Keynote Lecture Series

Sutureless aortic valve replacement

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The increasing incidence of aortic stenosis and greater co-morbidities and risk profiles of the contemporary patient population has driven the development of minimally invasive aortic valve surgery and percutaneous transcatheter aortic valve implantation (TAVI) techniques to reduce surgical trauma. Recent technological developments have led to an alternative minimally invasive option which avoids the placement and tying of sutures, known as "sutureless" or rapid deployment aortic valves. Potential advantages for sutureless aortic prostheses include reducing cross-clamp and cardiopulmonary bypass (CPB) duration, facilitating minimally invasive surgery and complex cardiac interventions, whilst maintaining satisfactory hemodynamic outcomes and low paravalvular leak rates. However, given its recent developments, the majority of evidence regarding sutureless aortic valve replacement (SU-AVR) is limited to observational studies and there is a paucity of adequately-powered randomized studies. Recently, the International Valvular Surgery Study Group (IVSSG) has formulated to conduct the Sutureless Projects, set to be the largest international collaborative group to investigate this technology. This keynote lecture will overview the use, the potential advantages, the caveats, and current evidence of sutureless and rapid deployment aortic valve replacement (AVR).

Keywords: Sutureless valve; rapid deployment prosthesis; minimally invasive; aortic valve replacement (AVR); International Valvular Surgery Study Group (IVSSG)

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Introduction

Aortic valve stenosis is the most frequent cardiac valve pathology in the western world, with a prevalence of 3% for individuals over the age of 75 years (1). The incidence of aortic valve stenosis is growing, a reflection of the rapid ageing of the population (2). As a result, there is an increasing number of elderly patients eligible for a prosthetic aortic valve replacement (AVR) who present with greater morbidities and underlying risk factor profiles. Based on extraordinary short- and long-term outcomes, conventional AVR (C-AVR) is the gold standard approach for the treatment of symptomatic severe aortic stenosis (3). However, the greater morbidities and risk profiles on the contemporary patient population has driven the development of minimally invasive interventions such as percutaneous transcatheter aortic valve implantation (TAVI) as well as techniques and technologies to reduce surgical trauma (4,5). The latter involve include minimally invasive approaches and sutureless prostheses (6-9).

Recent technological developments have led to an alternative minimally invasive option which avoids the placement and tying of sutures, known as "sutureless" or rapid deployment aortic valves. While this concept was first introduced approximately 50 years ago, sutureless valves have been redeveloped in the last few years based on modern experience with TAVI. Given its recent developments, the majority of evidence regarding sutureless aortic valve replacement (SU-AVR) is limited to observational studies (10-13), with only one small randomized controlled study to date demonstrating its feasibility, safety and efficacy (8). However, the current evidence demonstrates SU-AVR as a promising option for aortic stenosis which facilitates minimally invasive surgery while minimizing

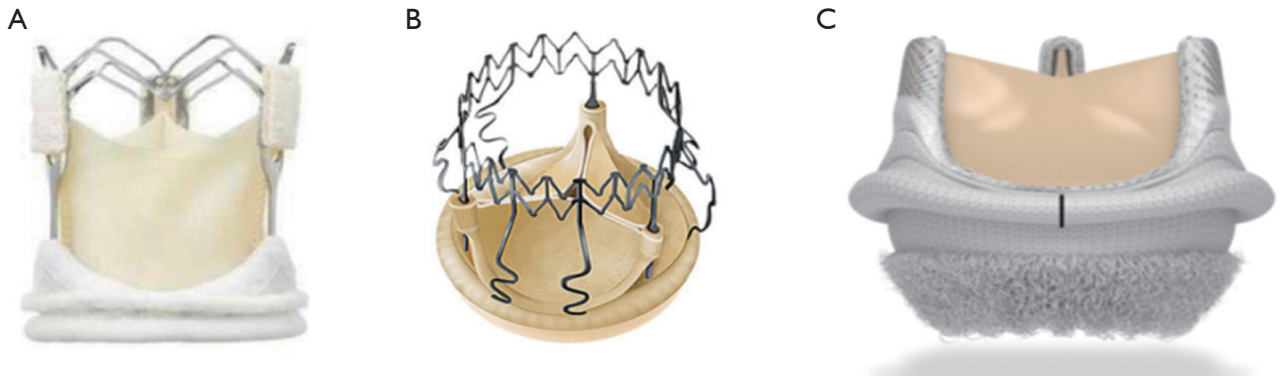

Figure 1 Commercially available sutureless aortic valves. (A) 3F Enable (Medtronic, Minneapolis, USA); (B) Perceval S (Sorin, Saluggia, Italy); (C) Intuity Elite (Edward Lifesciences, Irvine, USA).

