

Subacute cardiac perforations associated with active fixation leads

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Aims

Having several recently published reports on increased rate of cardiac perforation with some lead models as background, we assess the relation between cardiac perforations and models of leads used.

Methods and results

All pacing and defibrillation leads implantations between 1 January 2007 and 31 March 2008 were analysed retrospectively. There were 2247 leads implanted in 1419 patients aged 67.6 ± 14.1 , 1200 (53%) active and 1047 (47%) passive fixation leads. Cardiac perforation occurred in eight patients (0.5%). The number of perforations does not differ significantly between the pacemaker and implantable cardioverter defibrillator implantations (five and three cases, respectively, $P = 0.13$). All perforations were associated with the active fixation leads implantation (8 vs. 0, $P < 0.01$). Only four models of leads were associated with perforations, but the risk of their use was not statistically significantly increased, when compared with other active fixation leads placed in the adequate position.

Conclusions

The incidence of cardiac perforation related to pacing and defibrillation leads is low. The use of active fixation leads is associated with an increased risk of cardiac perforation. We did not find any correlation between the perforation rate and any particular model of the implanted lead.

Keywords

Cardiac perforation • Transvenous leads • Pacemaker • Implantable cardioverter-defibrillator • Complications

Introduction

Cardiac perforation is the most serious, but fortunately very uncommon complication of a pacemaker, implantable cardioverter defibrillator (ICD), or cardiac resynchronization therapy device (CRT) implantation. The published incidence of this complication varies from 0.4 even to 5.2%, but nowadays it is usually lower than 1%.^{1–6} The use of active fixation leads is associated with higher rate of cardiac perforations.^{6–8} Recently, several reports on increased rate of cardiac perforation with both active and passive defibrillation leads of one model have been published.^{1,9,10} The aim of this study was to assess the relation between the cardiac perforation and the model of both pacing and defibrillation lead in a single centre for a period of 15 months.

Methods

We analysed retrospectively all transvenous pacing and defibrillator leads implantations performed in our centre (a tertiary referral

centre with two independent electrophysiological labs) between 1 January 2007 and 31 March 2008. Both primary implantations and additional new leads implantations in patients with previously implanted devices (lead failures and device up-grade) were included in the analysis. All the procedures were performed by nine cardiologists in the operating rooms equipped according to the guidelines of the European Society of Cardiology.¹¹ Experience of the physicians ranges from 4 to 20 years, each of them performing more than 100 procedures per year. The leads and devices were implanted according to the manufacturers' recommendations.

The suspicion of cardiac perforation was based on the following signs and symptoms:

- (i) acute stabbing chest pain and/or dyspnoea
- (ii) pericardial effusion,
- (iii) significant changes in electrical lead parameters
- (iv) extracardiac lead location on chest X-ray, fluoroscopy, echocardiogram, or computed tomography (CT) (Figures 1 and 2).

In each case, the diagnosis had to be confirmed by at least one non-invasive, imaging test.

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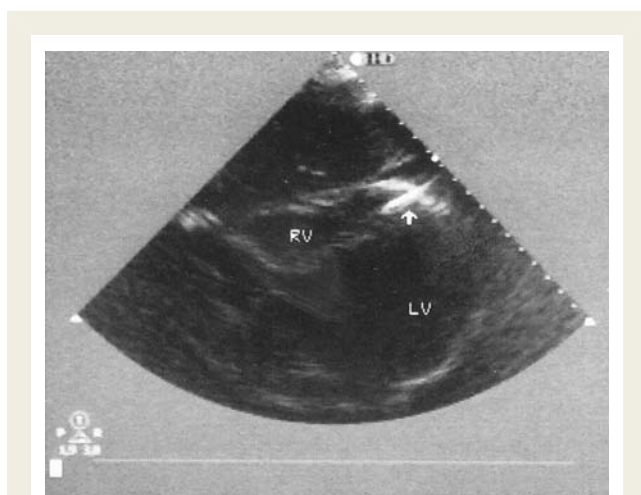


Figure 1 Diagnostics: a 2-D echocardiogram of a patient no. 4 (Table 3). The arrow indicates the distal part of the lead in an extracardiac location. LV, left ventricle; RV, right ventricle.

