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REVIEW

Reuse of Electrode Catheters and Pacemakers

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ABSTRACT

Reuse of electrophysiology catheters and pacemaker devices has been practiced safely in several countries with significant cost-savings. Data from the literature evaluating clinical end-points, device-related complications, such as infections, and mechanical performance, suggest that this is a safe practice with no increased risk of complications or mortality. However, there remain practical, legal and ethical concerns which need to be addressed before a more widespread use of such practice is adopted. Also, protocols for validation of cleaning and sterilization, and estimations of the potential risks of infective agent transmission need to be more rigorous.

KEY WORDS: *electrode catheters, pacemakers, device reuse, re-sterilization process, device infection*

INTRODUCTION

The use of electrophysiological procedures has increased tremendously during the past 2 decades. Data from the world survey of cardiac pacemakers and implantable cardioverter defibrillators (ICD) show that new device implants show a steady increase from 1997 to 2001.[1] This increase is much more pronounced with regard to new ICD implantations and implies a corresponding increase in electrophysiological studies.

Reuse of medical devices has long background, dating back to the 1970's.[2-4] Such practice has declined during the past several years, due to the increasing alertness for the possibility of transmission of infectious diseases, such as hepatitis B, human immunodeficiency virus (HIV) and Creuzfeldt-Jacobs disease. However, due to the realization that the health resources are finite, the issue of reusing medical devices remains important. This review will summarize an up-date on the subject.

REFURBISHMENT OF CATHETERS WITH A LUMEN AND LUMEN-LESS ELECTRODES

For many years, many institutions have routinely resterilized and reused catheters used in the catheterization laboratory. The catheters that can be resterilized and reused can be divided into two broad categories: (a) catheters with a lumen and (b) lumen-less catheters. The former include catheters used for right heart catheterization, diagnostic coronary angiography and interventional angioplasty procedures. With the current cleaning and sterilization techniques, these catheters are very difficult to be properly and adequately cleaned and, thus, refurbishment of these materials should not be practiced.[4] This review will focus on reuse of lumen-less catheters, i.e. diagnostic electrophysiology catheters and ablation electrophysiology electrode-catheters.[5-8]

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Review of the history of national control on reuse in Europe and USA

Various European countries have practiced different approaches. In Finland, under the Hospital Supplies Act of April 1985, industrially sterilized medical devices were labeled as HsterileΘ and as Huse once onlyΘ. In France, the Ministry of Health took a clear policy for Hno reuseΘ of sterile devices and a circular to this effect was issued in December 1994. In contrast, Sweden adopted a policy favoring reuse. An intermediate position was taken by the German and British Health authorities. In Germany, the German drug laws regulated sterile medical devices and the German Pharmacopoeia contained monographs on sterilization methods and sterility testing. The British Ministry of Health issued a HDevices BulletinΘ about reprocessing and reuse of single-use devices, drawing attention to the possible hazards and indicating that the liability of such practice falls on the hospital concerned.

In June 1998 the European Commission has issued a "Medical Devices Directive-MMD", which is mandatory in its application to all medical devices in the European Union market. The Directive does not address the question of whether products should be for single use, reusable or reprocessable, but leaves the responsibility with the manufacturer to determine this and to label the products accordingly. The MDD states that the label must bear the following particulars: (a) the word "*sterile*" where appropriate, and (b) the indication "*for single use only*" where appropriate. If the device is reusable, information on the appropriate process to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization and any restriction on the number of uses. Therefore, if a device is labeled as "*sterile*" and "*single use only*", the manufacturer is responsible for the integrity of that device for the first use only. If an institution reuses that device in a way not in accordance with the labeling and instructions for use (if any), then the institution is substituting itself for the manufacturer and should comply with the MDD. The hospital and/or the physician would be liable for all and any consequences arising from such misuse. However, since the manufacturers have financial conflicts, allocating the responsibilities of device reuse to the industry, clearly does not address the problem as a whole.

