Heart, Lung and Circulation (2020) **29,** 936–939
1443-9506/04/$36.00
https://doi.org/10.1016/j.hlc.2019.06.718

ORIGINAL ARTICLE

Increased Incidence of Noise in the Tendril Pacemaker Lead Detected via Remote Monitoring

Samuel Lovibond, MBBS, FRACP [a*], Nicholas Youngs, BASC [b], Emily Kotschet, MBBS, FRACP [c], David Adam, MBBS, FRACP [c], Anton Antonov, MBBS [c], Justin A. Mariani, PhD, FRACP [a]

[a]The Alfred Hospital and Baker IDI, Melbourne, Vic, Australia
[b]Remote Rhythm Management Pty Ltd, Melbourne, Vic, Australia
[c]Monash Medical Centre, Melbourne, Vic, Australia

Received 21 February 2019; received in revised form 9 May 2019; accepted 4 June 2019; online published-ahead-of-print 27 June 2019

Background Prior studies suggest increased rates of noise on the Tendril (St Jude Medical/Abbott, St. Paul, MN, USA) pacemaker lead. We aim to assess the incidence of lead noise in the Tendril and 5076 (Medtronic PLC, Minneapolis, MN, USA) pacemaker leads in our cohort and in the process assess the utility of remote monitoring for identifying lead malfunction.

Methods Deidentified, multi-centre, prospectively collected observational cohort data was obtained to assess the incidence of noise on the Tendril and 5076 pacemaker leads.

Results 148 Tendril and 737 CapSureFix Novus 5076 (Medtronic, MN, USA) pacemaker leads were remotely monitored. Incidence of noise on the Tendril was 8% and 0.27% on the CapSureFix Novus.

Conclusion Rates of noise in the Tendril lead are higher than a market competitor. Remote monitoring is useful in detecting this concerning anomaly.

Keywords Tendril pacemaker lead • CapSureFix Novus pacemaker lead • Pacemaker lead noise • Pacemaker lead failure • Pacing • Remote monitoring

Introduction

Recent studies [1–3] demonstrate higher failure rates of the St Jude Medical/Abbott Inc (SJM) (St Jude Medical/Abbott, St. Paul, MN, USA) Tendril pacemaker lead than with its market competitors. This is anecdotally consistent with our local experience.

Pacemaker lead noise can be correctly identified by the device, or interpreted incorrectly. Atrial lead noise may be inappropriately sensed as physiological and thus trigger an automatic mode switch or cause high rate ventricular tracking. On a ventricular lead, it may be inappropriately sensed as physiological (included in a high rate episode), which can result in inhibition of pacing.

We sought to assess the incidence of noise detection by pacemakers and implantable cardioverter-defibrillators (ICD) when connected to functioning 2088TC Tendril leads compared with a control lead, the 5076 CapSureFix Novus lead (Medtronic PLC, Minneapolis, MN, USA). We also aimed to assess the utility of remote monitoring of cardiac devices in closely monitoring long-term lead performance.

*Corresponding author at: Pacing and Heart Failure Fellow, 3rd Floor, Phillip Block, Alfred Hospital, 55 Commercial Road, Melbourne, VIC 3000, Australia. Fax +61 390765138., Email: slovibond@gmail.com

Material and Methods

Ethical clearance was obtained at an institutional level to cover an external remote monitoring database that follows up patients from multiple tertiary centres throughout Victoria, Australia. Prospectively collected deidentified data was collated, covering 115 patients with 2088TC pacemaker leads and 484 patients with 5076 leads. Patients had their devices implanted by one of 13 cardiologists. Baseline demographics, device and lead details, the presence of noise and the manifestation of the noise were collated for all patients with these leads managed by the monitoring service. Lead data for all devices was transmitted monthly via remote monitoring and reviewed by a cardiac technician. Treating clinicians were then notified of the events and subsequent management left to their discretion, which included early outpatient review or radiological imaging of the lead. This practice was part of standard of care and results were tabulated prospectively for the purpose of the study. Noise was defined as device electrogram (EGM) electrical activity not caused by normal device function, cardiac activity or extra-thoracic stimuli. Initial diagnosis of noise was made by an experienced cardiac technician and then confirmed by three separate cardiologists. Lifetime incidence of lead noise was then calculated for each lead type before being directly compared. This simple statistical method of comparison of incidence was utilised as it enables easy comparison between our work and other studies on the topic [1–3], which have analysed their data in a similar way.

