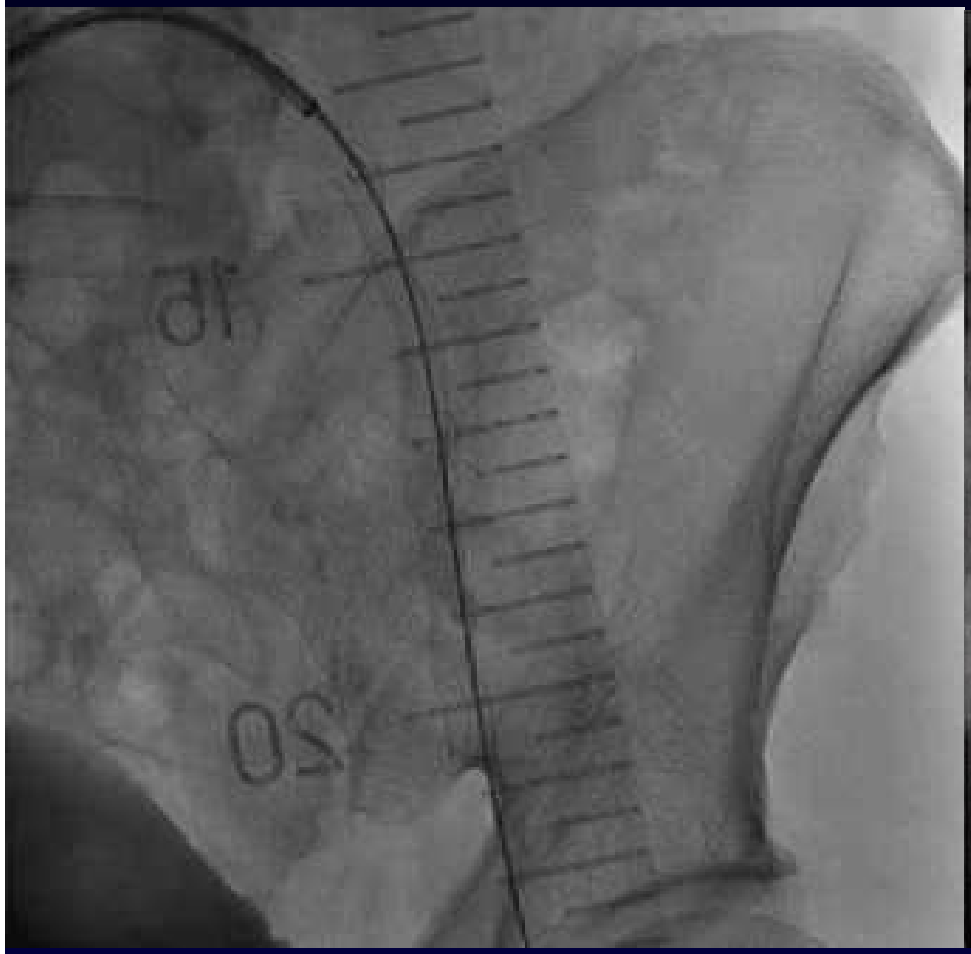
035” Terumo wire

6 x 80 mm balloon (10atm) at Lt. SFA

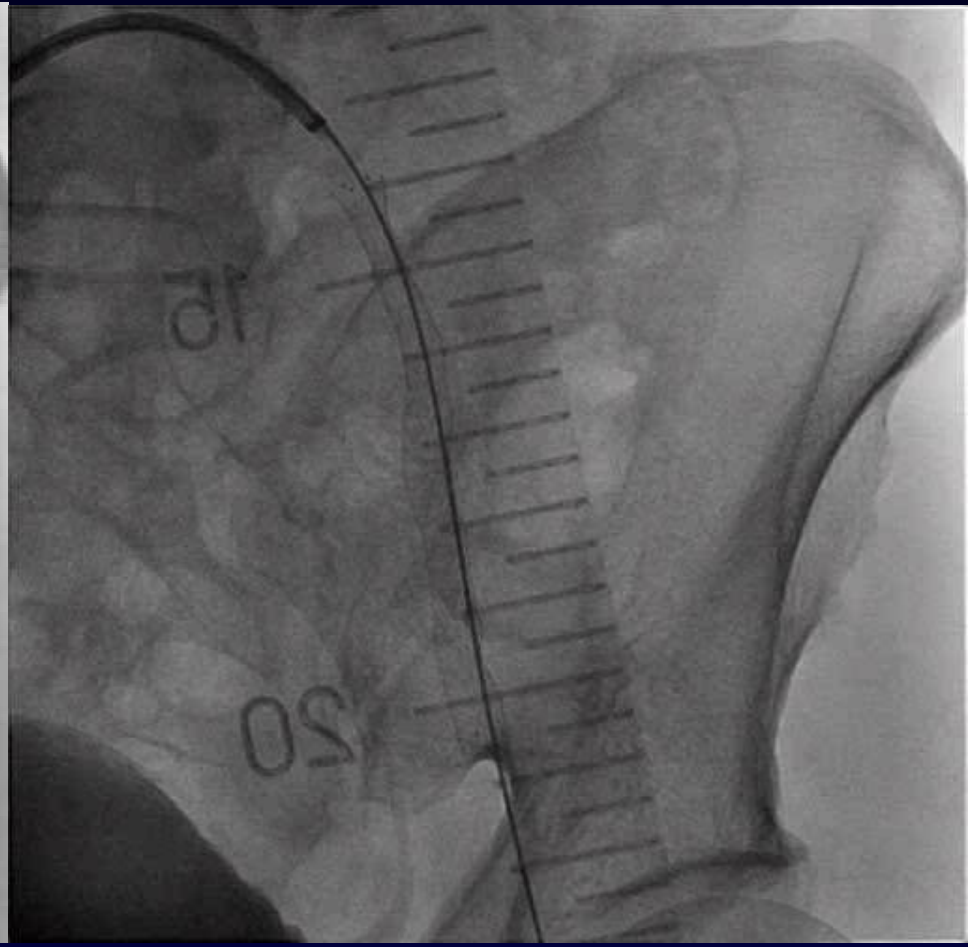




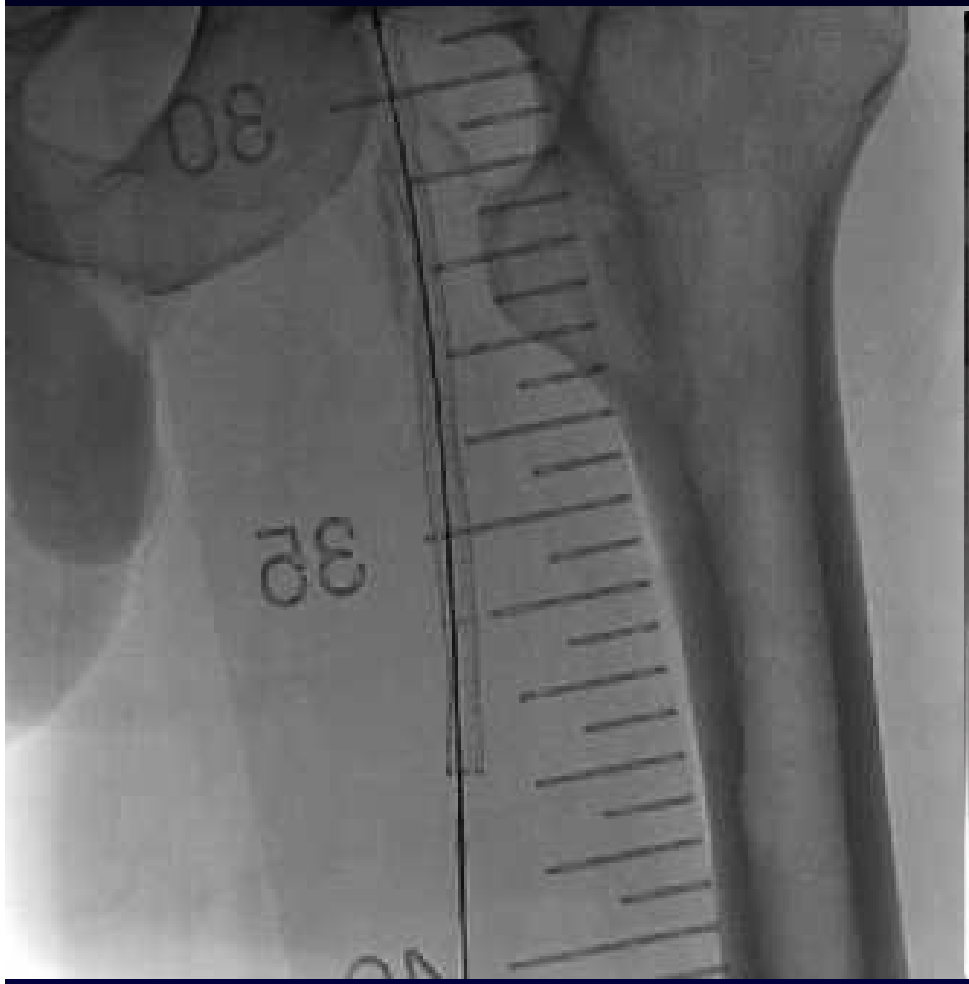
8 x 80 mm self-expandable stent at Lt. EIA



