ORIGINAL ARTICLE

Direct left ventricular wire pacing during transcatheter aortic valve implantation

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KEY WORDS
aortic valve stenosis, direct left ventricular wire pacing, transcatheter aortic valve implantation, transcatheter aortic valve replacement

ABSTRACT

BACKGROUND Rapid ventricular pacing is used during balloon aortic valvuloplasty, balloon-expandable transcatheter aortic valve implantation (TAVI), and for postdilatation. Right ventricular (RV) lead pacing has been regarded as a gold standard. Direct left ventricular (LV) wire pacing has recently been considered safe and effective in TAVI interventions.

AIMS This study aimed to analyze procedural outcomes of direct LV pacing compared with RV stimulation in unselected patients undergoing TAVI.

METHODS Direct LV wire pacing was provided via available preshaped guidewires and used only when no predictors of atrioventricular block were present. The primary study objective was the assessment of the efficacy of direct LV wire pacing. The secondary objectives included the evaluation of procedure duration and safety in comparison with the conventional method. A combined endpoint (major adverse cardiovascular event) was defined as the occurrence of death, stroke, venous puncture–related complications, and cardiac tamponade.

RESULTS In 2017 and 2018, 143 patients underwent transfemoral TAVI. Of these, 114 (79.7%) had self-expandable valves implanted. Direct LV wire pacing was the dominant method of pacing (82 patients [57.3%]), and its efficacy reached 97.6%. The median (interquartile range) procedure time was shorter in the direct LV wire pacing group (80 [70–90] min vs 85 [70–95] min; $P = 0.02$). Major adverse cardiovascular events were more frequent in the RV lead pacing group (11.5% vs 4.9%), but no statistical significance was achieved ($P = 0.13$).

CONCLUSIONS Direct LV wire pacing during TAVI is a simple, reproducible, and safe technique, which provides reliable, sustained stimulation with a low complication rate and potential reduction of procedural time.

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INTRODUCTION In developed countries, aortic valve stenosis is the most frequent acquired valvular heart disease requiring interventional treatment and, due to population aging, its prevalence is increasing. The frequency of aortic stenosis (AS) is approximately 4% to 5% in patients aged over 65 years and increases with age.[1] Aortic valve stenosis is nowadays the most common indication for valve surgery and transcatheter structural heart interventions.

Transcatheter aortic valve implantation (TAVI) is a widely accepted treatment method in patients with severe AS at intermediate and high surgical risk.[2,3] This minimally invasive technique does not require thoracotomy or use of cardiopulmonary bypass, reduces the overall risk of valve implantation, shortens hospitalization time, and is less limited by patient frailty. The procedure was initially intended for inoperable individuals and has revolutionized the care

WHAT'S NEW?

In this article, we report our center's experience in using the new direct left ventricular stimulation technique in patients undergoing transcatheter aortic valve implantation (TAVI) procedures. This is the first study to compare the use of direct left ventricular wire pacing and the conventional method (right ventricular lead pacing) in the population of unselected patients undergoing transfemoral TAVI procedures in a single Polish center. Our study confirmed the suitability of left ventricular guidewire pacing in a broad range of all-comers with the use of both balloon- and self-expandable valves to reduce the overall risk of valve implantation. Risk optimization in TAVI by simplifying the procedure is a new and up-to-date issue.

of patients with AS. Furthermore, indications for TAVI are constantly being extended towards patients at lower surgical risk.[4,5]

Although TAVI has already become a well-established technique with many improvements reducing procedural risk (subsequent generations of valves, downsized diameter of delivery sheaths, complete percutaneous approach, conscious sedation), the use of rapid pacing remained unchanged. Rapid ventricular pacing is used during balloon aortic valvuloplasty (BAV), balloon-expandable valve implantation, and postdilatation to ensure transient cardiac standstill. Traditionally, right ventricular (RV) lead pacing is used; however, direct left ventricular (LV) wire pacing via a routinely used guidewire is possible.[3-10]

Right ventricular lead pacing requires additional venous access and a pacing catheter, which may be the reason for higher complication risk in frail patients. It extends procedural time and radiation exposure. Left ventricular wire pacing may potentially shorten the TAVI procedure, reduce its complexity, and enhance safety. This approach is considered safe and effective and was previously described in BAV and TAVI interventions.[6-11]

Our study aimed to assess the safety and efficacy of this new technique as well as procedural outcomes in a population of unselected patients undergoing TAVI.

