

Reprocessing single-use cardiac catheters for interventional cardiology. A cost-minimization model for estimating potential saving at departmental scale and national level

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Abstract

Background: The utilization of single-use percutaneous catheters (SUDs) is a common practice in interventional cardiology, but the increasing of cardiac interventions and the consequent economic load demand for assessing SUDs' reuse. The study aimed at estimating the potential saving for Italian cardiology departments in the hypothesis that reprocessing and reuse of SUD is performed by guaranteeing safety and efficiency of the reconditioned device as high as the new marketed one.

Methods: A cost-minimization model was applied from the perspective of the health national service. Input parameters for the model were settled by reviewing published data on technical, hygiene and functional properties of reprocessed electrophysiology (EP) and percutaneous transluminal coronary angioplasty (PTCA) catheters. Potential saving at department level was calculated as percentage of the actual expenditure for purchasing single-use devices. Two-ways sensitivity analysis was conducted on main cost drivers. Finally, saving at national level was estimated.

Results: The revision of technical and safety data showed the feasibility of reprocessing and reuse of EP and PTCA catheters under determined constrains. Potential savings of 39%, and 12% were calculated at department level for EP and PTCA catheters, respectively. Sensitivity analysis showed saving was dependent primarily on departmental workload. Major variations in saving occurred in the range between one and 200 catheters per year. The cut-off between benefit and charges was also related to regeneration rate and maximum number of uses. The estimate of potential saving at national level ranged in the interval from €19.85M to €24.24M.

Conclusions: When safety and efficiency is assured by certified reuse processing, substantial saving could be achieved both at departmental and national level contributing to optimize budget allocation for the health-care system.

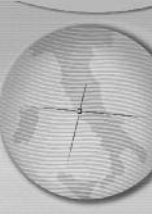
Key words: single use devices, interventional cardiology, catheters, reprocessing, reuse, cost minimization

Background

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 were conflicting results regarding

the safety and effectiveness of SUDs reprocessing and reuse [1-3], interventional cardiology is an area where such a policy seemed feasible [4-11].

In recent years, the clinical approach to percutaneous myocardial revascularization has changed considerably in that, in more than 90% of interventions, a coronary stent is introduced after percutaneous transluminal coronary angioplasty



(PTCA) [12]. The stented balloon cannot usually be reprocessed. However, use of bare balloons remains current practice for pre-dilatation of stenotic vessels before stenting, and sometimes for further dilatation after stenting. Bare balloons could be considered for reprocessing and reuse [5, 6, 8-10]. In electrophysiology (EP), new 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 [4, 7, 9, 11].

The study aimed at estimating the potential saving for budgets of cardiology departments in the hypothesis that reprocessing and reuse of SUDs is performed by guaranteeing safety and efficiency of the reconditioned device as high as the new one. By applying a specific cost-minimization model we intend to figure out the possible economic benefit both at departmental and national level.

Methods

The analysis was taken from the perspective of health national service and the time horizon was one year. Various sources of data were used in the presented work. Results of a multidisciplinary study, promoted by the local Provincial Government (SIX-SICC Project, Safeness in Interventional Cardiology and Cardiac Surgery, Founded by the autonomous Province of Trento, 2001), were reviewed to assess reprocessing feasibility on electrophysiology (EP) and coronary angioplasty (PTCA) catheters and to define the maximum number of uses sustainable by the devices. Experimental data on technical, functional and safety issues were needed to guarantee that the two considered policies (single-use vs. re-use) could produce equivalent outcomes. These findings were integrated with data from other sources to feed a cost-minimization model previously implemented [13]. Namely, the cost of new devices and other fixed costs (waste disposal, collection and handling costs, and assignment of new device contracts) were estimated from the statement of activities of a cardiology division in northern Italy (Dept. of Cardiology, S. Chiara Hospital, Trento: 609 PTCA and 199 EP interventions in 2004 [12, 14]) with a clinical burden on haemodynamics and electrophysiology comparable to that of a representative Italian cardiology department. Costs of reprocessing service and reprocessing

rate (probability of realizing a successful regeneration with functionality and safety of regenerated device as high as the new one) were derived from a European leader third-party reprocessor (Vanguard AG., Berlin, Germany). Costs were expressed in Euro (year 2004 values). Results from the field evaluation (i.e. average number of non stented balloons per procedure and non irrigated EP catheters) were obtained from the register of activity of the Cardiology Department of S. Chiara Hospital in Trento. Workload data on national cardiology departments were derived from the annual statement of activity published by Italian societies of Haemodynamics and Electrophysiology.

