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# Transcatheter aortic valve implantation in patients with uninterrupted vitamin K antagonists

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## KEYWORDS

anticoagulation, procedure simplification, transcatheter aortic valve implantation, Vitamin K, antagonists.

## Abbreviations

ACT. activated dotting time; BARÇ Bleeding Academic Research Consortium; LMWH, low-molecular weight heparin MACCE, major adverse cardiovascular and cerebrovascular events; TAV1, transcatheter aortic valve implantation; VARC-3. Valve Academic Research Consortium -3; VKA, vitamin K antagonist..

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# Abstract

## Background:

Bridging of vitamin K antagonist (VKA) with heparin is usually not promoted during interventional or surgical procedures related to increase risk of bleeding and thrombotic events but this strategy has not been evaluated during transcatheter aortic valve implantation (TAVI).

## Purpose:

The aim of this study was to evaluate the rate of major bleeding and vascular complications after TAVI performed in patients with uninterrupted VKA.

## Methods:

From January 2016 to October 2017, consecutive patients who underwent TAVI with uninterrupted VKA (international Normalized Ratio [INR] between 1.5 and 3.5) were prospectively included in a monocentric registry. TAVI was performed according to current guidelines and a 50 U/kg bolus of heparin was injected at the beginning of the procedure for all patients, Vascular and bleeding complications were assessed using the Valve Academic Research Consortium 3 (VARC3) and the Bleeding Academic Research Consortium (BARC) definitions at a 30-day follow-up.

## Results:

A total of 88 patients were included with a median age of 84 years (81.8~87.0), 42% being female. The median Society of Thoracic Surgeons score was 5.1 (4.1-7.5), the median CHADS<sub>2</sub>-VASc was 5.5 (5-6) and 60.2% had a chronic kidney failure. Median INR at the time of implantation was 2.1 (1.8-2.6). The main VKA indication was atrial fibrillation. Trans femoral access was used in 8.6% of the patients. Major bleeding (BARC ≥3) occurred in five patients (5.7%) and major vascular complications occurred in seven patients (8.0%). At 1 month follow-up, major bleeding (BARC 2-3) or vascular complications occurred in 10 patients (11.4%). In patients with major bleeding peripheral arterial disease (RR=10.95; 95% confidence interval (CI) 1.63-73.75; p=0.014) and carotid access (RR=8.56; 95% CI 1.19-61.51; p=0.033) were more common. INR > 2.5 was significantly associated with vascular complications (RR = 7.14; 95% CI 1.29-39.63; p = 0.025). At 30 days, mortality and stroke rates were 2.3% and 4.5%, respectively.

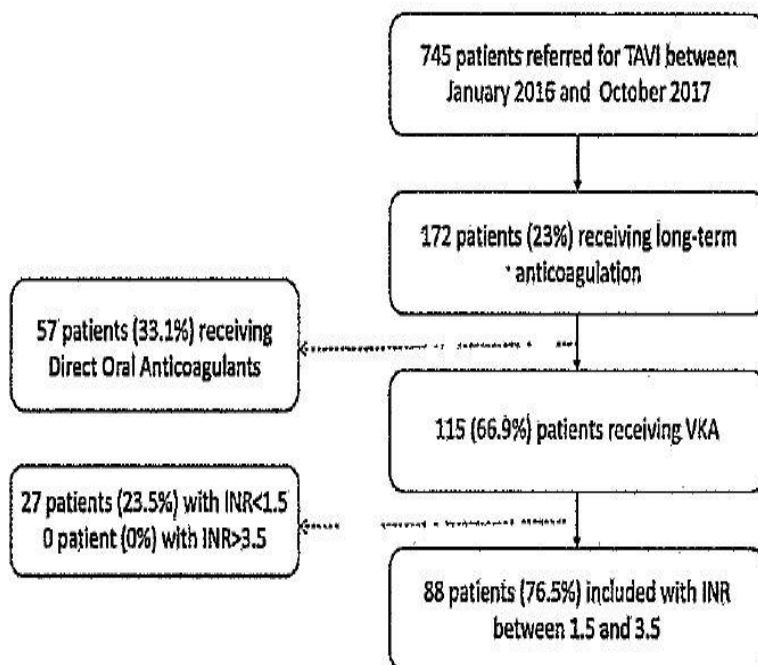
## Conclusion:

TAVI with uninterrupted VKA treatment seems feasible and safe with a low risk of major bleeding and vascular complications in this first single-center experience. Particular caution is advocated in high body mass index patients and to keep INR < 2.5.

