UCSF TAVR Pearls

INTRODUCTION

Indications:

Surgical aortic valve replacement (SAVR) is recommended for symptomatic patients with severe aortic stenosis (AS, Class I recommendation). Diagnostic criteria for severe AS includes mean transaortic gradient greater than 40 mmHg, peak velocity greater than 4 meters/sec, and valve area less than 1 cm^2. The natural clinical course of degenerative aortic stenosis is that of slow but predictable progression with concurrent compensations such as left ventricular hypertrophy (LVH). However, once symptoms develop—angina, syncope, and dyspnea on exertion—the prognosis declines quickly, and mortality occurs within 2 to 5 years if unoperated. AVR may be recommended in asymptomatic AS if the patient has left ventricular systolic dysfunction (LVEF < 50%), very severe AS (peak velocity > 5m/s), or exercise-induced hypotension. Diagnosis and management of low gradient (and low flow) severe AS is complex, and beyond the scope of this primer.

Transcatheter AVR (TAVR) is an alternative to SAVR. Landmark PARTNER trials demonstrated the feasibility and safety of TAVR in those patients with high or prohibitive surgical risk. TAVR prosthetic valves are in continuing evolution, and interventional cardiologists are constantly looking to expand their indications. In 2019, FDA approved the use of several TAVR valves for implantation in low risk patients. Unsurprisingly, that year, the number of TAVR performed in the U.S. surpassed that of SAVR for the first time, and the trend is likely to continue.

Patient demographics and selection

TAVR candidates undergo an extensive preoperative evaluation and assessment. Here at UCSF, each case is discussed in the structural heart conference, attended by cardiologists, interventional cardiologists, cardiac surgeons, echocardiographers, radiologists, and anesthesiologists. Ultimately, the endorsement by a UCSF cardiac surgeon is required to proceed with the TAVR. Clinical history, preoperative coronary angiography, echocardiography, and 3D CT or MR angiography of the aortic valve and aorta are reviewed. The patient's symptom, the severity of the AS, the anatomy of the aortic valve as well as the vascular anatomy can affect the candidacy for TAVR. The aortic valve annulus and the prosthetic size are best determined by the preoperative (TAVR protocol) CTA or MRA. CTA will report the diameters, degree of calcification and tortuosity of the aorta and peripheral vessel, which will determine the choice of access/approach. Concurrent procedures such as percutaneous coronary intervention (PCI), pacemaker implantation, vascular surgery, or perioperative mechanical support will also be determined at the conference.

While TAVR has been approved for low-risk patients, the majority of the patients here at UCSF are ASA III/IV with elevated STS scores for SAVR. Due to the slow progression of

AS, they tend to be elderly, often frail, and have significant comorbidities. Cardiovascular diseases, whether consequences of the severe AS, are common. Pulmonary, liver, renal and hematologic diseases are common, and may have influenced the decision to pursue a less invasive procedure. A subgroup of patients may have had previous cardiac surgeries and sternotomy. Repeat sternotomy carries significant surgical risk in itself—injury of right ventricle, great vessels, or previous bypass grafts. Such patient and the surgeon may choose TAVR as a safer alternative.

Types of valves

There are several different TAVR valves approved by the FDA. At UCSF, the two common ones are SAPIEN 3 (Edwards) and Evolut (Medtronic). There have been continuing research and development in these devices, and as of 2020, both Edwards and Medtronic valves are in their third iteration. Each system can be differentiated by its method of expansion, presence of external sealing skirt, re-capture/re-position-ability, size of the delivery system, and other design traits.

SAPIEN 3 and SAPIEN 3 Ultra are balloon expandable valves (bovine pericardium), i.e. the valve is loaded with an inflatable balloon catheter inside, and the inflation of the balloon expands the valve until it is “flush” against the annulus. It has an outer skirt for better contact and seal with the calcified annulus to decrease perivalvular leak. It has a lower profile height compared to the Medtronic valves, which is more favorable in those with low coronary ostial height. Balloon expandable valves have higher, though still rare, incidence of annular rupture.

