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ORIGINAL RESEARCH

FOCUS ON TRANSCATHETER AORTIC VALVE REPLACEMENT

Safety and Efficacy of TAVR With a Pressure Sensor and Pacing Guidewire

SAFE-TAVI Trial

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ABSTRACT

BACKGROUND The SavvyWire (OpSens Inc) is a 0.035-inch preshaped guidewire with dedicated pacing properties and a distal pressure sensor allowing for continuous hemodynamic pressure monitoring.

OBJECTIVES This study sought to determine the efficacy and safety of the guidewire during transcatheter aortic valve replacement (TAVR) procedures.

METHODS This prospective, multicenter clinical study included patients with severe aortic stenosis undergoing TAVR in 8 European centers. The primary efficacy endpoint was defined as effective left ventricular rapid pacing runs with the guidewire translating into a significant systemic pressure drop (below 60 mm Hg). The safety outcome included the absence of major procedural complications related to the guidewire.

RESULTS A total of 121 patients (mean age: 82.2 ± 5.9 years, 50% women) were included in the study, and 119 (98.3%) patients were finally treated with the study device. A balloon-expandable valve was implanted in 45 (37.8%) patients. Predilatation and postdilatation were performed in 89 (74.8%) and 14 (11.8%) patients, respectively. The primary efficacy endpoint was achieved in 116 (98.3%) patients, and the mean aortic systolic arterial pressure achieved during rapid pacing was 46.6 ± 11.3 mm Hg. Hemodynamic assessment with the use of the OptoMonitor 3 (OpSens Inc) without additional catheter exchange was achieved in 117 (99.2%) patients. The safety endpoint was achieved in 117 (99.2%) patients. No procedural mortality, stroke, or ventricular perforation was reported.

CONCLUSIONS The use of the guidewire during TAVR procedures appeared to be efficacious and safe. This device could help minimize interventions during the procedure and improve the clinical decision making after transcatheter heart valve deployment. (SavvyWire Efficacy and Safety in Transcatheter Aortic Valve Implantation Procedures [SAFE-TAVI]; NCT05492383) (J Am Coll Cardiol Intv 2023;16:3016-3023) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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Transcatheter aortic valve replacement (TAVR) has emerged as a widely recognized alternative to surgical valve replacement in the therapeutic landscape of severe symptomatic aortic stenosis (AS).[1,2] The number of TAVR procedures is anticipated to rise in the near future, particularly among younger patients with low-risk profiles. Given this trend, the necessity for continuous technological innovation and procedural refinement is underscored. These efforts are integral to minimizing periprocedural complications linked to TAVR, endorsing a minimalistic approach, and enhancing the clinical outcomes following TAVR.

The SavvyWire (OpSens Inc), a 0.035-inch preshaped guidewire, has been engineered to offer a 3-fold function in TAVR procedures. First, it facilitates aortic valve delivery and positioning. Second, it enables continuous hemodynamic measurement courtesy of a distal fiberoptic pressure sensor embedded within the wire. Lastly, it provides the possibility for left ventricular (LV) pacing. In 2022, the guidewire received regulatory clearance from the Food and Drug Administration. This guidewire is currently the only temporary pacing guidewire with continuous hemodynamic measurement capabilities approved by the Food and Drug Administration. Its safety and efficacy were initially assessed in a prospective registry, albeit with a limited sample size.[3] The SAFE-TAVI (SavvyWire Efficacy and Safety in Transcatheter Aortic Valve Implantation Procedures) trial was subsequently conducted to further investigate the performance of the guidewire during TAVR procedures. The objective of this study was to evaluate the safety and efficacy of the SavvyWire in TAVR using balloon- and self-expandable valve systems.

METHODS

TRIAL DESIGN AND OVERSIGHT. This prospective, premarket, multicenter, clinical study evaluated the use of a guidewire in patients with severe AS undergoing transfemoral TAVR. The trial protocol was developed by the principal investigators. An independent Data and Safety Monitoring Board assessed the safety of the subjects in the trial. The study was approved by the Institutional Review Board and local ethics committee of each participating center, and all patients provided written informed consent (NCT05492383).

