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REVIEW

ADULT CARDIAC

Transapical aortic 'valve-in-valve' procedure for degenerated stented bioprosthesis

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Summary

Standard surgical aortic valve replacement with a biological prosthesis remains the treatment of choice for low- and mid-risk elderly patients (traditionally >65 years of age) suffering from severe symptomatic aortic valve stenosis or insufficiency, and for young patients with formal contraindications to long-lasting anticoagulation. Unfortunately, despite the fact that several technical improvements have noticeably improved the resistance of pericardial and bovine bioprostheses to leaflet calcifications and ruptures, the risk of early valve failure with rapid degeneration still exists, especially for patients under haemodialysis and for patients <60 years of age at the time of surgery. Until now, redo open heart surgery under cardiopulmonary bypass and on cardioplegic arrest was the only available therapeutic option in case of bioprosthesis degeneration, but it carried a higher surgical risk when elderly patients with severe concomitant comorbidities were concerned. Since a few years, the advent of new transcatheter aortic valve procedures has opened new horizons in cardiac surgery and, in particular, the possibility of implanting stented valves within the degenerated stented bioprosthesis, the so-called 'valve-in-valve' (VinV) concept, has become a clinical practice in experienced cardiac centres. The VinV procedure represents a minimally invasive approach dedicated to high-risk redo patients, and published preliminary reports have shown a success rate of 100% with absence of significant valvular leaks, acceptable transvalvular gradients and low complication rate. However, this procedure is not riskless and the most important concerns are about the size mismatch and the right positioning within the degenerated bioprosthesis. In this article, we review the limited available literature about VinV procedures, underline important technical details for the positioning and provide guidelines to prevent valve–prosthesis mismatch comparing the three sizes of the only commercially available transapical device, the Edwards Sapien™, with the inner diameter of three of the most commonly used stented bioprostheses.

Keywords: Transapical aortic valve implantation • Valve-in-valve procedure • High-risk patients • Redo cardiac surgery • Degenerated aortic bioprosthesis

INTRODUCTION

Aortic valve stenosis (AS) is the most frequent valvular heart disease in developed countries, and affects the elderly population [1, 2]. Aortic valve replacement (AVR) with cardiopulmonary bypass, cardioplegic arrest and aortic cross-clamping through a median sternotomy, an upper mini-sternotomy or a right mini-thoracotomy, represents, for the time being, the treatment of choice for severe AS, and provides good operative outcomes and long-term results [3, 4]. Patients also affected by regurgitant aortic valves or by aortic endocarditis are eligible for standard AVR and, following the standard international guidelines, all patients over the age of 65 years at the time of surgery, or younger patients with contraindications to the long-lasting anticoagulation therapy, are ideal candidates for the implantation of a biological prosthesis.

In particular, stented bioprostheses, both pericardial and porcine, do not require anticoagulation, are easy to be implanted with a standardized and reproducible surgical technique, have excellent haemodynamic performances and, thanks to the improved treatments (anticalcification) and construction, have an increased longevity [5–8]. However, despite all attempts to decrease the incidence of leaflet calcifications and structural failure, early degeneration can occur (especially in young patients and in patients under haemodialysis) and, nowadays, the treatment of choice for the replacement of a malfunctioning bioprosthesis is a cardiac reoperation with a mortality rate that lies below 5% in the latest series [9–13]. Unfortunately, despite the fact that the redo itself is not an independent risk factor for re-AVR, redo valve surgery in the elderly high-risk patient with severe comorbidities is still related to a higher operative risk with increased hospital mortality and postoperative complication rate [13–15].

Thus, the transcatheter aortic valve procedure plays a key role, and the possibility of implanting stent-valves into failed stented bioprostheses, the 'valve-in-valve' (VinV) concept, represents an alternative for redo high-risk patients [16–19]. As regards to the transapical access for aortic VinV procedures, we are observing a burden in the number of performed cases, and experienced centres employ this technique routinely for selected cases. Moreover, a few VinV case reports and limited series have appeared in the literature showing a good outcome with low transvalvular gradients, no major leaks and few postoperative complications [18]. Nevertheless, the risk of valve–prosthesis

mismatch still exists [20]. In this article, we underline important details for transapical VinV in stented bioprostheses, we expose the review of clinical results and haemodynamic parameters and, in order to avoid the mismatch, we suggest guidelines for the sizing comparing the transapical Sapien™ platform with three common stented bioprostheses.

