

Minicorso GISE:
Interventistica per gli arti inferiori
e per il piede diabetico

Caso Clinico Interattivo 1

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DISCLOSURE

- **Consultant:** Boston Scientific, Cordis, Mediolanum Cardio Research
- **Lecture fees:** Bristol-Myers Squibb



LEARNING GOALS

- What is the optimal diagnostic approach to patients with claudication and stenoses/occlusions of the SFA?
- What is the optimal revascularization approach to such patients?
- What is the role of stenting in the SFA?
- What is the recommended peri- and post-procedural management?

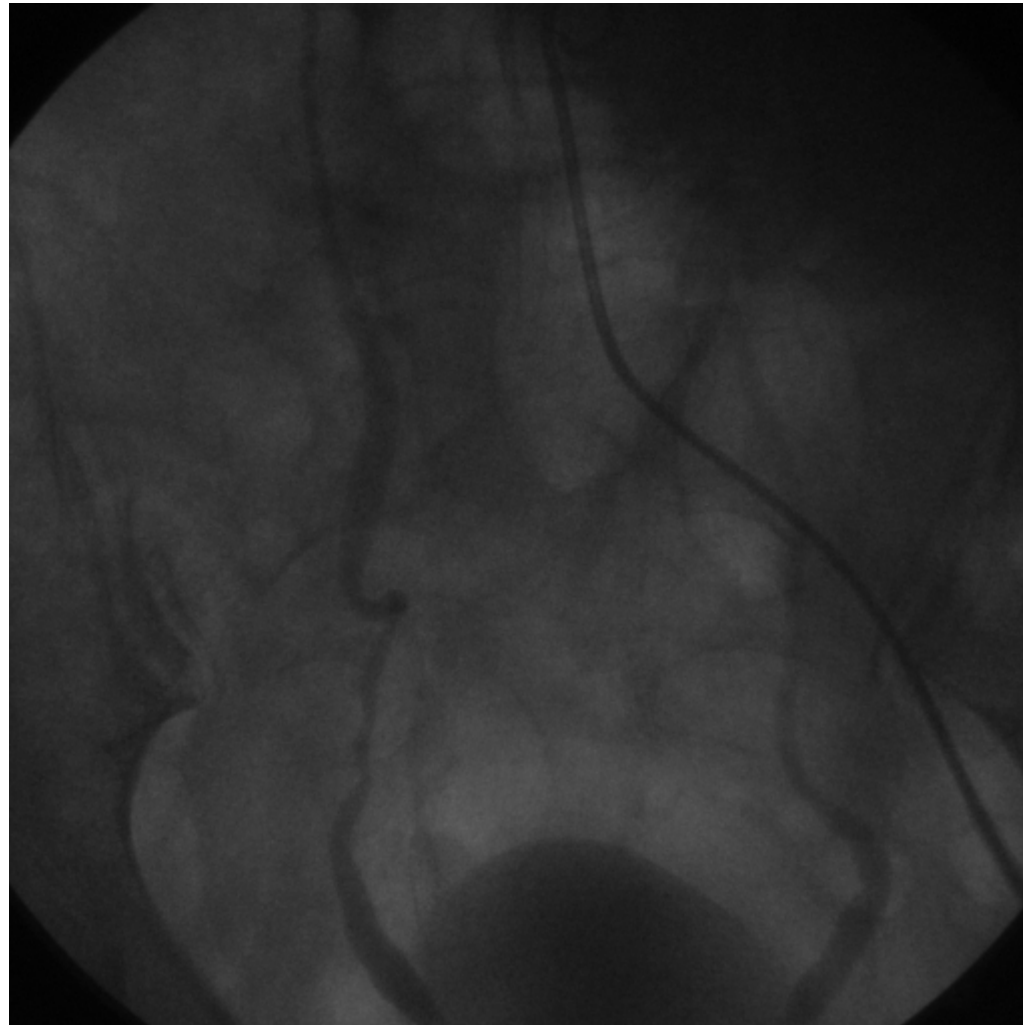


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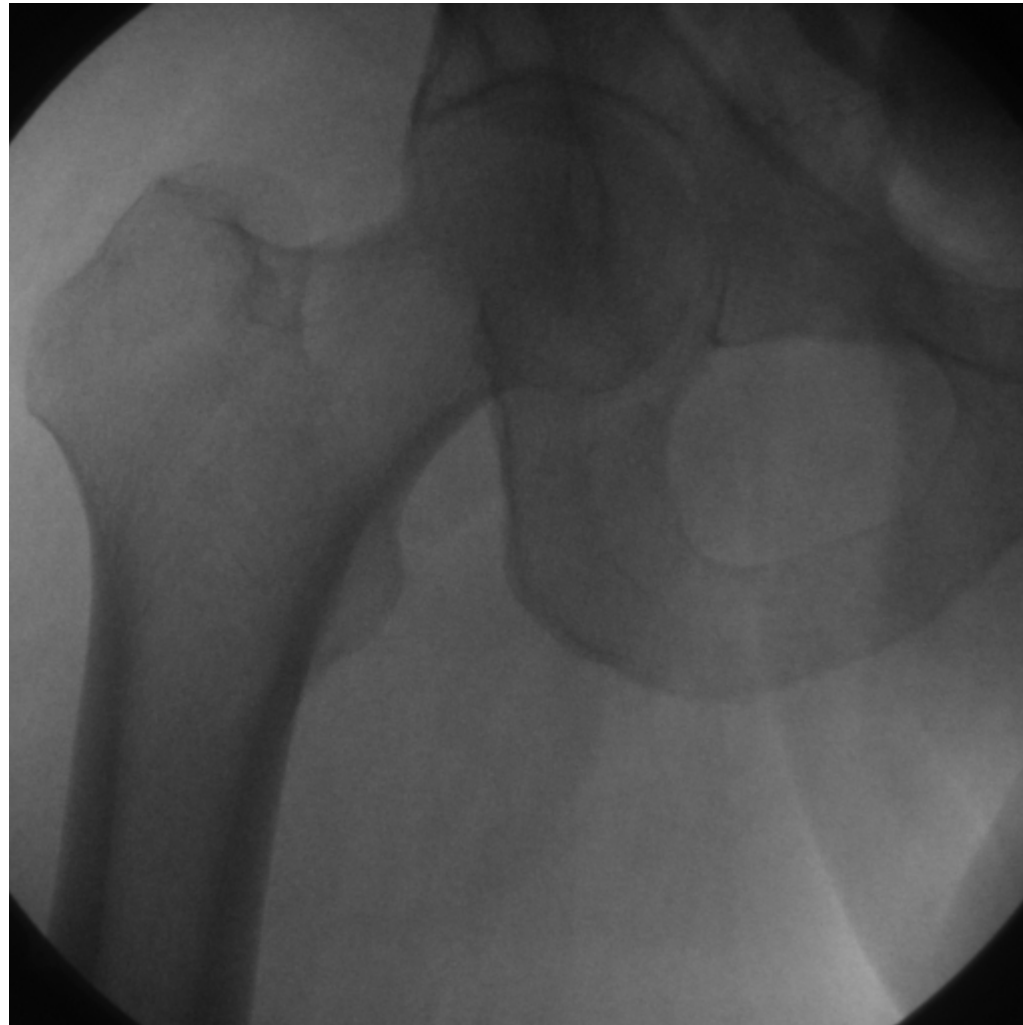


