



Clinical and Echocardiographic Outcomes of Sutureless vs. Transcatheter Aortic vs. Sutured Bioprosthesis Valves for Aortic Valve Replacement: A Systematic Review of Medical Literature

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Abstract

Objective: To compare the clinical and echocardiographic outcomes of Aortic Valve Replacement (AVR) with Sutureless Bioprosthesis (SU-AVR) vs. Transcatheter Aortic Valve Replacement (TAVR) vs. Sutured Bioprosthesis (SB).

Methods: A scoping review was conducted using a comprehensive search strategy from multiple databases (Medline, Embase, Cochrane Central Register of Controlled Clinical Trials). Two independent reviewers screened all abstracts and full texts according to predefined inclusion and exclusion criteria.

Results: Thirty-two studies were included in the analysis. Thirty-day mortality ranged from 0% to 5.8% for sutureless and 0% to 9.8% for TAVR. The TAVR group had higher rates of moderate/severe Paravalvular Leak (PVL) (sutureless 0%-19.4% vs. TAVR 1.6%-53.5%), Permanent Pacemaker Implantation (PPI) (sutureless 0%-14.5% vs. TAVR 0%-25.5%), stroke (sutureless 0%-4.8% vs. TAVR 0%-5.8%), and Myocardial Infarction (MI) (sutureless 0% vs. TAVR 0%-3.5%). Compared to other SB, mortality ranged from 0% to 6.4% for sutureless and 0% to 5.9% for SB. Incidence of PVL (sutureless 1%-19.4% vs. SB 0%-1%), PPI (sutureless 2%-10.7% vs. SB 1.8%-8.5%), stroke (sutureless 0%-3.7% vs. SB 1.8%-7.3%) and MI (sutureless 0%-7.8% vs. SB 0%-4.3%) were comparable. Patients with bicuspid aortic valves demonstrated a mortality rate of 0% to 4% and PVL incidence of 0% to 2.3%. Long-term survival was 96.7% to 98.6%. Studies also show that sutureless valves are more cost-effective compared to TAVR.

Conclusion: Sutureless bioprosthesis is a suitable alternative to surgical AVR due to its favorable hemodynamics, reduced implantation time leading to reduced cardiopulmonary bypass and aortic cross-clamp times, as well as shorter hospital length of stay.

Keywords: Sutureless; TAVR; Sutured; Long-term outcomes; Echocardiography; Pacemaker; Paravalvular leak

Introduction

Sutureless valves (SU-AVR) have been used for more than a decade for aortic valve replacement. Their use has permitted surgery in high-risk and frail patients with multiple comorbidities who would otherwise have been unable to undergo complex surgeries. In this context, SU-AVR characteristics

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of self-expanding make it suitable for patients with small annuli that would otherwise receive a 19 or 21-size bioprosthesis potentially leading to patient-prosthesis mismatch resulting in high transvalvular gradients [1].

Similarly, to Transcatheter Aortic Valve Replacement (TAVR), the sutureless bioprosthesis do not need suturing thus allowing for implantation times that are comparable to TAVR. In this context, fragile patients with high STS-PROM risk score, multiple comorbidities including peripheral vascular disease, may benefit from the reduced implantation time and speedy recovery.

Other reviews have previously elucidated both benefits and pitfalls of SU-AVR compared to sutured bioprosthesis for Surgical Aortic Valve Replacement (SAVR) [2-4], whereby most exhibit a clear benefit of SU-AVR. Similarly, TAVR has shown robust evidence in clinical trials for low and high-risk patients as shown in the PARTNER clinical trials [5-7], the SURTAVI trial [8] and other meta-analyses [9-10]. In addition, the underlying mechanism by which TAVR and SU-AVR exhibit superiority over sutured bioprosthesis supposedly involves the improved hemodynamics associated with approaches, as well as the self-expanding radial force, its ease of use in hostile aortic roots and faster surgical and recovery speed. In addition, the learning curve in both TAVR and SU-AVR has been shown to be short without multiple drop-off periods. However, one of the main burdens associated with both TAVR and SU-AVR is the high incidence of Permanent Pacemaker Implantation (PPI). In addition, the use of SU-AVR in patients with Bicuspid Aortic Valves (BAV), the cost-effectiveness of each approach, as well as the echocardiographic and long-term clinical outcomes after SU-AVR remain hindered.

This review aims to highlight key points from previous clinical trials and observational studies and raise a point of discussion for expanding the use of SU-AVR and TAVR.

