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TOPIC COLLECTION: IMPLANTABLE CARDIAC DEVICES: ACCESSIBILITY, VARIABILITY, AND COMPLICATIONS

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Letter from the Editor

Access to medical care varies tremendously around the globe. It is especially in advanced technology that this variability exists, and particularly between underdeveloped and developed countries.

Pacemakers and defibrillators are advanced technologies that are less available to patients in underdeveloped areas. In developed countries, devices are often removed and discarded while extended battery life still remains. In a novel long-term, multinational program reported in the *New England Journal of Medicine*, pacemakers and defibrillators collected after death in developed nations were resterilized and utilized in underdeveloped countries. Concerns about potential infection risk were unfounded. In 1051 patients with resterilized devices, no significant difference in infection rates occurred between these patients and 3153 patients who received new devices. Broadening this program to other centers and countries has a great potential to alleviate suffering and to prolong lives in underdeveloped countries.

In other research summarized in NEJM Journal Watch, Ranasinghe and colleagues showed that the quality of and complications related to permanent pacemaker and implantable cardioverter–defibrillator (ICD) implants varied greatly between hospitals; Tarakji et al. demonstrated that an antibiotic envelope reduced cardiac device infections; and Jukema and associates presented a randomized trial of ICDs in dialysis patients with left ventricular ejection fraction ≥35%, demonstrating no benefit.

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ORIGINAL ARTICLE

Infections Associated with Resterilized Pacemakers and Defibrillators

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ABSTRACT

BACKGROUND

Access to pacemakers and defibrillators is problematic in places with limited resources. Resterilization and reuse of implantable cardiac devices obtained post mortem from patients in wealthier nations have been undertaken, but uncertainty around the risk of infection is a concern.

METHODS

A multinational program was initiated in 1983 to provide tested and resterilized pacemakers and defibrillators to underserved nations; a prospective registry was established in 2003. Patients who received reused devices in this program were matched in a 1:3 ratio with control patients who received new devices implanted in Canada. The primary outcome was infection or device-related death, with mortality from other causes modeled as a competing risk.

RESULTS

Resterilized devices were implanted in 1051 patients (mean [±SD] age, 63.2±18.5 years; 43.6% women) in Mexico (36.0%), the Dominican Republic (28.1%), Guatemala (26.6%), and Honduras (9.3%). Overall, 85% received pacemakers and 15% received defibrillators, with one (55.5%), two (38.8%), or three (5.7%) leads. Baseline characteristics did not differ between these patients and the 3153 matched control patients. At 2 years of follow-up, infections had occurred in 21 patients (2.0%) with reused devices and in 38 (1.2%) with new devices (hazard ratio, 1.66; 95% confidence interval, 0.97 to 2.83; P=0.06); there were no device-related deaths. The most common implicated pathogens were *Staphylococcus aureus* and *S. epidermidis*.

CONCLUSIONS

Among patients in underserved countries who received a resterilized and reused pacemaker or defibrillator, the incidence of infection or device-related death at 2 years was 2.0%, an incidence that did not differ significantly from that seen among matched control patients with new devices in Canada.

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Quality and Complications of Device Implant Vary Greatly Among Hospitals

Choose your hospital carefully.

Complications from implantation of permanent pacemakers (PPMs) and implantable cardioverter–defibrillators (ICDs) can be serious and include life-threatening issues. To compare hospitals' risk-standardized complication rates of initial PPMs and ICDs, researchers used administrative databases from 2010 to 2015, covering 174 hospitals in New Zealand and Australia and involving 81,304 patients.

Most patients received a PPM (n=65,711). Overall, 8.2% of patients experienced a major complication. Rates of complications were higher for ICD recipients than PPM recipients (10.04% vs. 7.76%). Among the 98 hospitals that implanted >25 devices annually, the complication rate was lower. The most common in-hospital complication was lead reoperation (1.66%), followed by pneumothorax, hemothorax, or pleural effusion requiring drainage (0.99%); death, although not necessarily due to a complication, occurred in 0.46% of patients.

The risk-standardized rates of complications among the higher-volume hospitals varied from 5.3% to 14.3%. The authors did not examine characteristics of well-performing hospitals compared with poorly performing ones. However, a sensitivity analysis restricted to elective procedures produced the same wide range in complication rates.

COMMENT

This study highlights an important point — hospitals have widely varying complication rates for PPM and ICD implantation. However, these authors offer no clues as to the cause of such variation. The possibilities extend beyond implant technique to surgical preparation, ancillary staff, closure techniques, and postoperative care. Evaluation of the causes for the variation in complications is critical for reducing harmful outcomes in the future.

— Mark S. Link, MD

Harlan M. Krumholz, MD, SM, editor-in-chief of *NEJM Journal Watch Cardiology,* is a coauthor of this article but was not involved in its selection or summarization.

