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Aortic Valve Makeover: Understanding TAVI's Advancements and Outcomes

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ABSTRACT

Transcatheter aortic valve implantation has transformed the therapeutic landscape for symptomatic aortic stenosis by providing a less invasive option for high-risk or inoperable patients. TAVI began as Dr. Alain Criber's innovative notion in 1989, and its history has been distinguished by constant innovation, transforming it into the current gold standard. This detailed narrative analysis delves into TAVI's effectiveness, safety profile, and technical improvements by meticulously reviewing clinical trials, landmark papers, and developing techniques. The procedure's effectiveness is dependent on proper patient selection, anatomical compatibility, and interdisciplinary teamwork. Recent advances in valve technology, device innovation, and procedural approaches have expanded TAVI's application while dramatically reducing complications, and improving short- and medium-term results. Despite tremendous advances, problems remain, requiring greater investigation into patient-specific designs and tissue usage. As the scope of TAVI develops, future concerns will include individualized valve selection, cost-effectiveness studies, and research into next-generation transcatheter heart valves. The developing narrative surrounding TAVI emphasizes its transformational impact on a wide range of patient demographics and portrays it as a cornerstone in the care of aortic valve disease.

Keywords: Transcatheter Aortic Valve Intervention (TAVI), Aortic Stenosis, Interventional Cardiology, Minimally Invasive Valve Surgery

INTRODUCTION

The emergence of TAVI represents a new era in the management of Aortic valve stenosis. The idea of performing a Transcatheter Aortic Valve Implantation without utilizing the conventional surgical technique was envisioned during the year 1989, by French cardiologist Dr. Alain Criber.

After spending over a decade marked by relentless dedication to developing the valve design, and delivery system and improving the durability of the implanted valves, he performed the first human implantation of a valve via catheter technique in 2002 on an individual considered inoperative by traditional open-heart surgery. (1,2) TAVI is also gaining popularity as the procedure of choice for AV valve implantation in individuals with minimal operative and surgical risks. (3)

Aortic Stenosis is considered one of the most prevalent cardiovascular pathologies and the majority of affected patients are unfit for traditional open-heart surgery due to associated underlying diseases. (4) Clinical signs of AS include exertional chest discomfort or dyspnea, angina, disorientation, and syncope, and patients are at higher risk of sudden cardiac death. (5) The Food and Drug Administration has given TAVI permission for the same. (6)

This Narrative review provides a comprehensive overview gathered from clinical trials, review articles, and landmark studies describing TAVI's efficacy, safety profile, technological advancements, and clinical outcomes as well as shared observations on its challenges, and future direction.

MATERIALS & METHODS

This literature review involved a comprehensive search through databases such as PubMed and Google Scholar using the keywords- "TAVI", "Heart Valve Surgery", "Aortic Stenosis", "Interventional Cardiology" and "Minimally Invasive Valve Surgery".

RESULT

According to the literature search carried out, enough evidence and studies support that the newer generation Transcatheter Aortic Valve Intervention (TAVI) is an effective procedure in many facets for calcified aortic stenosis and other valvular pathologies, irrespective of threshold surgical risks, these involve high treatment outcomes, shortened hospital-stay, reduced recovery time in comparison to traditional Surgical Aortic Valve Replacement and improved wellbeing postoperatively for severely symptomatic cases. (4)

Additionally, the patient selection process, clinical indications, randomized trials comprising "Placement of Aortic Transcatheter Valve Trial", and the "CoreValve US Pivotal" for comparative surgical risk analysis, mortality, and life expectancy valuations for transfemoral access associated with Transcatheter Aortic Valve Implantation (TAVI) are well reasoned out in this study. (20, 21)

MAIN BODY

Valvular disease is a significant public health issue since it has a poor outlook and is closely related to the process of population aging. For individuals with extreme AS who exhibit side effects or noticeable signs, for example, left ventricular (LV) failure, valve replacement is the sole choice. (13)

