Problem Based Learning Discussion

**PBLD 23: Transcatheter Aortic Valve Replacement**

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**Presentation Overview/Learning Objectives**

1. Outline the procedural steps of Trans-catheter Aortic Valve Replacement (TAVR)
2. Highlight the potential pitfalls which can occur during each step of the procedure
3. Emphasize the multidisciplinary nature of the case and the need for optimal communication and collaboration during the procedure
4. Clarify the role of the Anesthesiologist during TAVR
5. Discuss potential strategies for optimizing case flow and outcome

**Background and Significance**

Trans-catheter Aortic Valve Replacement (TAVR) is an evolving procedure designed to replace a stenotic aortic valve using a catheter-based technique. Currently, there is one commercially available trans-catheter valve in the United States (Edwards SAPIEN), although a competing design is in clinical trial (Medtronic Core Valve). Medical considerations to be discussed refer specifically to the Edward SAPIEN valve, the published results from its evaluation in the PARTNER trial, and real life experience of the presenters.
Mortality for cardiac surgical procedures is often estimated utilizing STS database predictors. Variables including age, weight, proposed surgery, baseline cardiac function, prior cardiac interventions, and co-morbidities are compared to known outcomes to estimate 30-day mortality and surgical decision-making is influenced by such estimates. Patients being considered for TAVR typically have a predicted 30-day mortality exceeding 10%. As a subset they represent the sickest 5% of patients used to create the algorithm.

The PARTNER trial simultaneously studied the use of TAVR in two different populations. Cohort A, designed to compare outcomes between high-risk operative candidates randomized to traditional surgery vs. percutaneous replacement by either trans-femoral or trans-apical access, demonstrated comparable 1-year mortality (24.2% vs. 26.8%) but higher stroke rates (1 year stroke/TIA - 8.3% vs. 4.3%). Cohort A was felt to demonstrate non-inferiority to traditional AVR, although attempts to achieve better neurologic outcomes are being investigated. Cohort B, comparing maximum medical management in otherwise non-operative candidates to percutaneous replacement via trans-femoral access, demonstrated a decrease in 1-year mortality of 20% (30.7% vs. 50.7%).

Two different approaches are available for the Edwards valve: retrograde through percutaneous femoral access, or antegrade through the LV apex via left mini-thoracotomy. The percutaneous femoral approach requires that the patient’s vasculature accept a 27 French introducer sheath. Tortuous iliac vessels or high athermanous burden may preclude femoral vascular access. Endoluminal diameters of at least 8mm, as assessed by angiography or CT scan, are mandatory for trans-femoral TAVR. Patients with large vessel vascular disease may instead be considered for trans-apical TAVR.

Trans-femoral TAVR can be performed in a cardiac catheterization lab or hybrid OR; whereas trans-apical cases are more appropriate for an operating room but still require fluoroscopy and angiography. Regardless of where the procedure is performed, enough geographical space is required for general anesthesia, trans-esophageal echocardiography, and cardiopulmonary circulatory support, in addition to the space required by the proceduralists. Institutional financial and scheduling constraints factors may determine the ultimate choice of location for the procedure.

Delivery of an optimal anesthetic involves numerous considerations which may not be part of the scenario in typical OR cases because the proceduralist may not be a surgeon and there are multiple (non-physician) disciplines participating. The choice of anesthesia provider is therefore critical. Ideal staff members are good
communicators with cool heads who are pragmatic and comfortable with asking questions. Excellent resuscitative and echocardiography skills are required. The need for providers from all disciplines to participate fully in integrated, collaborative practice during these cases cannot be overstated.

For trans-femoral cases, general endotracheal anesthesia (GETA) is preferred by most providers, although institutions in the US and Europe report successful outcomes with conscious sedation. For trans-apical cases, GETA is a requirement. Invasive arterial pressure monitoring and central access are mandatory. The controversial utility of pulmonary arterial pressure monitoring is beyond the scope of this session, although PAC placement was a requirement of the PARTNER trial. Planning an anesthetic which permits the patient to be extubated is reasonable and is determined by the patient’s comorbidities and the course of the procedure itself. In our experience, patients having trans-femoral TAVR only occasionally require postoperative ventilation whereas those having trans-apical cases require it frequently.

