Challenges in Transcatheter Aortic Valve Implantation (TAVI)

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Part of the excitement surrounding the recent developments in aortic surgery is associated with transcatheter aortic valve implantation (TAVI) procedures. This relates to the prospect of taking a clinically tenuous patient, performing a percutaneous or minimally invasive procedure, extubating in the hybrid operating room, and having the patient discharged from the hospital on the sixth post-operative day. Additionally, many of these patients had been deemed inoperable and unsuitable for a standard median sternotomy aortic valve replacement. Fascinating when procedurally flawless, the management of these cases requires a heightened level of preparation and precise strategies. The challenges of successful TAVI management include the coordination of services across specialties, the comorbidities of the TAVI population, and the technical problems of the valvuloplasty and deployment of the prosthetic device.

TAVI procedures frequently involve multiple medical and surgical specialty groups in novel locations, such as the cardiac catheterization laboratory or hybrid operating room. The laboratory or operating room is either specifically designed for this purpose or post-construction retro-fitted for this purpose. Either way, the number of personnel required often exceeds the room design and a floor plan must be created to place necessary personnel in critical positions. Easy access to the patient, as well as emergency and resuscitative equipment must always be maintained. With surgeons, cardiologists, anesthesiologists, nurses, perfusionists, technicians, and device representatives in attendance, positions in the room with well-defined roles must be clearly established. This calls for the development of a protocol, which is best done in coordination with an experienced TAVI team from an outside institution. It can be done either by an outside visit, having that team advise or observe the developing team, or via web based discussions and observations. Important personnel protocol questions to be answered include: 1. How many surgeons are required for the safe entry during a transapical approach? 2. Who will establish arterial and venous groin access? 3. Will the procedure be performed under general anesthesia or sedation with local anesthesia? 4. How many anesthesiologists attend, and what should be their role? 5. Who is controlling the external pacemaker for the induction of ventricular tachycardia and rhythm maintenance, as well as who is at the helm of the external defibrillator? 6. Who will be responsible for the performance of the balloon angioplasty and valve deployment? 7. Which physician will remove the deployment systems and sheaths? 8. Who has the ability to abort the procedure and
under which circumstances? The protocol developed is highly institutional and device specific. Our collective experience includes 250 patients that involve two surgeons and two cardiologists. Groin arterial and venous access is secured by the cardiologist, with the device deployment and valvuloplasty generally performed by either the surgeon or cardiologist who was first consulted for the patient. The procedure is performed under general anesthesia due to the inherent risk of catastrophic complication. A second anesthesiologist is present to perform the TEE examination during the critical period of balloon valvuloplasty and device deployment, with the attending anesthesiologist being responsible for medical resuscitation from periods of induced VT and new or worsened AI during that time period. The cardiologist controls VT induction and the external pacing device, with the circulating nurse stationed at the defibrillator. As per safety protocol, prior to the initiation of the valvuloplasty an additional “time-out” is called during which all parties are identified that they are in place and ready to act. If at any time during the procedure a member of the team is uncertain that the equipment or their role cannot be performed, they announce this to the room at large. Positioning of the device is confirmed with TEE, fluoroscopy, and a computer generated model. Three-dimensional TEE imaging offers promising views of device positioning.1 Complications and near-misses can be minimized or avoided by striving for precision in performance with multiple personnel involved in a cardiac surgical procedure, which has minimal or no direct access to the mediastinum.

