



Valve-in-valve transcatheter aortic valve replacement for the degenerated rapid deployment Perceval™ prosthesis: technical considerations

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Abstract: Rapid deployment aortic valve prostheses or “sutureless valves” (SV) present a favorable hemodynamic and clinical safety profile but remain sensitive to structural valve degeneration (SVD) leading to valve dysfunction. In patients with SVD, valve-in-valve transcatheter aortic valve replacement (ViV TAVR) has become the preferred approach because of its high procedural success rate and the inherent risk of redo-surgery in an often-elderly population. However, careful consideration of anatomical characteristics and features of the surgical prosthesis is needed to assess feasibility of the ViV procedure, including meticulous attention to avoid coronary obstruction, device malpositioning, and high residual transprosthetic gradients. We systematically describe technical considerations for the transcatheter treatment of failing Perceval™ SV. By design, Perceval™ has the potential to serve as an ideal docking station for a transcatheter ViV procedure, offering a clearly visible radiopaque frame, circumferential expansion capabilities, and a low risk of coronary obstruction and sinus sequestration. We describe procedural tips and tricks and provide our own case experience. In a series of 784 Perceval™ implants, incidence rate of severe SVD was 0.54% per patient year (15 patients), of which only 9 were scheduled for and underwent successful ViV TAVR. Treatment resulted in all patients in clinical improvement and significant reduction of transprosthetic gradients and no residual aortic valve regurgitation.

Keywords: Valve-in-valve (ViV); structural valve degeneration (SVD); Perceval™

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Introduction

Bioprosthetic surgical aortic valve failure requiring reintervention is a frequent clinical problem with event rates ranging from 5% to 20% at 10-year follow-up, depending on the valve type (1,2). Most recent bioprostheses present novel

tissue treatment solutions primarily targeting a reduction in leaflet calcification leading to improved valve durability (3,4). Rapid deployment aortic valve prostheses [so-called “sutureless valves” (SV)] by design privilege a favorable hemodynamic profile, in part because valve anchoring relies on self-expanding

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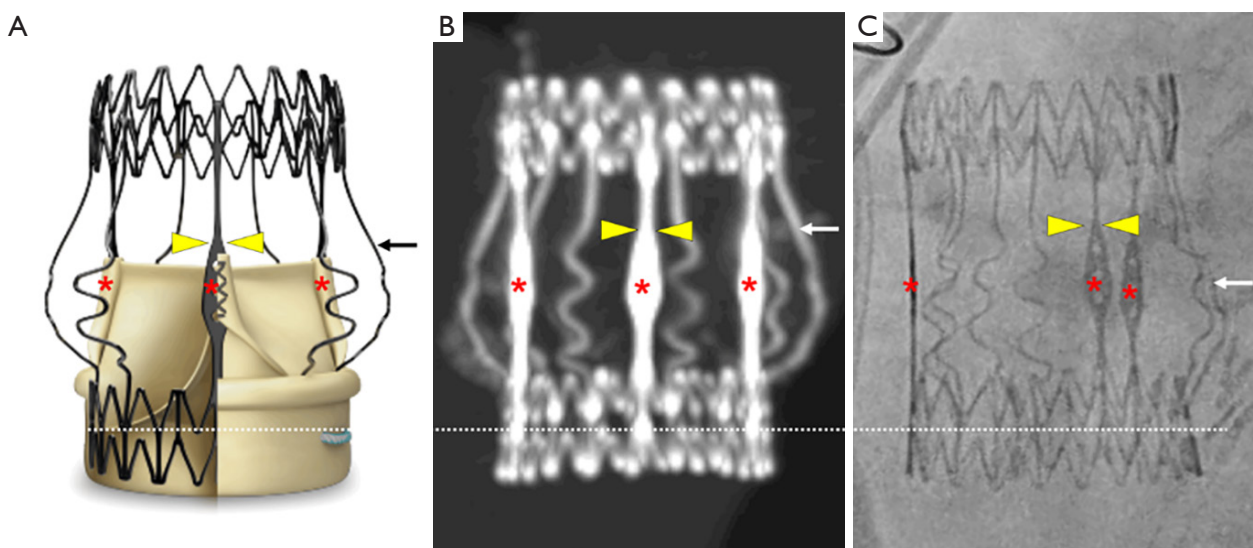


