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REPROCESSINGO OF SINGLE USE MEDICAL DEVICES FOR INTERVENTIONAL CARDIOLOGIST

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Abstract

The exercise of disposable bias is a implicit source of significant cost savings to hospitals. In particular, single- use percutaneous transluminal coronary angioplasty(PTCA) catheters and electro physiologic and ablation catheters(EP) have come a major expenditure in sanitarium budgets. We modelled the cost application of single- use catheters versus reused catheters for interventional cardiology. An algorithm was used in order to model the sanitarium costs related to the two options. The model was constructed using the factual costs at theS.Chiara General Hospital of Trento. Exercise of PTCA catheters has been associated with a implicit savings of€ 27,672(8.1) compared to single- use; with an increased number of reutilization up to 3 times of the same catheters the savings have further than doubled. Savings were advanced with electro physiologic and ablation catheters, about€ 53,191 i.e.31.8 of the costs for single- use catheter. Use of this model can be give the quantum of savings for each sanitarium with primary centers performing PTCA and electrophysiology.

Keywords : Single -use devices. Surgical instruments. Medical industry . Remanufacturing

1 INTRODUCTION

Medical Devices

Since the early period of scientific medicine the concept of medical device has been separated from medical treatment. Medical equipment including medicine represents the means by which doctors use their expertise to diagnose and treat patients diseases.

Over the last fifty years, the development of new materials (mostly polymers) and processing techniques has led to the development of medical devices, instruments, and specialized equipment For example, the spread of disposable medical equipment has changed the treatment an d improved the treatment process, while the development of minimally invasive surgical equipment has led to current and less effective changes. Recent advances in the fields of micro machining, robotics and cybernetics will enable significant advances in diagnosis and treatment and allow us to see significant changes in healthcare. Due to the continuous expansion and expansion of the production and marketing of medical devices, the law regarding this particular product has been redeveloped and updated. For comparison purposes, we publish medical dev ice definitions currently available in the United States and the European Union. The two term s have been coined recently and refer to a similar term for all tools, equipment, supplies and materials for diagnosis and treatment outside of medicine.

European Union: Medical Devices Directive MDD/93/42/EEC

Medical Treatment is the study, alteration or modification of the control of the anatomical or physiological thought process, which cannot achieve its main effect in or on the human body pharmacological, immunological or metabolic drugs, but may be a means of assisting it work.

United States: Federal Food, Drug, and Cosmetic Act Section 201(h). Medical device means any device, instrument, instrument, machine, implant, in vitro reagent or other similar or related product, including equipment, parts or substances recognized in the National Formulary or the Pharmacopoeia of the United States or any supplement. - For the diagnosis of diseases or other conditions in humans or other animals, or for the treatment, reduction or prevention of diseases,or to affect the structure or function of the bodies of humans or other animals not thro ugh the body. It is administered into the body of humans or other animals or drugs to achieve its primary purpose and does not rely on metabolism to achieve any of its primary purposes.

2 Aim of the study

This study aimed to define the fundamental steps for the assessment of a reprocessing procedure on interventional cardiac catheters labeled as single use only for a safe and efficient device reuse, the regeneration protocol should be designed to completely recover all hygienic and functional requirements provided by new devices. Available literature underlines the need to determine the correct sterilization techniques and the relevant quality control and subsequently the need for clear guidelines to define the organizational procedures and to place responsibilities in the use of reprocessed materials.

Several microbiological in vitro tests for assessing the safety of the reprocessed device will be combined with chemical and physical characterization of materials and surfaces. The efficiency of the devices will be ascertained in the specifically conceived set-up for testing functional performances. The experimental techniques applied in this work would supply parameters for an adequate assessment of the quality and safety of reprocessed devices. To that end, technical data and legal, bioethical, and economic issues are integrated to define the applicability andsuitability of SUD reprocessing.

The multidisciplinary approach wants to establish a solid scientific basement, founded on experimental evidence, to assess the safety and efficacy of a reprocessing protocol for interventional cardiology catheters.This complex approach to feasibility, suitability, safeness and effectiveness of introducing a reprocessing policy in hospitals and healthcare structures would corroborate and substantiate anyfuture clinicaltrial on the patent

3 Single-use vs. multiple-use medical devices

In the 1960s and early 1970s, most medical devices made of glass, rubber, or metal were gene rally considered reusable. This concept did not change until the 1970s, when medical devices began to be sold with single-use labels. The same decade saw major changes in medicine: Open surgery has been replace d by new minimally invasive procedures such as endovascular and laparoscopic interventions This type of surgery requires the use of new equipment that allows small, difficult surgeries to be performed through small incisions. Most equipment must have a certain impact distance from the operator's hand and have robust and efficient features.

