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

Nitinol stents in DM in the SFA

Retrospective 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)

Sabeti et al. JEVT 2005; 12:6-12
Nitinol stents in DM in the SFA

Retrospective 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.....

DeRupertis et al. JVS 2008; 47:101-8
SFA Lesions in Diabetic Patients

Retrospective 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 treatent
SFA Lesions in Diabetic Patients

Retrospective 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 (\( p=0.66 \))!

DeRupertis et al. JVS 2008; 47:101-8
Nitinol stents 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)

Je et al. Vascular Specialist Interventional 2015, 31:115-9,
Zilver PTX in DM in the SFA

Zilver PTX Freedom from TLR @ 2 years

Covariate analysis

Dake et al. JACC 2013, 61: 2417-27
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%

Mc Kinsey et, J Am Coll Int 2014; 7: 923-33
Jetstream-Rotationalatherectomy 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)

<p>| Table III. Major adverse events at 30 days, 6 months, and 12 months |
|---------------------------------|--------|--------|--------|--------|--------|--------|--------|--------|</p>
<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Diabetics</th>
<th>Nondiabetics</th>
<th>Diabetics</th>
<th>Nondiabetics</th>
<th>Diabetics</th>
<th>Nondiabetics</th>
<th>Diabetics</th>
<th>Nondiabetics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0</td>
<td>0 (0.0)</td>
<td>0</td>
<td>0 (0.0)</td>
<td>0</td>
<td>0 (0.0)</td>
<td>0</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>MI</td>
<td>0</td>
<td>0 (0.0)</td>
<td>0</td>
<td>0 (0.0)</td>
<td>1</td>
<td>1 (1.3)</td>
<td>0</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>TLR</td>
<td>0</td>
<td>0 (0.0)</td>
<td>0</td>
<td>0 (0.0)</td>
<td>8</td>
<td>8 (10.0)</td>
<td>17</td>
<td>17 (18.5)</td>
</tr>
<tr>
<td>TVR</td>
<td>0</td>
<td>0 (0.0)</td>
<td>0</td>
<td>0 (0.0)</td>
<td>1</td>
<td>1 (1.3)</td>
<td>3</td>
<td>3 (3.3)</td>
</tr>
<tr>
<td>Amputation</td>
<td>2</td>
<td>2 (2.5)</td>
<td>0</td>
<td>0 (0.0)</td>
<td>2</td>
<td>2 (2.5)</td>
<td>0</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Any MAE</td>
<td>2</td>
<td>2 (2.5)</td>
<td>0</td>
<td>0 (0.0)</td>
<td>12</td>
<td>11 (13.75)</td>
<td>21</td>
<td>20 (21.7)</td>
</tr>
</tbody>
</table>

MAE, major adverse events including all target vessel revascularization, death, amputation; TLR, target lesion revascularization; TVR, target vessel revascularization.
Nitinol stents / 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% non-TZD and 60.9% in TZD)

Figure 2: Freedom from SFA Stent TLR among all diabetics by TZD use. Freedom from TLR was 88.5% for diabetics taking thiazolidinediones at the time of SFA stenting vs. 61.2% for those not taking a thiazolidinedione at 2 years. This difference was statistically significant, p = 0.02, with a standard error < 10% at all points on the graph.

Walker et, BMC Cardiovascular disorders 2014; 14: 184
Nitinol stents / TZD in DM in the SFA

Walker et, BMC Cardiovascular disorders 2014; 14: 184

88,5%
61,2%

Figure 2 Freedom from SFA Stent Restenosis. Freedom from SFA stenting vs. 61.2% standard error < 10% at all points on +TZD.
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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