

Diabetic Foot :does long term endovascular therapy exist?

A.T.O. Abdool-Carrim

University of Witwatersrand

Diabetic Foot

- Atherosclerosis 5-10x more common
- Disease more diffuse and severe and earlier
- Frequent co-existence of neuropathy
- Definition of critical limb ischaemia is not applicable

Angioplasty Technical Requirements

- Dotter & Judkins – 1964 – tapered catheter.
- Gruntzig and hopff 1974 – coaxial balloon catheter
- Low profile catheter with non-compliant balloon and small calibre guide wire now the standard.
- Percutaneous technique,guide wire size 00.014-0.035 in. and 2.0-3.5 fr. balloon catheter. long length balloons now the standard
- Peri-procedural adjuvant treatment with vasodilators, antiplatelet and heparins have improved technical success.

Indication for Performing angioplasty

First choice for revascularisation?

- Operation not feasible due to patient not being fit
- Suitable conduit absent
- Isolated stenotic lesions in infrapopliteal vessel made angioplasty possible
- Improved run-off deemed necessary for proximal angioplasty

Diabetic Foot angioplasty (PTA) criteria

Lesion length and run –offs:

Ideal lesion focal with good run-off distally
into foot

Stenosis better than occlusions

Only 20-30% with tibial disease have
favourable anatomy for PTA

Severe three vessel disease very common

Proximal femoro-popliteal angioplasty may be
necessary

PTA in Diabetic Foot

- TASC A – Single stenosis < 1cm
- TASC B – Multiple focal stenosis
<1cm(±femoropopliteal stenosis)
- TASC C – Stenosis 1-4 cm and occlusion 1-2
cm
- TASC D – occlusions >2 cm/diffusely
diseased tibials

2000

TASC A and B -- Endovascular

2007

4 now endovascular therapy possible IF
EQUIVALENT OUTCOMES!

TASC EJVES 2000,TASC EJVS 2007

PTA

- PTA in severe leg ischaemia is controversial
- PTA in diabetic and non-diabetic increasing
6 fold
- Improvement in technique and devices
- Endovascular enthusiasm

