TO STUDY MINIMALLY INVASIVE TRENDS IN AORTIC VALVE REPLACEMENT PROCEDURES (SAVR TO TAVR): COMPARATIVE ANALYSIS IN THE USA AND PARALLELS WITH THE INDIAN SCENARIO

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in

Hospital and Health Management

By

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Under the Supervision and Guidance of

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2024

25th June 2024
Hyderabad

To,

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Dear **Mr. Tom**

Internship Certificate

This letter is to certify that **Midhun Mathew Tom** in partial fulfillment of the requirements for the award of the degree of MBA in Hospital & Health management from the IIHMR university, Jaipur is doing internship at Orbees Business solutions Pvt. Ltd. Since **18th March 2024** to **till date**.

For **Orbees Business Solutions Pvt. Ltd**

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Rakesh Valluru
Sr. Manager - Operations

DECLARATION BY STUDENT

I hereby declare that this dissertation titled **To Study Minimally Invasive Trends in Aortic Valve Replacement Procedures (SAVR to TAVR): Comparative Analysis in the USA and Parallels with the Indian Scenario** is the Bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published and unpublished work of others has been duly acknowledged in the text.

(signature)

Dr. Midhun Mathew Tom

Date: 05/07/2024

IIHMR UNIVERSITY

CERTIFICATE

This is to certify that dissertation titled **To Study Minimally Invasive Trends in Aortic Valve Replacement Procedures (SAVR to TAVR): Comparative Analysis in the USA and Parallels with the Indian Scenario** is a record of the research work undertaken by Dr. Midhun Mathew Tom in partial fulfilment of the requirements for the award of the degree of **MBA Hospital and Health management** from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

Faculty Guide

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Date 05/07/2024

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ABSTRACT

Objective

1. **To analyze** the evolution of minimally invasive trends in "SAVR (Surgical Aortic Valve Replacement)" and "TAVR (Transcatheter Aortic Valve Replacement)" procedures in the USA, focusing on:

    - Adoption rates and timeline comparisons between the two procedures.
    - Factors influencing the shift towards minimally invasive techniques (e.g., patient demographics, technological advancements, surgeon preferences).
    - Outcomes data associated with both procedures in the US context (e.g., mortality rates, length of hospital stay, patient recovery time).

2. **To identify** potential parallels between the observed trends in the USA and the current or emerging scenario in India for minimally invasive AVR procedures. This could involve:

    - Assessing the availability and accessibility of TAVR technology in India compared to the USA.
    - Evaluating current surgical practices and patient demographics in India to determine the potential for TAVR adoption.
    - Identifying drivers and barriers for adoption of TAVR in India.

3. **To analyze** current and potential players in the Indian TAVR market.

Methodology

This descriptive, comparative study will analyze existing data from academic journals, medical databases, government websites, and industry reports. A focused search strategy will target relevant keywords to gather information on minimally invasive AVR trends in the USA (SAVR vs. TAVR adoption rates, outcomes data) and the current scenario in India (TAVR availability, patient demographics). Microsoft Excel will be used to analyze and compare data from both countries to identify parallels and potential for TAVR adoption in India. Adhering to all ethical data citation practices, the study will be completed within three-months.

Results

Adoption trends of Surgical Aortic Valve Replacement - SAVR and Transcatheter Aortic Valve Replacement – TAVR, in the United States demonstrate a significant movement towards minimally invasive techniques. The conventional treatment for severe aortic valvular disease

SAVR has declined in the favor of TAVR since its FDA approval in 2011. The rapid acceptance of TAVR currently with about. 300.000 procedures globally points to its growing role in cardiac care. In contrast, SAVR procedures have only moderately increased. In other words, there has been a constant reliance on the traditional procedure protocol, with an increased prevalence of the disease. As of 2019, the count of TAVR procedures is already higher than that of the SAVR, led by the increasing size of the aging population, which seeks out increasingly minimally invasive options, as well as consistent technological advancements in procedural outcomes. This compares well with trends in India where, despite being slower than in the USA, efforts that are positive would appear in the face of regulatory policies and local anatomy. The path forward really should be to foster very close collaboration among stakeholders for optimization of the role that TAVR can play in the transformation of cardiac care across the globe, further emphasizing the need for incremental innovation and accessibility.

Conclusion

This research illustrates changes in preferences of surgical and transcatheter aortic valve replacement procedures within the United States as a result of demographic changes and technological advancement. Adoption of TAVR is driven by the minimally invasive method and better recovery outcomes compared with SAVR. Adoption lags in India, but trends similarly to early U.S. trends. It is buttressed by upcoming specialized procedural centers and local manufacturers such as Meril Life Sciences and Sahajanand Medical Technologies. Active stakeholder collaboration involving health providers, manufacturers, and academia, along with regulators, is important for technological advances in TAVR and in overcoming the end hurdles. Making strategic investments in infrastructure, training, and research will make the best use of TAVR opportunities to improve global cardiac care. Importantly, this study underlines the growing importance of TAVR in mitigation of the continuously growing burden of valvular heart disease across globe, and the need for continuous work to improve access, affordability, and patient outcomes in diverse populations.

Keywords

"Minimally invasive Aortic valve replacements", "SAVR vs TAVR adoption", "TAVR outcomes", "TAVR availability in India" and "patient demographics of TAVR" .

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ABBREVIATION

CABG	Coronary Artery Bypass Grafting
AS	Aortic Stenosis
AVR	Aortic Valve Replacement
TAVR	Transcatheter Aortic Valve Replacement
SAVR	Surgical Aortic Valve Replacement
MICS	Minimally Invasive Cardiac Surgery
ECMO	Extracorporeal Membrane Oxygenation
PCI	Per-Cutaneous Intervention
THV	Transcatheter Heart Valves
FDA	Food and Drug Administration
CE	Conformité Européenne
CDSCO	Central Drugs Standard Control Organisation
SMT	Sahajanand Medical Technologies

INTRODUCTION

Cardiac surgery is that field of surgery which treats pathologies of the heart and thoracic aorta. Cardiac surgery, since its inception in the late 19th century, has come a long way, through huge evolutions. A path of innovation and dedication that changed cardiac care to infuse life into millions of people. In fact, the history of this specialty dates back to 1882 when the first pericardiectomy was performed. Ludwig Rehn managed an ambitious operation for cardiac stab back in 1896, which removed the stereotypical beliefs about the surgical inaccessibility of the heart. The development of a cardiopulmonary bypass in the mid-20th century revolutionized this sphere, allowing more complicated interventions to be conducted and reducing mortality. The management of ischaemic heart disease has undergone a radical evolution. Primitive approaches, like the implantation of the internal mammary artery, implanted by Vineberg, initiated newer forms of intervention in the 1960s, such as CABG. Further advances in diagnostic methods, including cardiac catheterizations and coronary angiographies, allowed better visualization of coronary stenosis.

Valvular heart disease treatment evolved from closed mitral commissurotomy to the implantation of artificial heart valves. Among these, the Hufnagel cage and ball valve was developed in 1952 which was considered the "cat's whiskers". With procedures getting better or advanced, multi-valve procedures, doing novel things like the Ross procedure.

Congenital heart defect surgery saw its first major breakthrough in 1944 with the first tetralogy of Fallot operation. This led to procedures addressing various congenital heart defects.

Cardiac arrhythmia management has progressed from external electrode stimulation to sophisticated implantable pacemakers and complex surgical procedures like the Cox-Maze technique for atrial fibrillation.

Heart transplantation became a reality in 1967, opening new possibilities for end-stage heart failure patients. Parallel development of mechanical circulatory support devices provided additional options for critically ill patients.

Modern cardiac surgery requires highly skilled staff and advanced equipment to manage complex patient physiology and perioperative risks. The field had to face many challenges like inflammatory responses, myocardial stunning, and multiorgan involvement.