Evolut and Evolut PRO are self-expanding valves (porcine pericardium). Expansion without the use of balloon in theory avoids excessive force on the annulus and decreases the risk of rupture. However, the incidence of perivalvular leak is slightly higher. The valve can be repositioned after deployment and even retrieved, which the Edwards system cannot. Medtronic valves also cover a larger range of annular sizes, at the extremes.

There are other technical differences between the two systems. Registries have also shown minor differences in outcomes such the need for permanent pacemaker. Ultimately, the cardiologist makes the decision on which valve to deploy based on patient characteristics and the operator’s personal experience and preference.

Technique/Access plans

The key to TAVR is to access the aorta and deliver the prosthetic valve to the aortic root endovascularly. Trans-femoral, trans-subclavian, trans-carotid and trans-aortic approaches accomplish this by access the respective major arterial branch (or the ascending aorta), and deliver the prosthesis retrograde to the aortic root. Trans-apical approach delivers the prosthesis in the antegrade direction by entering the LV via an apical puncture. Trans-caval is a variation on the trans-femoral approach by crossing into the abdominal aorta via the IVC. See the Procedural Summary section for more details on each approach.

PREOPERATIVE ASSESSMENT

Cardiovascular: May be the consequence of end stage valvular disease or independently of

- Acute decompensated HF: may need medical optimization. However, cardiologists may insist they are at the limit of medical therapy
- ECG: preexisting conduction disease may suggest the need for postop pacing
- Pulmonary hypertension: could be caused by valvular cardiomyopathy or separate etiologies
- CAD:
    - High grade, untreated CAD is a risk factor for persistent hypotension after rapid pacing
    - AS patients may have coronary microvascular disease and ischemia due to LV hypertrophy and increased LVEDP and resultant decreased coronary perfusion pressure gradient
- Echocardiography: low LVEF is a risk factor for persistent hypotension after rapid pacing

Pulmonary:

- Pulmonary edema and inability to lay flat
- Obstructive sleep apnea: sometimes excessive diaphragmatic movement may hinder procedure

Neurologic:

- Dementia/delirium: may affect cooperation and sedation
- H/o stroke: the need for sentinel

Renal:

- CKD and the risk of contrast nephropathy: hydration and prophylaxis

Liver and complications of cirrhosis:

- Thrombocytopenia & coagulopathy: bleeding risk
- Encephalopathy
- Ascites: aspiration risk
- Portal hypertension and varices: the risk of TEE (if GETA)

Vascular access/restriction:

- Avoid right arm: radial access for cardiologists
- Planning conference should have determined the size and adequacy of the vessels for access

PREOPERATIVE PREPARATION

***** Consider every case as an aerosol generating procedure, regardless of anesthesia plan (sedation vs. GA) and take precautions as necessary. There is always the possibility to convert a monitored anesthesia care (MAC) case to GA

Room/Equipment Setup

- Arch ether shield on the bed to facilitate access to airway/TEE while draped
- Airway, circuit, CO2 extensions
  - o Glidescope and stylet need to be in the OR at all times. It greatly assists intubation under the drape during emergency conversion to GA.
  - o Supraglottic airways as rescue: LMA, iGel, Air-Q, etc. May be attending dependent, but LMA may be reasonable if purely to rescue ventilation failure due to sedation.
- **Double (Triple) transducers** on the table/shield: arterial and CVP, (third transducer would be useful in case of emergent SAVR and the need for retrograde cardioplegia)
- Alaris **pumps**: upper and downer for potential postop continuation to the PACU or ICU
- Pumps (can be syringe) for intraoperative sedation
- **Right IV pole**: pumps and fluid warmer
- NO IV pole on the left (C-arm)
- **ACT machine**: QC current for both LR and ACT+. Will use LR for normal cases, need to be able to run ACT+ if CPB conversion
- Backup transvenous pacemaker box on out machine
- Always have a MAC introducer kit in the room for potential bleeding and resuscitation: can be placed emergently under the drape or in the field by the proceduralist

