



Original Research Article

Cardiac Catheters Reprocessing for Limited Resources Hospitals: An Experimental Study

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A B S T R A C T

Keywords

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The aim of this work was to evaluate the efficiency of protocol for cleaning & sterilization of cardiac catheters employed for single use. The study was performed on three hundred and fifty cardiac catheters to assess the efficiency of three methods of cleaning, the first method was manual cleaning using enzymatic detergent, and the second method was cleaning by ultrasound irrigator using enzymatic detergent followed by manual rinsing & drying. The third method was using fully automated washer disinfectant releasing dried catheters ready for packing. Efficiency of two hydrogen peroxide plasma sterilizers for destruction of endotoxin as well as bacteria & fungi were verified. Results of cleaning by washer/disinfectant were promising for removal of residual blood & debris from cardiac catheters, the use of pretreated water as that used for dialysis made the reprocessed catheters non pyrogenic. From our study we concluded that, the implementation of the protocol on wide scale study is highly recommended for limited resources hospitals that use manual cleaning for life saving emergency cardiac catheterization for poor patients, yet the physical safety & functionality of reprocessed cardiac catheters need to be verified.

Introduction

Many medical devices exist worldwide to be used for detection, diagnosis & treatment of medical conditions. Such devices are available in both reusable & single use versions. Reusable devices are designed to be able to be thoroughly cleaned & to withstand appropriate disinfection or

sterilization between use in different patients; although adequacy of these processes even under normal circumstances has been questioned. Single use medical devices (SUDs) are designed by the manufacturer to be used once only. In fact, some experts have argued that many SUDs

are identical to the reusable version & the single use designation is a marketing choice. Based on the expense of SUDs, the environmental impact of their disposal, and the perception that some of them may be safely reused on different patients, internationally many healthcare institutions have decided to reuse SUDs (Alfa, 2000).

As a cost saving measure, many hospitals worldwide are reusing & reprocessing disposable cardiac catheters. The relevant issues identified were: risk of infection, functional reliability, cost/ effectiveness & legal issues. Patients are not subjected to infections with rigorous cleaning & proper sterilization. The 2002 study by Ischinger et al., which estimates savings made in Germany from reprocessing balloon catheters to be up to €20 million per year. The 15 years' experience with the reprocessing of cardiology medical devices in Germany clearly shows the substantial economic benefits that can be made through professional reprocessing. With an average of five reprocessing cycles per device, saving of around 50% per cycle can be obtained (Bracklo and Marczak, 2012).

The United States Food & Drug Administration (FDA) has issued multiple guidance documents setting forth its current thinking on applicability of legal & regulatory requirements to reprocessed SUDs. If reuse is to take place, there must be written guidelines & procedures for cleaning & sterilization and appropriate documentation of these processes whenever they occur. Therefore, the FDA expects that the reprocessors of SUDs should be able to demonstrate that: 1- the device can be adequately cleaned & disinfected or sterilized, 2- the physical characteristics or quality of the device will not be adversely affected by these processes and, 3- the device continues to comply with applicable

FDA requirements (Compliance Policy Guide, 2010).

In USA in 2007, nearly 45% of hospitals had agreements with third-party reprocessing companies, a number that increased to 70% in 2008 after the economic recession. Most of the reprocessed medical devices were reused under FDA surveillance by reprocessing companies. Medical devices were not only becoming an environmental concern, but its management also costs a huge amount. Reprocessing was guaranteed to reduce medical waste by more than 50% for a hospital per year (Moduga, 2010).

Catheters processed in hospitals are easily contaminated with fever producing lipopolysaccharides from tap water or from bacterial growth in residual moisture. Sterilization by steam or ethylene oxide does not destroy these lipopolysaccharides (Kundsinn and Walter 2001). But can be destroyed by hydrogen peroxide gas plasma sterilization (Association of Perioperative Registered Nurses (AORN, 2006). Endotoxin is toxic to the body & can cause multiple severe reaction, organ failure & even death. Reactions include lymphocyte migration, histamine release, vasodilatation, inflammation, coagulation, thrombosis & acute disseminated intravascular coagulation, which deplete platelets & various clotting factors & result in internal bleeding (Todar, 2008).