This has been the other way around, with recent years observing an upsurge in interventional and minimally invasive techniques, once more provoking reevaluation of the role of cardiac surgery. Trends of today are focused centers for cardiac arrest, wider applicability of ECMO, with emphasis on interdisciplinary decision-making of the heart teams. These frail patient populations also produce newer challenges and drive innovations into even more minimal-invasive and hybrid procedures. The future of cardiac surgery is going to hinge on combining cutting-edge innovations, such as robotic surgery and 3D printing, with better long-term results and less invasiveness. Cardiac surgery has grown from simple cardiac wound treatment to its own boundaries being expanded to tremendous growth with complex transplants. Further, the space will be continuously successful by the infusion of innovation, adaptation, and even collaboration among disciplines. Given this ongoing transformation, there is a responsibility for practitioners to keep abreast of newer medical advancements in ensuring the specialty continues to play a crucial role in heart disease treatment and improving patient outcomes.(1)

Trend towards minimally invasive cardiac procedures

As the cardiac surgery space matured, there came an increasing need to reduce the invasiveness of the procedures. It was driven by a growing trend toward less painful and more cosmetically acceptable intervention requested by the patient, patients getting back on their feet and back to work sooner to minimize both the qualitative and quantitative costs of lost work hours, less exposure to the risk of complications that resulted from surgery, and the continuous technological advancements in the field that make interventions more precise. MICS includes a variety of methods, some being small incision surgeries, endoscopic surgeries, and robotic-assisted surgeries. All these are used in myriads of procedures done in the cardiology domain and can include minimally invasive CABG, valve repairs or replacements, ablations of atrial fibrillation, and how can we forget, closing of an atrial septal, or any other kind of defect. Although MICS has been promising in terms of patient satisfaction and recovery times, debates still exist about its long-term outcomes compared with traditional open surgery. The complexity of learning and training associated with these techniques and the potential for longer operative times have also been a point of discussion within the surgical community. Probably, the most significant surge in the domain of cardiac surgery over the past few years is the explosive growth of interventional cardiology. Cardiac interventions with the use of percutaneous access with stenting over the years have become much safer and more of a common procedure. This tectonic shift in itself was big, on both volume and the nature of surgical cardiac cases across the globe. Major fairly recent developments in interventional cardiology include drug-eluting stents, transcatheter aortic valve replacement, transcatheter mitral valve repair techniques and left atrial appendage closure devices. These advancements have led to major changes in the field of cardiac care, including a decline in the number of traditional CABG procedures, expansion of percutaneous approaches to structural heart disease, capturing traditional surgical territory, shifting patient demographics for cardiac surgery, with a trend towards higher surgical risk and more complex cases, and increased competition between cardiac surgeons and interventional cardiologists for patients, particularly those considered high-risk for traditional surgery. Cardiologists have meticulously conducted studies comparing the outcomes of percutaneous interventions to surgical procedures. In many cases, these studies have shown equivalence or even superiority of PCI for certain patient populations. This evidence has further accelerated the shift towards less invasive approaches. While there is a overall trend global towards less invasive approaches, there are significant regional variations in the practice of cardiac surgery. There has been a steady decline in CABG volumes in developed countries, growth in complex valve procedures and mechanical circulatory support, rapid adoption of TAVR and other transcatheter techniques, and an emphasis on hybrid procedures combining surgical and percutaneous approaches. Emerging countries have experienced growth in both of traditional and minimally invasive cardiac surgeries which are driven by improving healthcare infrastructure and rising prevalence of cardiovascular disease. Access to advanced technologies remains limited in many areas of these countries which results in a mix of cutting-edge centers in urban areas and more basic facilities in rural regions. Heart surgery is still in its infancy in such countries whose main priorities are developing the necessary infrastructure and educating surgeons in critical procedures. They often rely on international partnerships and visiting surgical teams for complex cases.

Cardiac surgery faces several challenges as it adapts to the changing technologies and patient expectations. The shift towards percutaneous interventions has led to a reduction in traditional surgical cases like CABG. This could have implications for surgical training, hospital revenues and surgeon expertise. The complexity of modern cardiac surgery, combined with reduced case volumes, makes it challenging to provide comprehensive training to new surgeons, requiring the adaptation of training programs to include exposure to both traditional and newer techniques. High costs associated with cardiac surgery puts pressure on surgeons and hospitals to justify expensive procedures and competition from percutaneous options further complicates the economic landscape. Keeping up with rapidly evolving technologies requires continuous learning and investment in new equipment and training. This cost of acquiring and maintaining advanced technologies can be prohibitive for many centers. As less invasive options become available cardiac surgeons will handle more complex, high-risk cases. This can potentially affect outcomes and job satisfaction among surgeons. The crossing of boundaries between cardiac surgery and interventional cardiology raises questions about the identity of the specialty, with ongoing debate about the potential merger of these fields into a single "cardiovascular interventionist" specialty.

Several strategies have been proposed to address these challenges and ensure the continued relevance of cardiac surgery. These strategies include embracing hybrid procedures that collaborate with interventional cardiologists to develop combined surgical and percutaneous approaches, expanding skill sets by training cardiac surgeons in catheter intervention based techniques, focusing on complex cases where currently surgery still holds a clear advantage, advancing mechanical circulatory support, pioneering new technologies such as tissue-engineered heart valves and advanced imaging systems, improving outcomes through refined surgical techniques and perioperative care, participating in global outreach programs to expand access to cardiac surgery in underserved regions, diversifying practice into related areas such as thoracic surgery and vascular interventions and taking a more active role in organ procurement and transplantation programs.

These trends in cardiac surgery exert a huge impact on the specialty of cardiac anesthesia. Cardiac anesthesiologists evolve with changing roles and roles, and their skill sets change as the cardiac care landscape changes. This multi-disciplinary team not only anaesthetises cardiac surgical procedures, manages cardiopulmonary bypass, and performs intraoperative TEE, but also run ICUs, initiate and manage ECMO, run echocardiography clinics for cardiac assessment, lead the extracorporeal cardiopulmonary resuscitation team, and run hemodynamics in potential organ donors. Many others are diversifying their practice, applying their significant skills to non-cardiac surgical cases, and participating in structural heart disease interventions in the catheterization laboratory. Despite the challenges, cardiac surgery is likely to remain an essential component of cardiovascular care. Several trends point to potential areas of growth and innovation. As the global burden of heart failure increases, there will be a growing need for advanced surgical interventions, including ventricular assist devices, total artificial hearts, and novel approaches to cardiac transplantation. Advances in genomics and precision medicine may lead to more tailored surgical approaches based on individual patient characteristics, including personalized graft selection, individualized anticoagulation protocols, and targeted therapies for myocardial protection. The development of bioengineered tissues and organs could revolutionize cardiac surgery, offering new solutions for valve replacement, myocardial regeneration, and vascular grafting. Continued refinement of robotic systems and the integration of artificial intelligence may enhance surgical precision and enable new minimally invasive techniques, while AI could also play a role in preoperative planning, intraoperative decision-making, and postoperative care optimization. The increasing prevalence of hybrid operating rooms will facilitate more complex, multidisciplinary procedures combining surgical and interventional techniques, likely leading to the development of new procedures that blur the lines between traditional specialties. As our understanding of cardiovascular disease progression improves, there may be opportunities for earlier surgical or minimally invasive interventions to prevent or delay the onset of advanced disease. Efforts to expand access to cardiac surgical care in underserved regions will likely continue, potentially leading to innovations in low-cost, high-impact interventions. (2)

Treatment modalities

Major cardiac surgeries have seen significant advancements in recent years, with many procedures now having minimally invasive or transcatheter alternatives. These innovative treatments aim to reduce surgical trauma, shorten recovery times, and expand treatment options for high-risk patients. Here's an overview of major cardiac surgeries and their corresponding minimally invasive or transcatheter approaches:

1. Coronary Artery Bypass Grafting (CABG):
    1. Traditional:
        - Open-heart surgery via median sternotomy
    2. Minimally Invasive:
        - Minimally Invasive Direct Coronary Artery Bypass (MIDCAB)
        - Totally Endoscopic Coronary Artery Bypass (TECAB)
        - Off-Pump Coronary Artery Bypass (OPCAB)

2. Aortic Valve Replacement:
    1. Traditional:
        - Open-heart surgery
    2. Minimally Invasive:

        - Transcatheter Aortic Valve Replacement (TAVR/TAVI)
        - Sutureless aortic valve replacement
        - Minimally invasive aortic valve replacement through right mini thoracotomy

3. Mitral Valve Repair/Replacement:
    1. Traditional:
        - Open-heart surgery
    2. Minimally Invasive:

        - Minimally Invasive Mitral Valve Surgery (MIMVS) through right mini thoracotomy
        - Transcatheter Mitral Valve Repair (e.g., MitraClip)
        - Transcatheter Mitral Valve Replacement (TMVR)

4. Tricuspid Valve Repair/Replacement:
    1. Traditional:
        - Open heart surgery
    2. Minimally Invasive:

        - Minimally invasive tricuspid valve surgery
        - Transcatheter Tricuspid Valve Repair (e.g., TriClip)
        - Transcatheter Tricuspid Valve Replacement (still in early stages)

5. Atrial Septal Defect (ASD) Closure:
    1. Traditional:
        - Open-heart surgery
    2. Minimally Invasive:

        - Transcatheter ASD closure devices

6. Ventricular Septal Defect (VSD) Closure:
    1. Traditional:
        - Open-heart surgery
    2. Minimally Invasive:

        - Transcatheter VSD closure devices (for certain types of VSDs)

7. Left Atrial Appendage Closure:
    1. Traditional:
        - Surgical ligation or excision during open-heart surgery

2. Minimally Invasive:
    - Transcatheter left atrial appendage closure devices (e.g., Watchman)

8. Atrial Fibrillation Treatment:
    1. Traditional:
        - Cox-Maze procedure during open-heart surgery
    2. Minimally Invasive:
        - Minimally invasive surgical ablation
        - Catheter-based ablation procedures

9. Aortic Aneurysm Repair:
    1. Traditional:
        - Open surgical repair
    2. Minimally Invasive:
        - Endovascular Aortic Repair (EVAR)
        - Thoracic Endovascular Aortic Repair (TEVAR)

10. Ventricular Assist Device (VAD) Implantation:
    1. Traditional:
        - Open-heart surgery
    2. Minimally Invasive:
        - Minimally invasive VAD implantation techniques (still evolving)

As cardiac surgery continues to evolve, the integration of traditional open techniques with minimally invasive approaches and hybrid procedures offers an expanding array of options for tailoring treatment to individual patient needs. The ongoing development of new technologies, such as robotic-assisted surgery, promises to further refine and enhance the field of cardiac surgery in the coming years.