Monitor/Access:

- Standard ASA monitors
- Arterial line:
  - o If transfemoral TAVR under sedation, cardiology team will place in groin and pass back pressure line.
  - o If GA or alternative access (subclavian, apical, etc) we can a) place pre-induction radial line, usually on left side (cardiology need right radial for secondary access or Sentinel); b) have cardiology place a right radial access under local anesthesia
- Sentinel embolic protection device: Placed in R radial. We will keep the distal half of the right forearm free of lines so it can be prepped into the field. A hemostasis band will be placed at the site, so nothing on the dorsal forearm either.
- Defib pads: hooked up and defibrillator turned to "monitor." Anesthesia will be responsible for the defibrillation.
- Transvenous pacing (TVP)
  - o TVP will be placed in groin for most cases
  - o When there is high risk for post-op AVB, the cardiology fellow will place in the RIJ under fluoroscopy
  - o If anesthesia team plans for RIJ access, anesthesia will double stick RIJ, including the 7-Fr locking sheath for the TVP and have cardiology float the pacer.

- Echocardiography:
  - For most TF sedation cases, the TTE technician will be paged prior to deployment and will perform the post-deployment exam.
  - For most GA cases, there will be a dedicated cardiology echo team perform the intraop exam.
  - A functioning TEE machine and probe need to be in the room at all times. Cardiac anesthesia may need to perform emergency TEE.
- Processed EEG (Sedline): optional
- Cerebral NIRS: optional for sedation
- Foley is not routinely placed for sedation cases

Medications

- **Infusions** (discuss with attending on which ones to prepare)
  - Sedation: propofol, dexemedetomidine, and remifantail
  - Vasopressor: usually norepinephrine as 1^{st} line
  - Inotrope: epinephrine or dobutamine
  - Vasodilator: nitroglycerine, nicardipine, clevedipine, or nitropresside.
- **Bolus**
  - Premedication: midazolam, fentanyl as needed
  - Vasoactive agents: norepinephrine, vasopressin, $CaCl_2$, NTG/nicardipine
  - Epinephrine: useful in small boluses immediately after rapid ventricular pacing and valve deployment for sick hearts
  - Ketamine: can be useful in appropriate patients to keep still
  - Induction agents (elective or emergency GA)
    - Etomidate and rocuronium syringes on cart for emergent, hemodynamically unstable GA conversion
- **Heparin**: 10 ml syringe of 1000 unit/ml, 40 ml syringe of 1000 unit/ml in case of emergent CPB
- **Antibiotics**: typically cefazolin 2g unless allergic

Blood Products

ANESTHESIA MANAGEMENT

Monitored anesthesia care

- **Dexmedetomidine:** 0.5-1mcg/kg/hr, start as soon as possible, without a need for bolus as there usually 30 minutes or more of preparation by the OR/cath lab team.
- **Remifentanil** 0.03-0.1mcg/kg/min, or fentanyl 50-100mcg/hr, titrated to respiration.
- **Propofo**l infusion if low risk of airway obstruction.
- **Ketamine bolus** (10mg PRN) if needed for additional analgesia or hypnosis
- Both remifentanil and dexmedetomidine can exacerbate bradycardia, which may complicate the decision to keep TVP postop. The latter may also cause prolonged sedation and hypotension in the PACU.
- Additional PIV access as needed.

General anesthesia (Elective):

- See Monitor/Access section for pre-induction a-line.
- Induction and intubation per anesthesia team.
- Inhaled or intravenous anesthesia for maintenance is equally effective.
- Additional PIV or central venous access as needed.

PROCEDURAL SUMMARY/SPECIAL CONSIDERATIONS

Trans-femoral (TF): Most common approach at UCSF and world-wide. The aortic valve is retrogradely accessed via one of the femoral arteries.

