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RESEARCH ARTICLE

Use of the transfemoral access approach for cardiac stimulation device implantation when the superior venous approach is not feasible: A single-centre twenty-year series

Juan J. García Guerrero MD*[a], Joaquín Fernández de la Concha Castañeda MD[a], Antonio Chacón Piñero MD[a]

[a]: Department of Cardiology. Hospital Universitario de Badajoz. Badajoz. Spain.

***Corresponding author:** juanjose.gargue@gmail.com

ABSTRACT

Background: When permanent cardiac stimulation device implantation via superior venous access (i.e., cephalic, axillary or subclavian veins) is not possible or advisable, safe and feasible surgical alternatives must be used. The transfemoral approach is relatively unknown; therefore, it is seldom used and studied. This single-centre study analysed the 20-year outcomes of patients who underwent implantation using a transfemoral implantation approach.

Methods: Data on the implantation procedure (indication, approach, lead and pacemaker models, complications), patient characteristics (age, sex, medications, comorbidities), and follow-up were analysed for all patients who underwent permanent cardiac stimulation device implantation using the transfemoral approach between June 2001 and December 2021.

Results: A permanent cardiac stimulation device was implanted using the transfemoral approach in 66 patients (mean age, 76 years [range: 45-96], 40 [60%] men). The most frequent indication was atrioventricular block, associated with sinus rhythm in 36 patients and atrial fibrillation in 11 patients. The mean implantation time was 61 min (range: 20-210), and the mean fluoroscopy time was 7.9 min (range: 0.2-87). The minimum follow-up period was one year (December 2022), with a mean of 60 months [range: 2-180]). Overall, 26 patients (42%) were treated with oral anticoagulants postimplantation. No deaths, septic episodes, or severe complications were associated with the procedure in the short or long term. Follow-up data were available for 64 patients, of whom 52 (81%) died during follow-up (mean age, 84 years [range: 55-101]). No deaths were associated with the use of the transfemoral technique.

Conclusions: Permanent cardiac stimulation device implantation using the transfemoral access approach is feasible and straightforward for an experienced implant surgeon. The outcomes of systems implanted by the transfemoral access approach were comparable to those of systems implanted by the superior venous approach, and no severe complications were observed at the 20-year follow-up.

Keywords: transfemoral approach; permanent cardiac stimulation devices; iliofemoral; venous occlusion

Abbreviations:

AICDs: automatic implantable cardiac defibrillators
CRT: cardiac resynchronization therapy
LV: left ventricle
LV endo: left ventricular endocardium
RA: right atrium
RV: right ventricle

Introduction

When permanent cardiac stimulation device implantation at the superior venous tree via the preferred venous access approach is not possible, ideal or advisable (due to previous bilateral infection, chest radiation, acquired or congenital occlusion of the axillary or subclavian veins, congenital anomalies, etc.), epicardial cardiac stimulation device implantation is usually performed under general anaesthesia. This approach has an increased risk of medium- and long-term complications and higher thresholds and lead failure rates than the endocardial approach [1].

In contrast, the transfemoral approach, first reported in 1979 [2], permits the use of any kind of lead, does not require the use of general anaesthesia, and reduces the risk of complications and costs. As far as we know, this is the only way to perform the implant procedure avoiding the epicardial approach. Although the transfemoral or iliac approach has been described in case reports and patient series over the past 40-plus years [3-7], the number of implants and length of follow-up were very limited in most of the studies. In 2005, our team published the data for 12 patients implanted using a modified Ellestad technique [3], a true transfemoral approach that, in our judgement, was safer and simpler than the original procedure [8]; in 2017, we reported our 10-year experience including 50 patients, with comparable success to the usual upper venous tree approach [9]. This article presents the 20-year outcomes of the patients in our centre, which, in June 2001, began using this type of procedure for vein access when indicated. The aim of this study is to provide long-term data supporting the use of the transfemoral approach as an option when the usual route is not available.

Methods

This observational, prospective cohort study, enrolled patients implanted with cardiac stimulation devices via the transfemoral approach.