# 1 | INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has become the standard of care for patients with severe symptomatic aortic stenosis contraindicated or at high risk for surgical aortic valve replacement.<sup>1</sup> Despite improvements in operators' experience, low profile catheter, and valve design improvement, major vascular and bleeding events remain one of the main complications of TAVI procedures and may be associated with unfavorable clinical outcomes.<sup>1-10</sup> According to SOURCE 3, PARTNER 2, and FRANCE 2 registries, about one-third of TAVI patients require long-term oral anticoagulant therapy, mainly for atrial fibrillation.<sup>2,4,5</sup> Vitamin K antagonist (VKA) remain the preferred oral anticoagulant therapy in patients with mitral stenosis, mechanical prosthesis, severe renal dysfunction, or neoplastic disease.<sup>11</sup> Management of oral anticoagulant therapy is challenging during interventional procedures, particularly for old and often frail patients referred for TAVI. Discontinuation of VKA and bridging therapy with heparin has been associated with higher bleeding risk when compared to the uninterrupted VKA strategy during general surgery, catheter ablation for cardiac arrhythmias, and pacemaker or defibrillator implantations.<sup>12</sup> Therefore, the uninterrupted VKA is now the gold standard for most interventional cardiology procedures.<sup>13</sup> Considering TAVI as an interventional procedure associated with moderated to high bleeding risk, VKA treatment is often interrupted a few days before TAVI in many centers and replaced by low-molecular-weight heparin.<sup>14</sup> Few data are however available for supporting this strategy in the particular context of the TAVI procedure.<sup>15</sup>

The aim of this study was to evaluate the incidence of vascular and bleeding complications in patients undergoing TAVI with a strategy of uninterrupted VKA.



**FIGURE 1** Study flowchart [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

## 2 | METHODS

### 2.1 | Study design and population

This monocenter, observational, and prospective study was conducted between January 2016 and October 2017 in the cardiology department of Montpellier University Hospital, a high-volume center gathering TAVI procedures from other six French cardiology departments. All patients undergoing TAVI during the study period were screened. Patients with uninterrupted VKA treatment (INR between 1.5 and 3.5 at the time of implantation) were included in this analysis. Exclusion criteria were INR < 1.5 and treatment by direct oral anticoagulant (Figure 1). The registry was approved by the local ethics board (IRB number 160203) and the study was conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from each patient.

### 2.2 | TAVI procedure

The access route was left to the discretion of the operating team with femoral access as the default strategy. Last generation devices were implanted, including balloon-expandable Edwards SAPIEN 3 prosthesis (Edwards Lifesciences) and self-expandable Medtronic CoreValve Evolut R (Medtronic) devices. The prosthesis size (23, 26, or 29 mm) was left to the operator's choice according to the manufacturer's recommendations, and annulus sizing was performed by multislice computed tomography. TAVI implantation was performed with surgical cut down by using the ZIP technique<sup>16-17</sup>, or by a percutaneous approach using two preclosure devices (Proglide; Abbott Vascular Devices).<sup>18</sup> In most cases, second access was performed using the femoral artery. VKA treatment was uninterrupted for patients with INR between 1.5 and 3.5. A higher level of INR (but always <3.5) was allowed for patients with a mitral mechanical valve. All patients received additional unfractionated heparin (UFH) (0.5 mg/kg) at the beginning of the procedure, just after sheath insertion. After the procedure, all patients received VKA treatment in the following 24 h and after medical examination. Additional antiplatelet treatment was left at the discretion of the physicians after the procedure.

### 2.3 | Data collection and follow-up

In Hospital and 1 month follow-up were obtained for all patients. Major bleeding events according to BARC criteria (Bleeding Academic Research Consortium),<sup>19</sup> vascular complications, major adverse cardiovascular and cerebrovascular events (MACCE), and serious adverse events according to Valve Academic Research Consortium (VARC)-3 criteria were assessed.<sup>19,20</sup> Data on hospitalization period and at 1 month follow-up were obtained from medical records and by phone call or direct clinical evaluation. All the data were collected and analyzed according to the CNIL MR-003 reference.

