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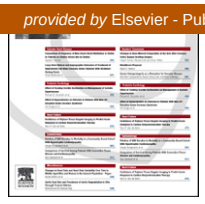

CLINICAL RESEARCH

A single-centre experience concerning the safety of Sprint Fidelis defibrillator lead extraction at the time of pulse generator replacement or in case of evidence of lead failure

Extraction systématique des sondes de défibrillation Sprint Fidelis lors du changement de boîtier ou lors d'une rupture de sonde. Étude monocentrique

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KEYWORDS
Failure rate;
Implantable defibrillators;
Lead failure;
Procedure complications;
Sprint Fidelis leads

Summary
Background. — The reported failure rate of the Sprint Fidelis defibrillator lead (SFDL) has increased more than initially expected, with emerging evidence of accelerating fracture rates. Current consensus guidelines continue to discourage prophylactic lead extraction, citing major complication rates of 1.4—7.3%. Therefore, data relating to the risks of systematic SFDL extraction are lacking, with no methodical extraction protocol reported to date. Moreover, few statistical analyses have identified predictors of SFDL failure.
Objectives. — The aims of this single-centre study were: to examine the safety and feasibility of systematic SFDL extraction at the time of pulse generator replacement or in case of lead failure; and to identify predictors of SFDL failure.
Methods. — Between January 2005 and October 2007, 218 consecutive patients underwent transvenous SFDL implantation in our centre.

Abbreviations: Afssaps, Agence française de sécurité sanitaire des produits de santé; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; RV, right ventricular; SFDL, Sprint Fidelis defibrillator lead.

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Results. — During a mean follow-up of 43 ± 15 months, SFDL extraction was performed in 49 patients (22.5%) for the following reasons: inappropriate shocks (n = 21; 9.6%), systematic extraction at time of pulse generator extraction (n = 23; 10.5%), high impedance (n = 3; 1.4%), high SFDL threshold (n = 1; 0.4%) and cardiac device-related infection (n = 1; 0.4%). No severe complications occurred, although two minor complications were reported (lead dislodgments). SFDL fracture was observed in 25 patients (11.5%; 3.2%/year incidence). The only predictor associated with SFDL fracture was the number of leads (P = 0.01).
Conclusion. — In our series, SFDL extraction at the time of pulse generator extraction or in case of evidence of lead failure was feasible and safe. Number of leads was identified as a new predictive factor for SFDL fracture.

MOTS CLÉS
Rupture de sondes ;
Défibrillateur implantable ;
Sondes Sprint Fidelis ;
Extraction

Résumé
Introduction. — Le nombre de ruptures des sondes de défibrillation Sprint Fidelis (SDSF) a augmenté très significativement au cours du temps. Les recommandations actuelles sont contre l'extraction systématique de ces sondes en raison d'un pourcentage de complications estimé entre 1,4 et 7,3 %. Cependant les travaux concernant les extractions de SDSF sont peu nombreux, rétrospectifs et sans protocole préalable.
Objectifs. — Les objectifs de cette étude sont de deux ordres : premièrement, évaluer la faisabilité et la sécurité de l'extraction des SDSF lors du changement de boîtier ou lors d'une rupture de sonde ; deuxièmement, identifier les facteurs prédictifs de rupture de sondes.
Méthode et résultats. — Entre janvier 2005 et octobre 2007, 218 patients ont bénéficié de la mise en place d'une SDSF dans notre centre. Au cours d'un suivi moyen de 43 ± 15 mois, une extraction de SDSF a été réalisée chez 49 patients (22,5 %) pour les raisons suivantes : chocs inappropriés chez 21 patients (9,6 %), une extraction systématique au cours d'un changement de boîtier chez 23 patients (10,5 %), une impédance élevée chez trois patients (1,4 %), un seuil élevé pour un patient (0,4 %) et une infection de dispositif chez un patient (0,4 %). Aucune complication majeure n'a été constatée et deux déplacements de sondes ont été observés. Une rupture de SDSF a été observée chez 25 patients (11,5 % ; 3,2 % rupture par an), et le seul facteur prédictif de rupture a été le nombre de sondes (p = 0,01).
Conclusion. — Dans notre série, l'extraction de sondes SDSF au moment du changement de boîtier ou lors d'une rupture de sondes est faisable avec des risques limités. Le seul facteur prédictif de rupture était le nombre de sondes implantées.