METHODS A retrospective, observational study was conducted in a single center performing more than 100 TAVI procedures annually. All consecutive patients with severe AS who underwent transfemoral TAVI were included.

Patients were divided into 2 groups: the direct LV wire pacing group and the RV lead pacing group. Direct LV wire pacing was used when no predictors of atrioventricular block (AVB) (first-degree AVB, Mobitz I block, right bundle branch block, or left anterior hemiblock) were present. Moreover, the final choice of the pacing method was left at the operator's discretion to obtain safe and effective stimulation.

The primary objective of the study was to assess the efficacy of direct LV wire pacing during TAVI procedures. Secondary objectives included the evaluation of procedure duration and safety in comparison with the conventional method. We defined a combined endpoint of major adverse cardiovascular events including death, stroke, venous puncture–related complications, and cardiac tamponade.

The study was approved by the local ethics committee and conducted in accordance with the 1964 Declaration of Helsinki with its later amendments.

Procedural technique In the RV lead pacing group, a femoral vein puncture was performed and an intravenous 6-French sheath was introduced. Stimulation was provided with a temporary transvenous pacing electrode (Hagmed, Rawa Mazowiecka, Poland) with a standard (without a balloon), flexible, curved distal tip. Pacing was performed with an output of 10 mA and a frequency of 140 bpm to 180 bpm. Femoral vein access hemostasis was routinely achieved with the 6-French Angio-Seal (Terumo Interventional Systems, Somerset, New Jersey, United States) vascular closure device.

No routine femoral vein puncture was performed in the direct LV wire pacing group.

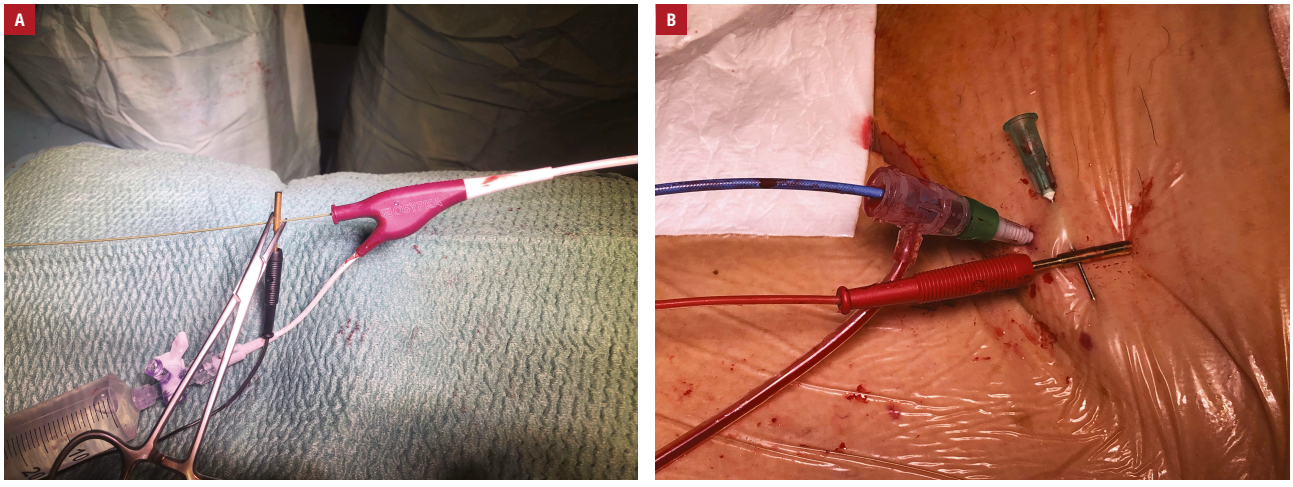

FIGURE 1 Pacing pins. The cathode is attached to the tip of the guidewire (**A**), and the anode to a needle inserted into the subcutaneous tissue of the groin (**B**).