Materials and Methods

This review was carried out in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [11]. The following databases were searched for studies that met our inclusion criteria and published before February 28th, 2023: PubMed/MEDLINE, Embase, SciELO, LILACS, CCTR/CENTRAL, Google Scholar and grey literature. The following terms were searched: ["Transcatheter Aortic Valve Replacement" OR "Transcatheter Aortic Valve Implantation" OR "TAVI" OR "TAVR" OR "transcatheter heart valve" OR "Valve-in-valve TAVR" OR "Valve-in-valve TAVI"] AND ["Heart Valve Prosthesis Implantation" OR "rapid-deployment aortic valve" OR "sutureless aortic valve" OR "Perceval" NOT "Enable"] AND ["Sutured vs. Sutureless" OR "Bioprosthesis versus Sutureless"]. Studies were selected with the following steps: 1) identification of titles of records through database search; 2) removal of duplicates; 3) abstract screening and selection; 4) assessment for eligibility through full-text papers. Data are available upon reasonable request.

Inclusion criteria

Studies that reported any of the following were included: 1) outcomes of sutureless compared with other heart valve prostheses or procedures; 2) analysis of complications with sutureless valve; 3) off-label experience; 4) learning curve analysis; 5) one or more cases of redo AVR with SU-AVR.

Exclusion criteria

Presence of any of the following criteria led to exclusion from the study: (1) outcomes of only other sutureless valves; (2) grouped outcomes of sutureless with other prostheses in the same cohort; (3) published in a language other than English; (4) not peer-reviewed; (5) conference abstract; and case reports (6).

Data collection

The data was collected on March 8th, 2023. One author (AD) screened the articles and subsequently reviewed them three times. The results were then reviewed by a different author (SS). Discrepancies were arbitrated by another author in order to attain consensus (MB). The primary reported outcomes of the study included a) clinical trials outcomes regarding sutureless valves; b) sutureless versus TAVR; c) sutureless versus other stented bioprostheses d) sutureless in BAV; e) sutureless valve durability; and f) hospital costs.

Results

This scoping review ultimately included 32 studies after exclusion of duplicates and ineligible studies.

SU-AVR vs. TAVR

A total of 1,701 patients in the SU-AVR group and 2,431 in the TAVR group were included in 12 retrospective clinical studies (Table 1). Thirty-day all-cause mortality was similar ranging from 0% to 5.8% for SU-AVR and 0% to 9.8% for TAVR. In addition, moderate/severe Paravalvular Leak (PVL) (SU-AVR 0%-19.4% vs. TAVR 1.6%-53.5%), PPI (SU-AVR 0%-14.5% vs. TAVR 0%-25.5%), stroke (SU-AVR 0%-4.8 vs. TAVR 0%-5.8%), and Myocardial Infarction (MI) (SU-AVR 0% vs. TAVR 0%-3.5%), were similar between group.

SU-AVR vs. sutured bioprosthesis

A total of 639 patients in the SU-AVR group and 1,636 in the sutured bioprosthesis group were included in 8 retrospective and prospective clinical studies (Table 2). All-cause mortality ranged from 0% to 6.4% for SU-AVR and 0% to 5.9% for sutured bioprosthesis.

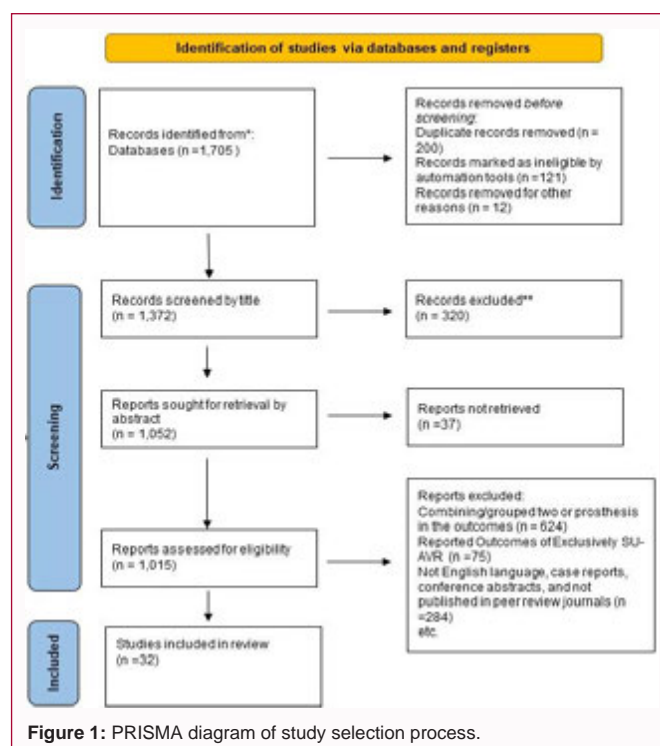


Figure 1: PRISMA diagram of study selection process.