The model for cost-minimization was used to describe the costs associated to catheters for interventional cardiology at departmental level in two different scenarios: single-use policy and re-use policy. Accordingly to that model, the single-use catheter's cost (c_K) was computed with the following expression:

$$c_K = P_K + S + \frac{G_K}{3N}$$

Where P_K is the new catheter price, S is the cost related to special waste disposal per single device, N is the total number of used catheters per year in the modelled cardiology department, and G_K is the cost for a competitive triennial contracts allocation of new devices.

Differently, in case of reprocessing and reuse of cardiac catheters, the expression was modified as follows:

$$c_R = i \frac{P_K + (n-1)P_R}{n} + (1-i)P_K + \frac{S}{n} + C + \frac{G_K}{3N} + \frac{G_R}{3N}$$

Where c_R is the cost for n -times used device, i is the reprocessing rate, P_R is the reprocessing cost per catheter, n is the maximal number of uses sustainable by the catheter. Additional parameters were considered, as costs related to collection and handling of used catheter after each use (C), and costs for competitive triennial contracts allocation of reprocessing service (G_R).

Potential saving, related to the introduction of a reprocessing SUDs policy, were eventually calculated with the following expression:

$$\text{Saving\%} = \frac{c_K - c_R}{c_K} \cdot 100$$

To better describe the influence of crucial parameters, a two-ways deterministic sensitivity

analysis was performed by varying the regeneration rate from 0 (never reprocessable) to 1 (always reprocessable) and the number of device uses from 2 (single reuse) to 15 (multiple reuse). Results were presented as a function of department activity (number of catheters used per year) that has been previously shown to be one of the main cost drivers [13]. The number of catheters used per year (N) ranged from 1 (low clinical activity) to 1,000 (high clinical activity). These parameter ranges were settled according to indications obtained by third party reprocessors and working activities reported in national registers [12,14].

In order to apply the model to an Italian representative cardiology department and to the national context, registers of Italian societies for electrophysiology and haemodynamic were accessed to obtain the total number of interventional procedures in Italy (I_{Italy}), and the number of procedure per department.

Median value (and inter-quartiles range) of the number of interventions ($\langle I \rangle$) multiplied by the average number of reprocessable catheter per procedure (c_p) was considered as the median (and inter-quartiles range) consumption of EP and PTCA catheters that can be considered for reprocessing in a representative Italian department ($\langle N \rangle$). Considering clinical and technical differences among devices type, the model was applied to describe three different categories of devices, namely EP catheters for electrophysiological study, EP catheters for ablation, and PTCA devices for angioplasty. Input values for device categories are reported in Table 1 and were used for calculating the potential saving percent in case of reprocessing and re-use of catheters. First and third quartile values of the main cost driver ($\langle N \rangle$) were used to give an estimate of the possible range for saving percent.

Extrapolation to the National level was obtained

by calculating the actual expenditure for potentially reprocessable catheters in Italy (obtained by considering the cost for single device (c_k) times the national number of interventions (I_{Italy}), times the average number of reprocessable catheter per procedure, (c_p)) and applying the percent saving, previously obtained at department level. Actual cost for SUDs and potential saving were than reported per 100,000 inhabitants in order to have a demographic cost-indicator.

Computation and data analysis were performed with a Microsoft Excel platform (Microsoft® Office Excel 2003) running on Intel® Pentium IV personal computer.

Results

From a technical point of view, the revision of recently published papers has shown reprocessing-induced modifications on surface and bulk that can alter the performance of both EP and PTCA catheters after excessive repeated reuse [15,16]. Functionality tests of EP catheters found no variations in ablation efficiency, electrode conductivity, thermometric sensor precision and accuracy [17]. However, tests of slipperiness showed worsening lubrication in regenerated EP devices after seven cycles, in accordance with the increase in surface roughness [15]. The functional properties of PTCA catheters were affected by both clinical use and reprocessing procedures but the changes in slipperiness did not compromise the functionality of in vitro catheters up to two reprocessing cycles [16]. These recent findings were in agreement with previous pre-clinical [2-4,6-9] and clinical [5,10,11] studies on reprocessing SUDs in interventional cardiology. Concerning safety issue of reusing reprocessed devices, sterility tests on in-vitro spiked and reprocessed EP catheters have shown no samples positive to the inoculated

Table 1. Italian workload on interventional cardiology in the year 2004.

