

Health Technology Assessment on Reprocessing Single-use Catheters for Cardiac Electrophysiology: Results of a Three-years Study

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Abstract—The study aims to define the technical, ethical, juridical and economic issues involved in the assessment of a reprocessing policy for single-use interventional cardiac devices (SUDs). The feasibility of reprocessing was evaluated for cardiac electrophysiology catheters by comparing the chemical, physical and functional properties of new and reprocessed devices. The issue of hygiene was addressed by developing microbiological tests for the quantification of bioburden, sterility and pyrogenic load. The results of more than 1500 tests, conducted on 531 catheters, suggested a precautionary number of regenerations of five cycles. The ethical aspects were reviewed and the European juridical framework was assessed, revealing a need for harmonization. Applying a specific economic model, potential savings were calculated for a representative cardiology department and estimated at national and European level. Potential savings of 41.2% and 32.9% were calculated for diagnostic and ablation catheters, respectively. Safe and effective reprocessing of SUDs could be pursued if quality control processes and certified procedures are met. A reprocessing policy in EP laboratory could lead to savings of about 27250 euros per 100,000 population, but the economic benefits are strongly dependent on the maximum number of regenerations and the regeneration rate.

I. INTRODUCTION

MINIMALLY invasive technology based on single-use devices (SUDs) is of great importance in modern medicine, but the increasing number of interventions and the consequent economic burden on health care systems has led many countries to consider a reprocessing policy. Although there are conflicting results regarding the safety and effectiveness of SUD reprocessing and reuse [1-3], interventional cardiology is an area where such a policy seems feasible [1,4-8].

In recent years, the clinical approach to percutaneous treatment of arrhythmias has changed. New electrophysiology (EP) catheters have been developed for mapping, recording from and ablating cardiac muscle. These proprietary systems need devoted interfaces and specific catheters that are usually difficult to clean and generally not reprocessable. Nevertheless, many ablation procedures and

EP studies are conducted using simpler ablation and recording catheters that can be considered for reprocessing.

Since SUD reprocessing represents the introduction of a new health technology, a Health Technology Assessment (HTA) approach is required, whereby stringent criteria of effectiveness, safety and suitability must be satisfied. The available literature underlines the need to determine correct sterilization techniques and relevant quality controls. Guidelines for defining organizational procedures and placing responsibilities for the use of reprocessed materials should also be provided [5-8]. Important HTA reports on SUD reuse have been delivered by international public agencies [1,5,6,8]. All of these reviews, based on extensive analyses of the best available evidence, highlight a substantial gap in knowledge regarding the safety and effectiveness of reprocessing. This gap demands original experimental evidence.

This study aims to define the fundamental issues involved in the assessment of a reprocessing policy for interventional cardiac catheters according to the Health Technology Assessment (HTA). The quality and safety of reprocessed devices is addressed by experimental techniques providing quantitative data on material properties, functionality and hygiene. Ethical and juridical issues are also considered, along with the economic implications. The technical data and legal, bioethical and economic findings are finally integrated to evaluate the applicability and suitability of SUD reprocessing on EP catheters.

II. METHODS

A. Priority Setting Definition

Following HTA methodologies, priority-setting indicated a need for safety, ethical, legal and economic investigations [9]. Accordingly, the study focused on four issues: i) physicochemical and functional testing of new and reprocessed devices; ii) microbiological tests for quantification of bioburden and pyrogenic load, and optimization of protocols for decontamination, cleaning and sterilization; iii) comparative analysis of the legal and ethical issues involved in the reprocessing and reuse of devices labelled for single use; iv) cost analysis for the introduction of a reprocessing policy.

B. Technical Aspects

The feasibility of reprocessing from a technical point of view was evaluated on non-irrigated EP devices for

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diagnostic and ablation, produced by major worldwide manufacturers. A total of 182 EP devices were subjected to physicochemical and functional studies.