Table 1: Sutureless aortic valve replacement versus transcatheter aortic valve replacement.

| Study author | Biancari et al. [15] | | Muneretto et al. [16] | | D'Onofrio et al. [22] | | Santarpino et al. [18] | | Miceli et al. [27] | |
|---------------------------------|----------------------|--|-----------------------|--------------|-----------------------|---------------|------------------------|----------------|--------------------|--------------|
| Clinical study methodology | Retrospective | | Retrospective | | Retrospective | | Retrospective | | Retrospective | |
| Valve brand and nr. of patients | Perceval N=144 | TAVR N=144 | Perceval N=53 | TAVR N=55 | Perceval N=31 | TAVR N=143 | Perceval N=443 | TAVR N=1002 | Perceval N=37 | TAVR N=37 |
| 30-day all-cause Mortality [%] | 1.4 | 6.9 | 0 | 1.8 | 0 | 7 | 4 | 2.9 | 0 | 3 |
| Bleeding [%] | 4.2 | 0 | 7.5 | 0 | NR | NR | NR | NR | 1 | 1 |
| PVL [%] | 2.8 | 53.5 | 1.9 | 9 | 19.4 | 28.7 | NR | NR | 2 | 30 |
| Stroke [%] | 0 | 2.1 | 0 | 0 | 0 | 2.8 | NR | NR | 0 | 2 |
| MI [%] | 0 | 0 | 0 | 1.8 | 0 | 3.5 | NR | NR | NR | NR |
| PPI [%] | 11.2 | 15.4 | 2 | 25.5 | 3.2 | 4.9 | 5.8 | 11.6 | 2 | 0 |
| AXC time in minutes ± SD | 42 ± 17 | NA | 32 ± 14 | NA | NR | NA | 43.4 ± 13.4 | NA | NR | NA |
| CPB time in minutes ± SD | 71 ± 24 | NA | 54 ± 25 | NA | NR | NA | 73.4 ± 23.1 | NA | NR | NA |
| TAVR types | NA | Core Valve Sapien Lotus Portico | NA | NR | NA | NR | NA | Sapien | NA | Sapien |

Table 1: Continuation.

| Study author | Muneretto et al. [19] | | Repossini et al. [49] | | Gerfer et al. [50] | | Zubarevich et al. [57] | |
|---|-----------------------|---|-----------------------|---------------|--------------------|--------------|------------------------|---------------|
| Type of clinical study | Retrospective | | Retrospective | | Retrospective | | Retrospective | |
| Valve types and nr. of patients | Perceval N=288 | TAVR N=367 | Perceval N=158 | TAVR N=158 | Perceval N=59 | TAVR N=59 | Perceval N=79 | TAVR N=169 |
| 30-day Mortality [%] | 5.8 | 9.8 | 1.9 | 5.8 | 5.1 | 1.7 | 1.8 | 0 |
| Bleeding requiring surgery [%] | 4.9 | 1.9 | NR | NR | NR | NR | 10.7 | 0 |
| Paravalvular leak [%] | 4 | 18 | 0.5 | 4.3 | 0 | 6.8 | NR | NR |
| Stroke [%] | 1.5 | 5.8 | NR | NR | 1.7 | 0 | 0 | 1.8 |
| Myocardial Infarction [%] | NR | NR | NR | NR | NR | NR | NR | NR |
| Pacemaker implantation [%] | 9.8 | 14.7 | 5.4 | 11.9 | 10.2 | 8.5 | 0 | 1.80% |
| Aortic cross-clamp time in minutes ± SD | 32.8 ± 12.6 | NA | NR | NR | 49 ± 22 | NA | 49.4 ± 17.4 | NA |
| Cardiopulmonary bypass time in minutes ± SD | 50 ± 11.5 | NA | NR | NR | 83 ± 32 | NA | NA | NA |
| TAVR types | NA | CoreValve, Sapien XT, Accurate TA | NA | NR | NA | Accurate NEO | Sapien XT, Sapien 3 | NA |

Incidence of PVL (SU-AVR 1%-19.4% vs. sutured 0%-1%), PPI (SU-AVR 2%-10.7% vs. sutured 1.8%-8.5%), stroke (SU-AVR 0%-3.7% vs. sutured 1.8%-7.3%) and MI (SU-AVR 0%-7.8% vs. sutured 0%-4.3%) were similar.

SU-AVR in BAV

One hundred and fifty-seven patients were included in 5 retrospective clinical studies (Table 3). Mortality rate was (0%-4%), stroke (0%-7.6%), PPI (0%-7%), PVL (0%-2.3%), MI 0%, aortic cross-clamping time 39 ± 13 to 45.9 ± 14 min. Cardiopulmonary Bypass Time (CPB) ranged between 54.5 ± 4.4 to 80 min.

Echocardiographic outcomes

Echocardiographic data were obtained from previously described studies (Table 4). Effective orifice area at hospital discharge ranged between 1.4 ± 0.4 to 1.56 ± 0.37 cm². This remained stable at 6-months (1.5 ± 0.3 to 1.5 ± 0.4 cm²), 1-year (1.5 ± 0.3 to 1.6 ± 0.4 cm²), and 2-years follow-up (1.51 ± 0.26 to 1.7 ± 0.5 cm²). Transvalvular (mean and peak) gradients at discharge and up to 2-years follow-up were not significantly different among groups (Table 4).

