

SFA Lesions in Diabetic Patients- What is different and how to approach

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting (Biotronik)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

Increased Burden of Diabetes mellitus

The International Diabetes Federation estimates that there are 381.8 million people with diabetes in 2013 with a projected increase of 55% to 591.9 million by 2035 ¹

Globally, 45.8% of all cases, or 174.8 million people, are estimated to have undiagnosed DM in 2013. ²

Undiagnosed diabetes has been reported to carry a similar risk of mortality to diagnosed diabetes, and is associated with a 1.5- to 3.0-fold higher risk of cardiovascular complication compared to normoglycaemic individuals ³

Nitinolstents in DM in the SFA

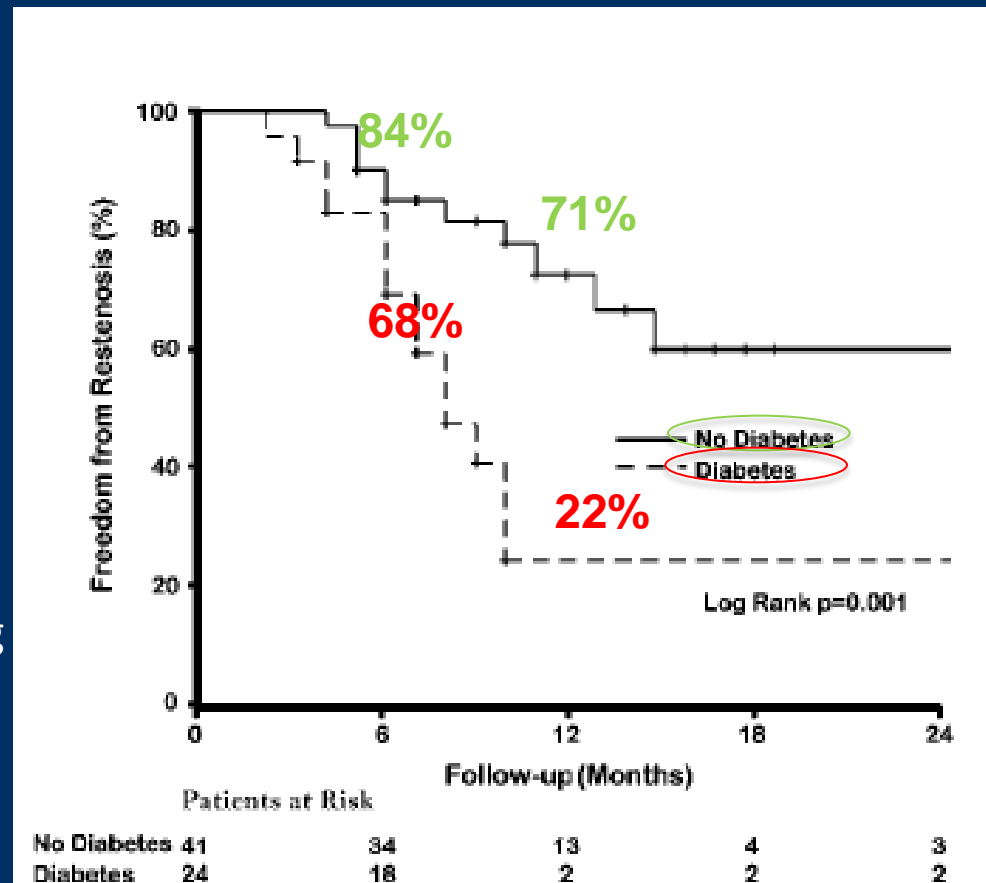
Retrospectiv cohort Study, n=65 femoro-popliteal lesions, mean length 16 cm (10-40 cm), treatment with PTA & SNS

.....Notably, all diabetic patients with restenosis exhibited **diffuse** recurrence!

.....Diabetes mellitus was associated with a **3.8-fold increased** adjusted risk for in-stent restenosis (95% CI 1.3 to 10.9, p=0.01).