A 56-Y-O MAN WITH CLAUDICATION



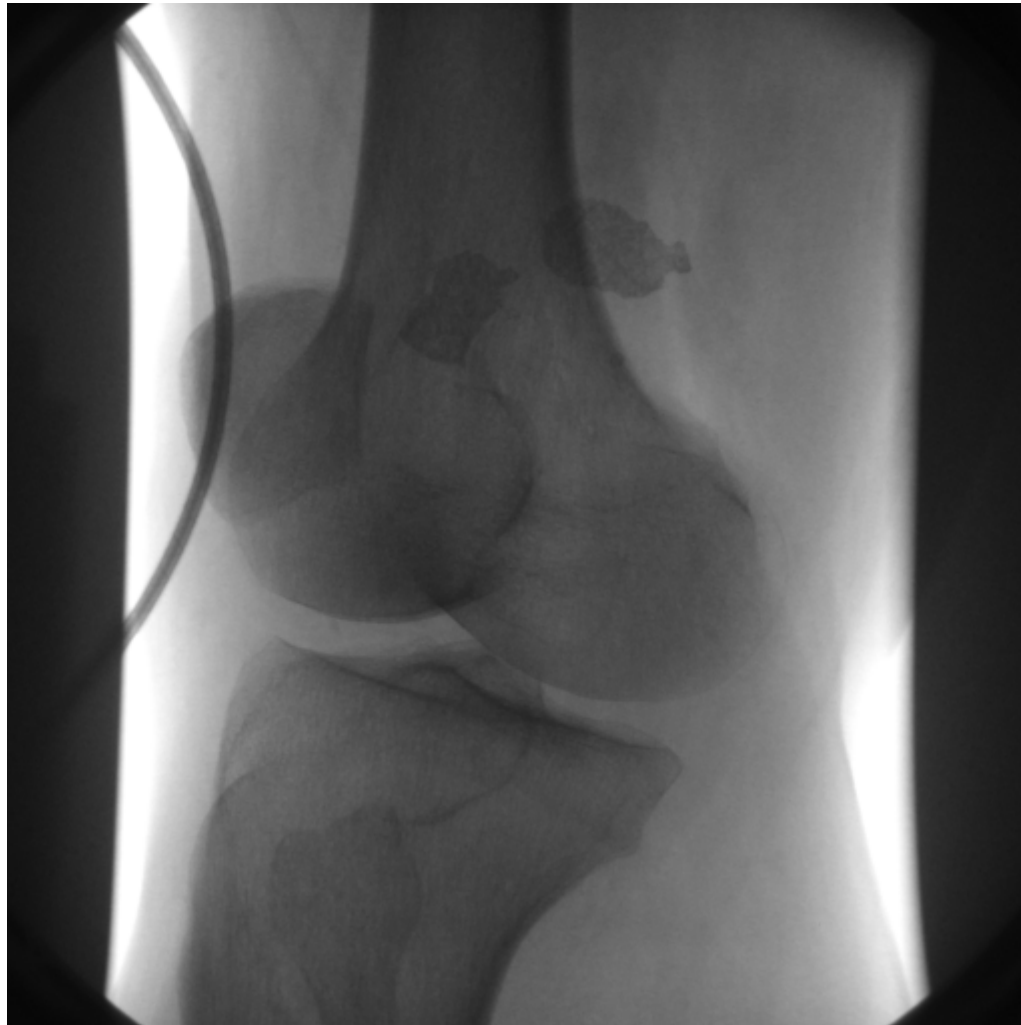


A 56-Y-O MAN WITH CLAUDICATION





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LEARNING GOALS

- What is the optimal diagnostic approach to patients with claudication and stenoses/occlusions of the SFA?
- **What is the optimal revascularization approach to such patients?**
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- **What is the role of stenting in the SFA?**
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MEET 2007

(June 13-17, 2007 • Cannes, France)

FAST

(**F**emoral **A**rtery **S**tenting **T**rial)
Final Results

Sven Braunlich

(on behalf of the FAST Investigators)