Long-term outcomes

Five-year clinical outcomes from one clinical trial and one large

retrospective study including 759 patients evidenced an all-cause death rate ranging from 7% to 28.7%, but cardiac related death was only 1.4% and 3.3%, respectively. Structural valve deterioration was 0% while only the retrospective study showed a stroke rate of 0.8%. In addition, only 1% of patients had a major PVL in the retrospective study (Figure 1, 2). Two other retrospective studies evidenced similar outcomes. Furthermore, at 5-years follow-up, the effective orifice area was 1.8 ± 0.3 and 1.69 ± 0.42 cm² in the retrospective clinical study and clinical trial, respectively. Mean transvalvular gradients at 5-years ranged between 8.8 ± 4.6 mmHg and 9.3 ± 5.5 mmHg, respectively (Table 5).

Hospital costs outcomes

A total of 3 retrospective clinical studies were used in the costs analysis. The entire costs outcomes were found to be \$12,825 USD for SU-AVR, \$69,389 USD for TAVR and \$13,543 USD for sutured bioprosthesis (Table 6).

Discussion

Summary of findings

1) Clinical and echocardiographic outcomes between SU-AVR and TAVR are comparable.

Table 2: Sutureless aortic valve replacement versus other stented bioprostheses.

| Study author | Muneretto et al. [48] | | Gilmanov et al. [20] | | Pollari et al. [21] | | D'Onofrio et al. [17] | | Vaquero et al. [23] | | Fischlein et al. [24] | |
|---|-----------------------|-------------------|----------------------|------------------------------------|---------------------|-----------------|-----------------------|------------------|---------------------|------------------|-----------------------|------------------|
| | Prospective | | Retrospective | | Prospective | | Retrospective | | Prospective | | Prospective | |
| Valves and patients | Perceval N=53 | Stented N=55 | Perceval N=133 | Stented N=133 | Perceval N=88 | Stented N=88 | Perceval N=31 | Stented N=112 | Perceval N=140 | Stented N=409 | Perceval N=447 | Stented N=449 |
| 30-day Mortality [%] | 0 | 0 | 0.8 | 1.5 | 2.4 | 3.7 | 0 | 1.8 | 6.4 | 5.9 | 1 | 1 |
| Bleeding requiring surgery [%] | 7.5 | 10.5 | 6.8 | 3.8 | 2.4 | 6.1 | NR | NR | NR | NR | 4.4 | 6.3 |
| Paravalvular leak [%] | 1.9 | 0 | NR | NR | NR | NR | 19.4 | 1 | 3.6 | 0.5 | 1 | 0 |
| Stroke [%] | 0 | 1.8 | NR | NR | 3.7 | 7.3 | 0 | 0 | 2.9 | 2.7 | 1.5 | 1.9 |
| Myocardial infarction [%] | 0 | 0 | 1.5 | 0 | NR | NR | 0 | 0.9 | 7.8 | 4.3 | 1 | 1.5 |
| Permanent pacemaker implantation [%] | 2 | 1.8 | NR | NR | 6.1 | 8.5 | 3.2 | 0.9 | 10.7 | 2 | 10.6 | 3.2 |
| Aortic cross-clamp time in minutes/SD | 30.8 ± 13.6 | 65.3 ± 27.7 | 56 | 90 | 47 ± 16 | 59 ± 23 | NR | NR | 65.3 ± 29.1 | 77.2 ± 30.3 | 48.5 ± 24.7 | 65.2 ± 23.6 |
| Cardiopulmonary bypass time in minutes/SD | 47±18.5 | 89.4 ± 20.4 | 88 | 120 | 71 ± 11 | 92 ± 33 | NR | NR | 81.3 ± 34.9 | 95.7 ± 37.9 | 71.0±34.1 | 87.8 ± 33.9 |
| Type of stented valves | NA | Perimoun, Edwards | NA | CE Edwards, Medtronic, CE standard | NA | NR | NA | NR | NA | Triflecta | NA | NR |

NA: Not Applicable; SD: Standard Deviation; NR: Not Reported

Table 2: Continuation.

| Study author | Dalen et al. [51] | | Forcillo et al. [61] | |
|--------------------------------|-------------------|------------------|----------------------|--|
| | Retrospective | | Retrospective | |
| Valves and patients | Perceval N=171 | Stented N=171 | Perceval N=76 | Stented N=319 |
| 30-day Mortality [%] | 1.8 | 2.3 | 5 | 6 |
| Bleeding requiring surgery [%] | 4.1 | 6.4 | 8 | 8 |
| PVL [%] | 0 | 1.2 | 0 | 0 |
| Stroke [%] | 2.3 | 1.2 | 0 | 5 |
| MI [%] | NR | NR | 0 | 0 |
| PPI [%] | 9.9 | 2.9 | 17 | 8 |
| AXC time in minutes/SD | 40 ± 15 | 65 ± 15 | 46 | 68 |
| CPB time in minutes/SD | 69 ± 20 | 87 ± 20 | 60 | 85 |
| Type of stented valves | NA | CE Perimount | NA | CE, Medtronic, Mitroflow, St. Jude epic, St. Jude Biocor |