Focus: Aortic Stenosis

A common valvular disease that causes blockage of the left ventricle's outflow is aortic stenosis. At least 2 m/s anterograde velocity over the aortic valve is the condition's defining characteristic. Aortic valve sclerosis, on the other hand, is characterized by the aortic valve thickening and calcification without a discernible shift in the pressure gradient. Aortic stenosis can have a hereditary cause, as in the case of bicuspid or unicuspid valves, or it can develop as a result of rheumatoid arthritis and calcific processes. Before experiencing any symptoms, such as exertional dyspnea or fatigue, which can later evolve into chest pain, heart failure, or syncope, patients frequently go through protracted periods of asymptomatic latent periods lasting 10 to 20 years. The aortic valve must be replaced as the sole curative option for aortic stenosis, either surgically or percutaneously. While the asymptomatic phase has a good survival rate, a few years after symptoms start to show up, mortality may exceed 90%. In wealthy countries, aortic valve stenosis is one of the most prevalent valvular disorders, affecting around 9 million individuals worldwide. Atherosclerosis is growing more prevalent as a result of both population aging and rising incidence of the condition. (3) The common reason leading to aortic stenosis in people less than 70 years of age in first world countries is bicuspid aortic valves in particular. On the other hand, developing nations are more likely to experience rheumatic valve disease, which causes the leaflets' commissures to fuse together, leaving a tiny central opening. Trichomonas calcification, systemic disorders including systemic lupus erythematosus, alkaptonuria, ochronosis, radiation, and metabolic disorders like Fabry disease are additional possible reasons. Changes occurring in mineral metabolism, as observed in latter-stage renal disease, can as well lead to calcification of the valves. Stenosis in the supra and sub positions of the valves can be caused by blockage of left ventricular outflow above or below the valve. Hypertrophic cardiomyopathy can also cause dynamic subvalvular stenosis. Obstruction of the left ventricle's outflow is most commonly caused by aortic valvular stenosis pathology. The defining feature of the condition is anterograde velocity over the aortic valve no less than 2 metres/second. Meanwhile aortic valve sclerosis is typified by thickened and calcified aortic valve without any appreciable change in the pressure gradient. Aortic stenosis can have a hereditary cause, as in the case of bicuspid or unicuspid valves, or it can develop as a result of rheumatoid arthritis and calcific processes. Before experiencing any symptoms, such as exertional dyspnea or fatigue, which can later evolve into chest pain, heart failure, or syncope, patients frequently go through protracted periods of asymptomatic latent periods lasting 10 to 20 years. The definitive treatment for aortic stenosis is the replacement of the aortic valve, which can be performed surgically or percutaneously.

In clinical contexts, symptoms of acquired AS include exertional dyspnea, syncope, angina, and in the end, heart failure. These symptoms are typically experienced between the ages of 50 and 70 in people with bicuspid aortic valves, and after the age of 70 in people with three leaflet calcified valve stenosis. These patients describe fatigue, effort-induced dyspnea, and a progressive decrease in their tolerance for physical exertion. Severe symptoms such as orthopnea, pulmonary edema, paroxysmal nocturnal dyspnea, and exertional dyspnea can indicate distinct phases of pulmonary venous hypertension. Angina is caused by the increased oxygen demand of a hypertrophied heart and severe coronary artery compression, which lowers oxygen delivery. Reduced cerebral perfusion during exercise, brought on by systemic vasodilation and insufficient cardiac output increase because of stenosis, as well as, in extreme situations, malfunctioning baroreceptors, are the causes of syncope. Non-cardiac symptoms include gastrointestinal bleeding, sometimes linked to angiodysplasia or other vascular anomalies, and brain emboli from microthrombi on thickened bicuspid valves. Furthermore, many individuals worry about infective endocarditis, particularly if they have bicuspid valves. A physical examination can identify pulsus parvus et tardus in severe cases, the right second intercostal space, and a mid-systolic ejection murmur that is usually best heard over the carotid upstroke.

Since echocardiography offers direct imaging of the orifice region, a severity assessment of valve calcification, and imaging of the valve architecture, it is utilized as the primary evaluation tool. Longitudinal systolic strain imaging is a sensitive marker of left ventricular function which predicts adverse outcomes, like mortality. Asymptomatic patients can be diagnosed through exercise testing; however it is not advised for symptomatic patients. Cardiovascular computed tomography is more frequently employed to assess calcific aortic valve disease when non-invasive testing is not able to provide definitive results, and cardiac magnetic resonance imaging is utilized when echocardiography is insufficient to assess left ventricular mass, function, and volume. There is little evidence that the course of medical care significantly affects the rate at which AS advances. Surgical or transcatheter AVR is preferred over pharmaceutical therapy in cases where symptoms are severe. Studies support the use of angiotensin-converting enzyme inhibitors and angiotensin receptor blockers by demonstrating that vasodilation can increase stroke volume even in situations of aortic stenosis with fixed afterload. Diuretics can help reduce volume overload symptoms prior to surgery. While balloon aortic valvuloplasty can temporarily improve hemodynamic status, there are no long-term benefits.

AVR is recommended for people with symptomatic AS, even in cases of mild symptoms. It is also recommended in asymptomatic patients with severe AS under specific conditions, such as a left ventricular ejection fraction(LVEF) below 50%, concurrent coronary artery bypass grafting or any other heart surgeries, abnormal exercise treadmill tests, peak velocity over 5 meters/second, mean pressure gradient of over 60 mm Hg, and rapid progression of peak velocity. Both transcatheter and surgical AVR are successful treatments; following either operation, many patients report increased exercise tolerance and decreased symptoms. The operational mortality rate for surgical valve replacement is approximately 3.2% in case of isolated, and <1% in patients less than 70 years old with moderate comorbidities. In patients at high and moderate risk, transcatheter AVR has been shown to be more effective than surgical AVR, and in non-surgical candidates, it has yielded superior outcomes than medication treatment. The durability of transcatheter AVR is still unknown. A common strategy that gains from a stepwise reduction in sheath size is the transfemoral approach. A multidisciplinary heart valve team of cardiac surgeons, interventional cardiologists, clinical and imaging specialists, nurses, anesthetists, and geriatricians is crucial in deciding whether to proceed with surgical or transcatheter AVR, depending on the complexity of each patient.

One aspect of aortic stenosis's differential diagnosis is separating conditions like syncope and angina from other conditions including cardiomyopathy and coronary artery disease. Lung diseases and other non-cardiac causes can also cause exertional dyspnea. The distinction between these conditions can be made using tests for pulmonary function and cardiopulmonary exercise. In addition, whether or not there is left ventricular outflow limitation, aortic sclerosis, subvalvular stenosis, and hypertrophic cardiomyopathy can cause an ejection systolic murmur. In particular, supravalvular stenosis is a commonly noted Williams syndrome sign.

According to staging, aortic stenosis develops in both asymptomatic and symptomatic phases. The hemodynamics of the valve is considered at every stage. The prognosis is good for asymptomatic persons, and routine imaging is recommended based on the degree of stenosis. A higher rate of disease development has been associated with numerous factors, including advanced age, severe leaflet calcification, hypertension, obesity, smoking, hyperlipidemia, renal insufficiency, metabolic syndrome, and high lipoprotein levels. It has been found that Doppler aortic jet velocity is the most accurate indicator of the onset of symptoms. Patients with symptoms have a poor prognosis without AVR, with an average survival time of one to three years after the onset of symptoms. Severe symptomatic aortic stenosis is associated with a higher risk of cerebral or systemic emboli, infective endocarditis, conduction issues, abrupt death, cardiac failure, and pulmonary hypertension. Effective patient education and postoperative care are essential, with a focus on symptom development, wound care, physical activity limitations, and drug adherence. An interprofessional healthcare team approach that incorporates comprehensive patient education and well-coordinated postoperative care is necessary for optimal outcomes. (4)

SAVR

Aortic valve disease is a serious health issue that is predicted to worsen over the next several decades, especially in the older population. The numbers of symptomatic aortic valve disease is anticipated to rise significantly as the world's population ages. For a considerable improvement in patients' quality of life and lower mortality rates with severe aortic valve disease, SAVR has been the gold standard of care since a long time. According to estimations from the most recent census, there will be a noticeable ageing trend in the population; by 2050, 88.5 million Americans will be over 65 and 5.4 million will be over 85. This change in demographics, in addition to the greater rate of symptomatic aortic valve disease in older patients, indicates a substantial rise in the number of people who may need treatment for this condition.