Figure 1 Perceval™ landmarks. Schematic drawing (A), CT (B), and fluoroscopic image (C) of Perceval™. The valve leaflets' nadir is positioned approximately in the middle of the two crowns of the inflow ring (dotted line). The valve commissures are aligned with the three stent columns (red asterisks), with the column taper indicating the valve leaflets' highest point (yellow opposing arrowheads). The Valsalva sinuses can be identified at the level of the sinusoidal struts (arrows). CT, computerized tomography.

properties of the valve frame at the level of the aortic annulus, without the need of multiple sutures on a suture ring. Therefore, the use of SV makes surgery faster and less invasive, on top of showing excellent early and late outcome, and a very low incidence of structural valve degeneration (SVD), even in challenging patients (5,6).

While redo cardiac surgery remains a valid option for symptomatic patients with bioprosthetic valve failure, valve-in-valve transcatheter aortic valve replacement (ViV TAVR) has become the preferred approach because of its high procedural success rate (>90%) and the inherent risk of redo-surgery in an often-elderly population (7). However, careful consideration of anatomical characteristics and features of the surgical prosthesis is needed to assess feasibility of the procedure. A systematic approach to planning of ViV TAVR has been described elsewhere, with meticulous attention to avoid coronary obstruction, device malpositioning and high residual transprosthetic gradients (8). We here systematically describe practical considerations for the transcatheter treatment of failing Perceval™ SV (Corcym srl, Milan, Italy).

All procedures performed in this study were in accordance with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from the patient for publication of this manuscript and any accompanying videos.

Perceval™ as a receptor for a transcatheter heart valve (THV)

SV have been designed to combine best of both worlds, incorporating decades of surgical bioprosthetic valve technology into THV-like stent frames, hereby improving hemodynamic performance and simplifying valve fixation. However, in case of SVD of the Perceval™ SV, redo cardiac surgery can be challenging, with a risk of annular injury and the need for root replacement. This is particularly relevant when use is considered in young patients, who may require multiple future procedures.

While initially not designed to serve as a docking station for transcatheter valves in case of SVD, Perceval™ combines several features that are of particular interest for a safe performance of ViV procedures. First, the nitinol radiopaque stent frame ensures clear visibility for imaging during preprocedural computerized tomography (CT) planning and fluoroscopy-guided valve implantation. Several essential landmarks can easily be identified on the stent frame, providing the operator complete control during the ViV procedure, having a precise indication of the position of the transcatheter valve in relation to the Perceval™ valve (Figure 1).

Second, Perceval™ provides for each size model [small (S), medium (M), large (L), and extra large (XL)] an even