Left ventricular wire pacing was provided via commercially available preshaped guidewires: Safari (Boston Scientific, Marlborough, Massachusetts, United States) and Confida (Medtronic, Minneapolis, Minnesota, United States). The cathode of an external pacemaker was placed using an alligator clamp or a connection pin on the tip of the wire, and the anode was connected to a needle inserted into the subcutaneous tissue of the groin (FIGURE 1). Insulation was ensured by a balloon or TAVI catheter. To achieve effective stimulation, pacing was performed with a maximal output of 20 mA and a frequency of 140 bpm to

TABLE 1 Baseline characteristics of the study patients

Characteristic	All study patients (n = 143)	Direct LV wire pacing (n = 82)	RV lead pacing (n = 61)	*P* value
Age, y, median (IQR)	81 (78–84)	81 (77–84)	81 (78–85)	0.68
Female sex	88 (61.5)	47 (57.3)	41 (67.2)	0.74
BMI, kg/m^2, median (IQR)	28.1 (25–31.2)	28.4 (25.1–31.3)	28.1 (24.7–31.2)	0.73
Patient history				
COPD	24 (16.8)	16 (19.5)	8 (13.1)	0.24
Stroke / TIA	12 (8.4)	5 (6.1)	7 (11.5)	0.47
PAD	16 (11.2)	9 (11)	7 (11.5)	0.83
Renal failure[a]	8 (5.6)	4 (4.9)	4 (6.6)	0.73
PCI	48 (33.6)	26 (31.7)	22 (36.1)	0.86
CABG	20 (14)	12 (14.6)	8 (13.1)	0.65
Frailty[b]	32 (22.4)	18 (22)	14 (23)	0.18
PH	31 (21.7)	16 (19.5)	15 (24.6)	0.69
Chest irradiation	6 (4.1)	4 (4.9)	2 (3.3)	0.69
Porcelain aorta	19 (13.3)	12 (14.6)	7 (11.5)	0.61
NYHA class				
I	5 (3.7)	4 (4.9)	1 (1.9)	0.2
II	59 (43.4)	37 (45.1)	22 (40.7)	
III	60 (44.1)	37 (45.1)	23 (42.6)	
IV	12 (8.8)	4 (4.9)	8 (14.8)	
Risk scores				
EuroSCORE II, %, median (IQR)	3.2 (1.9–5.4)	3 (1.8–4.9)	3.2 (1.9–5.7)	0.62
STS, %, median (IQR)	3.7 (2.7–5.8)	3.6 (2.5–5.1)	3.8 (2.8–6.8)	0.17
Echocardiography				
AVA, cm^2, median (IQR)	0.8 (0.6–0.9)	0.7 (0.6–0.9)	0.8 (0.6–0.9)	0.19
AVPG, mm Hg, mean (SD)	76 (27.1)	75.5 (25.6)	77.4 (29.1)	0.68
AVMG, mm Hg, median (IQR)	46 (36–56)	46 (36–55)	46.5 (36–57)	0.72
EF, %, median (IQR)	60 (50–65)	60 (50–65)	60 (52.5–65)	0.44
AR[c]	34 (24.6)	22 (28.2)	12 (20)	0.004
MR[c]	42 (30.9)	24 (31.6)	17 (29.3)	0.57
TR[c]	28 (20.7)	20 (25.6)	8 (14)	0.32

Data are presented as number (percentage) unless otherwise indicated.

a Creatinine >200 mmol/l
b Moderate and severe frailty according to the Clinical Frailty Scale
c Moderate and severe

Abbreviations: AR, aortic regurgitation; AVA, aortic valve area; AVMG, aortic valve mean gradient; AVPG, aortic valve peak gradient; BMI, body mass index; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; EF, ejection fraction; EuroSCORE, European System for Cardiac Operative Risk Evaluation; IQR, interquartile range; LV, left ventricular; MR, mitral regurgitation; NYHA, New York Heart Association; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; PH, pulmonary hypertension; RV, right ventricular; STS, Society of Thoracic Surgeons; TIA, transient ischemic accident attack; TR, tricuspid regurgitation

180 bpm. When high-grade AVB occurred during the procedure, temporary stimulation was provided through the LV guidewire, while venous access for RV pacing was obtained. Further stages of transfemoral TAVI procedures were carried out typically.

