

Review Article

Reuse of Devices in Cardiology: Time for a Reappraisal

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The rapid development of minimally invasive procedures for diagnosis and therapy has led to a considerable increase in the cost of medical equipment. Many medical devices, and in particular devices for interventional cardiology and electrophysiology, are nowadays placed on the market as single-use disposable devices (SUDs). Although there are conflicting results regarding the safety and effectiveness of SUD reprocessing and reuse,^{1,2} interventional electrophysiology is an area where such a policy seems feasible.^{3,4} Financial considerations are probably the main reason for the reprocessing of SUDs; a hospital's cost for an in-house reprocessed device is less than 10% of a new one and, on average, reprocessed medical devices are 50% cheaper than new devices.⁵ Some devices, both SUDs and those marketed as reusable, have been reprocessed in-house by hospitals and other treatment facilities since the late 1970s.⁶ Advances in technology have led to the development of more sophisticated and complex devices, generally made from novel plastics that are not resistant to high temperatures and therefore cannot undergo heat sterilization processes. In interventional cardiology new instruments have been developed with smaller lumens and more intricate, delicate working mechanisms, making the proper cleaning and sterilization of these

devices challenging. The practice of SUD reprocessing raises public health concerns, primarily regarding the potential risks of infection and device malfunction, and has led to complaints by the original device manufacturers.⁵ The scope of this article is to review the current European legislation and international literature on the reuse of SUDs in catheter-based coronary and electrophysiological interventions, permanent pacemakers and implantable cardioverter-defibrillators (ICDs).

Legislation and recommendations

The legal situation within Europe and elsewhere regarding the reprocessing and reuse of SUDs is rather obscure. Indeed, the European juridical approach is still quite heterogeneous, since the practice of reprocessing SUDs is not currently regulated at the European Union (EU) level. Different national legislations regulate this practice throughout Europe: in France, the reuse of SUDs is illegal;⁷ in the UK, health authorities have issued guidance warning of the potential risks and consequences when reusing a SUD;^{8,9} while the German Department of Health is the only European authority which has issued special regulations allowing the reuse of SUDs since July 1998.¹⁰ These regulations specify that the person or institute processing the medical devices should be

technically qualified, have access to the appropriate equipment, and employ validated procedures (such as cleaning, disinfection and sterilization). Guidelines by the German Robert Koch-Institut¹¹ require that reprocessed devices must meet their intended function to its full extent and ensure all safety relevant requirements without limitation. Reprocessing procedures have to ensure that further use of the device does not pose any danger of an injury to health, especially in terms of: (i) infections, (ii) pyrogen-related reactions, (iii) allergic reactions, (iv) toxic reactions, or (v) altered technical or functional properties of the device. In Greece, legislation regarding the reuse of SUDs is virtually nonexistent; however, during the late 90s, following some cases of legal prosecutions that appeared in the press regarding the reuse of electrophysiology electrodes, reuse was prohibited. The Directives which regulate the placing on the market of medical devices at the EU level are Directives 93/42/EEC¹² and 2007/47/EC,¹³ which, however, do not provide any guidelines regarding the reprocessing and reuse of SUDs. In order to address this limitation, the most recent Directive 2007/47/EC inserted the provisions that: (i) the Commission shall submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community; and (ii) in the light of the findings of this report, the Commission shall submit to the European Parliament and to the Council any additional proposal it may deem appropriate in order to ensure a high level of health protection. This task was assigned to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), which prepared the report on the “Safety of Reprocessed Medical Devices Marketed for Single-Use”.¹⁴ The recommendations of the SCENIHR committee considered reuse a potential option:¹⁴ *“Not all SUDs are suited for reprocessing in view of the characteristics or the complexity of certain SUDs. The possibility for reprocessing is dependent on the material used and the geometry of the medical device. In order to identify and reduce potential hazards associated with reprocessing of a specific single-use medical device, the whole reprocessing cycle starting with the collection of these SUDs after (first) use until the final sterilization and delivery step, including its functional performance, needs to be evaluated and validated”*. The European Parliament and the EC are committed to update accordingly the current Directives on the use of medical devices in order to regulate the reprocessing of SUDs at the European Union level. The recommendations of SCENIHR ob-

viously apply to the SUDs used in interventional cardiology and electrophysiology procedures. Therefore, particular SUDs that are used in such procedures are potentially suitable for reuse, provided that their material and geometry is suitable, and that both the reprocess cycle and their functional performance are adequately evaluated and validated.

