Impact of remote monitoring on reducing the burden of inappropriate shocks related to implantable cardioverter-defibrillator lead fractures: insights from a French single-centre registry

Zouheir Souissi1, Laurence Guédon-Moreau1, Stéphane Boulé1, Claude Kouakam1, Loïc Finat1, Christelle Marquié1, François Brigadeau1, Ludivine Wissocque1, Stéphanie Mouton1, David Montaigne1,2, Didier Klug1, Salem Kacet1, and Dominique Lacroix1

1Department of Cardiovascular Medicine, Lille University Hospital, Boulevard du Professeur Leclercq, Lille Cedex 59037, France; and 2Faculté de Médecine Pôle Recherche Amphi J et K, INSERM U1011, Lille 2 University, Lille 59045, France

Aims

Lead fractures in implantable cardioverter-defibrillator (ICD) patients may cause inappropriate shocks (ISs). An early diagnosis is essential to prevent adverse clinical events. Implantable cardioverter-defibrillator remote monitoring (RM) permits prompt detection of lead fracture. Limited data define the impact of RM on ISs specifically related to lead fracture. We sought to compare the number of ISs related to lead fracture in patients with vs. without RM follow-up.

Methods and results

We checked the registry of our institution and collected, between July 2007 and June 2014, 115 cases of right ventricular lead fractures. All relevant data were documented from patients’ files, device-interrogation printouts and electronic records, and remote transmissions databases when applicable. We assessed the ISs that were related to lead fracture. The first study endpoint was the number of ISs per shocked patient. Among the 82 patients with conventional follow-up (CFU) and the 33 patients with RM, a first IS occurred to 32.9% (n = 27) and 30.3% (n = 10, P = 0.83) of the patients, respectively. Shocked patients in the RM group underwent significantly fewer ISs with a mean of 6 ± 2 shocks per patient [median of 3.5 shocks (2–8)] than those in the CFU group with a mean of 18 ± 5 shocks per patient [median of 10 shocks (5–22), P = 0.03].

Conclusion

Remote monitoring helps to reduce the burden of ISs related to ICD lead fractures.

Keywords

Defibrillators • Lead fracture • Remote monitoring • Follow-up • Inappropriate shock

Introduction

Remote monitoring (RM) recently proved its efficacy and safety regarding the implantable cardioverter-defibrillators (ICDs) patients’ follow-up.1-9 This technology provides surveillance of system integrity and arrhythmias with automatic alerts.5 Some clinical cases and prospective studies6,7 pointed out RM abilities to reduce inappropriate therapies. This reduction is mostly driven by the reduction of therapies in relation with supraventricular tachycardias.7 But as RM permits prompt detection of ICD lead malfunction, it has been suggested that RM could reduce inappropriate shocks (ISs) due to right ventricular ICD lead fractures.6-8 Lead fracture is a rare and tricky complication of ICD follow-up that can lead to the delivery of many ISs. Limited data define the impact of RM on ISs related to lead fractures.

Therefore, the aim of our study was to compare the number of ISs related to lead fracture in patients, with vs. without RM follow-up.
What’s new?

- Remote monitoring is emerging as one tool in the current armamentarium used to reduce ICDs inappropriate shocks (ISs), whose main cause is supraventricular arrhythmias.
- This work is to our knowledge the first to focus on the impact of RM on the ISs specifically related to lead fractures.
- The results show that the ICD RM can at least reduce the burden of ISs. This effect is very important because of the very negative impact of multiple shocks for patients.
- Among pending algorithms and other new means developed to completely avoid ISs, the RM should be used for this purpose, in all patients and in addition to other existing protections.

Methods

Study population

We checked our institution registry of ICD lead revisions between July 2007 and June 2014 in order to identify patients with lead fractures. The leads were implanted transvenously. All kinds of lead fractures were considered regardless the device’s manufacturer. Right ventricular lead fracture had been diagnosed by oversensing of non-physiological signals (‘noise’), an increase (or a decrease) in pacing or defibrillation impedance, a decrease in sensing, an increase in pacing threshold, and/or a loss of capture. Patients who underwent a revision for an atrial or a left ventricular lead malfunction, a lead dislodgment, a myocardial perforation, a header-connector pin problem, or an ICD infection were excluded.