	Symbol	PTCA	EP	
			Ablation	Diagnostic
Total procedures in Italy	I_{Italy}	104,574 ¹²	11,979 ¹⁴	22,084 ¹⁴
Procedures per department	$\langle I \rangle$	444 (283; 749)*	78 (36; 170)*	135 (57; 243)*
Reprocessable catheter per procedure	c_p	1.7 ^a	0.75 ^a	3 ^a

* Statistic values are expressed as median (first quartile; third quartile) of the distribution.
^a According to the average number of reprocessable catheters per procedure in one year activity (2004) of the Department of Cardiology, S. Chiara Hospital, Trento, Italy.

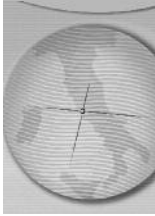


Table 2. Input variables for the cost-minimization model in a representative Italian Cardiology department.

Variable	Symbol	PTCA	EP	
			Ablation	Electrophysiology
Number of catheters/year	<N>	755 (481; 1,273)*	58 (27; 127)*	405 (171; 729)*
New device price (€)	P_k	302.50 ^a	1,118.00 ^a	450.50 ^a
Regeneration price (per catheter, per use) (€)	P_R	150.00 ^b	520.00 ^b	205.00 ^b
Regeneration rate (%)	i	48 ^b	95 ^b	95 ^b
Maximum number of uses	n	3 ^c	6 ^c	6 ^c
Cost for collection and handling of used device (€)	C	5.40 ^d	4.20 ^d	4.20 ^d
Cost for waste disposal (per device) (€)	S	2.00 ^a	2.10 ^a	2.10 ^a
Cost for competitive triennial contracts allocation of new device (€)	G_k	13,377.00 ^a	13,377.00 ^a	13,377.00 ^a
Cost for competitive triennial contracts allocation of reprocessing service (€)	G_R	13,377.00 ^a	13,377.00 ^a	13,377.00 ^a

* Statistic values are expressed as median (first quartile; third quartile) of the distribution.†

^a Department of Cardiology, S. Chiara Hospital, Trento, Italy.

^b Third party European professional reprocessor.

^c Cautelative value obtained by technical and biological data of the study.

^d Estimated by cost of personnel and consumables at Department of Cardiology, S. Chiara Hospital, Trento, Italy.

strain until the fifth reuse [18]. This cautelative estimate for maximum number of reuses was obtained under in-vitro experimental worst-case conditions. As a synthesis of technical and safety findings, the maximum number of uses (n) to enter in the cost-minimization model was set at 6 and 3 for EP and PTCA catheters respectively.

Human resources allocation, and time for used devices collection, handling and pre-processing were considered and quantified in the parameter S of the model, in accordance to reported issues underlining the importance of selecting chemicals and structured procedures to guarantee effective cleaning and disinfection [19], and to minimize contamination of gram-negative bacteria and pyrogenic risk [20].

As shown in Table 2, input data were sub-grouped for PTCA, EP diagnostic and EP ablation catheter because new device price and reprocessing costs were markedly higher for ablation catheters in respect to diagnostic EP devices, while the number of ablation catheters

per intervention was lower. Moreover diagnostic EP catheters were usually reprocessable, while ablation devices were often complex and not any catheter model was considered as reprocessable. So that the number of reusable EP catheters per intervention (cp), was settled at 3 and 0.75 respectively for diagnostic and ablation devices. The average number of non-stented reprocessable PTCA catheters per intervention was 1.7. Costs for the triennial competitive contract allocation of new devices and reprocessing service were settled at €13,377, independently from catheter category.

By running the cost-minimization model we obtained the potential saving at department level expressed as percentage of the actual expenditure for single-use device purchasing. Median percentages and inter quartile ranges (in parenthesis) were calculated according to the quartiles values of Italian department activity distribution. Reuse of PTCA catheters in the representative cardiology department could lead