PATIENTS. Patients were eligible if they had severe symptomatic AS and were accepted for a TAVR procedure. Patients were excluded if they had an extremely horizontal aorta (aortic root angle >70°), extreme tortuosity at the level of the iliofemoral arteries, or a thoracic or abdominal aorta; were unable to receive full anticoagulation during TAVR; or had prohibitive surgical risk precluding conversion to open heart surgery in case of a life-threatening complication.

TRIAL DEVICE AND PROCEDURE. The guidewire is a 280-cm long, 0.035-inch pressure guidewire. It can be divided into the following 3 sections (Figure 1):

1. Shaft: it supports the delivery of the transcatheter valve. The shaft is a stainless steel tube covered with a polytetrafluoroethylene sleeve that provides lubricity for the advancement of the valve delivery and electrical insulation for rapid pacing.
2. Sensor housing: this section joins the shaft to the tip and contains the pressure sensor. It includes a window for the exposition of the pressure sensor to the blood.
3. Tip: the tip has a more flexible distal end and is preshaped in a spiral shape for anchoring and to preserve atraumaticity during valve prosthesis advancement and deployment. The tip comes in 2 common sizes: extra-small (3.2 cm) and small (4.2 cm).

The guidewire is connected to the OptoMonitor 3 (OpSens Inc) through a fiberoptic interface cable. The monitor has a TAVR-specific interface. It displays the system status, performs pressure averaging, calculates hemodynamic indexes, and displays relevant graphic curves and data (Figure 2).

Aortic valve crossing was performed according to standard techniques. After crossing the aortic valve and exchanging the catheter, a pigtail catheter was advanced into the LV apex. The guidewire was prepared (zero and flush) and advanced through the

ABBREVIATIONS AND ACRONYMS

AS = aortic stenosis
LV = left ventricular
RV = right ventricular
TAVR = transcatheter aortic valve replacement

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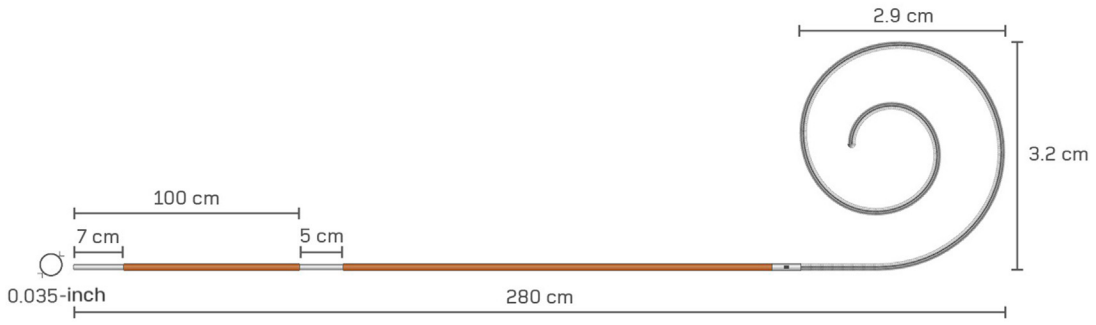
FIGURE 1 Guidewire With an Extra-Small Curve



An illustration of the guidewire with an extra-small curve displaying measurements for the wire, shaft, and tip. The tip diameter of the small curve variant is 4.2 cm.

pigtail catheter up to the LV apex. After retrieval of the pigtail catheter, ventricular pressure was recorded simultaneously with an aortic pressure recording. The electrodes of a standard temporary pacemaker were connected to the pacing connection zone of the guidewire and to a needle in the groin of the patient. A rapid pacing test was performed at a minimum of 180 beats/min for a duration of 10 seconds or until the systolic aortic pressure dropped below 60 mm Hg. Test capture was ensured using the standard cardiac pacing verification procedure. The temporary pacemaker was set to operate in an asynchronous mode, and its current output was set to the maximum output (at least 20 mA). Valve deployment including predilatation was performed according to standard techniques. The systemic and ventricular pressures were recorded during valve deployment and during dilatations (predilatation and postdilatation if needed). Simultaneous LV and aortic pressure measurements were obtained after each intervention (valve deployment and predilatation and postdilatation).

