Current Problems in Cardiology 51 (2026) 103214

Contents lists available at ScienceDirect

Current Problems in Cardiology

journal homepage: www.elsevier.com/locate/cpcardiol

Twiddler-, Reel-, and Ratchet-syndrome: an alternative approach to address the underlying mechanism of complication in cardiac implantable electronic devices

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ARTICLE INFO

Keywords:
Cardiac Implantable Electronic Devices
Lead dislodgement
Lead migration
Ratchet
Reel
Twiddler

ABSTRACT

The circumstances leading to the origins of "Twiddler", "Reel", and "Ratchet" in patients with cardiac implantable electronic devices (CIED) have not yet been fully determined. This retrospective study was performed to address different mechanisms that lead to impairment of implanted leads within the context of "Twiddler", "Reel", and "Ratchet".

From 2004 and 2023, 5966 patients underwent CIED procedures at our institution. 31 patients with lead impairment by rotation were identified with evidence of pulse generator mobility, lead dislodgement with retraction and / or associated coiling of the lead(s) radiographically or intraoperatively. A review of the literature from 1963 to 2024 identified 216 cases from 165 publications.

In less than half of our patients lead retraction could be attested, and a minority of patients had clinical symptoms attributable to lead impairment by rotation. Psychiatric comorbidities and patients´ manipulation could not be ascertained.

Thorough follow-up of all patients with CIEDs appears mandatory. Precise implantation techniques from the outset may limit lead impairment by rotation.

Introduction

Lead impairment by rotation is a rare complication of cardiac implantable electronic devices (CIED). Various attempts have been made to verify terms of "Twiddler", "Reel", and "Ratchet".[1,2] Rotation of a pulse generator (PG), patients´ movement, and redundant tissue may - amongst others - be a trigger for the longitudinal rotation of the lead(s)[1] The current data assessing the underlying mechanisms and possible prevention of lead dislodgements in CIED remains fragmentary. The majority of literature consists of case reports of varying informational content, while only few publications so far have dealt with establishing proper definitions or evaluating the mechanisms of "Twiddler`s", "Reel" and "Ratchet" syndrome. Over the past decades, efforts have been made to achieve a better understanding of what *Morales* et al. referred to as idiopathic lead migration[1] This umbrella term summarizes the entities of Twiddler`s, Reel and Ratchet syndrome, which differ in their respective postulated underlying mechanisms. As mentioned above,

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https://doi.org/10.1016/j.cpcardiol.2025.103214

Available online 24 November 2025

Twiddler`s syndrome means pulse generator rotation along its longitudinal axis, causing entanglement and often retraction of CIED leads. Reel syndrome is induced by rotation of the pulse generator along its sagittal axis, causing coiling of the leads around the generator. In contrast, Ratchet syndrome means the ratchet-like retraction of a lead through an insufficiently fixed suture sleeve[1] However, these changes cannot be attributed exclusively to an active role of the pulse generator (PG) and above all a passive role of the leads implanted. The underlying cause of the changes to the lead(s) remains the rotation of the lead(s) around its own axis. Consequently, the focus of this study is on the impairment of the lead(s).

Method

A retrospective cohort study of adult patients was performed after identifying all inpatient and outpatient encounters with the embedded term "Twiddler" or "Twiddleŕs", "Reel", "Ratchet", "lead dislodgement", "lead dislocation", and "lead retraction" at our institution from January 1st 2004 to December 31st 2023. The medical records and radiograms of each patient were reviewed by three independent reviewers (AK, CS, EÜ) to ensure criteria were met. Patients were defined as having Twiddler's, Reel, or Ratchet syndrome if there was evidence of pulse generator mobility, lead dislodgement with significant retraction and / or associated coiling of the leads around the pulse generator radiographically or intraoperatively. Patient demographics, CIED-related data and the clinical manifestation of Twiddler, Reel or Ratchet syndrome as well as intraoperative findings were collected.

Complementary, we searched the literature available in Pubmed, medline, SciElo, Ovid, Embase, Google Scholar database, journal archives and on the public internet according to the above criteria. Unless unavailable, data were collected similar to our own patients. Information concerning a certain variable was only included in our comparing analysis if itś presence or absence were explicitly stated in the respective case report.