Background

The Sprint Fidelis defibrillator lead (SFDL) (models 6930, 6931, 6948 and 6949; Medtronic Inc., Minneapolis, Minnesota) is a 6.6-F bipolar high-voltage implantable cardioverter-defibrillator (ICD) lead [1—8]. The lead was approved by the United States Food and Drug Administration in September 2004 and approximately 268,000 leads have been implanted worldwide [1]. However, concerns about the early fracture rate of the lead were first reported in April 2007 and on 15 October 2007 the manufacturer suspended distribution of the SFDL [1—8]. The reported SFDL failures have increased to a greater extent than initially expected, with failure rates estimated at 3.75% per year compared with the reported 1.7% per year in Medtronic's February 2010 update registry [8]. Current consensus guidelines discourage prophylactic lead extraction, citing major complication rates of between 1.4 and 7.3% [9]. Thus, recommendations regarding management include routine monitoring every 3 months after adjusting impedance alarm thresholds or SFDL extraction in patients with pacemakers or with confirmed or suspected SFDL fractures [9]. Two major multicentre surveys recently highlighted the risks associated with SFDL extraction in this clinical setting. Despite the large number of patients included in both multicentre studies, conclusions remain debatable due to several methodological shortcomings, such as retrospective evaluation, the absence of a systematic approach between centres and no long-term follow-up [10,11]. Moreover, only a few studies have sought to identify predictors of SFDL fracture [1,2,12]. Accordingly, the aim of this single-centre study was two-fold: to examine the safety and feasibility of systematic SFDL extraction at the time of pulse generator replacement or in case of evidence of lead failure; and to identify predictors of SFDL fracture.

Methods

Patient selection and implantation techniques

Between January 2005 and October 2007, 218 consecutive patients underwent transvenous SFDL implantation. Leads were inserted via left-sided or right-sided venous access by cephalic cutdown or via subclavian vein access using standard techniques. Leads were positioned in the right

ventricular (RV) apex. Defibrillation safety margins as well as pacing and sensing thresholds were determined according to usual practices in order to ensure adequate detection and termination of ventricular tachyarrhythmias, while providing rate support in the event of bradycardia. Atrial and left ventricular leads were added in patients requiring multichamber pacing and sensing. All ICD implantations conducted at our centre were recorded, while patient follow-up was carried out in our outpatient clinic. The SFDL model most frequently implanted was the dual-coil active-fixation lead (model 6949), followed by the single-coil active-fixation lead (model 6931). All patients with SFDL were identified, with details on any lead fractures being recorded in line with the recommendations of the *Agence française de sécurité sanitaire des produits de santé* (Afssaps).

Monitoring

In accordance with the manufacturers' recommendations, we reprogrammed devices and activated alarms in order to provide patients with a warning system in the event of impedance changes suggesting a lead fracture.

Endpoints

Lead failure was defined as non-physiological high-rate sensing with high pacing impedance suggesting a fracture, sudden change in sensing or pacing impedance, or rise in high-voltage impedance suggestive of coil fracture, resulting in the decision to perform lead replacement. Inappropriate shocks due to sensing of electrical noise artefacts from make-break potentials were also defined as SFDL fractures. At the time of pulse generator replacement, SFDL extraction was systematically performed in all patients except for those aged 80 years or more.