Table 3: Clinical outcomes of bicuspid aortic valve stenosis treated with sutureless valve.

| Study author | Durdu et al. [31] [mean ± SD] | Nguyen et al. [30] [mean ± SD] | Szeczal et al. [32] [mean ± SD] | Miceli et al. [27] [mean ± SD] | Suri et al. [62] [mean ± SD] |
|--------------------------------|----------------------------------|-----------------------------------|------------------------------------|-----------------------------------|---------------------------------|
| Number of patients | N=13 patients | N=25 patients | N=11 patients | N=88 patients | N=20 patients |
| Type of clinical study | Retrospective | Retrospective | Retrospective | Retrospective | Retrospective |
| 30-day Mortality [%] | 0 | 4 | 0 | 1.6 | 2 |
| Bleeding requiring surgery [%] | 7.6 | 1 | NR | 3.1 | 4 |
| PVL [%] | 0 | 0 | 0 | 2.3 | NR |
| Stroke [%] | 7.6 | 8 | 0 | 4.2 | NR |
| MI [%] | 0 | 0 | 0 | NR | NR |
| PPI [%] | 7.6 | 20 | 0 | 5.7 | NR |
| AXC time in minutes/SD | 40.3 ± 3.1 | 45.9 ± 14.0 | 39 ± 13 | 55 | 52.3 ± 19.6 |
| CPB time in minutes/SD | 54.5 ± 4.4 | 56.1 ± 14.9 | 66 ± 22 | 80 | 70.2 ± 27.8 |

NA: Not Applicable; SD: Standard Deviation

2) SU-AVR had a lower incidence of in-hospital complications and overall mortality compared to sutureless valve replacement versus sutured bioprosthesis.

3) SU-AVR and TAVR had lower hospital costs compared to

Comments

This review emphasized the latest outcomes from clinical studies

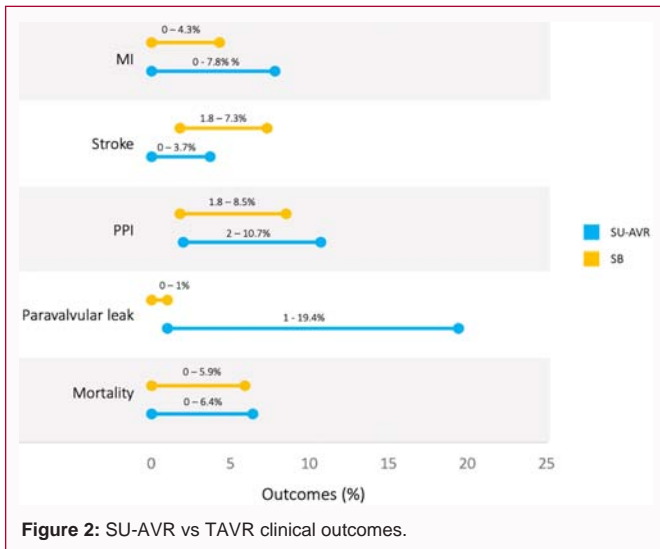


Figure 2: SU-AVR vs TAVR clinical outcomes.

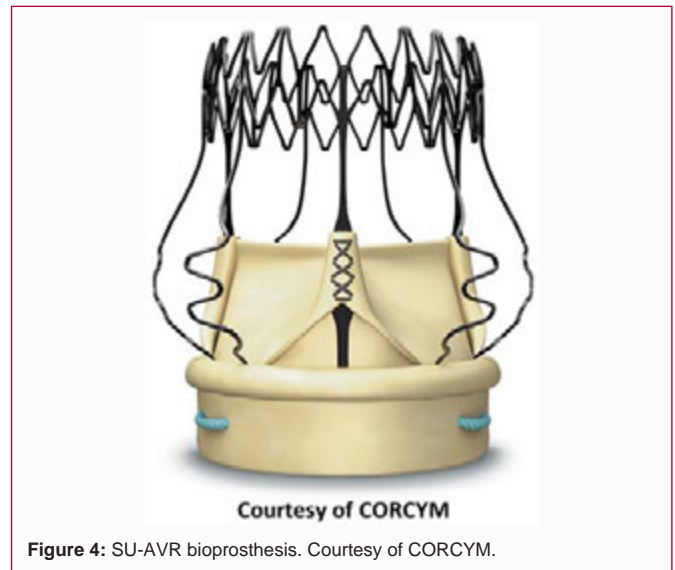


Figure 4: SU-AVR bioprosthesis. Courtesy of CORCYM.

