

# Complications of Transcatheter Aortic Valve Replacement

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## Conflicts of Interest

▶ NONE!!!!!!

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## Aortic Stenosis Incidence

- ▶ Aortic stenosis (AS) is one of the most common degenerative valvular diseases by far.
- ▶ The U.S. population is aging with recent estimates of aortic valve disease prevalence of 1.3% in persons from 65-74 years old and 2.8-4.6% in those older than 75.
- ▶ Open surgical replacement was the standard treatment but, it entails a major surgical procedure and is not available to a sizeable proportion of AS patients due to co-morbidities.
- ▶ The TAVR procedure has been available since 2002 and 5-year data has shown a better survival outcome over surgically replaced valves **but**, was only indicated in the segment of the population with AS that could not undergo surgical replacement.

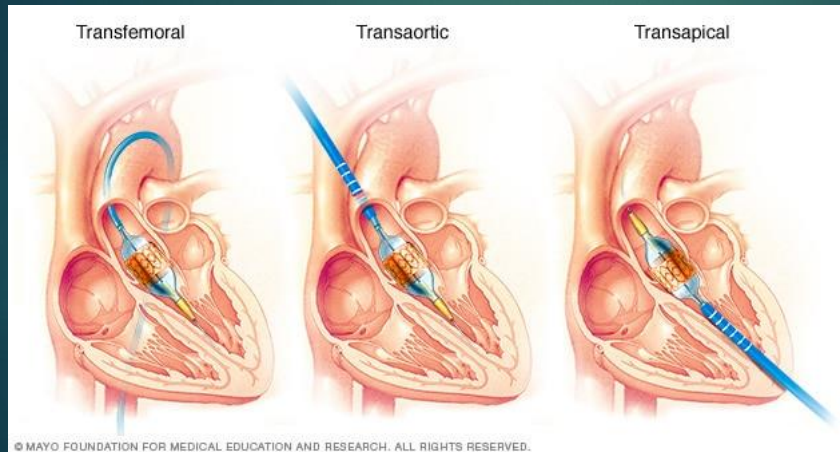
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## What is the TAVR

- ▶ The transcatheter aortic valve replacement (TAVR) is a minimally invasive method to replace the aortic valve – typically due to aortic stenosis.
- ▶ It is performed by one of three approaches:
  - ▶ Via the femoral artery like a cardiac catheterization.
  - ▶ Transapically by being inserted through the left ventricular apex.
  - ▶ Transaortic approach through the aorta just above the aortic valve.
- ▶ The native valve is dilated using a balloon valvuloplasty and then a second balloon with the folded up replacement valve is inserted and allowed to open up over the native valve.
- ▶ **As of August of 2019 it is now indicated even in patients at low risk of complications from a surgical valve replacement procedure.**

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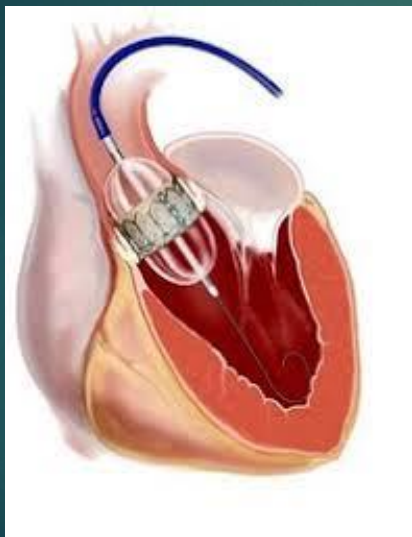
## TAVR Approaches



The transfemoral approach is the one typically used by a cardiologist with the transaortic and transapical approaches the province of the cardiothoracic surgeons.

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## The Key Part of the Procedure



The key part of the procedure involves the final deployment of the valve as the balloon inflates against the already flattened native valve. It then opens up with the replacement artificial valve now in place. The new valve has to be precisely situated and angled correctly. Easy to do in a picture, a bit trickier in real life.