.....**Hyperglycemia likely augments the hypertrophic** wound healing in response to vessel wall trauma following Implantation...

(Park et al. Circ 2001;101:815-19))



Nitinolstents in DM in the SFA

Retrospectiv cohort Study 2002-2005, n=385 interventions, Diabetes 57.2%

- Rutherford II-III (52%), IV (16.4%), V-VI (31.4%)
- PTA/Stent 85.2% & Atherectomy (14.8%)

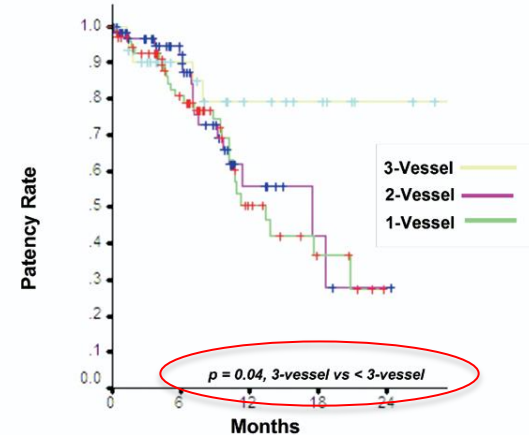
...Patients with diabetes demonstrate **advanced stage of disease** at presentation.....

	Diabetics	Nondiabetics	All	P value
Number of runoff vessels (n = 184 [†])				
Three-vessel	16 (16.5%)	25 (28.7%)	40 (22.0%)	P ≥ .05, ns
Two-vessel	38 (39.2%)	29 (33.3%)	67 (36.4%)	
Single-vessel	43 (44.3%)	33 (37.9%)	77 (41.6%)	
TASC classification* (n = 385)				P ≥ .10, ns
TASC A	9 (4.1%)	10 (6.1%)	20 (5.2%)	
TASC B	59 (26.8%)	46 (27.8%)	111 (28.8%)	
TASC C	85 (38.6%)	53 (32.2%)	135 (35.1%)	
TASC D	67 (30.5%)	56 (33.9%)	119 (30.9%)	

*For femoropopliteal lesions.

[†]Full completion angiograms of lower leg available for review.

Primary Patency Rate Stratified by Number of Tibial Outflow Vessels



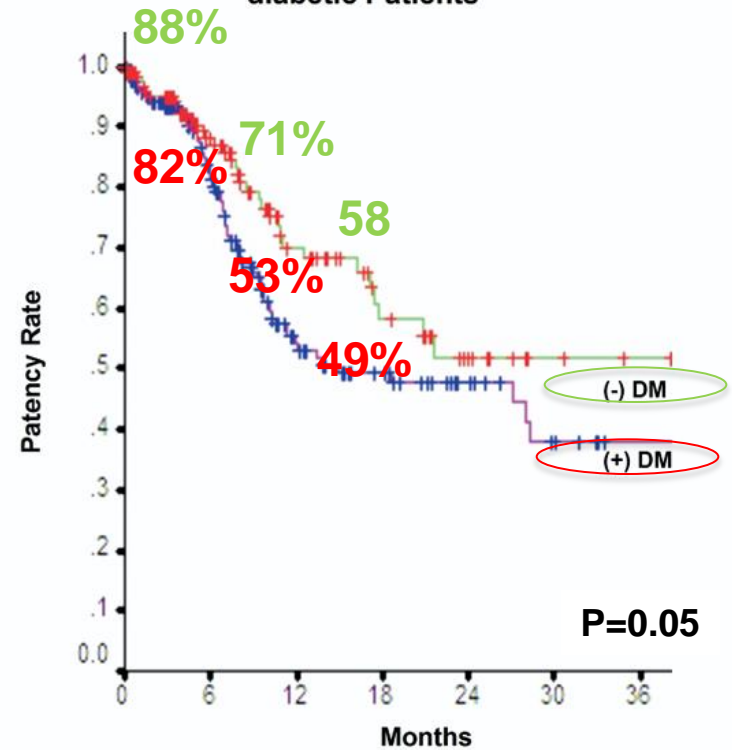
No. at Risk (3-vessel):	34	26	14	6	3
No. at Risk (2-vessel):	67	38	9	3	2
No. at Risk (1-vessel):	76	46	16	7	3

