
FONDAZIONE
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OSPEDALE MAGGIORE POLICLINICO
MANGIAGALLI E REGINA ELENA DI MILANO
Below the Knee Intervention
in 1.000 Consecutive Patients
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Below the Knee Intervention

- Successful revascularization reduces the major amputation rate in diabetic patients presenting with critical limb ischemia (CLI).
- The aim of this study was to evaluate the effectiveness and limits of PTA as first-choice revascularization in a consecutive population of patients with CLI.

Study protocol

1°

INFECTION TREATMENT

ULCER DEBRIDEMENT & URGENT SURGERY
(GANGRENE/ABSCESS/ PHLEGMON)

METABOLIC & CARDIOLOGIC TREATMENT

PRE-MEDICATIONS

2°

REVASCULARIZATION

“ONE STEP” ANGIO & PTA

PTA not feasible?

BY-PASS

3°

FINAL TREATMENT

- **MEDICAL**
- **SURGICAL**
- **ORTHOPEDIC**
- **REHABILITATION**

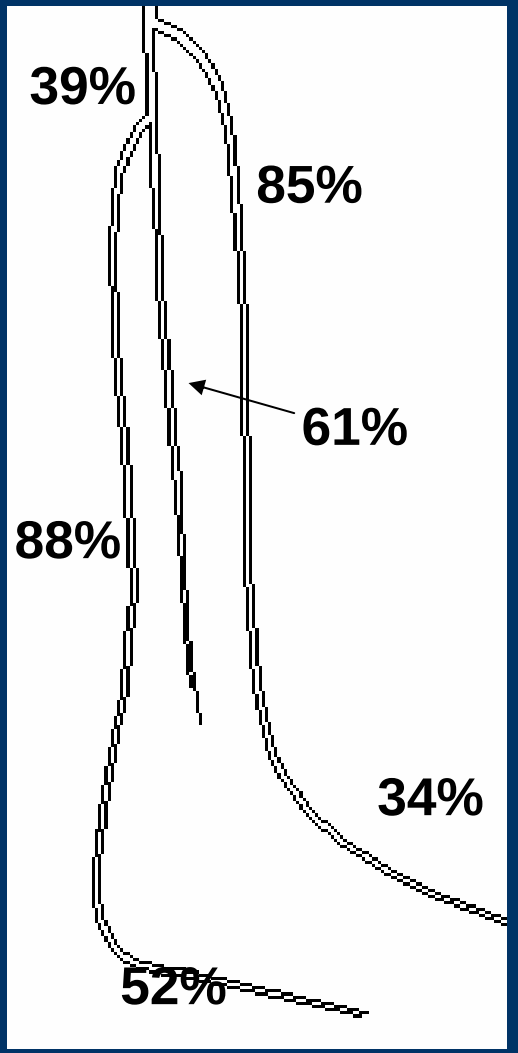
Study Population: *1124 patients*

(Jan. 2002 – Dec. 2005)

- Diabetic patients
- Foot lesions: ulcer/necrosis/gangrene
- Absence of pedal pulses
- $TcPO_2 < 40$ mmHg

