Reuse of cardiac catheters: a review

Reprocessamento de cateteres cardíacos: uma revisão

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Abstract

Hemodynamic catheters are widely reused mainly in developing countries where the cost of new devices is very high. Scientific publications point to an absence of validated cleaning and sterilization processes and there is a consensus that reusing these devices causes physical, chemical and functional damage. So what is the evidence related to the reuse of this kind of catheter? The objective of this study is to identify scientific evidence related to the effects of reprocessing. A search for publications in English, Portuguese and Spanish was performed in Medline/Pubmed and LILACS using Medical Subject Headings (MeSH) terms and free terms without stipulating restraints on time. In total 21 papers were analyzed. It was found that there is commonly damage to the surface polymers as identified by electronic microscopy. Failure in the cleaning and sterilization processes was identified by the presence of debris and microorganisms at the end of the procedure. The results of this study are very important when choosing to reuse hemodynamic catheters.

Descriptors: Balloon dilatation, instrumentation. Equipment reuse. Cross infection. Sterilization.

Resumo

Os cateteres de hemodinâmica são amplamente reprocessados, principalmente em países em desenvolvimento, onde os custos da utilização desses insumos são altos. A literatura científica aponta a ausência de processos validados de limpeza e esterilização e é unânime a afirmação de que o reprocessamento provoca alterações na integridade física, química e funcional desses materiais. Dentro desse contexto, questionam-se quais as evidências publicadas sobre os danos provocados pelo reprocessamento dos cateteres de hemodinâmica? O objetivo é identificar as evidências científicas em relação aos efeitos do reprocessamento dos cateteres, do ponto de vista mecânico, físico, químico e biológico. Foi realizada uma pesquisa na base de dados Medline/Pubmed e LILACS, sem restrições de tempo, em inglês, português e espanhol, usando vocabulário controlado e não-controlado. Um total de 21 publicações foi analisado. Os artigos analisados apontam a ocorrência de alterações físicas, mecânicas e químicas. A limpeza e a esterilização dos cateteres não foi eficiente, tendo sido identificada a presença de debris e microrganismos ao final do processo. Vale ressaltar a importância dessas informações para a tomada de decisão em relação ao reprocessamento e reuso de cateteres de hemodinâmica.

Descritores: Dilatação com balão, instrumentação. Reutilização de equipamento. Infecção hospitalar. Esterilização.

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INTRODUCTION

Paradoxally, the increase in the technological development in healthcare has been accompanied by a concern about the relationship of adverse events and cost of treatment. According to Merrit et al. [1], over the last 25 years, medical practice has been modified. Initially articles were cleaned, sterilized and reused but today the medical articles are disposable. Currently, the practice of reuse of disposable medical products implicates the cleaning of these materials. The practice of reuse is common in various countries around the world, in particular developing countries where the costs are an important worry [2].

There are three concerns related to safety with the reuse of disposable medical articles: the efficiency of cleaning and sterilization, the effects of cleaning, disinfection and sterilization on the chemical, physical and mechanical integrity of the articles and the safety of healthcare professionals who recycle these articles [1]. Moreover, this practice has caused a great preoccupation in relation to the additional risks for patients due to contamination by infectious agents, toxic substances, other possible noxious substances and even, the possibility of incompatibility or breakage of the medical products [2].

Cardiovascular diseases are the most important cause of morbidity and mortality in both developed and developing countries. It has been estimated that more than one million coronary artery interventions are performed worldwide, with a high cost to society. The most common procedures are angiography and angioplasty of the coronary arteries. One strategy to control the cost of angiographic and balloon catheters is by their reuse.

Heart catheters are considered complex articles as they have a long and narrow lumen and balloons that might make reprocessing difficult (cleaning, remounting and sterilization). They must be submitted to low-temperature sterilization processes as they are used within the blood flow which is considered a sterile topography and because of sensitivity to high temperatures. There are some questions to be answered by the literature such as: What is the evidence on the recycling of cardiac catheters? What is the efficacy of recycling and what are the risks of infectious diseases and pyrogenic reactions after the recycling of heart catheters?

The objective of this review is to describe the state of the art on the reuse of heart catheters in respect to the effect of reprocessing on the physical, mechanical and functional integrity of these catheters, as well as the risks for the patients with the reuse of catheters.

