Device implantation and complications: time to recalibrate our expectations?

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This editorial refers to ‘Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark’\textsuperscript{1}, by R.E. Kirkfeldt et al. on page 1186

There has been a worldwide increase in the number of patients receiving implantable pacemakers, defibrillators, and resynchronization therapy devices. Although, there is evidence from previous studies and clinical trials that implant complication rates modestly increase with the complexity of devices,\textsuperscript{1,2} these reports may not be entirely reflective of the real-world experience. This is of particular importance when discussing therapeutic options with our patients and keeping the goal of providing cost-effective ‘high value’ care. The relevance of institutional and country-specific metrics is further augmented by the rapidly evolving healthcare landscape and the need to administer personalized care via accurate assessments of the risk–benefit of therapeutic strategies such as device implantation. Device therapy is resource intensive, and its cost-effective use should be guided by real-world data on outcomes, risks, and complications. Kirkfeldt et al.\textsuperscript{1} now present the first nationwide, population-based study comparing pacemakers and high voltage device implantation procedures.

The authors describe complication rates for implantable cardiac devices in 5918 consecutive patients who underwent device implantation in Denmark from May 2010 to April 2011. The patients were enrolled prospectively with the aim of capturing pre-defined data. Importantly, although the data capture in this study was retrospective, rigorous ascertainment of complications was accomplished by chart review of every single subject. The results are provocative, showing a higher than expected rate of any complication (9.5%). Several known risk factors for device complications were confirmed, including higher rates for implantable cardioverter-defibrillators (ICDs) compared with pacemakers, and higher risk associated with more complex procedures such as dual-chamber and biventricular devices (Figure 1). The higher infectious risk associated with generator replacement over primary implants was observed. Other risk factors included female sex, low body mass index, and operators with low annual procedure volumes. The strengths of this report include thorough evaluation of all complications and inclusion of all patients undergoing cardiac device implants during the study period.

However, there are some limitations inherent in the study design. Primary among them is the lack of knowledge of patient-specific factors that are known to influence risk of procedural complications (e.g. renal function, diabetes, etc). Furthermore, understanding the indications for the procedures is an important part of the patient profiles, as these, in turn, can influence outcomes and complications. Without controlling for such patient-specific factors, it is difficult to know, for instance, whether low volume operators had intrinsically higher complication rates, or merely suffered from an unfavourable case mix.

Notably, the results show that in a real-world setting, complication rates are higher than seen in the large clinical trials. How can we account for this difference and should we be concerned? There are several reasons why complications might increase in the real world compared with clinical trials. One reason is because clinical trials are usually performed at high volume centres with more experienced operators, while the real-world experience may include a number of low volume operators and centres. However, differences in operator and centre experience may not entirely account for the observed differences. In a similar study to this, Al-khatib et al. found that subjects matched by propensity score from the US National Cardiac Device Registry (NCDR) had similar outcomes to subjects from MADIT-II and SCD-HeFT, suggesting that when patient-specific risk factors are controlled, real-world operators do as well as those involved in clinical trials for ICD implant outcomes.\textsuperscript{3} The data capture in this study was clearly exemplary, with no patient lost to follow-up. Could it be that complication rates were simply better captured by the rigorous chart review performed in this study? While this is a possibility, the prospective pivotal clinical trials performed for cardiac devices are highly rigorous with superb follow-up and are unlikely to have missed a large percentage of procedural complications. We are left then with the patients themselves. Could it be that in the real-world experience, complications are higher than in clinical trials?
world patients are simply higher risk than those enrolled in device trials? In addition to strict inclusion and exclusion criteria, there are additional selection biases in referring a patient for a clinical trial. There is also the real-world phenomenon of indication creep as patients who do not entirely meet approved indications undergo device implantation. As an example, many patients with end-stage renal disease continue to receive implantable devices, although this subpopulation has been routinely excluded from most device clinical trials. Very sick, class IV patients or those with narrower QRS intervals and significant symptoms of heart failure continue to receive resynchronization therapy. Although not elaborated by Kirkfeldt et al., in this study, patient-specific differences of the real-world population are perhaps the most likely explanation for the observed results.

The impact of these results ultimately depends on the basis of these patient differences. If these patients meet accepted indications for device implantation but just happen to have greater risk, there is little to be done. More concerning, however, would be if an indication creep were at play. Review of the NCDR in the USA has suggested that as many as 22% of ICD implants are not evidence based. What is worse, non-evidence-based subjects have a higher rate of procedural complications. Unfortunately, this is where the current study falls short. Without understanding the indications and relative contraindications for these devices, we cannot determine the appropriateness of their use. Such data would be critical to understanding whether we can act to improve patient outcome. In some cases, it may be a matter of education, such as the implantation of ICDs immediately post-myocardial infarction, where multiple clinical trials have failed to demonstrate any benefit. However, there may be other situations where despite the absence of clinical trial data, physicians feel that device implantation is in the patient’s best interest. In such cases, prospective clinical investigation might be able to provide evidence for or against current practices. Nevertheless, this report will provide information useful in advising patients about the procedural risks of cardiac device implantation and is a cautionary signal that we should rigorously evaluate our patients and the indications for the cardiac procedures we recommend.

Undoubtedly, as the population ages, the complexity of patients we care for will continue to increase, as will the potential for harm. The ability to individualize our approach by putting the risk for complications into context becomes significantly more important. It is also important to recognize that at the same time as the indications expand and device types increase, we will have a larger population of patients living longer, but with greater levels of risk when it is time to upgrade, revise, or replace the devices. Device therapy itself is expensive, and peri-implant complications in turn will further drain the healthcare funds. Needless to say, the ongoing adoption of device therapy will be continually tempered by the economic climate. In this era of healthcare reform, it becomes imperative to have granular data at every level from the healthcare organization, state and federal government, down to the individual patient. Such real-world data will help serve as a benchmark for quality and safety analysis, facilitating decisions regarding the allocation of resources and enhancing our ability to deliver patient-centric care through shared decision-making. In short, such data should help to recalibrate our own expectations.

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References