Calcified lesions – optimal treatment

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„I give you the latest innovation in balloon angioplasty.“
Nothing to disclose
“the degree of calcification in arteries appears to correlate highly with the extent of atherosclerosis” Solberg LA, Circulation 1971

More calcification -> more advanced and severe atherosclerosis

Increased cardiovascular morbidity and mortality (e.g. coronary artery disease, renal insufficiency, etc.)

Increased lesion complexity

Optimal therapy = multidisciplinary!
  Interdisciplinary vascular board
  Medical Therapy
Calcification – optimal treatment

In the absence of coronary artery disease, pharmacological treatments are greatly underutilized in PAD


References:
References:

**Figure 4.** Major adverse cardiovascular events and limb outcomes among patients adhering to 4 guideline-recommended therapies. Cumulative hazard curves to 3 years postprocedure showing the proportion free of (A) MACE (MI, stroke, or death; $P=0.009$), (B) death ($P=0.003$), (C) MALE (bypass graft surgery, thrombolyis, or major amputation; $P=0.005$), and (D) amputation or death ($P=0.003$). All curves are after propensity weighting. CI indicates confidence interval; MACE, major adverse cardiovascular or cerebrovascular events; MALE, major adverse limb events; MI, myocardial infarction.
ASSOCIATION OF SMOKING CESSATION WITH DECREASED MORTALITY AND IMPROVED AMPUTATION-FREE SURVIVAL AMONG PATIENTS WITH PERIPHERAL ARTERIAL DISEASE

Poster Contributions
Hall C
Saturday, March 29, 2014, 3:45 p.m.-4:30 p.m.

Session Title: Prevention: Diabetes, Obesity, and Lifestyle
Abstract Category: 20. Prevention: Clinical
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Background: Although smoking cessation is recommended for all patients with peripheral arterial disease (PAD), there is little data regarding the prevalence of smoking among patients at the time of angiography or the effect of smoking cessation on clinical outcomes.

Methods: Consecutive patients with claudication or critical limb ischemia who underwent peripheral angiography from 2006-2013 were included in an observational cohort analysis. Smoking status was assessed at the time of angiography and during follow-up clinic visits. Kaplan-Meier analysis was used to assess the relationship between smoking cessation and mortality or major amputation.

Results: Among 739 patients (423 men and 316 women, mean age 60 ± 12 years), 204 (28%) remained active smokers at the time of lower extremity angiography. The mean number of cigarettes smoked per day at the time of angiography was 16 ± 10, and the mean pack-years was 40 ± 25. During the course of the subsequent year, 61 (30%) patients successfully quit smoking and maintained continued abstinence. There were no significant differences in demographic characteristics or baseline medication use between groups. The mean ankle brachial index was also similar for quitters vs. nonquitters (0.55 ± 0.24 vs. 0.48 ± 0.22, p=NS). During a median follow-up of three years, patients who quit smoking had significantly lower all-cause mortality (9% vs. 24%, HR 0.34, 95% CI 0.10-0.88) and improved amputation-free survival (86% vs. 69%, HR 0.42, 95% CI 0.20-0.90) compared to patients who continued smoking.

Conclusions: Approximately one third of active smokers with PAD successfully quit smoking within a year after lower extremity angiography. Patients who quit smoking have lower mortality and improved amputation-free survival than patients who continue smoking.
Calcification - Background

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Atherosclerotic severely calcified lesions

Medial artery calcification
Calcification - Background

Atherosclerotic severely calcified lesions

- Focal or diffuse
- Any location
- Often flow-limiting

Medial artery calcification

- Diffuse,
- Concentric
- Flow-limiting mostly in smaller diameter btk vessels
- Occurs with and w/o adjacent atherosclerosis
- Mostly diabetics or patients with chronic renal insufficiency
- Vascular stiffness
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- Is Calcification present?
- Location / Type?
- Pattern of Longitudinal and Circular Distribution?
What makes calcified lesions specifically challenging?
Wire passage

- Chronic total occlusions
- Failure rates (mostly failure of wire passage) for complex below-the-knee (BTK) CTOs
  \(~15-20\%\)
Wire passage

- Interventionalist’s skill with wire and catheter
  - Balloon- or catheter assisted techniques to cross subintimal planes
  - Optimize pushability / penetration power
  - Special guidewires / catheters

- Alternative access routes
  - Re-access at closer site
  - Retrograde approach
  - Transbrachial Approach
  - Double-access
  - Pedal-plantar loop technique

- Subintimal passage
  - J-Wire
Limitation of subintimal angioplasty (10-15%):
- In case of inability to immediately re-enter the true lumen after subintimal passage of the occluded segment
- Vulcano Pioneer®, Cordis Outback® and others
- Limited use because of high costs
Limitations of Standard Balloon Angioplasty in calcified lesions

Speciality balloons aim to reduce vessel barotrauma and intimal injury.
Aim:
- by creating controlled incisions
- lower stenosis resoluting pressure is needed
- severy trauma to the vessel is avoided
Cutting balloons and focal force balloons

- Cutting balloon® (Boston Scientific)
- Angiosculpt® (Spectranetics)
- Vascultrak® (BARD)

- These devices still need to prove clinical benefit in controlled trials
Chocolate® balloon

- Unique nitinol "constraining structure"
- Controlled uniform inflation aims to minimize shear stress and "dog-boning"
- Chocolate BAR Trial: low dissection rate, low bail-out stenting rate
- Ongoing Trials
- Chocolate® Touch: DEB version (Paclitaxel-coating)
Lithoplasty® - Shockwave

Lesion modification by using lithotripsy in a balloon to disrupt calcification prior to dilatation

?- Improves vessel wall compliance prior to controlled, low pressure dilatation
?- Goal: minimize the need for stenting by tackling residual stenosis and dissections/wall stress
Lithoplasty® - Shockwave

- Lithoplasty® is safe and effective in the treatment of calcified SFA/Popliteal lesions according to DISRUPT PAD I results (n=35)
  - Good results without the need for stenting
  - Evidence of a return of physiologic compliance or positive remodeling

- Until now only limited data/experience in PAD. Enrollment for DISRUPT PAD II (n=60) finished
Limitations of standard Nitinol Stent Designs

- Limited radial force
- Stent fracture
Optimized Stent Designs for Calcified Lesions

Abbott Supera® Stent

- Interwoven nitinol stent
- Excellent primary patency in prospective trials and register studies
- Flexible; high radial force; no fractures

![Graph showing crush compression data for 6 mm stents]
Atherectomy

- Debunking to minimize residual stenosis especially interesting for highly calcified lesions
- Potential combination with DEBs
- Evidence for routine use limited
- Issue of reimbursement depending on country

Silverhawk® for directional atherectomy
Jetstream® for rotational atherectomy and thrombectomy
DCB + Atherectomy?

DEFINITIVE AR 12m results – Primary Patency

Atherectomy+DCB vs. PTA+DCB
Drug-eluting balloons

Figure:
Optimal treatment of calcified lesions

- Optimal therapy = multidisciplinary!
- Complex lesions and lengthy complex interventions; success remains challenging even with the newest devices
- Outcome is less favourable compared to non-calcified lesions
- With increased understanding of calcification, more sophisticated, individualized treatment regimens will likely evolve to make optimal use of the variety of dedicated technologies
- Limited data, no standard for calcium scoring, comparison of study outcomes potentially misleading
- Cost-effectiveness of advanced technologies
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