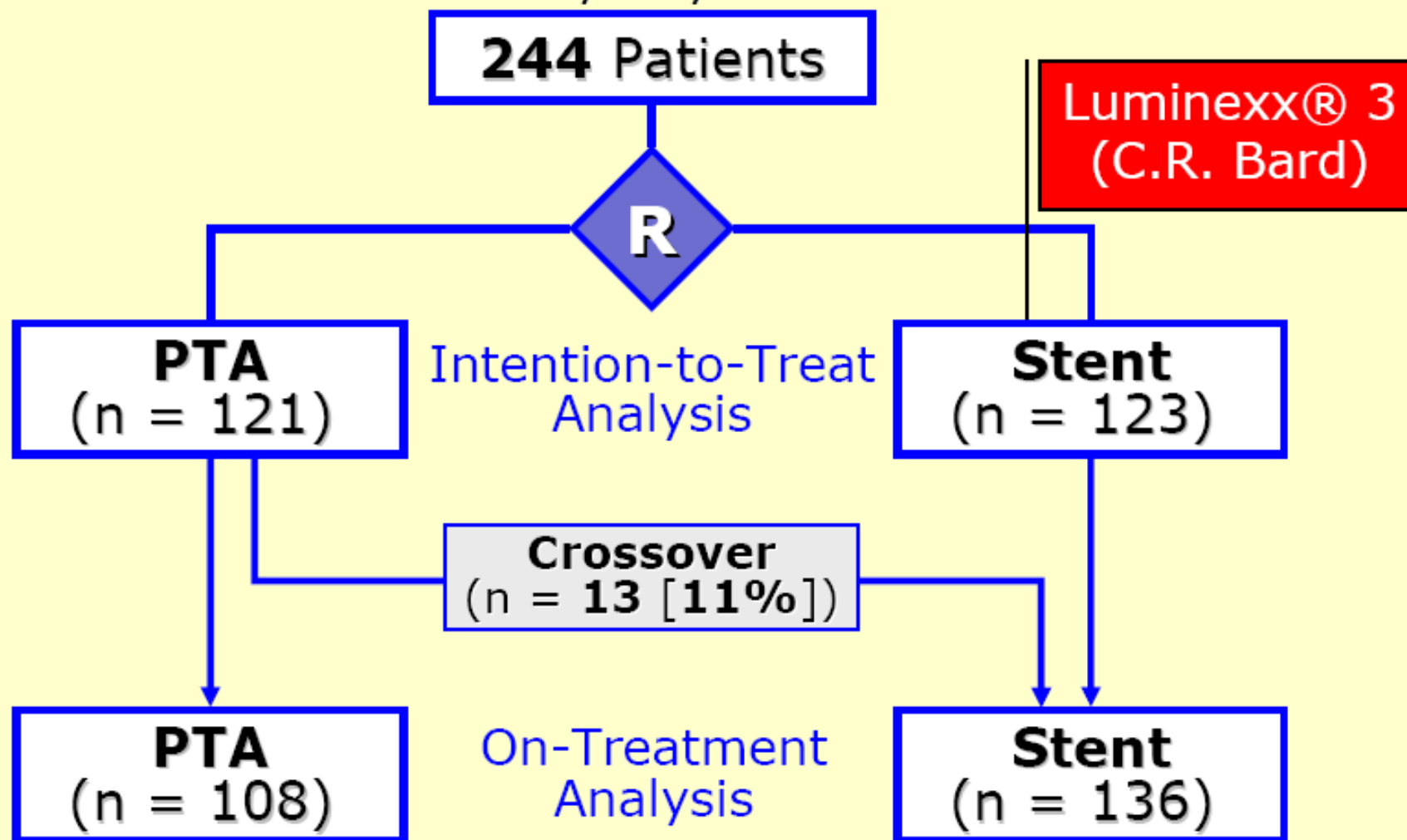
University of Leipzig – Heart center

Medical Clinic I, Angiology – Park Hospital Leipzig



FAST Trial Profile

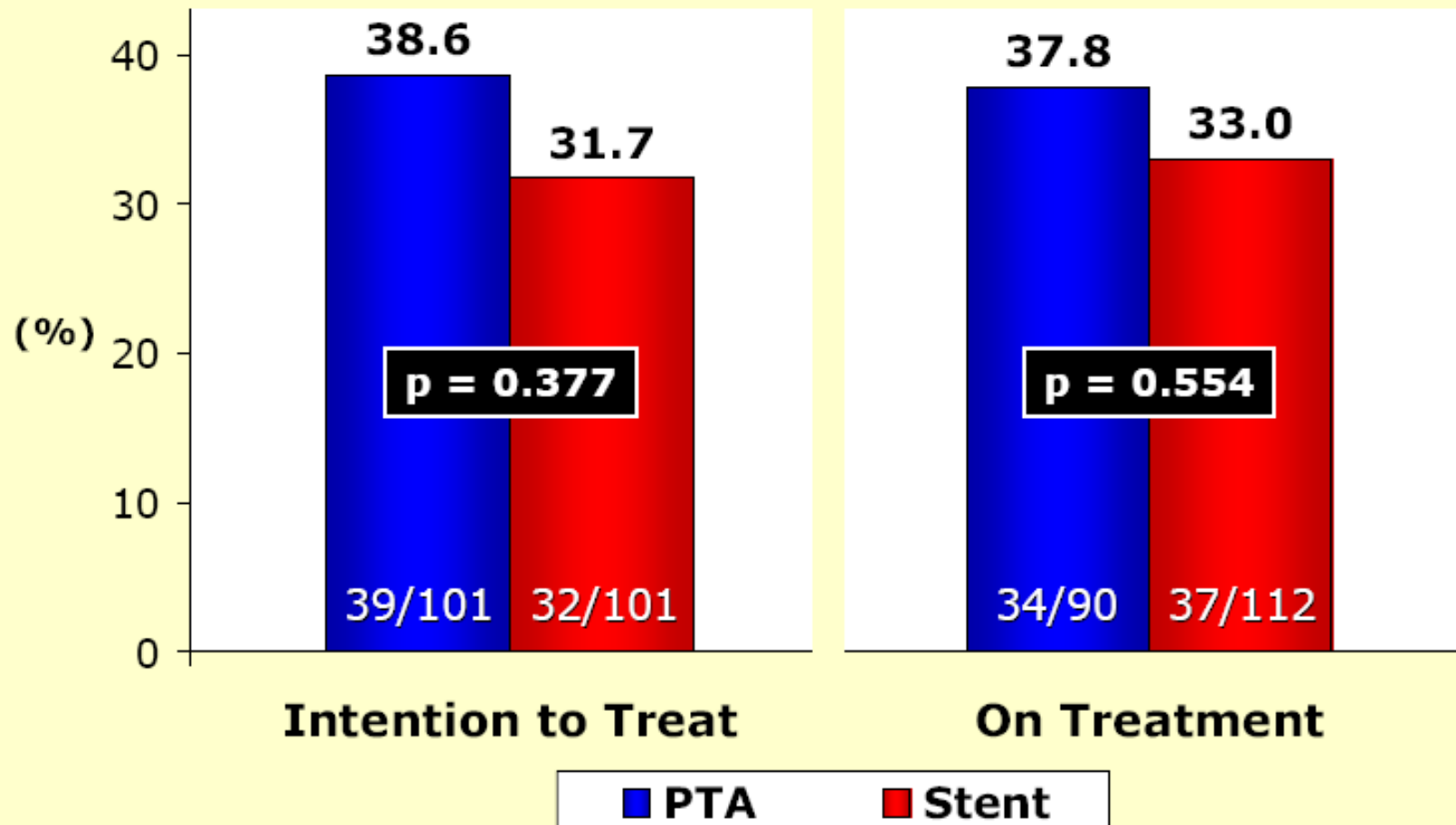
12/03-3/05:



FAST

12-Month Results

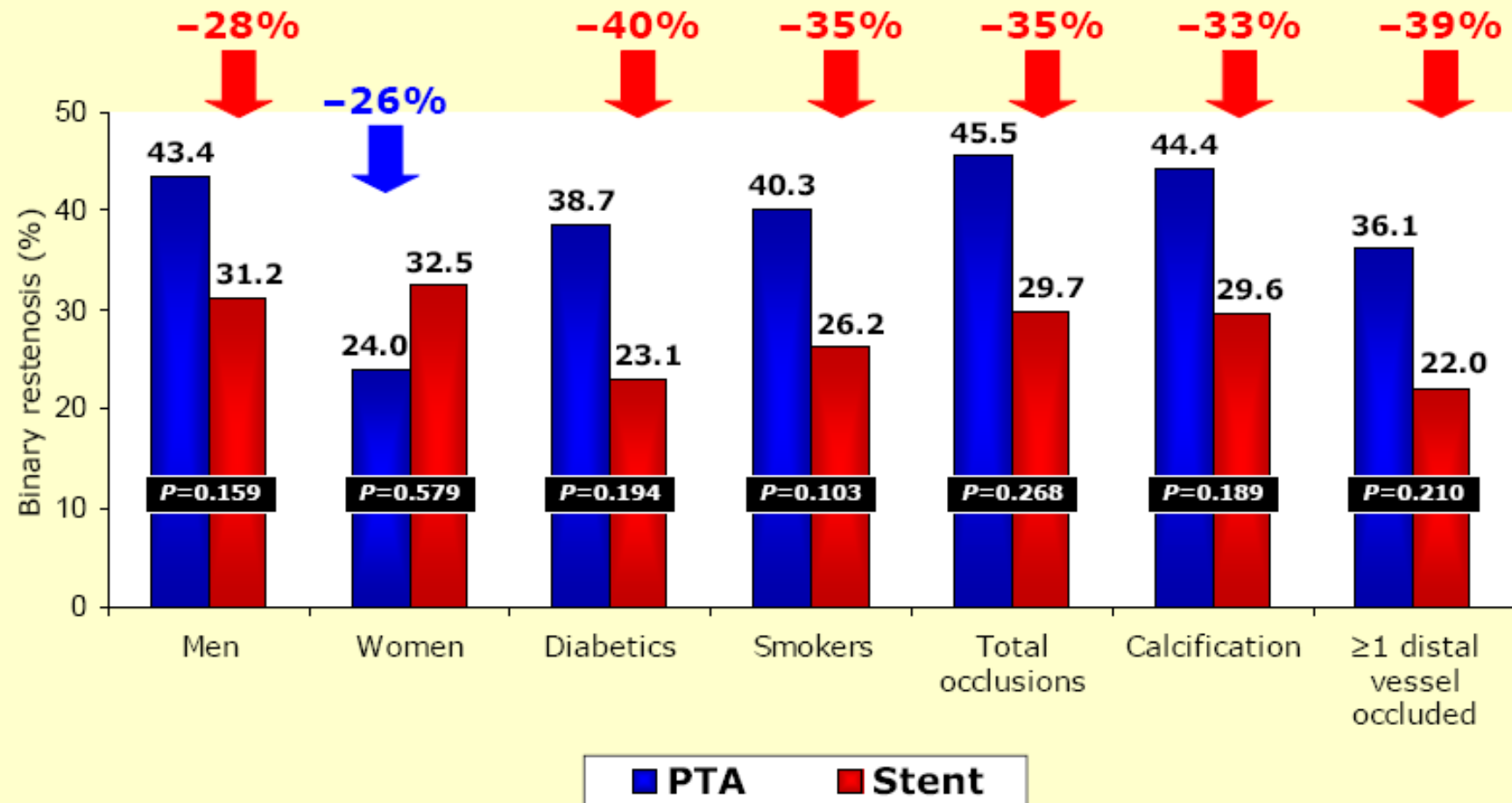
- Binary Restenosis (**1st** End Point)