cardiopulmonary bypass (CPB) and cross clamp durations.

This keynote lecture will outline the use, the potential advantages, the caveats, and current evidence of sutureless and rapid deployment AVR.

Sutureless and rapid deployment aortic valve prostheses

Available sutureless and rapid deployment aortic valve prostheses

Sutureless and rapid deployment aortic valves are biological, pericardial prostheses that anchor within the aortic annulus with no more than three sutures. There are three commercially available prostheses, including 3F Enable (Medtronic, Minneapolis, USA), Perceval S (Sorin, Saluggia, Italy), and Intuity Elite (Edward Lifesciences, Irvine, USA) (*Figure 1*). The 3F Enable and Perceval S sutureless prosthesis utilizes the "memory" of the nitinol metal frame, which deploys and positions the valve with no sutures required in the case of Perceval S valves and one suture for Enable 3F valves. The Intuity rapid deployment aortic valve prosthesis operates by a different mechanism, based on a balloon-expandable stainless steel and cloth-covered frame which is implanted with the aid of a balloon catheter delivery system and expands the frame within the appropriate annular position. Three sutures are required in the case of the Edwards Intuity valve.

Differences and similarities of sutureless valves with sutured and trans-catheter valve prostheses

There are several key similarities between sutureless and rapid deployment aortic valves *vs.* conventional prostheses for AVR. Both approaches will require surgical incisions, which can be performed using a full median sternotomy incision or alternatively, the use of minimally invasive incisions such as ministernotomy and minithoracotomy. Similarly to the traditional approach, sutureless valves do not preclude the need for CPB and aortic cross-clamping. In terms of surgical technique, the diseased valve is excised in either approach, to allow for the sutureless prosthesis to be deployed and positioned to minimize as much as possible paravalvular leak.

There are also several critical differences between the implantation of a sutureless valve *vs.* a traditional stented aortic prosthesis. The nature of sutureless valves is that these do not require extensive placement and tying of sutures. Subsequent to diseased valve excision, the sutureless and rapid deployment valve prostheses are sized and deployed requiring not more than three locking sutures to adequately attach to the aortic root orifice. This may translate into reduced operation duration, especially when a minimally invasive access is used to approach the aortic valve, the latter traditionally been thought to be associated with longer operative times due to complexity and learning curve (14-17).

Whilst sutureless valves is in principle based on a similar technology to TAVI prosthesis, the former does not require crimping of the pericardium. The sutureless surgical approach provides direct visualization of the implantation and target orifice location, in contrast to TAVI where visualization is achieved indirectly via the use of fluoroscopy. Current TAVI protocols do not involve excision of the diseased calcified aortic valve, in contrast to SU-AVR. Furthermore, calcium remove in sutureless aortic valve surgery may be effective in reducing brain embolic showers and injuries in comparison to TAVI, however, this hypothesis remains to be demonstrated in clinical studies.

Why sutureless or rapid deployment aortic valves?

Reduction in cross-clamp and CPB time

It is well established in the cardiothoracic surgical literature that extended CPB and aortic cross-clamping durations are significant, independent risk factors for mortality and morbidity in cardiac surgery (18-20). A recent retrospective analysis of 979 patients with aortic valve stenosis demonstrated that aortic cross-clamp time was a significant independent predictor of cardiovascular morbidity (21). A reduction in aortic cross-clamp demonstrated better morbidity outcomes, particularly in patients with a reduced left ventricular ejection fraction (LVEF) ≤40% or in patients in diabetes mellitus. Therefore, any technique which shortens cross-clamp or CPB time will have the potential to decrease the risk of complications and reduce long-term mortality, even after considering the latest and most sophisticated methods of myocardial protection.

