INNOVATIVE COLLECTIONS

CLINICAL DECISION MAKING

Pacing Output Failure After Electrocautery During Pulse Generator Replacement

1RANGADHAM NAGARAKANTI, MD, 1,2SATISH R. RAJ, MD, MSCI, FACC, FHRS and
1,2JEFFREY N. ROTTMAN, MD

1Departments of Medicine and 2Pharmacology, Nashville VA Medical Center of the Tennessee Valley Health Systems, Vanderbilt University School of Medicine, Nashville, TN

ABSTRACT. We report two cases of device malfunction with loss of pacing output during routine device generator replacement surgery after using electrocautery. These devices were nearing or had just reached the elective replacement indicator (ERI). Most current devices are relatively robust during electrocautery, although manufacturers warn of potential damage to the device. Device–electrocautery interactions, and these warnings, vary by manufacturer, and no specific guidelines/recommendations currently exist that specify the expected behavior of the device and the corrective measures needed with electrocautery. Current monitoring strategies for device (pacemaker and defibrillator) battery depletion include ERI and end of life (EOL). ERI results in predictable changes in device function, and allows programming of devices that can decrease the risks associated with electrocautery. However, those programming changes were not protective in the cases described. More detailed information regarding device-specific risks with electrocautery, including the specific testing performed, would be useful. Electrocautery should be avoided in pacemaker-dependent patients with generators subject to output circuit failure, such as those described here.

KEYWORDS. arrhythmia, cardiac devices, electrocautery, generator replacement.

Introduction

Pacemaker and implantable cardioverter-defibrillator (ICD) generators differ in their behavior as they approach battery depletion. All devices are intended to maintain support for basic pacemaker function when the battery voltage approaches ERI. In devices from most manufacturers, ERI disables rate response and some diagnostic features, and the mode of pacing may change (e.g. DDD to VVI mode). With a further decrease in voltage to the end of life (EOL) threshold, correct pacemaker function cannot be reliably supported. Manufacturers currently recommend replacement of pacemaker and ICD pulse generators within 3 months of reaching ERI. The expectation is that ERI provides a period of normal and safe pacemaker function, providing a window for a typical generator replacement procedure.

Electrocautery is often used to obtain hemostasis during pacemaker and/or ICD generator changes. No universally-applicable guidelines or recommendations currently exist regarding the expected change in pacemaker/ICD behavior. Manufacturers generically describe the potential damage to the pulse generator (Table 1). However, most clinical experience suggests that surgical electrocautery causes little or no damage to current device systems. A recent evaluation showed only rare cases of application of unipolar electrocautery in close proximity of the device causing electromagnetic interference (EMI), resulting in inappropriate sensing and no permanent damage. In a pacemaker-dependent patient, devices are often programmed to an asynchronous or triggered mode to pre-empt inhibition of pacing output and the tachycardia detection mode temporarily deactivated for a defibrillator.
We report two cases of loss of pacemaker output during an elective pulse generator replacement with use of electrocautery when the battery voltage was either greater than or at ERI, but not in EOL. Both of these cases occurred with St. Jude Medical (St. Paul, MN) devices. These cases are discussed in the context of electrocautery interaction with implanted devices.

**Case 1**

A 73-year-old male with history of hypertension, chronic obstructive pulmonary disease, sick sinus syndrome, complete heart block, and non-ischemic cardiomyopathy with left bundle branch block underwent a cardiac resynchronization therapy defibrillator device (CRT-D) implantation. His St. Jude Frontier II Model 5586 device (atrial lead, Guidant Model 4244 SN; RV lead, Guidant Model 4088; and LV lead St. Jude Model 1056) implanted in January 2007 approached ERI in November 2011 with a battery voltage of 2.53V (ERI voltage 2.50V and EOL voltage 2.20V). His underlying rhythm was sinus bradycardia with complete heart block. All the leads had stable impedances, and pacing and sensing thresholds. He was electively admitted for generator replacement 2 weeks later. Prior to starting the procedure, the device was programmed to the ventricular asynchronous pacing (VOO) mode because of the patient’s underlying pacemaker dependence (Figure 1a). Battery voltage at this time remained within the ERI window. All leads were programmed to bipolar pacing.