TECHNICAL ASPECTS

Edwards Sapien™

The only available transapical stent-valve is the Sapien™ (Edwards Lifesciences, Irvine, CA, USA) (Fig. 1A), a balloon-expandable stent with an inner bovine pericardial valve. It is available in two sizes, 23 and 26 mm, and is inserted using the Ascendra™ delivery system. Recently, a new XT generation (Fig. 1B), with the Ascendra II delivery system, was launched with some innovations such as the cobalt–chromium stent, a smaller delivery system (22F and 24F), a semi-closed leaflet profile and a bigger 29 mm size (for transapical).

Patients selection

Symptomatic patients with degenerated bioprostheses presenting with severe comorbidities are candidates for transapical aortic VinV (high-risk). The logistic EuroSCORE and the STS score calculate the predicted mortality, and the inclusion and exclusion criteria are similar to those proposed for standard TAVI [21, 22]. However, due to the fact that during VinV procedures in stented bioprostheses the fixation of the valve is guaranteed by radial forces applying against the rigid ring (unlike in standard TAVI where heavy calcifications of the annulus and valve are required for fixation), not only stenosis but also intra-prosthetic incompetence due to leaflet ruptures or tears is treatable with this approach. Bioprosthetic endocarditis remains a formal contraindication because the infected bioprosthetic leaflets are not removed during the procedure. The presence of a concomitant mitral prosthesis seems not to interfere with aortic VinV, and candidates for VinV procedures require neither specific preoperative exams nor cardiac imaging and do not even require an injected cardiac scan to measure the annulus, given that the size of the valve is pre-determined by the size of the bioprosthesis.

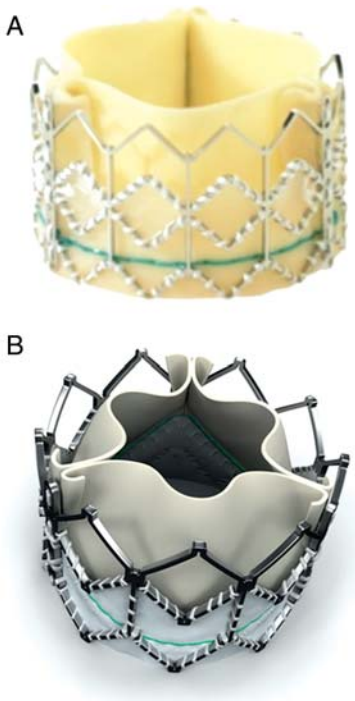

Figure 1: (A) the Edwards Sapien™ valve; (B) the new Sapien™ XT generation available in three sizes for transapical applications: 23, 26 and 29 mm.

Sizing (valve–prosthesis match)

During the implantation of a stent-valve within a stented bioprosthesis, there is a risk of severe mismatch, creating either a relevant transvalvular gradient, when the orifice of the bioprosthesis is too small compared with the stent-valve diameter, or a stent-valve embolization when the stent-valve is too small compared with the inner size of the prosthesis.

In order to identify which stent-valve fits perfectly into different sizes of a given stented aortic bioprosthesis, we measured the internal diameter of three common aortic bioprostheses, from the labelled size of 21–25 mm, using the Hegar cervical dilators (ranging from 15 to 27 mm). Then, we suggested which of the sizes of the currently available Sapien™ valve is the most indicated for aortic VinV when a degenerated St Jude Medical Trifecta™, Sorin Biomedica Mitroflow™ or Edwards Perimount™ Magna Ease is in place (Table 1).

In order to simplify the decision-making process, we can state that all 23 mm Sapien™ stent-valves implanted into the 21 mm size stented bioprosthesis are at risk for high postoperative transvalvular gradient (expected gradient >30 mmHg in clinical practice) [18, 20]. Thus, we suggest careful consideration of this option only for inoperable elderly patients with limited body surface areas (<1.8 m^2). Concerning the 23 and 25 mm sizes, the measured inner diameters can easily accept the 23 mm Sapien™. In the end, the 27 mm Sorin Mitroflow™ can accept a 23 mm Sapien™, whereas the 27 mm Trifecta™ and Perimount™ require the implantation of a 26 mm Sapien™ valve.

Imaging

TAVI requires high-quality imaging based on echocardiography and angiography. However, during VinV procedures, angiographies are almost no longer necessary and the procedure can be performed under transoesophageal echocardiographic and fluoroscopic control without contrast. Effectively, the positioning of the fluoroscopic machine on a plane perpendicular to the aortic valve is very easy and does not require repeated angiographies, given that the ring of the bioprosthesis is radiopaque (Fig. 2A). Moreover, during stent-valve positioning, the ring acts as a landmark and, again, angiographies are not necessary (see the next section) (Fig. 2B). In regard to postoperative control, the transoesophageal echocardiogram can confirm good valve placement and function within the diseased bioprosthesis: if the Sapien™ is well positioned, peri-prosthetic leaks will not appear as the stent-valve expands into a prosthetic cylinder without relevant burden calcifications (usually, degenerations and tears appear in the prosthetic leaflets). Fluoroscopy can show the circumferential stent-valve deployment whereas an angiography can confirm coronary patency (Fig. 2C and D).