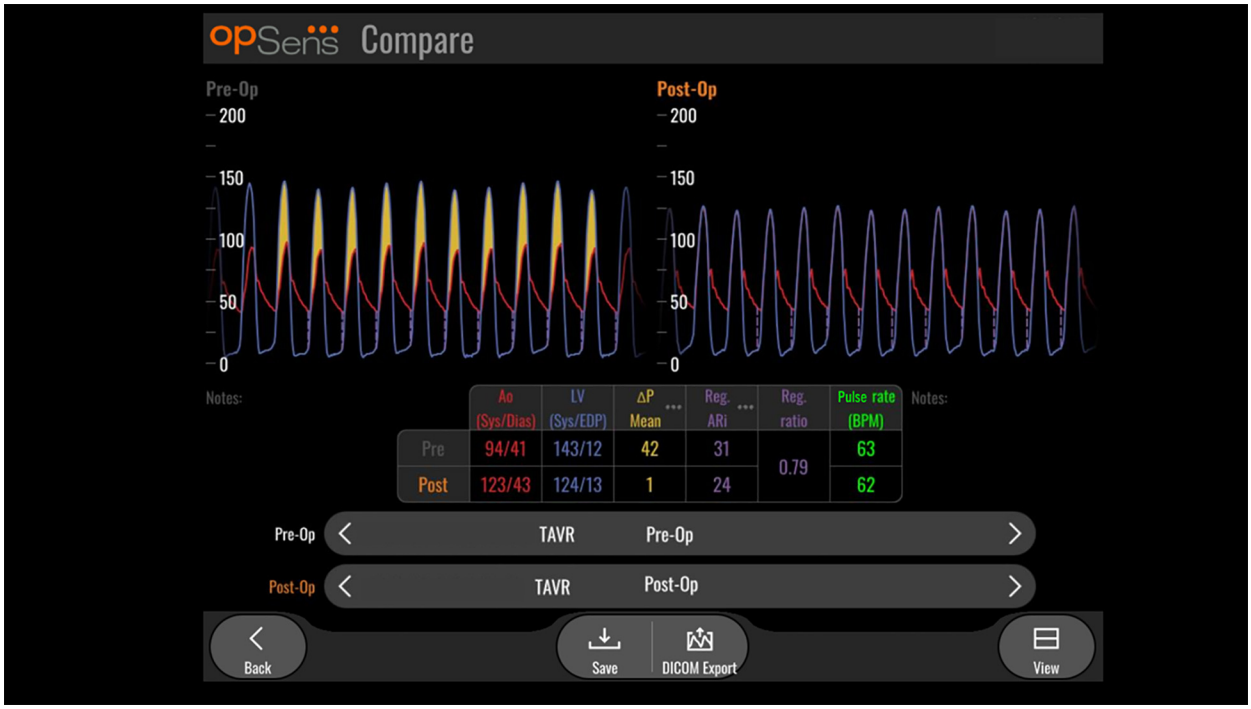
TRIAL ENDPOINTS. The primary endpoint was an effective rapid pacing run translating into a significant systemic pressure drop. The success criterion for this study was a reduction in systolic pressure below 60 mm Hg. The secondary safety endpoints included freedom from major complications related to the guidewire defined as a guidewire kink hindering the advancement of the transcatheter heart valve, LV perforation, and pacing capture failure translating into major clinical consequences. The safety endpoints were a nonhierarchical composite of the prior described events. The secondary efficacy endpoints included valve invasive hemodynamic assessment with a specific monitor without additional catheter exchange and valve advancement and positioning in the intended position. Follow-up was performed until patient discharge.