The prior incision was sharply opened and the device was freed from adhesions in the capsule using electrocautery. Electrocautery was stopped prior to reaching the generator. When the generator was removed from the pocket, pacing output was suddenly lost with loss of pacing (Figure 1b). Pacing output did not resume when the pacemaker generator was replaced in the pocket. Temporary pacing was emergently instituted using a unipolar connection with the header set screw (Figure 1c); the positive alligator clamp was attached to the surgical wound retractor, and the negative clamp was attached to a hex wrench that made contact with the set screw to the distal right ventricular (RV) electrode via the header grommet. The old generator was disconnected from the leads, and the lead analyzer was used to provide bridging pacemaker support. The leads were functioning correctly and were transferred to the new generator. The new generator and leads were returned to the pocket, and the function of new generator and leads were satisfactory and consistent with the previously measured values.

Repeat interrogation of the old generator confirmed that the old generator was at ERI and not EOL. The device was not noted to be in noise reversion mode, and no error parameters were identified. It was returned to the manufacturer for further evaluation, particularly because of the unexplained pacemaker output failure. No additional analysis has been reported at this time.

**Case 2**

A 79-year-old male with history of hypertension, coronary artery disease, and complete heart block underwent a dual-chamber pacemaker implantation with a St. Jude Integrity DR Model 5366 (atrial lead, St. Jude Model 1488; RV lead, St. Jude Model 1488) in January 2004. In November 2011, the device was near ERI with a battery voltage of 2.67V (ERI voltage 2.50V and EOL voltage 2.20V), and he was electively admitted for generator replacement because of impended travel to areas without reliable device follow-up. His underlying rhythm was sinus bradycardia with complete heart block. All pacing leads demonstrated stable pacing and sensing thresholds and pacing impedances. The device was programmed to asynchronous VOO mode due to the patient’s underlying pacemaker dependence prior to the generator replacement (Figure 2a). While the device was being freed from the adhesions in the pocket (using electrocautery), there was sudden decrease in heart rate, to a pacemaker delivered output rate of 30bpm (Figure 2b), corresponding to half of the previously programmed rate. The device was quickly removed from the pocket and the ventricular lead was disconnected from header and connected to the lead analyzer with restoration of ventricular pacing. The atrial lead was then disconnected from the old generator. Both

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Table 1: Management of electrocautery with implantable cardiac devices

<table>
<thead>
<tr>
<th>Manufacturer recommendations</th>
<th>Med</th>
<th>SJM</th>
<th>BT</th>
<th>BS</th>
<th>Sor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program pacemaker to asynchronous mode (VOO/AOO/DOO)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Turn off antitachycardia pacing (ATP) and shock therapies with the defibrillator</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Use bipolar electrocautery system if possible</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Use short, intermittent, and irregular bursts at the lowest feasible energy</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Place the ground plate as far as possible from the device and lead system (at least 6 inches (15.2 cm)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Keep temporary pacing and defibrillation equipment available.</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td><strong>Avoidance of electrocautery (</strong>)**</td>
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</tr>
<tr>
<td>After the procedure, perform assessment of the device</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
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</tbody>
</table>

* Med: Medtronic; SJM: St. Jude Medical; BT: Biotronik; BS: Boston Scientific; Sor: Sorin.

Specific manufacturer statements in their respective field manuals/guides: Med, “Avoid direct contact with the implanted device or leads.” SJM, “Do not use electrocautery in the vicinity of an implanted device.” BT: “Electrocautery should never be performed within 6 inches of an implanted pulse generator or lead.” BS, “Avoid direct contact with the pulse generator or leads.” Sor, “Electrocautery should not be used.”
leads were found to be functioning correctly and were transferred to the new generator. The new generator and leads were returned to the pocket, and the function of the new generator and leads were verified and were stable. The old generator was returned to the manufacturer for evaluation, with note made of the pacemaker output failure of a device that had not yet reached ERI or EOL.

Discussion

Predictable pacemaker behavior is necessary for appropriate management decisions and this is particularly important in pacemaker-dependent patients. Electrocautery is commonly used during pulse generator replacement. Although no universal guidelines or recommendations currently exist, most manufacturers and standard texts suggest predictable device (pacemaker, defibrillator) behavior after voltage decline to ERI, and recommend elective pulse generator replacement after the battery voltage reaches ERI. Multiple manufacturer manuals vaguely caution that electrocautery can result in abnormal device behaviors such as reprogramming, inhibition, or fall back to magnet mode. The common recommendations from these manufacturers are to use bipolar cautery, place the cautery groundplate/electrode farther away from device as possible, and use short intermittent bursts of pacing at permissible low energy levels (Table 1).4–11 A review from 1986 of electrocautery interaction with pacing devices ultimately recommended against use of electrocautery when possible.12

In general, current devices appear to be more robust to cautery interactions, and catastrophic consequences from the cautery are rare; with current technology, the most common problem encountered is reversion to reset/magnet mode.13 With defibrillators, the tachycardia detection mode is temporarily inactivated prior to cautery as spurious detection of ventricular fibrillation is common. Furthermore, performing the replacement procedure when the devices are still in ERI status allows the specified programming changes, and is usually thought to provide additional protection. However, these cases clearly reflect device-specific differences in the potential for and the consequences of cautery-induced device malfunction.