Table 1: Measured inner diameter of three commonly used aortic bioprostheses with the corresponding suggested Sapien™ size

	Labelled size (mm)	Inner diameter from industry (mm)	Measured inner diameter (mm)	Suggested Sapien™ size (mm)
Sorin Biomedica Mitroflow™	21	17.3	17	23[a]
	23	19	19	23
	25	21	20	23
	27	22.9	22	23
Edwards Perimount™ Magna Ease	21	20	18	23[a]
	23	22	21	23
	25	24	22	23
	27	26	24	26
St Jude Medical Trifecta™	21	18.3	18	23[a]
	23	20.3	20	23
	25	22.1	22	23
	27	24.1	24	26

[a]The suggested Sapien™ size will create high transvalvular gradients because of the too small inner diameter of the bioprosthesis. This option must be carefully considered only for inoperable patients.

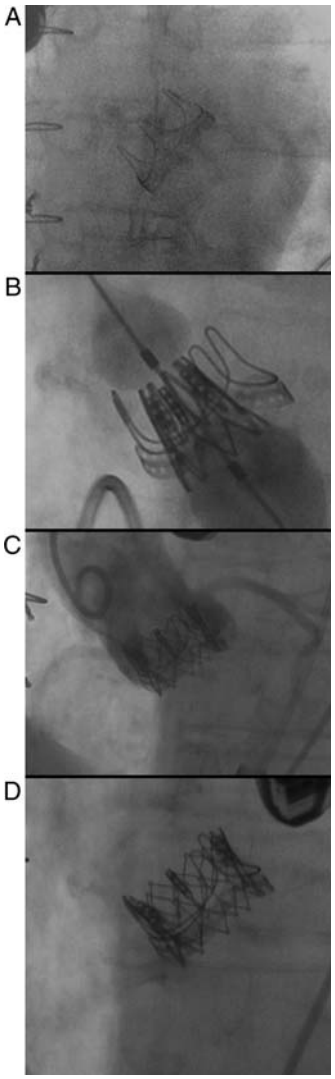

Figure 2: Fluoroscopic images from a VinV case: (A) the fluoroscopic machine is positioned perpendicular to the ring of the bioprosthesis; (B) valve positioning and implantation are facilitated by the presence of the ring and do not require angiographies; (C) angiographic control; (D) final result.

In conclusion, VinV does not require high doses of contrast and can be proposed for patients suffering from chronic renal failure [23].

Positioning

According to the experience obtained by the first VinV implanters, we suggest keeping the lower margin of the Sapien™ 2–3 mm below the radiopaque margin of the ring (Fig. 2D). Using this stratagem, the lateral shape of the Sapien™ remains rectangular or, at least, with the proximal diameter a bit smaller than the distal diameter (inverted trunk pyramid): in this way, valve function is preserved without risk of stenosis or malfunctioning. If, on the contrary, the stent-valve is positioned too low, the resulting lateral clepsydra shape can modify the Sapien™ geometry with the risk of stenosis and early degeneration. To better describe VinV stent-valve positioning, two drawings in Figs 3 and 4 explain this mechanism in standard Primount™ and Mitroflow™ valves.

Implantation

Stent-valve implantation follows, basically, the same rules of standard TAVI. Nevertheless, there is a general consensus in not performing valvuloplasty before, because of a potential risk of calcium embolization from the degenerated bioprosthesis.

RESULTS

Table 2 summarizes clinical and haemodynamic data from published aortic VinV series with 38 successful transapical procedures performed in 38 patients with degenerated stented bioprostheses [24–28]. During our personal clinical experience, we performed six aortic VinV procedures and, despite the limited experience, we can confirm that this technique has acceptable postoperative results. Haemodynamically, there were no leaks and the measured mean gradient was 18 mmHg. All patients were rapidly