Disease localization & diffusion

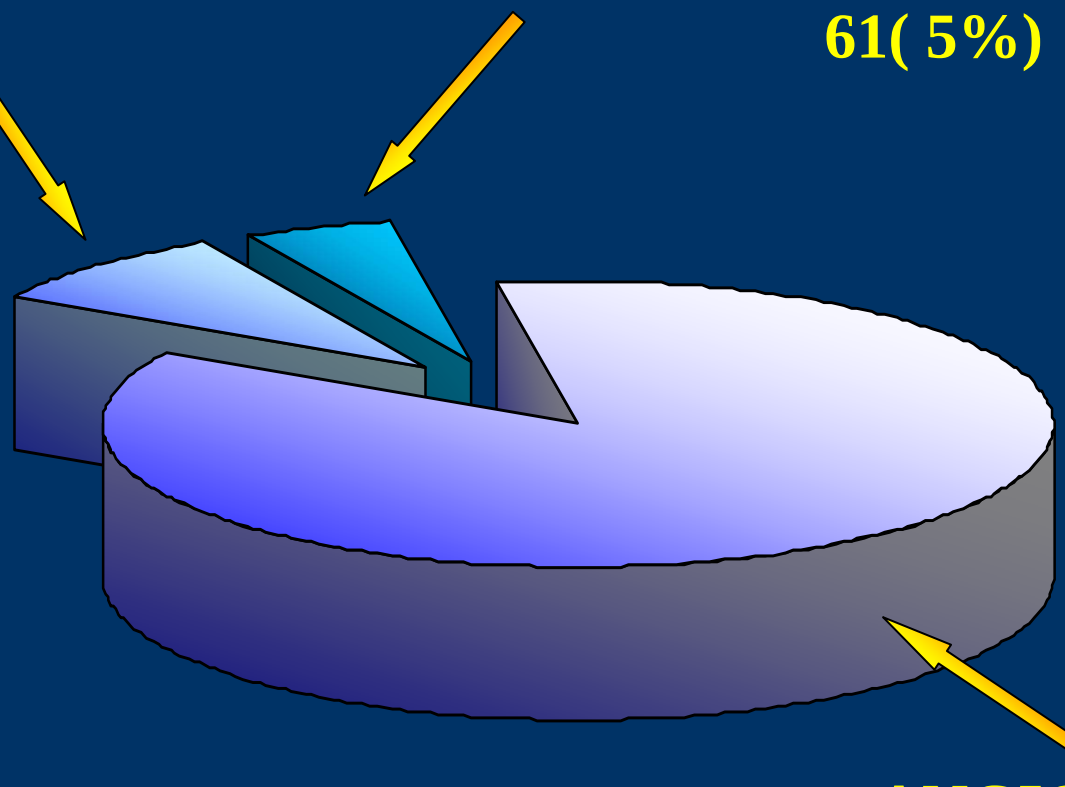
Patients n°		1124
TPT		39 %
1 vessel		10 %
2 vessel		20 %
3 vessel		65 %



Therapeutic Indications

BYPASS 96 (9%)

MEDICAL THERAPY 61(5%)



ANGIOPLASTY 967 (86 %)

Therapeutic Indications

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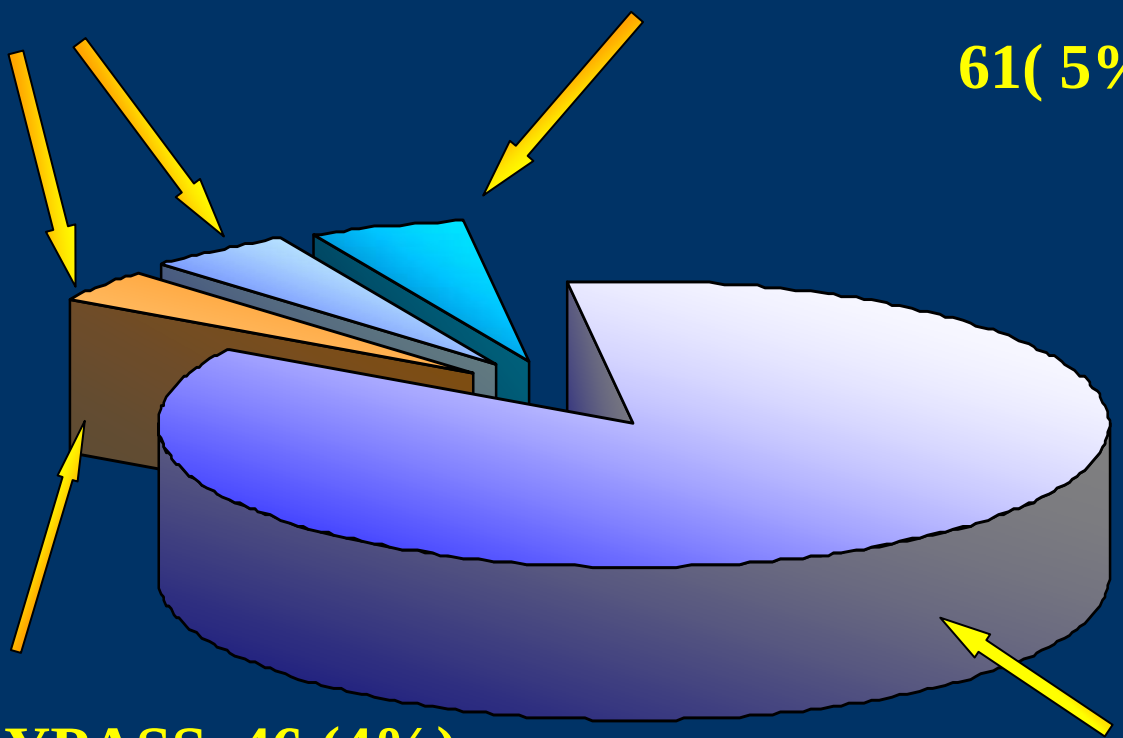