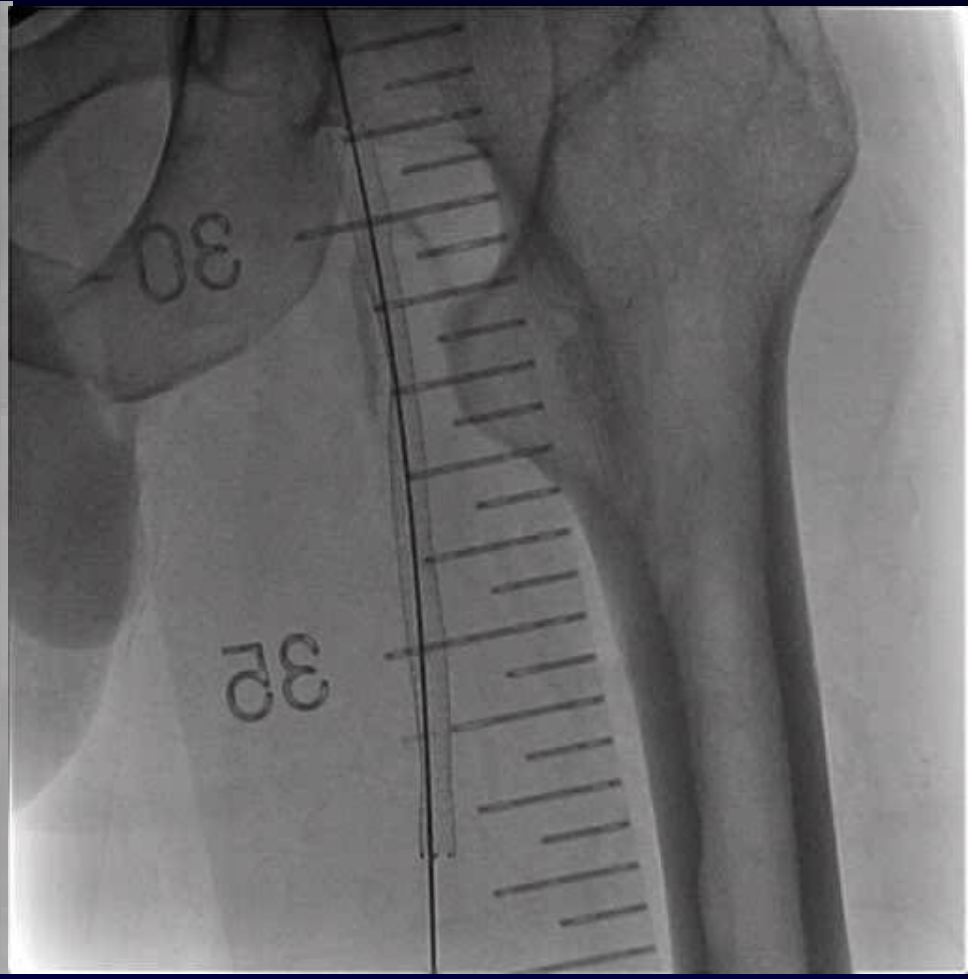
Angio after stent insertion



7 x 100 mm self-expandable stent at Lt. SFA

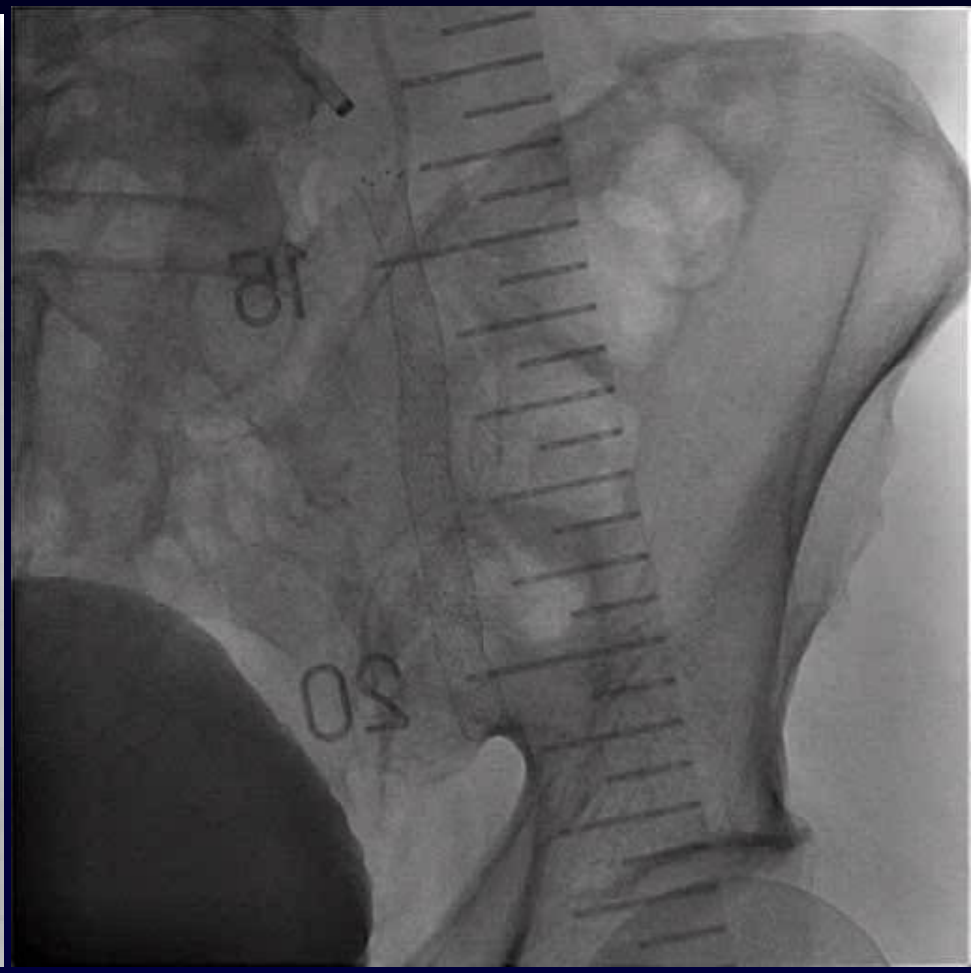


Angio after stent insertion