STATISTICAL ANALYSIS. The sample size was based on the primary effectiveness endpoint. Data from the EASY-TAVI (Direct Left Ventricular Rapid Pacing Via the Valve Delivery Guidewire in TAVR) trial showed that rapid pacing through right ventricular (RV) temporary pacing obtained an effective drop in systemic pressure (defined as a systolic pressure <60 mm Hg) in 87% (128/147) of TAVR candidates.[4] In the early feasibility trial with the guidewire,[3] LV pacing with the guidewire translated into a reduction in systolic pressure below 60 mm Hg in 95% (19/20) of patients. It was estimated that a sample size of 110 patients would provide similar results (ie, effective rapid pacing runs translating into systolic pressure below 60 mm Hg in 95% of patients) with a 95% CI ranging from 91% to 99%. Considering the possibility of inappropriate pressure recording in <10% of cases, the final sample size was increased to 120 patients.

The analyses included an intention-to-treat population, defined as all enrolled subjects, and a device implant population, defined as all patients for whom the device was used. Except where otherwise specified, the intention-to-treat population was used for descriptive analyses and the device implant population for endpoint analyses.

Continuous variables were summarized with the use of descriptive statistics; discrete variables were reported as counts and percentages. Statistical analyses were performed with SAS software version 9.4 or later (SAS Institute).

FIGURE 2 **Preoperative TAVR Measurements With the Monitor Interface in a Patient With Aortic Stenosis**



Comparison of preoperative and postimplantation pressure curves using the monitor interface. The bottom panel displays the corresponding measurements for each curve. BPM = beats/min; LV = left ventricle; TAVR = transcatheter aortic valve replacement.

RESULTS

A total of 121 patients at 8 European centers were enrolled from October 2022 to March 2023. Among them, 119 (98.3%) were treated with the study device and were included in the safety analysis. All subjects (except 1) who completed device implantation were included in the primary efficacy analyses. In this specific case, the device was inserted but removed before any attempt of a rapid pacing test. The main clinical characteristics of the study population are shown in **Table 1**. The mean age of the cohort was 82.2 ± 5.9 years with 49.6% being women and a median Society of Thoracic Surgeons score of 3.85 (Q1-Q3: 2.23-4.34). The mean ejection fraction was 57.0 ± 12.0%, and the mean aortic valve area measured by transthoracic echocardiography was 0.68 ± 0.18 with a mean gradient of 47.0 ± 14.1 mm Hg. Similar results were observed in the device implant population.

The main procedural characteristics of the study population are shown in **Table 2**. All patients were treated via a transfemoral approach. A balloon-expandable valve was implanted in 45 (37.8%) patients. Predilation was performed in 89 (74.8%) patients and postdilatation in 14 (11.8%) patients. There was a need for a second valve in 2 patients (1.7%). One patient had a valve embolization because of pacing capture failure during balloon inflation in a balloon-expandable valve implantation. The pacing capture loss was secondary to an unintended manipulation and movement of the guidewire tip during pacing. A second balloon-expandable valve was implanted. The second patient had a valve aortic migration after deployment not related to the guidewire. In this case, a second valve was needed to treat severe residual paravalvular regurgitation. There were no periprocedural neurologic events and no cases of acute kidney injury stages 3 or 4. There were no cases reported of hemodynamic instability or cardiogenic shock.

The primary efficacy endpoint (drop of systolic pressure below 60 mm Hg) was achieved in 116 (98.3%) patients, and the mean systolic arterial pressure achieved during rapid pacing was 46.6 ± 11.3 mm Hg (**Central Illustration**). The secondary efficacy endpoint (hemodynamic assessment with the use of a specific monitor without additional catheter exchange) was also achieved in 117 (99.2%) patients. The secondary

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TABLE 1 Patient Characteristics