Categorical data were summarized as frequency counts and percentages. Continuous variables were summarized as mean values and standard deviation (SD) and were compared using the non-parametric Mann-Whitney-U-test. Categorical variables were compared with Pearson's chi-squared test of independence. All tests are two-sided, and values of $p < 0.05$ indicate a significant difference. All analyses were performed using SPSS software version 29.0.0 (SPSS Inc., Chicago, IL, USA).

Approval for this study was obtained from the local Ethics Committee (reference number: 24-3887-104). Individual patient approval was waived due to the retrospective nature of the study.

Results

A total of 5966 patients underwent CIED procedures (3708 new implantations, 1347 lead revisions including upgrade procedures, and 911 battery exchanges) at our institution. 31 patients with a diagnosis of "Twiddler", "Reel" or "Ratchet" syndrome were identified. Nearly one-half of the patients were referred from other institutions with lead impairment by rotation. Literature review obtained 165 references with 216 eligible cases including 19 (8,8 %) recurrences.

Patient demographics

The majority of our patients affected were male, which differed significantly from the literature patient cohort (71.0 vs 42.0 %; $p = 0.002$). Further, obesity was detected more often in our patients (87.1 vs 65.0 %; $p = 0.034$). Psychiatric comorbidities, often proclaimed as risk factor for Twiddlerś syndrome, were not at all observed in our patient cohort ($p < 0.001$). There were no relevant differences concerning patient age or the presence of impaired left-ventricular function (Table 1).

CIED-related data

The most common indication for CIED implantation among case report patients was atrio-ventricular (AV) block (33.0 %), ahead of Sick-sinus-syndrome (16.8 %) and ischemic cardiomyopathy (13.7 %). In contrast, the most common indication for implantation of CIED in our patients affected was reduced left ventricular ejection fraction due to dilatative cardiomyopathy (45.2 %), followed by ischemic cardiomyopathy (19.4 %) and AV block (12.9 %). Accordingly, AV block ($p = 0.024$) and Sick-sinus-syndrome ($p = 0.014$) were observed more often amongst literature patients, whereas dilatative cardiomyopathy was seen more frequently in our patients ($p < 0.001$). Further details on all CIED indications can be obtained from Table 2.

The vast majority of our patients affected had implanted implantable cardiac defibrillator-cardioverter (ICD)s (83.9 %), whereas most of the case report patients had pacemakers implanted (57.5 %), which proved to be significant ($p < 0.001$). Concerning ICDs,

Table 1
Patient demographics.

Variables	n/N own patients (%)	n/N case report patients (%)	p-values
Male gender	22/31 (71.0)	89/212 (42.0)	0.002
Age (mean ± SD)	63 ± 14.4 ($n = 31$)	64,5 ± 16,6 ($n = 214$)	0.230
Obesity	27/31 (87.1)	26/40 (65.0)	0.034
Psychiatric disease	0/31 (0.0)	18/24 (75.0)	<0.001
Impaired left ventricular function (< 35 %)	17/31 (54.8)	19/36 (52.8)	0.123

Table 2
CIED diagnosis.

Variables	n/N own patients (%)	n/N case report patients (%)	p-values
Atrioventricular block	4/31 (12.9)	65/197 (33.0)	0.024
Tachycardia-bradycardia-syndrome	1/31 (3.2)	6/197 (3.0)	0.957
Sick-sinus-syndrome	0/31 (0.0)	33/197 (16.8)	0.014
Bradyarrhythmia	0/31 (0.0)	8/197 (4.1)	0.253
Ischemic cardiomyopathy	6/31 (19.4)	27/197 (13.7)	0.406
Dilatative cardiomyopathy	14/31 (45.2)	19/197 (9.6)	<0.001
Non-compaction cardiomyopathy	1/31 (3.2)	0/197 (0.0)	0.012
Hypertrophic cardiomyopathy	0/31 (0.0)	3/197 (1.5)	0.489
Myotonic dystrophy	0/31 (0.0)	1/197 (0.5)	0.691
Long-QT syndrome	0/31 (0.0)	2/197 (1.0)	0.573
Ventricular Tachycardia	2/31 (6.5)	22/197 (11.2)	0.426
Ventricular fibrillation	2/31 (6.5)	11/197 (5.6)	0.846
Brugada syndrome	1/31 (3.2)	0/197 (0.0)	0.012

there were no relevant differences between the occurrences of single- or dual-chamber devices or cardiac resynchronization therapy defibrillators (CRT-D). In both patients groups, the subclavian vein was the most common access (73.1 vs 51.7 %; $p = 0.423$). Subcutaneous (as opposed to submuscular) implantation was also more common in both groups, without reaching statistical significance ($p = 0.395$).