Some institutions in Europe report successful TAVR outcomes using intracardiac echo (ICE) and/or fluoroscopy alone, however in our experience; trans-esophageal echocardiography (TEE) has a critical role during several phases of the procedure. Before any intervention, aortic stenosis with trileaflet valve should be confirmed – TAVR cannot be performed with bicuspid valves. Degree of aortic insufficiency should be assessed pre-valvuloplasty; the presence of mild to moderate AI may be protective in cases of new-onset severe AI following BAV. Ejection fraction, degree of mitral and tricuspid regurgitation, the presence of MAC and mitral stenosis, estimated pulmonary artery pressures and coronary artery takeoff location are also useful measurements. Accurate measurement of aortic annulus aids in choice of prosthetic valve size. During the placement of the valve, real-time echocardiographic guidance can assess positioning of the prosthesis. Following valve deployment, rapid assessment of valvular function, presence of leaks and ventricular wall motion abnormalities are critical.

**Trans-femoral TAVR: Procedural Steps**

1. Establish appropriate anesthetic plane
2. Place Invasive Monitors, large access +/- PAC and Cerebral SvO2
3. Perform TEE in presence of entire team (cardiologists, surgeons, anesthesiologists) to confirm and discuss findings
4. Establish femoral vascular access with arterial sheath, contralateral trans-femoral aortic occlusion balloon and trans-venous pacer
5. Perform standard balloon aortic valvuloplasty (BAV)
- Refine ambiguous sizing with balloon
- Enlarge orifice to accept valve & balloon device
- Assess hemodynamic response to rapid ventricular pacing with interruption of systemic circulation
6. Sheath upsized to 27 French introducer via serial dilation
7. Trans-catheter valve advanced and positioned
   - Adequacy of location determined by fluoroscopy and echocardiography
8. Valve deployed under rapid ventricular pacing
9. Valve position and function assessed
   - Absence of occluded coronary ostia confirmed
   - Valve gradient measured
   - Perivalvular/Central leaks assessed
   - Determine need for any additional interventions
10. Sheath removal and vascular closure

**Trans Apical TAVR: Procedural Steps**

1. Establish General Anesthesia
2. Place Invasive Monitors, large access +/- PAC and Cerebral SvO2
3. Perform TEE in presence of entire team (cardiologists, surgeons, anesthesiologists) to confirm and discuss findings
4. Establish vascular access for (femoral) trans-venous pacemaker placement
5. Establish surgical access
   - Cannulation for Cardiopulmonary Bypass
   - Mini-thoracotomy incision
   - Apical purse-string sutures
   - Trans-apical guidewire thru LVOT into AscAO, avoiding mitral subvalvular apparatus
6. Perform Standard BAV
   - Assess tolerance of rapid v-pacing
   - Refine ambiguous sizing with balloon
   - Assess results post-BAV
7. Insert Sheath into Apex
   - Serial dilators, careful advancement
   - Sheath 24-27F
   - Anticipate blood loss
8. Trans-catheter valve advanced and positioned
9. Valve deployed under rapid v-pacing
10. Valve position and function assessed
    - Confirm non-occluded coronary arteries
    - Obtain Valve gradient
    - Assess Central & Perivalvular leaks
    - Determine need for potential additional intervention
11. Sheath Removal
    - Rapid v-pacing vs. CPB
Overview of Common Complications and Resolutions

Femoral access serves several purposes beyond the obvious placement of the valve apparatus. In the event of vascular catastrophe, contralateral arterial access permits inflation of an Endoluminal distal-aortic occlusion balloon, which can prevent fatal hemorrhage. If percutaneous access cannot be obtained, cut-downs or surgical access to the aortic bifurcation have been reported.

A transvenous pacing wire is required for the rapid ventricular pacing used to establish a near-zero cardiac output state during ballooning of the aortic valve. AV node dysfunction can occur after valvuloplasty or valve deployment, and post-procedure pacing may be necessary. One person at the table should be designated as the pacer operator; he/she should have no other responsibilities at that time. Poor communication during rapid ventricular pacing may be catastrophic. Premature cessation or loss of pacer capture during balloon valvuloplasty can place excessive traction on the native valve during balloon inflation and unexpected ventricular ejection may embolize the valve from the annulus during valve deployment. Clear and concise statement of pacing capture, initiation and cessation are essential

Edwards SAPIEN valves are available in two sizes, 23mm and 26mm, and can be placed in patients with aortic annulus diameters ranging from 18-25mm. Sizing is best accomplished with a mix of fluoroscopy and echocardiography, with a 23mm valve generally used for annular diameters of 18-22mm, and 26mm valve for annular diameters of 23-25mm. Valves are assembled and crimped onto an introducer balloon during the procedure. In our experience, valves should be immediately available for deployment in the event of cardiovascular compromise after BAV. In addition, valves left prepared on the balloon but otherwise undeployed for significant amounts of time may deploy improperly with leaflets that remain stuck open after deployment.