What happens on the other side of the Atlantic? A survey of 12 major medical centers in the United States in 1988 found that 9 of 12 centers reused diagnostic electrophysiology catheters.[2] With increasing cost constrains, it is likely that many more laboratories in the US have considered reuse.

The current regulations in the USA are in effect from November 11, 1977 and are described in the Compliance Policy Guide (CPG).[9] This CPG states that hospitals that reprocess devices that are intended for single use assume full liability and responsibility for their reprocessing actions and should ensure that the products are adequately cleaned and sterilized, and that device safety, effectiveness and quality are maintained. On May 5-6, 1999, the FDA and the Association for the Advancement of Medical Instrumentation (AAMI) cosponsored a conference at Crystal City, Virginia on the practice of reprocessing and reusing medical devices. After that meeting, the FDA made a commitment to reevaluate its position on the reuse of medical devises. The FDA's strategy will emerge, among others, from (a) information provided by the device manufacturers on risks associated with reuse of their devices, (b) exploration of recognized consensus standards that can be applied to reprocessing devices intended for single use (e.g. will verify and validate cleaning, disinfection and/or sterilization of devices), as well as from the exploration of the development of additional consensus standards to address the safety, effectiveness and performance of reprocessed devices. The FDA will consider developing a research program on reuse of medical devices and explore avenues to publish and disseminate research and other information on reuse.

REQUIREMENTS OF ELECTRODE-CATHETER REUSE

An electrode-catheter must fulfill the following requirements, in order to be safely reused:

1. It must be sterile.
2) It must be free of any remnants of cleaning materials, since these materials can be pyrogens or may cause hemolysis.
3) The material must be intact.
4) The catheter must maintain its original functional capacity.

RISK OF INFECTION

The risk of infection is probably of the greatest general concern. In a study of reused electrode catheters (USCI), surveillance cultures performed on 58 reused catheters failed to show any bacterial growth and biological indicators revealed adequate sterilization procedures.[10] In the 1988 USA survey,[2] the prevalence of bacteremia was 0.03% in the single use group and 0.018% in the reuse group; the prevalence of superficial skin infections at the site of catheter insertion was 0.03% in the single use group versus 0.002% in the reuse group. None of these differences were statistically different. It can be concluded that electrode catheters can be made safe for reuse with current cleaning and disinfecting methods.

FUNCTIONAL INTEGRITY

Dunnigan et al[10] studied diagnostic electrode-catheters used an average of 8 times. The testing protocol included (a) visual inspection for cracks and bends (b) manual flexion and (c) impedance measurements. Of the 178 catheters studied, 122 (68.5%) were deemed acceptable for reuse, while 32 were rejected due an insulation defect and 24 were rejected due to impedance increase.

Avitall et al[11] investigated the reuse of ablation catheters without a thermistor, used an average of 5 times approxi-

mately. Of the 69 ablation catheters examined, 33 (48%) were found flawless, while 17 were rejected because of insulation defect, 13 because of loss of deflection and 6 due to electrical discontinuation. Recently, a study from Sweden,[12] tested the performance of ablation electrode catheters with a thermistor. Of the 74 catheters used an average of 7.6 times, 33 (44.5%) were found functionally intact, while 14 showed a thermistor defect, 17 were rejected because of loss of deflection and 7 due to electrical discontinuation.

Thus, it appears that approximately 70% of diagnostic electrode catheters can be safely reused an average of 8 times, while 40% to 50% of ablation catheters can be reused approximately 5 to 7 times.

COST SAVINGS

It is conceivable that the cost savings of reusing lumenless catheters in the electrophysiology laboratory are enormous. It is estimated that the cost of an electrophysiology diagnostic study can be reduced by approximately 85% and the cost of an ablation procedure by approximately 60%. This would be of particular benefit for countries with less economic capacity, like Greece.

REUSE OF LUMENLESS CATHETERS: SUMMARY

The reuse of diagnostic and ablation electrode catheters in the electrophysiology laboratory appears feasible and safe and significantly reduces the cost of a diagnostic electrophysiology study or an ablation procedure. However, further clinical data are necessary. These data should address the effect of sterilization techniques on Creuzfeldt-Jacobs and other prion diseases. In addition, with the advent of newer ablation procedures, such as ablation of atrial fibrillation foci in the pulmonary veins, more HelegantΘ performance of the ablation electrode catheters may be expected. More data on these issues are awaited.

