UTILIZATION AND CLINICAL TRENDS OF TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) IN INDIA: A COMPREHENSIVE ANALYSIS OF ADOPTION, OUTCOMES, AND ACCESSIBILITY

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by

Shetty Vinamrata Shivashankar

Under the Supervision and Guidance of

Dr. Rahul Sharma

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Orbees Business Solutions Pvt. Ltd.
Q1, B1, B2, B3, 6th Floor, Cyber Towers, Hitec City, Madhapur, Hyderabad – 500 081. CIN: U72200TG2006PTC049670
Tel: +91 - 040 - 2311 4722, Fax: +91 - 040 - 2311 4723. info@orbees.com | www.orbees.com | www.orbeesmedical.com

6th June 2025
Hyderabad

To,

Ms. Vinamrata Shivashankar Shetty
406/B, Shree Saryu CHSL, Prabhat Residential Complex,
Nr. Toll plaza, Dahisar East, Mumbai- 400068.

Dear **Ms. Vinamrata Shivashankar Shetty**

Internship Certificate

This letter is to certify that **Vinamrata Shivashankar Shetty** in partial fulfillment of the requirements for the award of the degree of MBA in Pharmaceutical management from the IIHMR university, Jaipur is doing internship at Orbees Business solutions Pvt. Ltd. Since **17th March 2025** to **till date**.

For **Orbees Business Solutions Pvt. Ltd**

G. Praveen

Praveen Ginjupalli
Manager - Operations

IIHMR UNIVERSITY

CERTIFICATE

This is to certify that the dissertation titled **"Utilization and clinical trends of transcatheter aortic valve replacement (TAVR) in India: A comprehensive analysis of adoption, outcomes, and accesibility"** is a record of the research work undertaken by Ms. Vinamrata Shetty in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and her approach to research study has been sincere, scientific, and analytical.

Dr. Rahul Sharma
Faculty Guide
IIHMR University, Jaipur
Date:

Dr. Saurabh Kumar Banerjee
School Dean
IIHMR Jaipur
Date 17/6/2025

DECLARATION BY STUDENT

I, **Vinamrata Shetty** hereby declare that this dissertation titled **"Utilization and Clinical Trends of Transcatheter Aortic Valve Replacement (TAVR) in India: A Comprehensive Analysis of Adoption, Outcomes, and Accessibility"** 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 Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Signature: Shetty

Name – Vinamrata Shetty

Date - 18/06/2025

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Date:

Vinamrata Shivashankar Shetty
MBA (Pharmaceutical Management)
IIHMR University, Jaipur
2025

ABSTRACT

Title:
Utilization and Clinical Trends of Transcatheter Aortic Valve Replacement (TAVR) in India: A Comprehensive Analysis of Adoption, Outcomes, and Accessibility

Author Name:
Vinamrata Shivashankar Shetty

Advisor Name:
Dr. Rahul Sharma

Keywords:
TAVR, Aortic Stenosis, Cardiac Interventions, India, Accessibility, Clinical Outcomes, Health Policy

Background:
Transcatheter Aortic Valve Replacement (TAVR) has emerged as a transformative, minimally invasive procedure for patients with severe aortic stenosis—particularly those at high surgical risk. While globally embraced, India's adoption of TAVR remains limited due to infrastructural, economic, and policy-related challenges.

Objective:
To evaluate the current landscape of TAVR in India by analyzing procedural utilization, clinical outcomes, and systemic barriers, and to identify actionable strategies that can improve accessibility and adoption across diverse healthcare settings.

Methodology:
A descriptive, exploratory study was conducted using secondary data from peer-reviewed literature, hospital case series, government policy documents, and cardiac care conference proceedings. The analysis included thematic categorization, comparative global benchmarking, and a SWOT framework to assess TAVR's position in India's healthcare system.

Results/Findings:
The study found that TAVR procedures in India are largely confined to urban tertiary care centers with high procedural success rates (96–99%) and favorable short-term outcomes. However, access remains restricted by high costs (₹18–25 lakhs), absence of reimbursement under major public insurance schemes, and lack of trained interventional teams outside metropolitan regions. Long-term outcome data and a national registry are also currently lacking. Despite these barriers, rising academic interest, early policy dialogues, and the potential for local manufacturing offer pathways to expand TAVR access.

