Making the cut for generator replacements

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Editorial

Cardiac implantable electronic devices (CIED) have become a common treatment modality for cardiac arrhythmia with over 300,000 new implants every year in the United States. A growing number of patients will require device replacement procedures throughout their lifetime.[1] In a registry of 1744 patients undergoing CIED replacement procedures, lead damage or dislodgement requiring revision was found to occur in 1% of patients without previously planned addition of leads.[2] The resulting lead addition and extraction procedures give rise to added procedural time, risk of complications, prolonged hospitalization, and increased health care costs.[2] Polyurethane and copolymer insulation materials are more susceptible to thermal damage when compared to silicone.[3,4] Avoidance of lead damage during CIED replacement procedures has been a topic of increasing investigation, with studies evaluating differences between electrosurgical modes, power settings, blade orientation, and equipment manufacturers. Operators have the option to choose between standard electrocautery with non-insulated blades, and cautery with insulated blades (PEAK PlasmaBlade, Medtronic Inc., Minneapolis, MN, or Photonblade, Stryker, Kalamazoo, MI).

Electrocautery operates by generating a high current density which results in resistive heating and thereby cuts or coagulates tissue. PlasmaBlade uses a proprietary power output waveform to deliver energy along the exposed edge of a thin, insulated electrode powered by a proprietary electrosurgical generator. Photonblade

is an alternative insulated electrocautery blade that is compatible with a standard electrosurgical generator. In a retrospective study by Kypta et al, PlasmaBlade was associated with a lesser risk of lead damage and shorter procedure duration and hospital stay when compared with electrocautery and scissors.[3] In an ex vivo animal tissue model using Photonblade, coagulation mode during cautery was associated with more damage than cut, and this effect was greatest when contact occurred using the active edge as opposed to the insulated flat side of the cautery blade, and when the lead insulation consisted of polyurethane or copolymer. Visible lead damage was found to be more common with PlasmaBlade when compared to Photonblade. [4]

In this edition of the *Journal of Cardiovascular Electrophysiology* , Ananwattanasuk et al performed a retrospective analysis of traditional electrocautery vs PlasmaBlade on lead parameters and complications following CIED generator replacement procedures.[5] The study included 410 consecutive patients (840 leads) who underwent CIED replacement using conventional electrocautery (EC group) and 410 patients (824 leads) who underwent CIED replacement using PlasmaBlade (PK group). The power settings for the PK group were 6 in CUT mode and 8 in COAG mode. In the EC group, power output was set to 40 Watts for both CUT and COAG mode. CUT mode was used for tissue dissection and COAG was only used for hemostasis. The two groups had similar device systems and baseline characteristics. In comparison to the PK group, the EC group had a slightly lower proportion of silicone leads (78% vs 83%, $p < 0.01$) and a slightly higher proportion of polyurethane leads (19% vs 13%, $p < 0.01$). The study found no statistically significant difference in lead damage requiring lead revision between the EC group and PK group (0.6% vs 0.4%, p=0.5). There was no difference in procedural complications between the two groups (2.2% vs 1.2%, $p = 0.28$). There was no difference in lead sensing. There was a higher number of patients with a decrease in lead impedance in the PK group compared to the EC group (61.5% vs 52.1%, $p < 0.01$), and perhaps unexpectedly, more patients with an increase in lead impedance in the EC group compared to the PK group (46.8% vs 34.2%, $p<0.01$).

On average, the change in pacing impedance changed less than 10% in both groups. A majority of leads in both groups were comprised of silicone which may have been a primary contributor to the low rate of lead damage observed. These findings contrast with the older retrospective study that found a lower risk of lead damage with PlasmaBlade compared to a historical control group where titanium scissors were used with conventional electrocautery for hemostasis. The difference observed in the prior study between groups, and the overall higher rates of lead damage in that study may have been related to the use of scissors or perhaps a greater proportion of leads with non-silicone insulation (lead insulation material was not reported). The present study by Ananwattanasuk et al contributes to the literature with a larger cohort of patients and contemporary operative technique.

It is never too late to scrutinize the benefit of tools that have added costs as our procedural techniques evolve. The authors should be commended for rigorously collecting not only clinical outcomes but also electrical device parameters to assess for subclinical lead damage. Although generator replacements are short and less complex when compared to other EP procedures, the total cost of generator replacement procedures is estimated at several billion dollars yearly in the US alone.[6] Leadless pacemakers and the evolution of modular systems are attractive and may solve some problems related to lead damage during generator replacements, or perhaps one day eliminate generator replacements altogether. However, with the current number of CIEDs in operation and the aging population, a growing number of patients will continue to require generator replacement procedures over the next several decades. The overall safety of generator replacement procedures has improved though advances such as avoidance of routine capsulectomy, antibiotic-impregnated pouches for appropriate candidates, and prolonged replacement intervals due to improved battery longevity. Through an unremitting focus on safety and cost-effectiveness, we will stay on the cutting edge of straightforward and complex procedures in the EP lab.

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