These Trials Will Be Fraught With Problems And May Provide Little Useful Information

Mehdi H. Shishehbor, DO, MPH, PhD
Professor of Medicine, Case Western Reserve School of Medicine
Co-Chair, Harrington Heart & Vascular Institute
Director, Interventional Cardiovascular Center
Director, UH CMC Cardiac Catheterization Laboratory
Co-Director, Vascular Center
University Hospitals

Disclosure

Advisory Board: MDT, BSC, Abbott, Philips

Biased Treatment Approach

How Can in 2017 We Equate the Safety and Efficacy of DCB and DES to Angioplasty Alone?!

Major Selection Bias

Results
During the 6-month BASE audit, 585 consecutive patients presented with new symptoms inferior to the leg to recruiting centres (which between them recruited 615).

Biased Patient Selection – Not Generalizable

was given to many instances for responsible surgeons and radiologists not revascularising or not randomly assigning the remaining 386 patients was that the leg could not be revascularised by either surgery or angioplasty in 354 (44%).
The decision to recommend surgical or endovascular revascularization varies significantly among providers and is based on a range of factors, including disease pattern, availability of endovascular and surgical options, patient preference, and provider training and experience. Surgical and endovascular procedures share both risks and benefits, and may be complementary in certain patient populations.

WHY CREST 2 HAS CREDENTIALLING BUT BEST TRIAL DOES NOT?

Biased Experienced Level

Which is the more important Question?

1) Which procedure?

OR

2) Which Operator?
**Flawed Primary Endpoint**

- MALE:
  - Above ankle amputation
  - 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 BIOLUX P-II Randomized Trial (BIOTRONIK’S-First) in Man study of the Passero-18 LUX drug releasing PTA Balloon Catheter vs. the uncoated Passero-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!!**