It is imperative that symptomatic aortic valve disease patients receive immediate intervention because the annual mortality rate in the event that therapy is not received after symptom onset is close to 25%. This emphasizes how urgently many patients still require SAVR as their primary treatment, highlighting the vital need for prompt and efficient therapeutic alternatives. A counterintuitive drop in operative mortality has been noted, especially for medium-risk (group 2) and high-risk (group 3) surgical patients, despite the rise in higher-risk patients having SAVR. All patients' overall rates of surgical death were remarkably steady, with a minor decline noted from 2.7% in 2002–2006 to 2.5% in 2007–2010 ($p = 0.018$). Improvements in postoperative care protocols, improved intraoperative surgical procedures, and preoperative evaluation techniques are some of the reasons for this improvement in outcomes, even with a more complicated patient population.

For patients having SAVR, the Society of Thoracic Surgeons Predicted Risk of Mortality (STS PROM) score is still commonly used for risk stratification. Throughout the two time periods which were under investigation the mean STS PROM for patients in the intermediate risk category (group 2) stayed constant at roughly 5%. The overestimation of the actual measured mortality for this group is notable, though. All patients' overall rates of surgical death were remarkably steady with a minor decline noted from 2.7% in 2002–06 to 2.5% in 2007–10 ($p = 0.018$). Improvements in postoperative care protocols, improved intraoperative surgical procedures and preoperative evaluation techniques are some of the reasons for this improvement in outcomes, even in a complicated patient population.

For patients having surgical aortic valve replacement (SAVR), the Society of Thoracic Surgeons Predicted Risk of Mortality (STS PROM) score is used as a metric for risk stratification. Throughout the two time periods under investigation, the mean STS PROM for patients in the intermediate risk category (group 2) stayed constant at roughly 5%. The fact that this somewhat overestimated the actual measured mortality for this group is notable, though. Previous research indicates that the percentage of bioprosthetic valve implantations increased from 43.6% in 1997 to 78.4% in 2006, suggesting that this trend is a part of a longer-term change. Globally, comparable patterns have been noted; data from the United Kingdom suggests that the percentage of bioprosthetic valve implantations increased from 65% in 2004–2005 to 78% in 2008–2009.

The ageing patient population receiving SAVR, reported improvements in bioprosthetic valve longevity, and the desire to avoid the short- and long-term anticoagulation associated with mechanical valves are some of the variables that may be driving this trend towards bioprosthetic valves. The guidelines of the American College of Cardiology and the American Heart Association admit that, although mechanical valves may provide a small advantage in terms of longevity, the benefits of not using anticoagulation frequently outweigh this advantage, especially in elderly patients. This pattern is further supported by certain research that show better results with bioprosthetic valves in older age groups. Notably, SAVR continues to yield outstanding outcomes for patients in all risk groups, including those at high risk. The findings provide a valuable practical standard by which other treatments like TAVR could be assessed. SAVR continues to be a very successful and well-established treatment for patients with AV dysfunction across a large range of risk profiles. Operative mortality has stayed consistent or even dropped in spite of a rise in the percentage of higher-risk patients receiving SAVR. This suggests continuous advancements in surgical methods and postoperative care.

The trends in SAVR use that have been noticed such as the move toward bioprosthetic valves and the growing complexity of the patient base. These are a reflection of changing clinical procedures as well as shifts in patient demographics. The need for AVR is predicted to grow with the aging population. This could pose both possibilities and problems for cardiac surgery programs. Further research is needed in a number of important areas like comparative effectiveness studies between SAVR and TAVR, especially in intermediate and low risk populations, the long-term results of bioprosthetic valves in various age groups, the improvement of risk prediction models to more accurately stratify high-risk patients and strategies to maximize resource utilization and shorten postoperative length of stay, especially for high-risk patients.

TAVR

Since around 10 years Transcatheter aortic valve replacement or TAVR for short has emerged as a revolutionary therapy option for aortic valve malfunction. TAVR is particularly for patients who are deemed to be inoperable or to pose high risk of surgery. This minimally invasive technique has improved rapidly since its first-in-man implantation in 2002. It has marked a significant milestone in the disciplines of interventional cardiology and cardiac surgery. The management of patients with severe, symptomatic aortic stenosis (AS) has changed significantly in less than ten years. In 2011 the U.S. Food and Drug Administration's (FDA) first commercially approved of the technique.

In the European market with the Conformité Européenne (CE) mark in 2007, balloon-expandable SAPIEN of Edwards Lifesciences and the self-expandable CoreValve ReValving of Medtronic were the first two transcatheter heart valves (THVs) to be approved. Since then around 300,000 treatments have been carried out globally indicating the field's tremendous expansion and growing faith in the new technique.

Earliest "first generation" THVs had encouraging results especially in patient populations with a higher risk of surgery. However a number of TAVR-related problems were noted during the early acceptance stage as is the case with any novel medical intervention. The advent of second generation THVs were intended to further enhance results and lower procedure-related problems. The growing list of TAVR indications is a result of ongoing improvements to device design, implantation methods and patient selection standards.

Recent studies suggest patients who fall into the intermediate and low-risk groups in addition to those who are high-risk may find TAVR to be a viable alternative. This increase in potential candidates has caused a great deal of controversy in the medical world and has made it necessary to carefully assess the long-term results in younger and lower surgical risk patients. The heart team of multidisciplinary team of medical specialists is essential in helping each patient receive the best possible care by taking into account their unique needs, comorbidities, risk factors, and potential for quality-of-life improvement.

There are various ways to execute TAVR procedures. The most often used access routes are transfemoral (TF) and transapical (TA) approaches. Because the transfemoral method is less intrusive and could result in a quicker recovery and fewer issues it is typically used. Nonetheless, individuals with inappropriate peripheral vascular or other anatomical issues that make a transfemoral approach impracticable can require the transapical approach.

With the ongoing development of TAVR, newer manufacturers are releasing newer THVs into the market. Each device has a distinct size, distribution method and structural design. They are designed to accommodate a wide range of anatomical differences and patient demographics. Many valve alternatives make it possible to implement more individualized treatment plans, which may improve patient results. But this diversity also means that each device's features, implantation methods, and clinical and performance results from the past must be thoroughly understood.

A number of crucial factors are still at the forefront of clinical research and practice as TAVR's use in treating aortic valve disease grows. An important topic of research is the long-term endurance of transcatheter valves, especially in younger patients. Although the short- and medium-term results have been encouraging, it is still unclear how long these prostheses will last in comparison to conventional surgical valves, particularly as TAVR is increasingly being considered for younger and lower-risk patient populations.

It is impossible to overestimate the significance of using a heart team approach when making decisions, especially with the growing list of TAVR indications. The joint endeavor of interventional cardiologists, cardiac surgeons, radiologists, and additional medical experts guarantees a thorough assessment of every patient's distinct situation. Whether it be TAVR, surgical aortic valve replacement, or medicinal care, deciding best course of action requires a multidisciplinary approach.

While redo SAVR is still considered the gold standard for correcting surgical valve failure, a less invasive option called valve-in-valve (ViV) transcatheter aortic valve replacement (TAVR) is becoming more and more popular, with the promise to reduce short-term morbidity and mortality. However, the Food and Drug Administration has only approved it for individuals who pose a significant surgical risk for reoperation. TAVR within a deteriorated surgical valve (TAVR-in-SAVR), TAVR within a degenerated TAVR valve (TAVR-in-TAVR), and even TAVR within a TAVR valve that was previously inserted into degenerated SAVR valves (TAVR-in-TAVR-in-SAVR) are all included in the term ViV TAVR. (9) Another fascinating application for TAVR technology is the ability of doing ViV surgeries in the future, where a transcatheter valve is put inside a failing bioprosthetic valve (either surgical or transcatheter). This strategy might provide a less intrusive means of treating bioprosthetic valve degradation, which could lessen the need for high-risk reoperations in patients who are weak or elderly.

Indian Context

Although rheumatic heart disease still plays a major role in the development of valvular heart disease, age-related degenerative illness is the main reason for isolated stenosed aortic valves in India. According to the Global Burden of Disease report, severe calcific non-rheumatic AS is responsible for a significant number of deaths in India. Even though India lacks complete epidemiological data on valvular heart disease, extrapolations from Western research indicate that 2.5–3 lakh people with AS could be suitable for TAVR, which is more than the combined projections from North America and Europe.

The first TAVR treatment in India was carried out on a Medtronic CoreValve-using 80-year-old female patient in 2011. The uptake of TAVR has been steady but slow since then. Approximately thirty facilities in India currently undertake TAVR procedures, with seven centers handling the majority of cases. This figure shows room for growth because it is very less than the total cardiac catheterization laboratories in the nation.

There are a number of reasons for the delayed adoption of TAVR in India, such as the unwillingness of doctors and patients, the regulatory approval procedures, the absence of specialist training programs, the requirement for specialized centers, and the necessity for dedicated cardiac teams. Furthermore, the Indian population's anatomical peculiarities—such as smaller peripheral vessel and aortic valve diameters, high rates of bicuspid aortic valves (BAV) and rheumatic heart disease, low levels of coronary ostia, and heavy calcification of aortic valve leaflets—present special difficulties that affect the viability, longevity of prostheses, procedural complications, and long-term results of TAVR.