PTA POST BYPASS 46 (4%)

PTA 967 (86 %)

ANGIOPLASTY 1013 (90 %)

Below the Knee Intervention

Clinical Characteristics (n=1013)

Age (years)	70±9	
Males	670	(66%)
Diabetes therapy		
- Insulin	625	(62%)
- Oral agents	334	(33%)
- Diet only	54	(5%)
Diabetes duration (years)	16±11	
CAD	741	(73%)
Retinopathy	432	(42%)
Creatinine >110 mg/dl	547	(54%)
Dialysis	64	(6%)

PTA definitions

- PTA was considered successful when direct flow was obtained in the treated vessel (down to the foot), with no significant residual stenosis
- Any event that required specific medical or surgical treatment or prolonged hospital stay following PTA was considered a complication
- Clinical restenosis was defined as the reappearance of skin lesions and pain

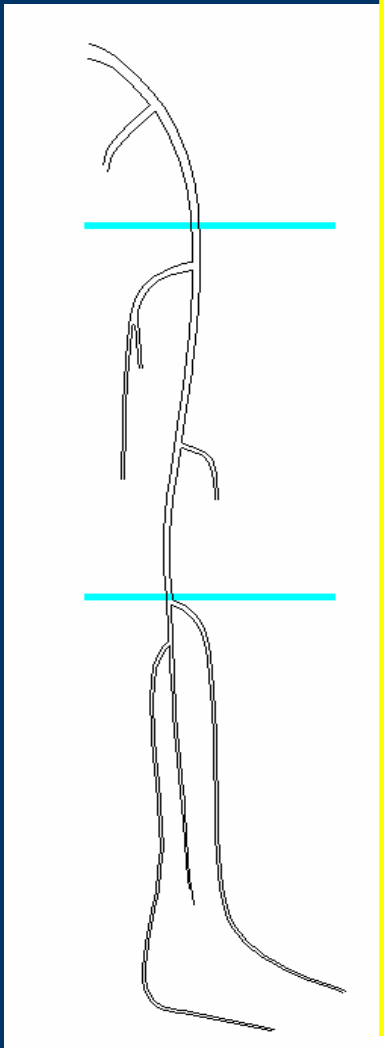
Vascular Approach

Controlateral approach	141	(14%)
Antegrade approach	872	(86%)

Antegrade femoral puncture

SFA selective injection	• high quality imaging • less contrast dye (85 mL/procedure)
Best endovascular device control	• treatment of CTO • subintimal angioplasty
4 French introducer sheath	• no closure device • less complications