Hemodynamic changes may occur at a variety of points during the procedure. Communication between providers of different disciplines is essential. Patients respond idiosyncratically to balloon valvuloplasty – new onset aortic insufficiency may require significant support and necessitate rapid valve introduction and deployment. Inotropic support may be necessary to maintain systemic blood pressure as balloons and crimped valves traverse the valve orifice. Invasive monitors typically reflect low cardiac output, falling SvO2 and high pulmonary artery pressures. The authors routinely have boluses of epinephrine, norepinephrine and vasopressin available in a variety of concentrations.

The following complications can occur during and after valve deployment:
- Perivalvular leak
- Asymmetrical deployment, with perivalvular leak
- Central leak
- Stuck leaflet
- Embolization into ascending aorta
- Embolization into left ventricle
- Coronary occlusion
- Cardiovascular collapse
- Aortic rupture
- Acute stroke
- Femoral vascular avulsion

Perivalvular leaks are frequently tolerated post-deployment, and most commonly occur near the aortic-mitral interface. Communication of the amount and location of the leak is essential to gauging results. Generally, a 2+ perivalvular leak is felt to be an acceptable result (much more than with surgical AVR!), although additional, subsequent interventions may be performed if the patient is not tolerating the amount of leak. Re-ballooning the valve may decrease the amount of leak. Valves may occasionally deploy asymmetrically against the native aortic annulus, and perivalvular leaks from a “crooked” valve may require a second, lower valve deployment with a valve-in-valve result. In addition, leaks may be reduced or eliminated with small perivalvar occlusion balloons during subsequent procedures. Central leaks are common, especially when the size of the annulus is near to the size of the valve. These are also frequently tolerated, although they may be remedied with a valve-in-valve technique if the leak is large or a leaflet is stuck. The possibility of a stuck leaflet should be considered in any cases of severe central leak and should be communicated immediately.

Embolization into the aorta can occur as a result of ejection due to inadequate pacer capture or inappropriately high deployment. Once a valve is in the aorta, it cannot be retrieved endovascularly. Lodging a valve in the descending aorta has been reported and is tolerated; however, a second valve must still be deployed in the aortic position. Valve loss into the ventricle may occur if deployment is too low. This result requires surgery for retrieval and may be fatal if comorbidities are significant.

Coronary occlusion may occur if native aortic valve tissue occludes a coronary ostium. Prior CABG with patent grafts is partially protective. Coronary guidewires may be placed in patients that are at higher risk. Skilled intervention is required to reopen occluded coronary arteries. Clear communication between all parties is essential in the event of regional wall motion abnormalities, ST-segment changes or hemodynamic compromise.

Cardiovascular collapse during trans-femoral cases may require cardiopulmonary support. Institutional variability exists regarding the type of support planned – some institutions have a primed cardiopulmonary bypass pump in the room, even if the case is in an out-of-OR cath lab; others have percutaneous-VAD support on-hand. In either case, a team effort with good communication is necessary in the event of emergent circulatory support. In the event of p-VAD support,
echocardiographic guidance may be necessary to guide trans-septal puncture for inflow cannula placement.

Aortic rupture has been reported; this is generally not a survivable event. Acute stroke might be detected with unilateral changes in cerebral oximetry readings. The higher stroke rate of Cohort A patients in the PARTNER trial was felt be a result of both ballooning of the calcified native valve and the introduction of a large balloon/valve apparatus across the aortic arch. Anesthetics allowing for early neurologic assessment are preferred.

Femoral vascular avulsion is possible upon removal of the introducer sheath, and the potential massive hemorrhage that may follow can be temporized with the distal aorta occlusion balloon residing in the contralateral femoral artery. Vascular surgical repair is obviously necessary in this event.

