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EDITORIAL COMMENT

The Price of Imperfection

Complications and Costs Associated With Transvenous Pacemaker Implantation*

Roger Carrillo, MD, MBA, Thomas A. Boyle, BS

As we consider complication rates associated with transvenous pacemakers, we must acknowledge the ever-growing denominator. Between 1993 and 2009, the pacemaker implantation rate in the United States soared from 46.7 to 61.6 per 100,000 persons (1). The rapid growth is often attributed to the aging American population and expanding indications. Despite improvements in technology and protocols, complication rates appear to have reached a stubborn plateau. A 2006 investigation by the U.S. Food and Drug Administration found a shrinking incidence of pacemaker generator failure, but a growing incidence of implantable cardioverter-defibrillator failure (2). Meanwhile, multiple studies have found the incidence of device infections to be rising out of proportion to implants (3,4).

In the current health care environment, widespread use brings sharp focus on affordability. Recognizing the role that complications play in overall costs, many large employers already turn exclusively to certified centers of excellence when their employees require joint, spine, bariatric, and cardiac surgery (5). Payers, meanwhile, are in a perpetual quest for value. An increasing number of operative complications are being classified as non-reimbursable care. As bundled payments become more common, complications related to pacemaker implantation could carry harsh financial consequences.

In this issue of *JACC: Clinical Electrophysiology*, Cantillon et al. (6) have made an important contribution to the understanding of pacemaker complications and their costs. They report complication rates higher than previous studies, especially in the 30 days immediately following implantation. Overall, they found 3-year pacemaker-associated complication rates of 15% to 16%. The events most commonly encountered in the acute phase were thoracic trauma, lead complications requiring revision, and infection. Among those, infection was by far the most expensive, adding $80,000 to the care of a single patient. Between 1 month and 3 years, the most common events were lead-related complications requiring revision, infection, and pocket-related complications.

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There are inherent problems associated with performing clinical research in administrative databases such as MarketScan (Truven Health Analytics, Ann Arbor, Michigan). Financial clerks, rather than trained clinicians, are responsible for most of the data entry. Matters become especially murky when these data are mined for information about pacemakers. The numerous and convoluted billing codes related to pacemakers and their complications leave room for widely variable estimates. Additionally, MarketScan, while large, contains data from a very particular segment of the insured population. It excludes self-insured, small employers, Medicaid, Traditional Medicare, and Medicare Advantage, leaving a population with relatively unfettered access to the highest quality care in the nation.

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From the Department of Cardiothoracic Surgery, University of Miami Miller School of Medicine, Miami, Florida. Dr. Carrillo has served as a consultant to Spectranetics and Sensormatic; has served on the Speakers Bureaus of Medtronic Inc., Sorin Group, and St. Jude Medical Corp.; and has received a research grant from St. Jude Medical Corp. Mr. Boyle has reported no that he has no relationships relevant to the contents of this paper to disclose.

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Cantillon et al. (6) have recognized many of these limitations and done their best to mitigate them. They justifiably point out that many previous studies on pacemaker complications drew data exclusively from academic centers. In clinical practice, device implantations are performed in a wide range of settings by practitioners with variable experience. These data may not constitute a "real world" cross section as Cantillon et al. (6) imply, but they are exceptionally useful.

Results showing worse outcomes than prior studies are likely to be met with skepticism. In reality, these data should serve as a wake-up call. In the acute phase, it is difficult to attribute events such as thoracic trauma and lead revision to anything other than device implantation. Cantillon et al. (6) also took measures to prevent overestimating long-term complications. In fact, the relatively small proportion of patients followed for the full 36 months—about 12%—raises the possibility of underestimation. With regard to infections, which are particularly morbid and costly, numerous studies agree or go further. Another recent investigation (7) based on MarketScan data divided infections into 4 categories based on the intensity of treatment and found that many carry incremental costs in excess of $200,000, which is more than double the number reported by Cantillon et al. (6).

There are many ways the implant community can improve these outcomes. We might begin by developing an obsessive focus on complications. The recognition, through studies such as this one, that even low adverse event rates have profound influence on a population level, should be a powerful motivator. Cantillon et al. (6) raise the prospect of leadless systems reducing complication rates, a reasonable hope for sure. However, new systems may also shift the natural history of device-related complications. It will be important to monitor the increasing use of these devices in a longitudinal and holistic manner, not assessing them solely in terms of the adverse outcomes we see now. In general, we can hope that industry will help advance the mission of reducing these complication rates, but the onus remains on the operator community to improve our training and protocols in ways that reduce trauma, infection, and other adverse events that detract from patient wellness and create unnecessary costs.

ADDRESS FOR CORRESPONDENCE: Dr. Roger G. Carrillo, Surgical Electrophysiology, Department of Cardiothoracic Surgery, University of Miami Miller School of Medicine, 1200 NW 12th Avenue, Miami, Florida 33140-2800. E-mail: rogercar@aol.com.

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