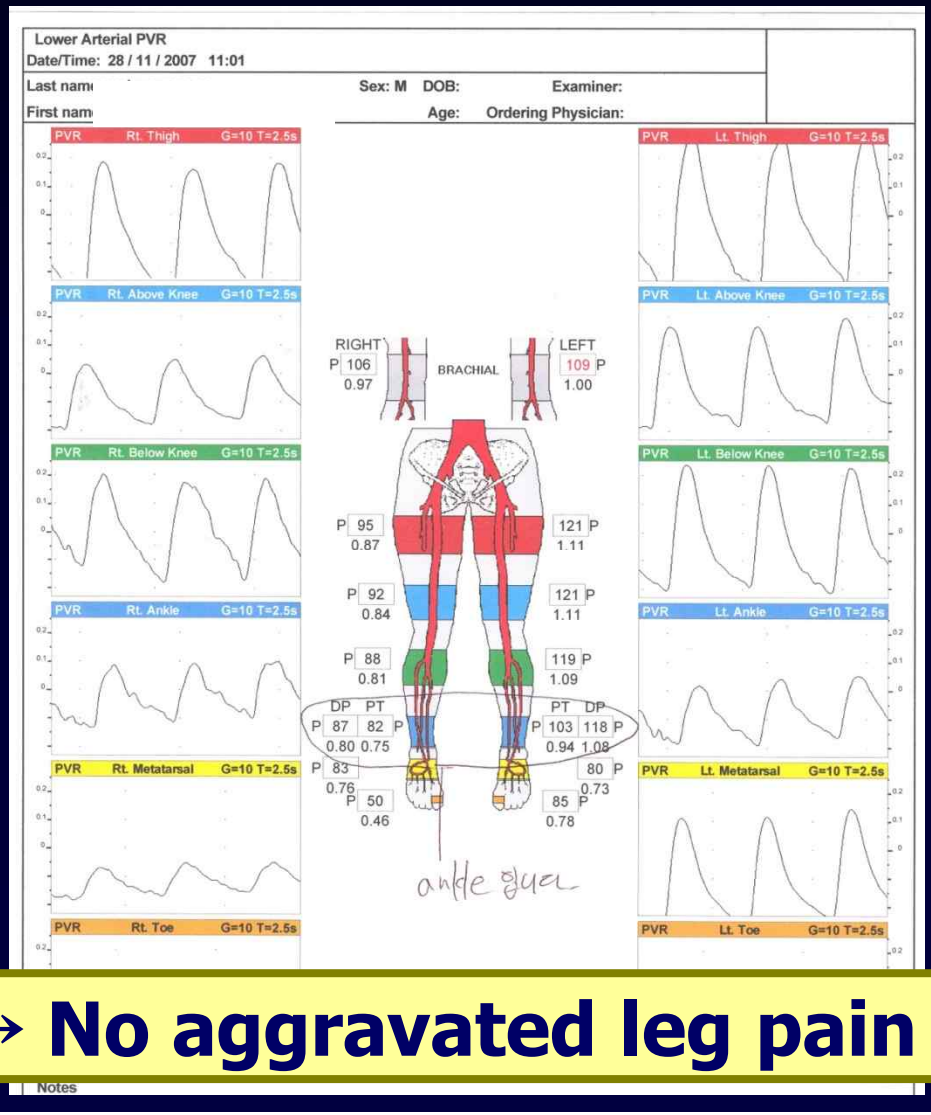


7 x 80 mm adjuvant balloon (10atm) at Lt. SFA

Final angio after adjuvant balloon angioplasty

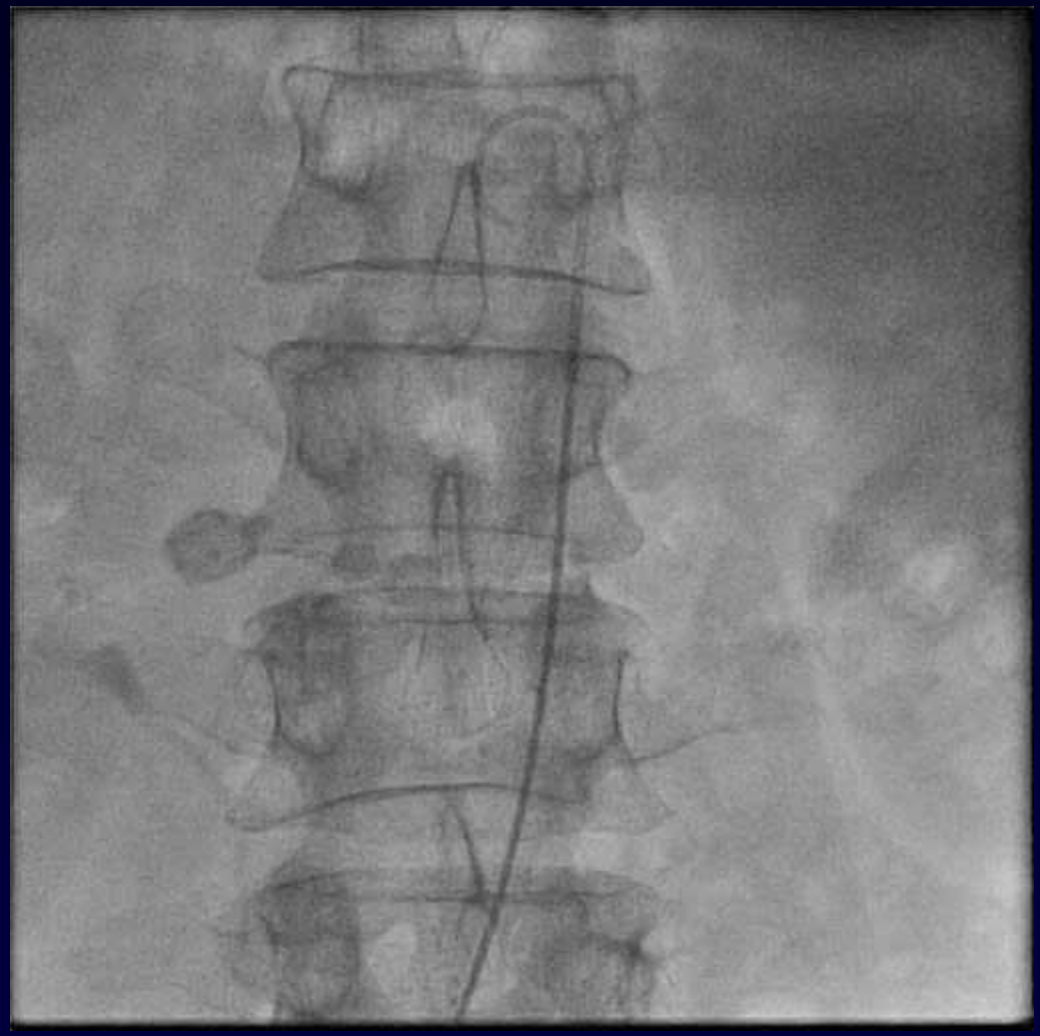


PVR after PTA (2007-11-28)