Case flow and procedural considerations for trans-apical TAVR differ from trans-femoral. Foremost, patients undergo a mini-thoracotomy to expose the left ventricular apex, so an operating room is a much more suitable environment. In the authors’ institution, trans-femoral TAVR cases are performed in the cardiac cath lab, but trans-apical cases are performed in the hybrid OR. In addition, because of the high rate of cardiovascular collapse, all trans-apical TAVR patients are cannulated for cardiopulmonary bypass via axillary arterial and percutaneous femoral venous access. After vascular and ventricular access is obtained, blood loss is invariable as the introducer sheath is inserted into the heart. Hemodynamic abnormalities are more common, and patients commonly require cardiopulmonary bypass for either cardiovascular collapse or to remove the introducer sheath from the left ventricle. For all of these reasons, the importance of clear and concise communication between providers is essential.

Case Presentation

An 88 year old man with coronary artery disease, COPD, and peripheral vascular disease presents with critical aortic stenosis. Eighteen years ago, he underwent a 3- vessel CABG. He did well for a number of years, but developed worsening shortness of breath over the last two years. Transthoracic echocardiography indicates that he has severe aortic stenosis with a valve area of 0.6cm², trace aortic insufficiency, mild mitral regurgitation, mild LVH, and an ejection fraction of 55%. Cardiac catheterization reveals patent grafts. STS Database mortality predictions estimate his mortality at 18% for a Reop-AVR. He presents to your institution for Percutaneous Trans-catheter Aortic Valve Replacement.

Questions for Consideration:
1. What is trans-catheter aortic valve replacement, what is the target patient population and why has this technique become so popular?
2. How is operative risk assessed for patients with aortic stenosis?
3. Is this patient an appropriate candidate for traditional surgical AVR?
4. If no surgery is available, what medical management options are available?
5. What was the PARTNER trial?
6. What outcome data was demonstrated for patients that were randomized to surgery vs. percutaneous replacement (Cohort A)?
7. What outcome data was demonstrated for non-surgical candidates that were randomized to maximum medical management vs. percutaneous replacement (Cohort B)?
8. What percutaneous aortic valves are commercially available in the United States?
9. What factors influence the decision to perform a trans-femoral vs. trans-apical aortic valve replacement?
10. Should the procedure be performed in an operating room, a cardiac catheterization lab, or a hybrid OR? What are the space requirements of the location for a safe anesthetic and procedure?
11. Which anesthesia providers are best suited for this procedure?
12. Is a general anesthetic mandatory?
13. What monitors are necessary?
14. Is trans-esophageal echocardiography mandatory?
15. Is an extubatable anesthetic reasonable?
16. What are the general steps of a trans-femoral aortic valve replacement?
17. What is the purpose of placing a trans-femoral venous pacing wire?
18. What is the purpose of placing an occlusion balloon in the contralateral femoral artery?
19. How large is the arterial introducer sheath that is placed into the descending aorta?
20. After a wire is introduced across the valve, why does the patient receive an aortic balloon valvuloplasty?
21. What are the hemodynamic and echocardiographic considerations to assess immediately post-valvuloplasty?
22. What size valves are available and how is a decision made regarding which to use?
23. What are the hemodynamic consequences of placing an undeployed valve and balloon apparatus through the orifice of a stenotic valve?
24. At the time of valve deployment, who is responsible for operating the transvenous pacer and why is this a critical consideration?
25. How is the proper landing zone for valve deployment identified? Is fluoroscopy superior to echocardiography?
26. What are the hemodynamic and echocardiographic considerations to assess immediately following valve deployment?
27. What is the remedy for a valve with a perivalve leak? Can a valve be re-balloonered?
28. What is the remedy for a valve with a central leak?
29. Can a valve-in-valve technique be utilized in either of these situations?
30. Should leaks be assessed with echocardiography, angiography, or both?
31. What happens if a valve is deployed too high and embolizes forward?
32. What happens if a valve is deployed too low and embolizes into the left ventricle?
33. What if the crushed remnants of the native aortic valve occlude the ostium of a coronary artery?
34. What resources are available in the event of cardiovascular collapse?
35. How would acute aortic rupture present?
36. How can patients be monitored for acute stroke?
37. What happens if the large aortic introducer sheath avulses the femoral artery upon removal?
38. How are the steps of a trans-apical aortic valve replacement different?
39. For trans-apical TAVR, how do surgical and patient considerations change decisions regarding venue, anesthetic plans, and available cardiopulmonary support?
40. How is collaborative practice an essential component to good patient outcomes in these cases?
41. At what points in these procedures can poor communication lead to critical failures?
42. What barriers to communication exist between surgeons and anesthesiologists? Between cardiologists and cardiac surgeons? Between Cardiologists and anesthesiologists?
43. What operational strategies should be put in place to minimize communication obstacles?

References