

Aortic Dissection

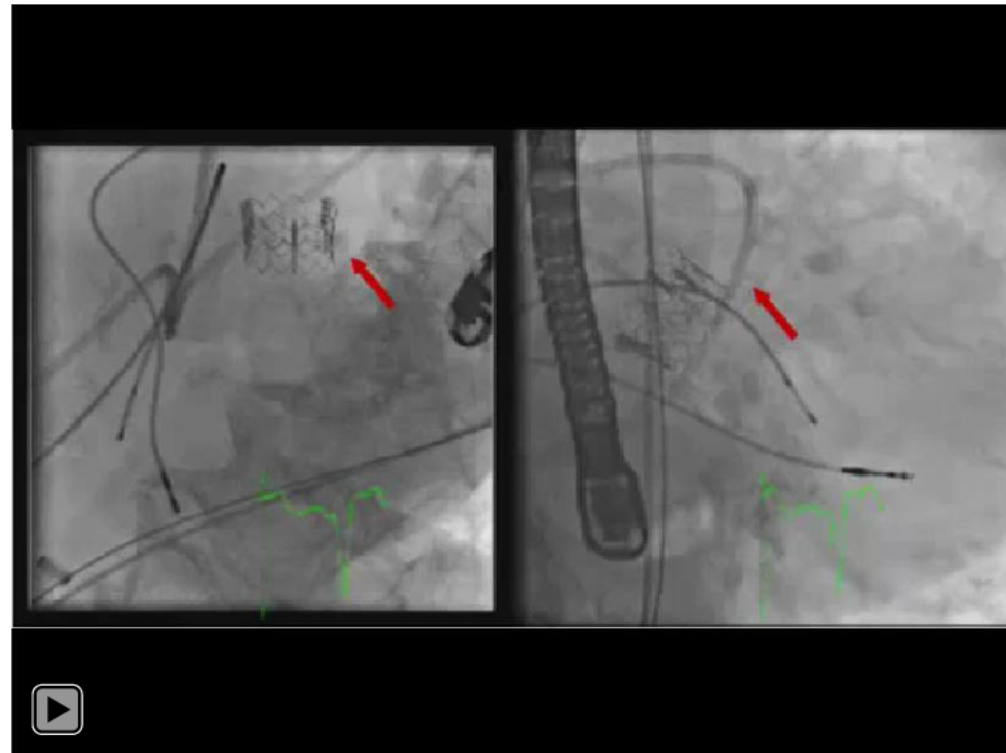
- Aortic dissection can occur with wire and catheter manipulation, balloon advancement or THV delivery system advancement and/or THV deployment
- Use caution with:
 - Severely obliterated sinuses of Valsalva
 - Sinuses of Valsalva less than 5 mm larger than annulus
 - Significant THV oversizing
 - Porcelain aorta
 - Narrowed calcified STJ
 - Calcification of native vasculature



Annular Rupture

THV Oversizing May Cause Annular Rupture Post THV Deployment

- Leads to hemodynamic collapse
- Management includes CPB and surgical intervention



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Previous generation device used for illustration

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147



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Page 147 of 172

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Edwards Lifesciences v. Boston Scientific Scimed
IPR2017-00060 U.S. Patent 8,992,608
Exhibit 2034 - Part 13
PROTECTIVE ORDER MATERIAL

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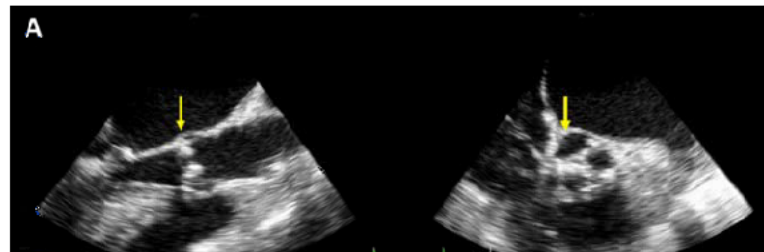
Periaortic Hematoma

Predisposing Conditions

- Advanced age
- Female gender
- Small body weight
- Steroid dependent
- Presence of bulky calcification
- Disparity between volume of cusp calcium and volume of the sinus of Valsalva
- Mismatch between annulus and device diameter
- Severe intra-procedural hypertension immediately following the procedure