REUSE OF PACEMAKERS

In many countries the reuse of pacemakers has been practiced for decades. Sweden has a long tradition of reusing pacemakers. By Swedish law, all implanted pacemakers and defibrillators must be explanted after death to avoid explosion of the device during cremation. Explantation of a pacemaker is not defined as an autopsy and can be performed by any physician or technician without permission from the patient's relatives. In other countries with a tradition of reusing pacemakers, such as Canada and the Netherlands, the patient must consent to donating his/her pacemaker for possible reuse. After death, consent for explantation must be given by the relatives.

When examining the issue of reusing pacemakers, one should provide answers to the following questions:

1. Is it safe?
2. Is it legal?
3. Is it cost-effective?
4. Is it accepted by the patients?
5. Is it ethical?

SAFETY ISSUES

Studies evaluating the safety of pacemaker reuse originate mainly from Sweden, from Canada and from the Netherlands. However, studies on this matter are also available from other countries, such as the USA, Italy and India. With the appropriate selection protocol (i.e. implanting reused pacemakers only at the beginning of their battery life) and carefully selecting patients to receive a reused pacemaker (i.e. mostly elderly patients), the percentage of generator replacement rate does not appear significantly different, compared to implantations of a new unit.[13,14]

The results of seven studies comparing the complication rates (including infections and technical malfunctions) of reused pacemaker implants versus those of new units showed that the complication rates were comparable.

LEGAL ISSUES

To date, there is no unanimous legislation among the members of the European Union. The first legal issue that needs to be addressed is whose property is the pacemaker. In Sweden, the pacemaker is the property of the implanting center that originally bought it. The implanting center has the right to retrieve explanted pacemakers. In other countries reusing pacemakers, such as Canada and the Netherlands, the pacemaker, once implanted, is the property of the patient. Furthermore, written consent from the patient elected suitable for the implantation of a reused pacemaker must be obtained. In Sweden and Norway consent from the patient, who is a candidate to receive a reused unit, is not mandatory and this issue is currently under debate. Besides the need for a consent form, other legal issues, that need to be addressed, are (a) whether a new HCE markΘ is required for the reused pacemaker and (b) liability issues.

COST SAVINGS

Reusing pacemakers is anticipated to reduce costs significantly. Taking into account that approximately 40% to 50% of new implants are dual-chamber pacemakers and taking a fairly conservative approach that only 20% of pacemakers are suitable for reuse, the estimated annual savings for Greece are at the range of 3.6 million Euros.

PATIENT ACCEPTANCE

Patient acceptance rates have not been extensively studied. Acceptance rates may vary in different countries, depending on cultural, religious and educational parameters. Studies in Canada[15] and in the Netherlands[16] indicate that a very high proportion of patients, at the range of 80% to 90%, consented to a reused pacemaker.

ETHICAL ISSUES

Ethics reflect the aspirations of a society emerging from a social consciousness and, as such, are bound to vary with time and place. With the development of society, older ethical concepts are being challenged and newer concepts ensue. Medical and scientific advances on one hand and the constraining costs on the other, are raising new questions and dilemmas, to which there are as yet no clear answers.

Several independent parties, such as politicians, government bureaucrats, hospital administrators, insurance companies are trying to "solve" the problem of cost-constraints, not always to the patients' benefit. It is my view that the physician, who is the final link in the long chain of the health care system, should play an active role in the decision-making process. Reuse of medical devices represents a major challenge in this regard.[17-19] There is much evidence to suggest that some medical devices, especially those used in the electrophysiology laboratory can be reused safely and that the risk is negligible. However, more evidence is needed. Of paramount importance is the fact that the reuse of devices can not only reduce costs significantly, but make therapies accessible to patients for whom these were not previously a possibility.

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