FAST

12-Month Results - ITT

- Binary restenosis by patient/lesion subgroups



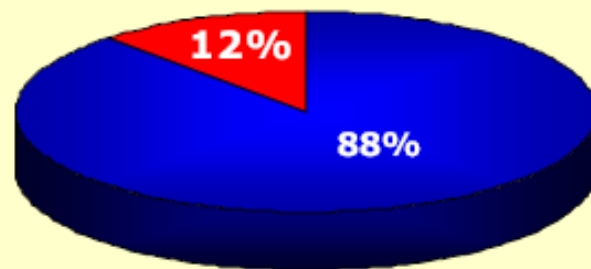
FAST

12-Month Results – ITT

- **Stent fractures**

- X-ray in 83/101 stent patients in whom restenosis was assessed @ 12 months
- 10 stent fractures

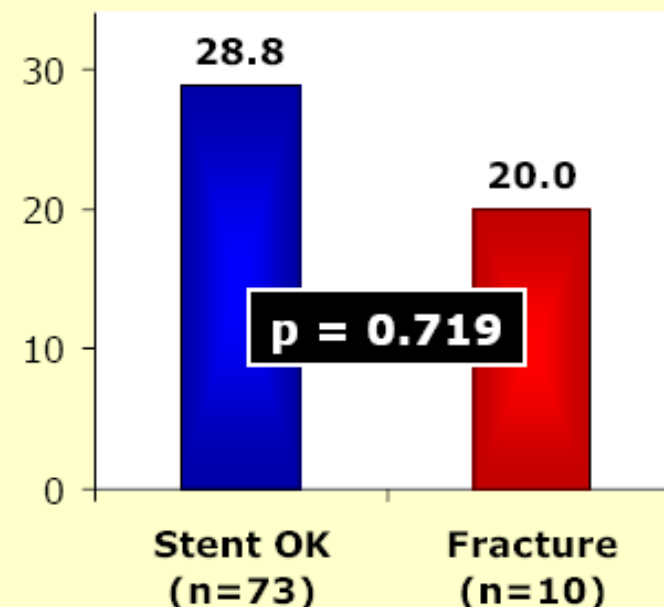
Stent Integrity



■ OK (n=73)

■ Fracture (n=10)

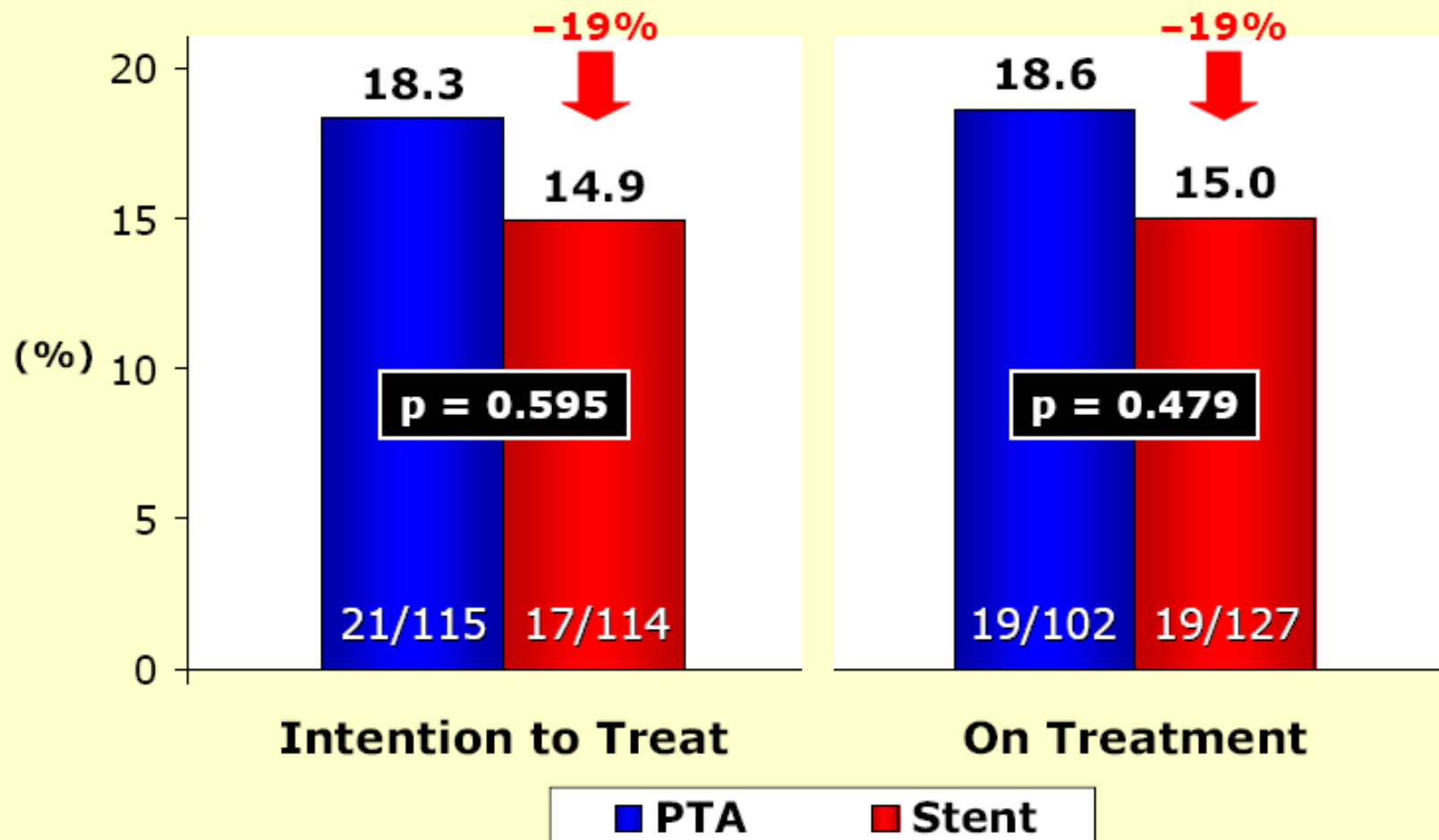
Binary Restenosis (%)