It was developed to treat valve disease. It is a minimally invasive treatment for patients with serious aortic stenosis, it involves replacing the damaged aortic valve with a prosthetic valve using a catheter inserted into the femoral artery. (14) TAVI's safety and efficacy have improved as technology, device design, and clinical methods have matured. (15)

TAVI device development has concentrated on obtaining characteristics such as durability, reduced thrombogenicity, excellent hydrodynamics, biocompatibility, and a low catheter profile. There are two forms of TAVI prostheses: balloon-expandable and self-expanding. A cobalt-chromium alloy frame is used in balloon-expandable prostheses, whereas a nickel-titanium (Nitinol) alloy frame is used in self-expanding prostheses. To avoid calcification and extend longevity, the valves are composed of carefully treated porcine or bovine pericardium. (15) It has developed significantly since its inception. (16) The approaches/procedures of TAVI have been described in the table.

Table 1. Femoral Artery Procedure (12)

Aspect	Details
Preferred Access Site	Femoral artery
Access Approaches	Surgical cut-down or percutaneous methods
Preferred Entry & Closure Techniques	Percutaneous puncture and suture pre-closure procedures are conducted under locoregional anesthesia.
Need for Open Surgical Access	20% of patients may require open surgical access, which might increase with patient complexity.
Conversion Options	Percutaneous closure devices and surgeries empower the transformation of percutaneous inclusions to open

	or half-and-half fixes.
Potential Risks	Injury to iliofemoral vessels; the most common femoral cut puncture is made between the inferior epigastric artery and the femoral bifurcation.
Vessel Requirements	Femoral and iliac diameters are 6-6.5 mm, with low vascular calcification and tortuosity; appropriate for 14-20 F TAVI delivery catheters.
TAVI Procedure Steps	Catheter insertion into the femoral artery, advancement to the aortic valve, and valve deployment with a balloon or self-expandable valve during high-rate pacing.
Post-Procedure Actions	Withdrawal of delivery complex, restoration of anticoagulation, sealing of access site, and descending aortic angiogram recommended to exclude complications
Advancements	Smaller valve delivery catheters enable complete percutaneous TAVI procedures

Table 2. Transapical Procedure (12)

Aspect	Details
Procedure Name	Transapical Approach
Purpose	Alternative access for patients with non-viable femoral access
Anesthesia	General anesthesia
Optimal Setting	Hybrid surgery room
Procedure Steps	1. Left anterolateral mini-thoracotomy through the fifth or sixth intercostal gap.
	2. Opening the pericardium and exposing the left ventricular apex
	3. Place a double purse-string suture (Teflon or pericardium) around the puncture site.
	4. Direct insertion of the left ventricular apex sheath.
	5. Crossing the aortic valve using a guided wire, followed by valve deployment.
Post-Deployment Actions	To maintain low pressure throughout repair completion, withdraw the sheath and tie sutures while using fast ventricular pacing.
Potential Complications	During thoracotomy, patients may have left ventricular pricking (myocardial or mitral damage), bleeding, hemodynamic/respiratory dysfunction, and discomfort.
Recommended Cases	High risk of embolic events or stroke; advanced peripheral arterial disease; extensively calcified thoracic aorta (porcelain aorta).

Table 3. Subclavian Procedure (12)

Aspect	Details
Approach	Subclavian Artery Access
Anesthesia	Local anesthetic and mild sedation
Surgical Procedure Steps	1. Surgical cutdown from the deltoid groove to the pectoralis major
	2. Either dissecting or retracting the pectoralis major to reveal the subclavian artery.
Criteria & Precautions	- Artery evaluation (diameter < 6 mm, significant calcification/tortuosity, or fixed stenosis not appropriate for angioplasty)
	- Proximity of brachial plexus above subclavian artery
Device Insertion Steps	1. Purse-string suture (5-0 polypropylene) is knotted in the anterior wall of the artery
	2. Placement of 6-Fr sheath with J-tip 0.035 wire
	3. Introduction of catheter into ascending aorta, switching to stiff Amplatz wire for dilator insertion
	4. The 18-Fr sheath is advanced via the subclavian artery to the proximal ascending aorta.
Device Deployment	Following the standard protocol of intervention
Post-Deployment Actions	Remove the sheath and tie a purse-string suture under direct visibility to determine the need for further sutures.
Considerations	1. Technical difficulty in device positioning with right subclavian artery if angle ≥30 degrees
	2. If the left subclavian artery has previously been utilized in a coronary artery transplant, it may restrict the flow of the left internal mammary artery.
	3. Caution is required in sheath insertion to avoid mammary artery dissection/occlusion in calcified or smaller subclavian arteries
Advancements	Recent developments in fully percutaneous procedures without surgical cutdown
Practice Status	Surgical exposure remains routine practice despite improvements in percutaneous approaches; not universally accepted