Postprocedural hemostasis was achieved either surgically or percutaneously with the use of double Perclose ProGlide (Abbott Vascular, Santa Clara, California, United States) and single 8-French Angio-Seal (Terumo Interventional Systems, Somerset, New Jersey, United States) devices for primary

TABLE 2 Procedural data by the pacing method used

Characteristic	All study patients (n = 143)	Direct LV wire pacing (n = 82)	RV lead pacing (n = 61)	*P* value
Complete percutaneous access	82 (57.3)	47 (57.3)	35 (43.1)	0.18
Valve type				
Self-expandable[a]	114 (79.7)	73 (89)	41 (67.2)	<0.001
Balloon-expandable[b]	26 (18.2)	9 (11)	17 (27.9)	<0.001
Mechanically expandable[c]	3 (2.1)	0	3 (4.9)	0.88
Procedure				
Procedure duration, min, median (IQR)	80 (70–95)	80 (70–90)	85 (70–95)	0.02
Radiation dose, mGy, median (IQR)	507 (324–920)	575.5 (356.8–974)	437 (265–664)	0.02
Contrast agent, ml, median (IQR)	150 (100–179)	150 (122.5–186)	120 (100–150)	0.007
Predilatation	112 (78.3)	71 (86.6)	41 (67.2)	0.006
Postdilatation	96 (67.1)	59 (72)	37 (60.7)	0.16
Complications				
Valve displacement	2 (1.4)	1 (1.2)	1 (1.6)	0.5
Second valve, bailout	4 (2.8)	1 (1.2)	3 (4.9)	0.1
AVB requiring pacing	7 (4.9)	3 (3.7)	4 (6.6)	0.01
Tamponade	2(1.4)	0	2 (3.3)	0.34
Cardiogenic shock	4 (2.8)	1 (1.2)	3 (4.9)	0.32
Conversion to surgery	0	0	0	NA

Data are presented as number (percentage) unless otherwise indicated.

a Medtronic Evolut R, Boston Scientific ACURATE Neo
b Edwards Sapien 3
c Boston Scientific LOTUS

Abbreviations: AVB, atrioventricular block; NA, not applicable; others, see TABLE 1

TABLE 3 Procedural data by the valve type used

Characteristic	Self-expandable[a] (n = 114)	Balloon-expandable[b] (n = 26)	Mechanically expandable[c] (n = 3)	*P* value
Pacing method, n (%)				
Direct LV wire pacing	73 (64)	9 (34.6)	0	<0.001
RV lead pacing	41 (36)	17 (65.4)	3 (100)	<0.001
Procedural data, median (IQR)				
Procedure duration, min	80 (70–95)	85 (70–90)	70 (67.5–71.3)	0.2
Radiation dose, mGy	507 (298–844.5)	639 (419–1024)	381.5 (341.8–445.5)	0.25
Contrast agent, ml	150 (120–170)	130 (100–196.5)	135 (115–162.5)	0.98

a Medtronic Evolut R, Boston Scientific ACURATE Neo
b Edwards Sapien 3
c Boston Scientific LOTUS

Abbreviations: see TABLE 1

arteriotomy. The secondary vascular access site was closed with a 6-French Angio-Seal (Terumo Interventional Systems) vascular plug.

Statistical analysis Standard descriptive statistics was applied to baseline, procedural, and postprocedural characteristics. Continuous variables with normal distribution were presented as mean (SD), nonnormally distributed variables were reported as median (interquartile range), whereas ranges and categorical variables were presented as numbers (percentages).

Distribution fitting, 2-way and multiway tables, the Wilcoxon test, the χ^2 test, the Mann–Whitney test, the independent *t* test, and the Spearman *R* statistical analyses were performed using the Statistica 13.3 software (Tibco Software, Inc., Palo Alto, California, United States). A *P* value less than 0.05 was considered significant.

RESULTS From January 2017 to December 2018, 143 consecutive patients underwent a transfemoral TAVI procedure in our center.