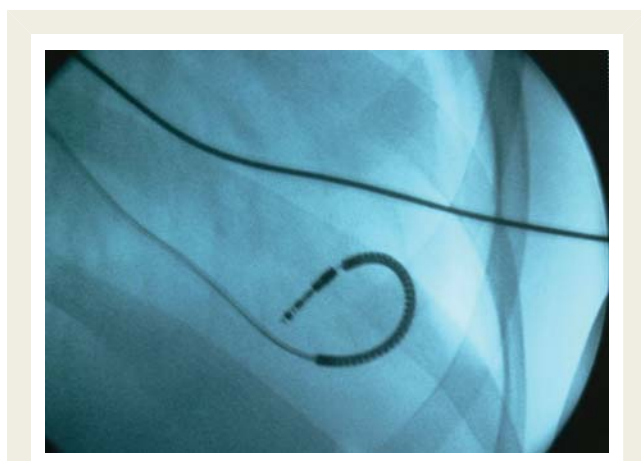


Figure 2 Fluoroscopy (PA view) frame taken from patient no. 5 (Table 3) before the percutaneous reposition of the lead. The curve of the lead coil, coming out of the right ventricle is shaped by the pericardium.

All the diagnosed cases of cardiac perforations were analysed with respect to the used type and model of the lead. The time to onset, clinical course and manifestations, results of chest X-ray or fluoroscopy, transthoracic echocardiography, and interrogation of lead parameters were collected for each case. Moreover, the data concerning the underlying heart disease, concomitant diseases, and pharmacological treatment, with special attention to steroids, antiplatelet, or anticoagulation drugs were also analysed.

Statistical analysis

Statistical analysis was carried out with the SAS 8e program using Fisher's exact test for comparing proportions and the unpaired Student's test for continuous variables. A P -value <0.05 was considered statistically significant.

Results

During the period of 15 months, there were 2247 leads implanted in 1419 patients with commonly accepted indications for either pacemaker or ICD or CRT implantation.^{11,12} The group consisted of 855 males (60%) and 564 females (40%). The mean age of the patients was 67.6 ± 14.1 years. The following devices were implanted or upgraded: 999 pacemakers [single chamber, 392 (27.6%); dual chamber, 607 (42.8%)]; 303 ICDs [single chamber, 190 (13.4%); dual chamber, 113 (8%)]; and 117 CRT devices [72 (5.1%) defibrillators and 45 (3.1%) pacemakers].

Implanted leads

From the total of 2247 leads from five manufacturers (Biotronik GmbH, Berlin Germany, Ela Medical—Sorin Group, Milan, Italy; Medtronic, Minneapolis, MN, USA; St Jude Medical, St Paul, MN, USA; Vitatron B.V. Arnhem, The Netherlands), there were 1200 (53%) active (A) and 1047 (47%) passive (P) fixation leads used for: right atrial position (476A/305P), right ventricular pacing (426A/576P), right ventricular pacing/defibrillation (301A/54P), and 112 (P) left ventricular leads for pacing via heart veins system (one epicardial left ventricular lead was not included in the analysis). Detailed characteristics of all implanted leads are listed in Table 1.

Cardiac perforations

Within the analysed period, the diagnosis of cardiac perforation was made in eight patients (four males and four females). The mean age of the patients with and without perforation was not statistically different (55.9 ± 25.1 years and 67.7 ± 14.0 years, respectively, $P = 0.2$). The number of perforations did not differ significantly between the pacemaker and ICD implantations (five and three cases, respectively, $P = 0.13$). Perforation rate was 0.35% of all implanted leads and 0.5% of the treated patients. All perforations were associated with the implantation of the active fixation leads (8 vs. 0, $P < 0.01$). In three cases, the perforations were caused by atrial pacing leads, in two cases by ventricular pacing leads, and the latter three cases were associated with ventricular pacing/defibrillation leads (Table 2). There were no perforations related to left ventricular leads implantation. Although only four types of leads were associated with the perforations, the risk of their use was not statistically significantly increased, when compared with other active fixation leads placed in the adequate position.