→ **No aggravated leg pain !!**

F/u peripheral angiography (2008-10-31)



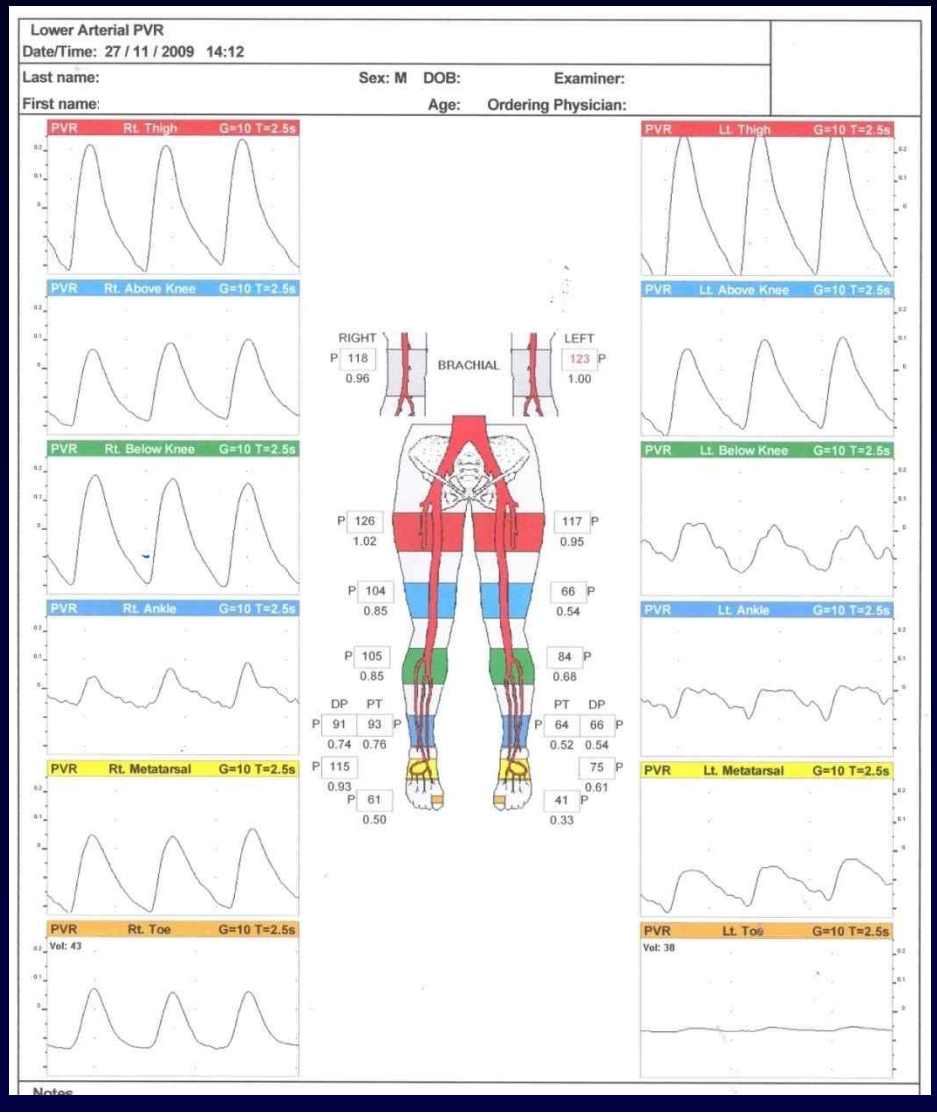
Case #2

M/68

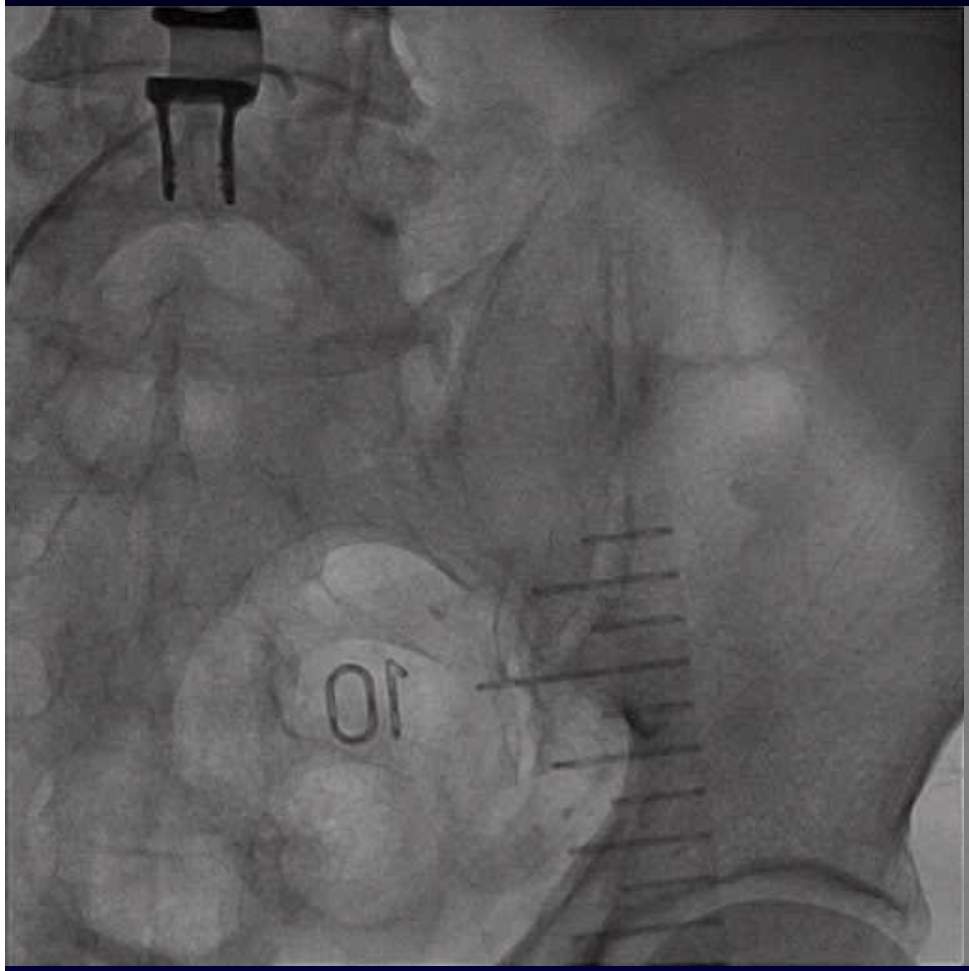
- C.C: Claudication of left leg
- D: 10 years
- PHx: HTN (-), DM (-), Dyslipidemia (+),
  HNP L4/L5 (+), Spinal stenosis, lumbar (+)
  -> Post-op state (2008.10)
- P/Ex: BP 130/80 mmHg, HR 70
- Lab: BUN/Cr 18.1/1.02 mg/dL