The physicochemical properties of new and reprocessed devices were assessed using optical microscopy (OM), electron microscopy (EM), atomic force microscopy (AFM) and infrared (IR) spectroscopy. To determine changes in their properties with reprocessing, the devices were assessed after different numbers of reprocessing cycles (0 to 14 cycles). To estimate the maximum number of sustainable reuses, synthetic tissue and organ phantoms were used to simulate clinical use and obtain quantitative and reproducible functional measurements.

C. Microbiological Analysis

A wide spectrum of microbiological tests was performed on EP catheters at different steps of the reprocessing procedure to assess bioburden, pyrogenic load, decontamination/cleaning efficiency and device sterility.

Different decontamination/cleaning protocols were tested to identify their biocidal properties and cleaning effectiveness. Eighty devices were contaminated with bacteria-spiked human blood and underwent different pre-sterilization protocols including use of chlorine-releasing agents, polyphenolic emulsion and enzymatic detergent [10]. EM and quantitative culture were used to assess cleaning and bactericidal effectiveness.

Sterility testing methodologies were developed to evaluate a total amount of 208 devices [11]. Samples were collected after clinical use, underwent repeated cycles of simulated use and regeneration and were cultured for 28 days in trypticase soy broth. Six cycles of regeneration, and four species of inoculated bacteria were considered.

Pyrogenic risk was specifically addressed and endotoxin content was assayed by the LAL test [12]. The pyrogenic status of 61 catheters was monitored before any treatment, after decontamination/cleaning and after reprocessing.

D. Ethical and Legal Comparative Analysis

The ethical-judicial aspects of reuse policy were assessed by a comparative analysis of current legislation in European and other Western countries [13]. HTA reports [2-7] and systematic reviews [1,8], as well as position papers of European medical devices associations, were considered.

E. Cost Analysis

The economic analysis considered the cost of new devices, the cost of regeneration, the average number of regenerations and the regeneration rate (percentage probability of successful regeneration) as crucial input variables for the calculation of cost savings by a specific model [14]. The economic implications of reducing waste, packaging and labeling, and the cost of assigning new and reprocessed device contracts were also taken into account. The number of reprocessable EP catheters used per year in a representative cardiology division was calculated, considering the annual report of the Italian society of Electrophysiology [15]. The maximum number of regenerations sustainable by the device was determined according to our technical findings.

An estimate of the potential savings for health care budgets was calculated at national level and extrapolated to the EU.

III. RESULTS

A. Technical Characterization of New and Reprocessed Devices

Physicochemical studies of reprocessed materials found changes related to the number of reprocessing cycles. OM analysis of EP catheters revealed reprocessing-dependent scratches on the polyurethane shaft surface [16]. EM and AFM documented physicochemical etching of polymers due to plasma sterilization, and increased nano-roughness. IR spectra suggested that low temperature sterilization did not modify the bulk characteristics of the polymers. The status of device materials is highly model dependent and should be verified after each reprocessing cycle. Functionality tests of EP catheters found no variations in ablation efficiency, electrode conductivity, thermometric sensor precision or accuracy [17]. However, tests of slipperiness showed worsening lubrication in regenerated EP devices after four cycles, in accordance with the increase in surface roughness.

B. Microbiological Analysis

The comparison of different protocols for decontamination and cleaning showed the need to optimize both disinfection efficiency and biological burden removal [10]. It is also mandatory to protect personnel from

TABLE I
CURRENT ESTIMATED COST AND POTENTIAL SAVINGS FOR EP INTERVENTIONS

Policy		Ablation (A)	Diagnostic (D)	A+D
No regeneration	Current Catheter cost/100000 inhabitants (€)	17766.08	51948.49	69714.56
	Current Catheter cost Italy ^a (M€)	10.38	30.34	40.71
	Current Catheter cost Europe ^b (M€)	81.19	237.40	318.60
Yes regeneration	Potential saving %	32.9	41.2	-
	Potential saving/100000 inhabitants (€)	5845.04	21402.78	27247.82
	Potential saving Italy ^a (M€)	3.41	12.50	15.91
	Potential saving Europe ^b (M€)	26.70	97.81	124.52

^a 58.4M inhabitants. ISTAT 2004.

