

Unresolved questions in the management of post-acute Type B dissections



Firas F Mussa, MD, MS



UNIVERSITY OF SOUTH CAROLINA
SCHOOL OF MEDICINE

Disclosure

Dear Dr. Mussa,

This is to acknowledge receipt of your application (Grant# 1UG3HL150436-01) for review by the Clinical Trials Review Committee (CLTR (OA)) on June 20, 2019. The meeting roster is available 30 days before the review meeting and may be under development until the meeting date.

NOT-OD-17-066 notifies applicants of the NIH post-submission supplementary materials policy and what can be provided, if applicable. In most cases it is restricted to unforeseen circumstances and supplementary materials may not be used to correct oversights/errors discovered after submission of the application. Any supplemental submission must be sent to the Scientific Review Officer by email in the form of a pdf. The communications with the attachment must come from your Authorized Organization Representative (AOR). A communication from the PD/PI only or with a "cc" to the AOR will not be accepted. Materials must be provided no later than 30 days prior to the review date.

If you have questions or need further assistance, please contact me by phone (301/435-0287) or by e-mail. Thank you for your cooperation.

Sincerely,

Keary A. Cope, Ph.D., M.P.H.
Acting Chief
Clinical Studies and Training Branch
Office of Scientific Review
Division of Extramural Research Activities
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Suite 7190
Bethesda, MD 20892-7924
copeka@nhlbi.nih.gov



Unresolved Questions....

- Clinical
- Imaging/Metabolic
- Engineering/Hemodynamic
- Technological
- Social
- Regulatory



Clinical:

The New York Times

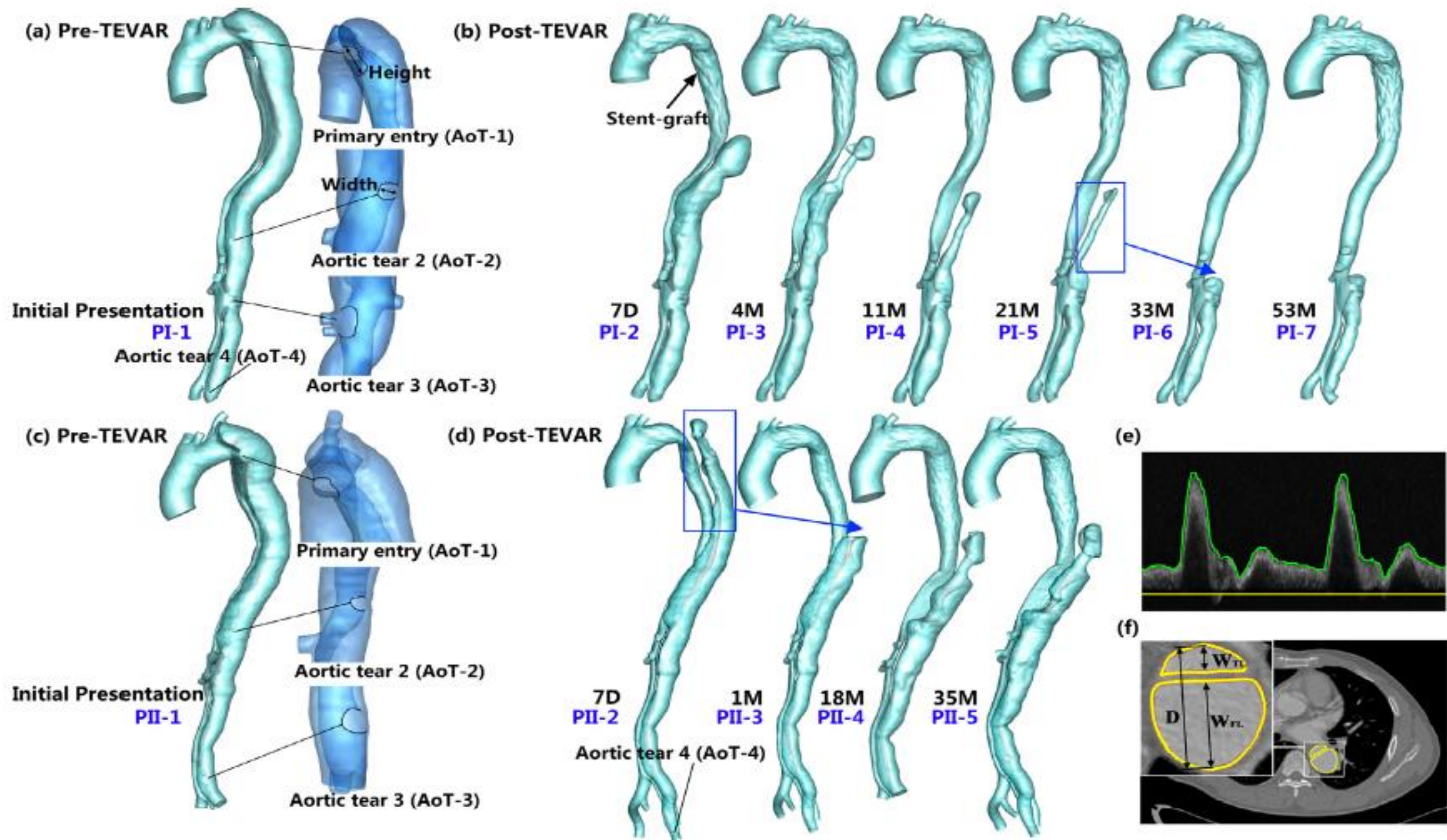
THE WALL STREET JOURNAL

- Dilate to 55 mm
- Rupture
- Repair (open or endovascular)
- Mortality (20% over 5 years)