Initial CT (2007-11-27)

Initial PVR (2007-11-27)

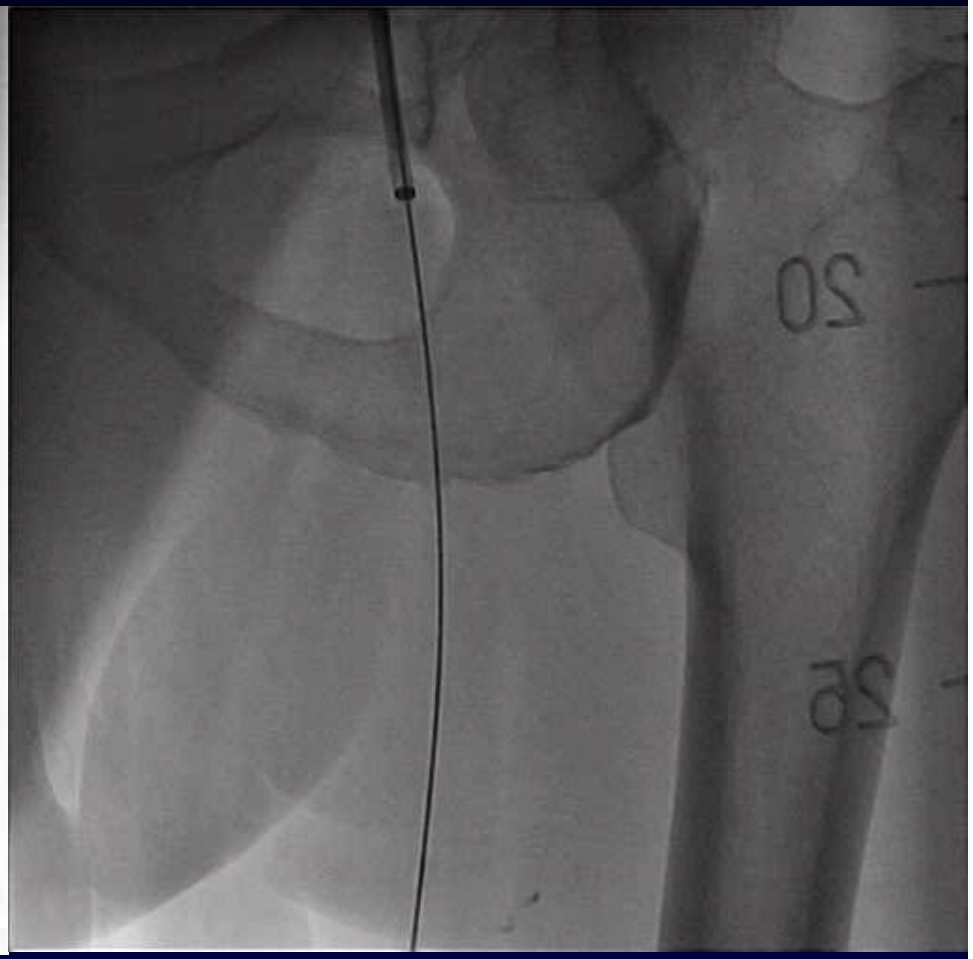


Left SFA total occlusion

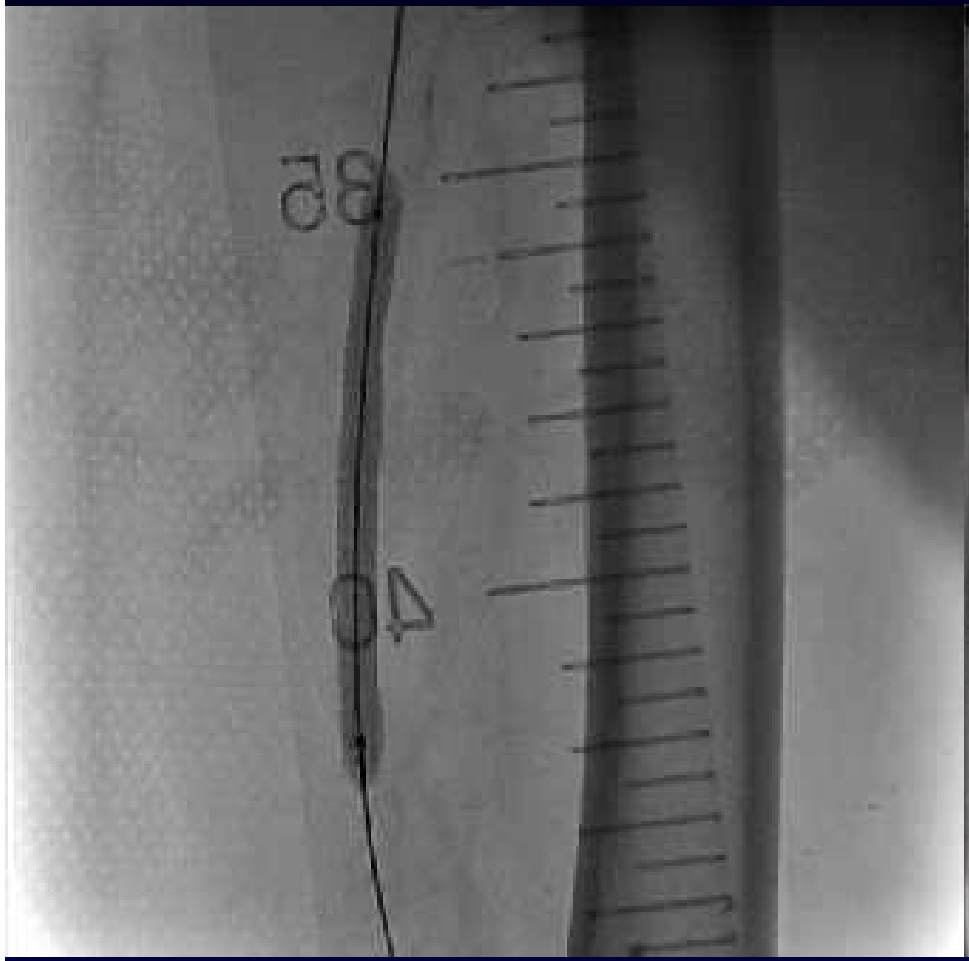


035” Terumo wire

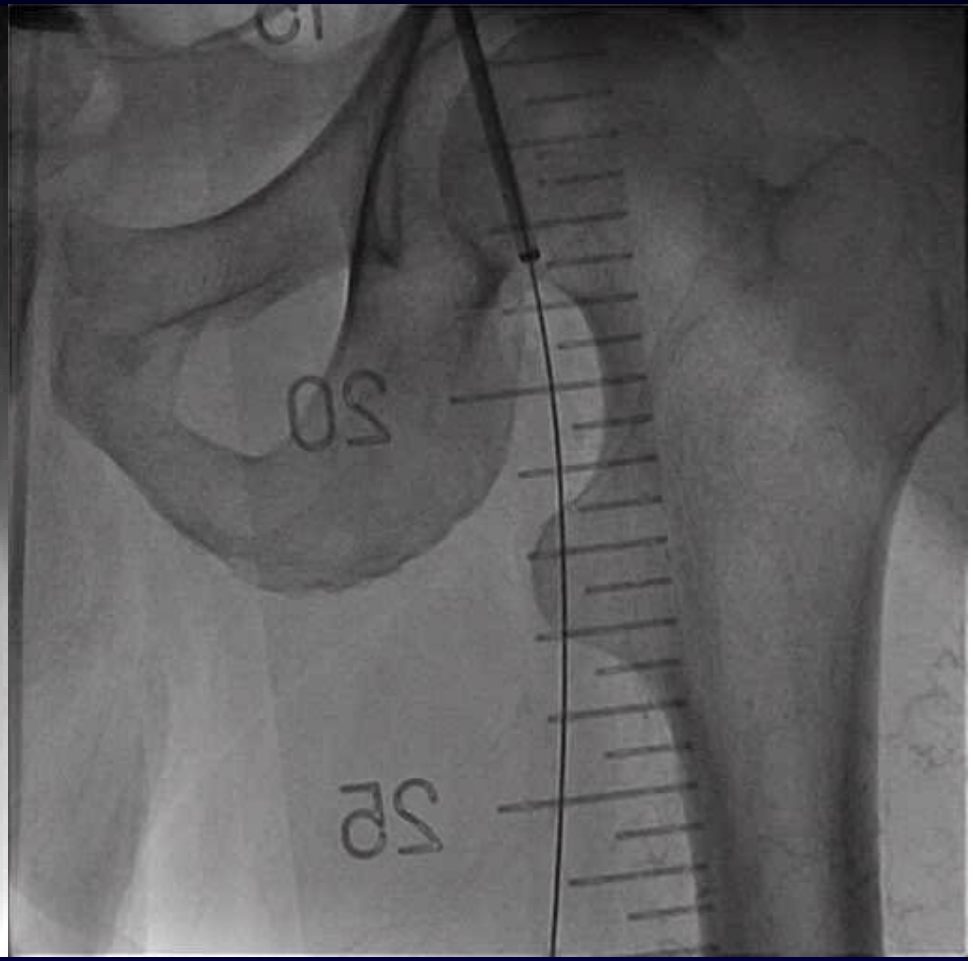
Angio after Powerflex 4 x 8 (10atm) at Lt. SFA



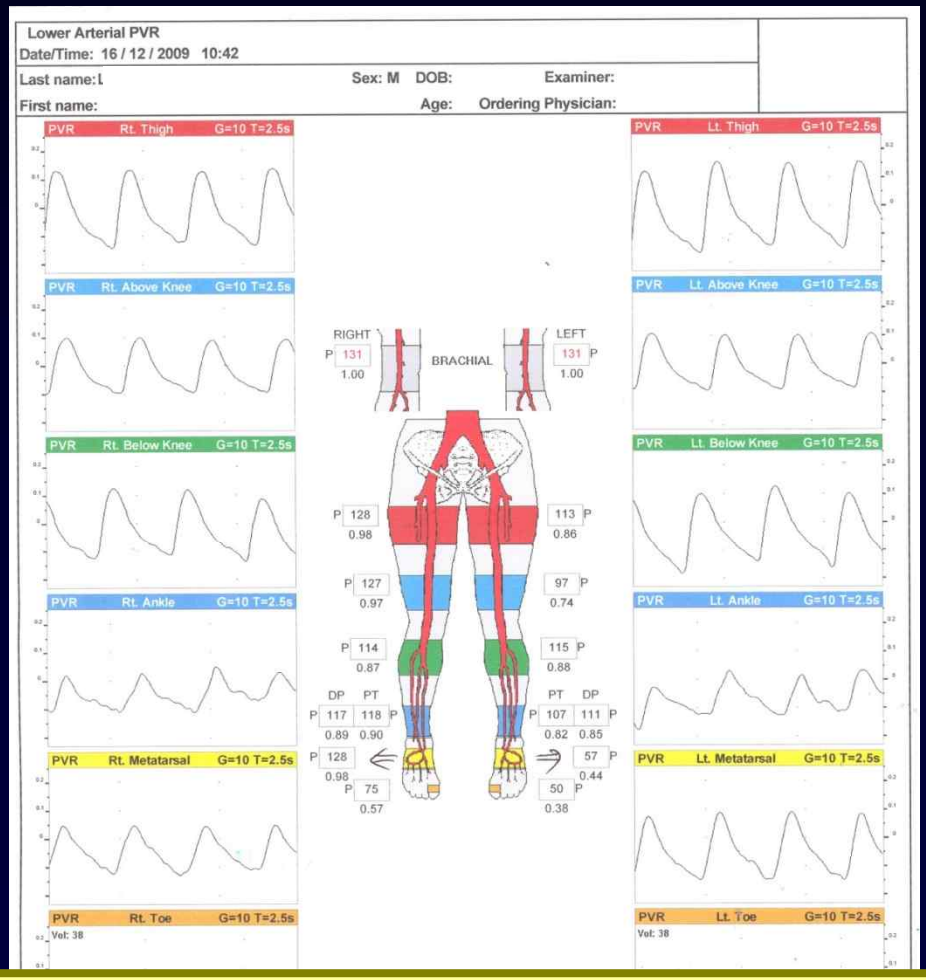
7 x 8 adjuvant balloon angioplasty



Final angio after adjuvant balloon angioplasty



PVR after PTA (2009-12-16)



→ **But, the leg pain persisted !!**

CT (2010-03-11)


HD MIP No cut
DFOV 60.5 x 121.1 cm
STND/+
Calcif. included
No VOI
1.2mm 0.984:1/1.2sp
W = 731 L = 257


Volume Rendering No cut
DFOV 39.0 x 78.1 cm
STND/+
Calcif. included
No VOI
1.2mm 0.984:1/1.2sp
W = 731 L = 257

PTA versus Surgery

PTA versus Surgery (I)

- There are limited RCTs comparing PTA versus surgery in the management of FPA disease.
- This is partly because the choice of revascularization modality depends on how extensive the disease is in the individual patient, with surgery being the most likely route of action in the setting of extensive or long lesions and in those with critical limb ischemia.

PTA versus Surgery (II)

- In a multicenter RCT of 263 men, Wolf and colleagues reported three operative deaths in the surgical arm (n=126) and none in the PTA arm (n=129).
- No difference in survival was noted, although there was a trend in favor of the PTA arm.

- Wolf GL et al, J Vasc Interv Radiol 1993

PTA versus Surgery (III)

- However, there was higher reported success rate and more limb salvage in the surgical arm than in the PTA arm.
- No differences were reported in clinical outcome on median follow-up of 4 years.

- Wolf GL et al, J Vasc Interv Radiol 1993

- In a small randomized trial, a 1-year patency rate of 43% in the PTA arm (n=30) versus 82% in the surgical arm (n=24) was reported.