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## TAVR Risks

- ▶ Transcatheter aortic valve replacement (TAVR) carries a risk of complications, which may include:
  - ▶ Bleeding – procedural, due to post-placement anticoagulation
  - ▶ Blood vessel complications
  - ▶ Problems with the replacement valve, such as the valve slipping out of place or leaking
  - ▶ Stroke
  - ▶ Heart rhythm abnormalities (arrhythmias)
  - ▶ Kidney disease from the IV contrast used during the procedure
  - ▶ Myocardial infarction
  - ▶ Infection
  - ▶ Death

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## TAVR Risks

- ▶ Clearly some of the cited complications/risks are not of concern in the ED that would occur during the procedure.
- ▶ However, any of those so cited could potentially occur either post-procedure or not seen during the procedure.
- ▶ Having a familiarity of the procedure and the type of approach can give the emergency physician idea of what to expect:
  - ▶ Trans-apical approach can cause cardiac tamponade, most typically noted at the time of the procedure but with anticoagulation might be delayed.
  - ▶ Valve malalignment or failure to deploy is also almost always noted at the time of the procedure and unlikely to be an issue that presents to the ED.

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## TAVR Risks - Bleeding

- ▶ Peri-procedural bleeding is generally picked up immediately during or just after the procedure.
- ▶ However, post-procedure anticoagulation places the patient at all the risks that are so commonly seen in any anticoagulated person.
- ▶ The initial studies used antiplatelet agents starting with just ASA and then progressing to dual-agent regimens i.e. ASA + clopidogrel.
- ▶ Given that a fair number of TAVR patients are frail there is an increased risk of bleeding complications estimated at 16% +/- 0.9%.
- ▶ The ARTE study comparing ASA with ASA/Plavix regimens found an odds ratio of bleeding of 2.24x in the dual platelet inhibitor group with an equal mortality between the two groups.

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## TAVR Risks - Bleeding

- ▶ The need for anticoagulation is to prevent valve leaflet thickening due to blood clotting on the leaflet causing valve malfunction, embolus, or a nidus of infection.
- ▶ With improved imaging leaflet thickening has been demonstrated in a concerning 13% of TAVR patients on dual-antiplatelet therapy.
- ▶ There is growing opinion to increase the anticoagulation regimen post-TAVR to using either a VKA or DOAC.
- ▶ Clearly the DOAC's are superior in efficacy and safety compared to coumadin – but not approved for valve replacement.
- ▶ In a small study of 21 TAVR patients at Mayo Clinic of which 92% were on a DOAC for atrial fibrillation or flutter the results were that the DOAC was well tolerated with only 2 patients experiencing a bleeding event and no thromboembolic events reported – 1/3 of TAVR patients have a history of atrial fibrillation.
- ▶ **Still these patients are going to fall, have spontaneous bleeding, or need an emergency procedure post-TAVR – all of which will fall to the emergency physician to manage.**

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## TAVR Risks – Blood Vessel Injury

- ▶ Typically complications of the procedure due to injury of a blood vessel are noted at the time or just after the procedure.
- ▶ The catheters used to place a TAVR are quite large so the femoral artery approach is the one used by cardiologists.
- ▶ AV fistulas and thrombosis of the femoral artery can occur in a similar manner to such complications post-cardiac catheterization.
- ▶ Aortic injury or direct injury to the heart with the transapical or transaortic approaches are almost always seen right at the time of the procedure and unlikely to present to the ED.

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## TAVR Risks – Valve Issues

- ▶ Failure of the valve to deploy, function, or mispositioned are almost always seen at the time of the procedure such as too low or too high implantation.
- ▶ Valve regurgitation can be seen immediately or later, potentially in the ED – symptoms can include fatigue, chest pain, syncope, or dyspnea.
- ▶ A new murmur might be detected on exam but, typically knowing that a patient has a murmur previously might not be known in the ED.
- ▶ Treatment in the ED includes stabilizing the patient, pressors to maintain perfusion, transthoracic echocardiology can be helpful, and immediate notification of cardiology/CV surgery.

