The Pacemaker and ICD Reuse Programme of the Pan-African Society of Cardiology

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Africa is witnessing a rapid epidemiological transition with the emergence of non-communicable diseases (NCDs). Indeed, Mensah and colleagues have shown that in sub-Saharan Africa (SSA), there has been a rise in cardiovascular disease (CVD) mortality since 1990, mainly due to population growth and an increase in the proportion of people older than 65 years.[1] Despite the increasing prevalence of CVD in developing countries including SSA, many patients in these countries do not have access to treatment modalities like pacemakers and implantable cardioverter defibrillators (ICDs) that are associated with substantial reduction in morbidity and mortality due to CVD in industrialised nations. For example, in a 2009 global review of pacemaker implantation in 61 countries, there was a large gap between the developed and developing nations in the number of implants; for example, there were 782 implants per million people in France compared with four implants per million in Pakistan.[2] Although the statistics on pacemaker implantation rates are not readily available in most SSA countries, cardiac pacemaker use remains dismally low at <10 implants per million population (with the exception of South Africa with 39 per million population, most for those with private health insurance).[3] This disparity is believed to be due to the high cost of new cardiac devices. The price of the pacemaker generator without accessories is between US$2500 and US$3000, while that of the leads is US$800–1000. An ICD generator price is between US$20 000 and US$40 000 and leads cost over US$10 000. These costs exceed the yearly earnings of the average citizen in most lower-income and middle-income countries (LMICs).[4]

Every year, one million people die due to lack of access to pacemaker treatment.[5] Apart from premature deaths, the non-availability of pacemaker treatment also adversely affects the individual's quality of life due to poor physical performance, persistent tiredness and recurrent syncope associated with symptomatic bradycardia. Untreated bradyarrhythmias negatively impact on the economy of developing nations by increasing the disability burden in countries where patients in their productive years do not have access to costly but effective therapy.[5]

In an ideal world with universal access to healthcare, fairness would demand that all patients who require new pacemakers are provided with them regardless of their ability to pay. However, this is not possible in reality for the majority of the people of the world who live in developing countries.[6] In SSA, there are three main barriers for pacemaker and ICD implantation, namely; availability of X-ray facility with fluoroscopy, lack of clinical expertise and high cost of the devices.[3] While many SSA countries have radiology facilities to serve the purpose of implantation, the problem of clinical expertise is being addressed by the Pan-African Society of Cardiology (PASCAR) Fellowship in cardiac pacing, which is used to train physicians and technologists from underserved SSA countries. The long-term objective of this programme is to train a team of pacemaker implanters for every country without a pacing service in SSA by 2030. Already, two fellows with their technicians from Kenya and Sierra Leone have been trained through a 6-month diploma in cardiac pacing at Groote Schuur Hospital and the University of Cape Town since the programme was launched in 2015. The PASCAR programme ensures that a team consisting of a physician and a technician is trained in the principles of implantation and follow-up and supported to ensure that they establish a pacing service in their institution of origin with the assistance of regional or national cardiac device companies.

The high cost of new pacemakers remains the major obstacle to establishing cardiac pacing services in many countries in SSA. To this end, PASCAR established a dedicated task force on pacemaker and ICD reuse that seeks to address this barrier of cost by seeking donations of used pacemakers and ICDs for reuse in the SSA countries.

It has been shown that nearly 45% of patients who died with a pacemaker in situ in the USA have their devices removed for reasons including family wish and risk of device explosion during cremation. Importantly, more than 80% of these removed devices are thrown away or stored as waste. Previous data on pacemakers suggest that the average period from implantation to death is 46 months. Considering the fact that the current battery life of pacemakers is 7–10 years, such devices have considerable useable battery life after the patient's death.[7]

The opinions of the general public and stakeholders like patients and funeral directors on any pacemaker/ICD reuse initiative are an important considerations. A study of pacemaker and defibrillator patients showed that 91% of pacemaker patients agree to donate their device to patients living in countries with scarce resources. More recently, another survey of 210 patients with implantable devices revealed that 84% would donate their device for reuse. Seventy-one per cent of 1009 members of the general public, confirmed the desire to donate postmortem devices to those less privileged than themselves. These studies imply that the bulk of patients with pacemakers and ICDs as well as the general public are prepared to consent to device removal for reuse in less fortunate countries.[8] Reuse of pacemakers and ICDs with sufficient battery life in order to further alleviate the burden of those less fortunate is therefore feasible and is a probable solution for reducing the rising burden of CVD in SSA.