Data retrieval

Clinical and device interrogation data were retrieved from the ICD database. Additional data were obtained from local clinical records and from the 'save to disk' files of patients with Sprint Fidelis model 6949 lead fractures. Between January 2008 and May 2011, each patient device was interrogated every 3 months in the outpatient clinic in line with the Afssaps recommendations. If available, telemonitoring was activated and data were analysed. The following variables were examined as potential predictors of lead fracture: age, risk factors, sex, vein of access (cephalic or non-cephalic), cardiomyopathy aetiology, number of electrodes implanted, device type (single chamber, double chamber or resynchronization), weight and most recent left ventricular ejection fraction (LVEF).

Extraction

Surgical reintervention was defined as a surgical procedure required for non-infectious or infectious implant complications. The extraction was performed using either simple traction or traction devices. Simple traction involved manipulating the lead so that it left the vasculature via the implant vein by using tools typically supplied for lead implants, with the addition of traction. These tools included items such as standard stylets (non-locking) and fixation screw retraction clips. Traction devices involved locking stylets, snares and sutures as well as grasping or other devices used to engage, entrap and remove the lead or lead fragments. Locking stylets are a special type of traction device designed to grasp the inside of the conductor coil along its length or near the distal stimulating electrode, thus improving tensile properties and preventing elongation of the lead body during traction [9]. If traction alone did not result in successful lead extraction, a laser-powered sheath system (Spectranetics Inc., Colorado Springs, CO, USA) was used. Major complications were defined as the following events: death; cardiac or vascular avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube or surgical repair; pulmonary embolism requiring surgical intervention; respiratory arrest or anaesthesia complications leading to prolongation of hospitalization; stroke; and pacing system-related infection of a previously non-infected site. Minor complications were defined as: pericardial effusion not requiring pericardiocentesis or surgical intervention; haemothorax not requiring a chest tube; haematoma at the surgical site requiring reoperation for drainage; arm swelling or thrombosis of implant veins necessitating medical intervention; haemodynamically significant air embolism; migrated lead fragment without sequelae; blood transfusion related to blood loss during surgery; pneumothorax requiring a chest tube; and pulmonary embolism not requiring surgical intervention. Patients were followed up in hospital, with 30-day procedure-related outcomes being reported.

Follow-up

In line with the Afssaps recommendations, the collected prospective data included: patient demographic and clinical characteristics; echocardiographic measurements; type of implanted device and number of leads; defibrillator interrogation; and occurrence of complications requiring reintervention. Patients were followed up by four experienced cardiologists. Electrocardiograms and device controls were performed the day after the procedure and immediately before patient discharge. Patients were examined in the outpatient clinic every 3 months, with a physical examination and device interrogation being carried out at these visits, in addition to weekly telemonitoring.

Statistical analysis

All clinical variables were assessed at the time of device implantation, with continuous variables expressed as mean $\pm$ standard deviation. Comparisons of continuous variables between the patient groups were conducted using the unpaired Student's *t* test or the Mann-Whitney test as appropriate. Categorical variables were compared using the chi-square test or Fisher's exact test as appropriate. The cumulative risk of SFDL fracture was interpreted using Kaplan-Meier curves and analysed by means of the log-rank test. Univariate analysis was fitted in order to investigate the relationship between each covariate and the risk of SFDL fracture. Backward elimination was also used, removing the least significant variables at each step to elaborate

Table 1 Patient characteristics ($n = 218$).

Characteristic	
Mean age ± SD (years)	66 ± 11
Female (%)	15.1
Hypertension (%)	41
Diabetes mellitus (%)	24
Hypercholesterolaemia (%)	42
Tobacco smoker (current or past) (%)	54
Cause of cardiomyopathy (%)	
Idiopathic dilated cardiomyopathy	56.4
Ischaemic cardiomyopathy	43.6
Indication (%)	
Primary prevention	26.1
Secondary prevention	24.8
Cardiac resynchronization	49.1
Device implanted (%)	
Single chamber	23.9
Double chamber	22.5
Cardiac resynchronization therapy	53.6
Mean LVEF ± SD (%)	29 ± 6
Venous access (%)	
Cephalic	78.5
Subclavian	11.5
SFDL active fixation	202
SFDL passive fixation	16
Mean number of leads/patient ± SD	2.2 ± 0.8

LVEF: left ventricular ejection fraction; SD: standard deviation; SFDL: Sprint Fidelis defibrillator lead.