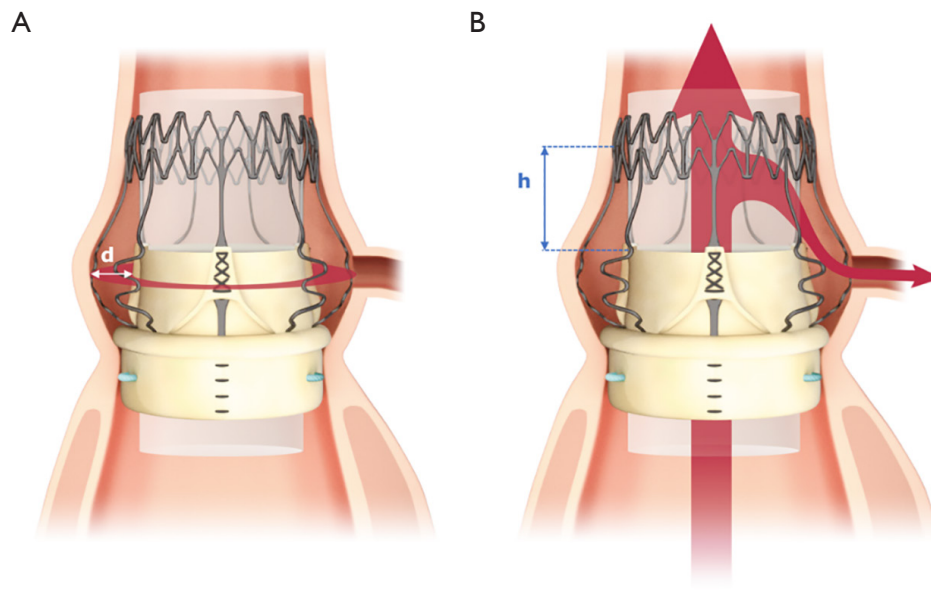


Figure 2 Perceval™ and coronary patency in ViV TAVR. (A) The VTC distance (d) is the space between the open leaflets of Perceval™ and the sinusoidal struts. This distance varies between 5 and 6.5 mm for different sizes of Perceval™, well above the risk zone for coronary obstruction. (B) Sinuses of Valsalva remain accessible over a distance (h) between the tips of the Perceval™ leaflets at maximal opening, and the sinotubular junction, hereby avoiding sequestration of the sinuses. ViV, valve-in-valve; TAVR, transcatheter aortic valve replacement; VTC, virtual transcatheter heart valve to coronary.

circumferential expansion of 2.5 mm above nominal size at the level of the inflow ring, allowing for greater compatibility with THV models and sizes, and translating into hemodynamic advantages (9).

Third, by design of the receptor valve, ViV TAVR in Perceval™ carries a minimized risk of coronary obstruction and of sinus sequestration. A virtual THV to coronary (VTC) distance (i.e., the horizontal distance between the coronary ostium and the THV frame on the preprocedural CT) of less than 4 mm has been identified as an independent predictor of coronary obstruction (10). In case of ViV TAVR in Perceval™, the VTC corresponds to the space between the sinusoidal struts and the open leaflets, a distance that varies between 5 mm for the Perceval™ S to 6.5 mm for Perceval™ XL and is not influenced by the THV frame (*Figure 2A*), except in case of gross oversizing of the THV. Similarly, by design, the Perceval™ leaflets do not touch the sinotubular junction when reaching their highest point in open position, hereby avoiding sinus sequestration, and maintaining coronary patency (*Figure 2B*).

As such, Perceval™ represents an ideal docking station for most currently available transcatheter valves in case of SVD (*Figure 3*). Depending on the size of the receiver

valve, and after cautious review of available CT images to assess true internal diameters and anatomic peculiarities, the size of the corresponding THV can be selected using the ViV aortic app [UBQO Ltd. (London, UK) and Dr. Vinayak Bapat (St. Thomas Hospital, London, UK)]. Ideally, a CT-based computer simulation of the implant should be performed to assess the interaction of the THV with the SV and with the surrounding anatomy. It remains important to consider limitations of some THV frames, when used in Perceval™ S. More specifically, the Acurate Neo™ (Boston Scientific, Marlborough, MA, USA) should be used with caution in these circumstances, since implantation may result in incomplete expansion of the upper crown and a higher transprosthetic gradient. Similarly, the larger and longer frame at the outflow side of other self-expanding THVs requires sufficient space to allow for maximal valve expansion of this upper segment, to improve hemodynamic outcome. Finally, depending on the specific patient context, transcatheter valves with intra-annular leaflet position or low commissural height and large open cells may be preferable in terms of coronary access after THV-in-SV. In this respect, general principles for the choice of a THV-in-THV equally apply to THV-in-SV with a stented frame (11).