All device implantations followed by the perforations were performed by five out of nine physicians involved in these methods of therapy in our hospital. Their experience in cardiac pacing is presented in Table 3.

All cases of perforation were symptomatic and the final diagnosis was made on the basis of clinical manifestation as described in the methods' section. All patients had stabbing chest pain and shortness of breath. It should be noted that the pain was intermittent in six patients. Clinical and echocardiographical symptoms of cardiac tamponade were present in one case. The symptoms occurred 0.25–16 days (mean 6.4 ± 5.6) after implantation, that is to say, the clinical symptoms were not evident during the procedure. The detailed characteristic of patients and their clinical

Table 1 Lead models, manufacturers, and numbers

Manufacturer	Type	Diameter (F)	Shape	Number (%)
Atrial passive fixation leads				305 (39)
SJM	IsoFlex 1642T 52 cm	7	J-shape	178 (22.8)
Vitatron	Excellence PS+53	5.3	J-shape	73 (9.3)
SJM	Membrane EX 1474T	7.5	J-shape	20 (2.5)
Ela Medical	JX26D	4.8	J-shape	14 (1.8)
Vitatron	Crystalline ICL08JB-53	8	J-shape	11 (1.4)
Medtronic	CapsSure [®] SP Novus 5592	6.0	J-shape	5 (0.6)
Biotronik	Synox SX 53JBP	7.8	J-shape	2 (0.3)
Ela Medical	Stelid II	7.7	J-shape	2 (0.3)
Atrial active fixation leads				476 (61)
SJM	Tendril ST 1782TC/52	6.8	J-shape	261 (33.4)
Medtronic	CapSureFix [®] Novus 5076	6.2	Straight	71 (9.1)
Vitatron	Crystalline ActFix ICF09B-52	6	Straight	69 (8.8)
SJM	Tendril SDX 1688T 52	7.5	Straight	43 (5.5)
Biotronik	Selox (53,45) SR	7.8	Straight	14 (1.8)
Biotronik	Setrox S 53	6.7	Straight	11 (1.4)
Ela Medical	Stelix II	7.7	Straight	5 (0.6)
Medtronic	CapSureFix [®] 5568	7.2	J-shape	2 (0.3)
Total				781 (100)
Manufacturer	Type	Diameter (F)	Number (%)	
Ventricular passive fixation leads				576 (58)
SJM	IsoFlex S 1646T 58	7		335 (33.5)
Vitatron	Excellence PS+58	5.3		131 (13.1)
Medtronic	CapSureFix [®] Novus 5076	6.2		40 (4)
Vitatron	Crystalline ICL08B-58	8		21 (2.1)
Medtronic	CapSure SP Novus 5092-58	6		19 (1.9)
Ela Medical	TX26D	4.8		17 (1.7)
Ela Medical	ICV 0700	11		14 (1.4)
Ventricular active fixation leads				426 (42)
SJM	Tendril ST 1788TC/58	5.9		274 (27.4)
Vitatron	Crystalline ActFix ICF09B-58	6		96 (9.6)
SJM	Tendril SDX 1688T-58	7.5		44 (4.4)
Biotronik	Selox (53,60) SR	7.8		5 (0.5)
Ela Medical	ICV 0643	11		2 (0.2)
Total				999 (100)
Manufacturer	Type	Diameter (F)	Number (%)	
Passive fixation defibrillation leads				54 (15)
SJM	Riata 1570 65	8		20 (5.6)
Biotronik	Linix TD65/16	7.8		20 (5.6)
SJM	Riata 7040 65	6.3		5 (1.4)
Medtronic	Sprint Quattro 6944-65	8.2		4 (1.1)
SJM	Riata 1572 65	8		3 (0.8)
Biotronik	Kentrox RV-S 65	9.3		1 (0.4)
SJM	Riata 7042 65	6.3		1 (0.4)
Active fixation defibrillation leads				301 (85)
SJM	Riata 1580 65	7.8		87 (24.5)
SJM	Riata ST 7000/7002/65	6.3		85 (23.9)
Medtronic	Sprint Fidelis [™] 6949/6931	6.6		53 (15.3)
Medtronic	Sprint Quattro Secure [™] 6947	8.6		29 (8.1)
Biotronik	Linix SD (65.75 cm)	7.8		28 (7.9)
Biotronik	Kentrox SL-S 65/16	9.3		14 (3.9)