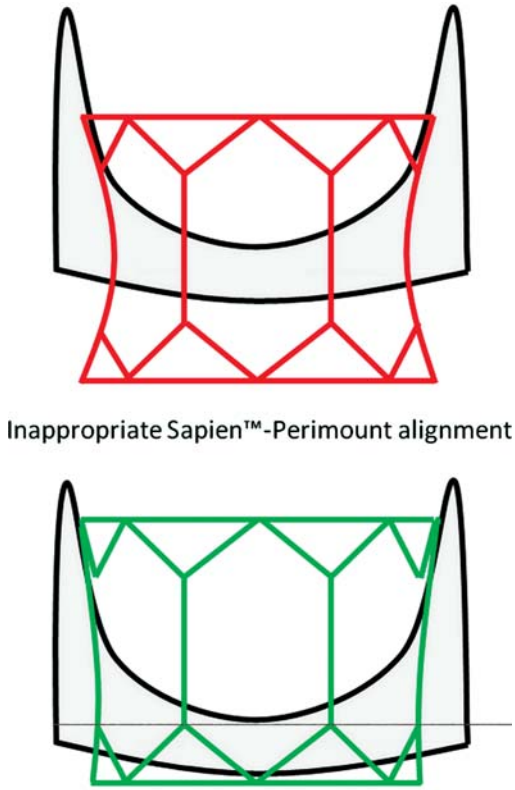

Figure 3: The schematic positioning of a Sapien™ within an Edwards Perimount™ aortic bioprosthesis.

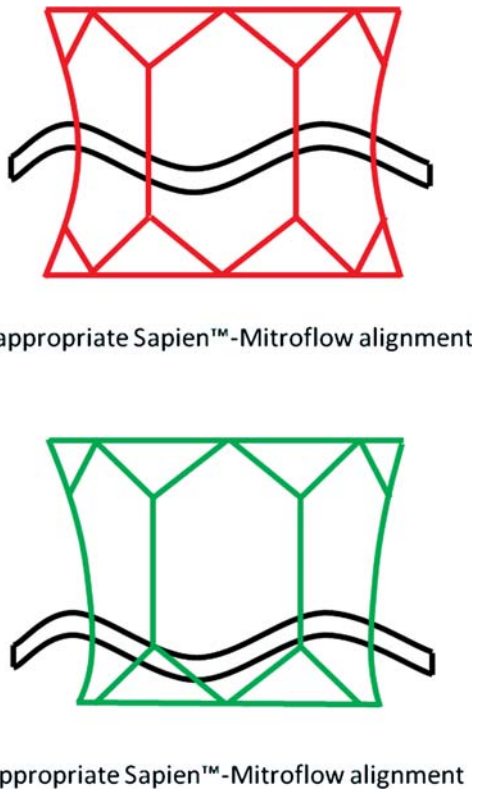

Figure 4: The schematic positioning of a Sapien™ stent-valve within a Sorin Biomedica Mitroflow™ aortic bioprosthesis.

extubated, they all left the intensive care unit at postoperative Day 1 and there were no relevant complications. In one case, we treated a patient with a degenerated 21 mm bioprosthesis and, as expected, we measured a high transvalvular peak gradient of 35 mmHg. The patient, an 86-year-old lady with a EuroSCORE of 51% and a porcelain aorta, was considered inoperable, and the VinV procedure was the only available option: in spite of the high gradient, she left our department without signs of cardiac decompensation. In another similar case with a 21 mm size bioprosthesis, Seiffert *et al.* [27] also implanted a 23 mm Sapien™ valve, with a transvalvular gradient of 35 mmHg and a good outcome [27], whereas Silva *et al*. [20] explanted the Sapien™ and the 21 mm Hankock bioprosthesis 1 year after VinV for progressive dyspnoea and a mean gradient of 43 mmHg. Following these findings, we do not suggest aortic VinV in the 21 mm bioprosthesis.

Our clinical results are in line with the published literature and the procedural success rate is 100% in all centres, confirming that valve positioning and implantation are feasible. However, despite these good operative results, one patient at extreme surgical risk (EuroSCORE >80%) died within 30 days from low cardiac output, and this event confirms the high-risk profile of this subgroup of patients [27].

Concerning the valve sizing, among a total number of 38 Sapien™ valves, 36 were 23 mm and 4 were 26 mm. This trend confirms our findings during the measurement of three commercial bioprostheses: the 23 mm Sapien™ fits within the 21 (risk of high gradients), 23 and 25 mm tested bioprostheses, and also into the 27 mm Sorin Mitroflow™, whereas the 26 mm Sapien™ fits into the 27 mm Perimount™ and Trifecta™.

However, in these first reports, the 26 mm Sapien™ was also employed in one 25 mm Edwards Perimount™, in one 25 mm CE Porcine and in two 25 mm Medtronic Hancock™, suggesting that the larger inner diameter of the 25 mm bioprosthesis can accept both the 23 and 26 mm stent-valves without risk of high gradients or embolization.