METHOD

A literature review without time restraints in English, Spanish and Portuguese was performed of the Latin American and Caribbean Health Sciences Database (LILACS). In the search of related articles, controlled vocabulary in Portuguese and Spanish was utilized – describers in Health Sciences (DeCS) – as follows: endotoxins OR Pyrogenic OR Angioplasty OR "heart catheterism" OR "balloon catheter" OR "balloon dilation"; without publications on the theme being detected. In the Medline/PubMed database, controlled vocabulary for indexed articles - *Medical Subject Headings* (MeSH) terms - were employed as follows: "Endotoxins" OR "Pyrogens" AND "Heart Catheterization" OR "Balloon Dilatation" OR "Angioplasty" OR "Angioplasty, Balloon" AND "Equipment Reuse". In this search, 34 articles were identified. On applying free vocabulary: Endotoxins OR Pyrogens OR Pyrogenic AND "Heart Catheterization" OR "Balloon Dilatation" OR "Angioplasty" OR "Angioplasty, Balloon" OR "cardiac catheter" AND "Reuse", another 9 articles were included giving a total of 43 articles.

From this list, 34 articles were excluded as 12 were not related to the subject, 11 were related to clinical cardiac responses, 9 were editorials and two review articles. To achieve the proposed objective another 12 articles were identified in a free search leading from the remaining articles. Hence, 21 articles were included in this review. These publications were categorized as follows: a) physical and mechanical data (5 articles); b) efficacy of cleaning and sterilization (3 articles); c) pyrogenic reactions (7 articles) and d) infectious diseases (3 articles). Three articles were included in both the physical and mechanical damage and the efficacy of cleaning and sterilization categories.

RESULTS

In an evaluation of the literature in respect to the mechanical and physical damage detected in hemodynamic catheters after recycling, it was noted that there is a great diversity of processes used to clean catheters. In the studies presented in Table 1, Anderson et al. [4] demonstrated at a magnification of 200 times, that the external surface of the catheter presented an undulating aspect and at a magnification of 670 times, the presence of scratches, depressions and protrusions were observed. The same aspect was observed on the internal surface of the catheter. Metallic guide-wires (magnification of 1520 times) were rough and there were sequestrated particles between the spirals suggesting remains of dried blood. The Teflon guides (magnification of 210 times) presented with irregular protrusions and cracks. Bourassa et al. [5] compared the alterations found in polyurethane and polyethylene catheters. The polyurethane catheters presented with more undulations and with diffuse irregularities that at a magnification of 300 times, presented an aspect of oatmeal and when observed at a magnification of 3000 times,

numerous crests and depressions and, in some areas, large cracks, holes and gaps were observed.

The polyethylene catheters also presented with an undulating roughness with crests and depressions and in some areas fibers were seen that crossed over the crests (magnification of 300 times).

Table 1. Experimental studies evaluating mechanical and physical changes

Authors	Materials	Methods	Cleaning	Sterilization
Anderson et al., 1974, USA [4]	• Teflon, polyethylene and polyurethane catheters • Stainless steel spiral guide-wires and Teflon covered guide-wires	• Electronic microscopy (ETEC), acceleration: 10kV, Polaroid film PN/55	• Immersion in detergicide (24 hours) + rinse in tap water OR • Detergicide (30 min) + Ultrasound in distilled water OR • Hydrogen Peroxide (24 hours) + rinse in tap water	• Autoclave - not described
Bourassa et al., 1976, Canada [5]	• Teflon covered polyurethane catheters • Polyethylene guide-wires covered with spiral stainless steel	• Electronic microscopy (JEOL/JJM-50A), magnifications of 100 to 30000 times	• Mixture of 4% glutaraldehyde and 4% sulphoxide dimethyl	• Was not described
Mussivand et al.., 1995, Canada [6]	• Balloon catheters (2.0 mm; 2.5 mm and 3.0 mm)	• Electronic microscopy (DSM940A), magnifications of 50 to 1000 times. • Bursting test using nitrogen • Measurement of balloon diameter	• Injection of distilled water in the catheter (5x) + Immersion in Formal (10 min) + rinse and immersion in Aseptzyme (5 min) + sonication (10 min) + drying under negative pressure with syringe (10min) + 0.2% glutaraldehyde (10 min) + drying (12 hours)	• Ethylene oxide
Brown et al., 2001, USA [7]	• 650 balloon catheters 30 different models from several manufacturers 2.5 mm and 3.0 mm	• Complacency test (diameter x applied pressure) • Experimental sliding test	• Immersion and jets with 10% sodium hypochlorite and washing with enzymatic detergent. detergent + repeated jets of tap water	• 10% ethylene oxide, 90% hydrochlorofluorocarbon at 54oC for 130 min
Unverdorben et al., 2003, Germany [3]	• 40 balloon catheters from two different manufacturers 1.5 mm and 3.0 mm	• Compression test and tensile force • Test of crossing profile • Measurement of nominal diameter • Bursting pressure test	• Laurilpropylenodiamine and dodecilbipropilentriamine (Korsolex) + desalinization + drying with air	• Ethylene oxide (7:15h)