Continued

Table 1 Continued

Manufacturer	Type	Diameter (F)	Shape	Number (%)
Medtronic	Sprint 6945–65	7.8		5 (1.4)
Total				355 (100)
Manufacturer	Type	Diameter (F)	Shape	Number (%)
Left ventricular leads (Passive Fixation)				
Medtronic	Attain® Unipolar OTW. 4193	4		69 (61.6)
Ela Medical	Situs OTW/LV	6		17 (15.1)
SJM	SJM QuickSite 1056T 86	5.6		12 (10.7)
Medtronic	Attain® Bipolar OTW. 4194	6		10 (8.9)
Biotronik	Corox OTW 75-BP	5.4		3 (2.7)
Biotronik	Corox LV-H 75-UP	4.9		1 (0.9)
Total				112 (100)

Table 2 Perforation ratio and lead model

	Perforation-related lead model	Incidence of perforation (vs. all other active fixation lead models in this position)	P
Atrial leads	Tendril ST 1782TC/52	3/261 (1.15%) vs. 0/215 (0%)	0.25
Ventricular leads	Tendril ST 1788TC/58	2/274 (0.73%) vs. 0/149 (0%)	0.54
Defibrillation leads	Riata 7000/7002	2/85 (2.35%) vs. 1/216 (0.46%)	0.19
	Sprint Fidelis 6949-75	1/53 (1.89%) vs. 2/248 (0.81%)	0.44

course is shown in *Table 3*. In none of the cases, either temporary pacing or steroids were concomitantly used.

The case number 7 is of special interest (*Table 3*). First, the patient complained of a sudden chest pain that occurred 12 days after the implantation and the echocardiogram revealed moderate pericardial effusion (up to 6 mm). Both sensing and pacing parameters, as well as the lead position on fluoroscopy, were similar to those obtained during the implantation and before the discharge. On the next day, the patient resuffered from the stabbing chest pain recurrence. The second echocardiogram indicated the decrease of pericardial effusion, but haemothorax and extra-cardiac lead positions were found on the chest X-ray. The device interrogation showed both loss of sensing and pacing capture. On the same day, the patient underwent a surgical removal of the lead. The location of the tip of the lead in the left pleural cavity was also confirmed by the surgeons.

Treatment

After the diagnosis was made, six patients underwent surgical intervention with median sternotomy but without the use of extracorporeal circulation. In four cases, the leads were repositioned to a site of acceptable pace/sense parameters under direct visual control. In two cases, the leads were surgically removed (*Figure 3*) and replaced by either epicardial or new transvenous lead. In all surgically treated cases, the sites of perforation were managed with double-patch sutures and haemopericardium was evacuated. In two cases, in which there was no pericardial effusion,

one lead was repositioned while the other was replaced by the new passive fixation lead. There were neither deaths nor other serious complications of the treatment.