	Intention to Treat (n = 121)	Device Implant (n = 119)
Age, y	82.2 ± 5.9	82.3 ± 5.8
Male	61 (50.4)	60 (50.4)
STS score, %	3.85 (2.23-4.34)	3.09 (2.23-4.34)
Coronary artery disease	32 (26.4)	32 (26.9)
Previous PCI	14 (11.6)	14 (11.8)
Previous CABG	8 (6.6)	8 (6.7)
Previous cardiac valve surgery	3 (2.5)	3 (2.5)
Prior stroke	9 (7.4)	9 (7.6)
Peripheral vascular disease	6 (5.0)	6 (5.0)
Prior permanent pacemaker	14 (11.6)	14 (11.8)
LVEF, %	57.0 ± 12.0	57.0 ± 12.0
Aortic mean gradient (echocardiography), mm Hg	47.0 ± 14.1	47.1 ± 14.2
Aortic mean gradient (SavvyWire), mm Hg	49.7 ± 18.4	49.7 ± 18.4
Aortic valve area, cm^2	0.68 ± 0.18	0.68 ± 0.18

Values are mean ± SD, absolute value (%), or median (Q1-Q3).
CABG = coronary artery bypass graft; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; STS = Society of Thoracic Surgeons.

safety endpoint was achieved in 117 (99.2%) patients (Table 3). No procedural mortality, stroke, guidewire kink, or ventricular perforation was reported.

DISCUSSION

The main findings of the SAFE-TAVI trial are as follows: 1) the use of the guidewire in TAVR procedures was effective, with an appropriate reduction of systolic aortic pressure during rapid pacing in the vast majority (98.3%) of patients; 2) the use of the guidewire during valve implantation was safe, with a single major complication related to the guidewire and no cases of procedural mortality, stroke, guidewire kink, or ventricular perforation; and 3) hemodynamic assessment with the use of a monitor and the guidewire without additional catheter exchange after TAVR was achieved in 99.2% of patients.

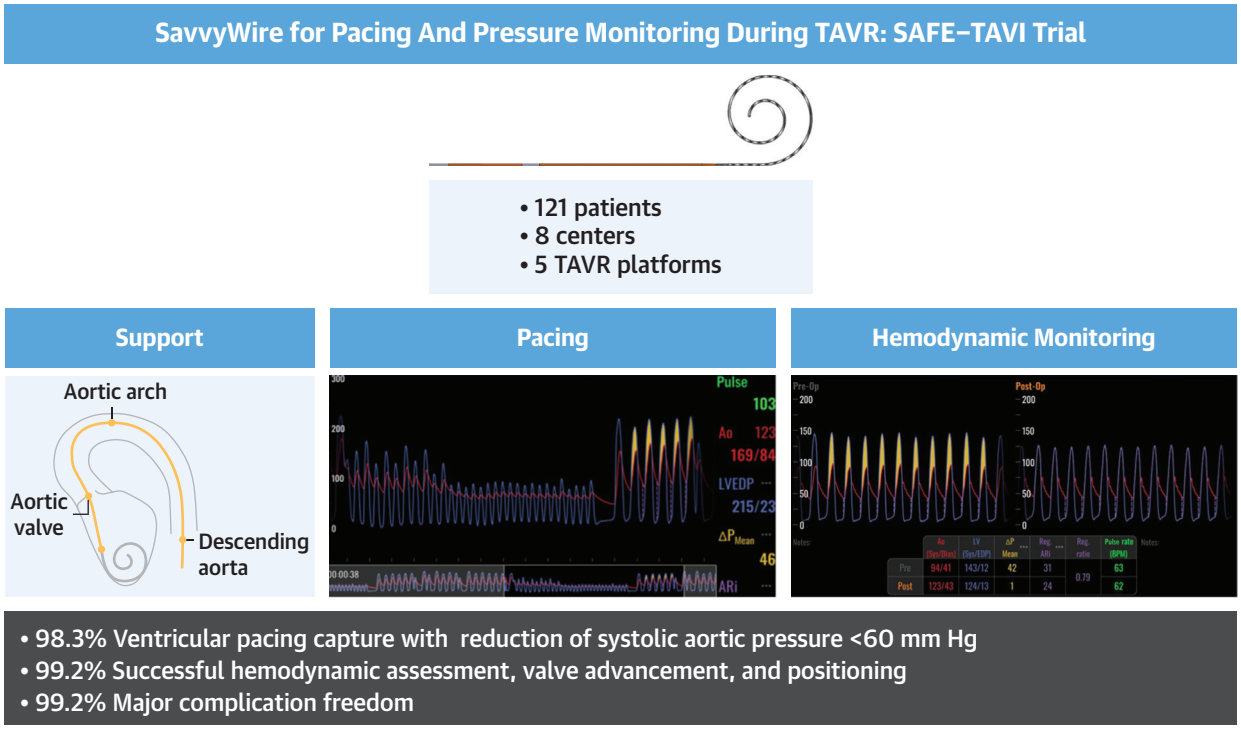
TABLE 2 Procedural Characteristics (N = 119)