Revascularisation for diabetic foot in Helsinki University Central Hospital

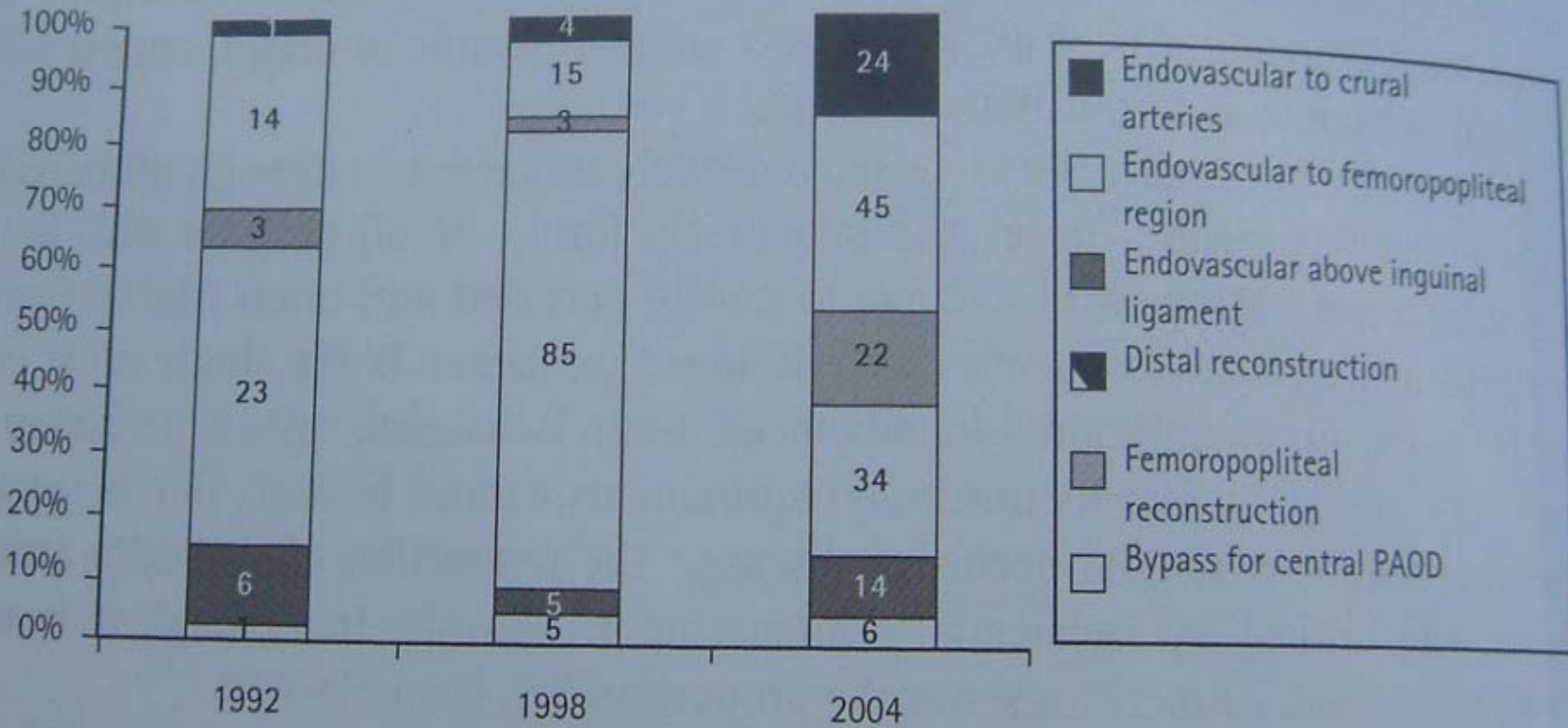


Figure 1. Revascularization procedures for diabetic foot with ulcer or gangrene (Fontaine grade IV) at Helsinki University Central Hospital. The numbers of different revascularization procedures are presented in different columns.

Diabetic Foot PTA

- The universally accepted indication for infra-popliteal angioplasty is limb salvage.
- Diabetes is present in 60-91% of patients undergoing PTA for limb salvage.
- The presence of end stage renal disease has a negative prognostic effect on the durability of PTA – not been accounted for in published series.

Diabetic Foot PTA

- Median age of patients undergoing angioplasty in published series is 69 years.
- Mortality in this group is high – 50% 5yr.
- Procedure related mortality is higher with surgery than PTA.

Diabetic Foot PTA

- Restoration of straight line flow to the pedal arch in one or more tibial arteries is necessary– never looked at in infra-inguinal angioplasty.
- Careful patient selection is therefore necessary.
- However, addressing a few short stenotic lesions may improve perfusion pressure sufficiently to heal an ulcer.

PTA

- Distal bypass reserved for CLI– good patency and clinical durability
- Standard against which PTA must be measured
- Most authors accept bypass alone not the ideal
- PTA studies hampered by small numbers and incomplete follow-up and varied groups

Endovascular vs. PTA

- Series that compare leg salvage and patency after lower extremity bypass and endovascular procedures show that patency-leg salvage gap is higher with endovascular treatment than bypass , amputation being carried out more often after graft occlusion of a bypass than endovascular treatment

Table 1. Leg salvage-patency gap: European experience

	N	DM (%)	Follow-up (mean)	Secondary patency (%)	Leg salvage (%)	Leg salvage-patency gap (%)
<i>Pedal bypasses</i>						
Staffa <i>et al.</i> 2005 ³²	54	68	4.5 years	78	81	3
Frankini & Pezzella 2003 ³³	43	NA	3 years	39	46	7
Dorweiler <i>et al.</i> 2002 ³⁴	49	100	4 years	89	87	-2
Biancari <i>et al.</i> 1999 ³⁵	165	70	3 years	41	60	19
Luther & Lepäntalo 1997 ³⁶	109	74	2 years	59	60	1
Eckstein <i>et al.</i> 1996 ³⁷	56	71	2 years	62	71	9
Isaksson & Lundgren 1994 ³⁸	33	100	1 year	89	89	0
Tordoir <i>et al.</i> 1993 ³⁹	30	49	3 years	64	82	18
Total	539					
Weighted mean (SD)				59 (17)	68 (11)	9 (9)
<i>Infrainguinal percutaneous angioplasty</i>						
Eskelinen <i>et al.</i> 2005 ⁴⁰	230	59	1 year	59	92	33
Laxdal <i>et al.</i> 2003 ⁴¹	46	NA	6 months	43	50	7
Matsages <i>et al.</i> 2003 ⁴²	50	50	1 year	63	98	35
Tisi <i>et al.</i> 2002 ⁴³	122	29	1 year	28	86	58
Löfberg <i>et al.</i> 2001 ⁴⁴	92	43	3 years	32	87	55
Boyer <i>et al.</i> 2000 ⁴⁵	49	73	3 years	88	87	-1
London <i>et al.</i> 1995 ⁴⁶	54*	49	2 years	78	89	11
Total	643					
Weighted mean (SD)				52 (21)	87 (11)	35 (21)