Magnification of 3000 times showed plaques of protruding material at the tops of the crests. In the two types of catheters, blood clots were found adhered to the internal and external surfaces. In relation to the mechanical integrity, Mussivand et al. [6] detected that the pressure to burst the balloon of catheters was between 13.6 and 21.1 atmospheres and that the smaller balloon catheters (2.0 and 2.5 mm) have a burst pressure greater than the 3-mm balloons. In this study, by means of electronic microscopy, it was possible to see particles on the burst balloons, probably resulting from clinical use or handling during recycling. These particles were not detected in new catheters, whose surfaces are polished, whilst the surfaces of used catheters present with cracks, grooves and depressions. Also, fragments suggestive of cellular remains or proteic deposits were observed on the surface of catheters.

More recently (still in Table 1) Brown et al. [7] demonstrated that the balloons become more complacent after simulations of reuse and re-sterilization using ethylene oxide and suggest that this effect tends to be cumulative according to the number of times they are reused. In respect to the bursting pressure, some balloons burst at a higher pressure than originally determined. In general, the authors concluded that the alterations detected are model-specific. Unverdorben et al. [3] also tested the mechanical and functional integrity of balloon catheters. The crossing profile suffered a statistically significant increase in all the balloons tested compared to new balloons. The nominal diameters presented with a great variability, with in general a reduction in the diameter of the balloons. The reduction in diameter was inversely proportional to the number of times they were reused. In respect to the bursting pressure of 1.5-mm balloons, the values obtained were higher than the new balloons and for the 3.0-mm balloons, the values were smaller than for new catheters.

In Table 2, the articles that mainly evaluated the occurrence of physical and mechanical damage are summarized together with the efficacy of sterilization.

Table 2. Experimental studies evaluating mechanical and physical changes and the efficacy of cleaning and sterilization

Authors	Materials	Methods	Cleaning	Sterilization
Grimandi et al., 1996, France [8]	• 70 balloon catheters of 4 manufacturers between 2.0 mm and 3.5 mm	• Electronic microscopy (JSM6400) under magnifications between 100 and 3000 times • Sterility test to detect pyrogens • Bursting pressure test • Measurement of the diameter of the balloon • Measurement of the resistance to fractures	• Injection of tap water + immersion in Hexanios G (15 min) + immersion in detergent in an ultra-sonic chamber + rinse in tap water (10 min) + final rinse with sterilized water + dried with syringe and gauze	• Irradiation by gamma rays: 25Kgray or 35Kgray
Bryce et al., 1997, Canada [9]	• Balloon catheters of 2 manufacturers, 2.5mm and 3.5mm	• Inculcation of catheters with vegetative bacteria • Sterility test • Balloon distenibility test and measurement of filling and emptying times of balloon	• Immersion in "CATHx solution". An equipment that performs peracetic acid jets (1h) automatically	• Peracetic acid
Karov et al., 2000, Canada [10]	• Balloon catheters from a single manufacturer 3.0 mm reused different number of times	• Electronic microscopy (S-2250N) under magnification of 50 and 3000 times) • Sterility test	• External: rinse in warm water + immersion in Aseptzyme (5-10 min) + repeated washings + drying with compressed air • Internal: 20mL syringe with 5mL water + over night drying, when necessary, vacuum drying at 37oC	• Ethylene dioxide

Table 3.   Experimental studies evaluating the efficacy of cleaning and sterilization