Discussion

The overall rate of cardiac perforation in our study was low (0.5% of the treated patients). Surprisingly, the perforation rate did not differ significantly between the pacemaker and ICD implantation. All perforations were related to the implantation of the active fixation leads placed in the right atrial appendage ($n=3$) or right ventricular apex ($n=5$) ($P < 0.01$). The factors that may influence the perforation ratio rate could be divided into three groups:

- (i) Lead design (diameter, fixation mechanism, construction of the lead tip, pre-shaped J-curve),
- (ii) Physicians' experience and training level,
- (iii) Patient-related factors.

Lead design

The use of helical screw ventricular leads was reported to increase the risk of perforation.¹³ Indeed, all the perforations reported in our Institute were related to the use of the leads with retractable screw. In three out of eight cases, the perforations were caused by the atrial leads. The high incidence of perforations related to atrial leads has also been reported previously.^{6,7} The number may be even higher because such perforations can be clinically silent if there is only a partial protrusion of the screw through the atrial

Table 3 Characteristics of patients and clinical course of perforations (cases in chronological order)

Gender	Age	BMI<20	Aetiology, indication for implantation, device	Time implantation-to-symptoms (days)	Lead model	Perforation location	Antiplatelet, anticoagulant agents	Treatment for complication	Steroid use	Cardiologist and years of experience in cardiac pacing
F	71	(-)	Sick sinus syndrome, syncopal events, DDDR	8	Tendril ST 1788TC/58 (active)	RV apex	Ticlopidine	Cardiac surgery	(-)	A, 4 years
M	62	(-)	Paroxysmal III degree AVB, DDDR	5	Tendril ST 1782TC/52 (active)	RA/VCS	(-)	Cardiac surgery	(-)	B, 14 years
F	79	(-)	Sick sinus syndrome, DDDR	16	Tendril ST 1782TC/52 (active)	RA appendage	UFH (subclavian thrombosis)	Cardiac surgery	(-)	A, 4 years
F	60	(-)	Rhabdomyopathy Paroxysmal II degree AVB, DDDR	4	Tendril ST 1788TC/58 (active)	RV apex	(-)	Lead revision-exchange for passive lead	(-)	C, 20 years
F	12	(-)	HCM, Primary prophylaxis, ICD-VR	1	Riata ST 7002/65 (active)	RV apex	(-)	Lead reposition	(-)	D, 14 years
M	74	(-)	CAD, VT, ICD-DR	5	Sprint Fidelis 6949-75 (active)	RV apex	Warfarin	Cardiac surgery	(-)	C, 20 years
M	31	(-)	HCM, primary prophylaxis, ICD-VR	12	Riata ST 7000-65 (active)	RV apex	(-)	Cardiac surgery	(-)	E, 17 years
F	76	(-)	Paroxysmal III degree AVB, DDDR	0.25 (6 h)	Tendril ST 1782TS/52	RA appendage	(-)	Cardiac surgery	(-)	E, 17 years

RA, right atrium; RV, right ventricle; TTE, transthoracic echocardiogram; AVB, atrioventricular block; VT, ventricular tachycardia; HCM, hypertrophic cardiomyopathy; CAD, coronary artery disease; VCS, superior vena cava; UFH, unfractionated heparin.

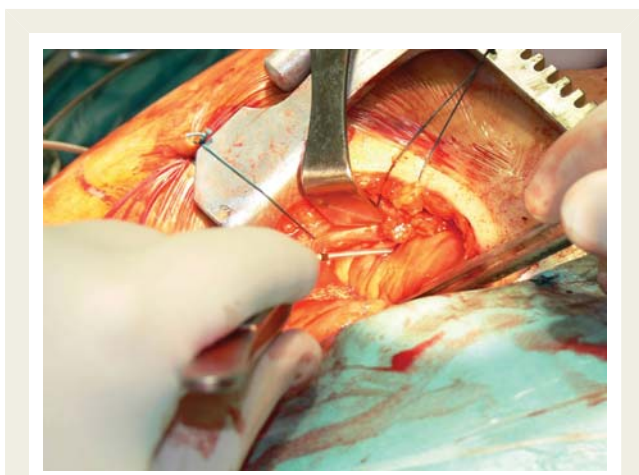


Figure 3 Surgical procedure in patient no. 1 (Table 3). The distal part of the lead is markedly protruding outside the right ventricle apex (white circle). The lead has been removed and an epicardial lead has been implanted.