Conclusion:

TAVR in India demonstrates strong clinical promise but is underutilized due to systemic access barriers. A coordinated strategy involving public-private partnerships, insurance reform, clinical guideline development, and training expansion is essential to democratize access and integrate TAVR into broader cardiac care services. Bridging these gaps can enable India to align with global benchmarks and offer equitable care to its aging cardiac population.

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Chapter 1:

Introduction

1.1 Background and Rationale

Over the last two decades, cardiovascular diseases have become one of the leading causes of death and disability in India. Among them, **aortic stenosis**—a condition where the aortic valve narrows and obstructs blood flow—has been a growing concern, especially in the ageing population. Traditionally, the treatment has involved **surgical aortic valve replacement (SAVR)**, which, while effective, carries significant risks in elderly or high-risk patients.

This is where **Transcatheter Aortic Valve Replacement (TAVR)** comes into the picture. A minimally invasive procedure that involves implanting a new valve without opening the chest cavity, TAVR has revolutionized the way we treat severe aortic stenosis in the West. Countries like the USA, Germany, and Japan have already integrated TAVR into standard clinical practice. In India, however, its utilization remains limited and somewhat fragmented.

During the course of my academic learning and research, I came across multiple instances where the **promise of advanced cardiac interventions** like TAVR exists—but is not yet fully accessible. This observation prompted me to look deeper into what's really happening on the ground in India. Are patients aware of this option? Are doctors equipped and trained to perform it? And what are the clinical outcomes for those who do undergo it here?

These questions led me to pursue this dissertation. The idea is not just to understand how many TAVR procedures are being done in India, but also to assess the **broader picture**—the trends, the gaps, the opportunities, and what needs to happen for TAVR to become more widely available and accepted across the country.

1.2 Problem Statement

While TAVR has emerged as a breakthrough technology in cardiac care worldwide, **India is yet to catch up** in terms of both volume and equitable access. Its current adoption is largely limited to top-tier hospitals in metropolitan cities, leaving vast segments of the population—especially in Tier 2 and Tier 3 cities—out of reach. High procedural costs, limited trained personnel, and lack of insurance coverage are key factors restricting its use. There is also a shortage of India-specific data that could help in assessing its safety, efficacy, and affordability in our healthcare ecosystem.

1.3 Research Aim

To evaluate the current state of utilization, clinical outcomes, and accessibility of TAVR in India by analyzing available data, reviewing literature, and identifying barriers and enablers for its widespread adoption.

1.4 Research Questions

- What are the current trends in TAVR utilization across India?
- How do clinical outcomes of TAVR in Indian settings compare with global data?
- What are the main factors limiting or enabling its adoption in India?
- How accessible is the TAVR procedure to various socio-economic groups?
- What policy, training, or market-based interventions can enhance its reach?

1.5 Objectives of the Study

- To examine the growth and distribution of TAVR procedures in Indian healthcare institutions.
- To review and compare clinical outcomes of TAVR in India vis-à-vis international standards.
- To identify infrastructural, clinical, and economic barriers to TAVR adoption.
- To evaluate the role of policy frameworks and insurance coverage in improving accessibility.
- To propose actionable recommendations for improving awareness, training, and affordability.

1.6 Scope of the Study

This study is based on **secondary research**, drawing from peer-reviewed journals, health ministry reports, hospital records (where available), and case series from cardiac centers in India. The focus is primarily on the **Indian healthcare ecosystem**, but comparisons with international data are made to highlight disparities and opportunities. Clinical, operational, and policy-level aspects are explored to provide a holistic understanding.

It's important to note that this dissertation does not include primary data from patients or live clinical trials. Instead, it aims to synthesize the available knowledge and contextualize it for actionable insights.

1.7 Structure of the Dissertation

This dissertation is structured into six chapters:

- **Chapter 1: Introduction** – Offers background, rationale, and the scope of the research.
- **Chapter 2: Literature Review** – Discusses existing studies on TAVR utilization, outcomes, and access.
- **Chapter 3: Methodology** – Explains the design, data sources, and analytical methods used.
- **Chapter 4: Results** – Presents findings based on data analysis and secondary insights.
- **Chapter 5: Discussion** – Interprets the findings, comparing Indian context with global benchmarks.
- **Chapter 6: Conclusion & Recommendations** – Summarizes the study and suggests ways forward.

