Telemedicine for Management of Implantable Defibrillators

Lessons Learned and a Look Toward the Future

See Article by Dalouk et al

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For decades, the field of cardiology has attempted to tackle the complex problem of providing care during critical periods between clinic visits or hospitalizations. Heart failure has been the prototypical disease for which to develop these interventions because care is complex and guided by subtle symptoms and signs of congestion and volume overload. Failure to make ongoing small but clinically significant titrations in heart failure medications was thought to increase risk of heart failure hospitalization and possibly mortality. Therefore, stakeholders sought to develop outside-the-office interventions to manage these patients.

In patients with implantable cardioverter-defibrillators (ICD), optimal management requires yet another layer of oversight, which is device management. Clinical evaluation of the ICD includes assessment of a range of programmed parameters, diagnostics, and tests well known to this readership. In addition, the device visit serves as an opportunity for nurses, nurse practitioners, physicians, and other clinical staff to assess overall and cardiovascular health and social history, which may lead to interventions beyond device therapy, including medication titration, diagnostic testing, and even timely referral to other specialty or primary care physicians. Despite the advent of home-based remote monitoring of cardiac implantable devices, periodic face-to-face visits are still considered essential in clinical practice guidelines, owing to the fact that devices cannot be programmed remotely. For patients and caregivers with difficulty accessing face-to-face care such as those from rural areas, this paradigm may pose challenges or inconveniences for clinic visits that may be perceived as routine or insignificant.

In this issue of the journal, Dalouk et al[1] sought to compare clinical outcomes from long-distance telemedicine ICD visits versus conventional in-person device clinic visits from a single practice site in the Veterans Health Administration (Portland). The telemedicine clinic consisted of clinicians at 2 locations. The patient site was a clinical site at largely rural regional sites in the pacific northwest. Accompanying the patient was a combination of a nurse and ICD manufacturer support representative or a nurse practitioner with expertise in device interrogation. The distance telemedicine practitioner, an MD or nurse practitioner, was based at the Portland VA and communicated via a telephone or video link. The investigators observed 523 patients who received telemedicine or in-office follow-up in Portland after ICD implant from 2001 to 2014. Patients with outside follow-up, presumably some who received follow-up at the same remote sites, were excluded. The outcomes assessed were time to first ICD therapy, inappropriate shock, any ICD shock, and death. Subjects were censored when they crossed over treatment arms. Baseline characteristics were similar in both groups with reasonably high

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optimal medical therapy (although 30% of patients were on digoxin, likely reflecting earlier patients in the study period). The telemedicine group had a slightly lower comorbidity burden based on the Charlson score and a lower proportion baseline prevalence of atrial fibrillation. During a median follow-up of 4.4 years, telemedicine care was noninferior of all outcomes. In multivariate models, age, Seattle heart failure score, ejection fraction, Charlson score, use of digoxin, and diabetes mellitus were associated with an increased risk across these outcomes. The authors conclude that telemedicine ICD follow-up is noninferior to in-clinic device management.

The study has some notable strengths. The VA is the largest integrated healthcare system in the United States and has a care and benefits structure that minimizes loss to follow-up and promotes coordination of care although patients are overwhelmingly male Veterans. Detailed chart review was performed rather than reliance on medical claims data alone, allowing for a rich assessment of baseline characteristics. ICD events were meticulously collected and adjudicated, which is often not possible in large healthcare system data sets unless complex data linkage is performed.[2] The authors also use a new-user design, starting observation at time of implant, thereby minimizing survival and other prevalence biases. Noninferiority statistical analyses were used to minimize type II error.

However, there are some important limitations that may challenge causal inference. These data are observational, and patients with follow-up outside of the Portland VA system were excluded. The excluded group may have patients who had face-to-face care at some of the telehealth sites because these sites had the capability to have device representatives see patients; some also had nurse practitioners. This could lead to substantial selection biases among the outlying patients who were nonrandomly assigned to telemedicine treatment. Similarly, VA benefits status, rurality, distance to hospitals, and concomitant use of Medicare or external care are important uncaptured confounders that have been shown to be associated with use of specialty cardiology care and with outcomes in the VA.[3,4] Additionally, these data were censored at treatment crossover. Although this type of on-treatment analyses can be useful, it may lead to informative censoring that could bias results. Intention-to-treat analysis, without crossover censoring, would be more helpful to understand the effects of telemedicine as an initial treatment strategy, similar to an analysis of a study intervention in a trial.

Finally, although the top-line results for outcomes of ICD therapies and death are noninferior, what is difficult to tease out from the analysis is why telemedicine patients fared comparably. Potential effect mediation could have been from device programming (high-rate or extended detection settings), better pharmacological therapy, decreased healthcare utilization,[2] increased appropriate healthcare utilization[5,6] including noncardiology or non-VA care, or other factors. Without knowing these factors, it is hard to ascertain which components of a complex telehealth intervention are beneficial, particularly if both arms of an observational group have elements of inefficient or suboptimal care (could care be designed to be even better than what was observed in the treatment arms?) For example, at 4 years of follow-up, ≈60% of patients in both arms received appropriate ICD therapy, which seems higher than contemporary practice and could reflect patient selection, background medical therapy, or programming settings, particularly among earlier patients from this long study period from 2001 to 2014. Future research will need to examine which process measures should be emphasized in broader implementation.

Despite these limitations, the study by Dalouk et al[1] is important, makes a compelling case for telemedicine, and highlights the need for more work in this area. Although the VA infrastructure is well resourced, a broader question is the scalability of the telemedicine intervention used here, which involved a device representative or trained clinicians at the remote patient site and synchronous specialty clinicians at the telemedicine clinical sites. Although convenient for patients, the model is resource-intensive model and may be difficult to sustain in other fee-for-service healthcare systems, which may have limited reimbursement for such encounters.

With the advent of Bluetooth Low-Energy connected pacemakers and ICDs, which are approved in parts of Europe and may soon be approved in the United States, a smartphone could be the only hardware required for both device interrogation and the phone or video visit. Therefore, it may be possible to perform device clinic quality checks from the patient's home. A patient's own smartphone could provide simplified device diagnostics and status, such as a green light if all systems are working, device is programmed appropriately and rationally (right ventricular pacing minimized, high rate or extended detection), and even provide information on atrial fibrillation episodes. Such a digital healthcare platform could also be used to perform home-based device programming, which after rigorous assessment of safety should be trialed in implementation. If successful, then a smartphone home-based telehealth encounter may be better, faster, more scalable, and even superior to in-office care.

AFFILIATIONS

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DISCLOSURES

None.

FOOTNOTES

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