DEBATE: Why A Randomized Controlled Trial (RCT) Of TEVAR And Medical Treatment vs. Medical Treatment Alone Is Needed For Acute Uncomplicated TBADs: Such A Trial (INTACT-AD) Has Been Designed With The Following Features...

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SOC 1960-2016

• After discharge → BP control and follow up @ 1,6,12 months and yearly thereafter
• Acute emergency (rupture) → TEVAR or open repair
• If aorta dilate (5 mm/6 months, 1 cm/1 year) or reach 5.5 cm in largest diameter → Repair (open or endovascular)

2016-2018

#TEVAR-for-uTBAD.VQI.com

• High-risk imaging criteria
• Non-compliant with medical therapy
• Young
• Lives far and less likely to follow up
• Never been validated
• TEVAR may not be 100% protective either
• So?! What if they never develop a complication?!
• TEVAR also need f/u
• TEVAR is NOT risk free

NEW DEVICE PATHWAY

Innovative postmarket device evaluation using a quality registry to monitor thoracic endovascular aortic repair in the treatment of aortic dissection

Adrian W. Beck, MD, Joseph V. Lombardi, MD, Dorothy B. Abol, MD, J. Roberto Mosales, MD, Danica Marinac-Dabic, MD, Grace Wang, MD, Ali Asizzadeh, MD, John Kern, MD, Mark Filingeri, MD, Rodney White, MD, Jack L. Cronenwett, MD, and Richard P. Cambria, MD, for the Society for Vascular Surgery Vascular Quality Initiative TEVAR Surveillance Project Steering Committee, Birmingham, Ala; Camarillo, Calif; and Boston, Mass.
I would ask Dr. Cambria, the SVS….

• Would you say that CREST II is not needed if CAS is shown to be safe for asymptomatic carotid artery disease using the VQI?

• What if you study a select group of high-risk plaque of carotid artery disease? Why spend >$100M

Specific Aim of INTACT-AD

• To test the hypothesis that upfront TEVAR is superior to the SOC in reducing all-cause mortality and incidence of major aortic complications at 5 years (clinical effectiveness)

• Major aortic complications (MAC) is defined as: need for extensive open repair, rupture, fistula, stroke, spinal cord ischemia, limb ischemia, renal failure, mesenteric malperfusion syndromes.

• INCLUSION
  • Within 90 days of confirmed diagnosis

• EXCLUSION
  • Initial aortic diameter > 45 mm
  • Unwilling or unable to comply with all study procedures

WHY WE NEED A TRIAL

• INTACT-AD will be the only effort that will potentially lead to change in SOC

• The so called “high-risk” group is half-baked collection of poorly collected and never been validated data

• VQI DOES NOT ANSWER IF PATIENT IS BEST SERVED WITH TEVAR OR LEFT ALONE

• SVS to join other societies in supporting INTACT-AD

RPC: 2012 Presidential Address

• SVS mission statement and core values of integrity, professionalism and commitment to our patients….

• WHY is our TRUE NORTH

• VOTE FOR INTACT-AD