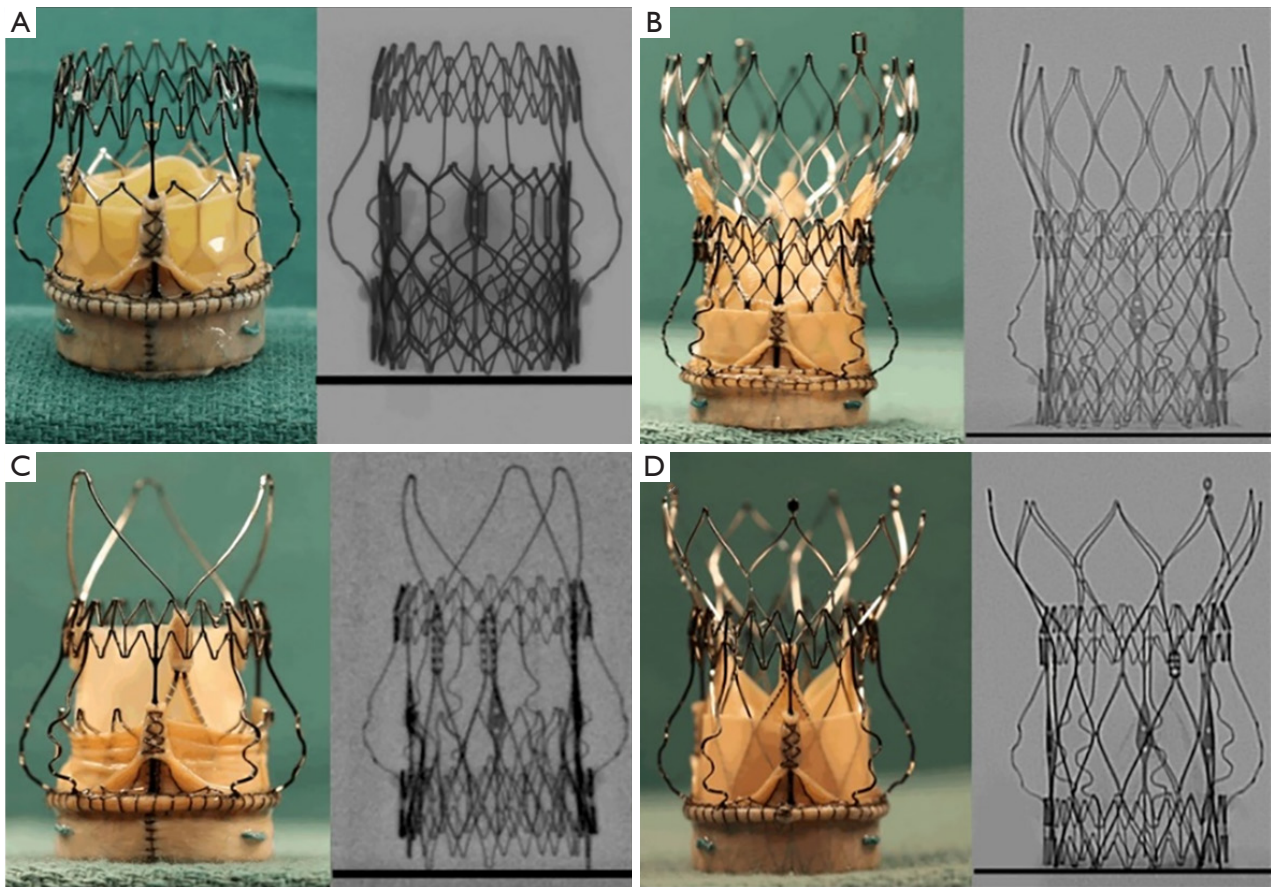


Figure 3 Paired bench and fluoroscopic images of frequently used THVs in PercevalTM. (A) SapienTM (Edwards Lifesciences, Irvine, CA, USA) in PercevalTM. (B) EvolutTM (Medtronic, Minneapolis, MN, USA) in PercevalTM. (C) AcurateTM in PercevalTM (Boston Scientific, Marlborough, MA, USA). (D) PorticoTM (Abbott, Chicago, IL, USA) in PercevalTM. Images were obtained from the ViV aortic app [UBQO Ltd. (London, UK) and Dr. Vinayak Bapat (St. Thomas Hospital, London, UK)] and reproduced with permission. THV, transcatheter heart valve; ViV, valve-in-valve.

Procedural tips and tricks

Procedural success of ViV TAVR in PercevalTM depends essentially on meticulous preprocedural work-up. Once the appropriate valve and size have been selected, the implant procedure itself is usually straight forward, with short procedure times and limited use of contrast. Care should be taken during retrograde wire crossing to avoid wire entanglement or “fausse route” outside the stented frame of PercevalTM, especially in patients with wide sinutubular junction. In these patients the outflow of PercevalTM typically is not apposed to the aortic wall, leaving a space for the crossing wire. In case of doubt, wire trajectory should be checked in several fluoroscopic projections, and free movement of the

pigtail catheter during wire exchange should be confirmed.

As with other ViV procedures, we usually don't recommend balloon predilatation of the degenerated bioprosthesis, as it may increase the risk for stroke and severe valve regurgitation. However, predilatation may be indicated in cases where severe calcification is observed on the preprocedural CT, especially to avoid severe underexpansion of a self-expanding prosthesis. In such cases, the THV should be prepared beforehand and ready to go for salvage of catastrophic acute aortic regurgitation.