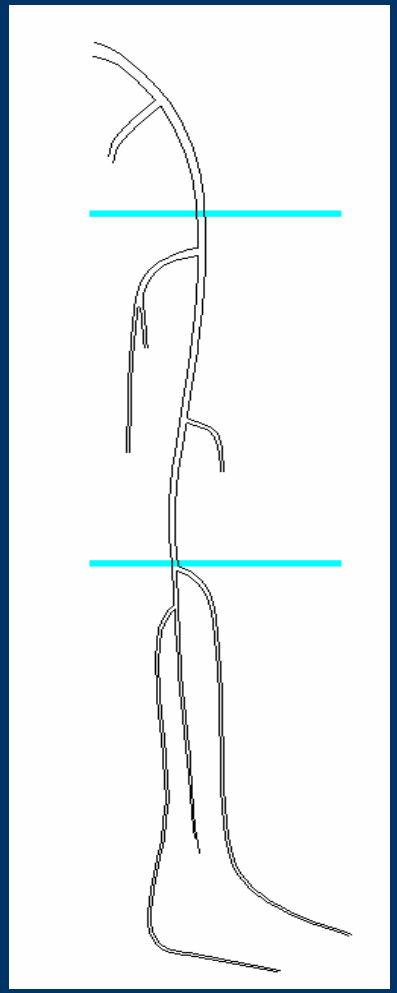
Lesion Length



	n°	Mean length
	91	33±28 mm
	782	80±63 mm
	1292	109±86 mm

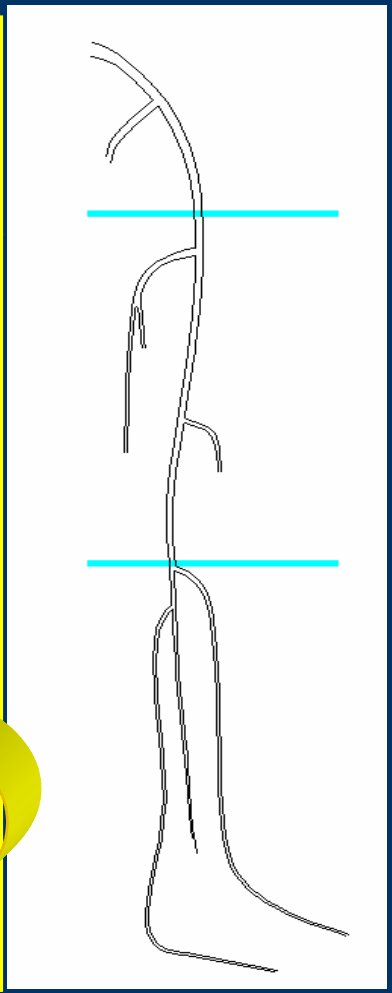
Chronic Total Occlusion

14/91	15 %
295/782	38 %
478/1292	37 %



CTO: *Subintimal approach*

0/91	0 %
49/782	6 %
86/1292	7 %



CTO: *Subintimal approach*

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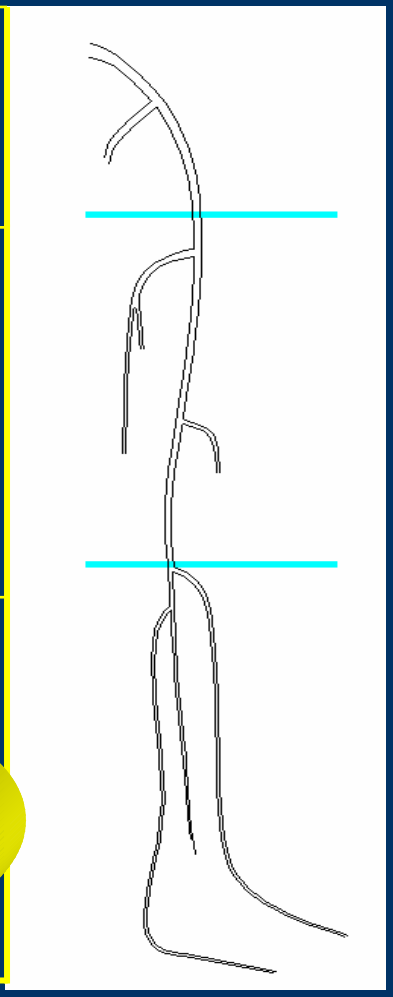
Stenting