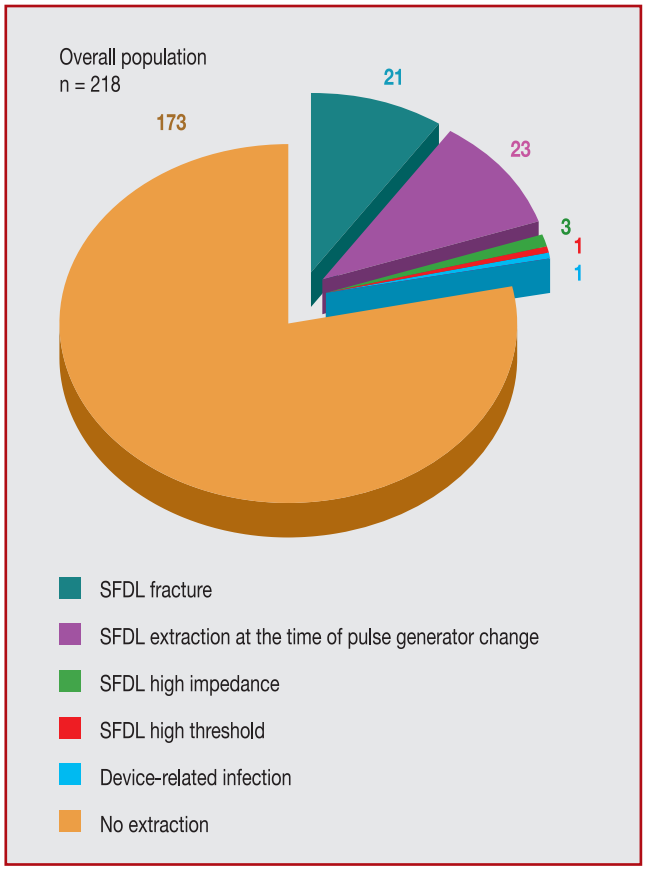

Figure 1. Sprint Fidelis population. SFDL: Sprint Fidelis defibrillator lead.

multivariable models if necessary. A probability value of $P < 0.05$ was considered statistically significant. All analyses were performed using StatView® 5.0 (StatView IV; Abacus Concept, Berkeley, CA, USA).

Results

Baseline population characteristics

Baseline clinical data are summarized in Table 1. The predominant Sprint Fidelis lead model extracted was the dual-coil active-fixation lead (model 6949; $n = 200$, 91.7%), followed by the dual-coil passive-fixation lead (model 6948; $n = 15$, 6.8%), then the single-coil active-fixation lead (model 6931; $n = 2$, 1.0%) and lastly, the single-coil passive-fixation lead (model 6930; $n = 1$, 0.5%).

Survival of patients with SFDL and predictive factors for SFDL fracture

Between January 2005 and October 2007, 218 consecutive patients underwent transvenous SFDL implantation. During a follow-up of 43 ± 15 months (range: 23 to 72 months), 45 patients died (20.6%; 5.7%/year incidence; mean age: 66.5 ± 8 years), six were transplanted (2.8%) and eight were lost to follow-up (3.7%). Among the 45/218 patients who died, causes of death were as follows: heart failure ($n = 24$; 11%); sudden death ($n = 4$; 1.8%); acute mesenteric ischaemia ($n = 3$; 1.4%); infection disease ($n = 3$; 1.4%); terminal kidney failure ($n = 2$; 0.9%); fatal car crash ($n = 2$; 0.9%); epilepsy-related death ($n = 1$; 0.5%); electrical storm ($n = 1$; 0.5%); prostate cancer ($n = 1$; 0.5%); and unknown ($n = 4$; 1.8%). SFDL extraction was performed in 49 patients (22.5%) for the following reasons: inappropriate shocks (appearance of non-physiological short V-V intervals) ($n = 21$; 9.6%); systematic extraction at the time of pulse generator extraction ($n = 23$; 10.5%); high impedance ($n = 3$; 1.4%); high SFDL threshold ($n = 1$; 0.4%); and cardiac device-related infection ($n = 1$; 0.4%) (Fig. 1). Device impedance alarm programming was implemented and programmed at nominal levels (> 2500 Ω). After hearing alarms, three patients consulted our centre, thereby avoiding inappropriate shocks. Among patients with SFDL extraction, fracture was observed in 25 patients (11.5%; 3.2%/year incidence) (Fig. 2). The extraction procedure was performed using a simple traction in two patients (4.4%), a locking stylet in 46 patients (93.8%) and a laser-powered sheath system in one patient (2.2%). Although no severe complications were noted following extraction, two minor complications occurred (two lead dislodgments).