SFA Lesions in Diabetic Patients

Retrospectiv cohort Study 2002-2005, n=385 interventions, Diabetes 57.2%

...the **advanced stage of disease** at presentation most likely leads to a reduced primary patency rates after percutaneous treatment

Primary Patency Rate of Treated Limbs in Diabetic and Non-diabetic Patients



No. at Risk (-DM):	137	80	41	22	15	6	3
No. at Risk (+DM):	199	113	47	38	29	12	6

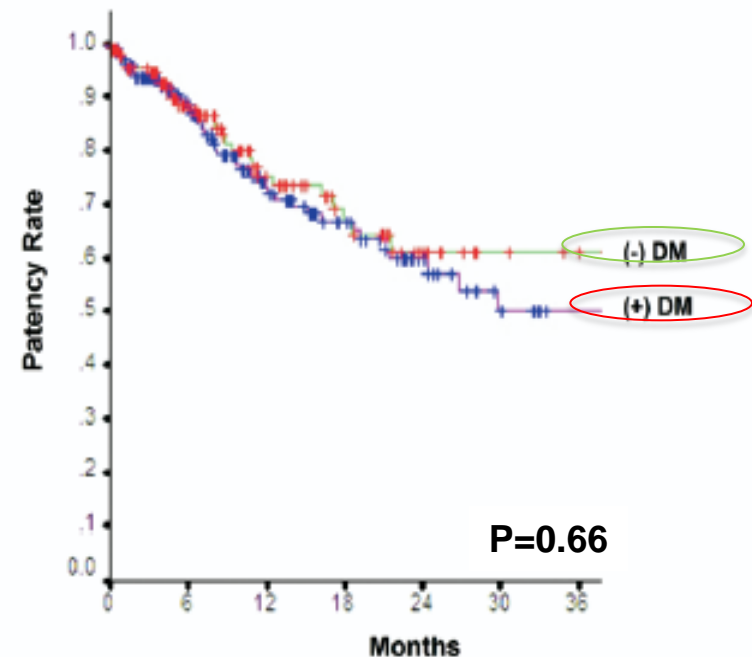
SFA Lesions in Diabetic Patients

Retrospectiv cohort Study 2002-2005, n=385 interventions, Diabetes 57.2%

TLR in DM vs non-DM 20.7% vs 12.7%; **p=0.1**

...**secondary patency did not differ**
...when examining rates for diabetics
and nondiabetics (p=0.66)!