The aim of this work was to evaluate the efficiency of protocol for cleaning & sterilization of cardiac catheters employed for single use.

Material and Methods

The study was performed on 350 cardiac catheters (Amplatz catheter, French size: 6F, diameter 1.9 mm, length 73&87cm) in the

period from April to July 2013, March to September 2014. Catheters were collected from Cardiac Catheter Laboratory in Cardiology Department in Ain Shams University Hospital. Laboratory tests were done in cardiac catheter reprocessing area, confirmatory tests were done in Bioservice Scientific Laboratories (Behringstrasse, Germany) as a reference laboratory.

Specimen Collection

Catheters were randomly selected from devices used for first time; after ruling out catheters according to the following Exclusion criteria

*Cardiac catheters used for patients positive for hepatitis B (HBsAg positive), Hepatitis C ((HCV antibody positive) & or HIV antibody positive). They are destructed as per department policy.

**Catheters showing change in size or shape, corrosion, surface cracking or pitting, swelling, increased brittleness, rigidity, flattening or blunting of the tip, presence of weak spots, wear between moving parts & resistance to insertion of guide wire or to the flow of liquid medium (Spanton, 1997).

Prewash step

Immediately after cardiac catheter was used, 2-3 ml of saline or water was injected inside its lumen then immersed in water or saline in leak proof container & transported to the cleaning room.

Cleaning step

Two to three ml of air was injected inside each catheter using blower gun to avoid dilution of cleansing solution.

Manual cleaning

One hundred catheters (group 1) were completely immersed in diluted enzymatic cleanser (Aniosyme 50 ml/ 1 litre water) (Anios, France) for 20-60 minutes & the outer surface was cleaned with soft brush then the inside was cleansed by repeated injection of enzymatic cleanser with insertion of guidewire to assure complete clearance of any debris or blood clots then catheters were washed using water by immersion & injection several times.

Ultrasonic irrigator cleaning

One hundred cardiac catheters (group 2) were cleaned inside US irrigator PC plus system with cannulated pulse enhancement (CPE) (Medisafe, UK). The ultrasonicator ensures that the insides were scrubbed & flushed as well as the outside. By connecting the catheter to the irrigation flush port, the sonically charged jet of fluid was directed along the inside of the catheter lumen & dislodged all organic matter thus providing an efficient cleaning process (Alex, 2010). The US irrigator used 3 E-ZYME (a combination of three high performance enzymes; which digested all residues & deposits normally found on invasive instruments & devices including proteins, lipids, carbohydrates & mucopolysaccharides at temperature 40-60°C).

Quality control: Cycle number, time, washing temperature, washing/ flush status & sonic status were monitored & recorded. The washed catheter was then subjected to rinsing by filtered water several times by repeated injection & suction to ensure complete removal of the detergent.

Washer-Disinfector Cleaning

One hundred & fifty cardiac catheters (group 3) were inserted into the ports of washer disinfector (Laoken, China) a complete automated washer, rinsing and drying system. One hundred (group 3a) the washer was attached to filtered water source while the other 50 (group 3b) the washer was attached to a source of dialysis water.

Drying step

Using air compressor gun, for catheters of groups 1 and 2.

All 350 catheters were subjected to the following steps:

Inspection step

All catheters were subjected to check for feasibility of its reuse regarding changes in properties of each catheter to rule out & dispose catheters according to exclusion criteria mentioned above.

Check for cleaning procedure

Assurance of complete cleaning was done using test for residual blood detection:

Diaquick FOB cassette (Dia-Lab production & chemicals, Wiener Neudorf, Austria): A rapid, visual sandwich immunochromatographic test for qualitative detection of human blood hemoglobin with the aid of extraction buffer.

Packaging

Using sealing machine; Speedy-seal 12 (Unident Co, Anios laboratories, France), temperature (50-200°C) was used to ensure complete sealing.