- **Obtaining arterial and venous access** (femoral and radial).
- Ideally IV sedation should have reached steady state without significant change to infusion. Local anesthesia should be used liberally by the cardiologist and the surgeon. <u>Open cut down</u> to femoral vessels can be done with local in most patients. Significant airway obstruction should be avoided.
- The femoral/iliac artery may be too calcified. <u>Intravascular lithotripsy (IVL, a.k.a. Shockwave)</u> may be used to safely expand the vessel.
- **TVP placed and test for capture** at low amp. A backup rate of 50 bpm will be set.
- Scrub nurse will hand arterial and venous line to connect if needed.
    - Anesthesia team's choice to use central venous access for bolus injection or infusion of vasoactive agents.
- Give **heparin** after arterial sheath is in (700-1000 units/kg initial bolus), follow ACT q20-30 minutes (goal ~250-300 seconds)
- <u>Cerebral embolism protection</u>. Sentinel device is usually inserted from the right radial artery. The filter baskets need to be positioned and deployed under fluoroscopy in the proximal brachiocephalic artery and left common carotid artery.
- A pigtail injection catheter will be used for **aortic root angiogram** to delineate the boundary of the aortic root.
- **Crossing the aortic valve** with a wire and followed by a catheter, then the sheath.
    - This can be time-consuming with a stenotic, calcified valve.

    - A common sign of success is ventricular ectopy due to the LV irritation by the wire.
- **+/- balloon valvuloplasty** (usually for Edwards Sapien valve) under rapid ventricular pacing (RVP). Ideally MAP 50 mmHg or less during pacing.
    - Pay attention to the rhythm and BP after termination of RVP. **Risk factors for persistent hypotension and/or ECG changes include**: low EF, severe cardiomyopathy, severe LM/LAD disease, and baseline heart block or arrhythmia. May require small bolus of epinephrine, but communicate with cardiology closely, sometime it just takes time.
- Other procedural-specific differential of hypotension:
    - Obstruction/occlusion of small LVOT or LV cavity by balloon/device/sheath. The team needs to decide if hypotension can be tolerated before device deployment, or if the sheath needs to be removed.
    - Aortic regurgitation (worsening) can result after ballooning causing low diastolic pressure. May need to temporize with pressors until the valve can be deployed.
- Echo technician will be called 5-10 minutes before valve deployment for post-deployment TTE check for effusion and perivalvular leak.
- During the procedure, a cath lab tech is preparing the valve on a back table, which usually require **proper crimping and loading of the prosthesis**. The orientation of the valve needs to be verbally confirmed as the deployment of a (unidirectional) valve in the wrong orientation is catastrophic.
- **RVP and valve deployment**. Hypotension, ST changes, ventricular tachycardia/fibrillation, and heart block can ensue. Differential diagnosis include:
    - New ischemia (CAD vs. hypoperfusion during RVP and deployment)
    - Valve regurgitation: perivalvular due to annular calcium, or transvalvular (intravalvular) leak due to malfunctioning leaflet(s). Both of which may be initially treated with additional ballooning.
    - Tamponade from rapidly expanding pericardial effusion or root rupture. Treatment may vary from watchful patience, pacing, pressors, CPR, ECMO or sternotomy and CPB.

Transaortic (TAo) and
Trans-subclavian (TS): Common approaches in patient with femoral/iliac arteries with small diameters or are severely diseased.

- Due to the larger surgical incision, the steady loss of blood from the aortic/arterial sheath (during balloon/device exchanges) and potential aortic dissection, the anesthesia team usually obtains their **own arterial and large (central) venous access** pre-incision.
- **TAo requires of hemi-sternotomy incision** to expose the ascending aorta.
- **TS requires of axillary cutdown** (either side) to expose the axillary/subclavian artery.
- The target **artery is accessed and cannulated** under direct visualization.
- The surgeons will be standing on both sides of the patient's chest during opening and closing, and at least one will continue to stand near the head during valve deployment.
    - This may require additional extension for airway and lines.

