

DEVICE THERAPY

Reuse of ICDs in developing countries —‘proof of concept’ data published

Cardioverter-defibrillators that have been explanted from their original recipients and resterilized could feasibly be reused in a different patient with no increased risk of infection or other complications. These findings from a retrospective study of cardiac device reimplantations in India represent an important contribution to the scarce literature on the subject. “This effort began as an altruistic gesture individually and separately by some of the USA-based authors,” explains investigator Behzad Pavri. “The only common link between us was a shared [Indian] heritage.” Since 2004, the investigators had collected explanted ICDs with useful remaining battery life, and sent them to the Holy Family Hospital in Mumbai, India for reuse. Pavri and colleagues realized that their scheme of making preused implantable cardioverter-defibrillators (ICDs) available at no cost to patients who could not afford a new device made a meaningful difference to the lives of these individuals. Together, the investigators decided to collate and publish their retrospective data of this experience.

The comparative availability of ICDs in high-income and low-income countries is a disturbing disparity in the field of cardiovascular medicine. The cost of these devices, which are proven to save lives, is prohibitive for societies in which health-care budgets are commonly directed towards improving basic sanitation, or the prevention and treatment of infectious diseases. In India, therapies considered to be beyond ‘basic health care’ are typically paid for by the patients themselves. The costs involved in cardioverter-defibrillator implantation and associated aftercare are well beyond the means of most individuals.

In resource-rich countries such as the USA, many ICDs are removed each year because of infection, device upgrade, or death of the patient. Data indicate that a

substantial proportion of explanted ICDs could have sufficient remaining battery life to warrant reuse. Yet, these devices are usually discarded. In fact, the FDA prohibits the reuse of explanted ICDs, and the manufacturers’ warranty does not extend to cover device reimplantation.

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ICDs selected by the investigators for reuse had ≥ 3 years of remaining battery life, or power of ≥ 3 Volts. Devices were deactivated, cleaned with saline, and then sterilized using hydrogen peroxide, povidone-iodine, and ethylene oxide gas. Owing to difficulties in shipping the devices, they were transported to India from the USA as checked-in baggage by the investigators. Pavri *et al.* cite this limitation as one of the greatest challenges to this work. They emphasize that a systematic method of transportation recognized by customs is needed for the wider use of the reimplantation strategy. All patients who received an explanted, sterilized ICD ($n = 81$) had an ACC/AHA class I indication for device implantation, and could not have afforded to pay for a new device themselves. The risks and benefits of the procedure were explained to patients in their own language, and written informed consent obtained. Patients did not pay anything for the device, and the study received no external funding.

Over time, the investigators were able to collect an increasing number of devices—18 before 2006, 36 in 2007–2008, and 52 in 2009–2011. The mean duration before device explantation from the original patient in the USA was 522 days, and the mean time between explantation and reimplantation in a patient in India



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was 374 days. The devices did not seem to deteriorate during this period. Outcome data were available for 92.6% of patients, but six individuals from remote, rural areas were lost to follow-up. Appropriate shocks were delivered in 42.0% of patients by 43.4% of devices. The rate of inappropriate shocks was not recorded. Seven patients received multiple shocks (>300 in one patient) for ventricular tachycardia or fibrillation storm and survived. No infectious complications or device malfunctions occurred. Several patients received a second, or even third, ICD when the initial device reached the required voltage for replacement. Mortality during follow-up was 11.1%, with a mean time to death of 771 days. Causes of death included dilated cardiomyopathy, postinfarction scar ventricular tachycardia, and stroke.

Pavri *et al.* hope that the results of their study could help to change current attitudes to the reuse of ICDs. “Provided the safety of this strategy is confirmed in larger, [prospective] studies,” concludes Dr Pavri, “there could be important humanitarian and economic effects for the citizens of low-income and middle-income countries”.

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Original article Pavri, B. B. *et al.* Reuse of explanted, resterilized implantable cardioverter-defibrillators: a cohort study. *Ann. Intern. Med.* 157, 542–548 (2012)