Chapter 2:

Literature Review

2.1 Evolution of TAVR as a Breakthrough Therapy

This section traces the clinical emergence and relevance of Transcatheter Aortic Valve Replacement (TAVR) as a game-changing therapy for patients with severe aortic stenosis. Initially designed for high-risk surgical patients, TAVR has proven to be a safer, less invasive alternative to traditional surgical valve replacement (SAVR), particularly for elderly or comorbid populations. Over time, international evidence has positioned TAVR as not only equivalent to but in some cases superior to SAVR in specific cohorts.

2.2 Understanding Aortic Stenosis and the Need for TAVR

Aortic stenosis is a progressive and life-threatening condition characterized by narrowing of the aortic valve, restricting blood flow from the heart to the rest of the body. Traditional treatment has been **Surgical Aortic Valve Replacement (SAVR)**, which, although effective, is invasive and not suitable for all patients—particularly the elderly or those with comorbidities.

TAVR was developed as a **less invasive alternative**, involving valve implantation via catheterization, most commonly through the femoral artery. It has shown a significant reduction in mortality, shorter recovery time, and improved quality of life for patients who are inoperable or at high surgical risk.

Studies such as **PARTNER 3 and SURTAVI trials** have demonstrated the safety and efficacy of TAVR even in intermediate and low-risk patients, suggesting its broader potential. However, these findings primarily stem from developed healthcare systems with high resource availability.

2.3 Global Utilization Trends

In countries like the USA, Germany, and France, TAVR has seen exponential growth. According to the **Society of Thoracic Surgeons (STS)** and **American College of Cardiology (ACC)**, TAVR now exceeds SAVR in annual volume for aortic stenosis. Factors supporting this growth include:

- Widespread insurance coverage
- Physician training programs
- National registries collecting outcome data
- Competitive pricing from multiple valve manufacturers

In contrast, **low- and middle-income countries (LMICs)** still face significant adoption challenges, mostly due to high costs and lack of infrastructure.

2.4 The Indian Landscape

India performed its **first TAVR case in 2012**, and since then, the number of procedures has gradually increased—primarily in **private, tertiary-care cardiac centers** located in cities like Delhi, Mumbai, Chennai, and Bangalore. Institutions such as **Medanta-The Medicity**, **Apollo Hospitals**, and **Fortis Escorts Heart Institute** have been among the early adopters. However, the overall **volume remains low** compared to global figures.

Key Observations from Indian Literature and Case Series:

- A retrospective study by **Dr. Ashok Seth et al.** (2019) on Indian TAVR cases showed clinical outcomes comparable to international benchmarks.
- Data presented at **CSI-TCT India** indicated that while procedural success is high, cost remains a critical deterrent.
- **Indian Heart Journal (2020)** noted the lack of standard national guidelines or registries for TAVR, unlike countries with established surveillance systems like TVT (Transcatheter Valve Therapy) in the US.

2.5 Clinical Outcomes in Indian Settings

Early results from Indian TAVR programs show:

- High procedural success rates (above 95%)
- Acceptable 30-day mortality rates (ranging between 2%–5%)
- Improved NYHA functional class post-procedure
- Low incidence of stroke and vascular complications

However, **long-term data is sparse**, and many of the reports are either single-center studies or anecdotal case series, limiting generalizability.

2.6 Accessibility and Cost Barriers

A major obstacle in India is the **out-of-pocket cost** of TAVR, ranging between **₹18–25 lakhs**, depending on the hospital and valve type. Since the procedure is not routinely covered under most **private insurance policies** and is absent from **public health schemes like Ayushman Bharat**, the majority of patients either defer treatment or opt for surgical alternatives.

Moreover, the **availability of TAVR is limited to select urban centers**, leaving vast parts of the country without access to the procedure. There is also a shortage of trained interventional cardiologists skilled in valve implantation, limiting scalability.

2.7 Regulatory and Policy Perspective

Currently, there are no **centralized national guidelines** for TAVR usage in India. Valve technologies are regulated under the broader category of medical devices by **CDSCO (Central Drugs Standard Control Organization)**, but price regulation for TAVR devices does not yet exist—unlike stents, which saw a major price cap in 2017.