Secondary Patency Rate of Treated Limbs in Diabetic and Non-diabetic Patients



No. at Risk (-DM):	137	87	45	27	20	7	4
No. at Risk (+DM):	199	129	65	46	31	13	7

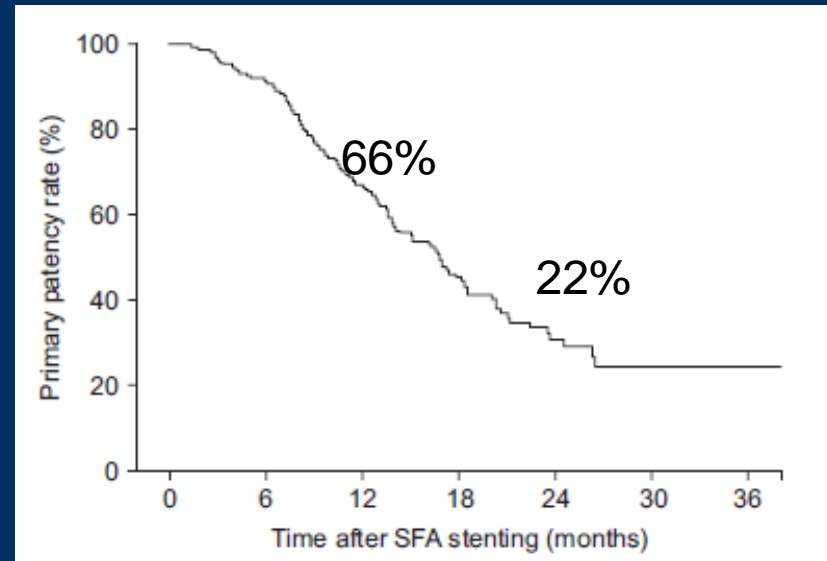
Nitinolstents in DM in the SFA

A retrospective database from January 2009 to December 2013, 168 patients, mean lesion length 10.32 cm

- Primary endpoint:
Patency rates
- Secondary endpoints:
Risk factors related to Reintervention
(patients and lesions variables)

Multivariate analysis:

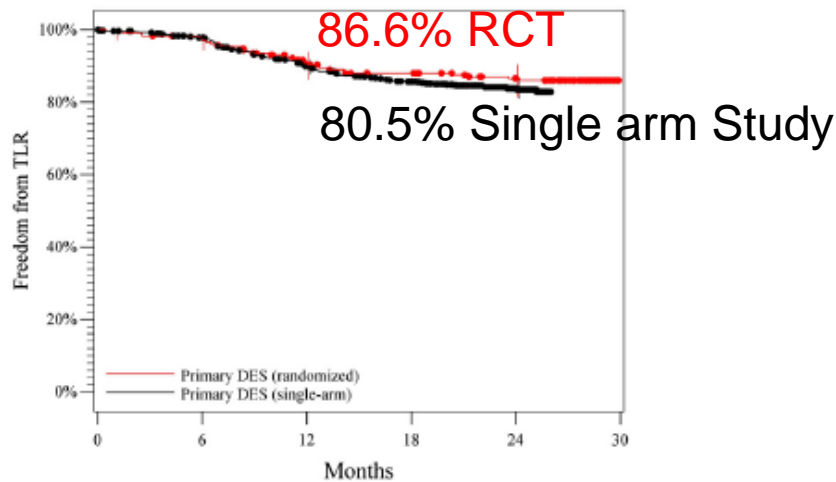
- Nr. of patent tibial arteries (HR 0.349; $p=0.028$)
- Diabetes mellitus (HR 3.420, $p=0.035$)



Zilver PTX in DM in the SFA

Zilver PTX Freedom from TLR @ 2 years

Covariate analysis



Kaplan Meier Estimates of Freedom from TLR, Values Represent Patients								
Months Post-procedure	Freedom from TLR ± Standard Error		Cumulative Failed		Cumulative Censored		Remaining at Risk	
	Primary DES (randomized)	Primary DES (single-arm)	Primary DES (randomized)	Primary DES (single-arm)	Primary DES (randomized)	Primary DES (single-arm)	Primary DES (randomized)	Primary DES (single-arm)
0	100.0 ± 0.0%	100.0 ± 0.0%	0	0	0	6	235	778
1	99.6 ± 0.4%	99.6 ± 0.2%	1	3	0	13	234	768
6	97.4 ± 1.0%	97.7 ± 0.5%	6	17	3	42	226	725
12	90.8 ± 1.9%	89.3 ± 1.2%	21	77	16	144	198	563
24	86.6 ± 2.3%	80.5 ± 1.7%	30	120	32	423	173	241