Management

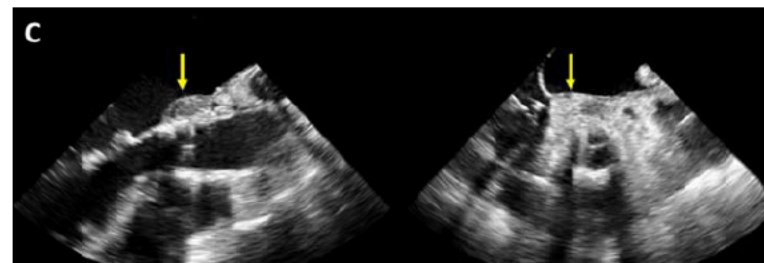
- Rigorous BP control (systolic BP < 130 mmHg)
- Give protamine
- Keep patient intubated and sedated x 24 h
- Consider pericardial drainage if fluid present



Panel A shows pre-procedural TEE (short- and long-axis views) showing a heavily calcified aortic valve with no peri-aortic hematoma



Panel B shows apparition of a small peri-aortic hematoma posterior and lateral to the aorta immediately after valve deployment



In Panel C, the hematoma appeared mildly larger (yellow arrows)

Genereux et al., Catheter Cardiovascular Interv. 2012 79(5): 766-776.

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148



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Coronary Occlusion

Coronary Occlusion Will Usually Result From the Displacement of a Calcified Leaflet in Front of an Ostium During THV Deployment

- **This risk should be assessed early on in the patient screening process in all patients** except those who are bypassed and have no residual significant myocardium perfusion by their native arteries
- Factors that should be evaluated and considered before THV positioning and deployment
 - Degree of calcification on leaflets
 - Annulus to coronary ostia distance
 - Length of the valve leaflet
 - Width of the Valsalva sinuses
 - Movement of the leaflets during BAV
 - Patency of coronaries during BAV
 - Expanded height of the intended THV

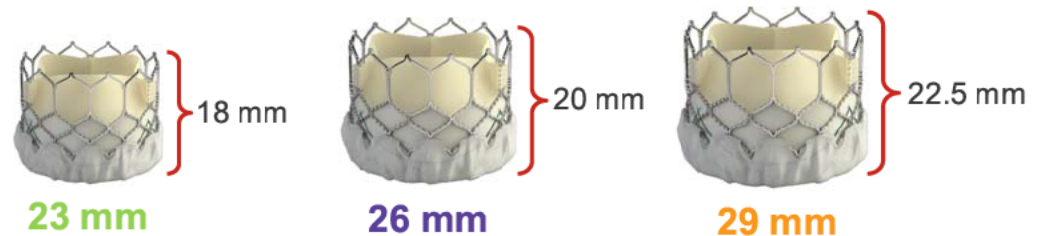
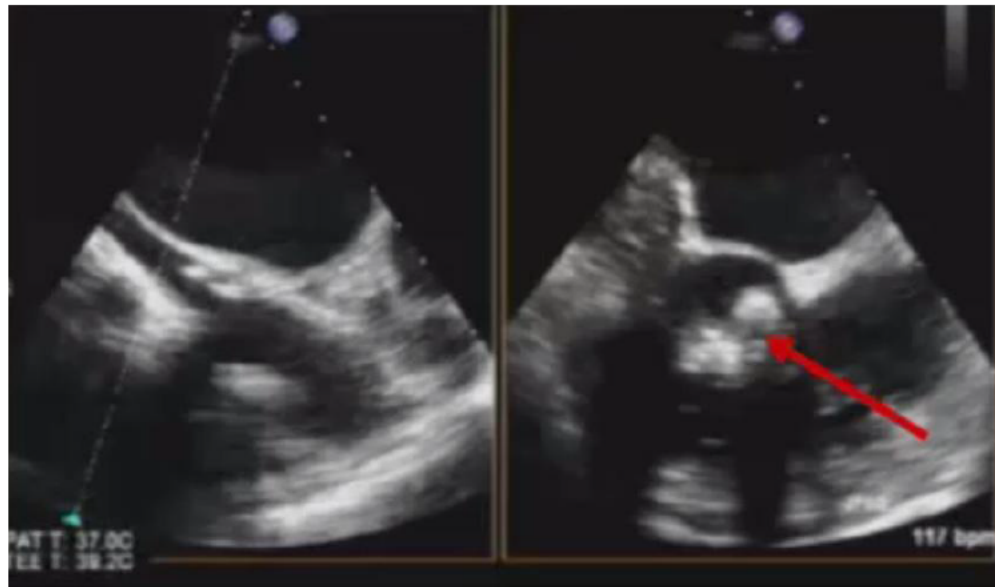


Webb et al., Circulation 2006 113: 842-850

Coronary Occlusion

Tips For Detecting Potential Coronary Occlusion Prior to THV Deployment

- Thorough prescreening with Aortogram, CT and Echo
- Reference expanded heights of THV
- During pre-dilation, note bulky calcification on valve moving toward ostium of coronaries
 - Use an aortogram during BAV to assess coronary flow
- Intraprocedural aortogram or TEE prior to THV implantation



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