The main advantage offered by SU-AVR is a reduction in cross-clamp and CPB duration, due to fewer placement and tying of sutures. From a recent meta-analysis by the International Valvular Surgery Study Group (IVSSG) (13), 12 observational reports were identified for quantitative analyses. The pooled cross-clamp and CPB duration for isolated AVR using a sutureless prosthesis was 56.7 and 33 min, respectively, half of that compared to values reported by the Society of Thoracic Surgeons (STS) National Database for C-AVR. Thus, the reduction of cross-clamp and CPB time with sutureless or rapid deployment aortic valves may improve results in all patients, but may particularly be beneficial in patients with significant underlying comorbidities and high surgical risk profiles. As such, the indication for operations is appealing in higher risk patients and may become standard of care once long term results have demonstrated efficacy and durability. Additionally, the use of SU-AVR may be particularly reasonable in higher risk patients who need to undergo AVR with concomitant cardiac surgery, complex operations with multiple interventions to minimize operational durations and improve outcomes (22-25).

Facilitates minimally invasive surgery

Minimally invasive aortic valve replacement (MIAVR) has shown to produce similar efficacious outcomes as C-AVR, but with decreased hospitalization, reduction in sternal wound complications, reduced surgical trauma and improved cosmesis (26). However, the minimally invasive approach has not disseminated widely, since associated with greater technical difficulty, longer cross-clamp and CPB durations and a longer and more difficult learning curve. As such, opponents of MIAVR claim that potential advantages are counterbalanced by longer operation durations, which are associated with poorer outcomes. Furthermore, no study has demonstrated any survival advantage or marked reduction in major complications after MIAVR compared with C-AVR. Recent meta-analyses (7,27,28) have also demonstrated similar conclusions. One aspect of the technical difficult which arises in MIAVR is the placement and tying of sutures through a smaller incision. Therefore, the use of sutureless aortic valves has the potential to simplify the MIAVR procedure, by avoiding the need to suture the aortic valve to the annulus through a small incision and limited surgical field. It is likely that MIAVR, with a reduction in operative times using sutureless prostheses, may record further improvements in results, particularly in critically ill patients at the highest operative risk. Studies have shown that there has been a significant increase in the use of minimally invasive approaches in sutureless aortic valve surgery. It is like that with time, as surgeons traverse the learning curve, sutureless aortic prostheses will be increasingly used to facilitate the advantages of the minimally invasive approach without the detrimental caveats of increased cross-clamp and CPB durations.

Excellent hemodynamic outcomes

Paravalvular leak is an important complication that always has to be considered when assessing the outcomes of implantation of a prosthetic valve. Recent evidence from TAVI trials demonstrates a significant correlation between paravalvular leak and poorer outcomes. For example, in a recent meta-analysis by Athappan *et al*., moderate or severe paravalvular leak was prevalent in 11.7% of patients (29), and similarly in the PARTNER trial (30), echo core lab results demonstrated prevalence of 12%. Paravalvular leak was demonstrated to be a significant predictor of 1-year mortality, even after multivariable adjustment.

Different from TAVI and similar to C-AVR, the nature of the SU-AVR approach is that it involves excision of the calcified valve and prosthesis placement under direct visualization on a still heart, which may reduce the risk of misplacement and paravalvular leak. In a recent meta-analysis, the pooled rates of paravalvular leaks were 2-4% at latest follow-up. This study also showed that paravalvular leak complications appeared to be a function of the SU-AVR learning curve, with significant reduction over time.