- Van der Zaag ES et al, Eur J Vasc Endovasc Surg 2004

PTA alone versus Stenting

European Heart Journal (2009) **30**, 44–55
doi:10.1093/eurheartj/ehn514

CLINICAL RESEARCH
Interventional cardiology and angiology

Routine stent implantation vs. percutaneous transluminal angioplasty in femoropopliteal artery disease: a meta-analysis of randomized controlled trials

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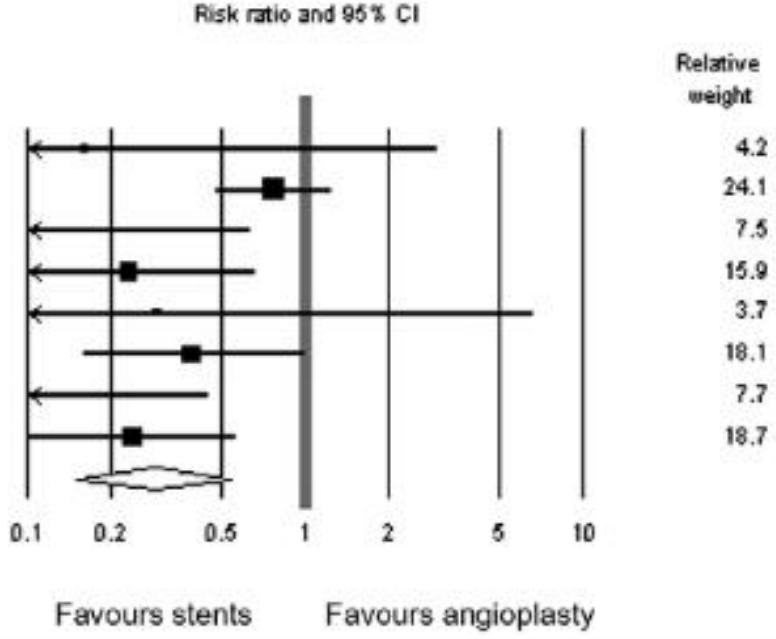
Methods

- Ten trials were pooled randomizing patients to routine stenting (n=724 limbs) or PTA with provisional stenting (n=718 limbs).
- They performed meta analysis to identify relevant articles from 1960 to October 2007.
- A follow-up period was 9-24 months.
- The endpoints of interest were immediate technical success/failure, rate of target vessel revascularization (TVR), and restenosis in 9-24 months of follow-up.

5.9% vs. 17.1%, RR=0.28 (95% CI=0.15-0.54, P<0.001)

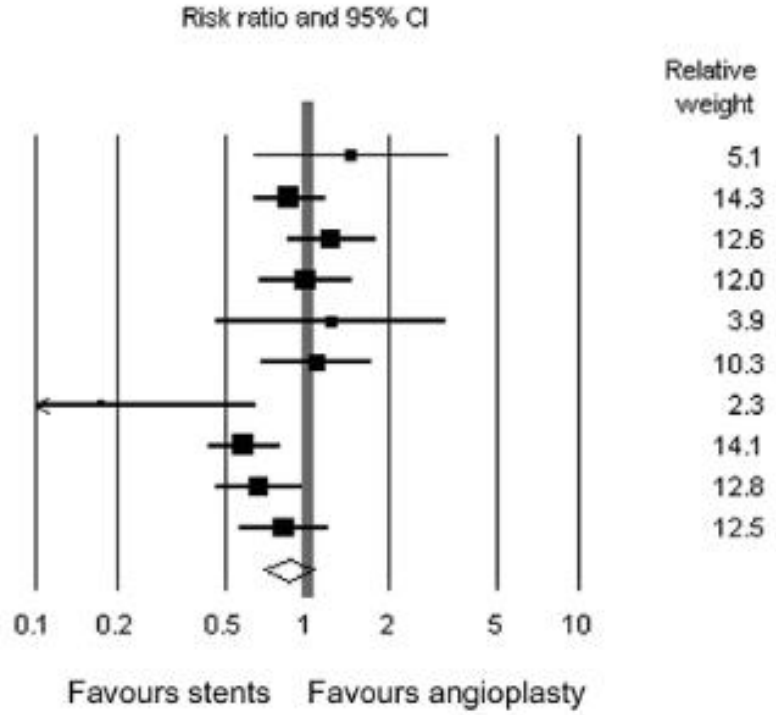
Study name	Stent type	Time point	Statistics for each study				Failure/ total	
			Risk ratio	Lower limit	Upper limit	*P*-value	Stent	Angioplasty
Vroegindeweij	Palmaz	1997	0.16	0.01	2.95	0.218	0/24	3/27
IntraCoil	Nitinol	2001	0.77	0.48	1.25	0.291	25/177	32/175
Cejna	Palmaz	2001	0.08	0.01	0.63	0.016	1/77	12/77
Becquemin	Palmaz	2003	0.23	0.08	0.66	0.006	4/115	17/112
Saxon	Stent graft	2003	0.29	0.01	6.60	0.439	0/15	1/13
Mahabn	Stent graft	2005	0.39	0.16	0.95	0.038	6/97	16/100
Schillinger	Nitinol	2006	0.06	0.01	0.44	0.006	1/51	17/53
Krankenberg	Nitinol	2007	0.24	0.10	0.56	0.001	6/123	25/121
Summary risk ratio			0.28	0.15	0.54	0.000		



The Forest plot of risk ratios of immediate technical failure using random-effects model. Sizes of data markers are proportional to the weight of eac h study in the meta-analysis.

37.6% vs. 45.3%, RR=0.85 (95% CI=0.69-1.06, P=0.146)

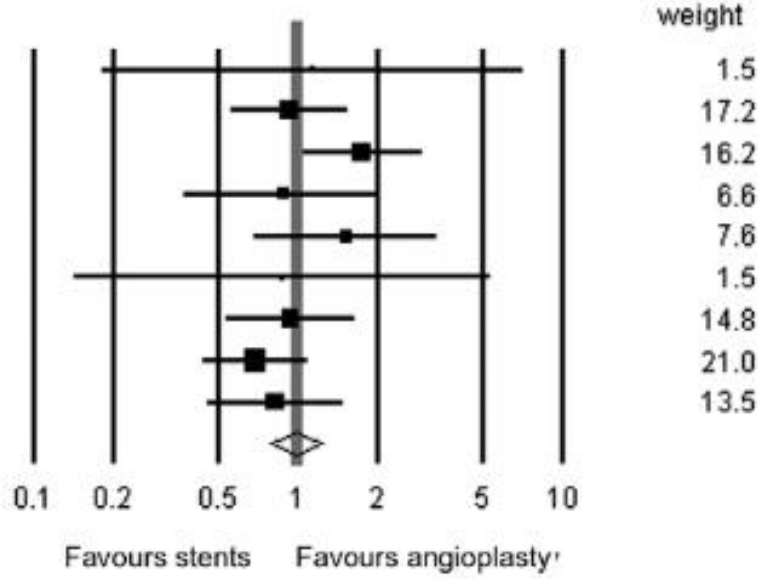
Study name	Stent type	Year	Statistics for each study				Restenosis / total		Relative weight
			Risk ratio	Lower limit	Upper limit	*P*-value	Stent	Angioplasty	
Vroegindeweij	Palmaz	1997	1.45	0.64	3.29	0.378	9/24	7/27	5.1
Zdanowski	Strecker	1999	0.86	0.63	1.16	0.321	10/12	8/8	14.3
IntraCoil	Nitinol	2001	1.22	0.84	1.78	0.288	40/97	31/92	12.6
Cejna	Palmaz	2001	0.98	0.66	1.46	0.929	26/56	26/55	12.0
Grimm	Palmaz	2001	1.23	0.46	3.26	0.682	8/30	5/23	3.9
Becquemin	Palmaz	2003	1.07	0.67	1.72	0.769	26/75	21/65	10.3
Saxon	Stent graft	2003	0.17	0.05	0.65	0.009	2/15	10/13	2.3
Viabahn	Stent graft	2005	0.58	0.43	0.80	0.001	34/97	60/100	14.1
Schillinger	Nitinol	2006	0.66	0.46	0.95	0.025	21/46	36/52	12.8
Krankenberg	Nitinol	2007	0.82	0.56	1.20	0.304	32/101	39/101	12.5
Summary risk ratio			0.85	0.69	1.06	0.146			



The Forest plot of risk ratios of restenosis using random-effects model. Sizes of data markers are proportional to the weight of each study in the meta-analysis.