TABLE 4 Hospital stay of the study patients

		All study patients (n = 143)	Direct LV wire pacing (n = 82)	RV lead pacing (n = 61)	*P* value
NYHA class					
I		27 (20.6)	12 (15.2)	15 (28.9)	0.045
II		100 (76.3)	66 (83.5)	34 (65.4)	
III		4 (3)	1 (1.3)	3 (5.8)	
IV		0	0	0	
Hospital stay characteristics					
Maximum creatinine level, mmol/l, median (IQR)		102 (82–127)	102.5 (85–126)	100 (79–127)	0.54
Lowest hemoglobin level, g/dl, median (IQR)		10 (9–11.1)	10 (9.2–11.4)	10 (8.9–10.9)	0.7
Vascular complications	Any	12 (8.4)	5 (6.1)	7 (11.5)	0.31
	Arterial	9 (6.3)	5 (6.1)	4 (6.6)	0.39
	Venous	3 (2.1)	0	3 (4.9)	0.08
	VARC-2 minor	9 (6.3)	5 (6.1)	4 (6.6)	0.39
	VARC-2 major	3 (2.1)	0	3 (4.9)	0.08
Blood transfusion		11 (7.7)	2 (2.4)	9 (14.8)	0.02
Hospitalization, d, median (IQR)		6 (4.8–7)	5 (4–7)	6 (5–7.8)	0.31
Permanent pacemaker		14 (9.8)	4 (4.9)	10 (16.4)	0.003
Stroke		4 (2.8)	3 (3.7)	1 (1.6)	0.30
In-hospital death		2 (1.4)	1 (1.2)	1 (1.6)	0.85
MACE[a]		11 (7.7)	4 (4.9)	7 (11.5)	0.13
Echocardiography					
AVPG, mm Hg, median (IQR)		15 (10–19)	14 (10–18)	15 (10–22.5)	0.12
AVMG, mm Hg, median (IQR)		9 (6–12)	9 (6–11)	10 (7–14)	0.58
EF, %, median (IQR)		60 (50–60)	59 (49–59)	62 (53–65)	0.04
PVL[b]		20 (14)	11(13.4)	9 (14.8)	0.81
MR[c]		25 (17.5)	17(20.7)	8 (13.1)	0.37
TR[c]		24 (16.8)	16(19.5)	8 (13.1)	0.49
Pericardial effusion		20 (14)	16 (19.5)	4 (6.6)	0.03

Data are presented as number (percentage) unless otherwise indicated.

a Stroke, death, venous puncture–related complications, cardiac tamponade
b Moderate, no severe perivalvular leaks
c Moderate and severe

Abbreviations: MACE, major adverse cardiovascular event; PVL, perivalvular leak; VARC-2, Valve Academic Research Consortium 2; others, see TABLE 1

The baseline characteristics of the 2 study groups did not vary significantly (TABLE 1).

Direct LV wire pacing was used in 82 patients and successfully implemented (systolic pressure drop below 60 mm Hg for more than 30 s without loss of capture) in 80 of them. Therefore, the efficacy of the new pacing technique was 97.6%. The loss of capture occurred in 2 patients during stimulation control and predilatation, yet it had no clinical consequences.

Self-expandable Medtronic Evolut R (78 patients) and Boston Scientific ACURATE Neo (36 patients) valves were mainly used in the study group. The most common pacing method was direct LV wire pacing, whereas RV lead pacing was used more frequently with balloon-expandable valves (TABLE 2).

The procedural time was shorter for LV wire pacing, but direct LV wire pacing required a higher radiation dose and a greater amount of a contrast agent (TABLE 2). These parameters did not differ when analyzed by the type of the implanted valve (TABLE 3). Left ventricular wire pacing was approximately EUR 130 (USD 145) cheaper than RV lead pacing considering costs of an intravenous sheath, a pacing electrode, and the Angio-Seal device.

No cardiac tamponade was observed in the direct LV wire pacing group, but it occurred in 2 patients in the RV lead pacing group, although no statistical significance was achieved. Both cases of tamponade were linked to temporary RV pacing. One case of valve dislodgement occurred in each study group and required implantation of a second valve. None of the patients required conversion to surgery. Procedural details are presented in TABLES 2 and 3.

Two patients died during hospital stay (TABLE 4), one in each of the study groups. Septic shock was the direct cause of death in both cases. The frequency of vascular complications and stroke rates were similar in both groups. Three patients in the RV lead pacing group had venous puncture–related complications (hematomas), confirmed by ultrasound, but no statistical significance was found. Patients in the RV lead pacing group required blood transfusion more frequently than those in the direct LV wire pacing group.

Major adverse cardiovascular events (a combined endpoint including stroke, death, venous puncture–related complications, and cardiac tamponade) were more frequent in the RV lead pacing group, but no statistical significance was found.

Patients paced with the guidewire had lower ejection fraction at discharge, more frequent clinically nonsignificant pericardial effusion, and more pronounced symptoms of heart failure at discharge.

DISCUSSION This study for the first time compared the use of direct LV wire pacing and the conventional method (RV lead pacing) in a population of unselected patients undergoing both self- and balloon-expandable transfemoral TAVI procedures.

