

Beyond the valve: Lessons learned and future directions for trans-catheter aortic valve replacement in resource-constrained settings

Abstract

In light of growing cases of aortic stenosis and aortic regurgitation secondary to degenerative calcific aortic valve disease from increasing population aging, the burden of valvular heart disease is only increasing. Third-world countries still need to catch up to modern practices and continue to perform surgical aortic valve replacement in high-risk patients. Current guidelines backed by significant research recommend Trans-Catheter Aortic Valve Replacement (TAVR) in high-risk patients. However, resource-constrained countries struggle to keep up with the cost and training requirements. This mini-review sheds light on the barriers to TAVR in third-world countries and provides future recommendations to optimize its integration into standard care.

Keywords: Aortic stenosis • Population • Smoking • Hypercholesterolemia

Introduction

Valvular Heart Diseases (VHD) such as aortic stenosis or regurgitation are on the rise due to increasing elderly populations and increased urbanization, leading to previously unexposed populations being exposed to risk factors such as smoking and hypercholesterolemia. Better imaging techniques have allowed more cases to be diagnosed early and the improved life expectancies allow more time for the disorders to become symptomatic. Severe aortic stenosis or regurgitation, usually caused by calcific degenerative disease or rheumatic fever, warrant treatment using Trans-catheter Aortic Valve Replacement/Implantation (TAVR/TAVI) or Surgical Aortic Valve Replacement (SAVR) [1]. A previous review in Pakistan contextualized the trends that led to the increasing burden of VHD and shed light on future indications regarding interventional and surgical approaches to replace aortic valves after symptoms develop. In countries where the procedure has not been introduced or the uptake has been minimal, high-risk patients are the stepping stone for introducing TAVI into standard care [2]. This review discusses indications in a broader demographic and key insights into TAVI uptake worldwide, with third-world countries in particular.

Literature Review

Key insights and findings

The previous review highlighted important guideline-changing findings for high-risk patients from The PARTNER trial, comparing TAVI and SAVR in high-risk patients with severe aortic stenosis, showing that TAVI was superior to SAVR when a first-generation self-expandable trans-catheter heart valve was used [3]. The results showed that in a carefully selected, high-risk subgroup of patients with aortic stenosis, trans-catheter replacement is a viable alternative to surgical replacement [4]. However, there is a lack of data regarding the durability of TAVI beyond 5 years, which implies that

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SAVR still has a role in treating young, symptomatic patients with extended life expectancies (under 65, as defined by current guidelines). The most predominant option for individuals with severe aortic stenosis at the moment is TAVI, which has been an innovative advancement in cardiovascular medicine. With minimal risk, quick recovery and encouraging long-term results, TAVI is a safe and reliable procedure. Most patients have benefited from its proven effectiveness across a range of surgical risk categories. There is much room for continuous improvement as TAVI use grows, thanks to technological advances, increasing amounts of high-quality evidence and increased experience among physicians and surgeons [5]. We found that Pakistan could increasingly benefit in long-term survival and quality of life on the back of these recent findings and that further effort in Asia and other risk factor-laden nations could be a lifesaver for many inoperable patients and for whom SAVR is too dangerous to be attempted, providing guided disease-specific intervention a step further from symptomatic treatment from medicine alone. However, the lack of trained interventional cardiologists and dedicated institutes, as well as a massive population to cater to, means that many patients are unable to receive the treatment they require. Furthermore, the percentage of the Gross Domestic Product allocated to healthcare is less than the World Health Organization recommendation, meaning these procedures would have to be paid for by the patients themselves. This financial burden is particularly heavy given the already high poverty rates, further limiting treatment access.

Comparative analysis

Asia and the Middle East: The quick growth of TAVI clinics in Asia is partly due to demographics. One of the most impacted groups that has TAVI procedures more frequently is the elderly, typically those over 65. Because of its older population, Japan has the highest incidence of aortic stenosis, followed by Hong Kong, South Korea, Taiwan, Singapore and China. In 2013, this therapy received commercial approval in Japan and patients received compensation for the expenditures associated with TAVI. This growth is not the case in most other Asian Pacific nations, though, where more significant out-of-pocket costs brought on by a lack of medical reimbursements may make it less accessible. TAVI is anticipated to cost roughly USD 35,000 in India and up to USD 47,000 in Thailand [6]. In underdeveloped nations, the economic and cost implications of TAVI are different. State health programs in nations like India cannot pay for a costly operation like TAVI. According to corporate data showing an increase in implant sales, TAVI is developing gradually in India despite all cost-related obstacles. In the past year, TAVIs have been performed in 39 centres nationwide (North India-7, East India-2, West India-10 and South India-20 Centers) [7]. In Turkey, considerable progress has been made in device technology, proper patient and valve selection, procedural technique and post-procedural treatment [8].

Discussion

South America

South American health systems have to face several challenges related to system/country characteristics, which could impair the outcomes of high-tech procedures. A recent systematic review and meta-analysis of real-world data revealed that short-term outcomes of TAVI in South America appeared worse than those in developed countries. A follow-up systematic review and meta-analysis revealed that in-hospital and 30-day death rates in South America have been declining gradually from 2011 to 2019 across a wide range of cohorts of patients with trans-catheter valves. Furthermore, this positive outcome persisted even after statistical adjustment for age and surgical risk, indicating that shifts in the demographics of the population did not bring it on. Nevertheless, according to national agencies in Argentina and Brazil, TAVI is not cost-effective [9].

