The relevance and limitations of angiographic endpoints

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Disclosure

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I have the following potential conflicts of interest to report:

- Consulting/ honoraria:
  C.R. Bard, J&J Cordis, Medtronic, Biotronik, W.L. Gore
Angiographic endpoints for lower limb studies:

LLL / Late Lumen Loss

Target lesion

MLD pre/ Minimum Lumen Diameter
Angiographic endpoints for lower limb studies:

LLL / Late Lumen Loss
Angiographic endpoints for lower limb studies:

LLL / Late Lumen Loss
Acute gain = MLD post – MLD pre
Angiographic endpoints for lower limb studies:

LLL / Late Lumen Loss

Acute gain = MLD post – MLD pre

LLL = MLD post – MLD FU
Angiographic endpoints for lower limb studies:

Percent Diameter Restenosis =
\[
\frac{(RVD - MLD_{FU})}{RVD} \times 100
\]
Angiographic endpoints for lower limb studies:

Binary Restenosis:

YES $\geq$ 50%

NO $<$ 50%

Reference Vessel Diameter / RVD

MLD FU

MLD post
Why do we need angiographic endpoints?

- Objective measurements
- Determined by the gold standard
- Derived from what the interventionalist sees
- Continuous endpoints with greater statistical power (e.g. LLL)
Limitations of angiographic endpoints

Leg hurts, not the Late Lumen Loss!

Complaints do not necessarily correlate with angiographic endpoints
Limitations of angiographic endpoints

Reality is not 2 dimensional!

Vessels are rather tubes and stenoses are not always concentric
Limitations of angiographic endpoints

Reality is not 2 dimensional!

Vessels are rather tubes and stenoses are not always concentric, CTA / IVUS / OCT might be superior
Limitations of angiographic endpoints

QVA was developed for coronaries but these are no coronaries!

Longer lesions, diffuse disease, fewer projections, bad quality, calification
Limitations of angiographic endpoints

Angio is invasive compared to DUS

Validity of DUS in Detecting Femoropopliteal Artery Stenosis is good
Validity of DUS in detecting binary femoropopliteal artery stenosis

50%

70%

PSVR p
PSVR d
PSV

> 90% Sensitivity and Specificity

Macharzina, Beschorner, Zeller et al JEV 2015
Not All Restenosis is Equal

In long lesions, standard measures of patency do not account for focal vs. diffuse restenosis.

FOCAL RESTENOSIS

DIFFUSE RESTENOSIS

Greater late lumen loss
Greater angiographic restenosis
Greater PSVR

Greater reduction in blood flow to foot

How do we show the difference between this and this numerically with a clinically meaningful endpoint?
Novel Endpoint – Transverse-view Vessel Area Loss (TVAL)

**TVAL:**

Transverse-view Vessel Area Loss

A measurement of AREA opacified by contrast, rather than the narrowest cross-section, which LLL defines

\[
LLL = MLD_{\text{baseline}} - MLD_{\text{follow-up}} \text{ (in mm)}
\]

\[
TVA = \text{shaded area within TL end constraints (in mm}^2\text{)}
\]

\[
TVAL = 100\% - \left(\frac{TVA_{f/u}}{TVA_{\text{baseline}}}\right)
\]
Conclusion

• Angiographic endpoints are important for prove of principle studies
• Quality is highly dependent on type of lesions
• Should always be assessed by an independent experienced corelab
• In long and diffuse lesions TVA should be considered as additional endpoint
• DUS should be used to assess femoropopliteal patency
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