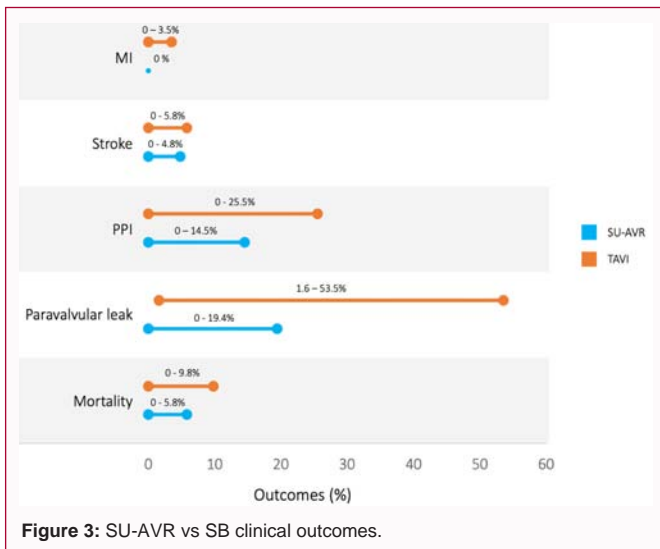


Figure 3: SU-AVR vs SB clinical outcomes.



Figure 5: Self-Expandable TAVR. Courtesy of Edwards.

discussing the benefits and pitfalls of SU-AVR and TAVR over sutured bioprosthesis, for AVR. In this context, we focused our attention in critical points including incidence of PPI, outcomes in bicuspid aortic valve, and echocardiographic outcomes. We additionally reported the overall hospital costs for each valve-type. This is important because often the prohibitive costs of the valves for underdeveloped countries which may preclude patients from the benefits associated with the implantation of TAVR and SU-AVR.

SU-AVR have advanced significantly in the last decade and the design has been accepted as the treatment of choice for patients who qualify for aortic valve replacement. However, critical steps need to be clarified for the success of the implantation of the valve. Device sizing is important because the device is designed to expand to an outer diameter larger than the patient’s measured annular diameter [12-15]. Stent expansion allows for adequate radial force to secure the valve in place and remain stable at physiological pressure, flow, and movement [25,26]. The selected SU-AVR size should match the measured aortic annulus diameter [28,29].

In addition, TAVR has proven its noninferiority to other sutured prosthesis. The major benefits of these valves include a) favorable hemodynamic outcomes, b) relatively easy implantation in a hostile

annulus environment such as endocarditis and reoperations, c) facilitating future valve-in-valve TAVR because the sinus struts protect the coronary ostia from obstruction and Nitinol cage expandable [32-36]. In this review we emphasized important clinical and procedural outcomes comparing SU-AVR to TAVR and other bioprosthesis (Figure 3). Outcomes including stroke, PVL, PPI, and echocardiographic reports favored SU-AVR and TAVR over sutured bioprosthesis. The PARTNER trials demonstrated noninferiority of TAVR compared to sutured bioprosthesis in both high and low-risk patients [4]. However, a future clinical trial comparing TAVR and SU-AVR vs. sutured bioprosthesis will help to customize the right prosthesis according to individual risk profile, anatomy, frailty, and comorbidities (Figure 4, 5). When SU-AVR is compared to sutured bioprosthesis, the latest revealed longer CPB and Aortic Cross-Clamp (AXC) times, and higher incidence of stroke and bleeding. The increased incidence of PPI in the SU-AVR group when compared to sutured bioprosthesis remains a concern. In this context, there are several points to be discussed including oversizing of the prosthesis, depth of implantation, excessive calcium removal from the aortic

Table 4: Hemodynamic outcomes.