73/91	80 %
245/782	31 %
65/1292	5 %



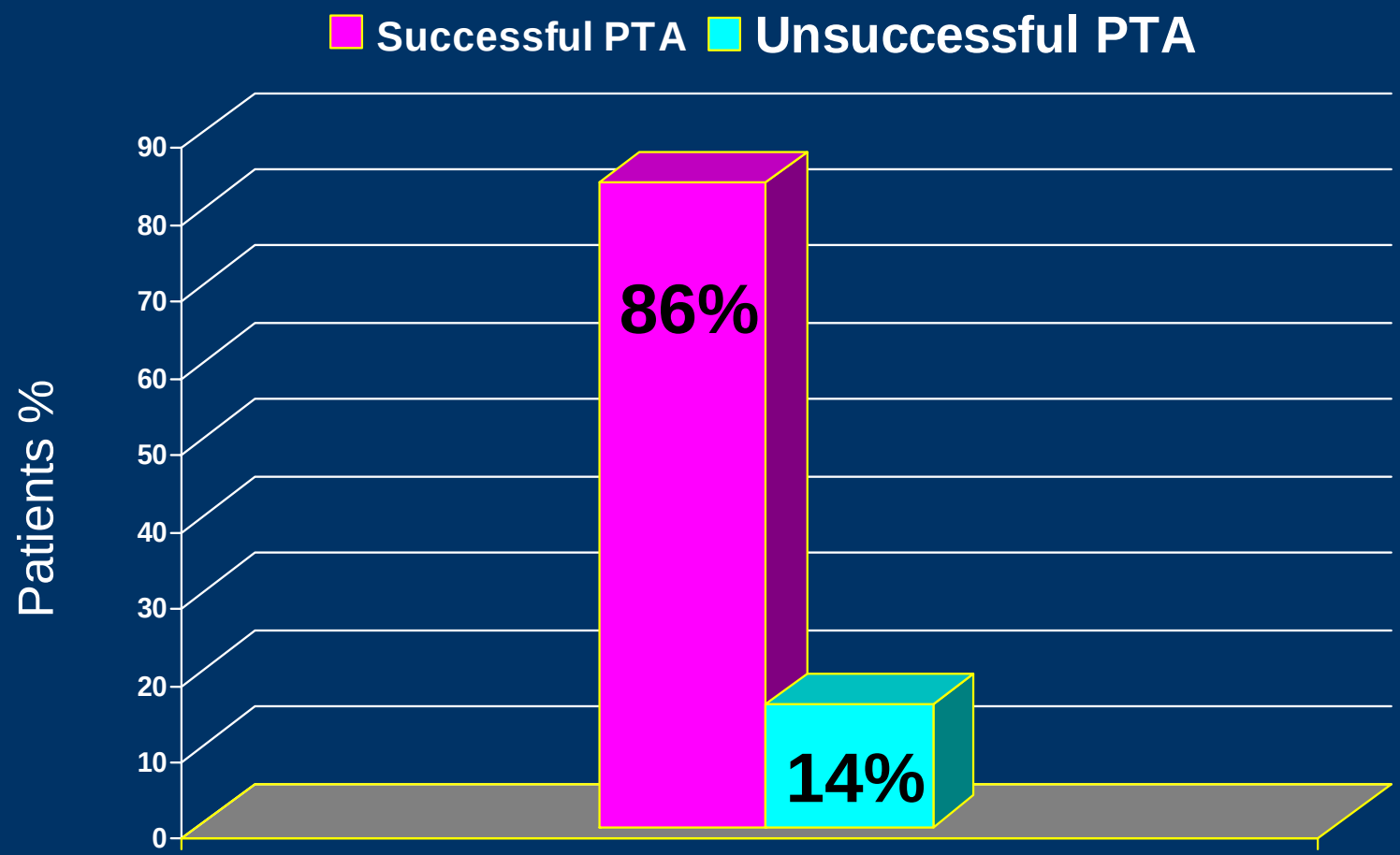
55% Coronary stent

45% Self-expanding stent

Stented segment length 38 mm

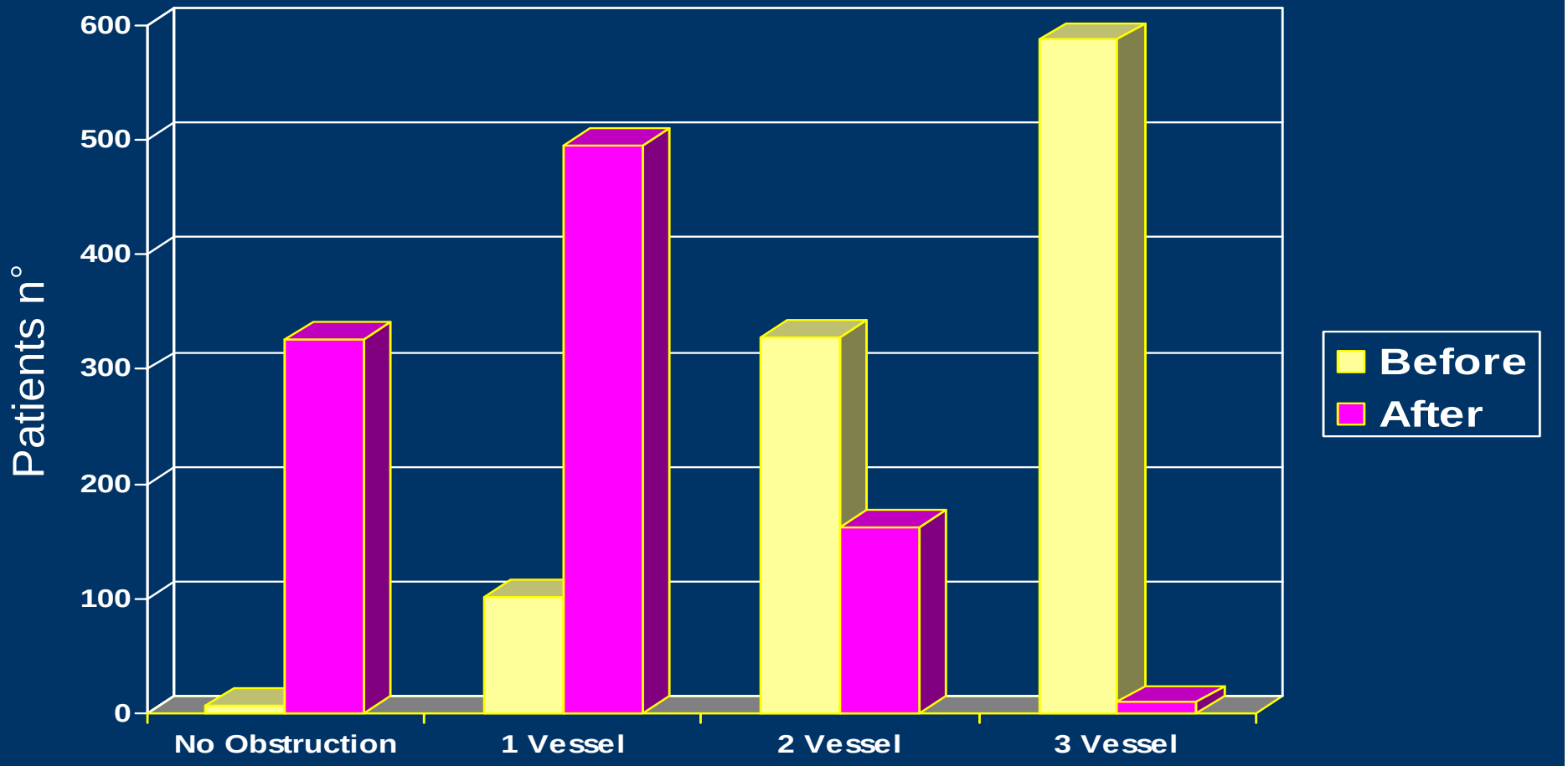
PTA below the Knee: *Angiographic Results*