wall into the pericardium. The pacing and sensing functions could be appropriate in such situations and the problem usually resolves due to self-healing properties of the myocardium. Similarly, as in previously published reports, all ventricular perforations occurred when the ventricular lead was placed in the right ventricular apex, which confirms the influence of the site of the ventricular lead fixation on the perforation rate.¹ So, the right ventricular apex seems not to be a first-choice pacing site for haemodynamic reasons as well as for being more prone to perforation. However, the increase in the defibrillation threshold should be considered with the septal or right ventricular outflow tract lead location.¹⁴

There were no cardiac perforations associated with Riata 1580 leads, although the number of Riata 1580 leads implanted in our site was smaller than in a cited study (87 vs. 130).¹ We also did not recognize any cardiac perforation related to Riata 1570 leads, which are equivalent of Riata 1580 with passive fixation mechanism.

All but one cardiac perforations were associated with the use of other models of active fixation leads from the same manufacturer (SJM: Tendril ST 1788TC/58, Tendril ST 1788TC/52 and Riata ST 7000); however, this fact is not statistically significant (Table 3). These leads are characterized by thin body diameter (Tendril ST 1788-5.9 F, Riata 7000-6.3 F, and Tendril ST 1782-6.8 F) and by the presence of the mapping collar at the tip of the lead.¹⁵ The mapping collar is designed to enable the threshold measurements before the extension of the helix and, consequently, to shorten the implantation time. It is possible that the collar stiffening the lead tip additionally increases the pressure exerted by the lead on the myocardial wall. What needs underscoring is the fact that this feature has been changed in newer generations of SJM defibrillation leads (Durata) as well as in new generation of Biotronik ICD leads (Linxx). In order to reduce the pressure, the tips of the new leads are more flexible and soft. The remaining perforation was related to the Medtronic Sprint Fidelis active fixation lead and also to a small body diameter lead.¹⁶

Although due to small sample size, our study is not powered enough to enable major conclusions, it was concerning enough to report because of the trend towards higher number of perforations with some lead models (Table 2).

Physicians' experience and training level

All the implantations that resulted in cardiac perforation were performed by the cardiologists experienced in the field of implantation of rhythm management devices. All but one physicians have been implanting the devices for more than 10 years and performing over 100 procedures per year on average. The remaining operator has been involved in cardiac pacing for 4 years with more than 100 unassisted implantations performed in the last 2 years. However, such human errors as overtorquing or leaving too much loop could not be excluded despite the physicians' immense experience and despite observing manufacturers' recommendations.^{15,17} It should be emphasized, however, that the recommendations differ significantly not only between manufacturers but also between lead models.

It should also be stated that the public hospitals in Poland are obliged by law to sign long-term contracts with the manufacturers for the delivery of the medical equipment. Therefore, the choice of the implanted lead depends not only on the cardiologist's discretion, but also on the availability of the leads in a given moment.

Patient-related factors

Since the number of patients with cardiac perforation was small ($n=8$), there was no point in comparing them with the patients without such complication. However, it should be pointed out that previously identified risk factors for the development of cardiac perforation (such as transvenous cardiac pacing, concomitant steroid use, low body mass index, age >80 years) were absent in our patients (Table 3).¹³ In one case, cardiac perforation was related to the intensive therapy with unfractionated heparin for the treatment of the subclavian vein thrombosis. However, the remaining patients were either not treated with antiplatelet or anticoagulants ($n=4$) or were receiving them in conventional doses.