Data collection

General demographic and clinical characteristics of the patients, type of ICD generators and leads, clinical presentation of lead fracture, date of diagnosis, and time of the last in-person office visit were documented from medical records and our database. All device-interrogation printouts and remote transmissions were reviewed and ISs related to lead fracture were assessed.

Alert systems

The main purpose of alert systems is to allow an early detection of clinical or technical adverse events, even asymptomatic. Alert systems may also prevent the occurrence of symptomatic adverse events, in particular ISs. Remote monitoring provides a key alert system. In our patients with RM, this was carried out by Home Monitoring® (Biotronik®), CareLink® (Medtronic®), Merlin.net® (St Jude Medical®), and Latitude® (Boston Scientific®) systems. Alerts consistent with the suspicion of lead fracture resulted from ventricular fibrillation (inappropriate) detection, (inappropriate) shock delivery, non-sustained lead noise, and pacing or defibrillation impedance disturbance. Moreover, some ICD brands provide lead fracture detection methods [such as sound alerts (Medtronic®)] or can vibrations (St Jude Medical®) embedded in the implanted devices, and triggered by ventricular fibrillation detection, shock delivery, increase (or decrease) in pacing or defibrillation impedance, and/or short RR intervals occurrence.

Endpoints

The first study endpoint was to compare the burden of ISs received by each shocked patient in the conventional follow-up (CFU) group vs. the RM group. The secondary endpoints were to compare the occurrence of a first IS and to determine the proportion of avoidable ISs in each group. Inappropriate shocks were considered avoidable when unstable lead parameters or oversensing had been recorded at least 48 h before the occurrence of the first IS. This delay was chosen as it is, taking into account the non-working days, the minimal time necessary to process remote transmissions and to react adequately. We also described the parameters that allowed to diagnose lead fracture in asymptomatic patients and we appraised, when available, the time between the first suggestive sign of lead fracture and its clinical diagnosis in asymptomatic patients. Conventional diagnosis was defined as clinical diagnosis occurring < 120 days after a heralding sign of lead fracture, whereas delayed diagnosis was defined as clinical diagnosis occurring > 120 days after a heralding sign of lead fracture. Delayed diagnosis concerned particular presentations of lead fractures for which the diagnosis of fracture was not conceivable at the moment of the first sign: gradual rise of stimulation impedance, one single rise or drop of stimulation/defibrillation impedance followed by stable and normal lead parameters, oversensing not suggestive of lead fracture. The patients granted their informed consent so that we could follow their evolution and monitor it in the future. This study was approved by our institutional review board and complied with the ethical principles formulated in the declaration of Helsinki.

Statistical analysis

Continuous variables with a Gaussian distribution are given as mean ± standard error of mean. Continuous variables without a Gaussian distribution are given as median (25th to 75th percentiles) or as mean ± standard error of mean. Categorical variables are given as the percentage (number) of patients with the respective attribute. Bivariate comparisons were performed using the t-test for normally distributed continuous variables or the Mann–Whitney U test for variables not normally distributed. Bivariate comparisons of categorical variables were performed with the χ² test or the Fisher’s exact test according to the size of the sample population. A value of P < 0.05 was considered statistically significant. All analyses were conducted using MedCalc Software® version 1993–2011 and GraphPad Prism® version 6.0.

Results

Study population

Patients’ and devices’ characteristics are summarized in Table 1. From July 2007 to June 2014, 115 right ventricular lead fractures in 109 patients had been managed in our institution. Thirty-three (28.6%) of them were remotely followed and composed the RM group. The two groups of patients were well-matched for most of the variables, except the ICD generator manufacturer and the type of implanted lead. Medtronic® and Sorin® ICD generators were significantly more frequent in the CFU group, whereas Biotronik® ICD generators were significantly more present in the RM group. Leads under advisory (Sprint Fidelis® and Riata®) were significantly more implanted in the CFU group, while Linox® leads were significantly more prevalent in the RM group.