1.47 lesion/patients



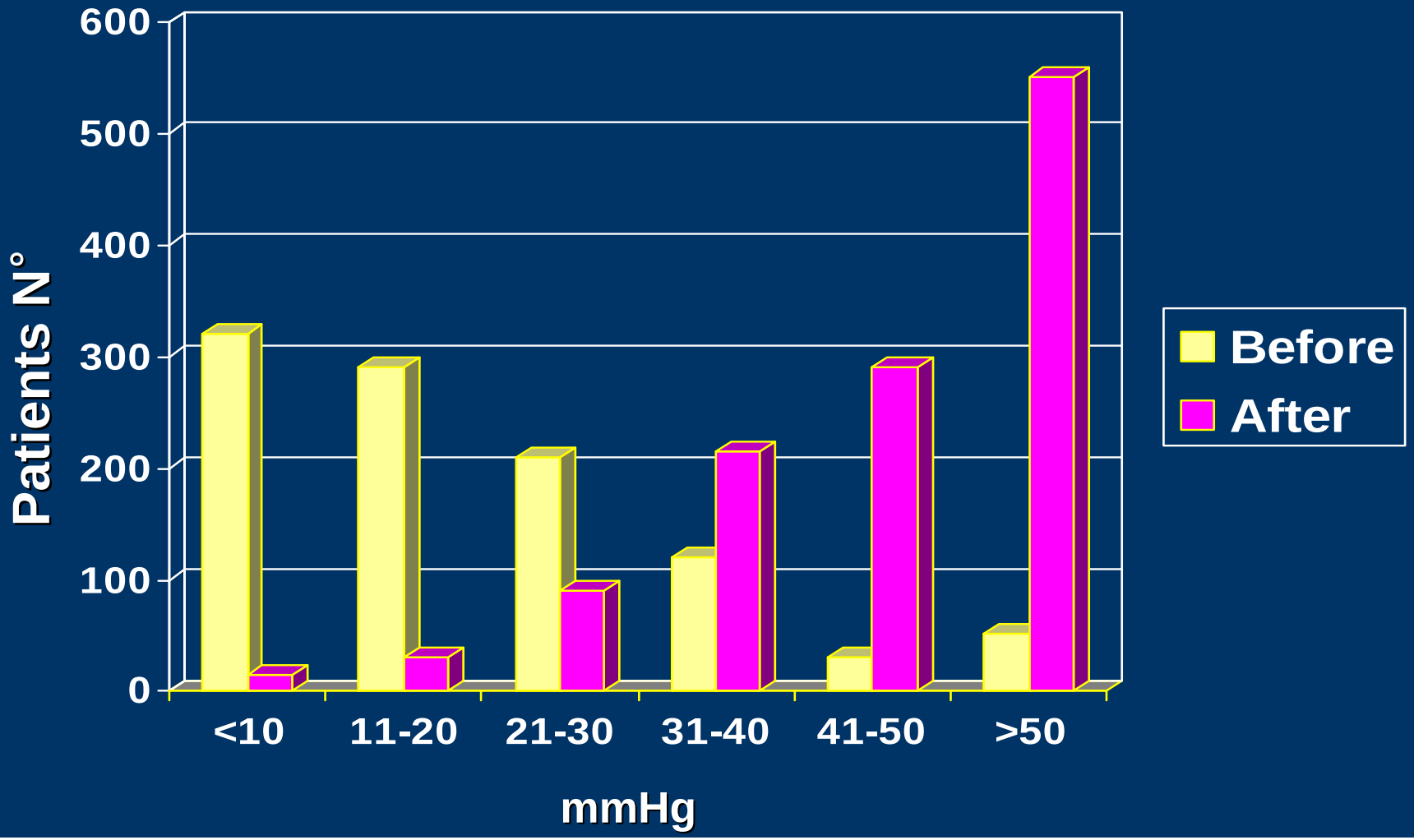
PTA below the Knee: *Angiographic Results*