Additionally, current results suggest that SU-AVR may be associated with excellent hemodynamic outcomes, with very low transvalvular gradients and reduced risk of patient-prosthesis mismatch (PPM). In a recent randomized trial comparing the Edwards Intuity sutureless valve with a conventional stented bioprosthesis (8), significantly lower mean transvalvular gradient (8.5 *vs.* 10.3 mmHg) and lower PPM (0% *vs.* 15%) was found for the sutureless cohort. Although a matter of a continuous debate, PPM has been associated with reduced symptoms relief, lesser regression of left ventricular hypertrophy, and reduced event-free late survival (31,32). Patients who are particularly at risk of PPM include those with smaller annulus (33,34). Wilbring *et al.* (35) showed that patients with smaller aortic annulus were found to be predominantly small, obese, elderly females with multiple comorbidities. As such, aortic root enlargement and use of stentless may assist in reducing PPM complications; however, these interventions add technically complexity, and certainly extend operative duration significantly, thus translating into increased surgical risk.

As such, high risk subset patients will more likely than others to benefit from SU-AVR, a promising alternative with excellent hemodynamic performance that facilitates minimally invasive and less traumatic approaches while minimizing CPB and aortic cross-clamp durations.

Current evidence

Recently, a systematic review and meta-analysis was performed by an international collaborative group of surgeons performing sutureless surgery. A total of 12 relevant articles were identified and included for qualitative and quantitative analysis. The pooled results demonstrated reduced cross-clamp and CPB durations of 56.7 and 46.7 min for all SU-AVR, respectively, which are lower compared to values current reported in the literature for AVR using conventional prosthesis. The rate of paravalvular leakage was low (3.0%) and excellent hemodynamic outcomes were achieved at up to 12-month follow-up. Furthermore, there was a significant negative correlation between rate of paravalvular leak and mid-point of study, suggesting that this complication is a function of learning curve, and is likely to even further reduce in the future as the learning curve for surgeons is traversed.

SU-AVR *vs.* C-AVR

There have been several comparative studies published on sutureless *vs.* C-AVR. Shrestha *et al.* (36) compared 120 isolated AVR procedures in patients with a small annulus, 70 patients with conventional valves and 50 patients with sutureless valves. CPB and cross-clamp times were significantly shorter in the sutureless valve group compared to conventional (CBP: 58.7 *vs.* 75.3 min; cross-clamp: 30.1 *vs.* 58.7 min). At up to 5-year follow-up, no significant differences in mortality was noted between the cohorts. As such, this study indicates the potential role of SU-AVR for reducing operative time and facilitating minimally access in geriatric patients with small aortic roots.

Gilmanov *et al.* (37) published a series of 515 patients undergoing right anterior minithoracotomy AVR, 269 with conventional prostheses and 246 using sutureless prostheses. CPB and cross-clamp time was significantly shorter in the sutureless group, whilst in-hospital mortality, perioperative strokes and pacemaker implantations were comparable. At median follow-up of 21 months, there was similar actual survival rate for all patients, but survival was 2-fold higher in octogenarian patients with sutureless compared to sutured valves (100% *vs.* 50%, P=0.02). This is likely due to this group susceptible to high mortality risk and morbidities under the duress of C-AVR compared to more rapid minimally invasive sutureless surgery.

In a German single-center propensity-matched study by Pollari *et al.* (38), 82 matched pairs of SU-AVR and C-AVR were studied. There were no differences in hospital deaths, but cross-clamp and CPB was significant shorter in the sutureless group. There was also a significant reduction in required blood transfusions, shorter intensive care unit and intubation time, as well as lower postoperative atrial fibrillation rate and respiratory insufficiency in the SU-AVR group. The authors concluded that the reduction in procedural time for SU-AVR is associated with better clinical outcomes in the SU-AVR group compared with C-AVR. In this study, a significant reduction in costs related for diagnostics and hospital stay was also found in the sutureless group (13,498 €) *vs.* conventional stented prostheses (17,905 €). This difference in cost was mainly attributed to reduced hospital stay (33% difference in cost) and diagnostics, radiology and laboratory tests (36% difference in cost).

Borger *et al.* (8) performed the only randomized multicenter trial published to date on minimally invasive SU-AVR *vs.* C-AVR. Forty-six patients with Edwards Intuity sutureless valve were compared to 48 patients with a conventional aortic valve. Similar to previous studies, minimally invasive SU-AVR was associated with significantly

lower cross-clamp durations (41.3 *vs.* 54 min), but similar CPB time (68.8 *vs.* 74.4 min). There was no difference in early clinical outcomes or quality of life measures between the two groups. SU-AVR patients had superior mean transvalvular gradients (10.3 *vs.* 8.5 mmHg). Overall, the authors conclude that sutureless valves may have a role in facilitating MIAVR.