Inappropriate shocks

Thirty-seven patients received at least one IS. The 10 shocked patients of the RM group underwent significantly fewer ISs than the 27 shocked patients of the CFU group, with an average of 5.9 ± 2.1 shocks per patient and 18.0 ± 4.8 shocks per patient, respectively (Figure 1). There was no significant difference between the
CFU and RM groups in the occurrence of a first IS (Figure 2). As Sprint Fidelis® leads were unequally distributed between groups, we assessed the burden of ISs according to this lead type. This analysis showed a trend to fewer ISs in shocked patients with RM regardless of lead brand. The Sprint Fidelis® leads delivered a mean of 18.2 ± 5.7 shocks per patient [median of 9.5 (4.8–23.3)] and a mean of 7.0 ± 2.5 shocks per patient [median of 4.5 (3–8.8)] in the CFU and RM groups, respectively (P = 0.12). In the same way, the other leads delivered a mean of 17.0 ± 8.5 shocks per patient [median of 12 (4.5–32.0)] and a mean of 1.5 ± 0.5 shocks per patient [median of 1.5 (1–2)] in the CFU and RM groups, respectively (P = 0.24). Sprint Fidelis® lead fractures are often described as the prototype of lead fractures that present with multiple shocks, but the number of shocks per shocked patient related to lead fracture was similar between Sprint Fidelis® and other leads in the study population (Figure 3).

Table 1

<table>
<thead>
<tr>
<th></th>
<th>Entire population (n = 115)</th>
<th>CFU (n = 82)</th>
<th>RM (n = 33)</th>
<th>P</th>
</tr>
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<tbody>
<tr>
<td>Age (years)</td>
<td>52.9 ± 1.6</td>
<td>52.3 ± 1.8</td>
<td>54.4 ± 3.3</td>
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<tr>
<td>Male</td>
<td>82.6 (95)</td>
<td>81.7 (67)</td>
<td>84.8 (28)</td>
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<td>Preserved*</td>
<td>41.7 (48)</td>
<td>43.9 (36)</td>
<td>36.4 (12)</td>
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<td>Moderately impaired*</td>
<td>22.6 (26)</td>
<td>20.7 (17)</td>
<td>27.3 (9)</td>
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<td>Severely impaired*</td>
<td>35.7 (41)</td>
<td>35.4 (29)</td>
<td>36.4 (12)</td>
<td>0.68</td>
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<td>Indication</td>
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<td>Primary prevention</td>
<td>34.1 (40)</td>
<td>34.8 (28)</td>
<td>36.4 (12)</td>
<td></td>
</tr>
<tr>
<td>Secondary prevention</td>
<td>65.2 (75)</td>
<td>65.9 (54)</td>
<td>63.6 (21)</td>
<td>0.83</td>
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<td>Underlying heart disease</td>
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<tr>
<td>Coronary heart disease</td>
<td>42.6 (49)</td>
<td>36.6 (30)</td>
<td>57.6 (19)</td>
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<td>Primary dilated cardiomyopathy</td>
<td>16.5 (19)</td>
<td>19.5 (16)</td>
<td>9.1 (3)</td>
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<td>Hypertrophic cardiomyopathy</td>
<td>9.6 (11)</td>
<td>12.2 (10)</td>
<td>3.0 (1)</td>
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<td>Channelpathy</td>
<td>12.2 (14)</td>
<td>13.4 (11)</td>
<td>9.1 (3)</td>
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<td>Other cardiac disease</td>
<td>19.1 (22)</td>
<td>18.3 (15)</td>
<td>21.2 (7)</td>
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<td>Implanted device</td>
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<td>Single chamber</td>
<td>53.0 (61)</td>
<td>54.9 (45)</td>
<td>48.5 (16)</td>
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<tr>
<td>Dual chamber</td>
<td>36.5 (42)</td>
<td>34.1 (28)</td>
<td>42.4 (14)</td>
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<td>Biventricular</td>
<td>10.4 (12)</td>
<td>11.0 (9)</td>
<td>9.1 (3)</td>
<td>0.70</td>
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<td>Device manufacturer</td>
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<td>Medtronic®</td>
<td>41.7 (48)</td>
<td>52.4 (43)</td>
<td>15.2 (5)</td>
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<tr>
<td>St Jude®</td>
<td>17.4 (20)</td>
<td>19.5 (16)</td>
<td>12.1 (4)</td>
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</tr>
<tr>
<td>Biotronik®</td>
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<td>2.4 (2)</td>
<td>63.6 (21)</td>
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<td>Sorin®</td>
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<td>0.0 (0)</td>
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<tr>
<td>Boston®</td>
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<td>9.8 (8)</td>
<td>9.1 (3)</td>
<td>&lt;0.01*</td>
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</tr>
<tr>
<td>Sprint Fidelis®</td>
<td>60.0 (69)</td>
<td>68.3 (56)</td>
<td>39.4 (13)</td>
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<td>Riata®</td>
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<td>6.1 (5)</td>
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<td>Linox®</td>
<td>10.4 (12)</td>
<td>7.3 (6)</td>
<td>18.2 (6)</td>
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</tr>
<tr>
<td>Endotak®</td>
<td>10.4 (12)</td>
<td>9.8 (8)</td>
<td>12.1 (4)</td>
<td></td>
</tr>
<tr>
<td>Other lead</td>
<td>14.8 (17)</td>
<td>8.5 (7)</td>
<td>30.3 (10)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Lead life expectancy (months)</td>
<td>45.6 (30.7–64.2)</td>
<td>43.2 (32.4–61.8)</td>
<td>53.7 (28.3–71.8)</td>
<td>0.52</td>
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<td>Hospitalization time (days)</td>
<td>8.9 (6.0–13.2)</td>
<td>9.0 (6.2–13.3)</td>
<td>8.1 (5.4–11.3)</td>
<td>0.19</td>
</tr>
</tbody>
</table>