N = number of patients. DM = diabetes mellitus. NA = not available. *Number of legs.

endovascular vs surgery

- BASIL trial ... lancet 2005
- Multicentre randomised trial
- At 6/12 two treatments – no difference in amputation free survival.
- After 2yrs surgery better amputation free survival
- Study show failed bypass had higher amputation rates
- Higher repeat intervention in the endovascular group

Endovascular vs. surgery

- Swiss Cardiovascular Centre... JVS 2007
- 5 year period 383 pts
- Prospective consecutive series
- At 1 year limb salvage rates similar in both groups

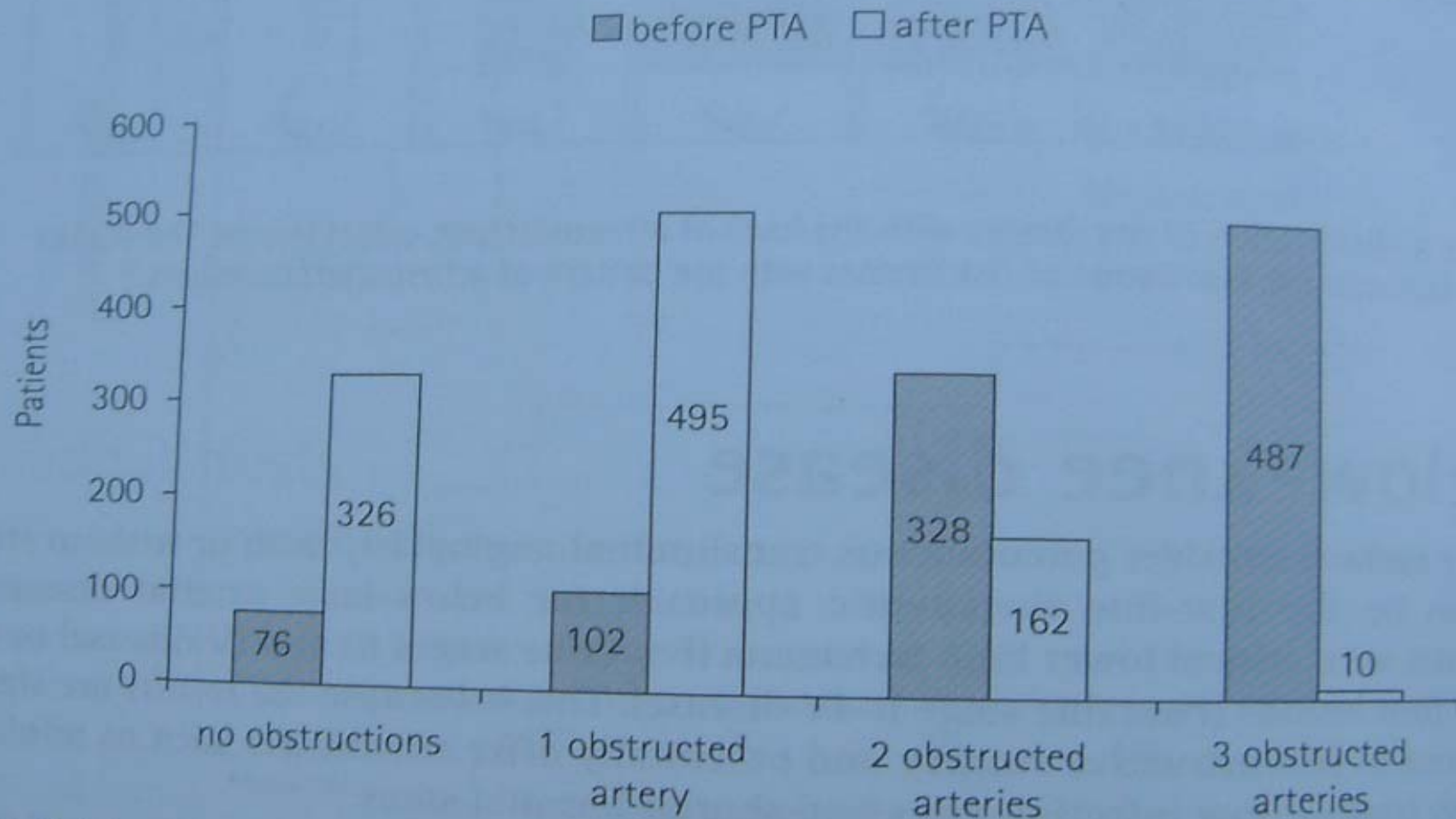


Figure 3. Number of patients with obstruction in the infrapopliteal arteries before and after angioplasty.¹⁹