The number of leads was the only predictor associated with SFDL fracture ($P = 0.01$) (Table 2). There were no differences between the SFDL fracture group and the non-SFDL fracture group concerning other variables, including age, LVEF, cardiomyopathy aetiology and venous access (Table 2). There were no differences between the SFDL fracture group and the systematic SFDL extraction group (Table 3).

Table 2 Comparison of patient characteristics in the SFDL fracture and non-SFDL fracture groups.

	SFDL fracture ($n=25$)	Non-SFDL fracture ($n=193$)	P
Mean age ± SD (years)	64 ± 14	66 ± 11	0.4
Women (%)	12	14.5	0.9
Mean LVEF ± SD (%)	27 ± 5	29 ± 4	0.1
Cause of cardiomyopathy			
Dilated cardiomyopathy	16 (64)	107 (55.4)	0.5
Ischaemic cardiomyopathy	9 (36)	86 (44.6)	
Indication			
Primary prevention	2 (7)	55 (28.5)	
Secondary prevention	6 (25)	48 (24.9)	0.1
Cardiac resynchronization	17 (68)	90 (46.6)	
Device implanted			
Single chamber	2 (7.1)	50 (26)	0.1
Double chamber	4 (16.4)	45 (23.3)	
Cardiac resynchronization	19 (76.5)	98 (50.7)	
Venous access			
Cephalic	21 (84)	150 (77.7)	0.5
Subclavian	4 (16)	43 (22.3)	
Mean number of leads	2.6	2.1	0.008

Data are number (%), unless otherwise indicated. LVEF: left ventricular ejection fraction; SD: standard deviation; SFDL: Sprint Fidelis defibrillator lead.

Table 3 Comparison of patient characteristics in the SFDL fracture and systematic SFDL extraction groups.

	SFDL fracture ($n=25$)	Systematic SFDL extraction ($n=24$)	P
Mean age ± SD (years)	64 ± 14	66 ± 9	0.4
Women (%)	12	16.6	0.9
Mean LVEF ± SD (%)	27 ± 8	31 ± 9	0.08
Cause of cardiomyopathy			
Dilated cardiomyopathy	16 (64)	18 (75)	0.6
Ischaemic cardiomyopathy	9 (36)	6 (25)	
Indication			
Primary prevention	2 (7)	5 (21)	0.3
Secondary prevention	6 (25)	7 (29)	
Cardiac resynchronization	17 (68)	12 (50)	
Device implanted			
Single chamber	2 (7.1)	4 (17)	0.4
Double chamber	4 (16.4)	6 (25)	
Cardiac resynchronization	19 (76.5)	14 (58)	
Venous access			
Cephalic	21 (84)	16 (67)	0.3
Subclavian	4 (16)	8 (23)	
Mean number of leads ± SD	2.6 ± 0.6	2.2 ± 0.7	0.1
Type of extraction			
Simple traction	1	1	
Locking stylet	23	23	0.9
Laser-powered sheath system	1	0	

Data are number (%), unless otherwise indicated. LVEF: left ventricular ejection fraction; SD: standard deviation; SFDL: Sprint Fidelis defibrillator lead.