Authors	Materials	Methods	Cleaning	Sterilization
Ravin & Koehler, 1977, USA [11]	• 10 polyethylene angiography catheters • 6 guide-wires covered with Teflon or not	• Inculcation with vegetative and sporulated bacteria • Sterility test	• Catheters: jet of water or heparinized saline + immersion in detergent (3-5 min) + rinsed in pressurized tap water (30-40 min) + drying with compressed air. • Guide-wires: immersion in 3% hydrogen peroxide (3-4 min) + rinse in hot water + cleaning with detergent + rinse in hot water + drying	• Ethylene oxide (180 minutes at 85oF)
Penna & Ferraz, 2001, Brazil [12]	• 54 angiography catheters from single manufacturer	• Inoculation of Bacillus subtilis • Quantification of colonies after cleaning	• Washing with 1000 mL filtered tap water (5 min) + immersion in hydrogen peroxide [1.5 ± 0.5%] (5 min) + rinse with filtered tap water (5 min) + Immersion in enzymatic detergent (5 min) + rinse with filtered tap water + rinse with 100 mL distilled sterilized water + drying with compressed air (10 min)	• Sterrad 100 (efficacy not tested)
Luijt et al, 2001, USA [2]	• 20 5F balloon catheters with different sized balloons	• Inoculation of enterovirus and adenovirus • Detection of virus by means of Polymerase chain reaction	• Jet of 25 mL of apyrogenic sterilized water + immersion in detergent (15 min) + Jet of 25 mL of apyrogenic sterilized water + drying + immersion in 2.2% glutaraldehyde + Jet of 25 mL of apyrogenic sterilized water + drying	• Not described

Grimandi et al. [8] demonstrated the efficacy of sterilization utilizing gamma irradiation at 35 Kgray, however, the presence of endotoxins was detected at the end of the process. At electronic microscopy, the surfaces of both new and recycled catheters were rough and there were deposits in different forms. This finding was maintained after re-sterilization, though, some catheters lost part of the polymeric lining of the surface. Numerous cellular elements were observed on the surface of the spirals of the guide-catheters.

Traces of dried fluids containing cellular elements, whose size and morphology were suggestive of red blood cells, were detected on the surface of some balloons. The diameters of the balloons used presented values very similar to the original values in spite of being visually deformed. The bursting pressure obtained was greater than recommended by their manufacturers. Some catheters presented a 30% reduction of the resistance to fracture after sterilization. Bryce et al. [9] used peracetic acid to sterilize

angioplasty catheters and none of the 349 cultures were positive. After five cycles in peracetic acid, one balloon burst immediately after exposure to an 8-bar pressure and the others burst between 1 to 4 minutes of exposure to pressures between 12 and 20 bars. Karov et al. [10] by electronic microscopy, identified that catheters used 4, 10 and 15 times presented with many large particles and fibers. On the surface of the catheters, lengthwise protuberances, cracks, scratches and holes were detected. Some balloons became wrinkled and others appeared to have an additional covering layer. A spectrometer was utilized which detected the presence of silicone residue on the balloons. These authors did not comment on the tests of sterility.

Articles exclusively related to the evaluation of the efficacy of cleaning and sterilization of catheters are presented in Table 3. Ravin & Koehler [11] demonstrated the absence of microbial growth in cultures obtained from angiographic catheters submitted to sterilization in ethylene oxide. Penna & Ferraz [12] detected a reduction of 50% of the microbial load of *B. subtilis* initially inoculated on catheters which were subsequently extensively cleaned. However, a sterility test was not performed. A study by Luijt et al. [2] evaluated the efficacy of 2.2% glutaraldehyde after intentional contamination with a virus. Removal of particles of adenovirus was possible but particles of enterovirus continued.

Endotoxins are biologically active substances that can cause simple clinical symptoms such as fever, trembling and leukocytosis and even irreversible shock. The diagnosis of pyrogenic shock is based on the clinical examination and epidemiological information such as exposure to a source known to be a bacterial pyrogen [13].

Lee et al. [13] published eight cases of pyrogenic reactions that occurred two or three hours after the initiation of heart catheterism. These authors reviewed the recycling of catheters and substituted the use of tap water for pyrogen-free water. Similar findings were published by Reyes et al. [14] in Detroit, USA where 25 cases of tremor and fever were identified after heart catheterism. At this time, the cleaning process was also reviewed and 3500 colony forming units (CFU) *A. calcoaceticus* and 1000 CFU *Pseudomonas spp* were found in the distilled water prepared inside the hospital and utilized for the cleaning of catheters. Additionally, less than 2×10^{-1} ng/mL of endotoxins were found in the fresh distilled water and after 72 hours in the same water 2×10^5 ng/mL of endotoxins were found.