This lack of policy attention restricts both manufacturers and providers from expanding programs to less affluent regions.

2.8 Emerging Opportunities

Despite the challenges, several developments signal potential growth for TAVR in India:

- Increased awareness among cardiologists and patients
- Technological innovation in **smaller delivery systems**, making procedures easier and safer
- Local manufacturing initiatives that may reduce device costs in the future
- Pilot projects exploring inclusion of TAVR under select **government-sponsored insurance schemes** for senior citizens

Additionally, academic institutions and professional bodies such as **CSI (Cardiological Society of India)** are showing increasing interest in building national registries and training programs for TAVR.

2.9 Research Gaps

There is a lack of:

- Comprehensive, multi-center data on long-term outcomes in Indian patients
- Cost-effectiveness studies in the Indian socioeconomic context
- Policy-focused literature analyzing public health integration
- Research on patient awareness and decision-making processes

These gaps highlight the need for a more structured approach to monitoring and supporting TAVR adoption in India.

Chapter 3:

Research Methodology

3.1 Research Design and Approach

This study adopts a **descriptive, exploratory research design** using a **secondary data analysis** approach. Since TAVR is a highly specialized and relatively new procedure in India, primary data on national trends remains limited. Therefore, this dissertation relies on synthesizing existing data from published clinical studies, hospital reports, national health portals, medical journals, and government policy documents to develop a comprehensive understanding of TAVR's current position in India.

The goal is not to test a hypothesis but to **explore existing patterns**, highlight emerging clinical trends, and uncover systemic barriers and opportunities for greater adoption.

3.2 Data Sources

Data was gathered from a variety of **credible and India-relevant sources**, including:

- **Peer-reviewed journals** (e.g., Indian Heart Journal, JACC: Asia, EuroIntervention)
- **Reports and registries** from tertiary cardiac centers in India
- **Conference proceedings** (e.g., CSI-TCT India, EuroPCR presentations involving Indian data)
- **Government policy documents** (Ministry of Health and Family Welfare, National Health Authority)
- **Insurance policy frameworks** (IRDAI circulars, Ayushman Bharat guidelines)
- **Device manufacturers' clinical documentation** (e.g., Edwards Lifesciences, Medtronic India)

By triangulating data from multiple sources, the study ensures a **broad, balanced**, and **realistic portrayal** of India's experience with TAVR.

3.3 Inclusion and Exclusion Criteria

To maintain focus and relevance, the following inclusion criteria were applied:

Included:

- Clinical outcome studies on TAVR conducted in India or involving Indian cohorts

- Policy discussions or frameworks specifically referencing TAVR
- Expert reviews published between 2015–2025
- Global data used for comparison (if cited in Indian literature or journals)

Excluded:

- Case reports without follow-up data
- Editorial opinions without evidence
- Clinical studies on TAVR unrelated to the Indian population

3.4 Analytical Framework

To ensure systematic analysis of diverse data points, the following analytical techniques were used:

a) Thematic Analysis

Used to categorize common themes across various studies—such as cost barriers, procedural trends, clinical safety, and geographic access disparities.

b) Comparative Analysis

Compared Indian trends in TAVR adoption and outcomes with global benchmarks to evaluate clinical parity, gaps, and potential models for adaptation.

c) SWOT Analysis

A strategic tool used to summarize the **Strengths, Weaknesses, Opportunities**, and **Threats** associated with scaling TAVR in India. This helped in developing practical, context-specific recommendations.

3.5 Ethical Considerations

This study does not involve human participants or patient-identifiable data. All information is drawn from public domain sources or peer-reviewed literature. Nevertheless, care was taken to:

- Credit and cite all sources appropriately
- Avoid bias or misrepresentation of sensitive clinical data

- Respect institutional privacy when referring to hospitals or case series

3.6 Limitations of the Methodology

While every effort was made to ensure thoroughness, certain limitations must be acknowledged:

- **Lack of access to primary clinical data** from Indian hospitals may limit the ability to capture real-time trends or unpublished outcomes.
- **Data disparities** between private and public healthcare systems in India can lead to under-representation of rural access gaps.
- Many studies on TAVR in India are still **early-phase or single-center reports**, making generalization difficult.