Ranasinghe I et al. Institutional variation in quality of cardiovascular implantable electronic device implantation: A cohort study. **Ann Intern Med** *2019 Jul 30; [e-pub]. (https://doi.org/10.7326/M18-2810)*

Wong JA and Devereaux PJ. Cardiac device implantation complications: A gap in the quality of care? **Ann Intern Med** *2019 Jul 30; [e-pub]. (https://doi.org/10.7326/M19-1895)*

Should Implantable Cardioverter–Defibrillators Be Used in Patients on Dialysis?

A randomized, controlled trial shows that ICDs do not help dialysis patients with ejection fractions ≥35%.

Multiple randomized, controlled trials have shown that patients benefit from implantable cardioverter–defibrillators (ICDs) for both secondary and primary prophylaxis. However, all of these studies have excluded patients on dialysis even though sudden cardiac death (SCD) is frequent in these patients, including those with preserved left ventricular ejection fraction (LVEF). In the manufacturer-sponsored ICD2 study (ISRCTN20479861), 188 patients on dialysis with LVEF ≥35% were randomized to receive or not receive ICDs.

Through follow-up (median, 6.8 years), SCD occurred in 11% of the ICD group and 9% of the control group. Over 50% of the participants died, with no difference between the ICD and control groups. In the ICD group, 14% received appropriate ICD therapy. Adverse events were common in the ICD group (22 of the 80 patients who actually received ICDs), including ICD explantation in 6 and lead dysfunction in 10.

COMMENT

These results thoroughly dash the hypothesis that primary-prevention ICDs would benefit dialysis patients with LVEF ≥35%. ICDs are not warranted in these patients, and it is unlikely that this population will be subject to another ICD study.

The results do not address ICD treatment for dialysis patients with LVEF <35%, who currently qualify for primary-prevention ICDs if life expectancy is >1 year. This trial creates a cause for concern that ICDs in dialysis patients may be futile. Editorialists note several possible explanations for the negative results: SCD was lower than expected; the study enrolled few patients initiating dialysis, the population most commonly experiencing SCD; nearly 30% received peritoneal dialysis, associated with a lower SCD risk; and ICDs might not be effective in terminating arrhythmias in this population. Whatever the reason, the trial's results are certainly disappointing to our dialysis patients and providers.

— Mark S. Link, MD

Jukema JW et al. Prophylactic use of implantable cardioverter-defibrillators in the prevention of sudden cardiac death in dialysis patients. **Circulation** *2019 Jun 4; 139:2628. (https://doi.org/10.1161/CIRCULATIONAHA.119.039818)*

Kaplan R and Passman R. Defibrillators don't deliver in dialysis. **Circulation** *2019 Jun 4; 139:2639. (https://doi.org/10.1161/CIRCULATIONAHA.119.040504)*

Preventing Cardiac Device Infections with a Minocycline/Rifampin Envelope

Placing an ICD within an antibiotic-eluting envelope reduces the rate of pocket infections.

Periprocedural systemic antimicrobial prophylaxis is employed to reduce risk for infection associated with implantable cardiac devices (ICD). To examine whether local antimicrobials at the site of ICD placement further reduce this risk, researchers randomized 6983 patients (72% male; mean age, 70) who were receiving an ICD to have either standard-of-care antibiotic prophylaxis (control) or standard prophylaxis plus an absorbable minocycline- and rifampin-impregnated envelope that held the ICD once placed. The primary endpoint of this multicenter, manufacturer-sponsored trial was ICD infection within 12 months after implantation.

Twenty-five (0.7%) of 3490 envelope recipients developed infection versus 42 (1.2%) of 3485 control patients, a significant difference (hazard ratio, 0.6). This difference was due to pocket infections (0.4% in envelope patients vs. 1.0% in control patients) and not to endocarditis or bacteremia (0.3% vs. 0.2% in envelope and control patients, respectively). Secondary endpoints (complications and deaths) raised no safety concerns.

COMMENT

This study clearly demonstrates a statistically significant reduction in infectious complications of cardiac device implantation with use of an antibacterial envelope. However, the number needed to treat of about 200 patients to prevent one infection is large. The additional costs incurred were not discussed, and the impact on antimicrobial resistance was not evaluated. Further, bacteremia and endocarditis, the most feared infectious complications of ICDs, were numerically (but not statistically) higher in the envelope group. All told, initial clinical deployment of local antibiotic therapy via absorbable envelope with ICD placement may best be reserved for patients at highest risk for infectious complications, such as those with *Staphylococcus aureus* colonization, diabetes mellitus, or other immunocompromising conditions.

— George Sakoulas, MD

Tarakji KG et al. Antibacterial envelope to prevent cardiac implantable device infection. **N Engl J Med** *2019 Mar 17; [e-pub]. (https://doi.org/10.1056/NEJMoa1901111)*