IMPLANTATION PROCEDURE: We collected data about the implantation procedure (indication, approach, lead and pacemaker models, complications) and patient characteristics (age, sex, medications, comorbidities) for all permanent cardiac stimulation device implantations using the transfemoral approach between June 2001 and December 2021. In all cases, the modified Ellestad technique was used, as previously described [8]. In brief, after an antiseptic shower on the morning of the procedure (when possible), the patient was moved to the operating room, and the surgical area was carefully cleaned with a chlorhexidine solution and then painted with 10% povidone-iodine solution. An adhesive fenestrated sterile drape was placed, with the fenestration slightly below the inguinal crease. Local anaesthetic was injected, any exposed skin was carefully dried, and an antimicrobial incise drape was placed to cover the incision area. Access to the femoral vein was achieved by percutaneous puncture 3-4 cm below the inguinal crease, and then a transverse incision was made at the cutaneous puncture site. A pulse generator pocket was created at the level of the quadriceps fascia in the anterior thigh. Extralong active fixation leads ranging from 85 to 110 cm in length were used for the right ventricle (RV) and right atrium (RA). Pacing leads were advanced under fluoroscopic guidance to the endocardial surface of the selected chamber, preforming the stylet as needed to reach the desired position. The same slittable, steerable guiding catheter (6227-DEF, Medtronic, Minneapolis, MN, USA) was used in every biventricular procedure. The ostium of the coronary sinus was cannulated, and then a standard left ventricle (LV) lead was implanted in the selected vein using the same technique as in the superior venous approach. After identifying an appropriate location based on capture and sensing threshold measurements, a nonresorbable suture was used to secure the lead or leads to the quadriceps fascia with the anchoring sleeve. The pulse generator was anchored to the underlying fascia through the suture hole in the generator's connector block.

FOLLOW-UP: The analysis was limited to patients for whom medical records data and/or contact information was available at the end of the study period in December 2022. The ending date allowed for at least one year of follow-up according to the usual criteria and protocols in our hospital unit. Details were collected about any interventions after the primary implantation (e.g., subsequent complications or battery replacements) and about the patients' clinical outcomes. At the end of the study period (December 2022), the life status of all patients was confirmed by direct contact during routine visits at our centre, by telephone when follow-up was carried out at other centres or the patient had been lost to follow-up for any reason, or by accessing our regional database.

In addition to the previous global analysis, we divided our patients into two groups to determine possible differences between the groups in characteristics and outcomes: Group A: patients implanted up to the end of 2011; and Group B: patients implanted after 2011.

STATISTICAL ANALYSIS. A descriptive analysis was carried out, and the results are expressed as percentages or mean values and ranges, as appropriate. All analyses were performed using SPSS v. 21.

RESEARCH ETHICS: The local Ethics Committee approved the study protocol, and all patients provided written informed consent to participate.

Results

PATIENT CHARACTERISTICS

A permanent cardiac stimulation device was implanted using the transfemoral approach in 66 patients (mean age, 76 years [range: 45-96], 40 [60%] men) at our hospital between June 2001 and December 2021, accounting for 0.83% of all permanent cardiac stimulation devices implanted during the study period. All 66 patients were included in the analysis. In all cases, it was impossible or inadvisable to use upper access to implant the electrodes or create a pocket for the generator. Transfemoral approach indications are shown in Table 1.

Table 1: Transfemoral implant indications

Indications	***Number of patients (%)***
Previous infection + CLV occlusion	*21 (32)*
Bilateral venous occlusion/not achieved	*18 (27)*
Mastectomy + Radiotherapy	*1 (1)*
Severe kyphosis	*2 (3)*
Very thin thoracic wall	*6 (10)*
Postsurgery thoracic wounds	*6 (10)*
Severe complications using UVT access	*3 (5)*
Double system infection	*3 (5)*
Superior access not advisable (HD)	*1 (1)*
No CS access	*4 (6)*
No suitable tributary veins	*1 (1)*

CLV, contralateral vein; CS, coronary sinus; UVT, upper venous tree; HD: Haemodialysis

In one patient, a dual-chamber system had been left in the subclavian area when inadequate veins precluded implantation of the LV electrode. Transfemoral access was used to implant an LV endocardial electrode using the atrial transseptal approach, program the femoral generator in VVT mode, and synchronize its action to the dual-chamber generator. Two patients had dual-chamber systems implanted using the transfemoral access approach after an unsuccessful attempt to implant an electrode in the LV to install a cardiac resynchronization therapy (CRT) system. After infection of the previous upper venous system, one patient had a transfemoral biventricular automatic implantable cardioverter defibrillator (AICD) implanted using an endocardial active fixation lead (implanted by puncturing the interatrial septum) and two 85-cm long single-coil leads (model 6935), one attached to the apex of the RV and the other attached to the lateral wall of the RA, to provide a good defibrillation vector between the two coils.

