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’ (VivV) concept, has become a clinical practice in experienced cardiac centres. The VivV 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 VivV 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’ (VivV) concept, represents an alternative for redo high-risk patients [16–19]. As regards to the transapical access for aortic VivV 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 VivV 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 bioprosthesis present-
ing 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 exclu-
sion 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 con-
traindication because the infected bioprosthesis 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 pre-
operative 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.

Sizing (valve–prosthesis match)

During the implantation of a stent-valve within a stented bio-
prosthesis, there is a risk of severe mismatch, creating either a
relevant transvalvular gradient, when the orifice of the bio-
prosthesis 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 differ-
ent 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 trans-
valvular gradient (expected gradient >30 mmHg in clinical prac-
tice) [18, 20]. Thus, we suggest careful consideration of this
option only for inoperable elderly patients with limited body
surface areas (<1.8 m²). 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, angiogra-
phies 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 angiogra-
phies, 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 pla-
cement 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 rel-
levant burden calcifications (usually, degenerations and tears
appear in the prosthetic leaflets). Fluoroscopy can show the cir-
cumferential stent-valve deployment whereas an angiography
can confirm coronary patency (Fig. 2C and D).

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.
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 malfunction. 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 stabilized.
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 Hancock 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.
(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.

REFERENCES