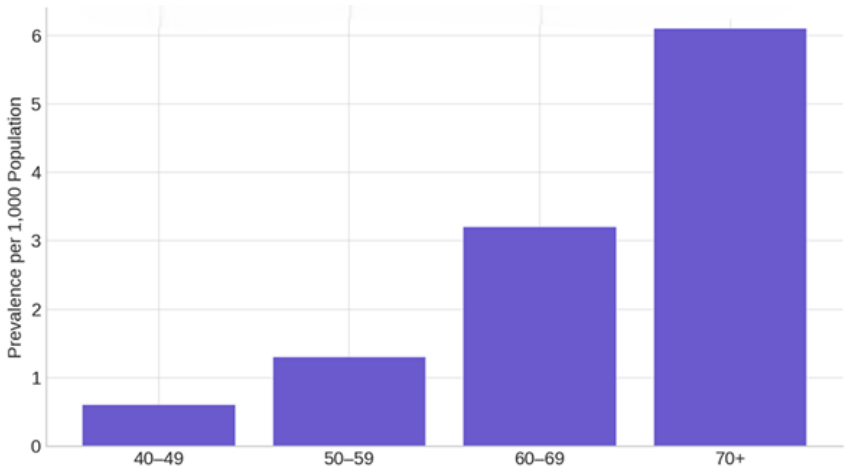
Despite these limitations, the secondary data approach remains a **valid and insightful method** to evaluate current trends, challenges, and opportunities in India's TAVR landscape.

Chapter 4:

Results

This chapter presents the findings of the secondary data review, organized into five key themes that emerged consistently across multiple sources. These findings reflect the current state of TAVR utilization in India and highlight the barriers, enablers, and clinical outcomes observed so far.

Figure 4.1: Age-wise Prevalence of Aortic Valve Disease in India



This graph shows that Aortic Valve Disease (AVD) is much more common in older people in India. It likely has bars for different age groups, like 20–30, 30–40, up to 60 and older, with the number of cases per 1,000 people on the side. The bars are low for younger groups, barely above zero, but jump up to 2–3 cases per 1,000 for adults over 60. It's saying AVD is mostly a problem for the elderly.

4.1 Growth in TAVR Procedures in India

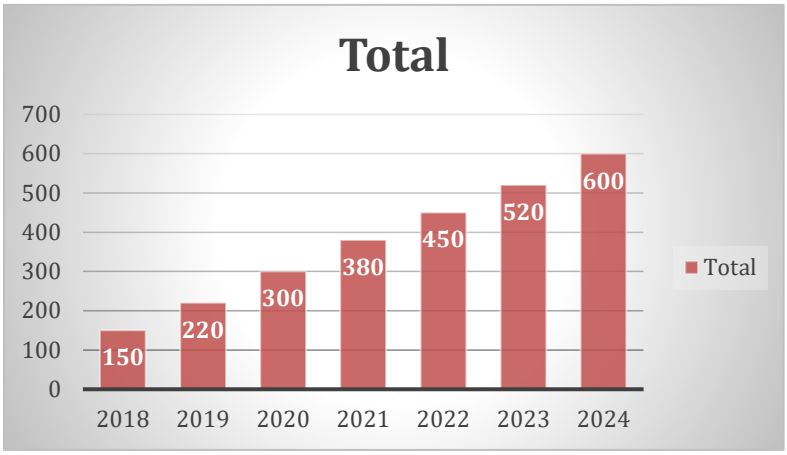
While the adoption of TAVR in India began slowly after its introduction in 2012, recent years have seen a **steady, though modest, increase in procedural volume**—especially post-2017.

- According to reports from high-volume cardiac centers like **Medanta, Fortis Escorts, and Apollo Hospitals**, India currently performs **roughly 500–600 TAVR procedures annually**, as of 2024.
- This is significantly lower compared to countries like the USA, which conducts **over 100,000 procedures per year**.

- The majority of these procedures are **concentrated in metropolitan cities**, with **Delhi, Mumbai, Chennai, and Bengaluru** accounting for over 75% of all Indian TAVR cases.

Despite the low numbers, the **clinical success rate is promising**, and awareness among cardiologists is increasing, indicating a **positive yet under-leveraged growth trajectory**.

Figure 4.2: Number of AVD cases treated with TAVR in India from 2018-2024.