Africa

Given that structural heart disease is more common in Sub-Saharan Africa than ischemic heart disease, percutaneous valve therapy might be utilized more in the future. Adoption of TAVI in Sub-Saharan Africa should be done cautiously, considering the current lack of long-term data on trans-catheter heart valves, the scarcity of skilled cardiac surgeons in the region and the high death rate linked to TAVI-SAVR even in skilled hands [10]. Even after more than ten years of TAVI in South Africa, strong funder resistance still makes it challenging to treat patients with aortic stenosis. South Africa's TAVI programme shows clear benefits to patients with aortic stenosis and the growing programme's high operative success and increased life expectancy in patients, as evidenced by local statistics, may be utilized to enhance access to treatment in the face of financial constraints [11].

Practical implications and future recommendations

TAVI is a revolutionary, less-invasive treatment for high-risk individuals with severe Aortic Stenosis. Even though TAVI has shown remarkable clinical improvement, many obstacles remain to overcome and prospects for the future [12]. However, challenges are linked to access to material, infrastructure, costs and physicians qualified for specific surgeries. The anticipated cost of the surgical valve is one-sixth that of a TAVI valve. The lack of doctors and specialists may present challenges in resource-limited areas of the world. Additionally, the strain in these areas is increased by migrating qualified medical professionals to better-developed nations. Despite having a sizable patient base, TAVI adoption in Asia has been slow, indicating a need for greater education and awareness in this area. Therefore, substantial strategies are required for the future implementation of TAVI. Increasing awareness and implementing nationwide education programs among

general populations and healthcare professionals to support its acceptance [13]. Governments should develop funding initiatives and encourage TAVI to be incorporated into National Health initiatives or Insurance Programs to make this procedure more affordable. The basis for integrating future TAVI practitioners and sites includes formal sponsor-required and society-based training programs such as hands-on exposure to TAVI equipment, simulation training, didactic sessions, imaging workshops and case presentations. Mobile cardiac screening units in rural areas should be developed to ensure that only high-risk patients are referred to specialized clinics in cities. Heart teams should include cardiothoracic surgeons, interventional cardiologists, structural heart disease experts and imaging specialists. The procedure necessitates sufficient infrastructure, which includes heart valve clinics, effective and speedy ECG and CT scan services, hybrid operating rooms and cath labs. Increased collaboration with developed nations' interventional cardiologists and cardiac surgeons for mentorship and training is necessary to introduce the latest practices and encourage domestic production of TAVI devices to lessen reliance on imports, reducing the strain on under-resourced healthcare systems.

Challenges and solutions

The challenge during the literature review was the need for a centralized disease database for valvular heart diseases similar to vast resources such as the Centre for Disease Control (CDC) in America and the European Centre for Disease Prevention and Control (ECDC). The only available Cardiac Registry, The Cardiac Registry of Pakistan (CROP) primarily focuses on Heart Failure, cardiac devices and acute coronary syndrome data [14]. Cardiovascular diseases are not covered comprehensively in regular surveys and estimates are based on sparse, outdated data. Pakistan currently lacks a national strategy to monitor, prevent and manage cardiovascular diseases in both rural and urban populations [15]. Tracking of death rates and post-surgical or interventional outcomes was scarce and to counter this methodological concern, most data was extracted from studies done elsewhere in the world. There is no data specific to TAVI in Pakistan and the outcomes in high-risk patients are merely estimations. Therefore, a central premise of the study was to call for clinical trials in the country and allocate resources to do so. Reliable news outlets reporting pilot TAVI trials were referred to. Data from the number of training programmes gave us insight into how many qualified physicians and interventionists who were up to par with the recommended skills required for TAVI were being trained. The state of affairs in already established programmes and the tremendous backlog observed provided valuable insights into the dire situation demanding human and technological resources. Foreign support is playing a non-negotiable role and current workshops are being conducted by foreign support, allowing training and procedures

to be started, especially in institutions like the flagship National Institute of Cardiovascular Diseases (NICVD) in Karachi, the largest and most important government-run dedicated Cardiovascular Institute in the country [16]. Better monitoring would allow for more precise indications for introducing this monumental trans-catheter procedure and put it on a pedestal in the eyes of the health regulatory authorities in all countries suffering from increased loads of patients with VHD.

Conclusion

This mini-review aimed to highlight more countries suffering from the same VHD burden to provide insight into the requirement and current progress of TAVI integration in countries that increasingly require it. Further research from individual countries not dependent on the US or Europe would make the field of interventional cardiology more self-sufficient and allow them to advocate the cause more passionately in government entities and health registries concerned, who are more likely to allocate funds to programmes. Dedicated program directors with a drive for improved patient outcomes and quality of life must spearhead the task to counter the logistical concerns. Old practices continue due to the monopoly of surgical boards in old and well-settled heart programs and there needs to be more regard for continuous medical education. Training cardiologists and a smooth supply chain of valve products and equipment in all VHD-burdened countries, backed by international support at first, could be the difference between safer life-prolonging intervention and complex, contraindicated surgery.

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