Additional challenges to the performance of TAVI include the inherent risks associated with comorbidities of the patient population. In order to be included in the PARTNER trial (Edwards SAPIEN valve, Edwards Lifesciences LLC, One Edwards Way, Irvine CA) as cohort A, patients must have had a minimum STS score of 10, operative mortality of ≥ 15%, and NYHA functional class II or greater.2,3 As cohort B, patients had medical factors which precluded operation and had a probability of death or serious, irreversible morbidity exceeding 50%. FDA approval for this device was achieved Nov. 2, 2011 to be used only in those patients who cannot undergo open heart surgery. This places some of the most high-risk, debilitated patients in an environment where the operators do not have full access to the surgical field-the heart and aortic root. The typical TAVI patient is likely to have had prior open cardiac revascularization, coronary stenting, hypertension, renal insufficiency, carotid disease, significant smoking histories, peripheral vascular disease, and is at an advanced age. Many of these patients are nutritional depleted and have limited physical mobility. Some candidates have had the intended date of procedure delayed in order to optimize their medical or physical status pre-operatively, including preemptive balloon valvuloplasty. Once in the operating room, due to the tenuous clinical status of the patient and the acute changes in hemodynamics expected during the procedure, having one anesthesiologist focused on the acute medical patient management and an additional anesthesiologist performing the TEE during TAVI maneuvers has proven to be optimal practice.4,5 Depending on the baseline LVEF, inotropic support may be
operating in inflation device for procedure placement (AI). Vasopressors are commonly used to help restore the blood pressure to acceptable means following periods of induced ventricular tachycardia during maneuvers. A goal mean arterial pressure should be agreed upon and following periods of rapid ventricular pacing adequate recovery time is allowed for recovery of hemodynamics. Those patients with pure AS (without AI) and small LV intracavitary size or reduced LVEF have proven to be particularly problematic following balloon valvuloplasty and its resultant acute AI. This situation can demand prompt device deployment which may preclude adequate recovery of baseline hemodynamics. If the procedure is performed under general anesthesia, the goal is to achieve extubation in the operating room for the transfemoral approach or within 4 hours post-operatively for the transapical approach. The anesthetic is designed with this time frame in mind, with frequent use of remifentanil/propofol infusions. This frail population recovers best when extubation is achieved earliest. The patient arrives in the intensive care setting with the arterial and venous sheaths in place, to be removed post-operatively. Heart block may be encountered post valve deployment, and rarely for the first time in the ICU, therefore the venous sheath +/- transvenous pacing wire may be left in place for the first 24 hours. Vigilant management allows for the most optimum recovery following TAVI.

Despite the most scrupulous care, technical problems are inherent to the procedure and this patient population. During the invasive line placement, following induction of general anesthesia, episodes of heart block or ventricular tachycardia have been encountered during placement of the pulmonary artery catheter. This is poorly tolerated in the AS patient, and therefore PAC advancement into the right heart is delayed, particularly in the presence of a complete LBBB, until groin venous sheath and right ventricular transvenous pacing is secured. Cardiac chamber perforations can occur as a result of the guide wire, balloon, or deployment device positioning and advancement. This is usually followed by rather prompt decay in hemodynamics and pericardial effusion, with or without frank tamponade, which can be detected via TEE. After balloon valvuloplasty brief increases in AI or acute new AI is problematic as mentioned above. Following valve deployment a variety of technical problems can ensue. Most commonly, due to either improper sizing or insufficient balloon inflation deployment of the valve, a paravalvular leak may be detected on TEE. A useful echocardiographic window to detect this is the deep transgastric zoom view. Repeat balloon inflation is usually repeated to facilitate proper seating of the valve. It is key to establish
whether the insufficiency is paravalvular versus intravalvular, and multiple echocardiographic windows may be interrogated to accurately detect the origin the regurgitation. Intravalvular insufficiency may be due to a damaged cusp during the crimping process of the valve or due to cusp damage during the balloon facilitated deployment. This is typically addressed by deploying a new valve within the prosthetic valve already in place. Rarely, the aortic root can suffer injury during the balloon valvuloplasty, but more likely during the valve deployment. This would result in hemodynamic compromise and ensuing pericardial tamponade as detected by TEE. An additionally catastrophic event would include malposition of the valve in a cardiac chamber or vascular structure, otherwise referred to as valve embolization. Aortic root injury or valve embolization would require a team decision as to whether to proceed to an open procedure or to secure the valve in the aberrant location, respectively. Likewise acute aortic or arterial branch injury can occur at any point as equipment is advanced, and a surgical decision would be required. Arterial and venous injury in the groin is typically easily addressed. The transapical TAVI carries the risk of bleeding at the site of LV apical trocar placement. Reversal of heparinization at the completion of the TAVI and avoidance of hypertension both aid in the control of blood loss. Although the mitral valve is at risk with any procedure in which instruments are introduced into the left heart, it has been more problematic with the transapical approach. Mitral valve function is monitored throughout the procedure to detect disruption of the MV apparatus. Systemic arterial embolism can occur and distal arterial pulses are assessed at the completion of the procedure, prior to leaving the operating room, to allow for prompt embolectomy. In the intensive care unit the patient is assessed for sequelae of embolic events.

Although fraught with challenges, it is a powerfully rewarding experience to take some of the most tenuous patients through an aortic valve replacement, without a chest incision or the risks of exposure to cardiopulmonary bypass. It is expectant that as the technology and skill improve, that these devices will be utilized in a healthier patient population.

References