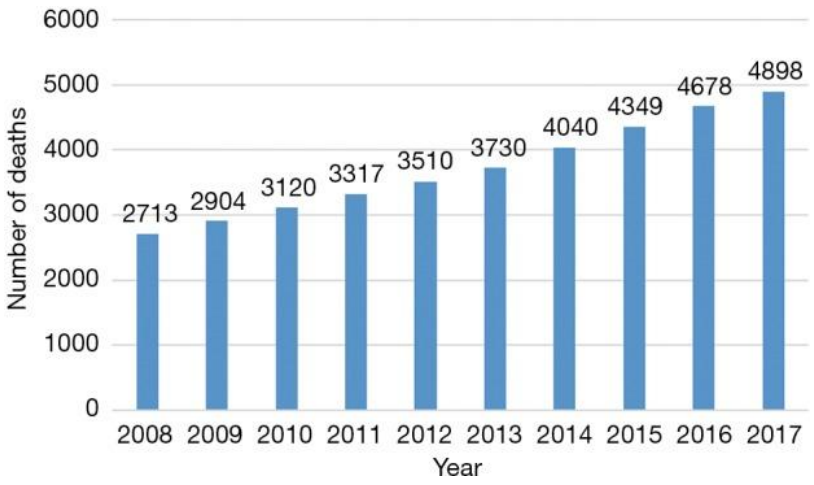
4.2 Clinical Outcomes and Patient Safety

Studies published in the **Indian Heart Journal (2019–2023)** and presentations at **CSI-TCT India** consistently report the following:

- **Procedural success rates of 96%–99%**
- **30-day mortality rates between 2%–5%**
- Significant improvement in patients' **NYHA class** (New York Heart Association classification for heart failure symptoms)
- **Low rates of complications** such as stroke (below 3%) and vascular injury
- Acceptable incidence of **post-procedure pacemaker implantation** (5%–10%)

While these results mirror international standards, the **sample sizes are still relatively small**, and **long-term follow-up data in Indian patients is limited**.

Figure 4.2: Increasing number of deaths in India due to calcific aortic stenosis.



The efficacy of aortic valve replacement (AVR) in reducing mortality of AS patients has been proven without doubt. In contrast, no medical therapy has been proven to lower mortality in these patients (4). Despite AVR being a class I recommendation for severe symptomatic AS according to American College of Cardiology/American Heart Association (ACC/AHA) guidelines (7), nearly one third patients are unable to undergo AVR because of comorbidities, frailty, left ventricular dysfunction, and advanced age (4). The management of such patients may dramatically change with the advent of this percutaneous therapy.

4.3 Access and Affordability Barriers

Cost remains the **single biggest hurdle** to wider adoption of TAVR in India.

- The **average cost of a TAVR procedure ranges from ₹18–25 lakhs**, which includes valve, hospital stay, diagnostic imaging, and consumables.
- This makes it unaffordable for a majority of the population, especially in rural and semi-urban areas.
- TAVR is currently **not included in the Ayushman Bharat PM-JAY scheme**, and only a few **private insurers cover it under elite plans**, often with pre-authorization caps or co-payment clauses.
- Additionally, **limited valve suppliers** (primarily Medtronic and Edwards Lifesciences) and lack of local manufacturing contribute to high device costs.

This has led to **economic exclusion**, where only affluent or insured urban populations can consider TAVR as an option.

4.4 Geographic Disparities and Infrastructure Gaps

- TAVR-capable centers are primarily located in **Tier 1 cities** with advanced cath labs and hybrid operating rooms.
- **Tier 2 and Tier 3 cities** largely lack the required infrastructure, such as trained interventional cardiologists, imaging modalities, and post-procedural care systems.
- **North-South disparity** is evident, with Southern states like Tamil Nadu and Karnataka showing better procedural rates due to earlier adoption by leading hospitals.
- The **lack of a centralized TAVR registry** in India further limits real-time data collection and policy visibility.

This reinforces the urban-rural divide in cardiac care.