Right ventricular lead pacing is time-consuming and may be associated with vascular complications, ie, bleeding, hematoma, infection, thrombosis, arteriovenous fistula, and pericardial complications ranging from trivial effusion to cardiac tamponade. Lack of stability and lead disengagement are common problems that can potentially lead to dramatic complications.

Traditionally, many institutions leave the RV pacing wire in situ for 24 hours, especially in patients receiving self-expandable valves, owing to the risk of late complete AVB. This approach is no longer required because of decreased occurrence of AVB associated with the new generation of valves, improved implantation technique, and frequent late (after over 24 hours) AVB development. In most centers, the RV pacing lead is instantly removed upon the end of the TAVI procedure. This technical progress and gained experience have enabled us to implement the new direct LV stimulation technique in our center.

Meier and Rutishauser[12] first reported on the use of guidewires for pacing during cardiac procedures in 1985. They described a LV pacing technique with the 0.035-inch wire used in a series of 10 patients undergoing diagnostic cardiac catheterization. This method was used in several cases of aortic valvuloplasty in both adult and pediatric patients and subsequently neglected.[7,13] Since then, the use of TAVI has rapidly expanded, procedures have been gradually simplified and become safer and less invasive. Meanwhile, this strategy has been reported only in a few publications.[6,8-11,14-16]

A randomized EASY TAVI (Direct Left Ventricular Rapid Pacing via the Valve Delivery Guidewire in TAVR) trial comparing LV guidewire pacing with conventional RV lead pacing has been recently published.[17] The main findings of the trial were that the use of the LV guidewire for rapid ventricular pacing during TAVI with a balloon-expandable valve was safe and effective. It was associated with reduced procedure duration, fluoroscopy time, and cost compared with the use of conventional RV lead pacing. The EASY TAVI trial included only a highly selected group of patients undergoing balloon-expandable TAVI procedures. On the contrary, our study confirmed the suitability of LV guidewire pacing in a broader range of all-comers with the use of both balloon- and self-expandable valves.

According to our observations, direct LV wire pacing simplifies the procedure by eliminating the need for a temporary pacing wire. This method provides very constant and stable stimulation in most patients (97.6%) and is reliable for use with balloon-expandable valves where consistent pacing is crucial. The technique reduces procedural time by 5% despite the more frequent use

of self-expandable valves; thus, it has a potential to increase implantation tolerance.

The reported technique is safe and seems to be noninferior to the traditional stimulation method, even though it requires a greater amount of a contrast agent and is associated with a higher accumulated radiation dose along with potential mild LV muscle injury (lower ejection fraction at discharge, more frequent pericardial effusion, more pronounced symptoms of heart failure at discharge). We associate these debatable adverse events with the necessity of more frequent predilatation in the direct LV pacing group rather than the pacing method itself.

A relatively low rate of arterial access–related vascular complications, compared with the results of previous domestic publications, was achieved with the systematic use of a combination of 2 suture-based and 1 collagen footprint–based closing devices.[18-20] According to local practice, angiographic guidance was used for the precise localization of the optimal common femoral artery puncture site. Surgical cutdown was chosen when a fully percutaneous approach was assumed to be unpredictable based on computed tomography characteristics of the femoral artery.[21]

Study limitations Undoubtedly, our study was limited by some factors. We reported only a nonrandomized series of patients, a relatively small population from a single TAVI center. Furthermore, the study design was retrospective, and the operator could have biased the decision on the use of particular pacing techniques. Moreover, in 2017 and 2018, balloon-tipped RV pacing electrodes, whose use is currently the gold standard, were unavailable in our TAVI center.

Conclusions This is the first study comparing the direct LV wire pacing technique and the conventional RV lead pacing method in a population of unselected patients undergoing TAVI procedures.

Direct LV wire pacing during TAVI seems to be simple, reproducible, and safe. This new technique provides reliable, sustained stimulation characterized by a low complication rate and showing a potential reduction in procedural time and cost.

Further studies, preferably a larger randomized trial, are necessary to confirm the benefits of this promising method.

ARTICLE INFORMATION

NOTE This study was presented at the 24th International Polish Cardiac Society Congress on September 16 to 19, 2020 and as a poster at the European Society of Cardiology Congress on August 31, 2019 in Paris, France.

CONFLICT OF INTEREST None declared.

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