Both domestically made devices and valves approved by the FDA in the United States are used in TAVR treatments in India. The CoreValve® Revalving system and the Medtronic EvolutR valve are the two most widely utilized valves. The MyVal THV system, created by Meril Life Sciences Pvt Ltd. in India, is a noteworthy example of the success that local valve development is experiencing. Due to its cutting-edge design, innovative delivery mechanism, and affordable price when compared to Western products, this CE-approved balloon-expandable valve has gained substantial traction in the Indian market.

Research Objectives

1. **To analyze** the evolution in minimally invasive trends of SAVR - Surgical Aortic Valve Replacement and TAVR - Transcatheter Aortic Valve Replacement procedures in the USA particularly focusing on:
    1. Adoption rates and timeline comparisons between the two procedures.
    2. Factors influencing the shift towards minimally invasive techniques (e.g., patient demographics, technological advancements, surgeon preferences).
    3. Outcomes data associated with both procedures in the US context (e.g., mortality rates, length of hospital stay, patient recovery time).
2. **To identify** potential parallels between the observed trends in the USA and the current or emerging scenario in India for minimally invasive AVR procedures. This could involve:
    1. Assessing the availability and accessibility of TAVR technology in India compared to the USA.

    2. Evaluating current surgical practices and patient demographics in India to determine the potential for TAVR adoption.
    3. Identifying drivers and barriers for adoption of TAVR in India.
3. **To analyze** current and potential players in the Indian TAVR market.

REVIEW OF LITERATURE

1. "Cardiac Surgery," a comprehensive article by Senst B, Kumar A, and Diaz RR, published in StatPearls in 2024. The authors provide an extensive overview of cardiac surgery's evolution and current state. Senst, Kumar, and Diaz trace cardiac surgery's roots to the late 19th century, highlighting early milestones like the first pericardiectomy in 1882 and Ludwig Rehn's groundbreaking cardiac stab wound operation in 1896. They emphasize the transformative impact of cardiopulmonary bypass development in the mid-20th century, which enabled more complex interventions. The authors detail significant advancements in various areas of cardiac surgery. They discuss the revolutionary introduction of coronary artery bypass grafting (CABG) in the 1960s for ischemic heart disease treatment. It also traces the development of the management of valvular heart disease from closed procedures to the current level of advanced artificial valve implantations. Major Surgical Advances and Historical Developments in Advanced Cardiac Care by Senst et al. The advent of surgical techniques to treat congenital heart defects, the control of cardiac arrhythmias, and heart transplantation is also discussed by Senst et al. They describe the first heart transplantation, which took place in 1967 and then the subsequent developments in mechanical circulatory support devices. The article addresses the recent trend toward minimally invasive and interventional approaches but also strongly puts a premium on growing interdisciplinary collaboration. These are the issues associated with the establishment of cardiac arrest centers, growing indications to ECMO, integration of advanced technologies, such as robotic surgery. This timely review by Senst, Kumar and Diaz gives an insight into the past achievements and future challenges facing cardiac surgery. The article serves as a landmark in the continuing evolution of this highly critical field.

2. The article by Chakravarthy M. "Is Cardiac Surgery Threatening to go the Dinosaur Way?" sums up the evolution of cardiac surgery and its challenges and prospect for the future. The rapid development of Cardiac Surgery is traced from its inception in 1953 with the invention of Cardiopulmonary Bypass. The article highlights this field's golden age from the 1970s to the 1990s which was marked by significant advancements in techniques and technologies. The article also outlines several challenges facing cardiac surgery like the rise of interventional cardiology. The growth of percutaneous coronary interventions (PCI) and other minimally invasive procedures has led to a decline in traditional surgical cases like coronary artery bypass grafting - CABG. The review discusses the shift towards more complex, high-risk cases for cardiac surgeons and the confusing lines between cardiac surgery and interventional cardiology. The trend raises questions about the future identity of the specialty which can be deciphered from the title. Despite these challenges, the article argues that cardiac surgery is adapting rather than becoming outdated. It outlines strategies for ensuring the field's continued relevance by embracing hybrid procedures, expanding skill sets through training and focusing on areas where surgery still holds clear advantages. The review concludes by suggesting that cardiac surgery will remain an essential component of cardiovascular care although in an evolved form. It predicts a

future with increased collaboration, technological innovation and a focus on complex, high-risk cases.

3. The article on the "Epidemiology of Valvular Heart Disease" elaborates in detail upon the epidemiology of valvular heart disease worldwide. The current article, published in 2022, enunciates how the distribution of different valvular heart diseases and their prevalence tends to increase every year. The authors highlight that rheumatic heart disease is the most dominant form of VHD, affecting around 41M globally. They note the rapid growth of the disease in developing nations as a result of the increasing population and rising access to medical interventions that reduce premature mortality, leading to the growth of age-related incidences. Interestingly, the study also points out the growth of the rheumatic heart disease incidence among socially deprived populations in developed nations, due to different reasons. Such a disease as aortic valve stenosis is identified as the predominant valvular disease in the developed countries and also affecting about 9M across the world. The authors try to suggest that its up-surge is explained by the population aging process and also by the rise in the numbers of atherosclerosis. They also discuss the growing incidence of aortic regurgitation in developed countries, associating it with diastolic hypertension. Mitral regurgitation affecting 24 million people worldwide is discussed in its forms as primary and secondary. The study alludes to the fact that in about 65% of cases, secondary mitral regurgitation is secondary to heart failure and ventricular dilation. The authors also consider that tricuspid regurgitation has seen dramatic increase in first world countries probably due to the ubiquitous usage of pacemakers. Finally, they look at the growth in the number of infective endocarditis cases within developed states, a factor seen through their aging populations and transcatheter and prosthetic valve interventions. The review furnishes very useful insight on the changing landscape of VHD while bringing forth important information for health planning and resource allocation on a global scale.

4. In the article "Aortic Stenosis" in StatPearls, Pujari SH and Agasthi P (2024) undertake a comprehensive analysis of this common valvular disorder. The authors describe in detail the etiology of the condition, pathophysiology, clinical presentation, diagnostic approaches, and alternatives for treatment. By their explanation, the authors define aortic stenosis to be a left ventricular outflow obstruction, which is characterized by > = 2 m/s anterograde velocity across the valve. They also stress upon its frequency quoting it as the second most cardinal valvular illness in the United States of America which affects around 5% of the population by the age of 65years and increases upward with age, etiological factors like congenital abnormalities in the form of bicuspid valves, calcific processes of the valves, and rheumatic disease besides others are also discussed by the authors. Results stress therefore the rampant stress, yet the long latent period of about 10–20 years, which is asymptomatic before classical symptoms develop usually in the form of exertional dyspnea, fatigue, precordial pain, heart failure, and syncope. The article offers comprehensive information reviewing the pathophysiological alterations caused by aortic valve stenosis-induced pressure encumbrance leading to left ventricular hypertrophy and dysfunction. Pujari and Agasthi also summarize the clinical presentation, modalities of evaluation, which primarily comprise echocardiography techniques, and treatment including transcatheter aortic valve replacement (TAVR) with a word that a. The authors present both surgical and transcatheter AVR techniques, indicating superior results for transcatheter AVR in high-and intermediate-risk patients. They underline the role of a multi-disciplinary heart valve team in decision-making for high-risk and complex cases. In this broad review by Pujari and

Agasthi, healthcare professionals who deal with this pathology would benefit from diagnosis, management, and prognosis of aortic stenosis.

5. In an article by Kim KM et al. in "The Society of Thoracic Surgeons Adult Cardiac Surgery Database: 2022 Update on Outcomes and Research" in The Annals of Thoracic Surgery 2023, there is detailed information on shifts and results in cardiac surgery with a clear focal area on aortic valve procedures. In fact, the authors depict data in such a way to further elaborately corroborate a sustained downward trend in the number of isolated SAVR and SAVR done concomitantly with CABG. Such was a trend consistent with previous updates. This further highlights what is already public knowledge that there has been a change in dealing with aortic valve disease. The operative mortality of the isolated SAVR in 2021 was 2.3%, and that for SAVR with concomitant CABG was 4.4%. This well indicates an increased risk concerning more complex therapeutic strategies: the highest in-hospital mortality (10%) was observed in SAVR cases with concomitant mitral valve replacement. Of interest, the valve choice used for isolated SAVR between 2015 and 2021 showed an interesting development: whereas bioprosthesis valves were used in the overwhelming majority (85.8% overall) of cases, there was simultaneously a distinct rise in the use of mechanical from 10.7% to 18.1%. The employment of bioprosthetic valves has declined from 88.9% to 80.9%. There was also a significant increase in the rate of concomitant annular enlargement techniques performed during the isolated SAVR, from 3.5% to 7.8%. This fact shows us the more dynamic clinical approach in cases of more complicated aortic root anatomy. This is particularly relevant, as Kim et al. underline, with the more recent indication of TAVR use in low-risk patients expanding since 2019. This coincides with the decreased number of surgically treated patients in the field's move toward minimally invasive therapies in the treatment of aortic valve disease. This comprehensive and detailed review by Kim et al. helps us understand this dynamic landscape of aortic valve interventions and further augments crucial data to its users in the field of cardiac surgery.