An experimental study was performed by Kundsin & Walter [15] to detect the presence of entoxins in new and recycled heart catheters using the *Limulus Amoebocyte Lysate* test. Thirteen recycled catheters were recovered which contained 50 pg/mL or more of endotoxins per catheter.

The hemodynamic processes are frequently associated with the occurrence of pyrogenic reactions. Cookson et al. [16] in an investigation of outbreaks, detected *Enterobacter cloacae, Stenotrophomonas maltophilia* and a small growth of *E. coli* in the cleaning solution mixed with tap water examined at the end of the day. Endotoxins were found in a container used for the preparation of nitroglycerine solution. Duffy et al. [17] investigated an outbreak in Belo Horizonte in which 25 patients presented with pyrogenic reactions after heart catheterism. Again, a review of the cleaning process was made in which 1100 CFU on average (range between 1 and 33000 CFU) of microbial load was found. Also on average 1460 EU/mL of endotoxins with a variation of 32.7 and 2080 EU/mL were detected in the deionized water used to clan hemodynamic catheters.

In order to control this outbreak, the water was passed through a 1-µm filter and 20,000-d ultrafilter (in series). Moreover, a solution of 5% sodium hypochloride was used to wash the water distribution system weekly. Depending on the amount of organic material found in the ultrafilter, 1% to 4% citric acid solutions were administered. In all these publications, the water supply system was the main source of microorganisms and pyrogens, demonstrating that the use of apyrogenic water is very important to reduce the risks for patients submitted to heart catheterism using recycled catheters.

A prospective study involving 122 consecutive children submitted to heart catheterism was performed by Gilladoga et al. [18] to assess the incidence of fever. In this study, the oral and axillary temperatures were measured at different times; before sedation, and continually during the procedure by means of a thermistor (a resistor that reduces the resistance with increases in temperature). The patients with oral and axillary temperatures higher than 37.8ºC or rectal temperatures higher than 38ºC were considered febrile. The incidence of fever during the procedure was 11.5% (14/122) and after the procedure it was 8.2% (10/122). This results were directly proportional to the duration of the procedure and the number of heart catheterisms performed together.

Other prospective studies were performed by Frank et al. [19] in the period of November 1986 to June 1987 involving 414 consecutive adult patients submitted to heart catheterism utilizing both new and recycled catheters. After the procedure the axillary temperature was measured two times per day and the catheter entry site was examined daily. Fever was defined as an axillary temperature higher than 37.4ºC. The heart catheters were processed as follows: immediately after the procedure, the catheters were rinsed in tap water for 10 minutes; subsequently they were disinfected using 3% Gigasept (an aldehyde) and were placed in a solution containing detergent for 1 hour. Following this they were again rinsed in tap water for 10 minutes and dried using compressed air. Finally they were

sterilized in ethylene oxide (15% ethylene oxide and 85% carbon dioxide) for 45 minutes. Before reusing, the catheters were aired at room temperature for 14 days. The incidence of fever in the patients who used new catheters was 4.4% (7/158); 4.7% (7/151) for patients who used recycled catheters reused once or twice and 6.0% (6/100) for recycled catheters reutilized more times. This difference was not statistically significant.

Some descriptive studies related to the occurrence of infectious diseases after heart catheterism have been published. Although they are studies with limited power of evidence, these studies point out some problems related to this type of procedure. Sande et al. [20] evaluated 106 patients to detect bacteremia after this procedure. They found 8.0% (3/38) positive blood tests that the authors interpreted as contaminates of the skin. In this study no cases of bacteremia were identified. Shawker et al. [21] studied 100 heart catheterizations and detected 23 patients with positive blood cultures. Of these 11 cases were considered to be contaminants of the skin or air and in 12 patients gram negative bacteria were detected. Transitory bacteremia was detected in four cases. The authors attributed this finding to a failure in the cleaning process.

According to Krause et al. [22] hemodynamic catheters access a critical area of the cardiovascular system in which infections and/or lesions can rapidly lead to a fatal outcome. The risk of transmission of prions by the blood can not be stimulated and this is a potential problem for any type of medical product. Thus, the incidence of infectious complications is low, but this depends on the size of the population and whether the study is retrospective or prospective.