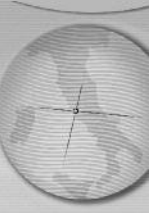
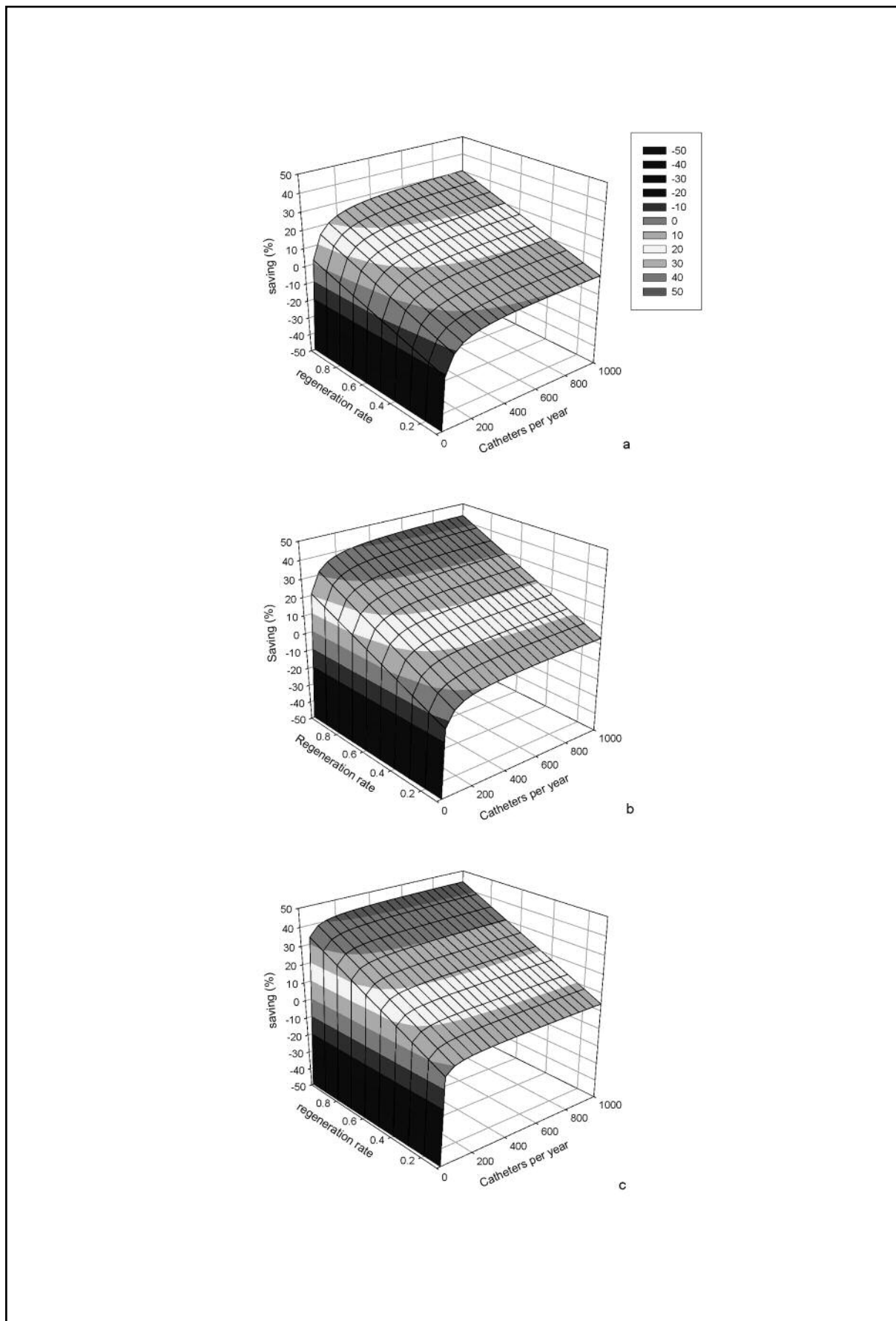


Figure 1. Sensitivity analysis surface-plot for the variation of the regeneration rate.