6. Thourani VH, Suri RM, Gunter RL, Sheng S, O'Brien SM, Ailawadi G, et al. in January 2015 published a landmark article in The Annals of Thoracic Surgery titled: "Contemporary Real-World Outcomes of Surgical Aortic Valve Replacement in 141,905 Low-Risk, Intermediate-Risk, and High-Risk Patients". The article elaborated on the outcomes following SAVR that had been undertaken in 141,905 patients stratified into low-risk, intermediate-risk, and high-risk categories primarily based on the STS PROM. The patients in this series were distributed into 3 population risk groups: from 2002 to 2010, n = 113,377 low-risk, Group 1: n = 19,769 intermediate risk, Group 2; and n = 8,759 high risk Group 3. The mean age was 65 years in Group 1, whereas in Groups 2 and 3, it was 77 years, with a median STS PROM of 1.84. The other major findings were that in-hospital mortality rates overall were generally a little lower than that predicted by the PROM across all three subgroups: 1.4% versus 1.7% in 'low' risk, 5.1% versus 5.5% in 'intermediate risk,' and 11.8% versus 13.7% in 'high' risk. This implies that the study represents a significant decline of operative mortality during the late surgical era, namely in 'intermediate' and 'high' risk patient categories. For instance, in group 2, mortality declined from 6.4% to 5.4% (p = 0.002), and in group 3, from 14.4% to 11.9% (p = 0.0004). According to the shown results, the authors conclude the outcome for approximately 80% of the SAVR patients treated was better when compared to the risk models; in medium-risk as well as high-risk patients, the improvement was quite notable over time-. It represents one of the

important real-world assessments in current therapeutic options for aortic valve stenosis and, therefore, serves as a telling benchmark of evolving efficacy of SAVR.

7. In the article "TAVR: From Then Until Now" written by an author on the American College of Cardiology website, the author generally discusses substantial progress in the treatment of severe, symptomatic AS over the last decade. He also marks year 2011 as a landmark in this history because it is when the U.S. Food and Drug Administration—the FDA—approved the first device specifically used for transcatheter aortic valve replacement: the TAVR. Since that time over 300 000 patients within the US have undergone TAVR, the transformative journey that began 31 years ago with the work of Henning Andersen in Denmark. Milestones in the evolution of TAVR include the first animal implantations in 1992, the inaugural human TAVR implantation by G. Alain Cribier in France in 2002, and the first U.S. studies in 2004. The regulatory landscape for TAVR was determined by 2 series of investigational device exemption (IDE) randomized trials which were the PARTNER trials for the balloon-expandable Sapien Valve from Edwards Lifesciences and the CoreValve / Evolut Trials from Medtronic which began in 2007. Enrolling 9682 patients, these trials determined the safety as well as effectiveness for TAVR. This paved the way for FDA approval in 2011 and reimbursement by CMS in 2012. The trials always showed that TAVR was better than medical therapy for the inoperable patient and was non-inferior to SAVR in high- and intermediate–risk patients. Clinical trials of TAVR have now shown the latter to be either superior or non-inferior to SAVR, with even low-risk surgical patients, with ten-year follow-up studies under way to establish longer-term results. Currently, some 716 centers in the United States are performing TAVR with about 75,000 patients treated as recently as 2019. The STS/ACC TVT Registry, a requirement for billing, allows full data capture and captures demographic characteristics and outcomes similar to those in the pivotal trials and, hence, demonstrates the real-world effectiveness of TAVR for the treatment of AS.

8. The study "Trends in Surgical Aortic Valve Replacement in Pre- and Post-Transcatheter Aortic Valve Replacement Eras at a Structural Heart Center" by Norton EL, Ward AF, Tully A, Leshnower BG, Guyton RA, Paone G, et al., published in *Front Cardiovascular Medicine*, investigates the impact of transcatheter aortic valve replacement (TAVR) on the trends and outcomes of surgical aortic valve replacement (SAVR). The advent of TAVR has revolutionized the management of aortic valve disease, prompting the U.S. Food and Drug Administration to approve it for prohibitive (2011), high (2012), intermediate (2016), and low surgical risk patients (2019). Consequently, TAVR volumes have surged while SAVR procedures have declined. The study analyzed 3,861 isolated SAVRs performed at a single academic quaternary care institution from January 2000 to June 2020, comparing pre-TAVR (2000–2011, n = 2,426) and post-TAVR (2012–2020, n = 1,435) eras. The post-TAVR group exhibited higher rates of diabetes, hypertension, dyslipidemia, heart failure, and reoperative SAVR but lower STS Predicted Risk of Mortality (PROM). The study found an increase in urgent/emergent/salvage SAVRs and a decrease in elective SAVRs post-TAVR. Additionally, there was a significant rise in bioprosthetic valve implantations (85% vs. 74%), larger aortic valve sizes (25 mm vs. 23 mm), and annular enlargements (5.9% vs. 1.6%) in the post-TAVR era. Postoperative outcomes in the post-TAVR era showed improvements, including reduced blood product transfusion (49% vs. 58%), renal failure (1.4% vs. 4.3%), pneumonia (2.3% vs. 3.8%), shorter lengths of stay, and lower in-hospital mortality (1.5% vs. 3.3%). These findings highlight the evolving landscape of

aortic valve disease management, emphasizing that SAVR remains a critical component with excellent outcomes even in the TAVR era.

9. The article by Perdoncin E, Paone G and Byku I on October 12, 2021 entitled "Valve-in-Valve Transcatheter Aortic Valve Replacement for Failed Surgical Valves and Adjunctive Therapies" reviewed the evolution of TAVR-in-valve as an alternative to redo SAVR for the failed surgical valve. Traditionally, redo SAVR remained to be the gold standard of care in degenerated surgical valves. The ViV TAVR option, on the other hand, is clearly less invasive and likely provides better short-term morbidity and mortality results. The authors sought out retrospective registry data, showing that the ViV TAVR option has promising outcomes, including excellent 1-year mortality rates and sustained valve performance with improvement in quality of life up to 3 years postprocedure. The article also highlighted that an adequate CT analysis was done for procedural planning, underlining that much needed in the near future will be training of operators in risk recognition and mitigation strategies for both coronary obstruction and patient-prosthesis mismatch. Clinical outcomes of VIV TAVR are shown to be feasible, with high success rates for the procedure and favorable patient outcomes. The review further provides recommendations for procedural planning, underlining the critical role of preprocedural imaging and assessment for optimal results. In addition, the authors review strategies for addressing technical challenges that may come up during ViV TAVR, such as accurate valve placement and management of potential complications. This article brings to the forefront that ViV TAVR is one of the federally mandated steps towards the management of failed surgical valves, an alternative to Redo SAVR with comparative promising clinical outcomes, and improves quality of life in patients. Perdoncin, Paone, and Byku have contributed a very educative review regarding procedural details and clinical benefits associated with ViV TAVR.

10. The paper "Transcatheter Aortic Valve Replacement: Clinical Safety and Performance Data" by van Baal JWPM, Roszek B, van Elk M, and Geertsma RE was published in the Expert Review of Medical Devices on October 3, 2019. It provides an overview of all the clinical safety outcomes and performance data pertaining to TAVR. The data in this review are of enhanced salience for those patients with severe aortic stenosis and concomitant regurgitation in whom the patients are either inoperable or have high surgical risk. The authors attempted a full review of 204 articles to provide a description of outcomes for 16 different TAVR devices. Of most importance in the clinical outcomes were the range of 30-day mortality rates, which varied from 0 to 23%, and of 30-day stroke rates, which ranged from 0 to 14.3%. Other important clinical endpoints were post-TAVR pacemaker implantation with the incidence of 0-44.9%. Valve performance was particularly measured by the amount of aortic valve regurgitation; in the majority of studies, it was 7 days. Notice also from the study that a different follow-up duration was noticed in studies, sometimes even to 6-month and 1-year follow-up, though fewer documents reported longer-term results or those in intermediate- and low-risk patients. 'The present study has shown that considerable heterogeneity in reported outcomes still exists even with the application of the standardized definitions of VARC-2'. For this purpose, van Baal and colleagues explicitly state that future studies need to use standardized definitions and set up the studies the same way. This makes achieving improved care for patients in general, and better outcome predictability, essential for the sake of clarity and consistency about the performance of and safety associated with TAVR devices.