Fagih & Eisenberg [23] published a review on the reuse of angioplasty catheters and the risk of Creutzfeldt-Jakob disease utilizing the Medline database and the following key words: PTCA, CJK, material and equipment reuse. In this review, the authors assumed that this disease might be transmitted by contaminated blood, but they did not find any reported cases involving heart catheterism. They then defend the reuse of catheters as a strategy to reduce costs.

Penna & Ferraz [12] evaluated the microbial load on angiographic catheters and detected the presence of organisms with a quantitative analysis between 3.5 and 5.5 x 10^{-1} CFU. The detection of these residues may be explained by the difficulty of cleaning devices to access the lumen of this type of catheter which is long and narrow [12,20].

DISCUSSION

Alterations in the physical integrity were clearly seen by means of the experimental studies that utilize different resources of electronic microscopy at different magnifications. Alterations were evidenced on the surface including scratches, cracks, depressions and protrusions and different structures suggestive of organic residue such as thrombi with platelets, deposits of fibrin and red blood cells, but electronic microscopy is limited in respect to identifying organic residue.

Alterations in the mechanical integrity were also objectively measured by different quantitative techniques such as evaluation of the bursting pressure, measurement of compliance and diameter of the catheters. It is important to stress that these evaluations were made in angioplasty catheters demonstrating both increases and decreases of the bursting pressure and of the original diameter, as well as alterations in the compliance and the presence of holes. However, there is clear evidence of the occurrence of physical and mechanical changes after recycling heart catheters. It is worth noting that the study of Brown et al. [7] carefully analyzed alterations of mechanical integrity. Although, catheters were kept in contrast for two weeks, which is considered an extreme situation which does not reflect reality during the clinical use of catheters. Moreover, these authors warn that the balloons were not submitted to real conditions that occur during clinical use such as the curviness of the vessel or the presence of calcifications.

In respect to the cleaning techniques presented, there were also more angioplasty catheters, probably due to the easily seen difficulty of recycling this type of material as they are extremely narrow. Several techniques using different cleaning agents were presented including anionic and enzymatic detergents and even hydrogen peroxide, heparin and sodium hypochloride solutions as well as ultra-sonic cleaning. Additionally, tap water submitted to different treatment methods was used to remove blood. Even so, only the study by Penn and Ferraz [12] showed a quantitative reduction in an intentionally inoculated microbial load. The other studies did not utilize methodological resources to allow an objective evaluation of this technique.

Similarly, different methods of sterilization were employed with a predominance of ethylene oxide. This is a toxic gas for patients if there is an interaction with water or saline solution in the internal lumen, as this interaction produces glycol ethylene and chloridrin ethylene, which are toxic for humans [20]. However, ethylene oxide has a high circulation and thus a greater capacity to penetrate long and narrow lumens. It is efficient in the sterilization of thermosensitive devices including hemodynamic catheters. Grimandi et al. [8] utilized gamma radiation. It is an efficacious technique but its application is restricted in practice due to the high cost and access for sterilization but these authors warned about the evaluation of the

presence of pyrogens that are frequently responsible for transitory and persistent inflammatory reactions in patients submitted to this type of procedure.

Catheters submitted to peracetic acid and glutaraldehyde were submitted to limited sterility tests, either in respect to the culture medium used or the use of non-destructive tests, which may not allow recovery of all microorganisms inside the catheter. Also the limitations of glutaraldehyde in respect to its efficiency as a sterilization agent over the time and concentrations utilized in the study are worth highlighting. Additionally, it is important to stress the difficulty to remove residues of this solution from articles with narrow lumens, as it is toxic mainly when in direct contact with the blood flow.

In spite of the publication of several primary studies, doubts have not been raised in relation to the safety of reuse in respect to the cleanliness and sterility of hemodynamic catheters. Moreover, the data that exist are insufficient to recommend the practice of reuse of these catheters. Thus, it is also considered important to carefully evaluate the reuse of hemodynamic catheters in relation to the clinical repercussions to determine the real safety of this process.

REFERENCES

1. Merritt K, Hitchins VM, Brown SA. Safety and cleaning of medical materials and devices. J Biomed Mater Res. 2000;53(2):131-6.

2. Luijt DS, Schirm J, Savelkoul PH, Hoekstra A. Risk of infection by reprocessed and resterilized virus-contaminated catheters: an in-vitro study. Eur Heart J. 2001;22(5):378-84.