Table 4. Direct Aortic Access (12)

Aspect	Details
Approach	Transaortic Access (Mini-Sternotomy or Right Thoracotomy)
Surgical Entry	A mini-sternotomy or right thoracotomy allows access to the proximal ascending aorta.
Considerations for Access Selection	- A right front thoracotomy is picked if the aorta is to one side and close to the rib confine, whereas a mini-sternotomy is utilized for the midline or deeper aorta.
	- Building a secluded stage using pericardium stitched-to-skin borders
Device Insertion Steps	1. Suturing a purse at the targeted access location, with the needle in the center
	2. Placement of 6-Fr sheath with J-tip 0.035 wire.
	3. Advancement to the aortic valve
Procedure Advantages	- Being close to the insertion location and reducing stress around the aortic arch make valve implantation easier and reduce the learning curve.
	- Hemisternotomy provides a larger aorta field, whereas thoracotomy eliminates the need for left-sided coronary bypass grafts.

	- Hemisternotomy has better results and lower complication rates than transapical surgery.
Advantages Over Other Approaches	- Lower risk of complications (bleeding, myocardial damage) and shorter critical care unit stay compared to the transapical method.
	- Eliminates the need for smaller arteries (iliofemoral or subclavian) by inserting a sheath directly into the aorta, lowering the risk of complications.
	-Allows for a direct upright line approach to the aortic valve, ensuring proper valve placement in horizontal roots.

Table 5. Transcarotid Approach (12)

Aspect	Details
Approach	The Transcarotid Approach Using Common Carotid Course
Characteristics	Direct access to the aortic valve, decreases the distance between arterial entrance and aortic root.
Advantages	Improved movement accuracy, increased sheath and delivery catheter stability, and more precise valve placement compared to the transfemoral technique.
Procedure Details	- Local anesthesia used with a small neck incision
	- Requirement: Patient tolerates temporary unilateral carotid blockage, sufficient anterior connecting artery at Circle of Willis.
Assessment for Feasibility	Transitory shunt into the common carotid to screen for inactive antegrade carotid circulation, guaranteeing satisfactory cerebral perfusion all through the system.
Clinical Reports	- Modine et al. reported the first incidence of symptomatic AS in an 89-year-old patient.
	- Modine's group later reported 12 cases. Uneventful implantation, no vascular problems or bleeding, one patient had a brief ischemia stroke.
	Azmoun et al. found favorable outcomes in 18 out of 19 patients (4 Edwards SAPIEN XT,1 Medtronic CoreValve) who underwent a carotid approach under local anesthesia.
	Complications included one death during preimplant balloon valvuloplasty, one before hospital discharge, and three patients requiring permanent pacemakers.
Future Considerations	Further study is required to show practicality as an option for patients who do not satisfy requirements for existing access ways.

Table 6. Caval Aortic Approach (12)