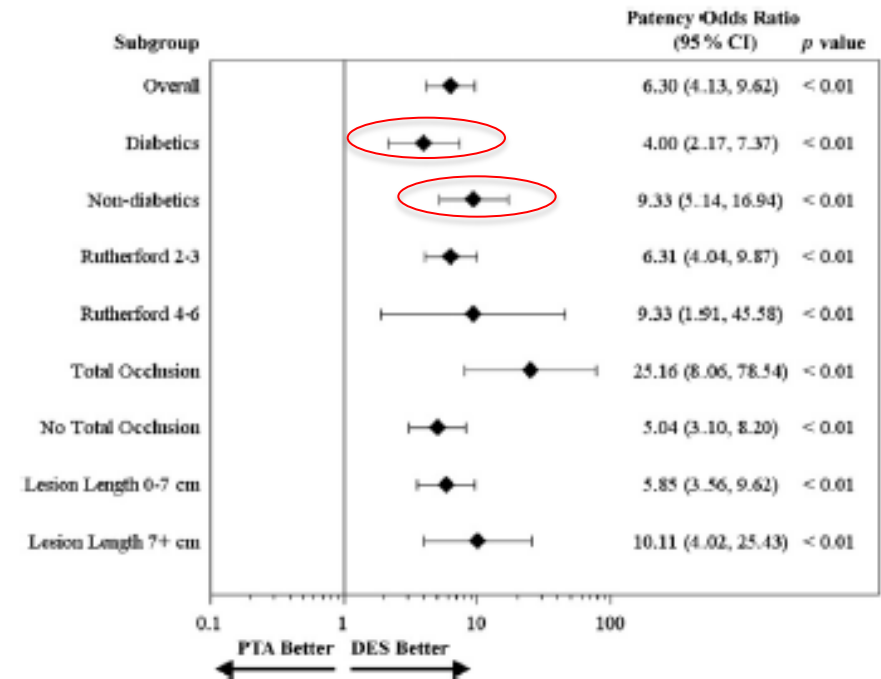


Figure 5

Patency Odds Ratio for DES Compared With BMS Among Subgroups of Interest

The diamonds indicate the point estimates, and the lines indicate the 95% confidence intervals (CIs). BMS = bare-metal stent(s); DES = drug-eluting stent(s).

DA-Atherectomy in DM in the SFA

Prospective single-arm multicenter study 4/2009-4/2011, n=800, Diabetes 52.3%
 lesion length 7.4 ± 5.3 cm

Technical outcome in the total cohort:

- Device success in 74.9%
- Procedural success 89.1% (<30% stenosis)
- Bail out stenting 3.2%
- 30 days MAE 1.6%
- Arterial perforation 5.3%