11. The article "Current Status of Transcatheter Aortic Valve Replacement in India" by Gupta P, Arora S, Qamar A, Gupta M and Seth A was published in *Cardiovascular Diagnosis and Therapy* in February 2020. It provides a comprehensive overview of the status and challenges of TAVR in India. TAVR has emerged as a pivotal therapy for patients with severe AS which is a condition that is prevalent in India and affects both rheumatic and non-rheumatic populations. The authors point out that although TAVR has transformed the management of non-rheumatic AS in the world its possible use for rheumatic AS could present a bright future for therapeutic alternatives in India. However the actual burden of AS in the Indian population remains difficult to quantify due to the lack of epidemiological studies. Despite varying estimates a significant number of patients could benefit from TAVR. However the adoption of TAVR in India faces numerous barriers. Significant obstacles include high expenses, insurance coverage gaps, poor government regulation, a shortage of skilled TAVR operators and healthcare practitioners unfamiliar with post-TAVR treatment. Specific difficulties are also presented by the distinct physical features of the Indian population like lower iliac and femoral artery calibers, smaller body surface area, smaller annulus size and poor coronary ostia take-off. These anatomical characteristics raise the possibility of difficulties and call for smaller hardware. The article also underscores the urgent need for policy makers and healthcare personnel in India to recognize the benefits of TAVR. It calls for strategic initiatives to facilitate the widespread implementation and accessibility of TAVR across the country which includes addressing financial barriers, enhancing training programs for operators and healthcare providers and adapting procedural approaches to meet the unique anatomical needs of the Indian population.

METHODOLOGY

This is a descriptive and comparative study. Information regarding the outcomes of minimally invasive AVR procedures in the USA will be extracted in detail from various academic literature, medical databases, government websites, and industry reports, and compared to the current scenario in India. A focused search strategy will then be undertaken using specific keywords such as "minimally invasive AVR," "SAVR vs. TAVR adoption rates," "TAVR outcomes data," "TAVR availability in India," and "patient demographics for TAVR."

The data will be analyzed with Microsoft Excel, discoursing the adoption rates, results, and patient demographics of TAVR and SAVR in the USA. It will also evaluate the availability of TAVR, the profile of patients, and related challenges in the Indian scenario. The datasets will be compared to identify meaningful parallels and hence opportunities for increasing TAVR adoption in India.

Adhering to stringent ethical data citation practices, all sources will be accurately documented to ensure transparency and reproducibility of the research. The entire study will be conducted within a three-month timeframe, allowing for a thorough yet efficient analysis. The comparison analysis yielded useful insights that could drive future measures to improve patient outcomes in India and enhance TAVR adoption by healthcare practitioners and policymakers in both nations.

Research questions:

1. How have adoption rates and timelines for SAVR and TAVR procedures evolved in the USA?

  - What are the key factors influencing the shift towards minimally invasive techniques in the USA, such as patient demographics, technological advancements, and surgeon preferences?

  - What outcomes data are associated with SAVR and TAVR procedures in the USA, including mortality rates, length of hospital stay, and patient recovery time?

2. What potential parallels can be drawn between the minimally invasive AVR trends observed in the USA and the current or emerging scenario in India?

  - How does the availability and accessibility of TAVR technology in India compare to that in the USA?

  - What are the current surgical practices and patient demographics in India, and how do they indicate the potential for TAVR adoption?

  - What are the main drivers and barriers for the adoption of TAVR in India?

3. Who are the current and potential players in the Indian TAVR market, and what roles do they play in the adoption and dissemination of TAVR technology in India?

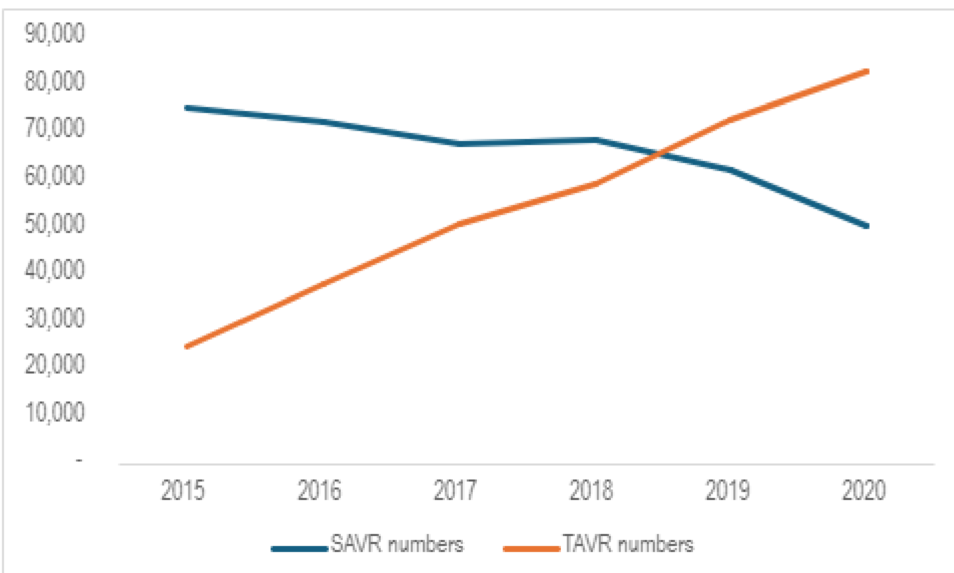
Materials and methods:

1. This was a descriptive exploratory study.
2. Secondary data was gathered from research papers, publications, journals, government websites, news articles, and other sources.
3. The study spanned three months.
4. Microsoft Excel was used for analysis.

RESULTS

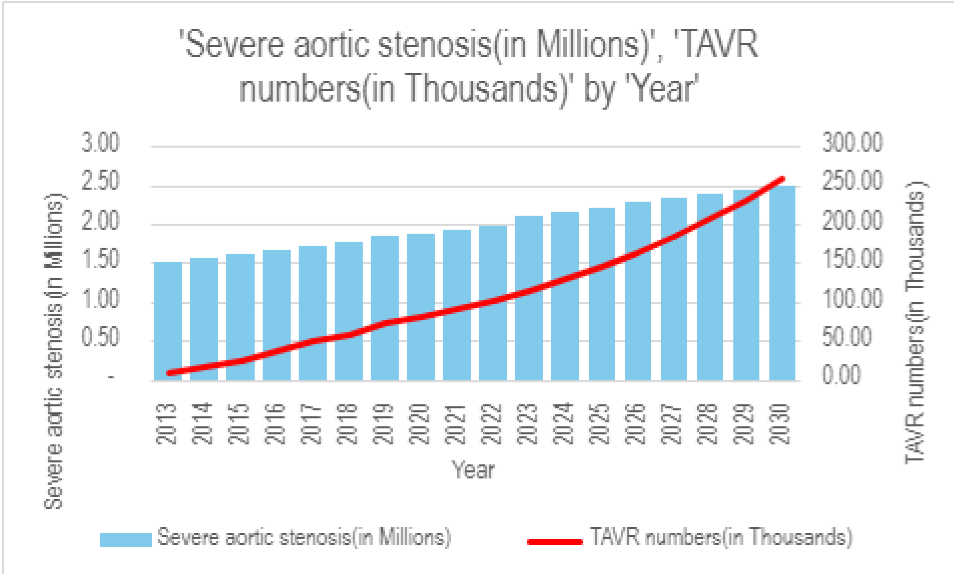
After review of the adoption rates and timeline histories of SAVR and TAVR in the U.S., several important trends become clear. SAVR, the historical considered primary treatment for severe aortic valve disease, has shown significant drops in utilization, thus representing a clear shift in treatment paradigms. Meanwhile, TAVR has seen tremendous growth since its FDA approval in 2011 following its first successful implanted clinical trials in 2002. This minimally invasive procedure has quickly been embraced the world over, with over 300,000 procedures carried out globally, showing its growing role in cardiac care over quite a short period.
Similar trends are also demonstrated by the data derived from the Society of Thoracic Surgeons STS Adult Cardiac Surgery Database, which reports that the total number of SAVR procedures is on a slight rise for the past few decades; for instance, from 63, 754 (2002-06) to 78, 151 (2007-10) which affirms both increasing disease prevalence and continued dependence on SAVR as major treatment modality.

By 2019, TAVR procedures surpassed SAVR procedures in total numbers, thereby suggesting a decisive change in the surgical technique of choice. In just 2019, there have been approximately 75,000 TAVR procedures performed at 716 U.S. centers as compared to the aggregate eight of all types of SAVR procedures.



Graph 1: Decline of SAVR numbers Vs TAVR numbers going up in the US

Several factors contribute to growing preference for TAVR over SAVR. The first includes the fact that an aging population makes up a greater incidence of aortic valve disease among elderly patients, often with several comorbidities that do not wish to undergo complex surgeries with longer hospital stays and recovery times. Continuous technological advancements have further improved TAVR's appeal with improvements happening in device design, implantation techniques, and patient selection criteria that have improved TAVR's applicability.



Graph 2: Increase in TAVR procedures vs Aortic stenosis cases in the US

Preference has been changing to the minimal invasiveness of TAVR, with increasing indications, and hence, the increasing number of TAVR procedures as strategies have been continuously reviewed. In this context, the isolated SAVR operation and its combination with others, such as coronary artery bypass grafting, have suffered performance loss since the introduction of TAVR.