Discussion

Comparative studies regarding SFDL extraction

Our study has provided additional data about the safety and feasibility of transvenous SFDL extraction, especially when coinciding with pulse generator replacement. Based on our experience, complete procedural success was observed in all cases regardless of the method of SFDL extraction, with no major complications or procedure-related deaths. Our results are in agreement with the recently published work by Maytin et al., who reported no major

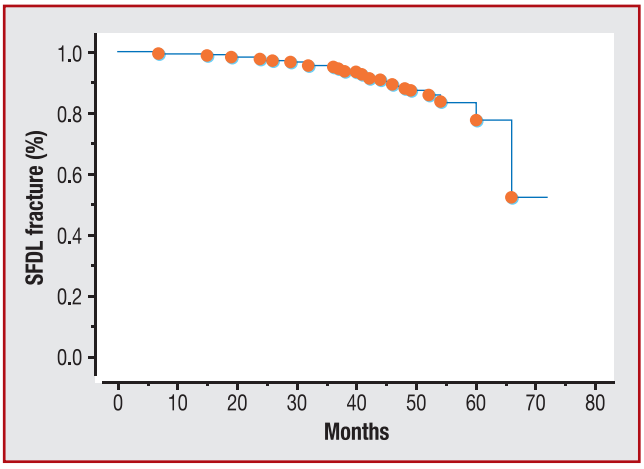

Figure 2. Kaplan-Meier curve: lead survival. SFDL: Sprint Fidelis defibrillator lead.

procedural complications or deaths [10]. In contrast, a Canadian national survey reported a SFDL failure rate of 4.97% at 40 months, with an overall complication rate of 14.5% for lead revisions, classified into 7.25% major and 7.25% minor complications [11]; in addition, two deaths (0.43%) were reported. In this study, the overall risk of complications (14.5%) was shown to be significantly higher in patients undergoing lead removal at the time of revision than in those with abandoned leads (8.6%; $P < 0.0008$). The prognosis discrepancy between these two published studies may be accounted for by differing experience levels, with the Canadian registry centres being less experienced and tending to use the laser lead extraction method [9,11—13]. Leads that were extracted at an early time following implantation were presumably easier to remove than older leads, which were more likely to require formal extraction, resulting in an increased rate of complications (40 vs 27.9 months) [10,11]. However, in our experience, SFDLs were removed after a long-term follow-up of 38 ± 14 months, without complications. Accordingly, the management of patients with an implanted SFDL is still challenging. In the setting of a device-related infection, patient management is based on a straightforward decision to extract the device. However, in cases of fractured or functional SFDLs, the management of non-infected patients appears to be more difficult. Previous treatment options included adding a new pace-sense lead. However, this approach is no longer recommended by Medtronic due to the risk of subsequent high-voltage conduction failure. The risks associated with each of these options must be carefully judged on a case-by-case basis, as recommended in the 2009 Heart Rhythm Society expert consensus document on transvenous lead extraction and as advised by the French Afssaps [9]. The essential question presently is how to optimize patient management. The initial letter addressed to physicians issued the following recommendations: turning on patient alert for RV pacing, RV defibrillation and superior vena cava defibrillation impedance; programming ventricular fibrillation detection for the initial number of intervals to detect to nominal settings (18/24) or longer at the discretion of the physician, and for the number of intervals to redetect to nominal settings (12/16); reviewing ventricular pacing lead impedance trends and programming lead impedance alert for RV pacing; and conducting 3-month evaluations in the outpatient clinic [9]. Several factors are associated with low-risk SFDL extraction, including small lead diameter, fixation screw retraction mechanism and short time interval from implantation to removal. Maytin et al. reported average lead implantation duration of 27.5 months, with 49.4% of the extracted leads being fractured and 26.5% being extracted prophylactically. Another major indication for extraction was infection (22.8%). Extraction was achieved with simple traction in 49.4% leads, the use of counter traction sheath assistance being required in 174 cases (50.6%) without laser. In our registry, laser was used in one case only, whereas a locking stylet was systematically employed for SFDL extraction at the time of pulse generator replacement. The absence of major complications supports this strategy.