FAST

12-Month Results

- Target Lesion Revascularizations





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Balloon Angioplasty versus Implantation of Nitinol Stents in the Superficial Femoral Artery

Martin Schillinger, M.D., Schila Sabeti, M.D., Christian Loewe, M.D., Petra Dick, M.D., Jasmin Amighi, M.D., Wolfgang Mlekusch, M.D., Oliver Schlager, M.D., Manfred Cejna, M.D., Johannes Lammer, M.D., and Erich Minar, M.D.

METHODS

We randomly assigned 104 patients who had severe claudication or chronic limb ischemia due to stenosis or occlusion of the superficial femoral artery to undergo primary stent implantation (51 patients) or angioplasty (53 patients). Restenosis and clinical outcomes were assessed at 6 and 12 months.

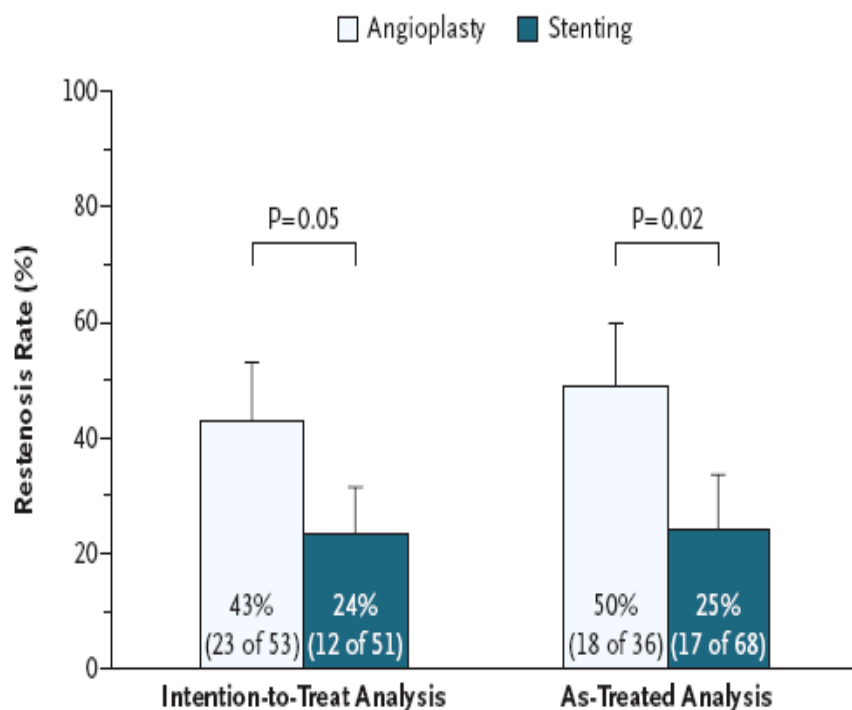
RESULTS

The mean (\pm SD) length of the treated segment was 132 ± 71 mm in the stent group and 127 ± 55 mm in the angioplasty group. Secondary stenting was performed in 17 of 53 patients (32 percent) in the angioplasty group, in most cases because of a sub-optimal result after angioplasty. At 6 months, the rate of restenosis on angiography was 24 percent in the stent group and 43 percent in the angioplasty group ($P=0.05$); at 12 months the rates on duplex ultrasonography were 37 percent and 63 percent, respectively ($P=0.01$). Patients in the stent group were able to walk significantly farther on a treadmill at 6 and 12 months than those in the angioplasty group.