Antibiotic prophylaxis was left to operator discretion: 34 patients were treated with cloxacillin, 10 were treated with 3rd generation cephalosporin, 17 were treated with vancomycin and 5 were treated with erythromycin. Only one dose was administered presurgery.

Overall, 28 patients (44%) were currently taking oral anticoagulants or had been treated with oral anticoagulants at least since implantation. The indication for anticoagulation was established according to the usual clinical criteria, and transfemoral implantation had no impact on this decision.

There were no significant differences in characteristics between the patients in Groups A and B, but the number of patients implanted was clearly different (50 in Group A and 16 in Group B); the length of time of every period was the same (10 years). Group A accounted for 1.9% of the overall cardiac stimulation device implants in the same period, and Group B accounted for 0.37%.

IMPLANTATION CHARACTERISTICS

The most frequent indication for implantation (36 patients, 54%) was 3rd-degree atrioventricular block associated with sinus rhythm, including 5 patients with severe LV dysfunction. All cardiac stimulation device implantation indications are shown in Table 2.

Table 2: Indications for cardiac stimulation device implantation

Indications	***Number of patients***
3rd-degree AVB with SR	*37[a]*
3rd-degree AVB with AFib	*12[b]*
Sinus node disease	*10[c]*
2nd-degree AVB Mobitz II with SR	*3*
HF with severe systolic dysfunction	*3*
HOC with severe subaortic gradient	*1*

[a] 3 patients had severe LV dysfunction.

[b] 1 patient had severe LV dysfunction.

[c] 7 patients had frequent, poorly controlled paroxysmal AFib.

AVB, atrioventricular block; SR, sinus rhythm; AFib, atrial fibrillation; HF, heart failure; HOC, hypertrophic obstructive cardiomyopathy

The most frequent type of stimulation mode used in our series was VVIR (34), followed by the DDDR (28), biventricular (4), VVT (1) and AAIR (1) modes. One of the 26 transfemoral ventricular single-chamber systems, which used a transseptal LV endocardial lead, was synchronized to a former DDDR system implanted via the left subclavian vein to achieve a biventricular system. Therefore, of the 5 types of biventricular systems implanted in our series, 3 were epicardial systems, using tributary coronary veins, and 2 were endocardial systems.

Generators manufactured by St. Jude Medical (St. Jude Medical Inc., Sylmar, CA, USA) were used for the primary implantations in the majority of our patients (51 patients), and other brands were used in the remaining patients (15 patients).

A total of 97 electrodes manufactured by St. Jude Medical and Medtronic were implanted using the transfemoral approach, ranging from 85 to 110 cm in length. The lead characteristics are shown in Table 3.

Table 3: Lead model length used by implantation site

RV	***n***	***RA***	***n***	***TVLV***	***n***	***LV endo***	***n***
*1388T-110**	*8*	*1388T-110**	*4*	*1056K-86**	*1*	*3830-110***	*1*
*1488T-110**	*2*	*1488T-110**	*1*	*1058T-86**	*1*	*1688T-100**	*1*
*1688T-100**	*32*	*1688T-100**	*12*	*4194-88***	*1*		
		*1888T-100**	*1*				
*2088TC-100**	*8*	*2088TC-100**	*2*				
*5076-85***	*12*	*5076-85***	*8*				
*6935-100***	*1*	*6935-100***	*1*				
TOTAL	***63***		***29***		***3***		***2***

*RV, Right ventricle; RA, Right atrium; TVLV, Tributary veins of the left ventricle; LV endo, Left ventricular endocardium; *, St Jude Medical; **, Medtronic.*

Right femoral vein access was used in 58 patients, and left femoral vein access was used in 8 patients. The mean implantation time was 61 min (range: 20-210) in all patients, 54 min (range: 20-181) in patients with single- or dual-chamber implants, and 141 min (range: 65-210) in patients with CRT system implants. The mean fluoroscopy time was 7.9 min (range: 0.2-87), 7.0 min (range: 0.2-87) and 19 min (range: 5-46), respectively. Acute electrical measurements are shown in Table 4.