Currently, patients and doctors are more concerned about the risk of infection, especially hunan immunodeficiency virus and hepatitis B and C. The solution to both needs are disposable devices (SUDs) made from innovative materials. The first is a polymer that is discarded afteruse by patients. Therefore, the production and use of medical waste products has increased in the last three years due to the nature of the disease, the need to improve products and reduce e apital costs.

4 SUDs Reprocessing

Although several advantages are related to the use of disposable goods medicine, singleuse devices are typically more costly on a peruse basis. SUDs are relatively expensive to purchase and their one-patient/one product nature necessitated the enlargement of hospital inventories and the resulting stream o f medical waste. These aspects have led to renewed interest in reprocessing and reuse of these devices.

Many hospitals began to explore the reprocessing and limited reuse of products intended for single use initially using on-site facilities as they have traditionally done with multiple- use metallic surgical instruments. As single- use products became more complex hospitals began to turn to third-party reprocessors to handle reprocessing needs. Recycling and reusing disposable medical devices (SUD) has gained popularity in recent years due to the rising costs of healthcare. Arece 30% of hospital admissions in the United States were for recurrent SUDs [GAO 2000]. Thesent study showed that approximately 20-mumbers may be underestimates because hospitals tend to underreport recurrent SUD use According to the US. General Accounting Office, significant cost savings can be achieved by re cycling SUDs, because home recycling can cost less than 10% of the cost of new equipment. while the cost of third-party recycling is approximately 50% of the cost of new equipment. New Percentage of Product Cost [GAO 2000]

5 The current status of reprocessing SUDs

The practice of reusing SUDs has now emerged in almost all developed countries where medical equipment and money are lacking, such as Africa, Asia, Eastern Europe, Central and Sout h America. The logic of reusing disposable equipment in these countries is simple but powerful [Quian 2002]. The huge demand for minimally invasive procedures leads to waste of materials and ethical is sues, otherwise patients with sufficient resources will benefit from this new system because the government cannot use technology wasted by the poor [Rufi 1995]. Evidence for the safety and effectiveness of SUD reuse is indirect, Most studies conducted in clinical settings examine surrogate outcomes such as medical device integrity and contamination after replication.

Some studies have addressed direct effects on patients. The lack of data on contamination and equipment loss makes it difficult to establish the relationship between patient exposure to contaminated medical equipment and poor patient outcomes. Existing studies are contradictory. Many studies have concluded that with repeatable procedures and stringent standards, SUD reuse can be safe and effective. Others advise against recycling and reuse because the testing equipment is not clean or sterile and variation in the equipment used is obvious. Conflicting results have been reported for cardiac devices [Bloom et al. 1997 Blomstrom-Lundqvist 1998, Azyman veark. 2002, Brown veark. 2001, Browne veark 1997 Chaufour v e ark. 1999 Nar2001 Luijt veark. 2001 Ma veark. 2003] Anestezikler [Daggan ve ark. 1999. Lipp et al.2000] Airway devices [Vezina et al. 2001] thiabpov tseg mourning trocars [Chan et al. 2000Gundodu et al. 1998 Ulualp et al. 2000 Ross et al. 2002]. With proper design, reuse and reuse of sphincterotomy equipment is considered safe and effective [Kozarek et al., 201 7]. 1997 Kozarak et al. 1999]. Studies evaluating biopsy forceps have consistently shown that repeat procedures are not followed due to unhygienic or unhygienic equipment (Hambric 20 01,Kinney et al 2001. 2002]