Patient Population

- PTA

68-100% had CLI.

Older age group mean age 66-75.

Extensive vascular disease.

Diabetics – 60-90%

High risk – natural history of CLI – 50%
5 year mortality

Diabetic Foot PTA

Results.

- Technical success 86-100%.
- Major complications 2-6%.
- Limb salvage 60-86% at 2 years.
- Long segment stenosis and distal outflow poor –15%.

Results of PTA

author	year	limbs	% cli	P/rate	L/s	F/up
Harvath	1990	71	na	96	na	na
Bakal	1990	43	99	86	67	24
Schwarten	1991	112	100	97	83	24
Bull	1992	168	76	80	85	26
Saab	1992	168	100	100	64	19
Brown	1993	14	84	64	na	26
varty	1995	40	50	68	77	24

Results of PTA

author	yr	limbs	% cli	P/ rate	L/s	F/up
matsi	93	84	100	53	56	12
wagner	93	158	68	94	88	17
wack	94	30	100	83	82	10
bolia	94	24	71	86	95	1
durham	94	14	100	na	77	17
marzelle	94	23	100	34	71	12
sivanathan	94	46	na	73	na	12

Results of PTA

author	year	limbs	% cli	P/ rate	L/s	F/up1
Ray	1995	29	100	53	75	6mth
Treiman	1995	25	80	26	na	44mth
Doros	2001	162	100	na	91(50	5 yrs
Faglia	2001	81	100	92	95	30mth
Faglia	2005	993	100	88	90	5yrs
BASIL	2005	452	100	50	50	3yrs

