Acute transient non-physiological over-sensing in the ventricle with a DF4 lead

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\textbf{Article info}

\textbf{Article history:}
Available online 19 October 2015

\textbf{Keywords:}
Implantable cardioverter defibrillator
DF-4 lead
Over-sensing

\textbf{Abstract}

The DF-4 is a new defibrillator lead technology. We present two cases of non-physiological transient ventricular over-sensing in patients who underwent implantation of an ICD for secondary prevention. Case 1 had ventricular over-sensing during pacing threshold evaluation post defibrillation testing while Case 2 had the lead integrity alert triggered immediately post discharge with transient over-sensing. No lead-connector issues were found. Case 1 was likely due to improper venting of the header and trapped air. Case 2 was hypothesized to be due to intermittent header pin non-contact secondary to blood in the header. These cases reveal that DF-4 leads are subject to both reported and potentially novel causes of transient acute ventricular over-sensing.

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The DF-4 connector is a novel defibrillator lead connection to the generator and is becoming an industry standard. No long-term data exist as to its safety and efficacy. We describe two cases of non-physiological ventricular over-sensing in the new DF-4 connector system.

\textbf{Case 1}

A 55-year-old male underwent implantation of a secondary prevention dual chamber Boston Scientific Incepta implantable cardioverter-defibrillator (ICD). A dual coil DF-4 lead (Endotak Reliance LLHH 64 cm) was positioned at the right ventricular apex (RVA) with normal intracardiac electrograms (EGM). Parameters were satisfactory (R-wave sensing of 7.9 mV, impedance of 960 \( \Omega \), threshold of 0.6 V \( \oplus \) 0.5 ms, and a high voltage impedance of 39 \( \Omega \)) and defibrillation threshold testing (DFT) was acceptable. Baseline sensing was set at 0.5 mV. Subsequent to defibrillation testing, unusual low amplitude and medium frequency signals were observed on the ventricular EGM (Fig. 1) and detected on the marker channel during pacing threshold testing (Fig. 2) which were clearly not related to T-wave over-sensing.

Fluoroscopic review of set-screw positioning was unremarkable and manipulation of the device did not influence the signals. No further intervention was performed at that stage and pacing threshold testing the next day demonstrated no over sensing recurrence and he proceeded to have an event free six-week follow-up.

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Peer review under responsibility of Indian Heart Rhythm Society.
http://dx.doi.org/10.1016/j.ipej.2015.10.008
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Case 2

A 42-year-old female underwent implantation of a secondary prevention dual chamber Medtronic Maximo II DF-4 ICD with a dual coil (Sprint Quattro Secure 6947M 64 cm) ventricular lead at the RVA. After multiple attempts at positioning the lead, the best R-wave sensing obtained was only 6.8 mV, while other pacing parameters were satisfactory (V-lead impedance of 684, V-lead threshold of 0.5 V @ 0.5 ms, high threshold impedance of 42 Ω and a DFT test of <25 J). R wave baseline sensitivity was set at 0.5 mV. At discharge, a small hematoma was managed conservatively with pressure bandaging. She represented one day after with lead integrity alerts due to high ventricular impedance (>3000). Device interrogation revealed ventricular over-sensing (Fig. 3).

Chest X-ray demonstrated the pin beyond the set-screw (Fig. 4).

During pocket revision, whilst the lead was still connected, only tapping the header reproduced similar “noise”, while traction of the lead and movement of the generator were unremarkable. A moderate hematoma was evacuated and lead testing unconnected to the header was also unexceptional. The header contained a significant amount of blood. Interrogation after the header was cleaned and reconnected.
showed normalized function with no further over-sensing. 6-week follow-up was normal.

**Discussion**

In this report, we present two unusual cases of intermittent ventricular over-sensing in the new DF-4 connector system. In both cases, causes of inappropriate sensing of physiologic signals such as myopotentials, T waves, P waves, R-wave double counting, after potentials, and far-field physiologic signals were not present. Consequently, causes of non-physiological over-sensing need to be evaluated. These include electromagnetic interference from an external source, lead/connector problems (loose set screw, adapter, or header), and lead failure (insulation defect or conductor coil fracture).

Both of our cases share several similar characteristics: (1) the over-sensing occurred acutely post implantation (within 24 h); (2) the over-sensing was intermittent and did not have a constant relationship to the cardiac cycle; (3) although the over-sensing could be reproduced with specific maneuvers (during pacing in Case 1, and only with tapping of the header in Case 2), manipulation of the leads and generator did not recreate the over-sensing; (4) the over-sensing had resolved spontaneously (as in the first case) or on reconnection without replacing the lead or the device (as in the second case); (5) peri-procedural lead function was normal; (6) there was no evidence radiographically to suggest incomplete lead advancement; and (7) no sources of electromagnetic interference, including electro-cautery were present. These features seem to make an obvious lead-connector problem or lead failure unlikely.