Results

One hundred and fifteen (115) patients were implanted with 148 SJM 2088TC leads and 484 patients with 737 Medtronic 5076 leads, respectively. On average the 2088TC leads had been in situ for longer than the 5076 (44 months vs 29 months). Noise was seen in 12, 2088TC leads (8%) and in two patients with 5076 leads (0.27%) (Figure 1). Of the 2088TC leads; nine noise cases were atrial leads and all resulted in automatic mode switching (AMS) to VVI (Figure 2); three cases were right ventricular leads, which resulted in two cases of ventricular high rate (VHR) sensing and one case of noise detection. Of the 5076 leads, both were atrial leads and resulted in AMS. All leads in the noise group were programmed bipolar except one ventricular lead, which was programmed to sense in unipolar configuration and pace in bipolar. Amongst patients in the 2088TC group, the frequency of demonstrable noise was usually seen to increase after the initial episode was seen.

All patients in the 2088TC noise group had SJM devices: five had CRT-D devices (1 Promote Quadra, 2 Unify Quadra and 2 Quadra Assura), five had Accent pacemakers (four dual chamber, one single) and two had Fortify ICDs. Both patients in the 5076 noise group had a dual chamber Medtronic Advisa pacemaker.

Across both groups, one patient in the 5076 group with demonstrable lead fracture, had their lead replaced at the discretion of the treating cardiologist. The remainder of patients continue to be monitored. The 2088TC leads had been implanted for an average of 60 months prior to the first episode of noise (95% CI 47–72 months) compared with 105 months for the 5076 leads. In the 2088TC lead group, 9 of the 12 cases had their first episode of noise seen between 51 and 68 months of lead life. Both 5076 leads with noise had a fixed sensitivity set at 0.9 mV. Of the 12, 2088TC leads with noise, autosense was on in seven cases and off in five cases with a fixed sensitivity of 0.2–1.2 mV.

As all patients were ventricular sensing at the time of the ventricular lead noise, there was no noise related inhibition of ventricular pacing and subsequently no clinical adverse events. Additionally, there were no obvious observed abnormal trends in impedance, sensing or pacing thresholds in any of the groups.

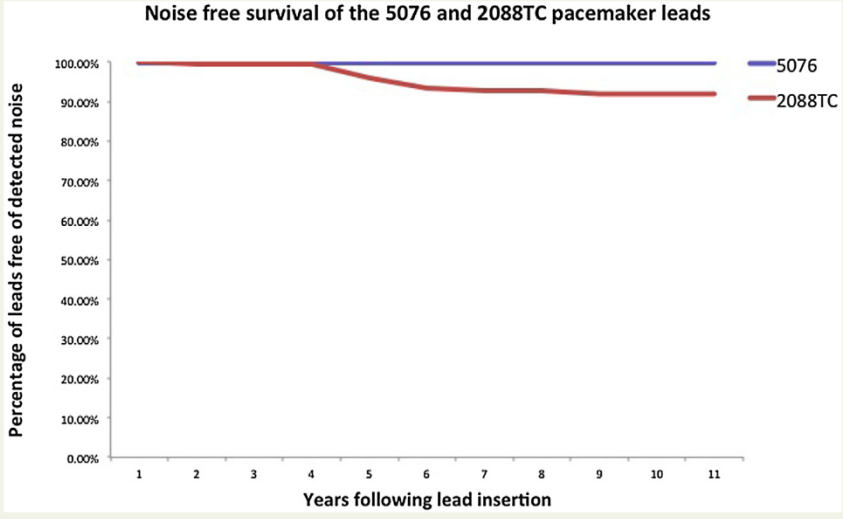

Figure 1 Noise free survival of the 5076 and 2088TC pacemaker leads.

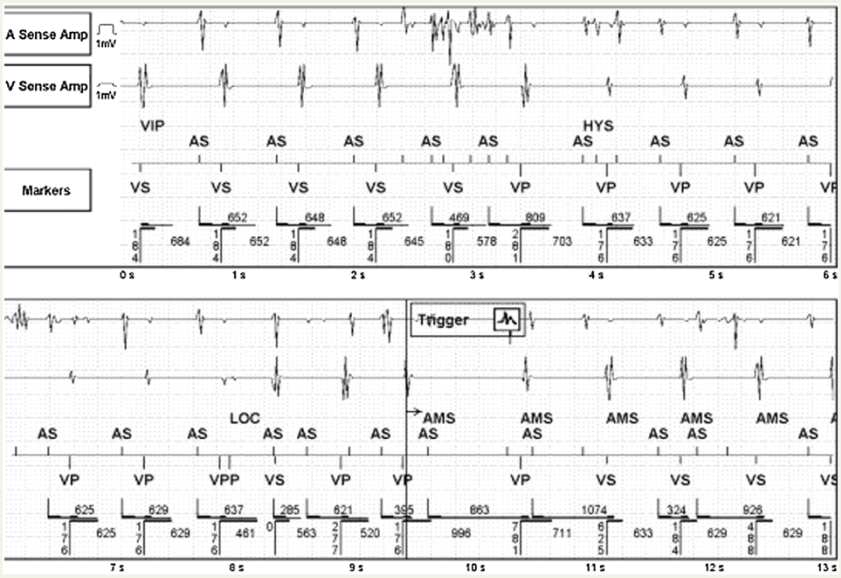

Figure 2 Example of transmitted electrogram (EGM) demonstrating atrial lead noise triggering an automatic mode switch episode on a 2088TC.