Table 4: Implant electrical measurements

	P/R wave (mV) Mean (range)	***Threshold at 0.4 ms (V) Mean (range)***	***Impedance (Ohm) Mean (range)***
RV	*11.5 (2.1-30.0)*	*0.79 (0.1-3.0)*	*731 (450-1250)*
RA	*2.5 (0.6-21.4)*	*0.80 (0.1-1.6)*	*588 (407-938)*
TVLV	*22.1 (9.4-30.0)*	*0.9 (0.7-1.1)*	*1157 (675-1905)*
LV endo	*2.7 (2.1-3.2)*	*0.8 (0.7-0.9)*	*676 (602-750)*

RV, right ventricle; RA, right atrium; TVLV, tributary veins of the left ventricle; LV endo, left ventricular endocardium

No deaths or severe complications (i.e., those that placed the patient at significant risk, requiring an intervention procedure or prolonged hospitalization for proper management) were associated with the implantation procedure. One patient needed femoral artery compression due to bleeding caused by accidental puncture of the artery during the procedure. There was one case of acute RV electrode dislodgement postimplantation. The electrode was repositioned the following day without any problems. Most patients (49 out of 66) were discharged 24-72 hours postimplantation. There were no retroperitoneal haematomas.

There were no significant differences between Groups A and B in implant characteristics, electrical measurements or acute complications, but there was a clear difference in the number of CRT patients (4 in Group A and only 1 in Group B). One AICD was implanted in Group B, while none were implanted in Group A.

FOLLOW-UP: Data were extracted from our database for 61 patients, and 3 patients were contacted by telephone because their follow-up had occurred at other medical centres. Two patients could not be located by any means and were lost to follow-up.
Of the 64 patients analysed, 52 (81%) had an uneventful outcome, 52 (81%) died, 6 (9%) needed a procedure to remove the transfemoral system due to infection or erosion of the battery pocket, 1 (1.5%) underwent a procedure 15 days postimplantation to treat a haematoma, and 1 (1.5%) needed surgery after one month because of an increased RV threshold. None of these patients developed septic episodes. Pocket revision was performed in 4 patients (6%), and they had an uneventful recovery. The mean length of follow-up was 66 months (range: 1-238) in all patients, 100 months (range: 24-173) in patients with no events, and 60 months (range: 2-180) in patients who died during follow-up. The mean time until system extraction was 44 months (range 4-106). Of the 52 patients with no events, 8 underwent surgeries for scheduled battery replacement, with a mean time to replacement of 108 months (range: 52-171). It was not necessary to replace electrodes in any of these patients.
Some differences in follow-up were noted between Groups A and B. There were fewer complications in Group B than in Group A, as 5 patients underwent extraction in Group A and only one underwent extraction in Group B, with no significant haematomas in Group B. Pocket revisions were performed only in patients in Group A.

No deaths (unknown cause, multiorgan failure of undetermined cause, cardiac failure, pneumonia, renal failure, cancer, stroke, undetermined sudden death, Alzheimer disease) were associated in any way with the transfemoral implantation approach. Twelve patients (19%) underwent new surgical procedures because of postdischarge complications. The transfemoral system was removed in 6 of these patients (5 in Group A) due to relapsing erosion or infection. In all patients, the complete system was removed with the usual extraction tools, without complications. One patient underwent a new procedure 1 month after discharge to reposition the electrode due to an elevation of the RV stimulation threshold, which was readily achieved. There was no X-ray evidence of electrode dislodgement. One patient underwent a second surgery for haematoma evacuation 15 days after discharge. The patient then had a normal recovery. No cases of clinical thrombosis in the lower venous tree or pulmonary embolism occurred in any of the 46 patients who completed the follow-up. Eight patients underwent the Echo-Duplex test at least 6 months postimplantation to test for subclinical thrombosis. No thrombosis was found. In addition, none of the patients in the study complained about discomfort in their thighs while walking or at rest.

Electrical measurements conducted during follow-up in our hospital unit were obtained from our database and are shown in Table 5. The R wave was not routinely measured. There were no electrode dislocations or fractures during the follow-up period.