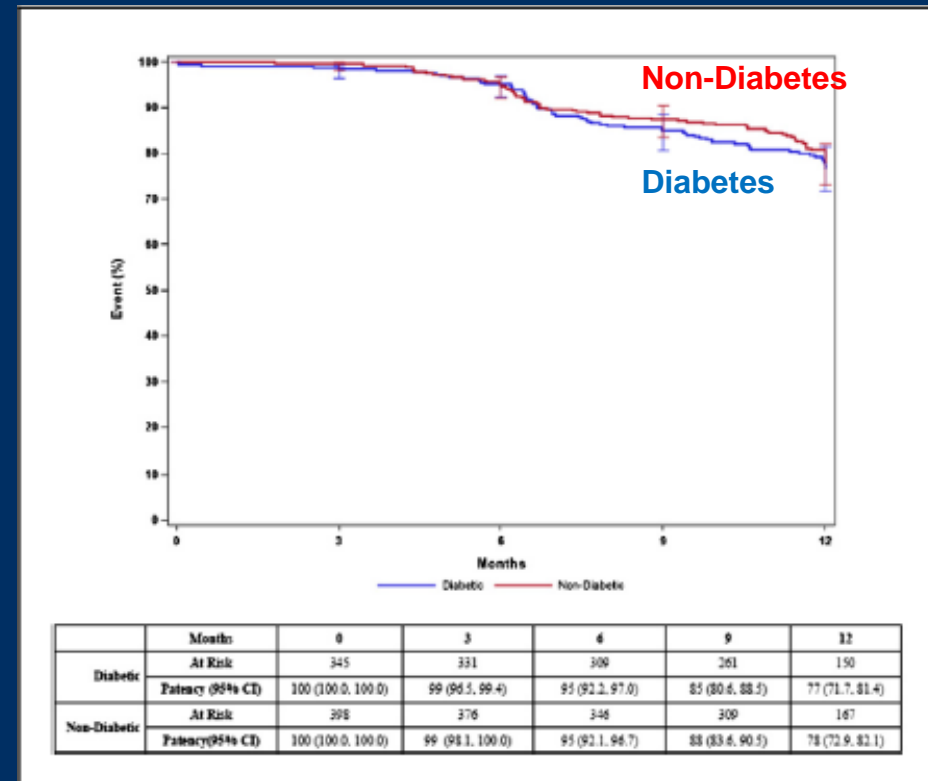


FIGURE 2 Patency Outcomes: Diabetic Versus Nondiabetic Claudicants

Kaplan-Meier estimates of patency (peak systolic velocity ratio ≤ 2.4) by lesion. CI = confidence interval.

Jetstream-Rotational atherectomy in DM in the SFA

Prospective single-arm multicenter study 2/2006-2/2007, n=172, Diabetes 46.5%