N° of patients with obstructions in the infrapopliteal arteries before and after PTA (N=1013)



TcPO2 values distribution before and after PTA

PRE= 23±14 mmHg POST= 46±15 mmHg



In-Hospital Complications (n 1013)

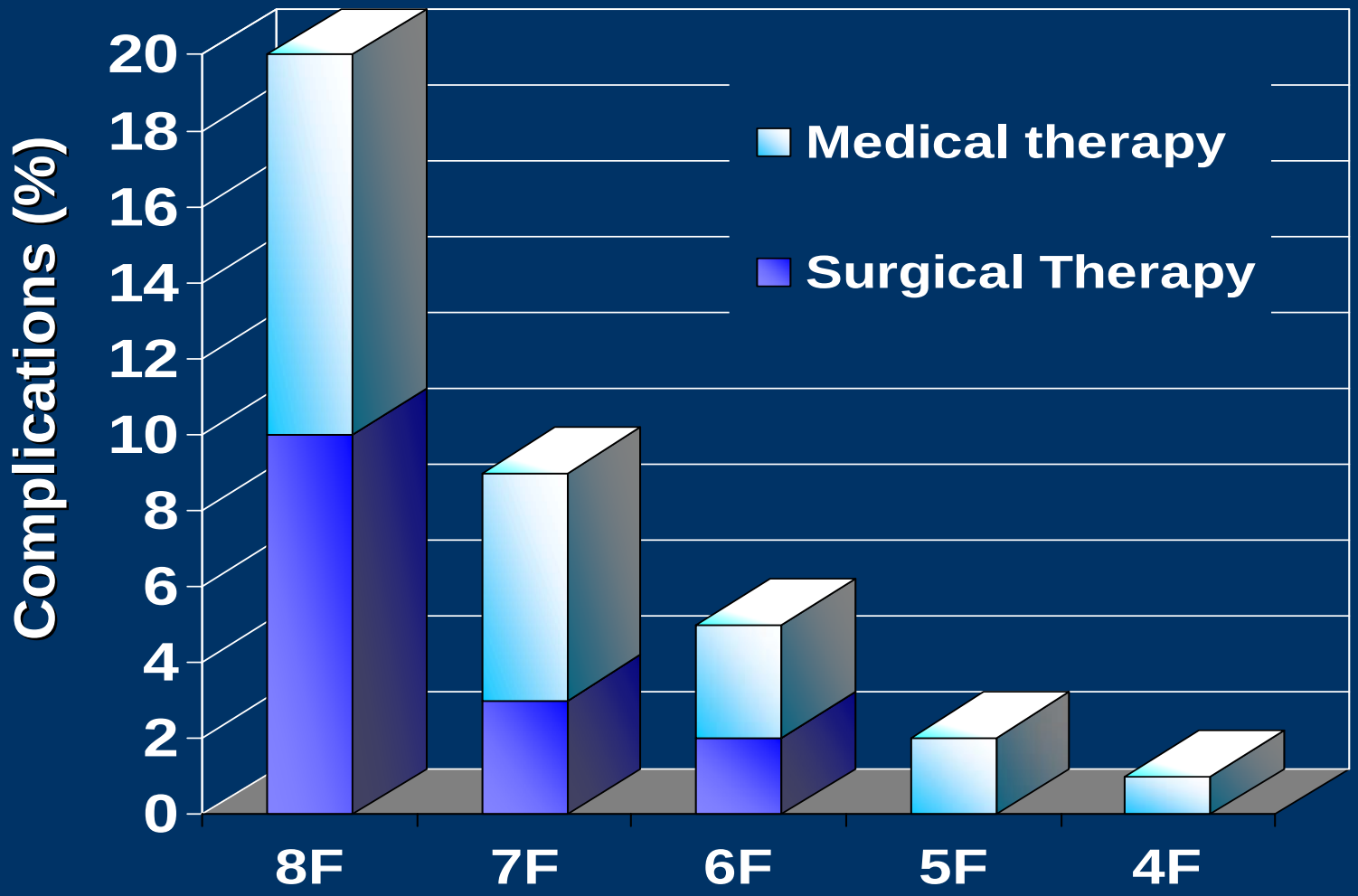
Cardiac death	3	
Myocardial Infarction	2	
Angina	1	
LV failure	2	
Acute Renal failure	1	
Access site complications	18	
Distal embolization	2	
Total	**29**	**(2.8%)**