While the surgical aortic valve replacement has remained stable or decreasing operative mortality rates with respect to the increasing number of high-risk patient groups, the early results of TAVR have been encouraging, quite particularly in the management of patients at high surgical risk. Still, there are concerns about long-term durability of such TAVR valves, especially in younger patients, for which reports require more research and studies.

Trends in minimally invasive aortic valve replacement have some similarities and differences between the United States and India. After being approved for use by the FDA in 2011, there has been an accelerated adoption of the game-changing TAVR technique in the treatment of severe aortic valve disease within the US. On the other hand, India showed a far slower take-up after the inception of TAVR. There are very few centers for TAVR in India. Presently about 30 centers in India provide TAVR services, a few in relation to the number of cardiac catheterization labs in the country, hinting at a possible bright future.

Among the many challenges that make TAVR technology less accessible in India are regulatory complexities, specialized training requirements, and requirements for dedicated heart teams, hence contributing much to a slow uptake compared to that in the United States. Unique anatomical considerations in the Indian population, like smaller aortic sizes, a higher prevalence of rheumatic heart disease, and heavy calcification of aortic valves, cause specific procedural challenges and impact the long-term outcomes and durability of the device.

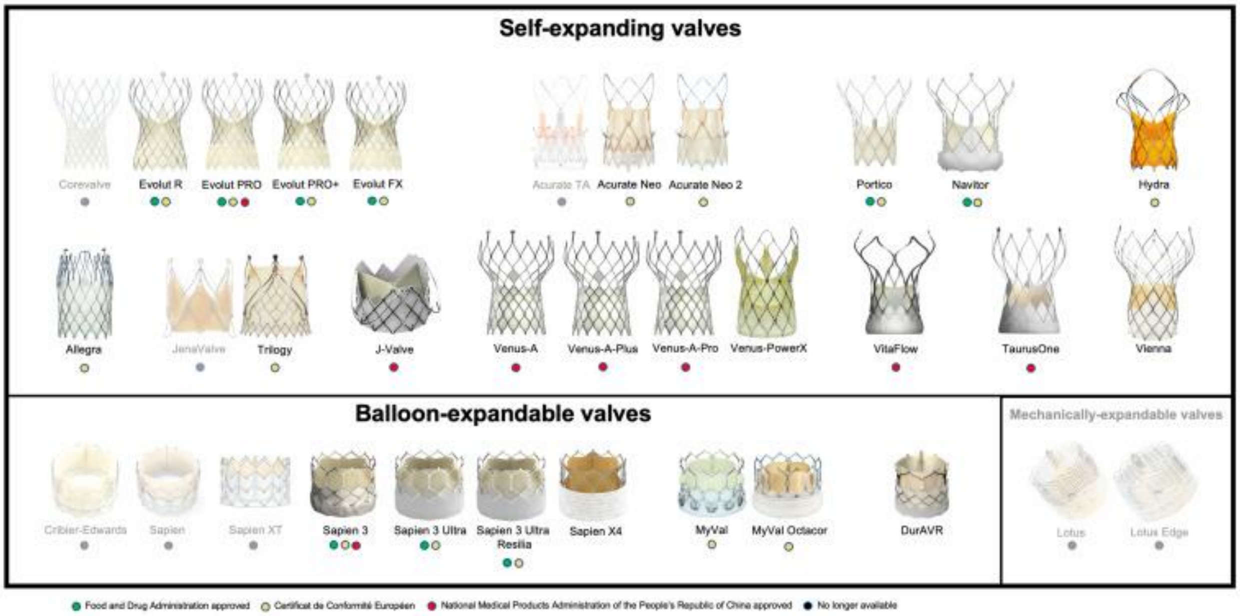


Figure 1: Current available TAVR products

Current surgical practices in India currently address rheumatic heart disease as a leading cause of valvular heart disease although age-related degenerative diseases like calcific aortic stenosis are increasingly prevalent. Estimates suggest a substantial patient population eligible for TAVR in India which could potentially surpass combined figures from Europe and North America. The age-related conditions were more reflected in the trend of the demographic, thus leading to an increasing interest in minimally invasive cardiac interventions—with the growing need for less invasive treatment modalities—such as TAVR.

Figure 2: MyVal TAVR by Meril Lifesciences

Figure 3: Hydra TAVR by Vascular Innovations (SMT)

Drivers for TAVR adoption in India include shift in demographics towards an aging population, hence more prone to aortic valve disease; advances in device design and procedural techniques; and increasing acceptance among health care providers as well as patients seeking less invasive alternatives. However, addressing the regulatory complexities, infrastructure limitations, specific anatomical considerations pertinent to the Indian population, and other such barriers will need to be undertaken to facilitate this broader adoption.

The results underline a dynamic landscape of AVR procedures in the United States and India and underline the rising prominence of TAVR as a preferred treatment modality in both developed and developing. Based on these broad findings, therefore, we can set the stage for the comprehensive discussion on the implications and future directions of TAVR in two settings concerning the adoption trends, demographic influence, technological advancement, and procedural outcomes.

DISCUSSION

The landscape of aortic valve replacement has seen vibrant changes in the USA with the advent of TAVR accompanying its counterpart SAVR. Historically, SAVR was the standard of care for severe disease of aortic valve. SAVR has been effective but relatively more invasive and has been associated with long recovery periods. The trend towards less and less use of SAVR increased manifold in recent years, which reflected general trends and changes in treatment preferences.

On the other hand, TAVR has demonstrated exponential growth since its regulatory approval by the FDA in 2011 after its successful venture through the initial procedures carried out in 2002. The minimally invasive approach has since been significantly diffused across the U.S beyond the number of procedures that are carried out through SAVR in 2019. The preference towards TAVR is attributable to several demographic trends of an increasingly older age of population with a high prevalence of aortic valve disease as well as constant innovation of the new AI devices alongside their evolution, ensuring better performance derived from the procedures as well as the overall patient recovery.

Implementing this trend in India reveals a relative one but slightly latent. The implementation of TAVR in India was made according to this timetable a few years behind America, and the initial adoption was only located in specialized centers. Around 30 centers throughout India make available the treatment of TAVR, paving the way for a few more, since the particular procedure is allowed in around 30 countries and is considered effective by many for patients who are not receptive of surgical procedures unless it is a critical case. Key stakeholders include large hospitals and cardiac centers. They play crucial roles in TAVR research, training and implementation efforts, paralleling their roles in the United States.

The Indian landscape also supports its indigenous TAVR manufacturers; for instance, companies such as Meril Life Sciences have developed their MyVal Transcatheter Heart Valve System to cater for local requirements. Sahajaand Medical Technologies, after a recent acquisition of Vascular Innovations, has its TAVR device—Hydra THV, which will be a probable strong influencer in the entire TAVR landscape in India. These indigenous solutions fill the gaps in device diversity and affordability but also contribute to overcoming regulatory and logistical challenges that are specific to the Indian market. The products could also tackle the specific anatomic requirements of the Indian population compared to its western counterparts. Looking forward to the future of TAVR in India, the same is very promising.

It somewhat belies the advances seen in the United States. To increase innovation, access, and patient outcomes, extended cooperation among care providers, device makers, regulatory frameworks, and academia is essential. Infrastructure, training, and research investments are strategic ways to overcome challenges at play and to ensure TAVR reaches its full potential in the transformation of care for all divers. TAVR technology is continuing to emerge in the national routine clinical application in India, was invigorated at this period by local innovations. The promise of improving patient outcomes with valvular heart disease under an increased burden is quite high in diverse populations in India.

CONCLUSION

From deep analysis of the trends in adoption and outcomes in SAVR and TAVR in the United States and India, several conclusions can be made.

From this perspective, a case in point of such dramatic changes in preferences is the evolving history of the procedure of aortic valve replacement in the US, from predominantly SAVR to changing trends in preference for TAVR, based on improved accessibility to care, technology evolution, and clinic outcomes data paving the way for a minimally invasive procedure with better patient recovery times.

In contrast, the TAVI adoption in India has been slow but it could really be a beast in terms of growth potential with the current trends akin to the early experience of the United States. Such growth is further backed by specialized centers and indigenous TAVI manufacturers like Meril Life Sciences and Sahajanand Medical Technologies that are assuming a burden of solving local barriers, more so with newer cardiac interventions on the horizon.

This study thus emphasizes the need for stronger collaborative work and scientifically built arguments between healthcare providers, device manufacturers, regulatory bodies, and academic institutions to develop technologies for TAVR further and for their effective application. These would prove to be key investments into strategic infrastructure, training, and research in light of the current challenges in the realization of optimal returns that this technology is envisaged to offer in transforming cardiac care in India.

Conclusion These findings underscore the dynamic landscape of contemporary aortic valve replacement therapies emphasizing the increasing role of TAVR across the world and its potential to deal with the growing burden of valvular heart diseases across different populations. As the countries navigate current regulatory and technological changes and those of the future, continued focus on improving access, affordability, and clinical outcomes is vital for patient care and survival.

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