^b 457M inhabitants. EUROSTAT 2004

infectious agents as HIV. Automation of cleaning could also minimize the risk of endotoxin contamination. Experimental results showed that clinical use does not represent a critical source of endotoxins. Use of tap water and manual cleaning increased the pyrogenic load by introducing Gram-negative microorganisms [12]. Use of microbiologically high-quality water is therefore recommended to avoid the pyrogenic risk.

Investigations of the sterility of EP catheters found no samples positive for the inoculated strain until the fourth cycle of reprocessing [11]. These results were in accordance with surface analysis, which showed changes in the materials' properties that might favor persistence of bacteria and limit the effectiveness of reprocessing after repeated cycles. Hence, over-reuse of devices could affect both their safeness and their efficacy. This estimate of the maximum number of reprocessing cycles is precautionary, as it is derived from experiments conducted under worst-case conditions.

C. Ethical and Legal Comparative Analysis

Unlike the US Food and Drug Administration (FDA), which has enforced priorities for SUD reprocessing, at present no European regulatory authority has a documented policy supporting the reuse of SUDs and there are no enforced regulations for safe reuse [1]. Some EU states have no legislation on the matter, and in some other countries non-binding recommendations or notes have been issued warning about the reuse of SUDs. Despite this, the practice continues in the EU. Conversely, in Germany, the Medical Device Act does not ban the reprocessing of medical devices labeled for single use, and advises users and institutions to use their own discretion.

According to European legislation, a disposable device ends its intended life after the first use, thereby removing the manufacturer's responsibility for subsequent reuse. The certificate of conformity system could be therefore extended to reprocessing activity [13].

Differently, in the German case, a manufacturer's indication of 'single use' is not considered in the notion of 'intended purpose'. Moreover, reprocessing does not entail the placing of the device on the market, since after processing it is returned to the first purchaser and it does not need to be re-marked with a new CE label [13].

From an ethical viewpoint, patient safety and distributive justice in the allocation of available resources must be considered. Health care professionals have an ethical obligation to cause no harm to patients, but the issue is complicated by the appropriate allocation of increasingly scarce health care resources and by the need to ensure the widest possible access to new and effective technologies. Finally, the perception of duplicity in medical care when informed consent is obtained has to be considered.

D. Economic Analysis: Cost Minimization

According to cost-saving calculations, reuse of EP

catheters is associated with a potential saving of 41.2% and 32.9% for diagnostic and ablation procedures respectively and a total of 27247.82 € could be saved per 100,000 population (Table I). By considering the current Italian workload in EP interventions [15], a potential saving of 15.91 M€ could be achieved with the widespread implementation of a reprocessing policy. The scaling to a population amount of European Community gives an extrapolated potential saving of 124.52 M€ per year from the introduction of regeneration practices in interventional cardiology.

IV. DISCUSSION

The study showed that a preliminary assessment by both destructive and non-destructive high-performance analytical techniques should be undertaken for each type of device that has never before been regenerated. This in-depth screening is required to exhaustively assess the feasibility of reprocessing. Once the correct regeneration protocol has been defined and optimized by successive quality feedbacks, only essential non-destructive tests need to be established in routine reprocessing activities. From the technical and hygiene perspectives, an efficient and safe reprocessing protocol is a unique and continuous procedure from post-use collection to re-delivery to the cardiology department. This workflow, ensure the best performance and hygiene, but requires devoted infrastructures, trained staff, specific knowledge, trackability of items, and allocation of responsibilities. The even more stringent criteria of active legislation and regulatory policies (e.g. FDA enforcements) require certified reprocessing procedures with guarantees of quality the same as those supplied by the original manufacturer. These requirements are unlikely to be achieved by small or medium-size hospitals, but could be affordable by health care institutions or third-party industry reprocessors.