Transfemoral approach	119 (100)
Balloon-expandable valve	45 (37.8)
SAPIEN 3/SAPIEN 3 Ultra (Edwards Lifesciences)	37 (31.1)
Myval (Meril Life)	8 (6.7)
Self-expanding valve	74 (62.2)
Evolut PRO/Evolut PRO + (Medtronic)	37 (37.1)
Navitor (Abbott)	19 (16)
ACURATE Neo (Boston Scientific)	18 (15.1)
Predilatation	89 (74.8)
Postdilatation	14 (11.8)
Systolic arterial pressure during rapid pacing test, mm Hg	46.0 ± 14.2
Postprocedure aortic mean gradient (predischarge echocardiography), mm Hg	10.5 ± 6.0
Postprocedure aortic mean gradient (guidewire), mm Hg	6.8 ± 6.0
Procedural complications	
Need of a second valve	2 (1.7)
Major or life-threatening bleeding	8 (6.7)
Major vascular complications	2 (1.7)
Permanent pacemaker implantation	21 (17.6)

Values are n (%) or mean ± SD.

Despite major advances toward procedural simplification during the last years, rapid pacing remains mandatory for balloon-expandable valve implantation, predilatation and postdilatation, and in some cases during self-expanding valve deployment for optimizing valve positioning. RV pacing using a transvenous temporary pacing lead is used in the majority of TAVR procedures. The use of an additional venous access and RV pacing lead carries the risk of vascular complications and RV perforation.[5] Rapid pacing through an LV guidewire was described several years ago for the treatment of pediatric patients with AS undergoing balloon aortic valvuloplasty.[6] The use of LV pacing strategy for balloon valvuloplasty and TAVR has been described in several registries.[7,8] The safety and efficacy of LV pacing via a guidewire were compared with standard RV pacing in the EASY-TAVI trial. In that trial with 307 randomized patients, it was demonstrated that LV stimulation during TAVR was associated with significantly reduced procedure duration, fluoroscopy, and costs with similar efficacy and safety. It is worth noting that efficacy was 84.9% for the LV pacing group (standard TAVR guidewires) and 87.1% for the RV pacing group.[4] The present study, which used the same pressure drop efficacy criterion, compares advantageously with an efficacy of 98.3% for LV pacing with the guidewire. The use of a dedicated wire with pacing properties might simplify the procedure compared with the use of a standard guidewire. This approach was studied in the initial early and feasibility study of the SavvyWire[3] and Wattson temporary pacing guidewire (Teleflex).[9] Furthermore, if backup pacing is required during the procedure, the wire length, along with its electrical insulation properties, allows for continuous pacing while the transcatheter valve system is removed and a pacemaker lead is placed in the right ventricle. Also, the results of SAFE-TAVI further extend the findings from the early feasibility study to a much larger number of different balloon- and self-expanding devices, showing that the efficacy of this wire was not limited to the SAPIEN (Edwards Lifesciences) and Evolut (Medtronic) valves, the 2 most commonly valve systems worldwide. This expansion represents a

CENTRAL ILLUSTRATION The SAFE-TAVI Trial



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SAFE-TAVI = SavvyWire Efficacy and Safety in Transcatheter Aortic Valve Implantation Procedures.

significant advancement because it broadens the scope of the wire's applicability and offers greater flexibility in choosing a valve system that is most suitable for individual patient anatomy and clinical circumstances. Moreover, it provides a robust evaluation of the wire's versatility and effectiveness across a spectrum of commercially available TAVR platforms.