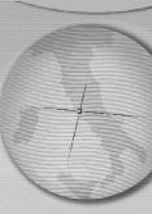
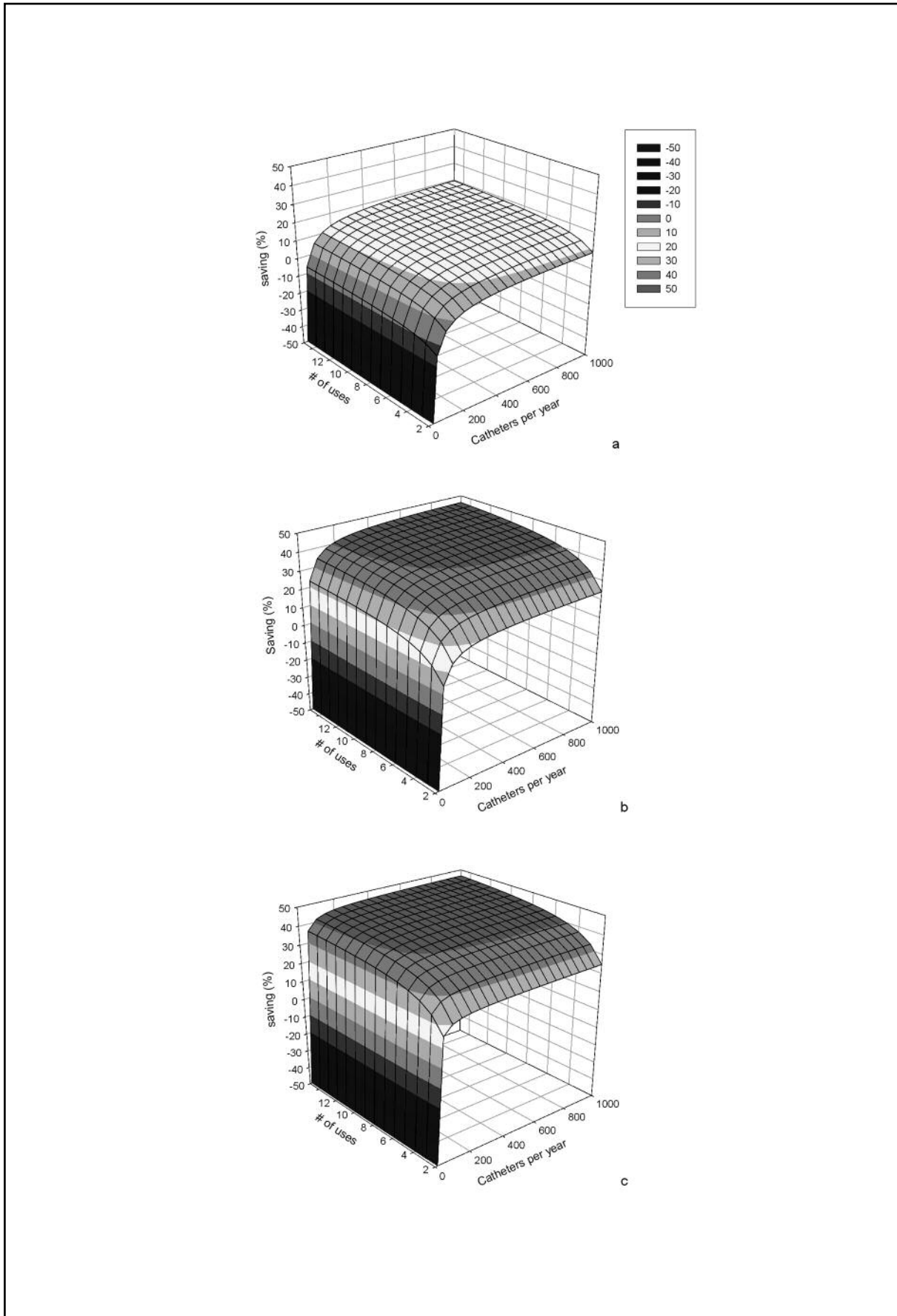
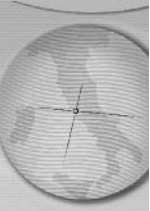


Figure 2. Sensitivity analysis surface-plot for the variation of the number of uses.





to a potential saving of 12.5% (11.3; 13.4). A markedly higher saving of 41.2% (36.8; 42.7) and 32.9% (23.8; 37.7) was computed for EP diagnostic and ablation procedures respectively. No charges were elicited for the introduction of reprocessing policy in departments with an annual consumption ranging from the first to the third quartiles of the clinical activity distribution of Italian cardiology departments.

Results of the two-ways sensitivity analysis on the three main variables, those are regeneration rate, number of uses, and catheter consumption per year, are presented in Figures 1 and 2.

Significant differences in savings between EP and PTCA catheters reprocessing are mostly related to the annual catheter consumption that is proportional to cardiac department activity. Major variations in savings occurred in the range between 1 and 200 catheters per year. Minor variations in the cut-off between benefit and charges were related to the remaining two investigated parameters. Percent savings generally grew as a function of regeneration rate (i) and maximum number of uses (n), but for high number of catheter usage per year (e.g. greater than 300) there was a tendency to a linear relationship between percent savings and regeneration rate (Figure 1), while a plateau in percent saving was reached by increasing the maximum number of uses (Figure 2).