Sterilization

Two hundred cardiac catheters of groups 1&2 were sterilized by using low temperature Plasma Sterilizer (model: HMTS-80). One hundred & fifty cardiac catheter of group 3 were sterilized by using Plasma Sterilizer (Laoken Plasma Sterilizer). Both were approved for sterilization of metal, non-metal heat & pressure sensitive devices & flexible endoscopes. Biological indicator together with QC on instrument were used to check every cycle.

Microbiological examination and endotoxin detection

When catheters were introduced into a patient, endotoxin was eluted from the liquid passing through the lumen as well as from direct contact of the outside of the catheter with blood. Precisely the dose of endotoxin causing pyrogenic reaction is unknown but approximately levels >50 EU/ ml can cause reaction however severity is not only limited to dose but to patient susceptibility as well (Kundsin & Walter, 2001).

Endotoxin was detected using LAL (Limulus Amebocyte Lysate test (Charles River Endosafe, USA). Endotoxin produced opacity & gelation of LAL reagent; while bacteria & fungi were detected using conventional culture media (blood, MacConkey's & Sabaroud's dextrose agar media).

Bioservice Scientific Laboratories Testing

Five catheters from group 3 were labelled, sent & examined as follows:

- a. Each device was cut into small pieces in sterile container filled with 100 ml preheated pyrogen-free water & left for 1 hour.

Membrane filtration was done, 2ml of filtrate was used for endotoxin assay while the remaining membranes were immersed in thioglycolate broth & soya-bean casein digest broth then incubated for 72 hours at 37° C & examined for microbial growth.

Endotoxin assay: was done using turbidimetric kinetic LAL test KTA according to manufacturer's instructions (Charles River Endosafe, Germany). Absorption was measured using Tecan Sunrise Mikrotiterplatten- Lesegrat, Germany. Evaluation of results was done using software 'EndoscanV'. The 5 catheters were selected randomly from the positive samples. Sample 1&4 from group 3a (washed in washer/disinfector attached to filtered water source) samples 2, 3 & 5 from group 3b (washed in washer /disinfector attached to filtered water used for dialysis unit)

Results and Discussion

Detection of residual blood, clots or debris revealed positive results in 72 out of 100 catheters cleaned manually (72%); washing catheters in ultrasonic irrigator improved cleaning efficiency that only residual blood was detected in 12 out of 100 catheters (12%) while washing in washer disinfectors with ports fitting catheter sizes revealed only one positive out of 150 tested catheters (0.7%) with highly significant difference (p value < 0.005) as shown in table (1).

Regarding endotoxin detection manual cleaning with washing with filtered dialysis water revealed endotoxin in 98 out of 100 catheters (98%), endotoxin was detected in 90 out of 100 catheters (90%), while in group 3a it was detected in 18 out of 100 catheters (18%), in group 3b connected to water source used for dialysis machines only 2 out of 50 revealed (4%) revealed positive

results as shown in table(2).

Endotoxin assay revealed levels less than 50 EU/ml which mean they are mostly non pyrogenic. Cultures done after sterilization, to detect if there were living organisms or not, were negative for microbial growth together with the catheters tested by Bioservice Scientific Laboratories as shown in table (3).

Table (4) revealed that the problem of residual endotoxin even on all sterilized items not only cardiac catheters remain a big issue in reuse even for surgical instruments that were rinsed with good quality water & may be improved if a pretreatment of reprocessing water is used in Central Sterile Supply Department (CSSD).

The designation of SUD denotes exclusively the manufacturer's definition and not the intended purpose as per legislation. In general, manufacturers are not interested in the reprocessing of their single use devices and hence refuse to give any information as to whether & how their single use devices can be reprocessed and resterilized. A company, for example, can decide to designate a stainless steel forceps for single use only, even though it can be easily & safely sterilized. Canada seems to be in the forefront of implementing a reuse policy, hospitals in the United States tend to fear legal consequences (Krause, 2000).