Data are presented as mean ± standard error of mean, percentage (number), or median (interquartile range).

CFU, conventional follow-up; LF, lead fracture; LVEF, left ventricular ejection fraction; RM, remote monitoring; RV, right ventricular.

*50%.

Between 30 and 50%.

<30%.

One patient was not hospitalized and did not undergo surgery intervention in the CFU group, the device was disabled.

Significant differences between the CFU and RM groups.
reach by phone the patient when the first lead abnormality was recorded. Furthermore, in the RM group, two pacemaker-dependent patients presented syncopes revealing lead fracture.

Asymptomatic lead fractures

Lead fractures were asymptomatic in 66.1% of cases. Parameters that led to the diagnosis are detailed in Table 3. The two groups of patients were well-matched for most of these parameters, except noise oversensing that was significantly more detected in the RM group. We noticed that less lead fractures were revealed by an increased pacing threshold, a loss of capture or a blunted sensing in the RM group. This trend was not statistically significant. Audible/vibratory alert was embedded in 58.2% (32) and 30% (6) of ICD generators from the CFU and RM groups, respectively. It was triggered for 78.1% (25) and 83.3% (5) of cases in the CFU and RM groups, respectively. Clinical diagnosis within 48 h was performed for 72% (18) and 60% (3) of patients with triggered audible alerts or can vibrations in the CFU and RM groups, respectively. It was not possible to determine accurately the time between the first sign of lead fracture and its clinical diagnosis for seven cases (12.7%) of the asymptomatic CFU group, because device-interrogation printouts and the medical records did not provide a reliable proof, or because they were missing. However, this data were available for all patients in the RM group. Considering all asymptomatic patients, the time between a heralding sign and clinical diagnosis of lead fracture was not significantly different, with a mean time of $52.1 \pm 13.2$ days in the CFU group vs. a mean time of $61.0 \pm 26.7$ days in the RM group.
Delayed diagnosis involved eight and five patients in the CFU and the RM groups, respectively. In these 13 patients, the first anomaly observed in the parameters, which occurred 120 days before the diagnosis of lead fracture, was not at all suggestive of lead fracture and was different from the anomaly that arose at the time of diagnosis. It was for example very slight initial rise of stimulation impedance, one single rise or drop of stimulation/defibrillation impedance followed by stable and normal lead parameters, oversensing pattern not suggestive of lead fracture. Patients with delayed diagnosis were significantly older (mean age of 60.7 ± 2.6 vs. 48.0 ± 2.3 years old, P = 0.01), more frequently equipped with St Jude Medical® and Boston Scientific® ICD generators (84.6 vs. 20.7%, P = 0.01) than those with conventional diagnosis. They were less frequently implanted with Sprint Fidelis® and Riata® leads (30.8 vs. 63.8%, P = 0.06) than those with conventional diagnosis. No recalled leads were implanted in remotely followed patients with delayed diagnosis of lead fracture, a trend to diagnose sooner lead fracture after a heralding sign in the RM cohort was noted with a mean of 8.8 ± 3.3 days in comparison with a mean of 19.1 ± 5.1 days in the CFU group (Figure 5).