Regarding patients with implanted pacemakers, single chamber devices were found more frequently in the case report cohort (34.1 vs 0 %; $p < 0.001$). The subclavian vein was also the preferred vessel for lead implantation in our patients (100 vs 38.6 %; $p = 0.006$). No further differences were observed between the patient groups (Tables 3 and 4).

Lead impairment by rotation

The device pocket was identified as the most frequent location of lead impairment by rotation in both our and case report patients (100 vs 95.7 %; $p = 0.242$). Lead retraction was observed in almost all literature cases, but in less than half of our patients (97.6 vs 41.9 %; $p < 0.001$). In accordance, only a minority of our patients had conspicuous findings in their device check-ups, contrary to most of the case report patients (38.7 vs 91.9 %; $p < 0.001$). Signs of device rotation were present in both groups. Approximately half of our patients underwent CIED surgery other than initial implantation (45.2 %). 22 of the case report patients were reported to have had previous CIED surgery. Lacking further information about how many literature patients did not have surgery other than the initial implantation, no comparison to the case reports was possible. Given the available data, our patients had a substantially longer period between the discovery of "Twiddleŕs" syndrome and the last CIED-related surgery (779.8 ± 1077.4 vs 306.1 ± 457.5 days; $p = 0.002$). There was also a noticeable difference in the dwell time of the affected leads, although this was not statistically significant (1076.2 ± 1259.2 days in our patients vs 1773.1 ± 2463.5 in case reports; $p = 0.244$). Recurrence rates were comparable in both groups (6.5 vs 8.8 %; $p = 0.662$). Table 5 provides further details hereto.

In surgical revision, one of the main reasons for the occurrence of "Twiddler's" syndrome was thought to be the presence of an excessively large implant pocket (58.1 % in our patients compared to 73.8 % of case reports; $p = 0.119$). Patient movement (75.0 %) and intentional manipulation of the pocket (74.5 %) are also reported in the literature as the main mechanisms for device rotation, while patient movement was suspected in only 29 % of our cases ($p < 0.001$). All our patients denied deliberate manipulation of their device pocket ($p < 0.001$). Other possible causes for the development of twiddler syndrome, such as infection, seroma or loose suture

Table 3
ICD.

Variables	n/N own patients (%)	n/N case report patients (%)	p-values
ICD	26/31 (83.9)	91/214 (42.5)	<0.001
VVI	15/31 (48.4)	42/214 (19.6)	<0.001
DDD	4/31 (12.9)	26/214 (12.1)	0.905
CRT-D	6/31 (19.4)	20/214 (9.3)	0.091
SICD	1/31 (3.2)	3/214 (1.4)	0.454
Single coil	13/31 (41.9)	25/64 (39.1)	0.267
Dual coil	12/31 (38.7)	39/64 (60.9)	0.267
Cephalic vein	6/26 (23.1)	9/29 (31.0)	0.266
Subclavian vein	19/26 (73.1)	15/29 (51.7)	0.423
Jugular vein	0/26 (0.0)	0/29 (0.0)	-
Epicardial lead	0/26 (0.0)	5/29 (17.2)	0.026
Implantation on right side	1/26 (3.8)	3/71 (4.2)	0.934
Subcutaneous layer	14/26 (53.8)	22/34 (64.7)	0.395
Submuscular layer	12/26 (46.2)	12/34 (35.3)	0.395

ICD implantable cardioverter defibrillator, VVI single chamber device, DDD dual chamber device, CRT-D cardiac resynchronization therapy – defibrillator, SICD subcutaneous implantable cardioverter defibrillator.

Table 4
Pacemaker.