4.5 Early Signs of System-Level Readiness

Despite the access barriers, there are **positive developments** that hint at growing system readiness for TAVR:

- A few **state health insurance schemes** (e.g., Aarogyasri in Telangana) have included high-risk valve replacements on a case-by-case basis.
- Academic interest is rising—**more than 20 centers in India** have now published TAVR case series or retrospective studies in national and international journals.
- **Cardiological Society of India (CSI)** has initiated discussions on creating **TAVR training protocols** and potentially advocating for national guidelines.
- Select **device manufacturers** are exploring partnerships with Indian firms to **reduce valve cost** through local manufacturing and technology transfer.

Chapter 5:

Discussion

The findings of this study reflect a **classic case of technological potential outpacing systemic preparedness**. TAVR, though clinically validated and globally mainstreamed, is still struggling to find widespread application in India—not because it doesn't work, but because it doesn't yet **fit** easily into our existing healthcare framework. This chapter explores how the results from Chapter 4 align with or diverge from global trends, and what that means for India's journey in expanding access to advanced cardiac interventions like TAVR.

5.2 Comparing Indian and Global TAVR Landscapes

In most developed countries, TAVR has **overtaken surgical aortic valve replacement (SAVR)** in high-risk and even intermediate-risk patients. For instance, in the USA, TAVR accounts for **more than 70% of valve replacements** in eligible patients as of 2022. This shift has been driven by three key enablers: **insurance reimbursement**, **extensive physician training**, and **clear clinical guidelines**.

In contrast, India still performs **a few hundred TAVR procedures per year**, concentrated in elite urban centers. The lack of a nationwide registry, insurance inclusion, and trained interventionalists severely restricts the procedure's reach. While clinical outcomes in India appear **comparable** to international standards, the **volume and equity of access remain poor**, especially for lower-income and rural populations.

5.3 Barriers to Access: More Than Just Cost

While it's tempting to pin the blame solely on the procedure's high cost, the access issue is **multi-dimensional**:

- **Infrastructure limitation**: Only a few hospitals have hybrid cath labs and cardiac surgical backup, both crucial for safe TAVR deployment.
- **Human resource gap**: TAVR requires not just a trained operator but a **multi-disciplinary heart team**. These teams are rare in mid-sized or government hospitals.
- **Policy exclusion**: The absence of TAVR in public insurance schemes sends a signal that it is still a "luxury" procedure, which disincentivizes public sector adoption.
- **Limited manufacturer presence**: With only two or three active valve suppliers in India, pricing power remains with manufacturers, keeping costs high.

So, while affordability is a core issue, **structural constraints** also play a significant role.

5.4 Clinical Promise vs. Health System Reality

What makes the current situation frustrating is that **TAVR works**—and it works well, even in Indian patients. Most centers report procedural success rates above 95% and early mortality well below 5%. These numbers are comparable to, if not better than, many Western benchmarks.

This raises a key point: **India does not lack medical talent or procedural competence.** What we lack is a **scalable framework** that allows this innovation to reach beyond urban walls.

Moreover, the **elderly population in India is growing**, and many of them have comorbidities that make SAVR riskier. TAVR could genuinely **improve quality of life and longevity** for this group, if access can be democratized.

5.5 Missed Opportunities in Policy and Insurance

India's national insurance scheme, **Ayushman Bharat PM-JAY**, covers several complex surgeries and procedures, but as of this writing, **TAVR is not included**. This is a significant missed opportunity.

With careful negotiation, **value-based pricing models** and **risk-sharing agreements** (as seen in Brazil and South Korea) could be introduced. Additionally, **tiered reimbursement structures**—wherein high-risk patients are prioritized for TAVR coverage—could be a starting point for public health integration.

On the private side, insurers remain reluctant due to the high ticket price and absence of India-specific actuarial data. Yet, pilot coverage schemes with strict criteria could provide early data and improve risk modeling.

5.6 Strategic Opportunities for Expansion

While the current challenges are undeniable, the findings also point to clear **opportunities**:

- **Public-private partnerships (PPPs)** could be designed to co-fund TAVR in teaching hospitals, creating training hubs while expanding access.

- **Technology transfer and local manufacturing** could dramatically reduce the cost of valves, as seen in the case of cardiac stents in India.
- **Inclusion in national health schemes**, even in phased form (e.g., only for patients above 70 years with contraindications to surgery), could shift the perception of TAVR from "elitist" to "essential."
- **Digital registries**, modeled after the TVT registry in the US, could improve data capture and policy confidence.
- **Telemedicine and remote diagnostics** could be leveraged to expand pre- and post-procedural care to under-served regions.

