Identifying and managing device and lead issues – Remote follow up an essential tool

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Introduction

• Overview of Swindon Remote Monitoring service
• Case study 1
  – MHRA alert device failure
• Case study 2
  – Lead failure
• Case study 3
  – Detection loss of capture via PIEGM
Remote Monitoring Service

• Remote monitoring offered to all patients
  – Since 2011
• RM service runs 6 days per week
  – Not Saturdays
• >2000 current patients actively followed up
• >18,000 device follow ups
  – 2011-mid 2016
Remote FU of CIEDS

• Loop Recorders
  – No formal clinic FU
  – Ad hoc remote alerts

• Pacemakers
  – 12/12 Remote FU
    • Automatic Threshold Functions ON

• CRTP/D and ICD
  – 12/12 in clinic
  – 4/12 and 8/12 remotely (if stable)
Staffing RM Service

• Core team of 6 physiologists
• All hold current post-graduate qualification in devices
  – BHRS
  – IBHRE
  – EHRA
• Flexible working patterns/Work from home
  – Retention
  – Recruitment
Device Issues- Case Study 1

- 75yo Gentleman
- SJM Unify Quadra CRTD
  - January 2012
  - Secondary prevention
  - No therapies since implant
Clinic FU 28/6/16

- Pre/Post op check
- AF with 71% BIVP
  - Previously detected via HM
- No therapies
- 100% AMS

- DDDR 70-120
  - Discussion regarding AVNA
Clinic FU 28/6/16

- **Battery**
  - 2 yrs
  - 9.9 sec charge time
- **A Lead**
  - 2.0mV (AF)
  - 310Ω
- **RV Lead**
  - 1V @ 0.5ms
  - 12mV
  - 380Ω
- **LV Lead**
  - 1.375V @ 1.0ms
  - 850Ω
- **Booked 4/12 Virtual FU**
Remote Monitoring Alert 26/9/16

• Device ERI on 24/9/16
  – No therapies
  – 90% BiVP
  – Lead values as before

• D/W manufacturers

• Admitted to CCU
  – Listed for urgent box change

• Box Change 28/9/16
Cause of the issue

• On October 10th, 2016, St Jude Medical issued a global advisory on certain ICD and CRT-D devices manufactured before May 23, 2015.

• Advisory based on the potential for premature battery depletion associated with short circuits induced by lithium deposits.
Important Medical Device Advisory

Premature Battery Depletion with Implantable Cardioverter Defibrillator

Affected International Models can be found in the Appendix to this letter

We are advising you of a risk of premature battery depletion associated with St. Jude Medical ICD and CRT-D devices manufactured before May 23, 2015. Affected models include Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™.

Among 398,740 devices sold worldwide, 841 devices returned for analysis due to premature battery depletion have had
The importance of Remote Monitoring

• **PATIENT MANAGEMENT RECOMMENDATIONS INCLUDE:**
  • Routine follow-up as per standard practice.
  • Prophylactic device replacement is not recommended.
  • Physicians are advised to enroll impacted patients in Merlin.net™ PCN during routine follow-up visit.
  • Ensure that the vibratory patient notifier is programmed “ON” for ERI alerts and remind and demonstrate to patients how it feels when the alert is triggered during routine follow-up visit.
Impact of Advisory

- 24 affected patients
- 23 already remotely monitored (96%)
- 1 non RM patient
  - Previously refused
  - Registered once advisory was explained
- 1 patient who was prophylactically box changed as device was for reposition
- No further events from this subset of devices
Interesting Points

• Patient did not respond to vibratory alert
• Had not yet had AVNA
• What would have happened ......
  – Had AVNA
  – Not registered on HM
Lead Issues- Case Study 2

- MRS Pacemaker
  - 51 years old
  - Dizzy Spells, SSS Brady, Wenckebach
  - DR PPM
  - Implanted 26/11/14
  - Active RV/RA leads
  - 77 minutes case time
  - “Multiple RV positions” “Small R waves”
- Placed on Remote Monitoring pre-discharge
Case Study 2- Measurements

- Implant
  - Threshold
    • 0.5V @ 0.5ms
  - Impedance
    • 772Ω
  - R wave
    • 12.8mV

- Post Implant 26/11/14- Same day discharge
  - Threshold
    • 0.6V @ 0.4ms
  - Impedance
    • 565Ω
  - R wave
    • 11.6mV
Post Implant X-Ray
1 day post implant

• Attended A+E
• Chest Pain
• X ray performed
• Discharged sent home with painkillers and advice
• No PPM check requested
• Cardiology advice not sought
• ECG reported as normal
Meanwhile

• The morning of attendance at ED
• Red alert via Remote monitoring
  – RV LEAD FAILURE
• This was Saturday
  – No action until the following Monday am
Action

• Brought in to clinic Monday PM

  – Measurements
    • Threshold
      – No capture 7V @ 1.5ms (uni/bi)
    • Impedance
      – 290Ω
    • R wave
      – 2mV

• X Ray
• Echo
• CT Scan
Echo
CT Scan
Conclusion

• Admitted to CCU
• Referred to tertiary centre for surgical lead removal
• Learning points
  – 24hrs+ until red alert acted upon
    • ?need for weekend cover
  – Need for cardiology review in ED
RM Issues-Case Study 3

• 94yo gentleman
  – 2:1 AV Block
  – Mildly impaired LV function
  – Severe AS
  – Previous CABG
  – Multiple non cardiac co-morbidities
  – Biotronik Epyra 8 DR-T 12/12/2016
    • DDI 50 (tracking Sinus Tachy)
    • Capture management would not work
    • Registered on HM
PIEGM Sent 11/1/17

- Failed to attend 4 week post implant check
  - Check of 30 day PIEGM
- Device reported no anomalies
  - Capture management off
  - R wave dropped to 4.5mV
    - Within normal limits
- PIEGM Displays intermittent loss of ventricular capture
- Urgent clinic review requested
PIEGM
Post Implant Xray
Clinic Appt

• Threshold risen to 3.0v @ 0.4mV

• Pt had AF and become PPM dependent @ 40ppm
Remote Monitoring......

- Allows greater flexibility for staff and patients
- Could enable device clinics to operate a 7 day service
- Helpful to an ageing population
- Ability to detect lead and device issues earlier than clinic based follow up alone
- Is not infallible
  - Requires specialist staff