3. Unverdorben M, Quaden R, Werner C, Bloss P, Degenhardt R, Ackermann H et al. Change of the mechanical properties of two different balloon catheters with increasing numbers of cycles of resterilization. Catheter Cardiovasc Interv. 2003;58(1):29-33.

4. Anderson JH, Gianturco C, Wallace S, Dodd GD. A scanning electron microscopic study of angiographic catheters and guide wires. Radiology. 1974;111(3):567-71.

5. Bourassa MG, Cantin M, Sandborn EB, Pederson E. Scanning electron microscopy of surface irregularities and thrombogenesis of polyurethane and polyethylene coronary catheters. Circulation. 1976;53(6):992-6.

6. Mussivand T, Duguay DG, Valadares MJ, Rajagopalan K, Mackenzie AM, Blohon R et al. Assessment of reused catheters. ASAIO J. 1995;41(3):M611-6.

7. Brown SA, Merritt K, Woods TO, Hitchins VM. The effects of use and simulated reuse on percutaneous transluminal coronary angioplasty balloons and catheters. Biomed Instrum Technol. 2001;35(5):312-22.

8. Grimandi G, Sellal O, Grimandi F, Crochet D. Risks of reusing coronary angioplasty catheters: results of an experimental study. Cathet Cardiovasc Diagn. 1996;38(2):123-32.

9. Bryce AN, Mack JH, Cantafio C, Neumann S. Evaluation of the Cathetron System for recycling angioplasty catheters. Cathet Cardiovasc Diagn. 1997;41(2):132-5.

10. Karov J, Chawla AS, Hinberg I. Effect of reuse on surface characteristics of balloon angioplasty catheters. Artif Cells Blood Substit Immobil Biotechnol. 2000;28(3):229-40.

11. Ravin CE, Koehler R. Reuse of disposable catheters and guide wires. Radiology. 1977;122(3):577-9.

12. Penna TC, Ferraz CA. Cleaning of blood-contaminated reprocessed angiographic catheters and spinal needles. Infect Control Hosp Epidemiol. 2001;21(8):499-504.

13. Lee RV, Drabinsky M, Wolfson S, Cohen LS, Atkins E. Pyrogen reactions from cardiac catheterization. Chest. 1973;63(5):757-61.

14. Reyes MP, Ganguly S, Fowler M, Brown WJ, Gatmaitan BG, Friedman C et al. Pyrogenic reactions after inadvertent infusion of endotoxins during cardiac catheterizations. Ann Intern Med. 1980;93(Part 1):32-35.

15. Kundsin RB, Walter CW. Detection of endotoxin on sterile catheters used for cardiac catheterization. J Clin Microbiol. 1980;11(3):209-12.

16. Cookson ST, Nora JJ Jr, Kithas JA, Arduino MJ, Bond WW, Miller PH et al. Pyrogenic reactions in patients undergoing cardiac catheterization associated with contaminated glass medicine cups. Cathet Cardiovasc Diagn. 1997;42(1):12-8.

17. Duffy RE, Couto B, Pessoa JM, Starling C, Pinheiro S, Pearson ML et al. Improving water quality can reduce pyrogenic reactions associated with reuse of cardiac catheters. Infect Control Hosp Epidemiol. 2003;24(12):955-60.

18. Gilladoga AC, Levin AR, Deely WJ, Engle MA. Cardiac catheterization and febrile episodes. J Pediatr. 1972;80(2):215-20.

19. Frank U, Herz L, Daschner FD. Infection risk of cardiac catheterization and arterial angiography with single and multiple use disposable catheters. Clin Cardiol. 1988;11(11):785-7.

20. Sande MA, Levinson ME, Lukas DS, Kaye D. Bacteremia associated with cardiac catheterization. N Engl J Med. 1969;281(20):1104-6.

21. Shawker TH, Kluge RM, Ayella RJ. Bacteremia associated with angiography. JAMA. 1974;229(8):1090-2.

22. Krause G, Dziekan G, Daschner FD. Reuse of coronary angioplasty balloon catheters: yes or no? Eur Heart J. 2000;21(3):185-9.

23. Fagih B, Eisenberg MJ. Reuse of angioplasty catheters and risk of Creutzfeldt-Jakob disease. Am Heart J. 1999;137(6):1173-8.