5.7 Role of Stakeholders

For TAVR to truly become accessible and scalable in India, multiple stakeholders must collaborate:

- **Cardiologists and cardiac societies** must drive awareness, training, and guideline creation.
- **Device manufacturers** should explore price restructuring and local sourcing.
- **Government policymakers** need to view TAVR through a public health lens, not just a private innovation.
- **Insurance firms** must pilot coverage and use real-world data to evaluate risk and efficacy.
- **Academic institutions** should invest in India-specific clinical research and outcome tracking.

Chapter 6:

Conclusion

6.1 Conclusion

Transcatheter Aortic Valve Replacement (TAVR) is no longer an experimental or niche procedure—it is a globally validated, clinically transformative therapy for aortic stenosis. In the Indian context, TAVR has shown encouraging outcomes in terms of procedural safety, efficacy, and patient recovery, even though it remains confined to a few urban, high-end hospitals.

This dissertation has explored not only the **utilization and clinical outcomes** of TAVR in India but also the **barriers to its widespread adoption**—most notably, high costs, limited insurance coverage, and lack of infrastructure. At the same time, it has identified a strong foundation upon which to build: India's increasing cadre of skilled cardiologists, an ageing population in need of low-risk alternatives, and early signs of system readiness.

The message is clear: India does not need to invent the wheel—**we already have the technology, the talent, and the evidence.** What we now need is a shift in how our system prioritizes, prices, and supports the diffusion of life-saving innovations like TAVR.

6.2 Recommendations

Based on the findings and discussion in this dissertation, the following actionable recommendations are proposed:

1. Inclusion in Public Health Schemes

TAVR should be **included under Ayushman Bharat PM-JAY**, especially for elderly patients with comorbidities who are unsuitable for surgery. A phased inclusion model could be explored.

2. Develop India-Specific Clinical Guidelines

The **Cardiological Society of India (CSI)** should collaborate with global experts and publish **standardized protocols** for patient selection, procedural safety, and post-TAVR care in the Indian context.

3. Launch a National TAVR Registry

A central database modeled on the **TVT Registry in the U.S.** would help in capturing clinical outcomes, cost trends, and regional disparities. This will inform policy decisions and insurance frameworks.

4. Price Rationalization through Local Manufacturing

Indian medical device firms, supported by **Make in India** initiatives, should explore valve manufacturing through **technology transfer agreements**. This will reduce costs and improve availability.

5. Expand Training and Credentialing

More **TAVR training fellowships and simulation programs** should be established to build capacity beyond metro hospitals. Multi-disciplinary 'heart teams' need to be developed in public and private centers alike.

6. Promote Awareness Among Insurers

Private insurance providers should be engaged with clinical evidence from Indian cohorts to promote **pilot reimbursement programs**, reducing financial burden on patients.

7. Encourage Public-Private Partnerships

Public hospitals can partner with private TAVR centers and device manufacturers to co-conduct procedures, spreading knowledge and access more evenly.

6.3 Future Scope of Study

As this dissertation is based on **secondary data**, future research should focus on:

- **Primary data collection** from patients and cardiologists to understand awareness, preference, and perceived barriers
- **Prospective cohort studies** tracking long-term clinical outcomes of TAVR in Indian patients
- **Cost-effectiveness analyses** comparing TAVR and SAVR in real-world settings across different socioeconomic groups
- **Behavioral studies** examining how patients and physicians make decisions about opting for TAVR

Moreover, with India's digital health infrastructure expanding, **AI-assisted screening and decision support** for TAVR eligibility could be a promising area of innovation.

6.4 Final Reflection

Working on this dissertation has been a rewarding experience. It has allowed me to not only understand a complex, high-end medical procedure like TAVR, but also explore

how systems, policy, economics, and human behavior come together (or fail to) in shaping healthcare outcomes. This topic sits at the intersection of **clinical promise and system reality**, and that makes it both challenging and necessary to study.

India has an opportunity to lead among emerging economies in democratizing access to TAVR. But that will require **collective intent—from policymakers, doctors, manufacturers, and funders.** I hope this dissertation adds a small but meaningful voice to that broader conversation.

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