Valve positioning is entirely guided by essential radiopaque landmarks on the PercevalTM. The golden rule here is proper alignment of the inflow of both the receptor and new implant. For self-expanding valves with a bottom-

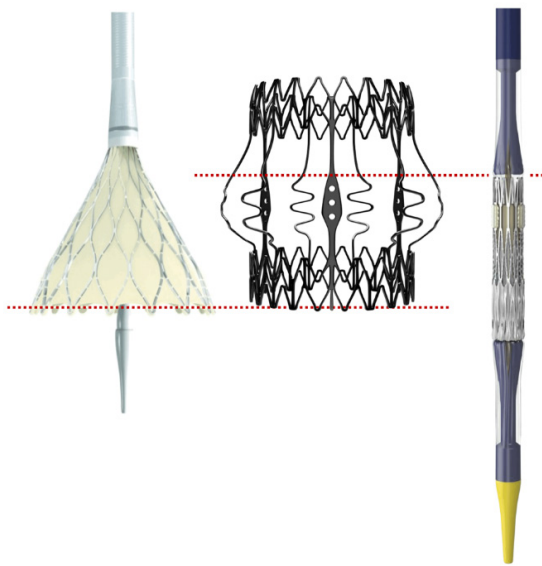
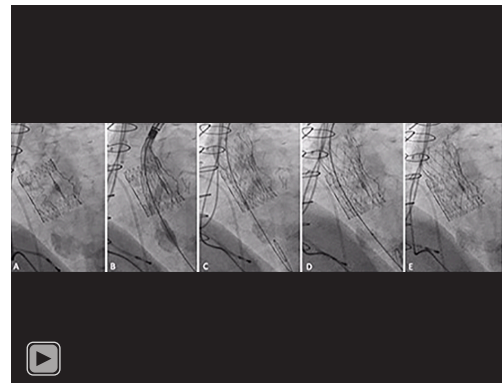


Figure 4 Alignment of THV during deployment. For Evolut™ and Portico™, the inflow of Perceval™ and the transcatheter valve should be aligned (left) during deployment. For Sapien 3™, the outflow of the valve should be aligned before valve expansion with the superior column tapers of Perceval™. At this stage, the inflow of Sapien™ is still protruding into the left ventricular outflow tract, and will foreshorten during valve deployment. Both inflows will align when maximal valve expansion is reached. THV, transcatheter heart valve.

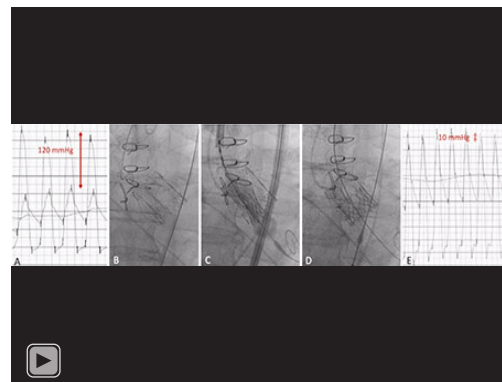
to-top expansion, such as Evolut™ or Portico™, a perfect overlap of both inflow rings can be targeted and adjusted during progressive valve deployment (Figure 4, left). When a balloon-expandable Sapien 3™ valve is used, one should account for the shortening of the valve frame at the inflow side. Therefore, the inflow side of the unexpanded Sapien™ is typically protruding into the left ventricular outflow tract, while the outflow is aligned with the column tapers of Perceval™. Such positioning accounts for the foreshortening of the valve during expansion and allows perfect alignment of both valve frames upon full expansion (Figure 4, right). Representative procedural steps of Evolut™ and Sapien™ in Perceval™ implantation are presented in Videos 1,2.

Case experience

The versatility of Perceval™ favors the use of this valve in a wide variety of clinical situations, especially in elderly patients. In our experience, despite the intermediate



Video 1 Evolut R™ 26 mm implantation in degenerated Perceval™ M. (A) Aortography showing radiopaque landmarks of Perceval™ and a patent left main coronary artery in a patient after bypass surgery. (B) Alignment of both valve inflows and release of Evolut R™ 26 mm. (C) Incomplete expansion of the inflow of Evolut R™. (D) Postdilatation with 23 mm balloon. (E) Improved expansion of the inflow of Evolut R™, with maintained patency of the left main coronary artery. Invasive peak-to-peak transprosthetic gradient after valve-in-valve transcatheter aortic valve replacement was 3 mmHg.