A recent cost-analysis assessment by Pradelli and Zaniolo (39) further demonstrated that Perceval S valve was associated with less complications and with savings compared with conventional sternotomy using traditional sutured valves, mainly due to reduced surgery costs and intensive care unit (ICU)/hospital stay. The savings range from 3,600 € (Italy) to 3,900 £ (UK) for isolated C-AVR, and 6,000 € (Italy) to 6,700 £ (UK) minimally invasive sutureless approach.

Dalén *et al.* (40) recently reported early postoperative outcomes and 2-year survival after SU-AVR via a ministernotomy approach *vs.* median sternotomy with a stented bioprostheses. From a propensity-score matching analysis based on 182 SU-AVR and 383 C-AVR patients with six European centers, it was demonstrated that 30-day mortality (1.6% *vs.* 2.1%) and 2-year survival (92% *vs.* 92%) were similar between SU-AVR *vs.* C-AVR. There were significant reductions in aortic cross-clamp time (40 *vs.* 65 min) and CPB time (69 *vs.* 87 min). SU-AVR was also associated with lesser requirement for packed red blood cells but increased risk of postoperative permanent pacemaker implantation. Again, this study supports prior findings that sutureless technology may facilitate minimally invasive surgery with acceptable short and mid-term results.

SU-AVR *vs.* TAVI

D'Onofrio *et al.* (41) performed a multicenter, propensity-matched analysis of 349 conventional surgery, 38 sutureless surgery and 566 TAVI procedures. Indications for TAVI were aortic valve area <0.8 cm^2, mean transaortic gradient >40 mmHg, and associated with either porcelain aorta, high surgical risk with log EuroSCORE >20%, or other severe comorbidities such as pulmonary disease, chest irradiation, or severe liver disease. Additional criteria for SU-AVR included age >75 years and patient frailty. There was no difference in 30-day mortality between the cohorts noted. There was a non-significant trend for lower aortic regurgitation, pacemaker implantations and renal replacement therapy in the SU-AVR group compared to TAVI. However, other perioperative complications and hemodynamic outcomes were similar between the groups.

Santarpino *et al.* (42) compared 37 propensity-matched pairs of SU-AVR and TAVI cohorts. Indications for TAVI were very high surgical risk with a logistic EuroSCORE greater than 20%. Indications for SU-AVR included patient aged greater than 65 years with an indication for isolated AVR, with low frailty scores. There was no difference found between the groups in terms of in-hospital mortality, permanent pacemaker implantations, or neurological events. However, higher paravalvular leak was noted in the TAVI group compared with SU-AVR (13.5% *vs.* 0%, P=0.027). At mean follow-up of 18.9 months, there was also a higher accrual survival rate in the sutureless cohort compared to TAVI (97.3% *vs.* 86.5%). The authors concluded that sutureless valves may be the ideal first-line treatment for patients in the "gray zone" between C-AVR and TAVI.

Muneretto *et al.* (43) compared 53 patients with sutureless implants and 55 patients who underwent TAVI procedures. Patients were chosen based on having an intermediate to high risk profile, as defined by STS-PROM score >4%. Whether the TAVI or SU-AVR approach was taken was determined by a multidisciplinary heart team. TAVI was associated with higher pacemaker implantations (25.5% *vs.* 2%), peripheral vascular complications (14.5% *vs.* 0%). No difference in in-hospital mortality was noted. At 24 months follow-up, survival free from major adverse cardiac and cerebrovascular events was worse in the TAVI group compared to SU-AVR (70.5% *vs.* 91.6%). Overall, these results suggest that TAVI in moderate-high surgical risk patients may be associated with greater perioperative complications and poorer survival long-term.