The economic analysis indicated that reuse of SUDs might be a source of savings to health care systems and hospitals. However, the scaling down to a single cardiology laboratory should be done cautiously. Low numbers of clinical procedures or variations in the cost of new devices might nullify any savings. It should also be noted that innovations in devices or reprocessing technology could affect the final savings by altering the maximum number of regenerations or the regeneration rate. The potential to reduce waste and raw material consumption might give further economic and ecological benefits.

A. Towards Clinical Use

This work was undertaken in laboratory settings and therefore does not provide outcomes directly related to patients. Experimental analyses were conducted after the first clinical use on patients, while subsequent reuses were simulated in vitro. To provide a definitive answer on the feasibility of SUD reuse in clinical settings, monitoring of

the efficacy and safeness in patients is mandatory, and multi-centre clinical studies should be designed to seek any causal link between reprocessing and adverse outcomes. However, there are ethical constraints on the use of patients for clinical studies designed to determine the risks of SUD reuse.

B. Study Limitations

Although some papers have reported on the iatrogenic transmission of viruses, the degree of risk of Creutzfeldt-Jakob disease (CJD) linked to the reuse of SUDs has not been adequately documented and needs more investigation in the light of new findings on CJD disinfection protocols.

Since reprocessing protocols and analytical techniques are highly device specific, the results of this study cannot be directly extended to other categories of medical instrument. However, the methodological approach could be used to assess the feasibility and safety of reprocessing for various types of SUD [18].

V. CONCLUSIONS

Safe and effective SUD reprocessing should be conducted following standardized and monitored processes, with guarantees of quality the same as those supplied by the original manufacturer

The maximum number of reuses sustainable by a device is a fundamental parameter and might be evaluated by comprehensive analysis of microbiological, chemical, physical and functional tests. According to our findings, the precautionary number of regeneration cycles sustainable by EP catheters were five. However, this number should be determined specifically according to reprocessing protocol and device type.

Substantial savings could follow the introduction of a reprocessing policy of EP devices in cardiology departments, but differences in the maximum number of regenerations, regeneration rate and unitary device cost have to be carefully considered.

The current lack of harmonization on legislation and standards conflicts with the general objective to conform European health care services to the highest standards available and to guarantee freedom of enterprise, positive competition in the market and products improvement.