Although LV pacing eliminates many risks associated to RV pacing through additional vascular access, some risks inherent to rapid pacing during TAVR remain, such as valve embolization caused by pacing loss during balloon expansion. The rate of valve embolization in various TAVR trials and registries ranges between 0.1% and 1.6% without evidence of a significant difference between RV and LV pacing cohorts.[10,11] There was 1 such case in this study (0.8%), which was attributed to the tip of the guidewire losing contact with the ventricle. This may have been avoided by maintaining forward pressure on the guidewire during valve deployment. Along with guidewire contact with the ventricle, other recommendations for LV pacing include the following: 1) setting the pacemaker to maximum output (20-25 mA) in asynchronous mode (no sensing) at a rate significatively higher than the intrinsic heart rate; 2) cautious monitoring of capture during a pacing test of appropriate duration in the same conditions (guidewire and pacemaker) as when deploying the valve; and 3) threshold testing may be done during

TABLE 3 Study Endpoints

Primary endpoint	N = 118
Adequate ventricular pacing capture by the guidewire leading to a reduction of systolic aortic pressure <60 mm Hg	116 (98.3)
Secondary efficacy endpoints	N = 118
Successful invasive hemodynamic assessment without additional catheter exchange	117 (99.2)
Successful valve advancement and positioning into the intended position	117 (99.2)
Secondary safety endpoints	
Freedom from major complications related to the guidewire	117 (99.2)

Values are n (%).

the pacing test to ensure there is a sufficient margin of the pacemaker output (ideally at least twice the capture threshold).

Some reports have shown significant discordances in the evaluation of the mean transvalvular gradient between echocardiography and invasive measurements, with an overestimation of the real gradient with echocardiography vs catheterization in most cases.[12] This discrepancy has been mainly attributed to the pressure recovery phenomenon and the limitations of the Bernoulli equation,[13,14] highlighting the importance of measuring valve hemodynamics during TAVR. The correlation between measurements done with a pressure wire and the pigtail technique before and after TAVR is excellent.[15] When using 2 pigtails, there is the inconvenience of multiple catheter wire interchanges, which might increase the risk of complications and procedural time. This is more pronounced in sheathless procedures and in procedures without echocardiographic guidance in which invasive hemodynamics guide postdilatation. By providing continuous pressure monitoring, the guidewire eliminates the need for potentially complex catheter exchanges in most of the cases.

STUDY LIMITATIONS. First, this was an observational study with no direct comparison with the standard RV pacing approach. Second, there are no long-term results that could depict the consequences of valve optimization with hemodynamic data.

CONCLUSIONS

The results of this study showed the safety and efficacy of the guidewire during TAVR. This device could help minimize interventions during the procedure and improve clinical decision making after transcatheter heart valve deployment.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

This study was sponsored by Opsens Medical. Dr Regueiro is a consultant from Abbott, Meril Life, and Opsens Medical. Dr Picard-Deland is an employee of Opsens Medical. Dr Rodés-Cabau is a consultant for and has received institutional research grants and consulting fees from Opsens Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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PERSPECTIVES

WHAT IS KNOWN? Given the rising prevalence of TAVR procedures, especially among younger, low-risk patients, there is a need for tools that can enhance procedural safety, efficiency, and outcomes. The guidewire offers a multifunctional approach by combining transcatheter heart valve positioning, continuous hemodynamic monitoring, and left ventricular pacing.

WHAT IS NEW? This paper provides comprehensive data from the SAFE-TAVI trial, which successfully evaluates the guidewire in TAVR procedures across a broad patient cohort and various valve systems. It reports high success in meeting primary efficacy and safety endpoints, enhancing the evidence for the device's utility in TAVR.

WHAT IS NEXT? Further research should investigate the long-term outcomes of valve optimization using continuous hemodynamic data.

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KEY WORDS aortic stenosis, hemodynamic assessment, left ventricular pacing, transcatheter aortic valve replacement