DISCUSSION

Results from limited transapical aortic VinV series suggest that this technique, dedicated to high-risk patients, guarantees acceptable transvalvular gradients in 23 and 25 mm degenerated bioprostheses with absence of relevant leaks and complications. VinV in the 21 mm bioprosthesis creates high gradients and should be considered only in inoperable patients. Thus, a few topics must be underlined in order to standardize the technique and facilitate the decision-making process for the sizing.

(i) The procedure does not require a specific preoperative cardiac imaging to measure the aortic annulus because the stent-valve sizing is determined by the inner diameter of the previously implanted bioprosthesis. We have personally measured the inner diameter of three commonly used bioprostheses, and we can say that our data do not differ from data given by the industry except for the Edwards Perimount™ Magna Ease where the given diameters are overestimated by 2 mm. Thus, a CT scan can be useful when a doubt exists about the real internal diameter of a bioprosthesis.

Table 2: Transapical aortic 'VinV' procedures for degenerated stented bioprostheses: review

Authors	Degenerated bioprosthesis	Sapien™ size	Success rate (%)	Mean transvalvular gradients (mmHg)	Leaks	30-day mortality (%)
Ferrari *et al.* [18]	1× Mitroflow 21 mm 2× Mitroflow 23 mm 1× Mitroflow 25 mm 1× Perimount 23 mm 1× Perimount 25 mm	6× 23 mm	100	18	No	0
Maroto *et al.* [24]	2× Hancock 25 mm.	2× 23 mm	100	15	2× Grade 1	0
Webb *et al.* [25]	1× Perimount 21 mm 3× Perimount 23 mm 2× Perimount 25 mm 1× Mosaic 21 mm 1× Ionescu Shiley 21 mm	7× 23 mm 1× 26 mm	100	20	2× Grade 1	0
Pasic *et al.* [26]	2× Hancock 21 mm 3× Hancock 23 mm 1× Mosaic 23 mm 2× Perimount 21 mm 1× Perimount 23 mm	9× 23 mm	100	19	No	0
Seiffert *et al.* [27]	1× Biocor 23 mm 1× Hancock 21 mm 1× Hancock 23 mm 1× Hancock 25 mm	4× 23 mm	100	19	No	25 (one extreme-risk patient died from low cardiac output)
Kempfert *et al.* [28]	3× Perimount 21 mm 2× Hancock 25 mm 1× Mosaic 21 mm 1× Epic 21 mm 1× Mitroflow 23 mm 1× CE porcine 25 mm	6× 23 mm 3× 26 mm	100	11	2× Grade 1	0

(ii) Once the inner diameter is determined, we suggest identifying the ideal stent-valve size that fits into the bioprosthesis. The 23 mm Sapien™ valve seems to be the most usable size because it fits into the mostly used stented bioprostheses: the 23 mm and the 25 mm. The 21 mm size bioprosthesis can also be treated by VinV, but high gradients are expected and, then, we strongly encourage the implantation of a 23 mm or a larger bioprosthesis during standard AVRs because it will allow further VinV options.

(iii) During the procedure, the ring of the bioprosthesis is useful for fluoroscopy orientation and valve positioning. VinV does not require high doses of contrast; it may even be performed without angiographies and can be performed in patients with chronic renal failure.

(iv) There is a consensus among expert implanters to not perform valvuloplasty before stent-valve implantation (risk of embolization).

(v) The stent-valve is implanted within the stented bioprosthesis with the lower margin 2–3 mm below the margin of the ring. This positioning guarantees correct valve functioning [28].

(vi) Concerning the durability of aortic VinV, we do not yet have mid-/long-term results because only a few patients have a follow-up longer than 1 year.

Another concept that should be taken into consideration is the possibility, as long as big sizes are a guarantee (>23 mm), of implanting biological bioprostheses in patients younger than 65 years of age: in fact, the risk of early degeneration can be compensated by the absence of long-lasting anticoagulation and by VinV options. However, bigger clinical series and mid-/long-term results are necessary before changing the clinical practice.

CONCLUSION

This limited clinical experience confirms that transapical VinV procedures for degenerated stented bioprostheses do not require a specific cardiac imaging (with limited contrast injections) and guarantee good results with acceptable gradients (excepting for the 21 mm bioprosthesis) and no major leaks. Concerning the sizing, the 23 mm Sapien™ seems to be the most useful stent-valve because it fits within the most widely used stented bioprostheses: the 23 mm and the 25 mm. In view of all of these facts, we recommend implanting a large bioprosthesis (equal or superior to 23 mm diameter) during standard AVRs in order to prevent size mismatch in case of VinV.

Conflict of interest: none declared.

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