

Reducing CIED lead dislodgements: Faithful alignment to small things

Be faithful in small things because it is in them that your strength lies.

—Saint Mother Teresa of Calcutta¹

Vigilance is critical for the perioperative and long-term successful implantation of cardiac implantable electronic devices (CIEDs). Often, an extra minute of attention can save hours and prevent complications with both clinical and economic consequences. Attention to the early, seemingly minor, details of the implant procedure can lead to a series of events resulting in either an excellent, efficient outcome or a prolonged procedure that becomes more complex than it was ever intended. Many CIED-related complications are now tracked as institutional quality markers. The US Center for Medicare and Medicaid Services' Physician Quality Report System requires reporting of Medicare and Medicaid patients who experience defibrillator-related procedural complications that require revision and any CIED infections within 180 days of implant.² Failure to meet these benchmarks can result in economic penalties for hospitals and clinicians. Unlike the more extensive benchmarks in place for cardiology, the development and compliance of electrophysiology quality measures remain in their infancy. Procedural benchmarks are even more difficult to maintain because of rapidly evolving technologies and procedural techniques. At an institutional level, the mitigation of these complications is further challenged as electrophysiology clinicians in larger groups are trained with differing surgical styles, resulting in procedural variability. One of the most important CIED implant complications is lead dislodgement (LD). Several studies have reported that LD and resulting lead revision are associated with infection, prolonged hospital stays, and increased mortality.^{3–5} Other complications included valve dysfunction, ventricular arrhythmias, cardiac perforation, and death.^{6–9} This month's issue of *PACE* highlights the importance of both vigilance and the provider alignment in reducing this important and often preventable complications.

Afzal and colleagues report the usefulness of a prospective standardized intraoperative protocol to assess lead stability in patients receiving pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization therapy devices.¹⁰ The implanters used intraoperative provocative measures, such as manual lead manipulation, and pacing threshold determination during deep inspiration or cough as well as sensing changes over time. Change in capture threshold during deep breathing or coughing was assessed in all three leads, while a provocative manual manipulation maneuver was performed in the right atrial (RA) lead. The protocol was initiated in consecutive patients for 2 months, then suspended for 2 months to control for increased vigilance of LD and then restarted. The single-site study population was quite large: 2361 patients in the intervention

group and 4292 in the control group. The control group's procedures were performed before the protocol initiation and during the 2-month period when the protocol was suspended. All implanted RA and right ventricular (RV) leads were active fixation leads and more quadripolar coronary sinus (CS) leads were implanted in the intervention group.

The standardized LD reduction protocol resulted in a 60% reduction in LD. Reduction in LD was observed in all three types of leads, with the biggest reduction in the CS lead, followed by the RA lead and then the RV lead. Importantly, reduction in LD was observed even when somewhat aggressive provocative manipulation was performed on the RA lead. The reductions in CS LD may be due to the increased use of quadripolar leads, which can be placed in a more stable, distal position while pacing from the more proximal electrodes. Due to large reductions in CS and RA LD, the distribution of RV LD increased from 35% of all dislodgements at baseline to 50% after the LD reduction protocol. Unlike prior reports, multivariate analysis showed no independent predictions of LD.

The study does have limitations. Prompting a sedated patient to cough or breathe deeply could make some of the provocative maneuvers difficult. No provocative manipulation was attempted in the RV lead, which could be used to identify potential LD. At follow-up, patients were referred for lead revision on clinical grounds without similar standardized criteria that were used at implant. Assessment of threshold with deep breathing or coughing was not assessed at follow-up visits. The authors did not mention whether the 2-month suspension of the LD protocol resulted in an increase in LD as compared to the preprotocol group or not. Since the biggest reduction in LD occurred in the CS lead group, one can question whether advancement in lead technology had a greater impact with this lead rather than any provocative measures.

So how is this study significant and how can we apply this to the single patient? A famous college football coach stressed the importance of *alignment* when he wrote, "Alignment is a key ingredient to elite performance, because without it, the best strategy in the world cannot be executed."¹¹ From this, we can conclude that any well-intentioned initiatives to improve quality can fail unless crucial stakeholders are aligned for its success. This requires the necessary structure to drive behavior. One such structure is demonstrated in this report, where clinicians clearly identified and defined the problem; agreed on a simple, standardized corrective action; and committed to its consistent execution. Interestingly, the solution was not a vast redesign of their enterprise—it was simply applying a small extra step of vigilance during a critical part of the implant procedure. This

vigilance combined with consistent alignment was crucial to achieve these outcomes. One can argue which measures were most impactful, but the most important step was consistent execution across all providers.

Quality metrics in electrophysiology procedures will continue to grow in the coming years. Changing reimbursement models will also increase pressure to minimize repeat procedures, especially due to avoidable complications. From this study, faithful attention to small steps combined with provider alignment can produce significant results.

Frank Pelosi Jr. MD

Department of Internal Medicine, University of Michigan Medical School,
Ann Arbor, Michigan

Correspondence

Frank Pelosi, Jr., MD, University of Michigan Medical School, 1500 East
Medical Center Drive, Ann Arbor, MI 48109.

Email: fpelosi@med.umich.edu

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