Variables	n/N own patients (%)	n/N case report patients (%)	p-values
Pacemaker	5/31 (16.1)	123/214 (57.5)	<0.001
VVI	0/31 (0.0)	73/214 (34.1)	<0.001
DDD	5/31 (16.1)	46/214 (21.5)	0.492
CRT-P	0/31 (0.0)	4/214 (1.9)	0.443
Cephalic vein	0/5 (0.0)	22/57 (38.8)	0.084
Subclavian vein	5/5 (100)	21/57 (38.6)	0.006
Jugular vein	0/5 (0.0)	7/57 (12.3)	0.405
Epicardial lead	0/5 (0.0)	7/57 (12.3)	0.405
Implantation on right side	2/5 (40.0)	49/99 (49.5)	0.679
Subcutaneous layer	3/5 (60.0)	38/45 (84.4)	0.177
Submuscular layer	2/5(40.0)	7/45 (15.6)	0.177

VVI single chamber device, DDD dual chamber device, CRT-P cardiac resynchronization therapy – pacemaker.

Table 5
Lead impairment by rotation.

Variables	n/N own patients (%)	n/N case report patients (%)	p-values
Site of impairment:			
Intracardiac	2/31 (6.5)	15/235 (6.4)	0.988
Venous system	1/31 (3.2)	3/235 (1.3)	0.402
Pocket	31/31 (100)	225/235 (95.7)	0.242
Previous CIED surgery	14/31 (45.2)	22/n.a. (-)	-
Lead-related previous CIED surgery	9/31 (29)	10/22 (45.5)	0.219
Lead retraction	13/31 (41.9)	200/205 (97.6)	<0.001
Lead fracture	11/31 (35.5)	30/60 (50.0)	0.187
Conspicuous device interrogation	12/31 (38.7)	148/161 (91.9)	<0.001
Detected in routine interrogation	29/31 (93.5)	41/86 (47.7)	<0.001
Days between last surgery and detection (mean ± SD)	779.8 ± 1077.4 ($n = 31$)	306.1 ± 457.5 ($n = 219$)	0.002
All leads affected	28/31 (90.3)	165/207 (79.7)	0.159
Dwell time of affected leads (mean ± SD)	1076.2 ± 1259.2 ($n = 31$)	1773.1 ± 2463.5 ($n = 21$)	0.244
Signs of device rotation	22/31 (71.0)	162/190 (85.3)	0.048
Recurrences	2/31 (6.5)	19/216 (8.8)	0.662

cuffs, were not observed in our own patient cohort (see Table 6).

Symptoms

Most of our affected patients had had a routine check-up, whereas more than half of the literature patients had their devices checked as a consequence of clinical symptoms (93.5 vs 47.7 %; $p < 0.001$). Only three of our patients presented with clinical symptoms attributable to Twiddler syndrome, while almost three-quarters of the case report patients were symptomatic (73.3 %; $p < 0.001$). Most of the latter complained of phrenic nerve (18.5 %; $p = 0.010$) or brachial plexus stimulation (16.1 %; $p = 0.016$), neither of which was observed among our patients. Suffering of inappropriate shocks was also observed more often amongst literature patients (10.6 vs 3.2 %; $p = 0.200$). Other conditions as bradycardia or syncope (each 9.9 %; $p = 0.067$) were only present in the case report cohort. Apart from inappropriate shock, only pocket site pain (3.2 %; $p = 0.415$) and imminent device erosion (3.2 %; $p = 0.022$) were found among our patients. A complete overview of the observed symptoms can be obtained from Table 7.

Discussion

With regard of CIED, various patterns of lead dislodgement can be observed. The theories established so far for the occurrence of significantly altered lead positions in the context of “Twiddleŕs”, “Reel”, and “Ratchet” syndrome almost exclusively result from

Table 6
Intraoperative findings.

Variables	n/N own patients (%)	n/N case report patients (%)	p-values
Spacious pocket	18/31 (58.1)	48/65 (73.8)	0.119
Patient movement	9/31 (29.0)	33/44 (75.0)	<0.001
Patient manipulation	0/31 (0.0)	35/47 (74.5)	<0.001
Loose suture sleeve	0/31 (0.0)	8/n.a. (-)	-
Infection	0/31 (0.0)	1/n.a. (-)	-
Seroma	0/31 (0.0)	3/n.a. (-)	-

Table 7
Symptoms.

