Considerations for Assessing the Inoperable Patient with Aortic Valve Disease

“Inoperable” is defined in the PARTNER trial as a probability of death or serious, irreversible morbidity associated after open AVR exceeding 50%. It must be acknowledged that “inoperable” is frequently an integration of multiple dimensions of an individual patient in whom no simple, single-factor quantifiable line can be drawn between operable and “inoperable.” Surgeons are required to ask themselves “Before TAVR was available, would I have offered this patient surgical AVR?” The answer must always be “no.”

The following guidelines describe the various anatomical and technical factors or medical comorbidities which alone or in combination lead to a designation of “inoperable”:

1. **Porcelain Aorta**: Heavy circumferential calcification of the entire ascending aorta extending to the arch such that graft anastomosis at the distal ascending aorta/arch using DHCA is impractical and simple aortic cross-clamping is not feasible.

2. **Hostile Chest**: Abnormal chest wall anatomy due to severe kyphoscoliosis or other skeletal abnormalities (including thoracoplasty, Potts’ disease), complications from prior surgery, evidence of severe radiation (especially 60Cobalt orthovoltage) damage, e.g., skin burns, bone destruction, muscle loss, diffuse calcification of aorta, aortic and mitral valves, and coronary ostia, radiation lung fibrosis or esophageal stricture, history of multiple recurrent pleural effusions or other reasons that make redo operation through sternotomy or right anterior thoracotomy prohibitively hazardous. History of reconstruction for sternal infection, in the absence of other unusual anatomic features, does not meet the definition.

3. **Pulmonary Disease**: Severe COPD, pulmonary fibrosis or restrictive lung disease that make the likelihood of postoperative respiratory failure > 50%

4. **RIMA/LIMA or other critical conduit(s) crossing midline and/or adherent to posterior table of sternum**: In patients with prior CABG, a patent LIMA or RIMA graft that is adherent to the sternum such that injuring it during re-operation is likely.

5. **Frailty**: A clinical syndrome in which multiple medical comorbidities result in debilitation such that the likelihood of meaningful functional recovery after open AVR is less than 50%. A majority of the PARTNER-II patients must be able to complete 6 minute walk testing by protocol; thus, neuromuscular impairments and motor sequelae of prior strokes argue against their candidacy. To be classified as frail, being the sole or primary reason for inoperability, must fulfill 3 out of 4 criteria: 1. Grip strength (< 18 kg), 2. 5 meter walk (> 7 secs), 3. Serum albumin (< 3.5 mg/dL), 4. Katz ADLs (4/6 or less).

6. **Dementia**: Neuologic impairment such that day-to-day functioning is impaired. Patients with early or intermediate dementia can be considered but those with severe dementia who are unable to consent for themselves should not be considered. A formal neuologic assessment is recommended but the following guidelines documenting severity can be considered: Early: May lose keys, occasional forgetfulness, still independent, often driving, may be on Aricept. Intermediate: more forgetful, still feeds, dresses, not driving, requires constant supervision. Late: Not living independently, cannot give informed consent, most in SNF or assisted living home requiring lots of attention. Palliative/supportive care only.

7. **Liver Cirrhosis**: Biopsy-proven cirrhosis with portal hypertension or hepatocellular dysfunction. Suggested documentation: MELD Score, Childs class, history and date of encephalopathy, esophageal varices, history of UGI bleed, TIPPS, history of portal-caval or spleno-renal shunt. Treatment plan from hepatologist and expected survival. Plan for intraprocedural imaging in patients with esophageal varices.

8. **Severe Cerebrovascular Disease**: Bilateral compromised anterior and vertebrobasilar cerebral circulation which is not revascularizable.
Pre-procedural Imaging for Transcatheter Aortic Valve Replacement—CHEST-ABD-PELVIS contrast CT (PARTNER Trial)

Two stage contrast enhanced CT angiogram with 64 channel CT.

1. Non-ECG gated helical CTA of the abdominal aorta and iliofemoral arteries to evaluate access vessel status.
2. ECG-gated CTA of the aortic root and thoracic aorta, where ECG-gating reduces cardiac motion artifacts that can distort or obscure the aortic root, aortic valve, and coronary origins.

In patients with normal renal function, two separate contrast injections are done, 80 cc’s for the first stage CTA of the abdominal aorta and access vessels, 70 cc’s for the second stage CTA of the thoracic aorta and heart. In patients with renal insufficiency, only a single contrast injection is administered for the CTA of the abdominal aorta. The ECG-gated CT of the chest is performed as a delayed scan after the abdominal aorta CTA, which still allows characterization of the amount and distribution of calcifications, and measurements of the aortic root. Image sets consisting of near isotropic voxels (thinnest reconstructed slice thickness – 0.625 mm) should be constructed and saved for 3D image post-processing.

Patient prep: Supine, feet first. Need ECG leads placed. No beta blockers or nitroglycerin provided. Load 150 cc Omnipaque 350 and saline for flush. IV should be placed in the Right Antecubital vein whenever possible.

**Stage I Abdominal Aorta CTA**

Scan phase, extent: Arterial = from diaphragm to lesser trochanter.
Contrast bolus: Omnipaque 350 (80 cc contrast @ 5cc/sec + 30cc saline chaser @ 3cc/sec).
Scan timing: Smart Prep at the level of L1. Twelve sec scan delay, ROI on aorta, Scan phase threshold when >70hu.
Technique: Helical acquisition with pitch 1.375:1; typical 120 kVp, xyz ATCM enabled (NI30 for 0.625 mm slice recons)

**Stage II prospective ECG-triggered CTA chest (following abdominal aorta CTA)**

Scan phase, extent: Arterial = from lung apices to diaphragm.
Contrast bolus: Omnipaque 350 (70 cc contrast @ 5cc/sec + 30cc saline chaser @ 3cc/sec).
Scan timing: Smart Prep below carina, 8 sec scan delay, ROI in ascending thoracic aorta, Scan phase threshold when >70hu
Technique: Axial step-and-shoot, prospective ECT-triggered. Rotation time 0.35 sec, to minimize dose padding 0 ms, 100 or 120 kVp and manual fixed mA set depending upon patient body size.