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## TAVR Risks - Stroke

- ▶ Heart valve disease is associated with stroke whether the native diseased valve is left in place, an allograft bovine or porcine valve is placed, or a mechanical valve is used such as the TAVR.
- ▶ Mainly due to debris from the valve breaking off.
- ▶ Antiplatelet and anticoagulation has reduced the incidence but, has its own inherent risks of bleeding.
- ▶ In the early TAVR trials the risk of stroke was 7.1% +/- 1.7%, not an inconsiderable incidence particularly as the number of patients undergoing this procedure increases.
- ▶ Newer imaging technology has demonstrated a high incidence of TAVR valve leaflet thickening and that is very concerning.

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## TAVR Risks - Stroke

- ▶ In the more recent **PARTNER 1B** study the risk of stroke depended on the overall co-morbidities with stroke/TIA rate of 1% at 1 month and 4.5% at one year.
- ▶ In higher risk patients that risk rose to 6.7% at one month and 10.6% at one year.
- ▶ What is concerning is that with MRI imaging the rate of new ischemic lesions is seen almost universally in TAVR patients though most often not clinically apparent.
- ▶ The clinical importance of this finding is not clear at this time.
- ▶ But, what seems to be evident is that as the indications for TAVR have expanded and the impact of post-procedure stroke is sure to be an ongoing area of concern.

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## TAVR Risks - Arrhythmias

- ▶ Given that the TAVR is placed right at the aortic root it is not surprising that the conduction system can be effected even given that 1/3 of patients already have atrial fibrillation.
- ▶ The incidence of a new LBBB is as high as 40% with the need for a permanent pacemaker seen in 20% of TAVR patients.
- ▶ Predisposing factors include intra-procedural complete heart or new right bundle branch block.
- ▶ The causes are felt to be mechanical involving the balloon valvuloplasty, edema, and inflammation effecting the conduction system.
- ▶ Proper sizing of the valve and the balloon must be made very carefully to reduced the chance of an arrhythmia though even in the best of hands it is commonplace.

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## TAVR Risks - Renal

- ▶ The incidence of AKI is common post-TAVR and can lower the survival rate particularly as patients with more co-morbidities are getting a new valve – though this is typically a complication at the time of hospitalization and not seen de novo in the ED.
- ▶ The pathogenesis of this complication is felt to be multifactorial including use of contrast agents, hypotension during the procedure, and embolization.
- ▶ While the definition of AKI varies from study to study using a consensus definition the incidence ranges from 15-57% with the need for RRT in 2-40%.
- ▶ For patients who present to the ED post-TAVR assessment of renal function and comparison to baseline is important.

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## TAVR Risks - AMI

- ▶ Given the population of patients undergoing a TAVR procedure it comes as no surprise that the incidence of CAD is quite high with the risk of an ACS episodes likewise high – a number of case reports highlight episodes of this.
- ▶ It is difficult to ascertain if the procedure itself is the cause of such events or just the natural history of an older population many of whom have a number of ACS risk factors if not already established CAD.
- ▶ The assessment and approach to cardiac ischemia in the ED is very much the same as in any such patient:
  - ▶ Rapid diagnosis, systemic anticoagulation if necessary, perfusion support.
  - ▶ PCI as soon as possible.
  - ▶ Thrombolytics if PCI is not available within 90 minutes.

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## TAVR Risks - AMI

- ▶ In a Canadian study of 779 TAVR patients the mean age was 79 +/- 9 years old who were followed for 25 months:
  - ▶ At least 1 ACS event occurred in 10% with 50% of those within the first year.
  - ▶ Factors that predicted an ACS event included male sex, non-transfemoral approach, and prior CAD.
  - ▶ ACS events included type 2 NSTEMI – supply/demand mismatch (36%), unstable angina (35%), type 1 NSTEMI – plaque rupture/ACS (28%), and STEMI (3%).
  - ▶ After a first ACS event the incidence of MACCE (all-cause death, MI, revascularization, CVA) was quite high at 47%.

