

Wait a Minute, There are Still Questions to be Answered

Brian T. Bethea, M.D.

Regional Medical Director of Cardiac Surgery Coastal Division

32nd Annual Interventional Symposium 2017



Low Risk: Are We Truly Ready to Forge Ahead

- Defining low risk
- Results outcomes and challenges
- Durability
- Extending TAVR to the low risk population: a slight paradigm shift

Defining low risk

- Are traditional surgical risk assessment models applicable to TAVR?
- Is age enough to define the patients risk population?
- Four RCT: 2 high risk, 2 intermediate risk: interesting all of these trials the mean age was essentially the same
- Perhaps life expectancy is a much more important factor in determining who is a low risk vs intermediate risk vs high risk patient population
- Age and life expectancy should be taken in conjunction

Defining low risk patients

- What about the patient who is in their 60s with chest radiation?
 - Is the risk the malignancy or is the risk of radiation and technical difficulties
- What about the patient who is in their 60s on isolated ESRD?
 - Is it the known poor longevity of patients on ESRD or age that determines the risk
- What about the patient in their 60s with pulmonary hypertension?

Results outcomes and challenges

- Predictability of SAVR are very good, are they as predictable for TAVR?
- The data from our trial are a two sided coin:
- For TAVR, there is a mortality benefit in the Medtronic trial and non-inferior in the intermediate risk groups
- For TAVR also, there is lower risk of Afib, major bleeding and acute kidney injury
- What about PVL? PVL has been shown to have an impact on life expectancy and it is impossible to unequivocally predict who is going to have a PVL.
- What about PPM and its inherent risks of long term dysfunction, infection, endocarditis and venous fibrosis

Additional Patient Challenges

- Should this influence our decision of TAVR vs SAVR in low risk patients?
 - Coronary artery disease
 - Mitral disease
 - Bicuspid aortic valve with dilated aortic root
 - Atrial fibrillation
 - Tricuspid regurgitation
 - MRI findings following TAVR
- Anatomic concerns regarding valve calcification:
 - Bicuspid aortic valves
 - Trileaflet valves with more malignant calcification
 - Asymmetric leaflet calcification
 - Calcification extending into the LVOT

Results outcomes and challenges

- What gives us confidence moving forward: the most important factor is mortality and in moderate and high risk patients there is a mortality benefit with TAV over SAV. This was exclusive of PVL, A-fib and PPM.
- One word of caution: all these were all patients in a carefully controlled study and not an all comers patient population.

What about TAVR Device Selection?

- Screening evaluation is absolutely crucial. Familiarity of the device deployed is extremely important bc you need a perfect outcome.
- Most TAVR sites have more than one device therefore it is equally important to fit the technology to the patient.
- Anatomical concerns and valve choice
 - For example, LVOT calcification likely better with self expanding valve technology versus small root and low coronaries probably benefit from balloon expandable.
- What about planning for future VIV?

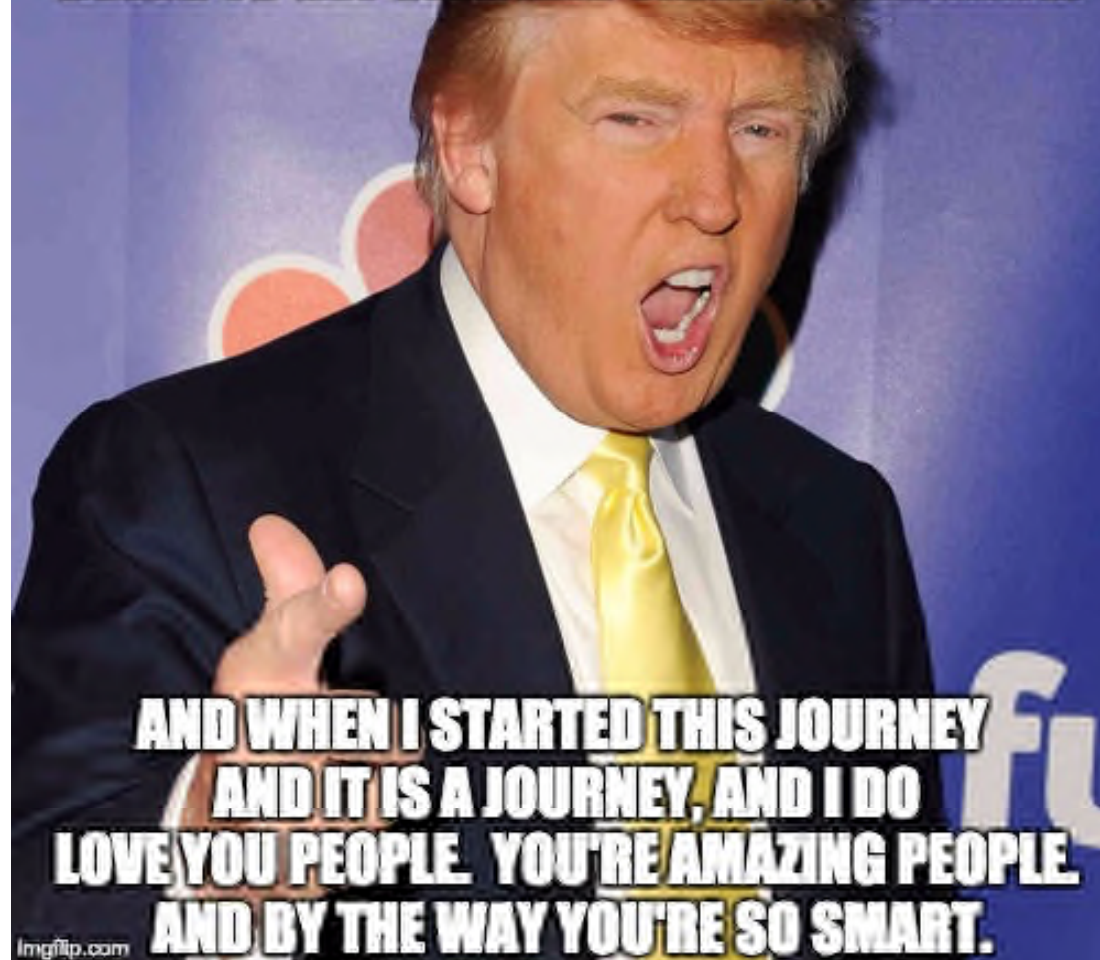
Durability Questions

- Structural valve deterioration is the Achille's heel of all bio-prosthetic valves.
- Age of the patient plays a significant role in the durability of a bio-prosthetic valve
- There is concern with the crimping process this may hurt the long term durability of the devices
 - From PCR one year ago, 50% deterioration of balloon expandable valves at 8 years
 - We have seen this with multiple SAVs in the past
 - The prepping of the valve may be a huge opportunity for improvement

Extending TAVR to the low risk population: A minor paradigm shift

- The importance of the heart team has never been more important
- Extensive heart team discussion before offering a certain therapy to a patient to provide realistic expectations
- Patient safety trumps all other arguments in a low risk population
 - If we have a difficult TAVR candidate the patient should be offered SAVR
 - If we have a difficult SAVR candidate the patient should be offered TAVR

**WE'RE GOING TO WIN SO MUCH YOU'RE ALL
GOING TO GET SICK AND TIRED OF WINNING.**



**AND WHEN I STARTED THIS JOURNEY
AND IT IS A JOURNEY, AND I DO
LOVE YOU PEOPLE. YOU'RE AMAZING PEOPLE.
AND BY THE WAY YOU'RE SO SMART.**