### 2.4 | Study end points

The primary endpoint was a safety combined endpoint, including major bleeding (BARC  $\geq$  3b)<sup>19</sup> and vascular complications<sup>20</sup> at a 1 month follow-up. Secondary endpoints included all bleeding complications, MACCE, including all-cause mortality, myocardial infarction, and stroke at a 1 month follow-up. Procedure length, transfusions, pacemaker implantations, and hospitalization length were also assessed.

## **2.5 | Statistical analysis**

A sample size of 85 patients was calculated as necessary to evaluate the incidence of bleeding and vascular complications with a precision of 5% according to the rate of bleeding complications and vascular complications, which were about 15% in registries at the beginning of our study.<sup>21-22</sup> Descriptive statistics were used for all baseline variables with means and standard deviation for normally distributed variables, medians, and interquartile ranges for nonnormally distributed variables using the Wilcoxon-Mann-Whitney test for continuous variables and the  $\chi^2$  or Fisher's test for categorical ones. Analyses were conducted with the use of SPSS statistic software version 24 (IBM).

# **3 | RESULTS**

## **3.1 | Baseline characteristics**

Of 745 patients admitted for TAVI, between January 2016 and October 2017 a total of 72 patients (23%) received long-term anticoagulant therapy and 88 patients (15.4%) were included and completed follow-up (Figure 1). The median age was 84 years (81.8-87) and 37 (42%) were female. The indication of VKA was atrial fibrillation for 79 patients (89.8%), mechanical mitral prosthesis for 5 patients (5.7%), and venous thromboembolic disease for 4 patients (4.5%). Baseline characteristics of the study population are presented in Table 1.

## **3.2 | Procedure and concomitant antithrombotic therapy**

Femoral access was used for 78 patients (88.6%) with surgical cutdown for 59 patients (75.6%) and a percutaneous approach for 19 patients (24.4%). The carotid approach was used for 5 patients (9.1%) and the transaortic access for 2 patients (2.3%). A total of 40 patients (45.5%) received additional antiplatelet therapy before the procedure, mainly related to concomitant coronary artery disease. The median INR on the day of implantation was 2.1 (1.8-2.6). The concomitant antithrombotic treatments are detailed in Table 1.

## **3.3 | Primary endpoint**

At 1 month follow-up, major bleeding (BARC2/3b) or vascular complications occurred in 10 patients (11.4%) (Figure 2). Vascular complications occurred in 7 patients (8.0%), including three major (3.4%) and four minor (4.6%) complications. Major bleeding (BARC  $\geq$  3b) occurred in 5 patients (5.8%) with 3 cardiac tamponades (3.4%), one carotid hematoma (1.2%), and one pseudoaneurysm (1.2%), both requiring surgical intervention.

## **3.4 | Secondary endpoints**

According to VARC-3 criteria, total bleeding occurred in 13 patients (14.8%). One patient (n = 1.1%) received intravenous vitamin K for the management of a noncritical carotid hematoma and red blood cell transfusion was required for seven patients (8%). The stroke rate was 4.5% (n=4) and no myocardial infarction occurred. Pacemaker implantation was required in 14 patients (16%) after TAVI. The median length of the procedure was 60 min (51-70). At 1 month follow-up, two patients died (2.3%) related to one postprocedural stroke and one sudden death occurring 20 days after the procedure, specific outcomes are summarized in Supporting Information: Appendix 1.

**TABLE 1** Baseline characteristics of the overall population (n = 88)

Female	37 (42%)
Age, median (years)	84 (81.8–87)
Age ≥ 90 years old	10 (11.4%)
Body mass index, median (kg/m <sup>2</sup> )	26.8 (24–28.7)
STS score, median	5.1 (4.1–7.5)
Euroscore 2, median	4.7 (3.2–7.7)
HAS-BLED, median	2 (2–3)
CHA <sub>2</sub> DS <sub>2</sub> -VASc, median	5.5 (5–6)
CHA <sub>2</sub> DS <sub>2</sub> -VASc ≥ 6	44 (50%)
NYHA class	
I, II	21 (23.9%)
III, IV	67 (76.1%)
Hypertension	67 (76.1%)
Diabetes mellitus	28 (31.9%)
Smoker	30 (34.1%)
Coronary artery disease	59 (67.0%)