Our study included 350 cardiac catheters which were used in Ain Shams University Hospital during the period from April to July, 2013 & from March to September 2014. Different catheter lengths (73 and 87 cm) and shapes were included in our study with no significant difference in sterilization efficacy.

Some SUDs may not be amenable to reprocessing. Reprocessed SUDs should be capable of withstanding necessary cleaning, disinfection or sterilization, and continue to comply with all applicable FDA requirements after each instance of reprocessing, up to the maximum number of times that the devices are intended by the reprocessors to be reprocessed (Compliance Policy Guide, 2010).

Our study clearly showed that from manually cleaned and sterilized cardiac catheters 72% showed residual blood or debris. While US irrigator as a method of cleaning revealed 12% positive results while the use of fully automated washer-disinfector revealed only 0.7% positive catheters.

Our work results of manual cleaning were matched & agreed with *Spach and his colleagues* (2003) who found that devices with long narrow lumens such as catheters and endoscopes present serious problems for the complete removal of bloody materials and verification of cleanliness. During reuse of these devices residual organic debris or blood proteins may enter the blood circulation, possibly together with infectious agents.

In addition, *Peter* (2004) found that there was conflicting evidence in the literature reviewed regarding the safety and effectiveness of single-use device reuse. About (50%) of the studies for cardiovascular medical devices concluded that the reprocessing and reuse of the SUDs under investigation was safe and effective under stringent controls but the other studies identified evidence of residual organisms, bio-material and device deterioration after reprocessing and difficulties generalizing study results because of model specificity.

Humphries and his coworkers (2006) who showed that (18%) of the tested endoscopes were still positive for blood residue after the first cleaning. This discrepancy may be explained by working on different device & use of different cleaning techniques.

Our study detected that there were blood residues on manually cleaned cardiac catheters, similar results were revealed by *Kovach* (2011) who revealed that more than (50%) of the tested flexible endoscopes were contaminated with blood soil residue after the first and second cleaning.

In this work, it was found that 98% of group, 90% of group 2 & 18% group3a, 4% group3b cardiac catheters were positive for endotoxin by LAL test which indicated presence of endotoxins in cardiac catheters after plasma sterilization.

Our study results were also higher than results concluded by *Heeg and his coworker* (2008) who showed that cardiac catheters assigned for reprocessing revealed only minor bacterial contamination. Random samples taken from reprocessed catheters were sterile and free from pyrogens. Among a total of 161 prospectively surveyed patients, 16 cases with a short increase of temperature up to 37.5°C were observed. Only results of group3 were matched with *Heeg & co-worker*, 2008.

Lee and his coworkers (2003) published eight cases of pyrogenic reactions that occurred two or three hours after the initiation of heart catheterization. Similar findings were published by *Reyes and his coworkers* (2005) in USA where 25 cases of tremors and fever were identified after heart catheterization. These were due to presence of bacterial endotoxins in reused catheters.

Our results revealed that inspite that the LAL test proved positive endotoxin the

levels detected by Bioservice Scientific Laboratory indicated they are not reaching the pyrogenic level which is 50 EU/ml.

Kundsinn and his coworker (2001) detected the presence of endotoxins in recycled heart catheters by using the Limulus Amoebocyte Lysate test. Thirteen recycled catheters were recovered which contained 50 pg/mL or more of endotoxins per catheter.

Duffy and his colleagues (2007) also investigated an outbreak in Belo Horizonte Hospital in which 25 patients presented with pyrogenic reactions after reused heart catheters.

In 2005 at Colorado State (USA), endotoxin contamination in a cardiac catheter lab caused the death of two patients and sickened another five patients. Endotoxin levels were 10 to 30 times greater than normal in the sickened patients (*Milt, 2009*).

Pyrogenic reactions reported also in many hospitals after reusing coronary angioplasty catheters and its accessories and this was estimated by *Mak and his coworkers* (2008), *Gremandi and his colleagues* (2008), *Jacobson and his colleagues* (2003), *Cookson and his coworkers* (2007) and *Frank and his colleagues* (2008).

