These Trials Will Have Big Problems and May Tell Us Little …

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Disclosure
NONE

Biased Treatment Approach

BEST Surgery
Single Segment SVG

VS

Worst Endo

WHATEVER THE F... YOU WANT TO DO

Major Selection Bias

66% excluded

Biased Patient Selection – Not Generalizable

Results
During the 6-month BASE audit, 585 consecutive patients presented with new onset ischemia to the top recruiting centers (which between them recruited 65% of patients). Was given to many instances for responsible surgeons and radiologists not randomising or not randomly assigning the remaining 186 patients was that the leg could not be revascularised by either surgery or angioplasty in 154 (34%).

Lancet. 2006 Jan 20;367(9501):1925-34.
MANY MANY Patients Excluded

- No Conduit
- No Target
- Too high risk
- Too calcified
- Too long
- Too short
- Prior Bypass
- Too many prior interventions
- Patients refused
- Not a good research patient
- Immunosuppressed

Over 30% of CTOs Can Not be Crossed in the Antegrade Approach

The decision to recommend surgical or endovascular revascularization varies significantly among providers and is based on a range of factors, including disease patterns, availability of autogenous conduit, physician training and experience, surgical and endovascular skill sets, access to an appropriate procedure armamentarium, and perhaps most importantly, disparate treatment biases [14–17].

Overall Operator Experience!!!

Regardless of the categories above, at least 5 of the lower extremity bypasses performed must have involved an artery below the knee joint, and at least 5 must have been performed with a venous conduit.

3.2.1 Open Surgical Revascularization

The investigator must be a board-certified vascular surgeon, cardiothoracic surgeon, or an equivalent surgeon who meets the criteria for open surgical revascularization.

3.2.2 Endovascular Revascularization

The investigator must also have performed at least 12 infrapopliteal endovascular procedures in patients with CLI involving an artery below the knee joint over the preceding 2 years.

Which is the more important Question?

1) Which procedure?

OR

2) Which Operator?
Flawed Primary Endpoint

- MALE:
  - Above ankle amputation
  OR
  - Major re-intervention

Very Few Interventions or Techniques Have Shown a Difference in AFS or MALE in CLI

Drug-Eluting Balloon Versus Standard Balloon Angioplasty for Paclitaxel-Coated Balloon in Infrapopliteal Arteries

12-Month Results From the BIOLOX P-II Randomized Trial (BIOTRONIK'S-First In Man study of the Passeo-18 LUX drug releasing PTA Balloon Catheter vs. the uncoated Passeo-18 PTA balloon catheter in subjects requiring revascularization of infrapopliteal arteries)

The Truth About BEST CLI

- Not generalizable with many screen failures (<10% randomized)
- No CORE lab for angios and procedures
- No qualitative check to assess perfusion post procedure
- Many many operators with minimal skill set
- No REAL guidance as to what a BEST endovascular treatment is
- Inadequate endpoints

THANK YOU!!