The major concerns regarding the re-utilisation of postmortem pacemakers or ICDs are the risks of device infection and malfunction. However, when these factors where examined between patients who received reused and new devices, studies from Europe, America and Asia showed no significant difference in infection or mortality rates with the reuse of cardiac devices.[9] However, most of the experience reported in the literature is of reuse of pacemakers. ICD reuse poses a much greater challenge, both related to the high cost of the electrode and the complexity of dealing with the complications.

In a recent retrospective study to determine the performance of reused pacemakers and ICDs at Groote Schuur Hospital, Cape Town, South Africa, by members of the PASCAR task force for pacemaker and ICD re-use, the

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investigators matched patients with re-used devices and new devices for age, gender and date of implantation on a 1:1 basis. After a median follow-up of 15.1 months for the reused devices and 55.8 months for the new devices, the pacemaker group showed no device infections, pacemaker malfunction, early battery depletion or explantation of pacemaker due to infection, malfunction and early battery depletion identified. In the ICD group, there was one device in the reused group that delivered unwanted shocks during the early stages of implantation and that led to generator replacement after 14 months. In this arm of the study, there were also no device infections identified after a median follow-up of 35.9 months for the reuse and 45.7 months for the new devices. The investigators found no procedure-related infections during the follow-up period.[9] Furthermore, a meta-analysis of 18 small clinical trials with a total of 2270 patients revealed that there was no difference in infection rates between reused and new devices (OR 1.31 (95% CI 0.50 to 3.41), P 0.58), but a slight increased risk of device malfunction. Reused devices malfunctioned at a rate of 0.68% (compared with new, OR 5.80 (95% CI 1.93 to 17.47), p=0.002); none of these malfunctions led to death or severe harm.[10]

There is increasing data to suggest the possibility of pacemaker recovery and reuse. It is therefore imperative to consider ethical issues surrounding device reuse. Surely pacemaker donation and reuse improves the well-being of recipients with no access to therapy. In addition, available data suggest that resterilised pacemakers do no harm as long as there is adherence to protocols regarding standardised sterilisation, proper device handling and implantation, oversight to prevent diversion or resale and patient education and follow-up.[4] Furthermore, informed consent is needed by both donors and recipients to establish respect for autonomy. In a recent publication, pacemaker reuse has been described as cost-effective, consistent with the principles of justice and beneficence and a commitment to stewardship of resources and the common good.[6]

Although arguments have been made that medical evidence rather than cost should guide pacemaker and ICD implantation, these arguments may not be applicable to LMICs, and the difficult socioeconomic conditions in these countries are unlikely to change substantially in the near future.[7] Nevertheless, there is need for a large prospective international multicentre randomised clinical trial (RCT) to provide the evidence as regards safety and efficacy of cardiac pacemaker reuse in LMICs. To achieve this, PASCAR has joined established agencies with similar initiatives—the project MyHeartYourHeart of the University of Michigan Cardiovascular Center, the Pace4life from the UK, the World Medical Relief and interested physicians from across the globe—to conduct an RCT to answer this important question. The objective of this trial, which has been initiated by project MyHeartYourHeart of the University of Michigan Cardiovascular Center, is to determine if postmortem pacemaker reutilisation can be shown to be a safe means of delivering care to patients in LMIC without resources. This is a randomised, multicentre, unblinded non-inferiority study of 260 patients with class I indications for pacemaker implantation and no financial means to acquire a new device. Consented patients will be randomised to undergo implantation of either a refurbished pacemaker or a brand new pacemaker. This trial will establish the safety and effectiveness of pacemaker reuse in developing countries. With the recent US Food and Drug Administration approval of export permit for pacemaker reuse in a number of LMICs including two African countries, a significant milestone has been achieved in execution of this important trial.

In conclusion, while we await the results of this important RCT, we believe that an overemphasis on offering the best therapy (a new pacemaker) may hamper the significant benefits that can be obtained from an otherwise effective treatment (a reused pacemaker), especially when the current alternative for the target population is no treatment at all—the perfect should not be the enemy of the good.[11]

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