Table 5: Follow-up electrical measurements

	P/R wave (mV)	***Threshold (V)***	***Impedance (Ohm)***
	Mean (range)	***Mean (range)***	***Mean (range)***
RV	*N/A*	*0.97 (0.25-5.0) at 0.4 ms*	*497 (175-1260)*
RA	*2.9 (0.5-11.2)*	*1.0 (0.25-3.3) at 0.4 ms*	*460 (150-1260)*
TVLV	*N/A*	*1.0 (0.5-3.75) at 0.71 (0.4-1.0) ms*	*652 (175-1905)*
LV endo	*N/A*	*0.75 (0.75-0.75) at 0.4 ms*	*545 (323-1275)*

RV, right ventricle; RA, right atrium; TVLV, tributary veins of the left ventricle; LV endo, left ventricular endocardium

The rate response function was analysed by treadmill stress testing in the first 10 patients implanted with a VVIR system. Adequate function was observed in all patients, and no reprogramming of the rate response was necessary.

Discussion

The transfemoral access technique for the implantation of cardiac stimulation systems is used in very few centres worldwide; however, a series of more than 10 patients has been published for more than 40 years and shows success with the use of this technique in both adults [3-5,7-9] and children [6] when the more usual and superior approach is problematic. In addition, success with transfemoral access has been reported in problematic cases involving single- and dual-chamber pacemakers [10], automatic implantable cardiac defibrillators (AICDs) using subcutaneous patches [11], active-can [12], CRT stimulation mode [13], and even CRT mode using an endocardial electrode in the LV with transseptal access [7,9,14]. Nonetheless, the technique remains widely considered the very last resort [15].

The number of intracardiac stimulation device interventions is increasing because of the expanded indications for cardiac stimulation and defibrillation. The related increase in complications [16] points towards a growing need for alternatives to the upper access approach [17,18]. When the upper access approach is not possible or not recommended for other reasons, an epicardial system is usually implanted, even though this procedure requires general anaesthesia, is a more aggressive surgical option and leads to worse long-term results than endocardial systems in patients with cardiovascular disease [1] and congenital heart disease [19]. In a study, the abdominal approach was associated with an increased infection rate in patients with AICDs compared to the chest approach [20]. Although the leadless pacemaker is currently available for use, this type of stimulation device is still not widely available and is only available in the single-chamber mode [21]. Therefore, better alternatives are clearly necessary.

The present article describes 20 years of experience at a single centre using the transfemoral access technique in patients with occlusion in the superior veins or when upper venous access was not possible or advisable. To our knowledge, our series has one of the longest mean follow-ups in adults and the largest number of patients meeting the current selection criteria [4,5,7,9,22].

Our technique is a modification of the procedure first reported by Ellestad [3] and compares favourably with the traditional upper access method in safety and simplicity. This comparison applies to implantation and fluoroscopy times and both acute and chronic sensing values, impedance, and stimulation thresholds [23]. In our opinion, the modified Ellestad technique devised by our team and described in previous publications [8,9] can be performed successfully by anyone experienced in upper access implantation.

There was an important difference between the two groups in our study: the number of patients was much lower in Group B than in Group A, while the period was the same (10 years). We believe the reason is twofold: first, our infection rate dropped dramatically after the 2001-2011 period, close to 5.5% at the beginning and then declining slowly and constantly to the stable rate of ~ 1% in the 2012-2022 period (unpublished data). This fact could reduce the number of patients with the most frequent indication for transfemoral implants in our series: infection due to a previous stimulation device and contralateral occlusion. Second, our progressive improvement in achieving superior vascular access with the increased use of long and steerable sheaths, which, in our judgement, led to a better rate of success in difficult veins, the second most frequent reason for using the transfemoral approach (Table 1).

The greatest problem observed with the iliofemoral technique was electrode dislodgement in 28% [4] and 20% [5] of patients. This was reduced to a minimum in our patients, with a single acute case of dislodgement (1.5%) across 20 years, which was resolved the day after the procedure and before the patient was discharged. There were no dislodgements in the medium or long term during our 20-year follow-up. We attribute these improved results to the routine use of active fixation electrodes and to the implantation of the leads in the lateral wall of the RA rather than in the RA appendage. Any dislocation of the electrode could be promptly noted during the procedure and immediately addressed.