Video 2 Sapien 3™ 23 mm implantation in degenerated Perceval™ M. (A) Invasive measurement of peak-to-peak transprosthetic gradient showing severe valve stenosis (120 mmHg). (B) Radiopaque landmarks of Perceval™ before introduction of the transcatheter valve. (C) Alignment of the outflow of the Sapien™ valve with the superior column tapers in Perceval™; the balloon of the valve delivery system was filled with an additional 2 mL of contrast solution above nominal volume. (D) Perfect alignment of the inflow of both valves; access to the coronary arteries is maintained, above the level of the outflow of the Sapien™ valve. (E) Invasive peak-to-peak transprosthetic gradient after valve-in-valve transcatheter aortic valve replacement was 10 mmHg.

Table 1 Patient and procedural characteristics

Gender, age [†] (years)	Perceval TM size	TPG post-implant (mmHg), peak/mean	Time interval (years)	Before ViV procedure			TAVR device	After ViV procedure	
				TPG (mmHg), peak/mean	AR grade	EF (%)		TPG (mmHg), peak/mean	AR grade
F, 74	L	32/15	5.0	61/37	Severe	30	Sapien 3 TM , 26 mm	21/13	None
F, 83	L	20/10	5.8	114/68	Mild	62	Sapien 3 TM , 23 mm	31/18	None
F, 75	L	20/13	4.6	95/48	None	58	Sapien 3 TM , 23 mm	26/17	None
M, 82	M	23/13	3.6	89/52	Mild	55	Sapien 3 TM , 23 mm	21/12	None
M, 76	L	23/14	7.6	59/34	None	60	Sapien 3 TM , 26 mm	26/14	None
F, 80	M	27/19	6.5	67/44	Moderate	55	Evolut R TM , 26 mm	19/11	None
F, 78	M	23/15	4.9	72/49	Moderate	50	Sapien 3 TM , 23 mm	50/28	None
F, 79	S	19/13	4.5	51/30	Moderate	32	Sapien 3 TM , 23 mm	17/8	None
M, 82	XL	20/12	6.1	91/52	None	60	Evolut R TM , 29 mm	32/17	None

[†], age refers to the age at ViV TAVR. TPG, transprosthetic gradient; ViV, valve-in-valve; AR, aortic regurgitation; EF, ejection fraction; TAVR, transcatheter aortic valve replacement; F, female; L, large; M (in gender), male; M (in size), medium; S, small; XL, extra large.

risk profile of the treated population, long-term clinical outcomes were good, with incidence rates of endocarditis of 0.46% and severe SVD of 0.54% per patient year (15 patients in 784 implants) (5). Of these 15 patients with pure SVD, only 9 were scheduled for and underwent successful ViV TAVR. Patient and procedural characteristics are presented in *Table 1*. Most received their PercevalTM before we adapted our sizing strategy in 2017 (6), and none of them were treated with Perceval PlusTM, since this valve with FREE tissue treatment was only introduced in our practice in 2020 (4). None of the patients underwent predilation of the degenerated PercevalTM. Postdilation was performed in patients receiving EvolutTM only, due to visible underexpansion in one, and high invasive peak-to-peak transprosthetic gradient in the other (45 mmHg). In these patients, postdilation resulted in residual invasive peak-to-peak transprosthetic gradients of 2 and 20 mmHg, respectively. The patients in *Table 1* are currently undergoing serial clinical and echocardiographic follow-up at 1 and 6 months, and yearly after THV-in-SV, and all patients present transprosthetic gradients similar to the immediate postprocedural result and absent or trivial aortic regurgitation. The longest available follow-up to date is 3 years after the ViV procedure.

Conclusions

While SVD is rare in large patient series undergoing SV

implantation, PercevalTM appears to be ideally suited to receive a transcatheter valve, without compromising future valve hemodynamics and coronary patency, provided meticulous valve selection is performed.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures described in this article were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from the patient for publication of this manuscript and any accompanying videos. A copy of the written consent is available for review by the editorial office of this journal.

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