Aspect	Details
Approach	Transcaval Aortic Access for TAVI
Technique Description	Accessing abdominal aorta via femoral vein through connecting inferior vena cava; aortic hemorrhage directed to patent cava hole; closure with nitinol occluder device.
Advantages	Larger, compliant iliofemoral veins with little risk of bleeding; procedural timings comparable to transfemoral; lowering puncture attempts and crossing-closing durations.
Preprocedural Assessment	Contrast-enhanced CT for calcification, diameter, trajectory, and tortuosity evaluation; identifying feasible crossing locations without intervening structures.
Limitations & Considerations	Difficulty with heavily calcified porcelain aorta; potential issues with severely narrowed iliac vessels; need for experienced operators and specific patient anatomy
Ideal Candidate Criteria	The proximity of the inferior vena cava and aorta; window free of calcium at crossing target; enough aortic diameter for closure device; lack of intervening structures.
Avoidance Zones	To prevent occluder device encroachment, maintain a distance of at least one centimeter from the left renal vein, the lowest renal artery, or the aortic bifurcation.
Anticoagulation	Recommended to abstain from aortic or caval thrombosis, however not yet documented as a problem in the transcranial method.
Prospective Studies	There is a potential need for studies comparing outcomes with existing surgical approaches

Patient selection and pre-procedural evaluation are critical elements in ensuring successful transcatheter aortic valve implantation (TAVI). The procedure's anatomical compatibility, surgical risk, and patient comorbidities are all considered throughout the selection phase. Imaging modalities such as computed tomography (CT) and echocardiography are critical in determining aortic root diameters, valve calcification, and access pathways. (12)

Valves Types and Devices

TAVI has experienced substantial advances in valve types and device innovation. The types of Valves:

1. Mechanical Valves: These artificial valves have a lifespan of 10 to 20 years and are comprised of carbon and polyester materials. They do, however, require lifelong blood thinners to prevent blood clots.
2. Biologic Valves: These are valves constructed of human or animal tissue. Allografts (human donor tissue), porcine valves (pig tissue), and bovine valves (cow tissue) are among them. Biologic valves do

not raise the risk of blood clots and may not require anticoagulant medication for the rest of one's life. They may, however, need to be replaced in the future.
•An allograft, also known as a homograft, is a tissue transplant that is taken from the donor's heart
• Porcine valves are composed of pig tissue. These valves may be implanted with or without a stent frame.
• Bovine valves are made from cow tissue. Silicone rubber connects it to your heart. (13)

Device Innovations

Transcatheter Heart Valves (THV) in the Future: New THVs have been created to treat conditions such as paravalvular aortic regurgitation (PAR), annular rupture, and conduction problems. These devices are capable of repositioning/recapturing, performing paravalvular sealing operations, and providing better imaging modalities. (14)

Improvements in THV prosthesis and TAVI-enabling devices have streamlined the surgery, decreased complications, and improved short- and long-term results. These developments have allowed TAVI to be used on intermediate- and low-risk patients. (15)

Personalized Valve Selection: With a rising number of devices available, finding the best TAVI valve for each patient is critical. To obtain the greatest results, valves should be chosen based on patient-specific clinical and anatomical factors. (16)

TAVI (transcatheter aortic valve implantation) has shown promising clinical findings and efficacy in a wide range of patient populations. Several studies have demonstrated that it increases survival rates, functional performance, and overall quality of life. (17) One study examined the long-term clinical and hemodynamic outcomes of TAVI patients. The study found that the overall survival rates at one, three, and five years were 85.5%, 69.9%, and 61%, respectively. Another research examined the clinical outcomes of TAVI patients with low to intermediate surgical risk. The study found that participants at low or intermediate risk had superior clinical outcomes, including decreased mortality rates after 30 days and one year 2. (17) Although TAVI has shown encouraging outcomes, it is necessary to assess patient features and comorbidities. TAVI mortality risk factors include end-stage renal sickness, liver illness, congestive cardiovascular breakdown, ongoing obstructive aspiratory infection, atrial fibrillation, and cellular breakdown in the lungs. (8)

Several research has been undertaken to look at the cost-effectiveness and healthcare implications of TAVI. In a study, TAVI was found to be more cost-effective than medical treatment in patients who were not suitable for surgical aortic valve replacement (SAVR). Another review found that TAVI was more costly however more viable than treatment in patients who were not contenders for SAVR, with an expense viability proportion (ICER) of £12,900 each quality-changed life year (QALY). (8)