Infringuinal percutaneous angioplasty

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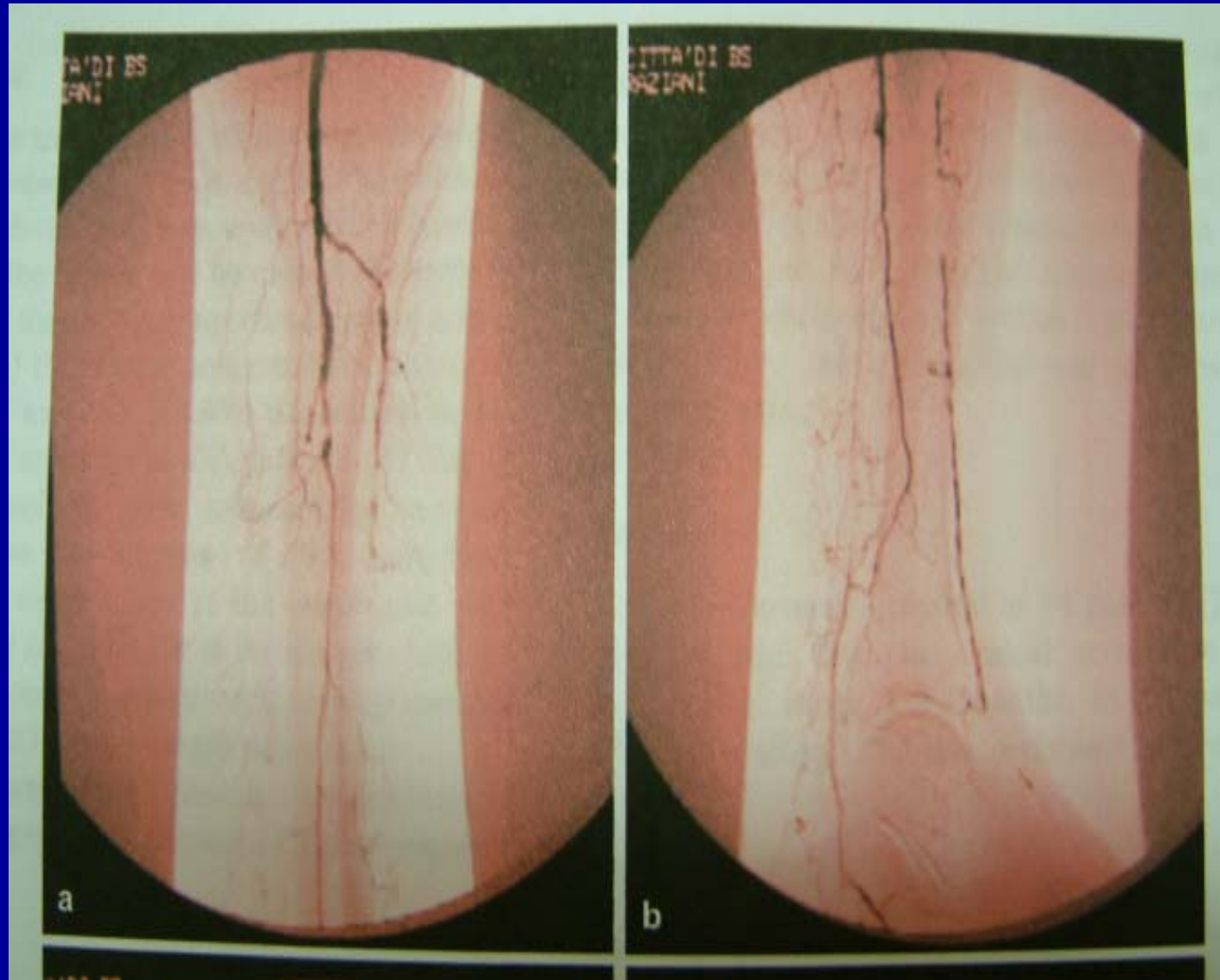
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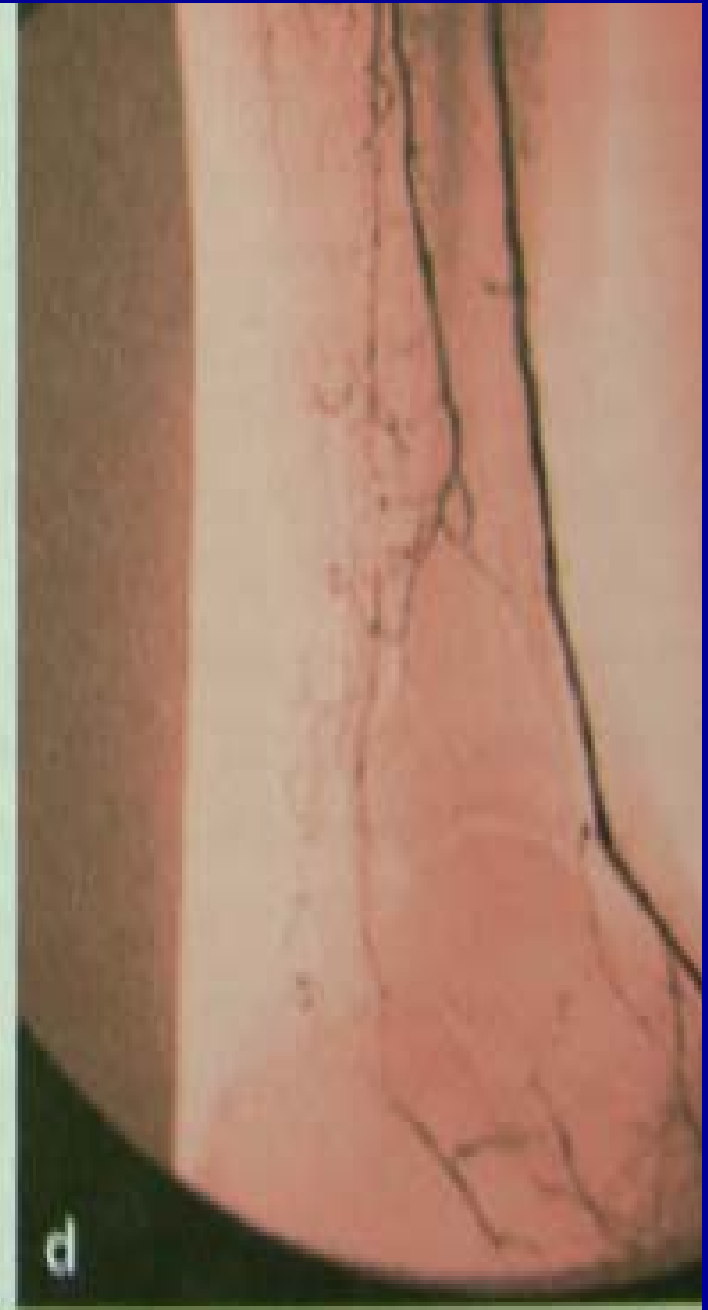
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Distal Bypass