Discussion

This study reflects the care conditions of patients undergoing lead fracture in current clinical practice. Our purpose was to describe and to define the role of RM in the follow-up of patients with ICD lead fracture. The main findings are that RM reduces the number of ISs related to lead fracture per shocked patient and could allow an earlier diagnosis in asymptomatic cases of lead fractures.

Clinical presentation of lead fractures

In this single-centre study on ICD patients with lead fractures, two distinct types of scenarios were characterized—a symptomatic one and an asymptomatic one. On the one hand, the symptomatic form occurred in about one-third of cases (Blanck et al.14 reported almost 42% of symptomatic patients with Fidelis® lead fractures), was mostly unpredictable, and resulted in ISs or syncope. Fortunately,
no patient died from consequences of lead fracture and no real arrhythmia was induced by inappropriate therapies. On the other hand, asymptomatic lead fractures had an insidious presentation, were revealed by unstable lead parameters or oversensing (extremely short non-physiological intervals), and might confront clinicians with diagnostic difficulties.

Impact of remote monitoring

In the early 2000s, Luria et al. showed that two-thirds of lead fractures were symptomatic in a large population of ICD patients. In the late 2000s, the incidence of ISs related to lead fractures was between 40 and 50%. In our cohort, the lowest incidence of symptomatic lead fractures could result from a close ambulatory follow-up of recalled leads (quarterly), from the use of early warning systems (audible tones, can vibrations, and especially RM), and from the implementation of Lead Integrity Alert® algorithm (when triggered, Lead Integrity Alert® not only provides an early alert, but also increases the number of intervals to detect ventricular fibrillation in order to avoid ISs).

However, despite these improvements, an irreducible number of patients is exposed to ISs when lead fracture occurs. This clinical setting is stressful and harmful. Although ISs in the context of device malfunction does not seem to worsen mortality, several ISs generates significant morbidity and a psychological traumatism.

Therefore, any measure able to quickly stop inappropriate therapies related to lead fractures is welcome. The mean number of ISs per shocked patient was three times lower with RM follow-up compared with CFU. This reduction is very likely the result of a shorter delay between the first IS and the beginning of the medical management led by an emergency physician. Unfortunately, this assumption was not checked, because data were lacking to calculate this delay. All means that cannot avoid shocks (even more multiple shocks) are valuable and RM is a relevant one.

It is commonly thought that the occurrence of ISs would encourage patients to promptly seek medical advice. In clinical practice, despite therapeutic education performed during in-person office visits, a substantial proportion of patients does not spontaneously report ISs occurrence to physicians. Particularly for these patients, but also for all of them, remote follow-up shortens medical reaction delay and avoids multiple ISs delivery.

Whereas Sprint Fidelis® lead fractures are known to cause multiple shocks, the lower burden of ISs in the RM group cannot be assigned to a lower proportion of this lead type in this group. Moreover, the number of ISs per shocked patient was comparable between Sprint Fidelis® and other lead fractures.

The lower burden of ISs in the RM group cannot be explained by a high prevalence of protective algorithms (i.e. Lead Integrity Alert®) in this group. Indeed, most of the patients of the RM group had a
Biotronik® device which did not provide any protective algorithm. Conversely, the majority of patients of the CFU group had a Medtronic® device equipped with the Lead Integrity Alert®. Similarly to Blanck et al. findings,14 we noted that the combination of the RM and an IS protective algorithm was perfectly effective, even if the sample size was small.

Avoidable ISs were arbitrarily defined as the first IS occurring at least 48 h after that a first abnormal value of lead parameters and/or an oversensing were recorded. Almost one-quarter of cases showed avoidable ISs in the both groups. In the RM group, the circumstances of management of avoidable shocks might suggest that device clinic oversight (and not transmission breakdown) is a weakness in RM as Varma pointed out.19 That is why it could be of utmost importance to develop organizational strategies in order to further shorten medical reaction delay.