Variables	n/N own patients (%)	n/N case report patients (%)	p-values
Symptomatic	3/31 (9.7)	118/161 (73.3)	<0.001
Inappropriate shock	1/31 (3.2)	17/161 (10.6)	0.200
failed shock	0/31 (0.0)	1/161 (0.6)	0.660
Pain at pocket site	1/31 (3.2)	2/161 (1.2)	0.415
Imminent device erosion	1/31 (3.2)	0/161 (0)	0.022
Bradycardia	0/31 (0.0)	16/161 (9.9)	0.067
Tachycardia	0/31 (0.0)	3/161 (1.9)	0.444
Presyncope	0/31 (0.0)	6/161 (3.7)	0.275
Syncope	0/31 (0.0)	16/161 (9.9)	0.067
Dyspnea	0/31 (0.0)	8/161 (5.0)	0.205
Device alarm	0/31 (0.0)	4/161 (2.5)	0.375
Phrenic nerve stimulation	0/31 (0.0)	29/161 (18.5)	0.010
Brachial plexus stimulation	0/31 (0.0)	26/161 (16.1)	0.016
Chest pain	0/31 (0.0)	4/161 (2.5)	0.375
Fatigue	0/31 (0.0)	1/161 (0.6)	0.660
Dysphonia	0/31 (0.0)	2/161 (1.2)	0.533

individual observations.

Few authors have dealt with the detailed description of these complications of CIED therapy.[1-3] We wonder whether the proposed definitions of “Twiddler”, “Reel” and “Ratchet” are sufficient in order to recognize and resolve the causes of visible macroscopic lead impairment by rotation. The images we see are the results of multifactorial forces acting on the implanted systems. The decisive factor of (impending) malfunction of leads is the potentially preventable cause. Any form of twiddling is based on an axial rotation of the lead (s), although axial rotation of leads does not in itself result in twiddling phenomena. It can only result in any kind of twiddling if the lead has a fix point in the periphery, either suture sleeve, tip fixation, or adhesions. The trigger for the axial rotation of a lead must be identified and eliminated.

Incidence

The discrepancy in the sample sizes of affected patients at our institution and in the literature is due to the deliberately chosen, significantly longer period covered by the literature search (from the beginning to the present). As with the present topic, observational reports of a complication form the basis for further considerations, taking empirical data into account. Therefore, case reports published before the study period for our patients were also included.

The incidence of “Twiddleŕs”, “Reel” and “Ratchet” syndrome is estimated between 0.07 % and 7.1 %.[2,4-8] In our patient population, an overall incidence of 0.5 % was recorded, with a recurrence rate of 6.6 % compared to up to 50 % in the literature.[2,7] Only three of our patients presented withed clinical symptoms attributable to lead dislodgement. Of the remaining 28 patients who were registered for routine follow-up, 12 had unremarkable lead values. In patients with neither clinical symptoms nor conspicuous device-follow-up, lead dislodgement was found incidentally in routine chest x-ray before planned CIED-related surgery (i.e. exchange of PG, lead revision or device upgrade). These findings emphasize the importance of thorough follow-up for all patients with CIEDs, especially since the vast majority of our affected patients had an ICD implanted. Undoubtedly, an abnormal CIED device interrogation should be followed by at least radiological diagnostics.

The impact of morbidities

A statistical analysis of demographic characteristics between affected and unaffected patients was omitted, mainly as half of the affected patients were referred to us by external institutions. Older women, flappy subcutaneous tissue, obesity, weight loss, mental disorders such as dementia, and childhood have been described as predictors.[8,9] Most of our patients affected were male. Consistent to the literature, women in our cohort were older and more obese. Mental disorders, patients ́manipulation, and anxiety were not recorded in our patients. None of our patients received antidepressant medication.

The impact of pulse generator rotation

The most common cause of macroscopic lead impairment by rotation is undoubtedly an inappropriately sized device pocket, which promotes rotation of the PG around its axes. PG rotation is crucial in the development of any changes to the implanted lead(s). An oversized pocket can be caused by surgical misjudgment, postoperative hematoma or seroma, and by manipulations or physiological movements of the patient. In our patients, an excessively large device pocket was also identified as the most common cause.