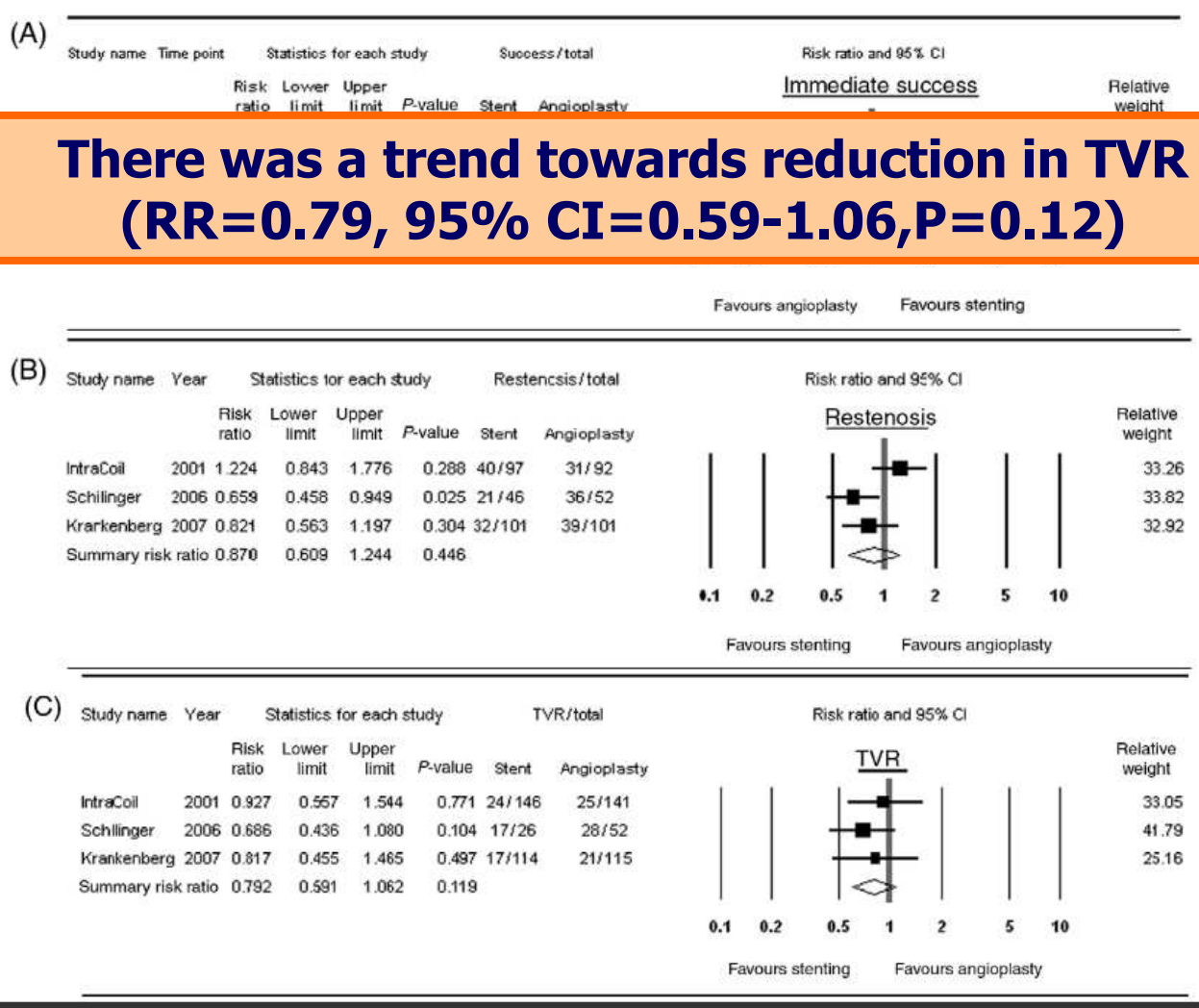
20% vs. 20.2%, RR=0.98 (95% CI=0.78-1.23, P=0.89)

Study name	Stent type	Year	Statistics for each study				TVR/total	
			Risk ratio	Lower limit	Upper limit	*P*-value	Stent	Angioplasty
Zdanowski	Strecker	1999	1.13	0.18	7.09	0.894	2/15	2/17
IntraCoil	Nitinol	2001	0.93	0.56	1.54	0.771	24/146	25/141
Cejna	Palmaz	2001	1.75	1.03	2.96	0.037	28/77	16/77
Grimm	Palmaz	2001	0.88	0.37	2.06	0.762	8/30	7/23
Becquemin	Palmaz	2003	1.51	0.68	3.36	0.306	14/115	9/112
Saxon	Stent graft	2003	0.87	0.14	5.32	0.877	2/15	2/13
Viabahn	Stent graft	2005	0.93	0.54	1.62	0.805	19/97	21/100
Schillinger	Nitinol	2006	0.69	0.44	1.08	0.104	17/46	28/52
Krankenberg	Nitinol	2007	0.82	0.46	1.47	0.497	17/114	21/115
Summary risk ratio			0.98	0.78	1.23	0.889		



The Forest plot of risk ratios of target vessel revascularization (TVR) using random-effects model. Sizes of data markers are proportional to the weight of each study in the meta-analysis. One study was excluded from the analysis, as there were no data on TVR.

There was a trend towards reduction in TVR (RR=0.79, 95% CI=0.59-1.06,P=0.12)



Subgroup analysis for the use of nitinol stents. The Forest plots of risk ratios of immediate technical success (A), restenosis (B), and TVR (C) using random-effects model. Sizes of data markers are proportional to the weight of each study in the meta-analysis.

Conclusions

- Despite the higher immediate success, routine stenting was not associated with a significant reduction in the rate of restenosis or TVR.
- Their data do not support use of routine stenting as the primary endovascular treatment for short FPA lesions.

Summary (I)

- There are limited RCTs comparing PTA versus other procedures including surgery and routine stenting in the management of femoropopliteal disease.
- There was a higher immediate success rate and a symptomatic relief in surgery group compared with the PTA group in the management of femoropopliteal disease.
- However, no differences were reported in long-term clinical outcome.

Summary (II)

- In the femoropopliteal lesions, routine stenting was better in immediate success after procedure compared with angioplasty alone.
- However, there were no significant differences between routine stenting and angioplasty alone in terms of long-term patency rates.

Take Home Message

- **Balloon angioplasty is not inferior to surgery in the femoropopliteal arterial disease.**
- **We do not need use of routine stenting as the primary endovascular treatment for femoropopliteal arterial lesions.**
- **Stenting is indicated as a salvage procedure after complicated PTA (flow-limiting dissection or thrombosis)**

Thank you for your attention !!