Editorial

Interventional Cardiology

A case for sutureless valve devices in the arena of aortic valve replacement

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Received date: 18-Apr-2025, Manuscript No. FMIC-25-164633; Editor assigned: 21-Apr-2025, PreQC No. FMIC-25-164633 (PQ); Reviewed date: 12-May-2025, QC No. FMIC-25-164633; Revised date: 19-May-2025, Manuscript No. FMIC-25-164633 (R); Published date: 26-May-2025, DOI: 10.37532/1755-5310.2025.17(1).970

Description

Sutureless Aortic Valve Replacement (SuAVR) has emerged as a surgical alternative with the potential to reduce operative times and facilitate minimally invasive procedures. However, despite its theoretical benefits-including reduced cross-clamp and cardiopulmonary bypass times, and ease of implantation-the adoption of SuAVR has been surprisingly limited [1]. This limited uptake reflects widespread skepticism within the surgical community, primarily due to inconsistent data on long-term outcomes, questions about cost-effectiveness, and a perception that the marginal operative time savings do not justify a significant shift in surgical practice.

The key purported advantage of SuAVR lies in its ability to simplify valve implantation, potentially decreasing operative times. However, in real-world surgical practice, many experienced surgeons are able to implant a conventional sutured prosthetic valve in about 20 minutes more than it takes to implant a sutureless valve. Consequently, the marginal reduction in cross-clamp time is not considered compelling enough to justify the higher cost of the device. This cost-benefit imbalance has been a major barrier to widespread adoption.

We performed a bibliometric analysis showing a geographic delocalization in the adoption of SuAVR and demonstrating that the use of this technology is confined to a relatively small number of centers and surgeons, typically those with a focused interest in Minimally Invasive Cardiac Surgery (MICS). Among 538 analyzed studies, 80% originated from Europe, with Italy and Germany alone accounting for nearly half. By contrast, North America and Asia contributed relatively little to the scientific literature on SuAVR. Furthermore, the majority of SuAVR-related publications were produced by academic centers with established MICS programs. This aligns with findings by Concistre, et al. which show that SuAVR is most frequently employed in the context of MICS, where its ease of use offers tangible technical benefits [2]. In these procedures, where access is restricted and placing annular sutures is more technically demanding, SuAVR provides a practical solution that can significantly streamline the operative workflow.

Another major limitation of SuAVR lies in its learning curve. Early experiences with the device were marked by technical missteps such as valve undersizing or oversizing, which led to suboptimal outcomes and reinforced skepticism among surgeons. This learning curve is well described by Murzi, et al. who highlighted the challenges and pitfalls encountered during initial adoption [3]. These early results significantly impacted surgeon confidence and contributed to the slow diffusion of the technology. However, the newest generations of the sutureless devices and the cumulated experience have reduced these issues and a recent large multicentric registry has shown impressive results with this technology [2].

Another important consideration regards the role of SuAVR in the competition with transcatheter aortic valve replacement (TAVR), which has rapidly expanded its indications and currently dominates the landscape of aortic valve intervention. The widespread adoption of TAVR-even in younger and lower-risk patients—has put pressure on surgical approaches to remain relevant and competitive. Yet emerging data suggest that the long-term outcomes of TAVR in low-risk cohorts are questionable, making the case for robust surgical alternatives more urgent [4-7]. Even more, data suggesting a higher incidence of valve degeneration, thrombosis, and re-intervention within this population further strenghtens this idea [8].

In this context, MICS might be considered a more adequate comparator for TAVR, and SuAVR offers a unique opportunity in this field. It represents the only currently available surgical technology that facilitates a minimally invasive approach with implantation characteristics that mirror those of TAVR. Indeed, several comparative studies and meta-analyses have shown that SuAVR may offer favorable outcomes compared to TAVR, particularly with respect to paravalvular leak and pacemaker implantation rates [1,9]. These findings support the concept that minimally invasive surgery SuAVR could serve as the surgical counterpart to TAVR, especially in younger or intermediate-risk patients for whom valve durability and the possibility of future re-interventions are critical.

The development of robotic-assisted cardiac surgery may also expand the applicability of SuAVR in the minimally invasive landscape. This technique is very similar to the MICS right anterior thoracotomy approach, while utilizing multiple small incisions and a 4-port surgical robot. Robotic surgery offers advantages over more traditional MICS techniques due to the precise tissue handling ability and ability to properly position the valve using even smaller access points [10].

Beyond low-risk patients, several clinical scenarios make SuAVR (via MICS or standard approach) an attractive option, particularly when the decision between conventional SAVR or TAVR remains in the grey zone [1].

Elderly and frail patients who are not ideal candidates for SAVR due to frailty may benefit significantly from SuAVR. The reduced cross-clamp and CPB times associated with SuAVR make the procedure more easily physiologically tolerable for elderly or otherwise frail patients. Additionally, elderly patients are particularly vulnerable to hospital-associated complications, such as delirium, functional decline, and nosocomial infections, making the shorter hospitalization associated with SuAVR more advantageous [11,12].

Patients with a small aortic annulus represent another ideal cohort. These patients are at risk for patient-prosthesis mismatch (PPM), which can negatively impact postoperative hemodynamics and long-term outcomes. Sutureless valves typically offer a larger effective orifice area compared to traditional sutured surgical valves of the same size, thereby reducing the likelihood of PPM [13,14].

Reoperative cases also represent an opportunity for SuAVR. Patients requiring redo AVR often present technical challenges due to adhesions and altered anatomy. SuAVR allows for shorter operative times and more straightforward valve implantation in this setting, while also reducing surgical trauma and recovery time [15-17]. Though these cases are relatively rare, they highlight the versatility and potential value of SuAVR in complex scenarios.

Final considerations

While transcatheter devices have undergone multiple iterations and refinements, the world of surgical valves has remained largely unchanged. This stagnation is further complicated by the difficulty of generating high-quality comparative data. As highlighted in a recent editorial [18], the rapid pace of device evolution in the transcatheter space renders many trials outdated by the time results are available. When TAVR devices are compared in randomized studies, the platforms often become obsolete during the trial's follow-up period. This undermines the applicability of the data and complicates efforts to draw meaningful comparisons.

In contrast, surgical trials often suffer from heterogeneity in technique, limited sample sizes, and lower commercial support. The level of evidence supporting SuAVR remains limited and inconsistent, further reinforcing the reluctance toward its adoption.

Another relevant aspect is cost as SuAVR prostheses are more expensive than standard sutured bioprostheses [19,20]. Without clear superiority in hard clinical outcomes, the economic argument for SuAVR remains speculative, based primarily on the reduction of operative time and hospital length of stay.

In patients with a small aortic annulus, for example, sutureless valves offer larger effective orifice areas, thereby reducing the incidence of patient–prosthesis mismatch [13]. Similarly, in redo operations-often complicated by adhesions and difficult exposure-the ability to rapidly deploy a valve without extensive annular manipulation is highly beneficial [15]. SuAVR may also provide physiologic advantages in elderly or frail patients, where reducing cross-clamp time can translate into lower perioperative stress and potentially improved recovery [21,22].

However, where SuAVR finds its most meaningful role is in the context of MICS as a tool enabling and streamlining the surgical procedures. By simplifying minimally invasive implantation and offering comparable outcomes with potential long-term advantages, SuAVR has the potential to contribute meaningfully to the evolving landscape of aortic valve therapy, strengthening the position of MICS as a legitimate surgical comparator for TAVR.

Ad hoc randomized clinical evidence comparing MICS SuAVR to TAVR are eagerly awaited.

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