Implanted devices and leads are constantly exposed to a variety of multidirectional forces, e.g. from daily patient movements that result in differently directed force vectors through the surrounding tissue[10] The localization of the pocket (laterally or medially, cranially or caudally, in a subcutaneous, subfascial, or submuscular layer), its adapted size and the design of the PG as well as other components of the PG influence these force vectors and vice versa. Redo procedures may also alter the surrounding of the device. It is striking that 45 % of our affected patients had previously undergone revision surgery, be it a battery exchange (different size and design of the PG) or a lead revision, as has been published previously[5] This emphasizes the importance of special precautions during revision surgery. Implementing these considerations may avoid stress on the PG pocket in patientś physiological movements (e.g. elevation the arms, lying on the side of the implantation site), as has been described by other authors.[4,5, 11-13]

In general, rotation of the PG can occur along the x-, y- and z-axis (Fig. 1), with the x-axis being the most uncommon variant. The external design of a PG will be subject to a preferred axis of rotation, but does not exclude other axes of rotation. The PGs of different manufacturers and types have considerably different shapes (e.g. Abbott Fortify Assura™ versus Biotronik Intica Neo™). It is obvious and understandable that different PGs therefore are prone to rotate around different axes. For this reason, the exact assignment of the axes is essential in order to be able to argue consistently.

Obviously, only the position of leads and PG at the time of the radiological/intraoperative control can be taken into account, but not the rotational movements over time. Seven of our patients and seventeen in the literature had a device dwell time of more than four years. This raises the question whether the impairment occurred much earlier and we are only now taking notice of it. Consequently, it is not possible to draw conclusions about the PG's axes of rotation, even if this were an obvious explanation, as published literature would have us believe[2] It may have a limited correlation with reality.

Rotation along the z-axis can occur towards the connector side or the rounded side of the PG. Depending on the rotational direction, different axial rotations of leads result. If the lead is rotated in the direction of the rounded side of the PG, the diameter of the loops decreases continuously, unless adhesions within the pocket prevent unrestricted loop formation (Fig. 2). In the opposite direction of rotation, on the other hand, it leads to an enlargement of the loops, provided there is sufficient space in the device pocket. If there is no further space for loop formation, the lead flips over and displays the typical twiddling pattern (Fig. 3). In cases of insufficient lead fixation at the suture sleeve, reverse twiddling or reeling will occur.

Ultimately, the direction of movement of the PG is irrelevant. What is crucial is that movement can occur at all within the pocket.

However, the rotation of the PG does not necessarily explain the behavior of the electrodes. Rotation of the PG can lead to a typical braid-like winding of the electrodes, but it can also wrap around the head of the PG or the PG itself.[14,15] As already mentioned, a distal fixed point of the respective electrode(s) is required so that rotation can lead to winding of the electrode in the surrounding tissue or vasculature. This fixed point can be anchorage or adhesions.

Macroscopic lead dislodgement or retraction is not necessarily observed. More than half of our patients showed no evidence of lead retraction at all. *Parsonet* et al. as well as *Sekimoto* reported similar findings.[15,16] Rotation of the PG in the device pocket can initially occur without lead retraction, making it invisible from the outside. This has been previously described.[17,18] Furthermore, damage to the leads does not necessarily occur, which was the case in half of our patients.[19–21] However, the risk of breakage rises with increasing rotation of the lead(s).