Canadian Healthcare Association (2006) also showed that during air-drying of the catheters a thin protein film may become firmly attached to the surface of lumen or balloon, resulting in poor penetration of the cleaning and sterilization agents.

Alfa and his colleagues (2006) showed that when long narrow lumens were inoculated with bacteria, microbial killing by ethylene oxide (EO) is detrimentally affected by the presence of 10% serum and 0.65% salt in the bacterial suspension. It was hypothesized that the combination of serum and salt

caused a poor penetration of the gas into the narrow lumen and, as a result, protection of the bacteria.

Peter Sch (2011) also reported that none of the reprocessed single-use instruments were

effectively cleaned, disinfected, or sterilized. This condition provided an opportunity for the viability of nonresistant or nosocomial organisms and viruses. Additionally, reprocessing procedures resulted in material destruction of fragile devices.

All cases of pyrogenic reactions reported were due to the fact that endotoxins are heat stable (boiling for 30 minutes does not destabilize endotoxin), but certain powerful oxidizing agents such as superoxide, peroxide and hypochlorite have been reported to neutralize them. Endotoxins, although antigenic, cannot be converted to toxoids, which are toxins that are no longer toxic (*Milt, 2009*).

In our work there was no bacterial growth on conventional culture techniques after plasma sterilization of the 350 cardiac catheters (100%).

This result agreed with the study of *Aton and his colleagues* (1994) who showed no bacterial growth detected on any of the cultures, which indicated that the reprocessed catheters are effectively sterilized. As well as, *Ravin and his coworkers* (2003) who demonstrated the absence of bacterial growth in cultures obtained from angiographic catheters submitted to sterilization in ethylene oxide which agreed with our results.

Bryce and his colleagues (2007) also found that using of peracetic acid to sterilize

angioplasty catheters resulted that 349 growth. cultures of reused catheters had no bacterial

Table1.Results of residual blood testing as a marker of cleaning efficiency in the 3 groups

	Positive	Negative	P value
Group 1 (100 catheters)	72(72%)	28 (28%)	<0.05
Group 2 (100 catheters)	12 (12%)	88 (88%)	<0.05
Group 3a,b (150 catheters)	1 (0.7%)	149 (99.3%)	<0.005

Table.2.Results of LAL test for endotoxin detection after sterilization of catheters of the 3 groups

LAL	Positive	Negative	P value
Group 1 (100)	98(98%)	2(2%)	<0.005
Group 2(100)	90(90%)	10(10%)	<0.005
Group 3a(100)	18(18%)	82 (82%)	<0.005
Group 3b(50)	2 (4%)	48(96%)	<0.005

Table.3.Results of endotoxin assay of 5 catheters done by Bioservice Scientific Laboratories

Sample	Endotoxin conc.EU/ml solution	Endotoxin Conc.EU/device	Positive Product Control recovery rate%	Validity
1	0.32	32	103%	Valid
2	0.03	3	110%	Valid
3	0.03	3	86%	Valid
4	0.3	30	12%	Not Valid
5	0.05	5	111%	Valid

*r-value<-0.98/PPC

Recovery rate: 50-200%

entotoxin content of -ve control <0.005 EU/ml

Table.4.Distribution of the studied tests results residual blood test, LAL and cultures among the 3 studied groups

Tests	Negative	Positive	Main problem
Residual Blood test	265	85	Residual endotoxin
LAL	142	208	
Culture	350	0	

According to Pantos and his coworkers (2013), reused catheters did not result in an increase in the risk of infection and that catheters were sufficiently durable to be reused well in excess of five times.

In conclusion, results of cleaning by washer/disinfector were promising for removal of residual blood & debris from cardiac catheters, the use of pretreated water as that used for dialysis made the

reprocessed catheters non pyrogenic. Implementation of the protocol on wide scale study is highly recommended for limited resources hospitals that use manual cleaning for life saving emergency cardiac catheterization for poor patients, yet the physical safety & functionality of reprocessed cardiac catheters need to be verified.

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