QuickSite Cardiac Resynchronization Therapy Lead Conductor Externalization

A Short Story

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Abstract

Conductor externalization (CE) is a known phenomenon in the St. Jude Medical QuickSite and QuickFlex families of leads. This is generally considered a benign finding, not associated with electrical abnormality. We report a case of a 1056T QuickSite Cardiac Resynchronization Therapy (CRT) lead CE, leading to electrical failure.

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Key Words:

Cardiac resynchronization therapy • Pacemaker lead failure • Conductor cable externalization

Background

In 2012, St. Jude Medical (SJM) issued an advisory on its QuickSite and QuickFlex lines of CRT pacing leads, due to the risk of conductor externalization (CE). Although electrical anomalies of leads had been described, these had not been linked to CE. In fact, the initial report from SJM states that "there have been no electrical dysfunctions attributable to the externalized conductors" [1]. This position is brought into question by a recent report of 1156T QuickFlex CRT lead failure associated with CE [2]. We report a case of a 1056T QuickSite CRT lead CE, leading to electrical failure of the lead and a precipitation of clinical heart failure.

Figure 1. SJM 1056T lead prior to (A) and following (B) extraction. CE is noted on both conductors just proximal to the ring electrode (**arrowheads**), with an additional segment of CE proximal to the S-curve of the lead (**arrows**). The appearance of the lead after extraction matches that prior to extraction.

Methods

The patient is a 63-year-old male with past medical history (PMH) notable for nonischemic cardiomyopathy (NICM) (left ventricular ejection fraction (LVEF) 15%, New York Heart Association (NYHA) 3 functional class), hypertension (HTN), diabetes mellitus (DM), and hyperlipidemia (HLD). He had previously undergone implantation of a biventricular implantable cardioverter defibrillator (ICD) in 2011, with subsequent improvement in his clinical status to NYHA 2. His ICD system encompassed a SJM Unify CRT-D pulse generator, SJM 2088TC RA lead, Medtronic 6947 RV lead, and SJM 1056T CS lead. He was evaluated for a worsening of his heart failure symptoms 3 years after device implant and was found to have a newly elevated LV capture threshold in the bipolar configuration (1.75 V at 1.0 ms, up from 0.5 V at 0.5 ms at implant) with loss of LV capture preceding the onset of heart failure. Further investigation revealed CS lead impedance intermittently dropped to the 100-ohm range, from a chronic and previously stable range of about 500 ohms. Fluoroscopic evaluation of the CS lead showed externalization of two conductor segments in

Figure 2. Electrical testing of SJM 1056T lead: (A) in air; (B) in 0.9% saline; (C) in air with saline applied only to the segment of dual conductor externalization.

Table 1: Post-extraction Electrical Testing of SJM 1056T Lead

Condition	Bipolar impedance
Suspended in air	Infinite
Immersed in 0.9% saline	310 ohms
In air with saline applied to CE segment	2825 ohms

the region just proximal to the ring electrode (Figure 1A). An electrical short between the externalized conductors was suspected as the reason for abnormally low impedance measurements and the loss of biventricular pacing.

After discussion with the patient, CS lead revision was planned, with the strategy of extracting the chronic CS lead if possible.

At the time of the procedure, the CS lead was noted to be free of any gross insulation defects in the pocket. After the lead was freed of intracapsular adhesions, a nonlocking stylet was advanced to the lead tip. The CS lead was then withdrawn with gentle manual traction. There was minimal resistance, and the lead was extracted in its entirety. Following the implantation of a new CS lead (SJM 1458Q), all leads were reconnected to the pulse generator and the pocket was closed. The patient tolerated the procedure well, and was discharged the following day with functional LV pacing via the new lead.

After extraction of the CS lead, conductor externalization was confirmed on gross examination and on high-resolution fluoroscopy (Figure 1B). Impedance testing was performed on the lead *ex vivo*, in air and in a saline bath (Figure 2 and Table 1). This confirmed the suspicion of an electrical short between the two externalized conductor filaments. The lead was returned to SJM for further analysis.

At his follow-up visit, the patient reported an interim improvement in his functional status, and was again in NYHA 2 range. Interrogation of his ICD showed consistent biventricular pacing since system revision.

Discussion

Since there are many potential causes for pacing lead malfunction, it was important to explore the mechanism of lead failure in this case. Previous reports of CE in the QuickSite family of leads, even when associated with electrical anomalies in lead performance, have not been shown to be the cause of lead malfunction. This is in contrast to the Quick-Flex family of leads, in which there is at least one reported case of CE associated with electrical failure of the lead [2]. In the present case, the loss of insulation on both conductors led to suspicion of an effective short between them, causing loss of capture.

The fluoroscopic appearance of the lead was confirmed on gross examination following lead extraction. It is reasonable to conclude that there was no damage to the lead as a result of the extraction itself, based on the fact that an extraction sheath was not used, there was no resistance to lead withdrawal, and the gross appearance of the lead matched the pre-extraction fluoroscopic appearance. Thus, any electrical abnormality following extraction should be directly relevant to the lead's *in vivo* performance.

Changes in lead impedance have been observed with deterioration of aging polyurethane in cardiac pacing leads [3] and marked changes in impedance in different circuit configurations is diagnostically informative [4]. Deviation of lead impedance from usual norms for a patient is a predictor of lead failure [5].

These well-established principles are applied here in a novel context.

While the bipolar impedance reading in air was expectedly high, it decreased abnormally in a saline bath, which served as a proxy for lead performance in biological tissue. This points to an electrical abnormality in the lead, and specifically suggests an insulation defect, presumably in the ethylene tetrafluoroethylene applied to the externalized conductor, once the protection of the outer silicone layer is lost. The impedance reading was also abnormally low while suspended in air with a miniscule drop of saline applied to the externalized portion of the conductors (Figure 2C). This suggests that the electrical abnormality was localized to the region spanned by the saline meniscus, and likely confirms the suspicion of an electrical short between the two conductors as the cause of the lead malfunction.

At the time of the 2012 advisory, there were more than 100,000 SJM QuickSite and QuickFlex leads in service. The rate of CE is estimated at 3–4%; and the rate of electrical anomalies is less than 0.02% [1]. There exists a single published report of QuickFlex lead failure secondary to CE; in this case, the electrical anomaly led to an audible patient alert without a precipitation of heart failure symptoms [2]. An adverse patient event has not been previously reported as a result of CE in the QuickSite family of leads. However, the present case demonstrates that possibility.

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Cite this article as: Aznaurov SG, Rottman JN. QuickSite CRT lead conductor externalization. *Arrhythmia Grand Rounds* 2015;1(2):60-62. DOI: <http://dx.doi.org/10.12945/j.agr.2015.005-15>

Conclusions

CE has been previously reported in the SJM QuickSite and QuickFlex lines of CRT leads, and a recent case report demonstrated the possibility of electrical failure of the QuickFlex family of leads. There has not been a previous report of an adverse patient event stemming from such a malfunction, and likewise an electrical failure of a QuickSite lead has not been previously reported as a result of CE. This case is the first report of such an occurrence. The electrical anomaly in this case led to a loss of biventricular pacing, causing progression of the patient's heart failure symptoms. Revision of the CS lead restored the patient's clinical response to CRT. Electrical testing of the extracted lead confirmed the suspicion that the externalized conductor segments were responsible for electrical malfunction of the lead.

Conflict of Interest

The authors have no conflicts of interest relevant to this publication.

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