The impact of lead behavior and suture sleeve

The suture sleeve plays a crucial role in the implantation of CIEDs. It serves to fix the lead at a specific point between device pocket and heart, thus securing the position and length of the lead as it is inserted.[22] In a good third of our patients, a glove-fit pocket was noted without any evidence of PG rotation. Several authors have had published similar findings.[10,13,18,23]

In addition to the rotation of the device along the z-axis, other force vectors appear to act particularly on the excess electrode portion between the device and the suture sleeve. This portion is usually twisted into loops during implantation, which are then neatly positioned beneath the device in the pocket. Any conscious or unconscious movement of the adjacent muscles can exert tensile or compressive forces on this portion of the electrode, which in turn may be accompanied by a slight rotation of the lead. Repeated occurrence of such movements can cause the lead to coil due to rotation. Consequently, not only the rotation of the PG is important, but

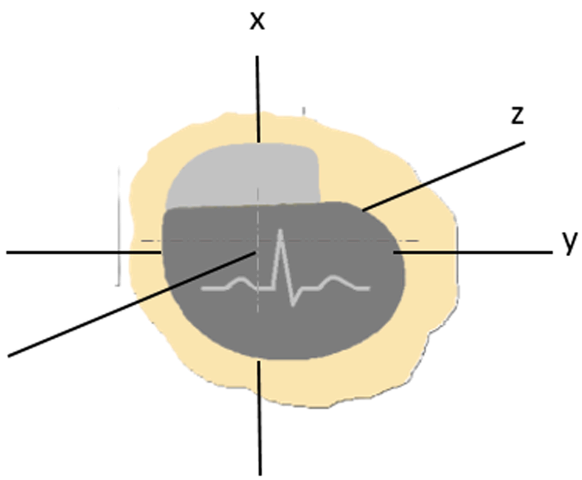

Fig. 1. Possible axes of rotation of a pulse generator: longitudinal (x), transverse (y), sagittal axis (z) or any combination of both.

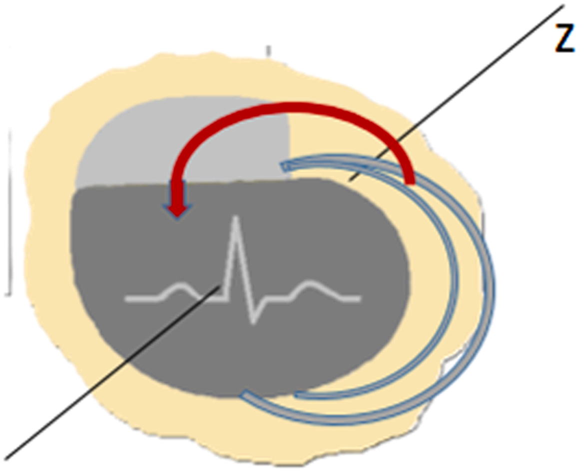

Fig. 2. The lead is rotated in the direction of the rounded side of the pulse generator in the sagittal (z) axis; the diameter of the loops is constantly reduced.

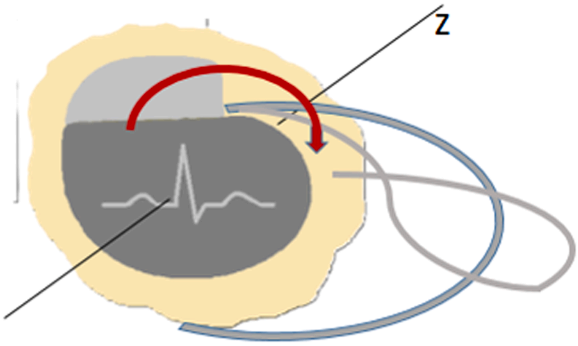

Fig. 3. The lead is rotated in the direction reverse to the rounded side of the pulse generator in the sagittal (z) axis, resulting in increasing size of the loops, provided there is sufficient space in the device pocket. If there is no further space for the loops to form, the lead flips over and shows the typical twiddling pattern.

also the rotation of the lead around its own axis. The force vectors responsible for this may not necessarily be immediately apparent (e.g., a garden hose hanging in loops or a coiled extension cable). If the lead can no longer be coiled into loops, a braid-like pattern is formed. This is well demonstrated in the literature.[9,17,24]

Different rotation axis of a PG should exert the same tensile force on an inserted lead. This means that only the traction angle on the lead(s) at the suture sleeve(s) differs. If the lead is insufficiently fixed to the suture sleeve, an acute angle of the lead when entering the suture sleeve prevents tensile force to act upon the lead(s) beyond the suture sleeve. This results in a higher risk of lead fracture.