Overall, the current evidence suggests that SU-AVR is a valid alternative to C-AVR with similar clinical mid-term outcomes, but shorter CPB and aortic cross-clamp duration. Compared with TAVI, SU-AVR also has similar clinical results for high risk but operable patients, but may be associated with lower incidence of paravalvular leak, likely due to accurate decalcification of the diseased valve. Valve decalcification should also theoretically reduce brain micro embolisms compared to TAVI, however, this speculation requires further investigation in future studies.

Caveats

There may be several caveats associated with the sutureless aortic prosthesis. Firstly, whilst SU-AVR is designed to simplify the technical challenge of AVR, the implantation procedure is quite different to C-AVR, and requires

proctoring for the surgeon to traverse the learning curve. Sizing the valve is absolutely important, and if the size is not ideal, paravalvular leaks, valve migration, and root dehiscence will be the catastrophic resulting complications. Given that SU-AVR is still surgical procedure with cross-clamping and CPB, associated complications associated with surgical trauma will still be present. Indeed a recent case report demonstrated transcatheter aortic valve-in-valve implantation (A-ViV) as a procedure to "rescue" a leaking sutureless self-expandable valve (44). This may be a valuable option in elderly patients with significant comorbidities, where traumatic alternatives such as C-AVR may not be ideal. Like other valves, SU-AVR is also susceptible to "stent creep", a permanent inward deflection of stent posts which may lead to valvular leak (45). Therefore, sizing is still a critical assessment step during the use of sutureless aortic valves.

There are also concerns around "stent fatigue" in sutureless valves, which may lead to longer-term paravalvular leak complications (45). However, given that most of the current studies have only reported short-term outcomes and complications, this potential complication requires further investigation in long-term studies.

There have also been reports of post-operative conduction disorders following implantation of the Perceval S sutureless valve. In an observation study of 31 patients who underwent Perceval S implantation, four patients (13.3%) required permanent pacemaker implantation due to total atrioventricular block (46).

Furthermore, there is a still a lack of long-term follow-up data available for sutureless valves and limited worldwide experience. Mid-term durability data for SU-AVR have been reported for 3-5 years follow-up, which is considerably less compared to the 20-25 years follow-up reported for some stented prostheses. The majority of current evidence is limited to European centers. Long-term durability and susceptibility to structural valve degeneration is still unknown for this new technology, and as such, it remains a challenge to project or predict long-term safety and efficacy rates.

IVSSG Sutureless Projects

There is still a paucity of robust clinical evidence for SU-AVR, limited to short-term studies with small sample sizes and inadequate statistical power. The lack of robust data prevents the development of high-quality evidence based guidelines. An international collaborative effort will be required to allow sufficiently powered analyses to best evaluate sutureless technology.

Recently, the IVSSG has formulated to conduct the Sutureless Projects, set to be the largest international collaborative group to investigate this technology. The IVSSG Sutureless Projects comprises over 36 surgeons from 27 centers worldwide, and it is envisaged that this global collaborative effort will shape clinical guidelines, optimize patient outcomes, and set future directions of research for SU-AVR.

The primary objectives of the Sutureless Projects will be to generate an international multi-center retrospective and prospective registry database for SU-AVR, which will serve as a robust platform to perform powered analyses, propensity-score matching and risk-stratified analyses. Other objectives of this project will be to: assess short-term and long-term hemodynamic profiles and safety outcomes, to compare ministernotomy *vs.* minithoracotomy *vs.* full sternotomy SU-AVR approaches, as well as to assess outcomes for the use of SU-AVR in complex cardiac procedures including coronary artery bypass grafting (CABG), double valve surgery etc. The Sutureless Projects will be the largest collaborative effort with the primary aim of providing the best available evidence for sutureless technology.

Conclusions

Despite the recent introduction of sutureless technology, current evidence suggests SU-AVR as a promising alternative to C-AVR, with the major advantages being a reduction in cross-clamp and CPB duration. There is limited evidence outlining its safety, efficacy, hemodynamic profile, and perioperative complications. However, this evidence is mainly constrained to observational studies, with a distinct absence of robust, adequately powered randomized evidence. An international collaborative effort led by the IVSSG will hopefully set up to provide clinical robust evidence for the safety, efficacy and long-term complications profile for sutureless aortic valve technology.

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