Peripheral artery disease	13 (14.8%)
Ischemic stroke history	14 (15.9%)
Left ventricular ejection fraction	
≤30%	6 (6.8%)
30%–45%	18 (20.5%)
>45%	64 (72.7%)
Chronic kidney failure	
GFR < 60 ml/min/1.73 m <sup>2</sup>	53 (60.2%)
GFR ≤ 30 ml/min/1.73 m <sup>2</sup>	9 (10.2%)
Creatinine (μmol/L) median	100 (82.5–126)
Hemoglobin (g/dl) median	12.3 (11.5–13.7)
Antiplatelet therapy	
Simple	32 (36.4%)
Double	8 (9.1%)
Vitamin K antagonist	
Fluindione	54 (61.4%)
Warfarine	32 (36.4%)
Acenocoumarol	2 (2.2%)
INR, median	2.1 (1.8–2.6)
Indication of VKA	
Atrial fibrillation	79 (89.8%)
Mechanical mitral prosthesis	5 (5.7%)
Venous thromboembolic disease	4 (4.5%)

Abbreviation: STS, society of thoracic surgeons.



### 3.5 | Risk factors for major bleeding and vascular complications

In univariate analysis, only high BMI (OR= 1.26; 95% confidence interval 1.02-1.6; p=0.034) and INR>2.5 (OR=18.9; 95% confidence interval 1.6-221.3; p =0.019) seems to be associated with major bleeding or vascular complications (Table 2).

## 4 | DISCUSSION

This prospective study investigated the incidence of vascular and bleeding complications in patients undergoing TAVI on uninterrupted VKA therapy with three main results:

- (1) Incidence of VKA treatment in the TAVI population reached 15% and included 2/3 of patients with anticoagulant therapy.
- (2) Rates of bleeding and vascular complications observed with the uninterrupted strategy were acceptable in this specific population of patients under anticoagulant treatment with a usual high risk of bleeding and vascular complications.
- (3) Identification of bleeding and vascular complications risk factors (higher BMI and INR>2.5) might be useful to initiate preventive strategies.

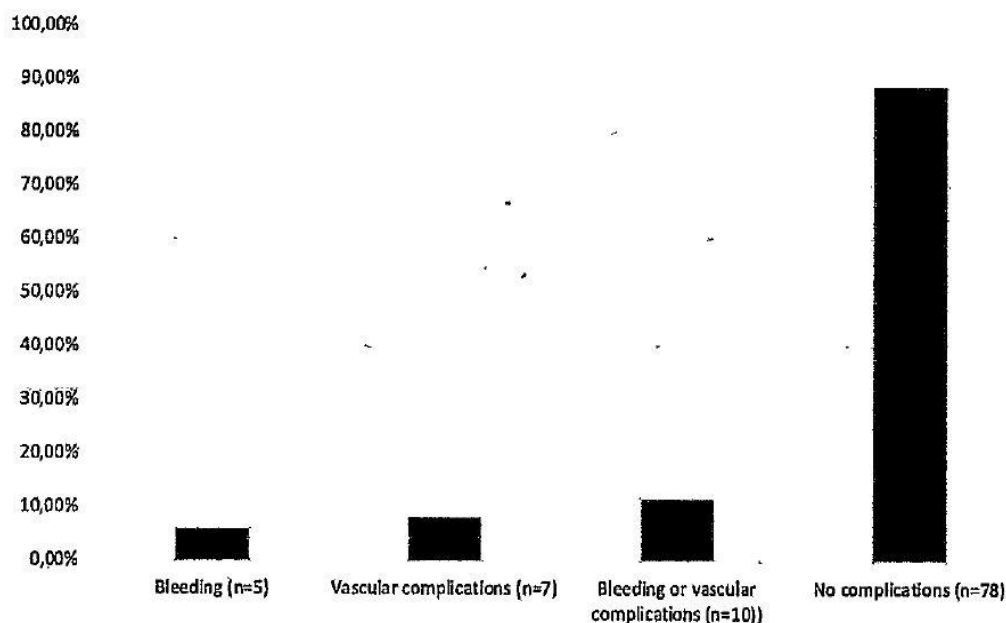
### 4.1 | Anticoagulant therapy in TAVI patients