6 Reusing SUDs in interventional cardiology

One of the few areas being re-implemented today for both safety and cost effectiveness is cardiovascular intervention [Lindsay et al 2017] 2001 Bourassa 196CETSQ 1994] Radiofrequency catheter ablation and percutaneous transluminal coonary angioplasty have become important treatments for patients with various cardiac arrhythmias and coronary artery disease. Although radiofrequency ablation and percutaneous coronary dilation are effective and noninvasive, the procedures are expensive. The majority of the surgical cost is represented by the cost of the multi-electrode diagnostic and ablation electrophysiology catheter (EP) or coronary angioplasty balloon catheter (PTCA). Currently, both catheter types are licensed and marketed for single use. Similar to other SUDs in the past, as the demand for disposable products increased, hospital a administrator's and doctors began to realize that some products presented as Waste were the same products that had previously been used and could be recycled. A major cardiac catheterization company announced in a letter from the manufacturer that the manufacturing process for our braided polyester intracardiac electrodes has not changed. These electrodes are made of t he same material and look the same as before" [CCHR 2000]. Informally, the practice of repr ogramming SUDs evolved to reduce costs and equipment. This practice involves important e quipment such as electrophysiology and PTCA catheters, adding complexity to the decontamination and sterilization process increases. The role of the hospital team includes doctors, nurses, specialists, risk managers, hospital lawyers and specialists. Rehabilitation was developed to monitor the safety of the rehabilitation process. Many hospital leaders set best practice: some hospitals use a third-party system and others abandon the practice altogether. In the current context, advances in materials and technology have led to the maximum production and introduction of high- quality electronic products and equipment that provide more treatments but at the expense of more interventions. Given the lack of financial resources in global healthcare, the issue of rese and reproducibility in areas such as cardiovascular interventions has attracted significant attention and has become a popular topic for Avery.

7 The clinical knowledge of Reprocessing SUDs in interventional cardiology

Questions about the safety and effectiveness of reusing catheters focus on the risk of patient to patient transmission and the design and efficiency of catheters relative to the frequency of use in different patients. Although reproducible procedures are appropriate for most catheter models, objective measurements of catheter integrity have not been adequately documented. While some catheters experience little stress during the procedure, other catheters may experience significant changes in deflection or maneuverability. Luminal cleansing, antibiotics, and patency are important an d require prompt and good procedures, especially for removal of iodinated contrast medium f rom the balloon lumen of the PTCA catheter. Additionally, healing time can affect the material used in catheter design and affect performance.

Electrophysiology catheter

A few published studies have evaluated the safety of reusing catheters for electrophysiological studies and have addressed some of these issues. O'Donoghue and Platiasurveyed 12 medic al centers to determine the safety of reusing catheters [O'Donogue and Platia 1988] The inci dence of infection related to atotal of 14640 electrophysiological studies involving 48075 cathater uses wasreported. At three centerscatheters were automatically discarded after a singleuse

These centers carried out 1245 electrophysiological studies using 3125 catheters. At nine othercenters, catheters are sterilized for reuse. 13,395 studies using 44,950 catheters in thereusegroup. The incidence of bacteremia (bleeding) and skin infection at the catheter site was0.03% and 0.03%, respectively, in the control group and 0.018% and 0.002%, respectively, in the reuse group. The authors concluded that sterilization and reuse of the catheters used in this study did not increase the risk of infection. They argue that these catheters are strong enough to be reused more than five times, and that disposable catheters seem like an unnecessary and expensive policy.

Dunnigan et al. Similar results were obtained in a prospective study evaluating catheter reuse over 5 years, in which 178 catheters were used 1576 times in 847 electrophysiology studies [Dunnigan et al., 2017] 1987] Keep detailed records of catheter testing and use. There were n o problems during the work. All reused catheters functioned for cardiac pacing and recording of cardiac electrical signals.

Angioplasty catheter

Similar to EP catheters, few clinical studies have been conducted to evaluate the safety and effictiveness of reprocessed catheters in angioplasty, and only one double-blind clinical study is available in the English-language literature. The first important and controversial study was conducted by Plante et al. in 1994. To determine the effectiveness, safety, and costs associated with reusing angioplasty catheters and compare these results with those from existing centers in Canada using a reuse strategy [Plante et al, 2017] 1994] a In a prospective study, information was collected after each angioplasty procedure and within 10 months before the patient was discharged. A total o f 693 patients were registered in both centers. Clinical and wound characteristics were similar except that the incidence of unstable angina was higher at reuse sites. The angiographic success rate was the same between the two centers (88%), but repeated techniques were associated with a higher rate of side effects, longer operating time, and the use of increasingly different equipment, especially non- treating bacteria. Enter from the beginning of the bubble and the following patients Unstable angina.