Case 1 likely relates to the improper venting of the grommet seal plug (and similar issues have been previously reported with IS-1 systems). The seal plug is a polymer plug with a narrow slit through which the set-screw torque wrench is inserted through to the grommet. It is designed to allow access of the wrench to the set-screw and maintain electrical isolation afterwards by preventing body fluids from entering the header ports once the wrench is removed. At wrench insertion, care should be exercised to locate the pre-slit depression of the seal plug and carefully guide the wrench through the slit to the set-screw cavity beneath prior to insertion of the lead into the port. This will open up the seal plug, relieving any potential pressure build-up within the lead port by providing a pathway to release trapped fluid or air during lead insertion. If this is not performed adequately, or if damage occurs during wrench insertion or faulty from manufacturing, the trapped air (an electrical insulator) is able to intermittently escape the header, altering the baseline contact between the normally separated extracellular fluid and the conductive elements of the connector causing transient alterations in the voltage input to the sense amplifier and resulting in “make-break” potentials. Once the air has fully escaped, there is equilibration of charge and the over-sensing ceases [1,2].
In our case, it is likely that the wrench was not adequately engaged prior to lead insertion into the header considering that gross review of the seal plugs revealed no clear abnormality, and that the signals resolved spontaneously without the need for generator replacement. The resulting signals, however, had occurred post DFT testing only \[1,2\] and oversensed during ventricular threshold testing. During defibrillation testing chest wall movement or transient pressurization from the shock or both, could also have encouraged air-bubble release \[2\]. Curiously, the over-sensing had only occurred during instances when the signals were located just after the post-pacing blanking period. This may relate to the ICD’s automatically adjusted sensitivity programing. After a paced ventricular event, all ICDs have the ability to adjust sensitivity dynamically, beginning from the end of the blanking period, with the threshold starting at a more sensitive setting.

Our second case, however, raises some novel risks that may need to be considered with this new generation lead-connector system. This technology encompasses a combined single port cavity with four contacts of which both high- and low-voltage applications can be placed within the same cavity which result in compromised space for insulation and sealing. Furthermore, contact pressure of the seals and the pins has to be limited to allow for easy insertion and retraction of the lead connector. This was achieved by alterations in the design with integration of the sealed rings within the header itself (instead of being mounted on the lead) as well as the development of a unique torque wrench activated leveraging of the spring loaded pin contacts \[3\]. Consequently, DF-4 lead plugs have to go through four seals with three intermediate spring contacts while its predecessor, the IS-1 lead connectors, have only one seal on the lead and no spring contacts. This raises potential issues with sealing failures, which may cause sensing problems or short circuits.

In Case 2, we hypothesize that blood from the hematoma may have entered the header via a “grommet punch-out” post wrench removal (which has been previously reported in Medtronic DF-1 header connections) or forced into the header through imperfections of the more complex-designed sealed rings. The nature of seal plugs though may also provide an alternate explanation. The silicone rubber used for seal plugs has a “shape memory”. However, during the re-bonding process after wrench removal, they may require a short time to reseal. Until the seal fully closes, it is possible that the header may be infiltrated by body fluid. This could have been further compounded by issues with trapped air that were mentioned earlier in the manuscript. The extracellular fluid in the header from Case 2 could then have contributed to minute misalignment of the newly developed spring contacts with the lead, causing the observed increase in impedance and the intermittent non-physiological ventricular over-sensing. This hypothesis was supported by the resolution of the “noise” when the system was cleaned and simply reconnected without changing the device, as well as by the lack of any macroscopic appearance of lead-connector or set-screw issues.

To the best of our knowledge, cases of non-physiological ventricular over-sensing have rarely been reported involving the new DF-4 system. The advantages of this standard over its predecessor mainly relate to procedural ease and patient comfort by reducing the risk of lead-to-port mismatch, reduced risk of lead-to-can abrasion (because of fewer connectors), a reduced size of device header and subsequently a much less bulky pocket. However, these design changes may have several potential risks as we have highlighted as well as some logistical drawbacks. The compact system is also likely to be less flexible like in instances where there may be a need for the addition of pace/sense leads (in cases of sensing problems) or additional shock leads (e.g. subcutaneous arrays). Currently, a single post-market study has demonstrated that the DF-4 lead has performed well at a 36-month follow-up period in 1701 cases with complication rates reported to be at a low 0.015 per patient-year of follow-up with no adverse set-screw events \[4\]. However, it is important to note that there have been two previous adverse event reports found in the Manufacturer and User Facility Device Experience (MAUDE) database run by the FDA. They both relate to noise and inappropriate therapy, and were put down to lead-connection issues but with no conclusive evidence of set-screw problems \[3\].

The DF-4 connector system is becoming industry standard but our current cases underscore that potential problems regarding lead header attachment, that were seen with the older connector systems, continue to remain an identifiable cause for over-sensing. Furthermore, they highlight certain concerns over novel lead-connector problems that need to be adequately tackled to reduce improper delivery of device therapies and increased patient morbidity. Unanticipated problems with DF-4 ICD leads are likely to accumulate. In a comprehensive review on this topic in Europace in April 2012, Sticherling and Burri express concern that the complex design of the header/lead interface could lead to sensing or electrical isolation problems \[3\]. Correct torque wrench technique continues to be an important aspect in device implantation, but it is clear that further research and development is required to address any other potential newer causes of non-physiological over-sensing whose magnitude of risk may not yet be fully evident at the present time.

Disclosures and financial sources

No conflicts of interest for all authors and no sources of funding were sought.

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