| Endpoints | Santarpino et al. N=658 (mean ± SD) [1] | Rubino et al. N=314 (mean ± SD) [63] | Mazine et al. N=215 (mean ± SD) [64] | Folliguet et al. N=208 (mean ± SD) [11] | Shrestha et al. N=30 (mean ± SD) [65] | Shrestha et al. N=243 (mean ± SD) [54] | Miceli et al. N=37 (Mean ± SD) [27] | Repossini et al. N=158 (Mean ± SD) [49] |
|-------------------------------------|---|--------------------------------------|--------------------------------------|---|---------------------------------------|--|-------------------------------------|---|
| Type of clinical study | Prospective | Retrospective | Retrospective | Retrospective | Prospective | Retrospective | Retrospective | Retrospective |
| EOA [cm ²] at discharge | 1.5 ± 0.4 | NR | 1.56 ± 0.37 | 1.4 ± 0.4 | NR | 1.5 ± 0.4 | NR | NR |
| EOA [cm ²] at 6-months | 1.5 ± 0.3 | NR | NR | 1.5 ± 0.4 | NR | 1.5 ± 0.4 | NR | NR |
| EOA [cm ²] at 1 year | 1.5 ± 0.4 | NR | NR | 1.5 ± 0.3 | 1.55 ± 0.35 | 1.6 ± 0.4 | NR | NR |
| EOA [cm ²] at 2-years | NR | NR | NR | NR | 1.51 ± 0.26 | 1.7 ± 0.5 | NR | NR |
| Mean gradient [mmHg] at discharge | 10.3 ± 4.5 | 14 ± 6 | 13.3 ± 6.4 | 10.4 ± 4.3 | NR | 10.1 ± 4.7 | 11.4 ± 3.7 | 10.9 ± 5.4 |
| Mean gradient [mmHg] at 6-months | 8.9 ± 4.1 | NR | NR | 8.9 ± 3.2 | NR | 8.9 ± 4.2 | NR | NR |
| Mean gradient [mmHg] at 1-year | 9.2 ± 5 | NR | NR | 8.7 ± 3.7 | 9.9 ± 4.6 | 8.9 ± 4.6 | NR | NR |
| Mean gradient [mmHg] at 2-years | NR | NR | NR | NR | 8 ± 4.1 | 9 ± 3.4 | NR | NR |
| Peak gradient [mmHg] at discharge | 19.4 ± 8.1 | 27 ± 11 | 24.5 ± 10.8 | 21.3 ± 8.6 | NR | 20.3 ± 9.9 | 19.2 ± 6.9 | 18.7 ± 9.1 |
| Peak gradient [mmHg] at 6-months | 16.8 ± 7 | NR | NR | 19.6 ± 6.7 | NR | 18 ± 7.6 | NR | NR |
| Peak gradient [mmHg] at 1-year | 17.1 ± 8.7 | NR | NR | 18.8 ± 7.6 | 20.9 ± 9.2 | 17.5 ± 8.2 | NR | NR |
| Peak gradient [mmHg] at 2-years | NR | NR | NR | NR | 16.6 ± 7.2 | 18.3 ± 5.6 | NR | NR |

EOA: Effective Orifice Area; SD: Standard Deviation; NR: Not Reported

Table 4: Continuation.

| Endpoints | Chung et al. [59] | Suri et al. [62] | Durdu et al. [31] | Miceli et al. [27] | Nguyen et al. [30] |
|-------------------------------------|-------------------|------------------|-------------------|--------------------|--------------------|
| Type of clinical study | Retrospective | Retrospective | Retrospective | Retrospective | Retrospective |
| EOA [cm ²] at discharge | 1.6±0.4 | 1.4 ± 0.3 | 1.81 ± 0.38 | NR | 1.86 ± 0.6 |
| EOA [cm ²] at 6 months | NR | NR | NR | NR | NR |
| EOA [cm ²] at 1 year | 1.5 ± 0.3 | NR | NR | NR | NR |
| EOA [cm ²] at 2 years | NR | NR | NR | NR | NR |
| Mean gradient [mmHg]at discharge | 14.7±3.8 | 10.3 ± 3.7 | 13.6 ± 4.4 | 14.8 ± 5.8 | 12.7 ± 6.4 |
| Mean gradient [mmHg] at 6-months | NR | NR | NR | NR | NR |
| Mean gradient [mmHg] at 1-year | 12.4 ± 5.3 | NR | NR | NR | NR |
| Mean gradient [mmHg] at 2-years | NR | NR | NR | NR | NR |
| Peak gradient [mmHg] at discharge | 27.5±7.0 | NR | NR | 28.3 ± 10.9 | NR |
| Peak gradient [mmHg] at 6-months | NR | NR | NR | NR | NR |
| Peak gradient [mmHg] at 1-year | 23.8 ± 8.8 | NR | NR | NR | NR |
| Peak gradient [mmHg] at 2-years | NR | NR | NR | NR | NR |

EOA: Effective Orifice Area; SD: Standard Deviation; NR: Not Reported

annulus, and operator experience. Therefore, the learning curve is admirable, and it is highly recommended that at the earliest beginning of SU-AVR experience a surgeon should be proctored by a senior expert surgeon in SU-AVR implantation. However, recent studies analyzing the SU-AVR learning curve evidenced a 99% success of implantation rate and a 0.7% overall mortality incidence [37-47].

The cost of SU-AVR appears to be lower compared to sutured bioprosthesis. In addition, results from PARTNER 3 clinical trial evidenced that procedural costs with TAVR were nearly \$19,000 USD

higher, and total index hospitalization costs were only \$591 more with TAVR compared with sutured bioprosthesis [52,53]. Follow-up costs were lower with TAVR which led to cost savings of \$2030/patient after 2 years compared to sutured bioprosthesis [58,60] (95% CI, -\$6222 to \$1816) and an increase of 0.05 quality-adjusted life-years (95% CI, -0.003 to 0.102) [68]. However, financial outcomes are difficult to compare due to variability in cost amongst different hospitals among different countries and the annual currency inflation.