We described two cases of pacing output failure. One was a pacemaker and the other was a defibrillator.
with different circuit platform by design. Both procedures were elective generator replacements as the device battery voltage has reached or was approaching ERI. As a routine practice in our laboratory during generator replacements, electrocautery was used during both these procedures. Standard precautions were taken, such as reprogramming to asynchronous mode for both devices, and tachycardia therapies were turned off for the defibrillator prior to cautery use. During both procedures, there was sudden pacing output failure requiring immediate measures as described in the cases to restore ventricular pacing. The device platforms are fundamentally different between these devices, but the analog output circuit design may be similar. ICDs differ importantly from pacemakers in not reverting to unipolar mode under noise conditions; thus, in an ICD the failure to pace after electrical noise generally is not due to an incomplete shoulder return circuit.

There are multiple means by which cautery can interfere with pacemaker function. Oversensing of the cautery electrical activity can inhibit paced output, but this inhibition should stop with the cessation of electrocautery. Devices programmed to asynchronous mode should be immune to this inhibition. Cautery can trigger noise reversion, and this may reprogram pacemaker output polarity to unipolar mode. When a unipolar device is removed from the pocket, the current return path for pacing is interrupted, and effective pacing can be lost. However, recreating this return path should restore pacing, and ICD systems do not typically change RV pace polarity. This mechanism therefore cannot explain the output changes noted in these two cases, and noise reversion was not observed on device interrogation. Indirect coupling of radiofrequency energy, including cautery, to the leads can result in a changed lead–tissue interface, but the absence of any change in lead parameters when attached to the new generator argues against this mechanism here. The likely mechanism in both of these cases was direct damage to the output circuit with complete (Case 1) or partial (Case 2) loss of effective output. The only effective response in this circumstance is to provide an alternative source of pacing energy prior to transfer of the leads to an unaffected generator. This is similar to a report from 1992 in which output failure in a Medtronic pulse generator after electrocautery is detailed.14 Complete loss of output in response to electrocautery in generators at or before ERI status is now very unusual. A St. Jude Technical Service memorandum15 described the estimated frequency of “circuit damage leading to erratic function or loss of pacing” as “rare.” The two cases described here occurred in rapid succession. The temporal juxtaposition of these two cases suggests that it may be less rare than anticipated, and suggests that shared output circuit design features may predispose to this problem. The findings observed cannot be attributed to the unreliable device function that may be expected after transition from ERI to EOL.16 We accordingly recommend that cautery is avoided during generator replacement in pacemaker-dependent patients with devices in these St. Jude Medical generator families.

It would be beneficial for manufacturers to more accurately describe the range of behaviors that may be expected with their specific devices in response to

Figure 2: Case 2: 79 year-old male undergoing pulse generator replacement of his dual chamber pacemaker before reaching ERI Panel A: Asynchronous VOO mode at 60 bpm prior to pulse generator replacement procedure; Panel B: Sudden decrease in pacing output rate and heart rate to 30 bpm with electrocautery. Pacing output remained inhibited for several seconds after the electrocautery was discontinued.
cautery, the specific testing that has been performed, and the frequency and predisposing factors to this behavior. Finally, with the availability of alternative coagulation and cutting instruments such as the “cold knife” and “Plasma Blade,” the device-dependent characteristics of these alternative technologies should also be evaluated and reported.

Conclusion

Catastrophic output failure in response to electrocautery can be observed with devices currently requiring generator replacement, and is not necessarily prevented by performing the replacement procedure during early ERI status or by programming to asynchronous pacing mode. Certain devices may be especially prone to this mode of failure, and cautery should be avoided during replacement procedures with devices where this mode of failure has been reported. More complete disclosure of electrocautery interaction and testing would be desirable for optimizing procedural aspects of cardiac rhythm device management.

References

15. Effects of Electrocautery on St. Jude Medical Implantable Cardiac Pacemakers, Rev 11/08, Technical Services.