Mean lesion length 3.5 cm

Technical outcome in the total cohort:

- Device success in 99%
- 30 MAEs rate of 2.5% (DM) vs 0% (non-DM)
- 12 months TLR rate of 20% (DM) vs 28% (non-DM)

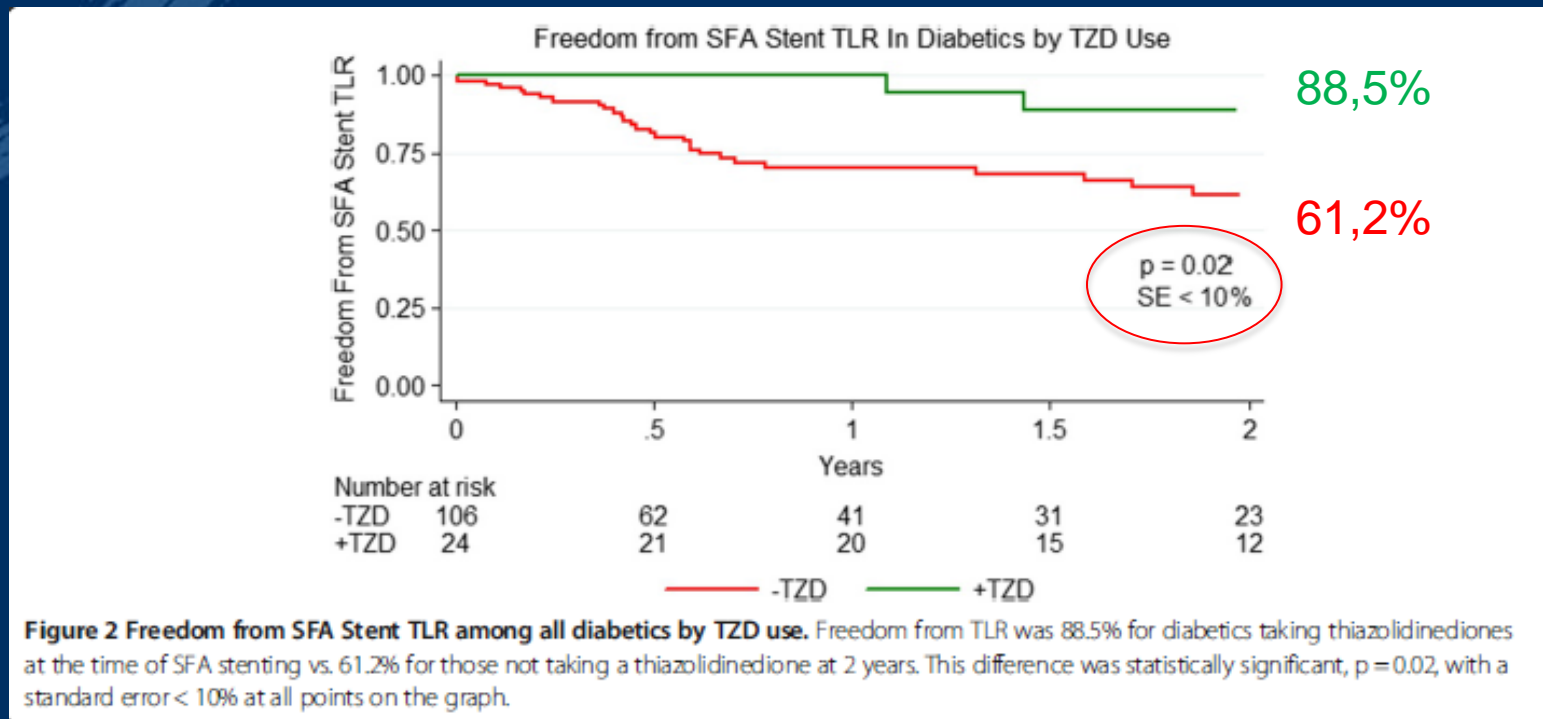
Table III. Major adverse events at 30 days, 6 months, and 12 months