Achieving true femoral vein access instead of iliac access differentiates our technique from previously published methods [3,5,6]. This approach can greatly reduce the likelihood of retroperitoneal bleeding, which was reported in two cases in another publication [3]. The transfemoral technique also eliminates any potential for haemothorax or pneumothorax during venous access. No deaths or significant complications occurred during the procedures, and any bleeding was easily controlled in the operating room. The placement of the generator pocket in the thigh and 4-5 cm below the inguinal crease likely reduced the complexity of the technique.

For the first 10 patients implanted with a VVIR system, we conducted a treadmill stress test to determine if their rate response function was similar to that achieved in patients with cardiac stimulation devices located in the chest area, given the different mobility of the generator located in the upper thigh [8]. To our knowledge, this function has not previously been studied in patients with permanent transfemoral pacemakers. We found no differences in function between the transfemoral systems studied and traditional pacemakers implanted via the upper approach. None of our patients reported difficulties in walking related to the generator position in the upper thigh. Some patients reported that this location was more comfortable for them than the subclavian location.

The presence of one or multiple electrodes in the lower venous tree leads to some questions about potential secondary vein thrombosis. This threat has been well studied in various publications about temporary pacemakers, where the rate of thrombosis has been very high (25-39%) [24] and the subclinical pulmonary embolism rate was 60% in patients with confirmed thrombosis [25]. The use of anticoagulants at therapeutic and prophylactic doses in a series of patients with temporary transfemoral pacemakers was associated with significant rates of thrombosis [24]. However, the use of temporary active fixation electrodes reduced the rate of vein thrombosis by allowing early patient mobilization after electrode implantation [26], similar to patients implanted using a permanent transfemoral system.

In the series published about permanent iliofemoral pacemakers, only one case of thrombosis was reported, and there were no reports of frequent thrombotic events [4-9,22]. It could be suggested that the difference in vein thrombosis incidence for temporary vs. permanent pacemakers implanted using transfemoral access is due to early mobilization: all patients in our series were mobile on the day after implantation of a permanent pacemaker, and there were no cases of clinical thrombosis in our patients during the 20 years of follow-up. The use of oral anticoagulants in 28 (44%) of our patients also might have helped to reduce the number of thrombotic episodes, as previously reported for upper access implantation [27].

Another important concern with this type of implant is an increased rate of infections due to puncture or the placement of the generator pocket in an area containing a microbial flora different from that found in the chest area [28]. Nonetheless, no previously published series reported high rates of infection [4-9, 22]. Our series showed a 9% overall infection rate during the 20-year study period, although the rate differed between the first part of the series (pre-2005) and the later part. In the 16 patients implanted before 2005, there were 3 extractions due to infection (18.7%), 2 in the remaining patients in Group A (5.8%), and only 1 in Group B (6%). It is possible that the high proportion of our patients treated with oral anticoagulants, which increases the risk of infection [29], might have had some influence on the infection rate. In addition, the number of our patients with previous infections might have had some impact (Table 1) on the results, as this has been shown to be a factor in reinfection risk [30].

Martin and Lever [31] recently published a rather short series (11 patients) using their own transfemoral technique, which is very similar to ours [8]. During follow-up, 7 patients had their systems electively removed in a short median time (5 months). They considered the transfemoral implant approach to mainly be a transient procedure, able to provide sufficient time to address the problems that preclude a new implant in the upper venous tree, after experiencing different problems with previous conventional systems. They adopted this approach due to the lack of sufficient long-term data regarding its use in a definitive manner. We believe the present report provides sufficient long-term data to support a definitive and long-lasting approach using the transfemoral technique as an option when the upper venous tree technique is unusable.

Limitations

This was a single-centre series, and the number of patients analysed in this report, although rather high compared with the published data addressing this technique, was very low and does not permit generalizing our results to any other implant group using this approach. The global utility of the technique is directly related to patients' existing conditions leading to its use (anatomical problems, rate of infection, ability to achieve upper venous tree access, etc.).

Conclusions

Permanent cardiac stimulation device implantation using the transfemoral access technique offers a feasible, stable, long-lasting solution when the superior venous access technique cannot be used. The procedure can be learned and used successfully by any experienced surgeon with standard implantation training. Data on electrical activity obtained from these cardiac stimulation devices are comparable to those from any system implanted by endocardial access using the superior venous

approach. No severe complications were observed at the 20-year follow-up.

Conflict of Interest Statement: JJGG and JFCC have received fees for lectures and advisory from St Jude Medical, Medtronic and Boston Scientific.

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