Fattori et al, JACC 2013

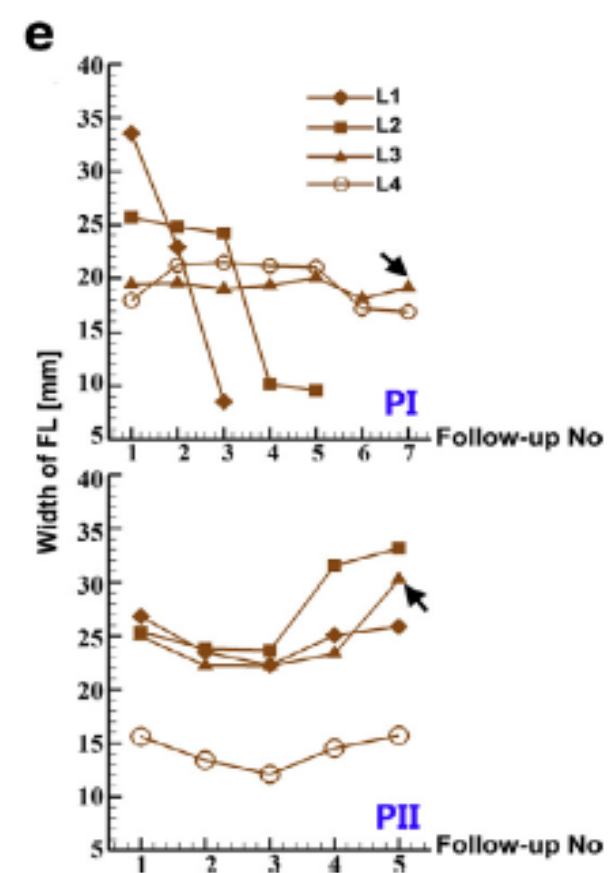
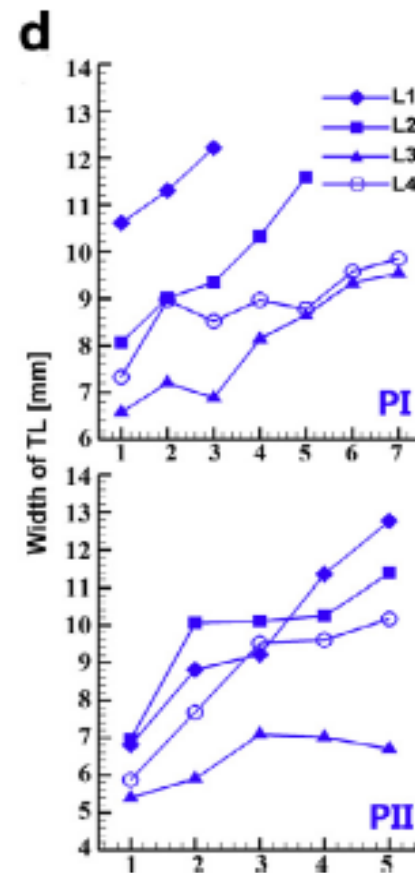
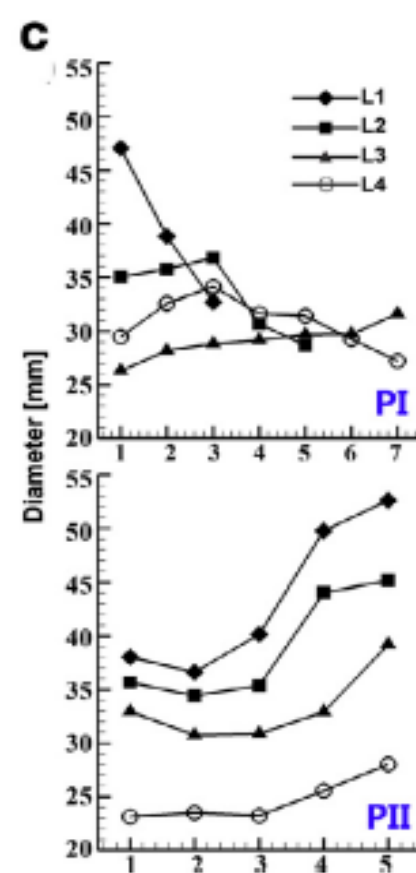
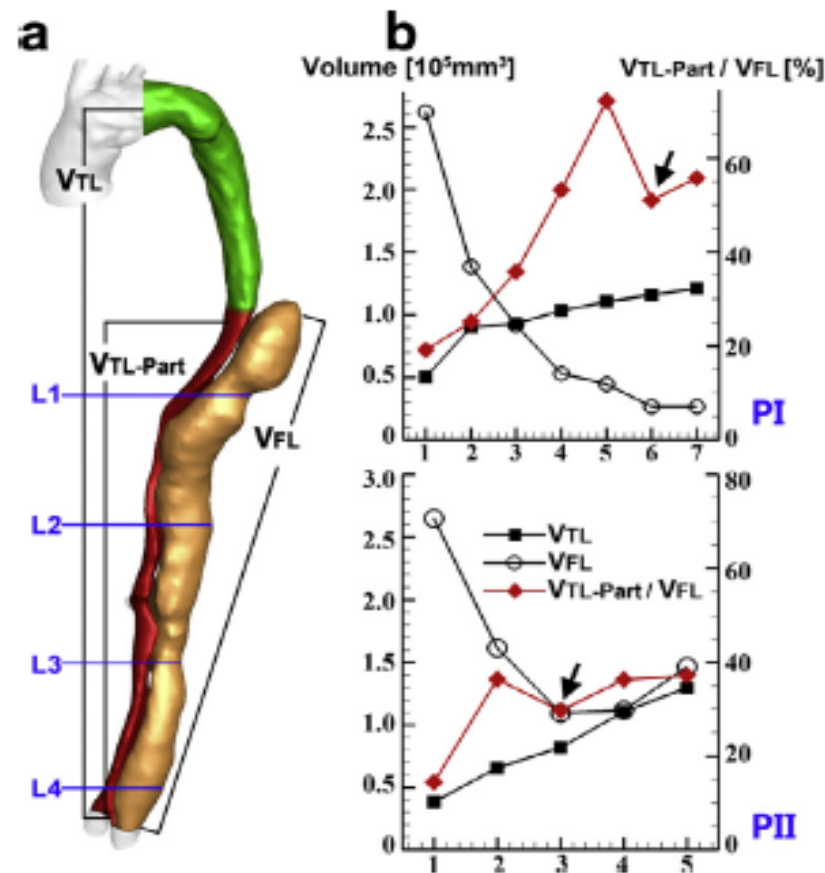
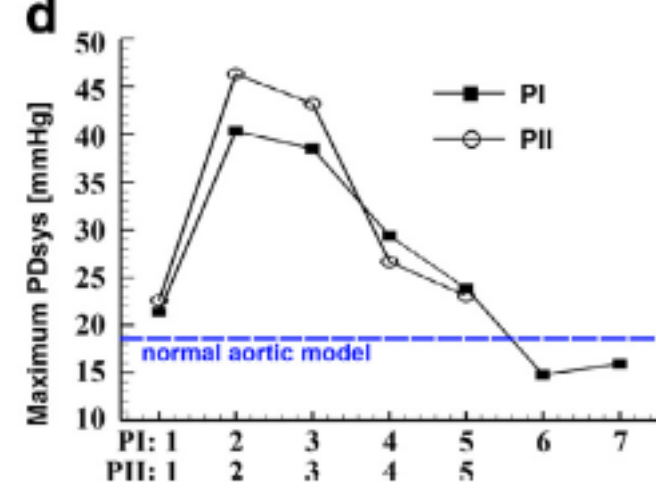
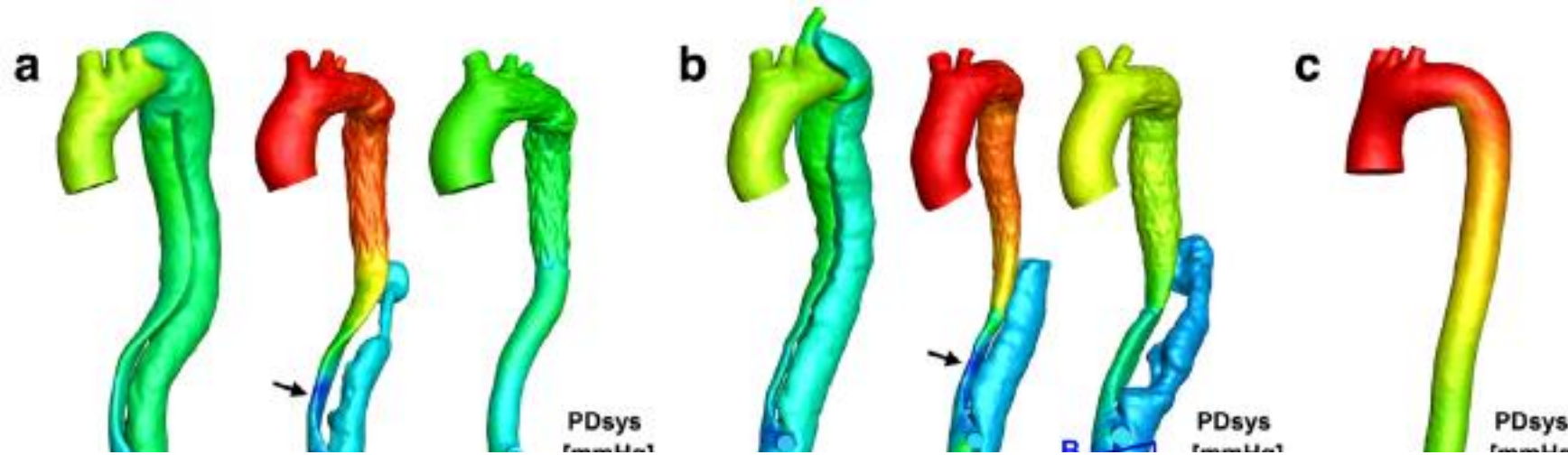
Nienaber et al. INSTEAD-XL-2013