Compared to other clinical studies in medical literature,

Table 5: Long-term outcomes of sutureless bioprosthesis.

| Late events> 30 days. studies | Shrestha et al. [54] N=729 patients | Meuris et al. [12] N=30 patients | Dokollari et al. [55] N=101 | Concistre et al. [56] N=1,652 |
|------------------------------------|--|-------------------------------------|--------------------------------|----------------------------------|
| Type of study | Retrospective | Prospective clinical trial | Retrospective | Retrospective |
| Follow-up duration | 5 years | 5 years | 7 years | 7 years |
| All-cause mortality [%] | 7 | 28.7 | 12.1 | 4.5 |
| Cardiac Deaths [%] | 1.4 | 3.3 | 5 | 1.9 |
| Valve Explants [%] | 1.5 | 0 | 0 | 0.8 |
| Major PVL [%] | 1 | 0 | 0 | 0 |
| Endocarditis [%] | 1.6 | 6.6 | 1 | 0.5 |
| Structural valve deterioration [%] | 0 | 0 | 0 | 0.2 |
| Valve thrombosis [%] | 0 | 0 | 0 | 0 |
| AV block III [%] | 1.4 | 3.3 | 5 | 1.7 |
| Stroke | 0.8 | 0 | 10 | 0.2 |

Table 6: Long-term echocardiographic outcomes [5-year follow-up] of sutureless bioprosthesis.

| Study | Shrestha et al. [54] N=729 patients [mean ± SD] | Meuris et al. [12] N=30 [mean ± SD] | Concistre et al. [56] N=197 [mean ± SD] |
|--|--|--|--|
| LVEF at 3 years [%] | 67 ± 9 | NR | NR |
| LVEF at 4 years [%] | 66.1 ± 9.1 | NR | NR |
| LVEF at 5 years [%] | 65.8 ± 7.7 | NR | NR |
| Mean transvalvular gradient at 3 years mmHg | 7.7 ± 2.8 | 8.3 ± 2.5 | NR |
| Mean transvalvular gradient at 4 years mmHg | 7.8 ± 3.8 | 7.6 ± 3.6 | NR |
| Mean transvalvular gradient at 5 years mmHg | 8.8 ± 4.6 | 9.3 ± 5.5 | 13.7 ± 10 |
| Peak transvalvular gradient at 3 years mmHg | 16 ± 5.2 | 16.6 ± 6.2 | NR |
| Peak transvalvular gradient at 4 years mmHg | 17.8 ± 8.1 | 17.5 ± 7.8 | NR |
| Peak transvalvular gradients at 5 years mmHg | 21.1 ± 9.7 | 21.4 ± 11.5 | 23 ± 15 |
| EOA at 3 years [cm ²] | 1.64 ± 0.42 | 1.68 ± 0.4 | NR |
| EOA at 4 years [cm ²] | 1.68 ± 0.43 | 1.68 ± 0.43 | NR |
| EOA at 5 years [cm ²] | 1.8 ± 0.3 | 1.69 ± 0.42 | 1.5 ± 0.4 |

Table 6: Costs outcomes of the Perceval Valve, TAVR and Sutured Valves.

| Author | Villa et al. [66] | Villa et al. [66] | Povero et al. [67] |
|---------------------|-------------------|-------------------|--------------------|
| Study year | 2019 | 2019 | 2018 |
| Type of study | Retrospective | Retrospective | Retrospective |
| Type of valve | Perceval | Sutured | TAVR |
| Costs in US dollars | 12,825 | 13,543 | 69,389 |

this review evidenced the differences in short- and long-term outcomes of three different types of bioprosthesis altogether with their echocardiographic outcomes. In this context, other reviews tend to compare either TAVR vs. SU-AVR or SU-AVR vs. sutured bioprosthesis but not all three bioprosthesis. In addition, those reviews do not include cost differences among bioprosthesis. In the spectrum of AVR bioprosthesis, there must be a borderline where to use TAVR and SU-AVR compared to sutured bioprosthesis. Surgical experience alone is not enough to set the pathway, but a heart-team experience is mandatory.

Conclusion

SU-AVR is a dependable device for conventional AVR and mini-AVR due to its speed of implantation, reduced CPB and aortic cross-clamp times, and ultimately shorter intensive care unit and hospital length of stay. Additionally, SU-AVR and TAVR bioprosthesis adoption for hostile roots and redo operations make them a great tool

in the surgical armamentarium. SU-AVR and TAVR implantation expectation is zero PVL. Any PVL is likely a consequence of sub-optimal implant which requires revision. Reduction of PVL demands adequate annular debridement and familiarity with the optimal technique to implant the prosthesis.

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