Reuse of devices in interventional cardiology

Percutaneous coronary interventions

Percutaneous coronary intervention (PCI) catheters are hollow with narrow lumens; thus, cleaning and sterilization of these devices is challenging. Although the safety and effectiveness of reused PCI catheters have been debated (Table 1),¹⁵⁻¹⁸ in practice their reprocessing is actually widespread in western countries.¹⁹ To assure the safety of restored PCI catheters both mechanical and sterility requirements must be satisfied. Some of the mechanical changes in PCI catheters imposed by reprocess, such as the deflated profile, may not necessarily pose a significant threat to the patient, but may result in a more cumbersome or even impossible procedure with reused devices. The functional specifications of reprocessed balloon catheters vary to a maximum of 6.2% from nominal values, showing the conformity of reprocessed devices with the manufacturers' original specifications ($\pm 10\%$). However, the mechanical properties of reused balloon catheters raise questions concerning their routine clinical use, since reuse is associated with considerably worse quality regarding the crossing profile, nominal diameter, and burst pressure.²⁰ With reused coronary angioplasty balloon catheters, operators achieve success rates equivalent to those published with new coronary angioplasty balloons,²⁰ however follow-up parameters, such as late loss, late loss index, percent stenosis, and binary restenosis rate, are significantly higher when stand-alone balloon angioplasty is attempted with reused balloons compared to new ones.²¹ Assessment of the sterility of reprocessed balloon catheters is usually based on experimental studies, in which catheters are challenged with a bacterial load before applying the reuse protocol and then tested for bacterial growth. It has been shown that, after effective cleaning and sterilization procedures, bacterial growth is not detected on the reprocessed PCI catheters;^{7,22} however, sterilization is not effective if blood is not efficiently washed off the inside and outside of the catheter before ster-

Table 1. Summary of patient studies on reused cardiology devices

Study	Number of patients	Main findings
Percutaneous coronary interventions:		
Plante et al ¹⁸	693	Reused balloon catheters may be associated with a lower success rate in crossing lesions, longer procedure times, and higher complication rates.
Mak et al ¹⁷	693	Reuse of balloon catheters is not associated with an increased rate of in-hospital complications.
Unverdorben et al ²¹	238	Reused balloon catheters achieve success rates equivalent to those of new devices
Cardiac electrophysiology:		
Dunnigan et al ²⁶	847	Electrode catheters may be safely reused after thorough cleaning
O'Donoghue et al ²⁹	n/a	Electrode catheter reesterilization and reuse is safe and cost-effective
Avitall et al ²⁵	336	Electrode catheters can be reused an average of five times without any major catheter failure or any major adverse clinical complication.
Pacemakers and implantable cardioverter-defibrillators:		
Linde et al ⁴¹	200	Reuse of pacemakers can be carried out without increased risk to the patients, provided there is a proper routine for technical control and sterilization
Rosengarten et al ⁴²	70	New and refurbished pacemakers are similar with respect to pacemaker-related survival and complications
Nava et al ⁴³	603	Pacemaker reuse is feasible and safe. Other than the expected shorter battery life, reuse of pacemaker generators is not inferior to the use of new devices.
Mugica et al ⁴⁵	3701	The reutilization of pacemakers appeared to be in no way detrimental to patients
Pavri et al ³⁷	81	Explanted ICDs with 3 or more years of estimated remaining battery life can be reused after they are cleaned and reesterilized. These devices function normally without an increased risk for complications.

ilization.²³ Regarding the organic debris deposited on the surfaces of reused balloon catheters, although the clinical consequences of such findings are not clear,⁷ some consider that if residual organic material is found the reuse protocol has to be aborted,^{7,24} while others argue that organic debris does not necessarily represent a risk if the material is sufficiently adherent to the surface.²³

Cardiac electrophysiology

Electrophysiology (EP) catheters represent high-cost medical devices that are used in large numbers. These catheters, unlike PCI devices, are solid (non-lumen) devices of relatively simple design, are amenable to reprocessing, and have a history of being reused in hospitals for over 25 years (Table 1).²⁵⁻²⁸ Initial studies on the safety and efficacy of reused

EP catheters were conducted in diagnostic EP procedures before the advent of deflectable catheters. These studies have shown that reused catheters did not result in an increase in the risk of infection and that catheters were sufficiently durable to be reused well in excess of five times; thus, one-time use appeared to be an unnecessary and expensive policy.^{26,29} These findings are confirmed by recent studies that tested the clinical performance, sterility and safety of modern EP catheters and defined the maximum number of reprocessing cycles sustainable by the device in hygienically safe conditions. Indeed, reprocessing guaranteed device sterility up to a maximum of five reuses³⁰ and cleaning with enzymatic solution revealed good cleaning properties with efficient bio burden reduction.³⁰ The issue of patient safety was addressed by developing microbiological tests for the quantification of bio burden, steril-

ity and pyrogenic load, and the results validated the precautionary number of five cycles of reprocess.³¹ Total organic carbon (TOC) determinations indicated that detergent residues on reprocessed EP catheters were nominal and significantly lower than organic carbon levels present on new catheters.³² Determination of the mean residual organic carbon and protein contaminants on reprocessed EP catheters further indicated that TOC and protein were reduced ($\geq 99\%$ of residue removed) below previously reported levels and currently accepted standards.³² Early studies of the electrical, physical and mechanical changes of EP catheters have shown that catheters could be safely reused an average of five times.^{25,33} A recent study of the performance of reprocessed EP catheters with five actual use/reprocessing cycles has validated the view that reprocessed catheters are functionally equivalent to new catheters and that they meet, or exceed, industry standards and regulatory requirements.³⁴