A firm fixation to the suture sleeve provided, the lead can only move between the suture sleeve and the generator. Lead fracture due to excessive rotation occurs almost exclusively between the device pocket and the suture sleeve. The localization of the suture sleeve(s) is crucial, as the surrounding tissue has an impact on tensile forces. A fixation at the fascia infraclavicularly close to the origin of the clavicular portion of the pectoral major muscle reduces rotational forces.

Initially, muscle movements can cause tension on the lead with slight rotation, reducing its diameter. This allows the lead to be pulled through the now relatively loose suture sleeve. Releasing the tension normalizes the lead diameter again, making it impossible to return to its original position[10] Inadequately secured electrodes are more susceptible to tensile forces, which can lead to gradual traction. Ultimately, this means that the so-called ratchet mechanism engages in all macroscopically visible lead dislodgements, unless the suture on the suture sleeve is not tight enough. As is well known, there is no described ratchet mechanism for all electrodes involved, which underscores the great importance of the individual suture sleeve and its electrode. In other words, reel and ratchet may have the same entity.

Loop formation of a lead within the subclavian vein, the innominate vein or heart cavities can only occur in affected leads insufficiently fixed at the site of the suture sleeve, as leads preferably curl up in spacious areas, including their periphery. We observed this special phenomenon, previously described in the literature, in three of our patients.[11,23] Furthermore, the conduct of other components within the lead itself must be considered. Most of our patients had defibrillation leads affected. These leads are considerably more technically complex than pacer leads, consisting of conductor (wires), integral and other insulations, central axis, pacing and /or shocking coils, and compression chambers. The complex structure of a lead in cases of winding within the subclavian or innominate vein or even in the heart cavities remains uncertain and may be due to adherences to the vasculature or heart structures.

The impact of lead fixation and adhesions

Passive fixation (tines) of leads was observed in 13 affected leads as compared to 34 leads with active fixation (screw) in our patients, dual coil defibrillation leads were seen in 12 of the 31 patients. The dwelling time of leads exceeded 1000 days in a third of our patients. With increasing dwelling time, fibrous tissue adhesions and calcifications fix leads to adjacent vascular walls. This limits or even completely prevents axial rotation of the leads at these precise locations. Furthermore, this environment does not enable movement of a lead within the adhesion or calcifications without exceeding traction forces described for lead retraction within suture sleeves. This would explain why none of the patients with a dwell time of their implanted leads of 600 days or more experienced lead retraction.

Limitations

This study has several limitations. It is a retrospective study conducted at a single center with highest care level. There may be a selection bias, as nearly half of the patients were referred to our center, limiting the generalization of the findings. Although unlikely with three independent investigators, it is possible that not all affected patients were included due to the retrospective nature of the study.

Conclusion

Due to increasing numbers of CIED implantations, the incidence of any kind of lead impairment will increase. In addition to intentional or unconscious manipulation by the patient, the implant is also exposed to quite ordinary physiological movement sequences that eventually end in malfunction, lead dislodgement or lead fracture. The increasing age of the individual patient and thus changes in the musculature / environment of the device, as well as possible changes in lifestyle can change the location of the implanted material. The same applies for surgical risks like inadequate pocket size and location as well as insufficient fixation of the suture sleeves. However, if precise implantation techniques are used from the outset, lead impairment by rotation can be limited.

Disclosure and declaration

Approval for this study was obtained from the local Ethics Committee (reference number: 24-3887-104). Individual patient approval was waived due to the retrospective nature of the study.

Funding

The study was not founded, neither regarding the design of the study, nor with regard to the collection, analysis, and interpretation of data, or the writing of the manuscript. None of the authors has any financial relationship with a commercial entity that has an interest in the subject of the manuscript or other conflicts of interest.

Availability of data and materials

The authors declare that all data supporting the findings of this study are available within the article and its additional files.

Authors' contributions

AK, CSt, ASt, EU, CJ, and SS designed the study and are responsible for finalizing the protocol, analysis, and completion of the final manuscript. AK and CSt developed the search strategy in consultation with EU and CJ. AK and CSt conceived the project, developed the protocol, and wrote and revised the manuscript; ASt, SW, CS and SS contributed to the writing of the manuscript. All authors critically revised the protocol and the final manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Declaration of competing interest

The authors declare that they have no competing interests.

Acknowledgement

Not applicable.

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