Discussion

The finding of an incidence of noise in the Tendril pacemaker lead of 8% with a mean follow-up of 44 months is consistent with other studies. Chu et al. [3] reviewed their cohort of patients that had received a 1688, 1788, 18888 or 2088 Tendril lead over a mean length of follow-up of 3.9 years. They demonstrated a 10% rate of noise in the 2088 lead and a combined rate of noise in all Tendril leads (1688, 1788, 1888 and 2088) of 9%. Interestingly, to exclude a primary generator issue, they also assessed a 145-patient cohort with a 5076 lead attached to a St Jude Medical/Abbott pulse generator. The rates of noise in that group were less than 1%. Sayegh et al. [1] compared 751 Tendril leads with 269 CapSureFix Novus leads over a mean of 2.4 years. They found a rate of malfunction in the Tendril leads of 6.8% compared to 0.4% in the CapSureFix Novus. In the Tendril malfunction group, an insulation breach was documented in 76.5% of cases, which manifested as noise in over half.

The major discrepancy between our groups at baseline was the difference in lead age, with the 2088TC leads being in situ for on average, 15 months longer than the 5076 leads (44 vs 29 months). This reflected implanting practice in our area at the time, but could create a degree of follow-up bias. Our data suggests that 2088TC leads experience noise earlier than the 5076, which is problematic given the shorter duration of follow-up for the 5076. However, with only two patients in the 5076 group experiencing noise, trends to the timing of noise on that lead should be viewed with caution.

Association has been drawn between the Optim coating which was involved in the Riata lead (SJM) recalls and the Optim insulation that is used in the Durata leads (SJM) as well as the Tendril [4]. Our study adds to the body of evidence suggesting a structural issue with the Tendril lead that should prompt internal assessment at a company level. Large scale, independent multinational device and lead registries could independently monitor the performance of all cardiac implantable electronic devices and should be considered.

The data demonstrates the value of remote monitoring in prompt detection of lead noise. Noise detected either directly as noise, or indirectly as AMS or a VHR, can be seen as an alert within 24 hours or at routine download, depending on the alert setup of the remote monitoring system. This offers benefit over traditional outpatient clinic based pacemaker interrogation, which may only be occurring annually by the time the first noise episode is seen (mean time to first noise was 5 years in the 2088TC group in our study). This earlier detection can then prompt closer surveillance of problematic leads as well as timelier device reprogramming or lead intervention as required, all of which can help to reduce adverse clinical outcomes.

Conclusion

Our data demonstrates a high rate of noise with the Tendril lead within an Australian cohort. This is consistent with recent data reported internationally. The first episode of lead noise was usually seen between the fourth and sixth year of lead life. It also highlights the utility of remote monitoring in the early detection of device and lead malfunction, to allow close follow-up of lead abnormalities.

Disclosures

The lead author, Dr Sam Lovibond, via the Baker Institute, receives joint funding for his fellowship from Boston Scientific, St Jude Medical (Abbott) and Medtronic.

The co-author, A-Prof Justin Mariani has previously received research funding from Boston Scientific, St Jude Medical (Abbott) and Medtronic for other projects.

None of this funding was directly or indirectly involved in this trial.

Consent

Consent for the study was obtained via the Alfred Hospital Office of Ethics and Research Government with input from the Alfred Hospital Legal department, such to cover the observational cohort study involving an external database. Patient consent was thus not directly obtained, as only deidentified observational data would be used.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.hlc.2019.06.718.

References

[1] Sayegh M, Rao B, Peddareddy L, Patel A, Lurgio DB, Hoskins MH, et al. Prevalence and management of tendril leads malfunction. Presented at Heart Rhythm Society, May 9–12 2018, Boston.

[2] El-Chami MF, Rao B, Shah AD, Wood C, Sayegh M, Zakka P, et al. Long-term performance of a pacing lead family: a single center experience. Heart Rhythm 2019;4(April):572–8.

[3] Chu MM, Zager AJ, House CM, Zhi EW, Zhu LL, Lavell KA, et al. Inappropriate noise sensing is a common finding in St Jude Tendril leads. Circulation 2018;138:A16457.

[4] Mandrola J. Potential major problem with a common pacing lead. theheart.org Medscape Cardiology. May 2018. https://www.medscape.com/viewarticle/896877#vp_1. [Accessed August 28, 2018].