Ultrasound vs. angiographic follow-up: What is appropriate for each vascular bed?

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

☒ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Background

Main Outcome parameters for Device tested

➢ Primary endpoints
  ✓ Device has to prove Safety and Efficacy

  □ Safety eg
    Composite
    ▪ 30-day freedom from device- and procedure-related mortality
    ▪ 12-month freedom from major target limb amputation and clinically-driven TVR

  □ Efficacy eg
    12-Month Primary Patency
    ▪ Freedom from clinically-driven TLR and freedom from restenosis as determined by……

  *Efficacy needs to be visualized*
Efficacy

can be addressed by measuring restenosis as

Late lumen Loss/LLL synonymous with Target lesion restenosis/TLR

The difference between the minimum lumen diameter (MLD) immediately after angioplasty/stent deployment and the MLD at follow-up

Percent Diameter Restenosis

Percent diameter restenosis (or just percent diameter stenosis) is typically calculated as the difference between the minimal (or minimum) luminal diameter (MLD) from the target reference vessel diameter (RVD), divided by the RVD, and multiplied by 100 to get the percentage of stenosis

Binary Restenosis

Binary restenosis is traditionally defined as a reduction in the percent diameter stenosis of 50% or more (≥50%)
The term "binary" means that patients are placed in 2 groups, those who have ≥50% stenosis and those who have <50% stenosis

Binary restenosis is an epidemiological method of analyzing percent diameter stenosis for observing not only an individual patient, but also performing statistical techniques on group of patients to determine averages
How do measure Restenosis?

**Angiographically**

**Advantage**
- Good reproducibility (radiopaque ruler, fixed measurement points)
- Investigator independent
- Whole Target limb visualisation
- Additional information (inflow and outflow)

**Disadvantage**
- Radiation applied
- Invasive procedure (complications can occur)
How do measure Restenosis?

DUS

Advantage
- None Invasive Procedure
- Can be repeated as often as necessary
- Additional information about vessel wall (calcification, Intima Hyperplasia, flow pattern…)
- Good reproducibility (measurement from the groin)

Disadvantage
- Investigator dependent
- No Whole Target limb visualization (segmental)
- Spare Additional information (inflow and outflow)
- Anatomical Challenges

DUS_Angio_FU
How do we measure Restenosis?

DUS

**Standardized Doppler Technique**

- **Protocol**
- **SV Center Stream**
- **60 Degrees**
Document waveforms from just above the increased PSV, the maximum PSV from with the stenosis, and from just below.

Prox to PSV 90 cm/s

dSFA TL1 @10cm

How to document a stenosis

PST

Distal to
Pre stenosis, in stenosis, immediately distal to

Normal waveform proximal to stenosis
How do measure Restenosis?

<table>
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<th>Method</th>
<th>Measure</th>
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<td>Digital Angiography</td>
<td>Lumen diameter</td>
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Discussion about PSVR rate and reference/relevant stenosis degree
How do measure Restenosis?

Digital Angiography
Lumen diameter

DUS
Peak systolic velocity Ratio

Discussion about PSVR rate and reference/relevant stenosis degree

DUS findings were considered indicative of hemodynamic stenosis if the peak systolic velocity (PSV) was >180 cm/s or the PSV velocity ratio was >2.0 \(^1,2\)

PSVR ≥2.5 suggesting a >50% reduction in luminal diameter (comparing the stenosis with a proximal reference segment >50% \(^3\))

Some trials are using PSVR >2.4 (Inpact SFA..)

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How do measure Restenosis per anatomical region

**SFA/PA**

FIH ➔ Digital angiography
to be able to establish the best possible objective investigator independent outcome parameter concerning TLR (relevant as first step in device efficacy evaluation)

All other trials (large RCT’s, Registries…) ➔ DUS
Proven and validated imaging tool
Guidelines promote it as reliable tool
Practicability in large studies!

Mostly easy to perform in every patient

*Only Issue: matter of relevant PSVR*
How do measure Restenosis per anatomical region

**BTK**

All trials ➔ Digital angiography
to be able to establish the best possible objective investigator independent outcome parameter concerning TLR

DUS ➔ A not validated tool in BTK evaluation

Mediasclerosis
Difficulties in following all 3 vessels to the foot by anatomical variants
Individual patient’s ability to catch up with an extended DUS exam
(moving legs, hold their legs in the same position for some time, wounds, pain…)

*Up to date no large RCT has published TLR data on DUS FU*
DUS_Angio_FU

Recommandation of Efficacy evaluation

SFA/PA
BTK

DUS valid data
Digital angiography

DUS A not validated tool in BTK evaluation
Thank you for your attention!
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