By scaling the estimation of potential saving to the national workload in interventional cardiology, a potential saving of €22,790,000 could be achieved by a widespread implementation of a reprocessing policy (Table 3). This estimation accounted for an amount of €6,880,000 in PTCA catheter reprocessing and €15,910,000 in EP catheter reprocessing. Current estimated costs for a 100,000 population are reported in Table 3. Potential saving of €39,021 for a 100,000 population were estimated in case of reprocessing

SUDs in interventional cardiology at national level.

Discussion

The multidisciplinary approach of this study took into consideration previous experimental findings on safety and functional effectiveness to properly address the economic savings coming from the introduction of SUDs reprocessing in interventional cardiology.

The economic analysis indicated that reuse of SUDs might be a source of savings both at national and department level, as shown for the median Italian cardiology department. However, the scaling to a specific working unit should be done cautiously. Since the cost saving depends on the number of devices used per year, regeneration might be economically unfavourable if a small number of clinical interventions is performed. With PTCA catheters, for which the potential saving is more limited, low numbers of clinical procedures might nullify any savings. The number of catheter used per year is therefore the most immediate parameter for establishing the cut off between benefits and charges in reprocessing SUDs. Consequently the definition of the representative cardiology department was critical. In this study, we extracted information from the national registries of haemodynamics and electrophysiology of the year 2004. Considering the non-normal distribution of department activity in Italy, median and quartiles were chosen as statistical descriptors.

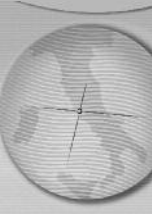
Besides the three parameters investigated in the sensitivity analysis, an additional critical one is the price of new device. Namely, decrease in the cost of new devices could sensibly modify potential saving and, in case of limited percents of benefits as PTCA catheters, a decrease in new device price could nullify the benefit of reprocessing [13]. Moreover innovations in devices or reprocessing

Table 3. Current estimated cost and potential saving for interventional cardiology at national level.

Policy		PTCA	EP			Interventional cardiology (PTCA+EP)
			Diagnostic (D)	Ablation (A)	D+A	
No regeneration	Current catheter cost Italy ^a (M€)	55.00	30.34	10.38	40.71	95.72
	Current catheter cost/100,000 inhabitants (€)	94,181.91	51,948.49	17,766.08	69,714.56	16,3896.47
Yes regeneration	Potential saving Italy ^a (M€)	6.88 (6.22; 7.37)*	12.50 (11.16; 12.95)*	3.41 (2.47; 3.91)*	15.91 (13.63; 16.87)*	22.79 (19.85; 24.24)*
	Potential saving/100,000 inhabitants (€)	11,772.74 (10,642.56; 12,620.38)*	21,402.78 (19,117.04; 22,182.00)*	5,845.04 (4,228.33; 6,697.81)*	27,247.82 (23,345.37; 28,879.81)*	39,020.55 (33,987.93; 41,500.19)*

* Statistic values are expressed as median (first quartile; third quartile) of the distribution

^a 58.4M inhabitants. ISTAT 2004.



technology could affect the final savings by altering the maximum number of regenerations and the regeneration rate. At present, third-party professional reproprocessors guarantee up to 12 reprocessing cycles for EP catheters. Using this figure, the estimate of national saving further increases to about €1,020,000. In general, the higher the average number of regenerations and the regeneration rate, the larger the economic benefit.

The potential to reduce waste and raw material consumption might give further ecologic and economic benefits in the medium and long term. Although reprocessing procedures could involve the use of hazardous sterilizing and disinfecting media as well as water and energy, it is however arguable that reprocessing SUDs could be a non negligible contribution to lower the ecologic impact of non-biodegradable or environmentally harmful materials.

From the technical and hygienic perspectives, a safe and effective reprocessing protocol is a unique and continuous procedure from post-use collection to re-delivery to the cardiology unit. This workflow, while ensuring the best performances, requires devoted infrastructures, trained staff, specific knowledge, trackability of items, and allocation of responsibilities that should be considered in a more exhaustive economic assessment. Economic findings and requirements concerning the even more stringent criteria of active legislation and regulatory policies (e.g. FDA enforcements) [21] suggest that SUDs reprocessing could be affordable only by large health-care institutions or third-party industry reproprocessors as considered in this study.