In this study, an intermediate-risk TAVI population was included with a median Society of Thoracic Surgeons (STS) score of 5.1% and a median age >80 years, comparable with recent registries.<sup>4,7,23</sup> A high rate of comorbidities was observed in our population with more than 5% of mechanical mitral prosthesis and more than 2/3 of patients with coronary artery disease. This is underlined by the high CHA<sub>2</sub>DS<sub>2</sub>-VASc score in our population, which has been previously referred as a powerful predictor of adverse outcomes after TAVI.<sup>24</sup> As all our study patients had anticoagulant therapy, comparison with bleeding events observed in all comers registries must be done with caution.<sup>12,15</sup>

### 4.2 | Bleeding and vascular complications

At 1 month follow-up, the incidence of major bleeding (BARC = 3b) and vascular complications in our population with VKA therapy was higher than reported in TAVI studies but comparable with the data on patients under long-term oral anticoagulation.<sup>7,8,15</sup> There is no specific recommendation for the management of VKA therapy during TAVI procedures. The only previous observational study of TAVI patients with anticoagulant therapy comparing interrupted versus uninterrupted anticoagulation strategy reported 10.2% major bleeding and 8.6% major vascular complications in the continuation of the anticoagulation group compared with 10.8% (OR=0.85) and 10.3% (OR=0.58) of patients with interruption of anticoagulation.<sup>15</sup>

These results are comparable with those reported in the major registries on TAVI in the intermediate-risk population. The rates of major bleeding and major vascular complications were respectively 10.4% and 7.9% with a median STS of 5.1% in PARTNER 2<sup>4</sup> and 12.2% and 6% with median STS of 4.4% in SURTAVI.<sup>8</sup>



**FIGURE 2** Major bleeding (BARC  $\geq 3b$ ) and vascular complications (VARC-3 criteria) at a 1 month follow-up [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

### 4.3 | Predictive factors of bleeding and vascular complications

A high level of INR ( $>2.5$ ) was typically associated with vascular complications in patients undergoing interventional procedures;<sup>25</sup> In our practice, a systematic bolus of heparin was used regardless of the INR value at the time of sheath insertion. Administration of heparin during PCI in patients with INR  $> 2.5$  has been associated with an increased risk of bleeding complications;<sup>25</sup> The same excess was also observed in our TAVI population, suggesting that no additional bolus or heparin or a reduced dose of heparin may be proposed for these patients. Patients treated with double antiplatelet therapy on top of VKA also had a trend for more bleeding complications.<sup>26</sup> Triple therapy has been associated in PCI with more bleeding complications,<sup>27</sup> the same observation is probably true also for TAVI and suggests avoiding this combination. In the recent POPULAR TAVI, the incidence of serious bleeding was higher with the combination of anticoagulation and clopidogrel as compared with anticoagulant alone. Extremes BMI are also associated with bleeding or vascular complications, probably linked to femoral access difficulties,<sup>28</sup> thus a lower level of anticoagulation may be preferable in this special population.

Compared with the literature, the rate of female gender included in our study are low (42%)<sup>24</sup>; this could be explained by the small size of our sample. This finding should be considered as it is well known that the female gender is an independent predictive factor of bleeding and we noticed a trend toward an increased risk of vascular complications and major bleeding among women in our study ( $p = 0.088$ ).