- **Femoral artery and vein are accessed** to deliver a pigtail injection catheter for root angiogram and TVP.
- The remaining steps are similar to the TF approach.

Trans-apical (TA): A rarely used approach nowadays due to its high morbidity and mortality, having largely been replace by TAo, TS or the use of IVL in TF.

- Due to the need for thoracotomy, possible apnea/lung isolation, potential for exsanguination from LV sheath, sudden hemodynamic collapse from numerous causes, **TA requires GETA, arterial monitoring, and large bore venous access.**
- A pre-incision TTE is used to identify the location of LV apex.
- **Anterolateral mini-thoracotomy** at the fifth or sixth intercostal space to gain direct access to the LV apex.
- The surgeons will **prepare the LV including purse-string sutures** for the delivery sheath.
- **Femoral artery and vein are accessed** to deliver a pigtail injection catheter for root angiogram and TVP.
- The **LV is punctured**, a wire inserted, followed by a sheath to establish intraventricular access.
- A stiffer catheter is used to cross the aortic valve into the arch, followed by a stiffer wire, and exchanged for the larger **delivery sheath**.
- **Balloon valvuloplasty** (if needed) and **valve deployment** are performed through this sheath during periods of **RVP**.
- **Hypotension** can occur during any point of the procedure, due to
    - <u>Blood loss</u> through the needle, through sheath, or around the sheath
    - New myocardium dysfunction due to <u>direct injury</u>, or new ischemia from <u>coronary artery injury</u>
    - Loss of LV preload due to a large sheath inside a hypertrophic heart <u>obliterating the small LV cavity or LVOT</u>
    - Other causes shared with other TAVR approaches
- The prosthesis needs to be loaded in an antegrade direction for deployment.
- Hypotension can persist after the device deployment for many of the reasons above.
- **Surgical repair of the LV**, after the removal of the sheath, may be challenging, and require resuscitation by the anesthesia team.

Trans-caval (TC): A rare strategy, often used as the last resort for a patient with impossible arterial access. Given the aortic access is gained via an iatrogenic connection between the IVC and abdominal aorta in the retroperitoneal space without direct access, be prepared for sudden catastrophic bleeding.

Post-deployment:

- **Assessment of the new prosthetic valve** by echocardiography (TTE or TEE) and angiogram.
- **Additional balloon valvuloplasty** can be used to treat partially stuck leaflet (transvalvular leak) and under expanded ring (perivalvular leak).

- It is common to have **hypertension** after successful, uneventful valve deployment as the LV cannot immediately compensate for the sudden loss of outflow obstruction. Short acting anti-hypertensive may be used.
    - NTG and/or nicardipine: afterload reducing with a direct arterial dilator may be more effective. Hydralazine may also be used, with ample time (20 min) it see its effect before redosing
    - Discuss with the cardiologist the BP goals. May have periods of significant hypertension after valve deployment which you will want to control, but having a short acting drug here is advantageous because the hypertension may not last.
- **TVP will be removed** if there is no evidence of heart block or bradycardia. If postop pacing is necessary, pacer is in the groin, RIJ sheath needs to be placed for more sterile and comfortable access.
- Begin to **titrate down or off sedation**. Dexmedetomedine has a long tail, and often causes prolonged bradycardia, hypotension and/or sedation in the elderly patient.
- Small dose of **protamine** to reverse heparin upon request by cardiology.

Postoperative recovery

- Uncomplicated TF patients usually goes to PACU to recover.
- Complicated cases, non-TF, intubated patients and those requiring postop pacing will go to the ICU.
- **Postprocedural hypotension** is common. Common causes include residual anesthetic, preoperative cardiomyopathy or heart block. More rare and serious causes include bleeding, pericardial effusion, myocardial ischemia, paravalvular leak, or prosthesis stenosis. Many can be easily ruled out with ECG and echocardiography. Occult bleeding in the retroperitoneal space may be more difficult to diagnose. Some patients have idiopathic hypotension, which has been described with potentially poorer long term outcomes.