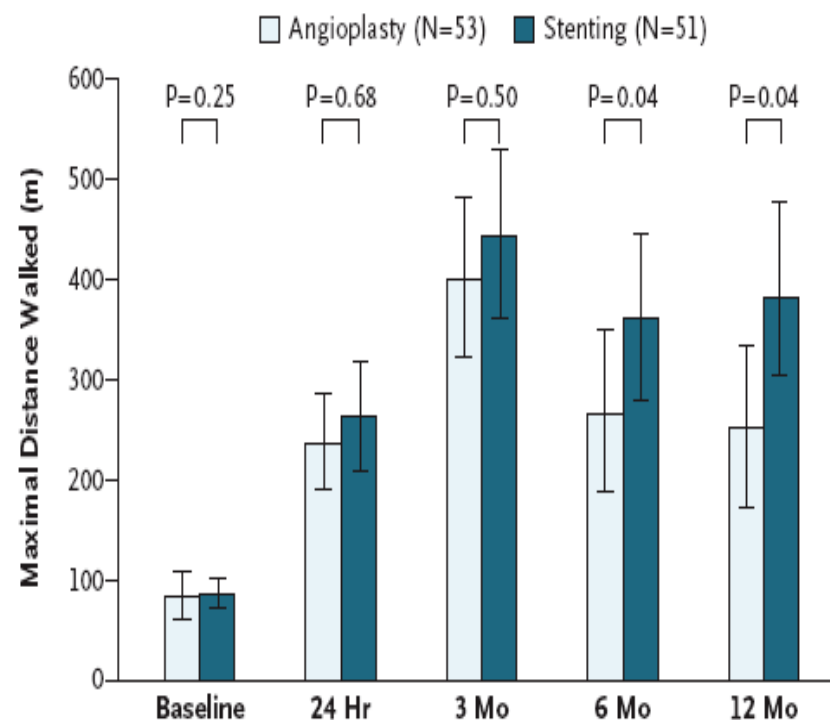


Balloon-angioplasty vs stenting in the SFA

Binary angiographic restenosis



Maximum walking distance





Balloon-angioplasty vs stenting in the SFA

Outcome	Stent Group (N= 51)	Angioplasty Group (N= 53)	P Value
Maximal angiographic degree of stenosis at 6 mo — %	30±30	50±30	0.01
Clinical worsening — no./total no. of patients (%)†			
Within 30 days	0/51	0/53	—
Within 3 mo	0/51	0/53	—
Within 6 mo	1/51 (2)	1/53 (2)	0.99
Within 12 mo	1/49 (2)	1/52 (2)	0.99
Thrombosis or reocclusion within 12 mo — no./total no. of patients (%)	6/49 (12)	6/52 (12)	0.99
Ipsilateral reintervention within 12 mo — no./total no. of patients (%)			
Balloon angioplasty	10/49 (20)	15/52 (29)	0.45
Stent implantation	1/49 (2)	1/52 (2)	0.99
Bypass surgery (supragenicular)	3/49 (6)	0/52	0.22
Stent fracture — no./total no. of patients (%)			
Within 6 mo	1/51 (2)	0/17	0.99
Within 12 mo	1/49 (2)	0/17	0.99
Amputation — no./ total no. of patients (%)			
Within 6 mo	0/51	0/53	—
Within 12 mo	0/51	0/53	—
Death — no./total no. of patients (%)			
Within 6 mo	0/51	0/53	—
Within 12 mo	1/51 (2)	0/53	0.99



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QUESTIONS?



TAKE HOME MESSAGES

- The default diagnostic strategy for SFA lesions, after non-invasive evaluation, should be a retrograde contralateral approach, unless infra-popliteal disease is very likely
- A gentle approach with a 0.035" wire is often successful. In case of difficulties, down-sizing to 0.018" or 0.014" wires is recommended
- After predilation and optimal balloon dilation, we recommend stenting with self-expandable devices to tackle up dissections and resistant plaques
- Peri- and post-procedural dual antiplatelet therapy is recommended for at least 1 month