- > 70% primary and secondary patency rates at 12 months → ↓ 50% at 3 years
- Limb salvage rate - 80% at 12 months
- Mortality rate higher - 50% at 5 years
- Morbidity rate high – wound sepsis at 10%





Primary Infra-popliteal PTA

- Satisfactory primary patency rate 34 – 100% (13 series)
- Limb salvage rate 64 – 95%
- Mean follow-up short 1-24 months
- Patency after PTA better than limb salvage → patency after PTA not a prognostic indicator for limb salvage as patency after bypass.
- Results better if Lesions <5cm, <6 stenotic lesions and and if no proximal stenosis

Problems in Reviewing Literature

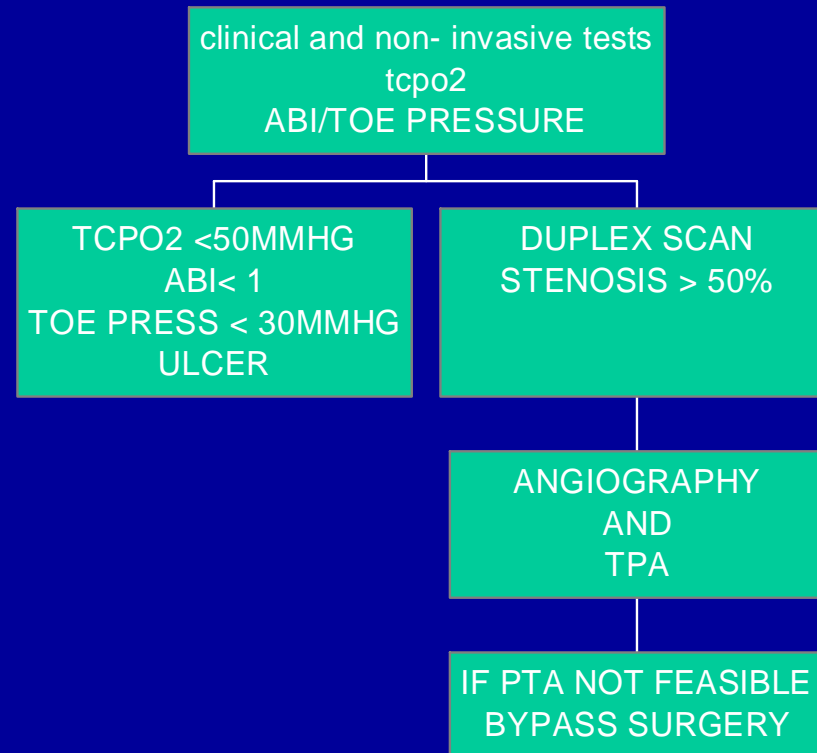
- Numbers small but substantial experience in effectiveness and safety
- Non-critical ischaemic patients skew results towards PTA
- 1 randomized study as regards infra-popliteal disease to determine when PTA be performed as treatment of choice
- Considerable uncertainty when concomitant proximal PTA done
- Variable criteria used in reporting results
- Mixed selection of patients

What Is Needed

- Controlled trial that randomize PTA first vs. Bypass first on an intention to treat
- Rigorous and well defined selection criteria, disease classification, measurement of outcome in both treatment groups
- Particularly important are length of time spent incapacitated and patients perception of outcome only then can objective recommendations be made.

Diagnostic and Therapeutic Work-up

DIABETIC FOOT



Conclusion and recommendations

- Rate of infrapopliteal PTA increasing in diabetics
- Careful case selection needed
- Short stenosis/occlusion with good inflow and outflow
- Establishment of at least one vessel run-off to foot is important
- Diabetic patients marginally worse because of calcification and extensive disease
- No compromise to subsequent attempt at surgical bypass
- Diffuse disease poorer outcome

Does long term endovascular therapy exist?

- Not yet !

But

Endovascular techniques improving and with repeat intervention longer term outcomes are improving so the future is bright !