**TABLE 2** Vascular complications (VARC-3 criteria) or bleeding (BARC  $\geq 3b$ ), univariate analysis

	n	%	Vascular complication or bleeding (n = 10)		p
			No complication (n = 78)		
	n	%	n	%	
Female	30	38.5	7	70.0	0.088
Age (years) <sup>a</sup>	84	81-87	84.5	82-87	0.947
Age $\geq 90$ years old	9	11.5	1	10.0	1.000
Body mass index (kg/m <sup>2</sup> )	26.5	23.6-28.4	28.3	27.0-32.9	0.034
STS score	4.8	4.0-7.3	7.1	4.6-9.9	0.150
EuroSCORE 2	4.6	3.1-7.1	7.5	3.2-10.0	0.258
HAS-BLED	2.0	2-3	1.5	1-3	0.255
CHA2DS2-VASc	5.0	5-6	6.0	5-7	0.423
CHA2DS2-VASc $\geq 6$	38	48.7	6	60.0	0.739
NYHA class					0.441
II	17	21.8	4	40.0	
III	53	67.9	5	50.0	
IV	8	10.3	1	10.0	
Hypertension	59	75.6	8	7.6	1.000
Diabetes mellitus	23	29.5	5	50.0	0.278
Smoker	29	37.2	1	10.0	0.154
Coronary artery disease <sup>b</sup>	34	43.6	3	30.0	0.510
Peripheral artery disease	10	12.8	3	30.0	0.163
LVEF $\leq 30\%$	5	6.4	1	10.0	0.526
GFR < 60 ml/min/1.73 m <sup>2</sup>	45	57.7	8	80.0	0.304
GFR < 30 ml/min/1.73 m <sup>2</sup>	7	9.0	2	20.0	0.270
Creatinine (mmol/L)	100.0	83-125	100.0	79-163	0.684
Hemoglobin (g/dL)	12.3	11.5-13.9	12.5	11.4-12.9	0.554
Antiplatelet therapy					0.217
0	42	53.9	6	60.0	
1	30	38.5	2	20.0	
2	6	7.7	2	20.0	
DAPT	6	7.7	2	20.0	0.224
AVK					1.000
Fluindione	48	61.5	6	60.0	
Warfarine	28	35.9	4	40.0	
Acenocoumarol	2	2.6	0	0.0	
INR					0.019
<2	39	50.0	1	10.0	
2 - 2.5	49	24.4	3	30.0	
>2.5	20	25.6	6	60.0	

**TABLE 2 (Continued)**

	n	%	No complication (n = 78) n	Vascular complication or bleeding (n = 10) %	p
Indication for VKA					1.000
Atrial fibrillation	68	97.2	10	100.0	
Mechanical mitral	4	5.1	0	0.0	
Venous thromboembolic	6	7.7	0	0.0	
Valve					0.493
Edwards SAPIEN 3	52	68.0	8	70.0	
Medtronic CoreValve Evolut	26	32.0	2	30.0	
Femoral access	70	89.7	8	80.0	0.317
Valve size					0.029
23	12	15.4	4	40.0	
26	29	37.2	5	50.0	
29	37	47.4	1	10.0	

Abbreviations: CABG, coronart artery bypass graft; PCI, percutaneous coronary intervention; STS, society of thoracic surgeons.

<sup>a</sup>Median and interquartile range.

<sup>b</sup>Previous PCI or CABG.

#### 4.4 1 Practical considerations

Our results are consistent with observation on uninterrupted VKA strategy in many surgical or interventional cardiology procedures.<sup>14,29</sup> This no bridge strategy seems feasible in the TAVI population. Extension of this strategy for all TAVI procedures needs confirmation of efficacy and safety in larger and randomized studies as previously performed for pacemaker and defibrillator implantations,<sup>14</sup> especially with percutaneous arterial closure, which is now the gold standard.

#### 4.5 | Limitations and bias

The first limitation of this study is the small population analyzed without a control group given that all procedures were performed without interruption of oral anticoagulant during the study period.

A single-center study could also appear as a limitation. Although six independent operating teams worked in our high-volume center. The operators were aware of the anticoagulant strategy and this could have led to adapting their practice during the intervention. Nonetheless, this is a real .life study with peri-procedural anticoagulation strategy.

### 5 | CONCLUSION

This study investigates vascular and bleeding complications in patients undergoing TAVI without interruption of VKA treatment. This strategy seems feasible and safe with an acceptable rate of bleeding and vascular complications. Larger randomized trials comparing uninterrupted VKA to bridging therapy regarding both bleeding and embolic risk will be required to validate this practice.

## CONFLICTS OF INTEREST

P. Robert has received research grants from Edwards. M. Akodad has received research grants from Edwards and Medtronic. B. Lattuca has received research grants from Biotronik, Daiichi-Sankyo, Fédération Française de Cardiologie, and Institute of Cardio metabolism And Nutrition; consultant fees from Daiichi-Sankyo, Eli Lilly and Medtronic; and lecture fees from AstraZeneca and Novartis. G. Cayla has received research grants from Abtiott, Amgen, AstraZeneca. Bayer. Bristol-Myers Squibb, Medtronic, and Pfizer. Sanofi F. Leclercq has received research grants from Edwards, Medtronic, Boerringer: consultant fees from Boehringer; and lecture fees from Astra Zeneca and Bayer.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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