REFERENCES

- [1] P. Day, "What is the evidence on the safety and effectiveness of the reuse of medical devices labelled as single-use only?" *New Zealand Health Technology Assessment, Technical Brief Series* vol. 3, 2004.
- [2] Z. Quian, W. R. Castaneda, "Can labelled single use devices be reused? An old question in the new era", *J. Vasc. Inter. Radiol.* vol. 13, pp. 1183-1186, 2002.
- [3] D. S. Luijt, J. Schirm, P.H. Savelkoul, A. Hoekstra, "Risk of infection by reprocessed and resterilized virus-contaminated catheters: an in-vitro study", *Eur. Heart. J.*, vol. 22, pp. 378-384, 2001.
- [4] I. Ayzman, S. R. Dibs, J. Goldberger, R. Passman, A. Kadish, "In vitro performance characteristics of reused ablation catheters", *J. Interv. Card. Electrophysiol.*, vol. 7, pp.53-59, 2002.
- [5] B. D. Lindsay, S. P. Kutalek, D. S. Cannon, S. C. Hammill, G. V. Naccarelli, "NASPE policy statement. Reprocessing of electrophysiology catheters: clinical studies, regulations, and recommendations. A report of the NASPE Task Force on Reprocessing of Electrophysiological Catheters", *Pacing Clin. Electrophysiol.* Vol 24, pp. 1297-1305, 2001.
- [6] Conseil d'Evaluation des Technologies de la Sante du Quebec. "The reuse of single use cardiac catheters: safety, economical, ethical and legal issues", *Can. J. Cardiol.*, vol. 10, pp. 413-421, 1994.
- [7] C. Blomstrom-Lundqvist, "The safety of reusing ablation catheters with temperature control and the need for a validation protocol and guidelines for reprocessing", *Pacing Clin. Electrophysiol.*, vol. 21, pp. 2563-2570, 1998.
- [8] Canadian Hospital Association. "The reuse of single-use medical devices", <http://sprojects.mmi.mcgill.ca/heart/carecha2ca.html>. (last access: 1 October 2006)
- [9] C. Henshall, W. Oortwijn, A. Stevens, A. Granados, D. Banta, "Priority-Setting for Health Technology Assessment. Theoretical Considerations and Practical Approaches", *Int. J. Technol. Assess. Health Care* vol. 13, pp. 144-185, 1997.
- [10] F. Tassarolo, I. Caola, M. Fedel, P. Caciagli, G. M. Guarrera, A. Motta, G. Nollo, "Different protocols for decontamination affect cleaning of medical devices. A preliminary electron microscopy analysis", *J. Hosp. Infect.*, vol. 65, pp. 326-333, 2007.
- [11] F. Tassarolo, I. Caola, P. Caciagli, G. M. Guarrera, G. Nollo, "Sterility and microbiological assessment in reusing single-use cardiac electrophysiology catheters", *Infect. Control. Hosp. Epidemiol.*, vol. 27, pp.1385-1392, 2006.
- [12] F. Tassarolo, I. Caola, G. Nollo, R. Antolini, G. M. Guarrera, P. Caciagli, "Efficiency in endotoxins removal by a reprocessing protocol for electrophysiology catheters based on hydrogen peroxide sterilization", *J. Hyg. Environ. Health*, vol. 209, pp. 557-565, 2006.
- [13] U. Izzo, B. Sief, S. Winkler, "Dispositivi medici monouso. Rigenerazione di dispositivi medici e responsabilità. Verso nuovi equilibri fra tecnologia, medicina e diritto", *Danno e Responsabilità*, vol. 7, pp. 769-803, 2004.
- [14] S. Capri, P. Ferrari, F. Tassarolo, G. M. Guarrera, F. Fontana, G. Nollo, "Modello di calcolo della convenienza economica per l'ospedale: il caso dei cateteri cardiaci rigenerabili vs. i cateteri monouso", *Politiche Sanitarie*, vol. 6, pp. 188-196, 2005.
- [15] G. Inama, P. Della Bella, M. Landolina, A. Bonso, C. Pandozi, "Attività dei laboratori di elettrofisiologia italiani nel 2004" *Giornale Italiano di Aritmologia e Cardioritmologia*, vol. 4 supp. 1, pp. S1-S15, 2005.
- [16] F. Tassarolo, P. Ferrari, G. Nollo, A. Motta, C. Migliaresi, L. Zennaro, A. Rigo, G. M. Guarrera, "Evaluation and quantification of reprocessing modification in single use devices in interventional cardiology", *Applied Surface Science*, vol. 238, pp. 341-346, 2004.
- [17] F. Tassarolo, P. Ferrari, R. Antolini, G. Nollo, "Radiofrequency ablation on heart-equivalent phantom. Functionality testing of percutaneous single-use catheter", In: A. Mendez-Vilas ed. *Recent Advances in Multidisciplinary Applied Physics*. Elsevier, 2005. pp. 229-234.
- [18] G. Fichet, E. Comoy, C. Duval, K. Antloga, C. Dehen, A. Charbonnier, G. McDonnell, P. Brown, C. I. Lasmezaz, J. P. Deslys, "Novel methods for disinfection of prion-contaminated medical devices", *Lancet*, vol. 364, pp. 521-526, 2004.