As Rozeman and colleagues note, whether these differences are related to differences in recovery strategies or patients cannot be determined from this analysis. 1994] a Mak and colleag ues reevaluated clinical data from Plante's study using a multivariate design to control for differences between patients in the two clinics and to determine whether catheter reuse was associated with increased complications [Mak et al. 1996] a Reanalysis shows balloon catheter use is not associated with increased hospitalizations. In contrast, other risk factors, such as angina severity and pain morphology, have been shown to bepredictors of poor hospital outcomes. Similarly, when adverse events were analyzed in patients with stable angina, no differences were found between repeated and single use. However, a uthors encourage the development of multicentric randomised trials to further assess the safety and the cost/benefit ratio of reuse strategy, a study conducted in the United States by Browne andco-workers aimed to evaluate the performance of angioplasty catheters, restored under a strict re manufacturing process [Browne et al. 1997]

8 Pakeging

•To package consists of one or two layers of sterile bags selected according to the Sterilization process to be performed To ensure sterility within the expiration date the packaging process must be valid and effective.

•Pakeging material must provide adequate protection for transportation and storage.Additional packaging should be provided after Sterilization to maintain device functionality.protect sensitive areas and control the type of storage and transportation the device will endure.

•Not all medical equipment should be recycled before use

9 Lebeling

•All medical devices processed must be labelled completely and in detail to allow complete product tracking.

•The number and type of repetitive operations should be eliminated.

• Factors to consider when determining the expiration date include product modification, storage environmen t, and type of packaging used.

10 Sterilization

• Through cleaning of medical equipment is prerequisite for safety and Sterility.

• Sterilization cleaning performed using valid and effective methods that have been checked for compatibility with medical devices (material and design).

• The condition, packaging, and frequent loading and adjustment of sterile product are also important for Sterilization.

• Sterilization from commercial product and disinfectants should be reduced.

11 Conclusion

This study provides new information on the safety and suitability of SUDs for reuse in cardiovascular interventions. After completing various clinical trials, the material modification achieved significant results such as bioload efficiency, sterility and pyrogen load. It continues to make comparisons between legal issues and provides cost-effectiveness models for cost- saving measures. Since this study is conducted in the laboratory, it does not provide direct results to patients. Taking a preventive approach, new sterile and reproducible devices are tested after initial treatment in patients and reused after being simulated in vitro. No rehabilitation e quipment is reused for the patient. The study provides experimental data from evaluation of more than 650 devices, including E P and PTCA catheters from major manufacturers around the world. More than 2000 tests were performed on the equipment, with EP and PTCA catheters reprocessed 14 and 4 times, respectively. When reworking a new device or category of devices, a similar effort should be made in testing and evaluating ideas. All materials that have not been previously remanufactured must be inspected for the first time using high-quality non-destructive and non-destructive techniques. This in-depth and comprehensive evaluation of products and equipment is a prerequisite for anaccurate and complete evaluation of the post-production process. Moreover, this approach solves the problem of determining a non-destructive and operational process that guarantees the quality of recycled materials. Once the correct construction process has been determined and optimization is required through continuous reporting, only non- destructive testing can be performed. It is part of the daily job. The best and safest reprocessi ng option, both in terms of hygiene, will be a unique and permanent solution that provides the entire treatment, from collection of products used in the cardiac department to sterilization.

While this new structure provides cleanliness, it requires infrastructure, trained personnel and special knowledge.

These special considerations, in addition to the law regarding the need for qualification and approval of the charity and the entire recovery process, agree that this practice is carried out on ly in hospitals and clinics with a high level of activity. However, increasingly stringent standards required by law and regulatory agencies (such as the US. Food and Drug Enforcement Agency) highlight the need for revalidation procedures from the original manufacturer with the same problems. These conditions may be difficult to meet for small and medium- sized hospitals, but may be feasible for qualified hospitals or third-party providers. Considering the complexity of the recycling protocol, organizational issues,margins, and legal requirements for qualification and certification of each aspect of the recycling process, "in- house" recycling is not recommended. To obtain a clear answer about the feasibility of SUD exercise in the clinical setting, the effectiveness and safety of SUD exercise must be addressed and more clinics must be designed to support the link between recycling and adverse problem.

12 Reference

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