Study limitations and perspectives

The study examined costs, demographic data, and interventional cardiology workload for the year 2004. Although non-negligible changes in input data occurred in following years, major findings of the study could apply also in current context. Sensitivity analysis showed that the average number of procedures per laboratory is one of the critical parameters for saving computation. Moreover, as previously reported [13], major influences on economic savings are given by changes in new and regenerated device prices. Finally, the total number of procedures at the national level drives the global computation of potential savings. Last available data on interventional cardiology workload show a general increasing trend in the national number of procedures performed both for angioplasty (+11% in 2005, +7% in 2006) and electrophysiology

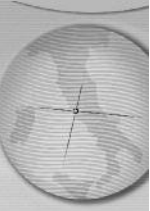
(+19% in 2005) interventions [22-24]. These variations in the global workload are mainly determined by a similar increase in the number of the active laboratories. This results in a slight increase in the average number of procedures performed per single laboratory, making conservative the estimated percent saving.

Alternatively, the price of new devices is affected by major changes due to technological advancements as well as single competitive contract conditions. However, market dynamics forces the stabilisation of the ratio between new catheter prices and regenerated device's cost, to be in the range of 0.4-0.5 by third party reproprocessors (Table 2). This would support the reliability of the estimated percent saving for a more updated context.

Additional information could derive from the development of a probabilistic sensitivity analysis, but this approach needs a certain number of observations or alternatively requires assuming a distribution of values for the model parameters that were not available at the time of the study.

The presented results come from the assumption that no differences in safety and efficacy are present between reprocessed and new devices. This assumption allowed excluding risk analysis for the adoption of a SUDs reprocessing policy. Differently, quotes for patient's insurance and risk management should be introduced in the model, more complex cost-effective analyses have to be performed and decision model processes should be applied [25]. To support the working hypothesis, experimental data carried out in laboratory settings were considered. These evidences did not provide outcomes directly related to patients. Anyway, it is in the opinion of clinical societies that "if the use of reprocessed devices is not associated with material risk, then there is no ethical reason why this issue must be added to the long list known to be associated with the procedure" because "relative to the overall risk of the procedure, the risk of reusing electrophysiological catheters is insignificant" [7]. In order to have a definitive answer about SUDs reuse feasibility in clinical settings, monitoring reuse efficacy and safety on patients is mandatory, and multicentric clinical studies should be designed to evidence any causal link between reprocessing and adverse outcomes. However, there are ethical constrains in enrolling patients for clinical studies designed to determine the risk associated with SUD reuse.

At the national level, the Italian Ministry of Health on April 1st 2005 released a circular warning about reprocessing procedures on SUD



(Italian Ministry of Health, DGFD.M.III/P/9773/I.I.c.r.l, Rome, 1st April 2005). Using a cautelative approach, the ministry found insufficient technical evidences to support the equivalence of new and reprocessed devices, but confirmed that no explicit ban for reprocessing activity was present in the European and national legal framework. Providing safety and efficiency parameters for reprocessed devices and a new CE mark, the reuse of reprocessed device seems therefore achievable. Further, this study adds evidence on the potential benefit on economical budget.

Conclusions

The introduction of a reprocessing policy in interventional cardiology could be a source of savings to health care systems and hospitals. Sensitivity analysis showed saving was dependent primarily on departmental workload. The maximum number of reuses sustainable by a device is a important parameter in economic assessment of a reprocessing policy and might be evaluated by comprehensive analysis of microbiological, chemical, physical and functional tests.

Since differences in the maximum number of regenerations, regeneration rate and unitary device cost are present between haemodynamics and electrophysiology devices, the economic benefit with EP catheters resulted markedly superior to that with PTCA. The proposed cost-minimization model applied to a median Italian cardiology department figured out an average budget reduction of about 39% and 12% for EP and PTCA catheters, respectively.

The calculation of potential saving revealed that a reprocessing policy in interventional cardiology could lead to save about €39,000 for a 100,000 population and the estimate of potential saving at national level could range from €19,850,000 to €24,240,000.

Competing interests

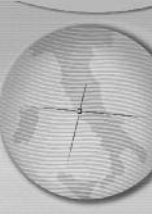
The authors declare that they have no competing interests.

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