Adverse event	30-days				6-months			
	Diabetics		Nondiabetics		Diabetics		Nondiabetics	
	Events (n)	Patients with event n (%)	Events (n)	Patients with event n (%)	Events (n)	Patients with event n (%)	Events (n)	Patients with event n (%)
Death	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (1.1)
MI	0	0 (0.0)	0	0 (0.0)	1	1 (1.3)	0	0 (0.0)
TLR	0	0 (0.0)	0	0 (0.0)	8	8 (10.0)	17	17 (18.5)
TVR	0	0 (0.0)	0	0 (0.0)	1	1 (1.3)	3	3 (3.3)
Amputation	2	2 (2.5)	0	0 (0.0)	2	2 (2.5)	0	0 (0.0)
Any MAE	2	2 (2.5)	0	0 (0.0)	12	11 (13.75)	21	20 (21.7)

MAE, major adverse events including all target vessel revascularization, death, amputation; TLR, target lesion revascularization; TVR, target vessel revascularization.

Nitinolstents / TZD in DM in the SFA

Retrospective database 8/2001-7/2012, n=128, n=24 Thiazolidinedione (TZD)
TASC A and B lesion, Claudicants and CLI (33,3 nonTZD and 60.9% in TZD)



Nitinolstents / T2D in DM in the SFA

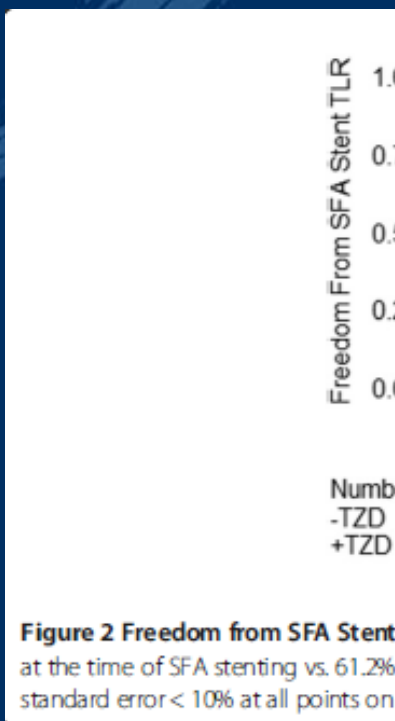
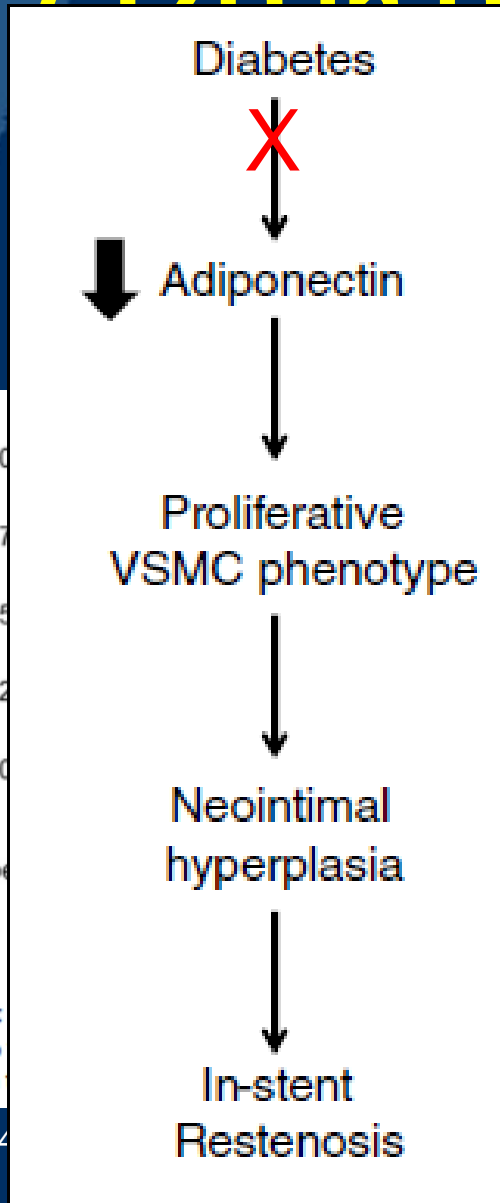
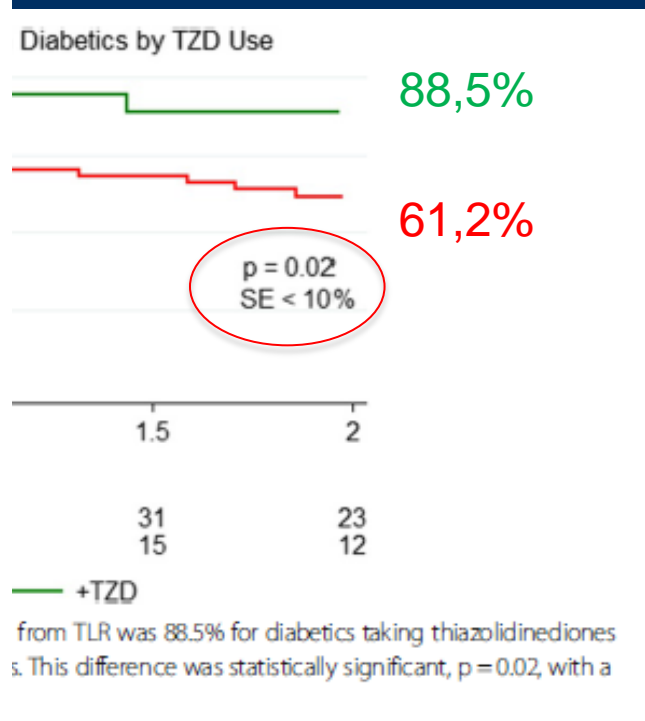


Figure 2 Freedom from SFA Stent at the time of SFA stenting vs. 61.2% standard error < 10% at all points on



Summary and Conclusion

There is a growing incidence of (also non-diagnosed) diabetes mellitus (DM) with high risk for cardiovascular complication

Patients with DM usually present with an advanced stage of disease in the infrainguinal arteries

Long-term patency in patients with DM seems to be worse related to limited outflow (BTK) and the interventionalist should be familiar to treat it

There are only limited data available for PTA and Nitinol-Stents in the SFA in DM, however there seems to be an increasing risk of restenosis with a pattern of diffuse recurrence

DES and Atherectomy in the SFA seems to show comparable results in DM and non-DM

Thiazolidinedione might have some antiproliferative effect to lower the risk of in-stent re-Stenosis in the SFA after Nitinol-Stenting

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