Pacemakers and implantable cardioverter-defibrillators

The availability of used pacemakers and implantable cardioverter-defibrillators (ICDs) is a result of: (i) device upgrades, (ii) device infections, or (iii) death.³⁵ The longevity of pacemakers depends on the capacity of the battery, patient use, programming, and design. The average time from implantation to death is 46 months,³⁶ thus, given that the battery life of today's pacemakers is 7 to 10 years, such devices have substantial remaining serviceable battery life after the patient's death. A used pacemaker with voltage and rate programming that has a life expectancy of 19 years will easily outlive a new nonprogrammable pacemaker that has an average life expectancy of 8 years. Modern ICDs have a projected battery life of 6 to 10 years, depending on the type of device.³⁷ Although data on time to death after ICD implantation are sparse, a suggested median value of survival time after ICD implantation in patients older than 75 years is 5.3 years;³⁸ thus, ICDs also have reuse potential after the patient's death. Pacemaker, ICD and biventricular pacemaker pulse generators can be recovered easily from deceased persons by embalmers, and in fact must be removed prior to cremation to prevent explosion in the crematorium chamber. Device donations from funeral homes and crematories are a potential resource for device reutilization.³⁹ Reused devices may have been recovered from patients with infectious diseases, such as hepatitis or human

immunodeficiency virus; thus, a procedure to ensure the sterility of recovered devices is essential. There have been no reports of infection transmitted by a reused pacemaker, despite diverse methods of sterilization, and thus it is reasonable to believe that properly resterilized devices are biologically safe.⁴⁰ Previous studies have shown no significant difference in outcome when comparing pacemaker reuse with new device implantation in a control population (Table 1).⁴¹⁻⁴³ A recent meta-analysis of the safety of pacemaker reuse demonstrated that there is no significant difference in infection rate between pacemaker reuse and new device implantation; however, there was an increased risk for malfunction in the reuse group.⁴⁴ Adequate sterilization of pacemaker or defibrillator pulse generators requires removal of all protein material, which is complicated by crevices in the plastic components if the device is grazed or cracked. Studies have, however, demonstrated that there is no increase in the rate of infection^{41,42,45} or in mortality⁴⁵ associated with reused versus new pacemakers. Similarly, explanted ICDs with 3 or more years of estimated remaining battery life can be safely reused, since these devices functioned normally and delivered life-saving therapies without an increased risk for complications.³⁷

Ethical and liability considerations

The issue of patient information and prior informed consent before the medical procedure needs to be considered. The reprocessing of SUDs may create different levels of healthcare provision and, as a consequence, may create inequalities between patients. The above mentioned ethical considerations should, however, be balanced with the potential cost savings generated by the reprocessing practice, which, in a context of cost containment for healthcare services, could be seen as a way to facilitate and increase patients' access to innovative technology. Regarding liability, in the case of new medical devices the original manufacturer is responsible for the safety and performance of the device and, similarly, in the case of reusable devices, the manufacturer remains responsible for product-related aspects when the appropriate process defined by the manufacturer is followed. In the case of reprocessed SUDs, either by the user (hospital) or via a third-party reprocessing service provider, the sharing of liability between the user and the reprocessing service provider currently appears unclear.

Conclusions

Accumulated experience and recent evidence suggest that reuse of SUDs is feasible in certain clinical settings of cardiology. The reuse of PCI balloon catheters is not generally recommended, since there are contradictory conclusions as far as patient safety is concerned: one side claims that PCI catheters are already being reused in many countries and that there is no evidence for increased risks, while the other group accepts a risk in the presence of mechanical alterations or compromised sterility, which raises both health and legal issues. Reprocessed EP catheters – and particularly temporary pacing and diagnostic catheters – are more suitable for reuse due to their design and geometry; there is virtually no evidence that their reuse compromises patient safety or procedural efficacy, and various studies have validated that reused EP catheters are functionally equivalent to new ones and remain sterile for up to a maximum of five reuses. Similarly, extracted pacemakers and ICDs that have adequate life expectancies can be safely reimplanted provided that they are properly reprocessed. Nevertheless, in cases of reprocessed SUDs clinicians should always be aware of the ethical and liability considerations that arise from their reuse.

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