Predictive factors for SFDL fracture

The underlying mechanisms that cause Sprint Fidelis and Sprint Quattro fractures are still unclear. Three factors are likely to contribute to ICD lead fracture: lead construction; implantation technique; and patient-related features. To date, few clinical factors have been identified as predictors of fracture, with cephalic vein access reducing the risk compared with subclavian access, as well as LVEF [2]. Two recent case series suggested that younger age may be a key variable, perhaps linked to more vigorous cardiac motion or increased physical activity [1,12]. More recently, a larger series study demonstrated that compared with Sprint Quattro leads, the survival of SFDL continued to decline, with the SFDL failure rate being notably higher in younger patients, women, subjects with hypertrophic cardiomyopathy and patients with arrhythmogenic right ventricular dysplasia or channelopathies [14]. These findings have significant implications for managing SFDL patients, as they show the relevance of weighing clinical variables when assessing ICD lead performance [14].

Our centre is the first to report that the risk of fracture is dependent on the number of leads implanted, being higher for patients with two or more leads, as is the case for resynchronization therapy. In general, failure mechanisms of ICD leads may involve shocking coils or the pace-sense electrodes. The two major failure modes of SFDL relate to pace-sense conductor fractures, affecting either the cable to the anode (ring electrode) near the tip of the lead or the coil to the cathode (tip electrode) near the anchoring sleeve [14—19]. These fractures are most commonly present with rapid oversensing, resulting in inappropriate shocks. They may also present as failure to deliver bradycardia or antitachycardia pacing due to elevated impedance or pacing inhibition by oversensing. Fracture of the high-voltage electrode occurs less frequently [14—19]. Although never described before, the mechanism linked to the number of leads may be due to interlead friction, which is likely to lead to constraints, traction, friction, wear and finally resulting in pace-sense conductor fractures.

Clinical implications

Managing patients with SFDL remains challenging. To prevent complications such as inappropriate shocks, failure

of stimulation or death, systematic SFDL extraction is favoured. Conversely, recommendations regarding management include routine monitoring after adjusting impedance alarm thresholds. According to Medtronic and its Independent Physician Quality Panel, the current failure rate is estimated at 0.92% per year, which appears insufficient to justify prophylactic lead replacement, given the major complication rates of extraction of between 1.4% and 7.3% [7,8,11,20—23]. In our series, we report a higher incident risk of 3.2% SFDL fractures per year, with a very low level of complications related to SFDL extraction, particularly in cases when systematic extraction was performed at the time of pulse generator replacement. Our study supports the approach of extracting SFDL as early as possible, thereby avoiding the higher risks associated with extraction on long-term follow-up. This approach is in line with the observations of Maytin et al. [10], provided that the extraction is performed by experienced operators, thus preventing the problems associated with abandoned leads on long-term follow-up [10,11,24—35].

Study limitations

Our study has several limitations. Although a retrospective design was used for evaluating predictive factors, systematic extraction at the time of pulse generator replacement was carried out prospectively. No data on the site of lead fracture in our individual cases were available and as our sample size as regards SFDL extraction was small, systematic extraction needs to be further assessed in a larger patient population. Regarding the advantages of our study, our follow-up is the longest published to date in this field, with a routine examination being performed every 3 months. In addition, our findings relating to systematic SFLD extraction at the time of pulse generator replacement provide supporting evidence for this kind of approach.

Conclusion

SFDL extraction at the time of pulse generator extraction or in the case of evidence of lead failure was shown to be feasible and safe. The number of leads was the only new predictor of SFDL fracture identified.

Disclosure of interest

Antoine Da Costa is a consultant for Biotronik, Boston Scientific Corporation, Medtronic and Saint Jude Medical.

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