In the growing proportion of patients with asymptomatic lead fractures, noise signals, as impedance abnormalities, were recorded in more than half of cases among these patients belonging to the RM group. It enabled earlier diagnosis in patients with conventional presentation of lead fracture. We found a comparable proportion of lead fractures detected by oversensing between our asymptomatic CFU group and Luria et al.’s asymptomatic patients (29 and 27%, respectively).15 Typical non-physiological oversensing was documented almost twice as often in the RM as in the CFU group. In fact, noise is a major sign that, by its presence and aspect, facilitates the diagnosis of lead fractures.

Hence, asymptomatic lead fracture seems to be diagnosed at an earlier stage of the disease in the RM group than in the CFU group since less lead fractures were revealed by an increased pacing threshold, a loss of capture or a blunted sensing in the RM group than in the CFU group. This trend coincided with sooner diagnosis in the RM vs. CFU group among patients with conventional presentation of lead fracture. Similar results were displayed in other studies.4,12,20 One main implication is that an early interruption of repeated charge cycles may prevent early battery exhaustion and exert a favourable impact on battery longevity.20

**Study limitations**

This study is limited by its single-centre and observational design. Although ISs related to lead malfunctions can also be caused by lead dislodgments or header-connector pin problems, we intentionally limited the population of our study only to lead fractures for two main reasons. First, lead dislodgments cause more often undersensing than oversensing. So, they rarely trigger IS. Secondly, dislodgments or header-connector pin problems are usually diagnosed very early, even before the patient is discharged, which restricts the potential role of RM for these issues. A multivariate analysis of endpoints according to the type of lead or the ICD brand was not

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**Figure 5** Time between the first sign of lead fracture and its clinical diagnosis in asymptomatic patients with conventional diagnosis, defined as clinical diagnosis occurring < 120 days after a heralding sign of lead fracture (CFU group vs. RM group). Medians of 1.7 (0.0–32.0) and 0.9 (0.0–15.0) days were counted in the CFU and the RM groups, respectively. Statistical analysis with the Mann–Whitney test. Medians are represented by large vertical bars, interquartile range by small vertical bars. The days’ count is represented by turquoise circles and red triangles for patients belonging to the CFU and RM groups, respectively. CFU, conventional follow-up; ns, no significant statistical difference (P = 0.40); RM, remote monitoring.
Reduction of shocks caused by lead fractures

possible due to the small sample size. Actually lead fracture is a rare complication during ICD patients follow-up, so that large multicentre prospective randomized trials cannot provide enough data to analyse the impact of RM on ISs specifically related to lead fractures. It is likely that a larger number of patients would have enabled to show the impact of RM not only on the reduction of ISs burden but also on the reduction of the number of patients with one or more ISs, which is certainly a better performance. In addition, in the future, probably no one will have the opportunity to compare RM with CFU, given the widespread use of RM, which is the new standard of care, as a result of its already proven performances. The key elements necessary to improve outcomes related to lead fractures are a rational processing of data associated with an ability to quickly react to any clinically relevant alert at any time (even outside working days). It is also important to continue to develop new technologies and algorithms to limit ISs related to lead fractures, with the help of manufacturers.

Conclusions

Since the beginning of the 21st century, RM centres appear and contribute to the enhancement of ICD patients’ management. Remote monitoring has a critical role to play in patients concerned by lead fractures. It reduces the burden of ISs related to lead fractures and permits an early diagnosis in asymptomatic patients.

Conflict of interest: Z.S. has received travel support from Biotronik, Medtronic Inc., and Sorin Group. S.B. has received travel support from Biotronik and St Jude Medical. L.G.-M. and D.K. have received consulting fees from Biotronik, Boston Scientific, Medtronic Inc., St Jude Medical, and Sorin Group. F.B. from Biotronik, Boston Scientific, St Jude Medical, and Sorin Group. C.K. from Biotronik, Boston Scientific, Medtronic Inc., and Sorin Group, D.L. from Medtronic Inc. S.K. has received institutional grants and consulting/speaker fees from Biotronik, Boston Scientific, Medtronic Inc., St Jude Medical, and Sorin Group. The authors have no other relevant conflicts of interest to disclose. None of the companies cited above had any involvement in the work, financially or otherwise, of this retrospective study.

References