Engineering

- TEVAR lead to thrombosis in the FL and morphologic change in TL
- Correlation of hemodynamic parameters (the false-to-true luminal pressure difference) to the development of post-TEVAR FL remodeling
- Stentgrafts occluding all re-entries would be required to effectively reduce inter-luminal communication
- Accurate simulation model with material property measurements



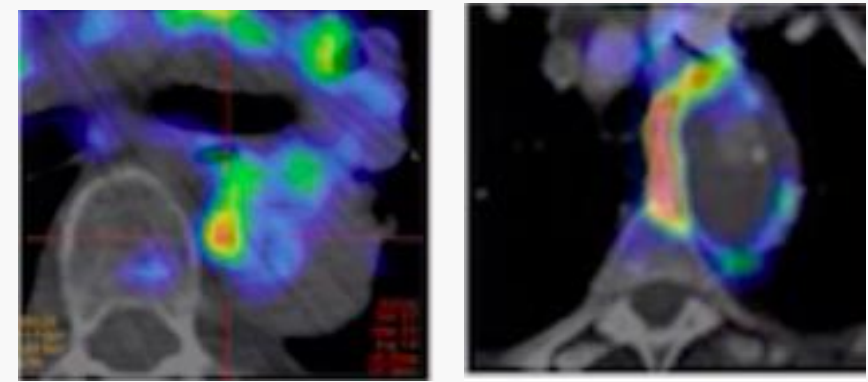


Technological

- Artificial Neural Networks (ANNs) have been implemented to enhance shopping experience, speech to text recognition and have governed the automated driving systems (Uber and Google)
- Artificial Intelligence can use personalized data (clinical, imaging, socioeconomic and, genetic) to derive a predictive model of risk/benefit ratio of pre-emptive TEVAR on major aortic complications
- IRAD, GenTAC: transform the data from the domain of medical experts into the domain of AIML and create a centralized repository that will be HIPAA-compliant with an unrestricted sharing feature required by data analysts



Imaging



- Doppler ultrasound provides velocity information at a certain position of the vessel
- 4D-PC MRI measures stroke volume and velocity in the false lumen which correlate with the rate of aneurysmal formation.
- PET-CT can study the uptake and wall shear stress leading to aortic aneurysms and complications of AD



Social: Patient-Centered Outcome & Cost-Effectiveness



Regulatory: FDA is not NICE

- On July 12, 2006 CMS released a guidance document titled National Coverage Determinations (NCD) requiring, as a condition of coverage, collection of additional patient data to supplement standard claims data
- Applicable to CAS in asymptomatic patients where reimbursement is limited to trial participation and certain very select conditions
- TEVAR not included in NCD and compensation is not linked to data reporting or FDA approval status



Conclusion

- We need INTACT-AD
- No two TBAD are the same
- We need to take a step back and personalize treatment (computational)
- Newer stents and material
- AIML to calculate future risk
- What patients want and at what cost
- Change the discussion