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## TAVR Risks - AMI

- ▶ Clearly this is a complication of TAVR that most likely will present to the ED.
- ▶ Aside from the CAD extent in the cohort of TAVR patients it is also possible that one of the artificial valve leaflets can obstruct the ostia of coronary arteries.
- ▶ EM physicians should have a high suspicion for presentation of ACS in TAVR patients, particularly NSTEMI.
- ▶ Most of those patients in the Canadian study did in fact go on to cardiac catheterization.

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## TAVR Risks - Infection

- ▶ The specter of infection of a heart valve – be it native or artificial – is a considerable concern particularly as this is an issue that will likely present to an emergency department.
- ▶ Infective endocarditis post-TAVR carries a high mortality risk in a similar manner to that of a surgically implanted valve.
- ▶ **Early detection is easy to say, much harder to do.**
- ▶ In a study of 20,026 TAVR patients at 47 medical centers from 2005 – 2015 the rate of endocarditis was 1.1/person-year with a mortality of 36%.
- ▶ Even with treatment 67% of patients who developed endocarditis died in the subsequent two years of follow-up.

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## TAVR Risks - Infection

- ▶ Risk factors for infection post-TAVR included:
  - ▶ Male
  - ▶ Younger patient
  - ▶ DM as a co-morbidity
  - ▶ Moderate to severe aortic regurgitation
- ▶ The prevalence pathogens were enterococcus (24.6%) and staph aureus (23.3%).
- ▶ Vessel access through the groin is suspected to be a factor for enterococcal endocarditis.
- ▶ One approach to reduce the risk is using prophylactic antibiotics before and for 4-5 days after the procedure.
- ▶ While infected surgically implanted valves are routinely removed this is not practical for a TAVR valve so infected patients may be on lifetime antibiotics.

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## TAVR Risks - Infection

- ▶ Presentation to the ED for post-TAVR patients with endocarditis are to large extent as with any patient with this complication and include:
  - ▶ Fever, other non-specific symptoms
  - ▶ Chest pain, SOB, DOE
  - ▶ Septic embolic sequelae
  - ▶ A suspicion of endocarditis by an emergency physician
- ▶ Treatment includes basic labs, lots and lots of blood cultures, echocardiogram, and admission on broad spectrum antibiotics.

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## TAVR Risks - Death

- ▶ Outside of death during the procedure or in the immediate peri-procedure time frame it can be difficult to precisely separate mortality due to the procedure vs. mortality due to co-morbidities and age.
- ▶ The mortality rate for TAVR has dropped significantly from 10.48% to 2.27% over a 10 year period from 2007 to 2016.
- ▶ Overall mortality should drop even lower as greater experience is obtained, fewer cases using the transaortic or transapical approaches that have a higher complication rate, and performing the procedure on younger patients who are healthier at baseline.

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## Summary

- ▶ The TAVR procedure uses three approaches: transfemoral (becoming the most common), transaortic, and transapical.
- ▶ The procedure is now approved for any patient requiring aortic valve replacement, not just those who are not surgical candidates.
- ▶ As such it will become much more common in our aging population.
- ▶ Patients will likely be anticoagulated either with antiplatelet agents (usually ASA plus one other) or one of the DOAC's or a VKA.
- ▶ Complication rates are relatively low and survival high, particularly compared to the traditional open surgical approach.

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## Summary

- ▶ Many of the complications will be seen at the time of the procedure or soon thereafter – unlikely to be seen the ED.
- ▶ The major ones that would be seen in the ED includes:
  - ▶ Bleeding.
  - ▶ Infection, endocarditis.
  - ▶ Stroke.
  - ▶ Arrhythmia.
  - ▶ AMI.
- ▶ Some of these complications can be just from patients who are older and have more co-morbidities.
- ▶ Many are directly the result of the procedure itself, having an artificial valve, or the need for post-procedure anticoagulation.

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## Summary

- ▶ To a large extent the complications from the TAVR procedure would be addressed as any other presenting to the ED.
- ▶ Most approaches are independent of the fact that there is a mechanical valve, i.e. bleeding or endocarditis.
- ▶ Having a high suspicion for such complications and a working knowledge of the procedure is helpful in addressing what is surely going to be a relatively frequent group of patients presenting to the ED.

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Thank you for your kind attention.

Questions?

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