Clinical presentations

Similarly, like in other recent reports, none of the perforations were evident during the implantation.^{1,5,9,10} The time between the implantation and the onset of the symptoms varied from 6 h to 16 days. A recurring, stabbing chest pain was present in all cases. In one case, the lead penetrated to the left pleural cavity which caused haemothorax and pseudo-curative drainage from the pericardium. This case is worth remembering as a diagnostic trap: as the complication progressed, there was no pericardial effusion on the echocardiogram.

Though the role of echocardiography for the diagnosis should be emphasized, its value as a routine pre-discharge test seems to be limited. The vast majority of our patients had a pre-discharge echocardiogram performed up to 48 h after clinically uncomplicated implantation and in six out of eight cases with cardiac perforation, the echocardiographic signs of pericardial effusion appeared later.

Management

Pericardial effusion or tamponade may be caused only by protrusion of the distal part of the screw through the heart wall. This is the most probable scenario for the thin atrial walls and screw leads. In these cases, the percutaneous pericardiocentesis with placement of a drain and lead repositioning under fluoroscopic control is often a recommended method of the treatment.^{1,6,7} However, in our institution we usually refer our patients to cardiac surgery, especially in the cases of delayed perforation. The rationale for such treatment is the possibility that during the subacute perforation, there is enough time for the lead to hollow the tunnel in the myocardium, which is partially closed by the lead.¹⁰ However, severe bleeding may occur after its repositioning. Nevertheless, it should be noted that in two cases, despite the haemopericardium, the exact perforation place was hardly identified by the surgeon. This is an argument for pericardiocentesis as the first therapy. In two out of eight cases, in which extracardiac ventricular location of the lead with no significant effusion was diagnosed, we decided to manage the complication with reposition of the lead (Figure 3) followed by the echocardiographic control and surgical stand-by.

Limitations of the study

The study has certain limitations. The main limitation of this study is its retrospective character. This is also a single-centre study and may not reflect experiences in other centres. Since there is a large number of clinically silent perforations (15% diagnosed accidentally during CT performed for other indications),¹⁸ some cases of perforation could have been missed or not recognized. Also, the number of some lead models was too small to estimate the risk associated with their use.

Conclusions

The incidence of cardiac perforation related to pacing or defibrillation leads is low. The use of active fixation leads is associated with the increased risk of cardiac perforation. We did not find any correlation between the perforation rate and any particular model of the implanted lead.

Conflict of interest: M.S. has received a proctoring contract for Medtronic, scientific grants from Medtronic, Sorin and Vitatron, travelling grants from Medtronic, Biotronik, SJM, and Sorin, and lecturer's fees from Medtronic, SJM and Sorin. He is also a consultant for Biotronik. A.P. is a consultant for Biotronik and a principal investigator in Medtronic's sponsored trial, and has received a scientific grant from Biotronik, travelling grants from Medtronic, Biotronik, and SJM and lecturer's fees from Medtronic and SJM. A.M. has a proctoring contract for Medtronic Poland, scientific grants from Vitatron, Medtronic, Sorin, and Biotronik, travelling grants from Medtronic, SJM, and Biotronik, and lecturer's fees from Medtronic, Biotronik, and SJM. P.S. has travelling grants from Medtronic, SJM, and Sorin, and scientific grants from Sorin and Medtronic. M.P. receives scientific grants from Vitatron,

Medtronic, and Sorin, travelling grants from Medtronic, Biotronik, SJM, and Sorin, and lecturer's fees from SJM. M.L. receives scientific grants from Sorin, Biotronik, and Vitatron, travelling grants from Medtronic, Biotronik, SJM, and Sorin, and lecturer's fees from SJM. B.F. receives a scientific grant from Sorin, and travelling grants from Medtronic, Biotronik, and SJM. M.K. receives travelling grants from Medtronic and SJM. H.S. receives scientific grants from Medtronic, Vitatron, and Sorin, travelling grants from Medtronic, Biotronik and Sorin, and lecturer's fees from Medtronic. I.L., P.K., G.R., and F.W. have no conflicts of interest to declare.

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