TAVI has progressed tremendously in the recent past, yet there are still issues and future choices to consider. Some of the challenges include the need for long-term follow-up data, expanding indications for TAVI in lower-risk patients, optimizing antithrombotic therapy, reducing complications such as paravalvular leakage and conduction disturbances, and addressing anatomical limitations in specific patient populations. TAVI's future possibilities include the development of next-generation transcatheter heart valves, the research of TAVI in patients with bicuspid aortic valve disease and pure aortic regurgitation, and the improvement of procedural methods and imaging modalities. (19)

DISCUSSION

The success of TAVI hinges on precise patient selection and risk assessment, where guidelines recommend utilizing tools like EuroSCORE II or Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) (20). Important trials like the

Placement of AoRTic TraNscathetER (PARTNER) Valve Trial and the CoreValve US Pivotal have firmly established TAVI as the preferred approach for high-risk patients (21). It's worth mentioning that TAVI is now being used widely for healthier patients with lower surgical risk. (22)

However, a multidisciplinary heart team must extend their evaluation beyond surgical risk scores, considering factors such as frailty, physiological capacity, cognitive function, and comorbidities, as well as the potential for improvements in quality of life or life expectancy. Although TAVI has significantly improved survival rates there are still concerns about complications. One major concern revolves around bleeding events as they have been linked to higher mortality rates in the months following the procedure (23, 24). Interestingly TAVI has shown success not in immediate surgical risk patients but in those with lower surgical risk. (25) The scope of TAVI indications has expanded beyond the treatment of AS to encompass a broader range of valve pathologies. As the landscape evolves, the choice of technique in TAVI becomes pivotal, influencing the speed of recovery. Patients who undergo transfemoral TAVI typically recover faster than those who choose Surgical Aortic Valve Replacement (SAVR), while those opting for SAVR may experience quicker recovery than those undergoing transapical TAVI. (26)

An in-depth analysis of the National Inpatient Sample (NIS) has yielded noteworthy findings: despite a significant comorbidity burden, TAVI patients exhibit a low mortality rate of 2.2%. Specific comorbidities, including end-stage renal disease (ESRD), liver disease, congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), atrial fibrillation (AF), and lung cancer, have emerged as significant predictors of mortality in TAVI patients. Furthermore, patients who succumb during hospitalization experience prolonged stays and higher costs, emphasizing the need for comprehensive post-procedural care (3). Studies also shed light on the complex interplay of comorbidities in shaping TAVI outcomes, with ESRD, AF, and lung cancer identified as independent predictors of mortality. The presence of ESRD (27), often overlooked in landmark PARTNER trials, surfaced as a significant factor associated with higher odds of mortality (28,29). Additionally, the analysis highlights the elevated mortality rate associated with the presence of AF and lung cancer, challenging previous studies suggesting comparable outcomes for active cancer patients undergoing TAVI (30). Despite the inherent limitations of a retrospective design and the absence of comprehensive data, the findings contribute valuable insights into the predictors of mortality in the context of TAVI. This comprehensive understanding adds depth to the evolving narrative surrounding TAVI, reinforcing its transformative impact across a spectrum of patients with diverse aortic valve pathologies.

CONCLUSION

In conclusion, transcatheter aortic valve implantation (TAVI) has emerged as a possible treatment option for patients with symptomatic aortic stenosis who are considered at high risk or for those patients not suitable for surgery. Although the current evidence shows promising improvements in both outcomes and blood flow for up to two years there are still uncertainties about its long-term safety and durability. TAVI, particularly via the transfemoral approach, is considered the modern gold standard, especially for those considered unsuitable for conventional surgery. The future of TAVI envisions custom-made devices, potentially utilizing tissue-engineered, 3D-printed scaffolds, delivered via minimally invasive methods. It is crucial to address challenges such as calcium deposits and leaks around the valve area, which highlights the importance of research and studies comparing TAVI with surgical aortic valve replacement (SAVR). As TAVI continues to evolve, careful attention must be given to commercialization processes, training programs, and post-market surveillance to ensure controlled adoption and widespread availability. Additionally, it is essential to identify high-risk patients, incorporate new data into practice guidelines, and explore cost-effectiveness factors when integrating TAVI into the overall treatment options available.

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