Site Access Complications

Therapy:	Medical	Surgical
Groin hematoma	10	2
Retroperitoneal hematoma	4	1
Acute femoral thrombosis	-	1
Total (1013 Pts)	14	4
	2 %	

All complications are antegrade femoral approach related

Complications and sheath dimensions



P<0.05

Clinical restenosis (FU 12 ± 9 Mo)

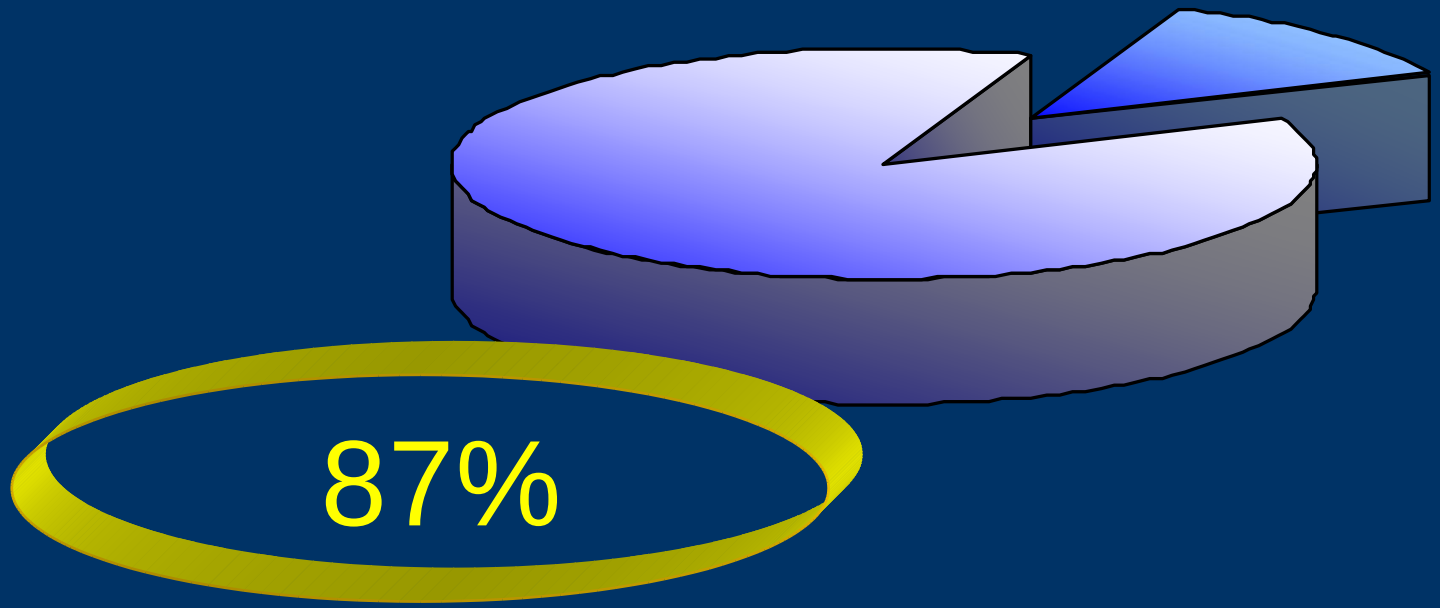
Clinical restenosis	**121 patients (12%)**
- Repeat PTA	88 patients
- Bypass	8 patients
- Medical therapy	25 patients

Limb Salvage (FU 12 ± 9 Mo)

Salvage of a foot suitable for prosthesis

Amputated 135/1044

13%



Saved 909/1044

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Conclusions

- PTA should be considerd the first-choice for revascularization in diabetic ischemic foot.
- PTA is feasible in most patients (90%), complications are infrequent and mortality is very low.
- Clinical restenosis was an infrequent finding and the procedure could be succesfully repeated in most cases.