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Research Article

Clinical Outcome with the Use of the Reprocessed Single-Use Devices in Cardiac Catheterization Laboratory

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Abstract

Background: Most studies focused on the cost and the environmental effects of the reprocessed single-use devices (SUDs), rarely on their clinical effects. We aim to evaluate the reprocessed SUDs use safety.

Methods: A prospective charts review between January 2017-August 2018 was conducted in a tertiary care hospital in Amman, Jordan. The hospital has a policy to re-sterilize the SUDs up to three times not based on an evidence but was based on staff observations/opinions of the cardiac catheterization (CC) supervisors, central sterilization and supply department, and the infection control department staff. Reprocessed SUDs were color-marked for ranks. The CC laboratory supervisor who collected data was aware of the ongoing study and the infection prevention and control coordinators. Our primary measure was CC-related adverse events; fever, sepsis, bleeding, and up to a month all-cause mortality.

Results: There were 818 Patients, males 582 (71.1%), age (mean 61.85 years, median 59 (IQR 49-69). For all reprocessed SUDs ranks, the admission diagnoses were coronary artery disease, valvular heart disease, acute coronary event and heart failure. Commonest comorbidities were hypertension and diabetes mellitus.

Conclusion: Four evaluated outcomes revealed no significant differences for patients who were in various ranks; no fever, sepsis ($p>0.2$), bleeding ($p>0.2$), and all-cause mortality ($p>0.2$).

Keywords: Single-use device; Reprocessed single used device; Cardiac catheterization laboratory; Reuse of single use devices; Reprocessed single-used device outcome

Abbreviations:

SUD(s): Single-Used Device(s); CC: Cardiac Catheterization; COPD: Chronic Obstructive Pulmonary Airway Disease; CAD: Coronary Artery Disease; EO: Ethylene Oxide Sterilizer.

Introduction

The last few decades witnessed major advances in the continued evolution of sterilization techniques. The impact of such techniques contributed to the substantial reduction in the hospital infection rates, mostly surgical sites infections (SSI) [1,2]. In the meantime, a rapid evolution of medical and surgical procedure such as Cardiac Catheterization (CC), Percutaneous Trans-Aortic Coronary Artery Angioplasty (PTCA) and coronary stenting, and open-heart surgery took place. This was paralleled by the introduction and evolution of the Single Used Devices (SUDs) and its wide-scale acceptance among health care professionals.

A practical value for SUDs is their ready availability with no time wasted waiting for reprocessing in-between consecutive procedures. Nonetheless, a trend to reprocessing and reusing the SUDs is recognized in CCL in many worldwide hospitals to cut down on costs. Though, concerns about the hazards of incomplete cleaning, incomplete sterilization and technical failure were worried about due to the possible changes in the physical properties of SUDs with the repeated re-sterilization [3,4]. Furthermore, the sensitivity of the subject was a concern in many health care systems, and the procedure was acknowledged

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by the Joint commission International in its recent policies (Standard PCI.7.1. Joint Commission International Accreditation Standards for Hospitals 6th Edition. Including Standards for Academic Medical Center Hospitals. 6th Edition. Effective 1 July 2017)

Despite the concerns on the reprocessed SUDs safety, new reprocessed SUDs are introduced into the daily used SUDs pool in CCL side-by-side with the new ones, while discarding the visually obvious defective SUDs. The anticipated benefit would be cost containment due to allocating the new SUDs high cost to the pool of patients [5,6].

In this study, we focused on the clinical outcome associated with the reprocessed SUDs for patients who had CC, as these procedures are in direct contact with the intravascular system, a sterile compartment and classified as critical [7,8]. Our aim is to answer the question, how many times we may reprocess the SUDs without increasing the adverse events. This may contribute to an educated guidance to draft recommendations, and policies on how many times a SUD can be safely reprocessed and reused without causing harm to patients, and obviating guilt feeling and liability while reducing hospital bills [9].

Materials and Methods

Study type and settings

A prospective observational study conducted in a private hospital in Amman, Jordan. Charts were reviewed for the period between 1 January 2017-22 August 2018. The institutional review board provided approval of the study. The hospital policy directives state that SUDs are to be used up to three times (Re-sterilization of Single Use Device Policy, KHMC-PCI 17), this was before banning the reuse of the SUDs on 22 August 2018 by Jordan Food and Drug Administration (JFDA, memo 34686/1/1/5).

The decision to re-sterilize the SUDs up to three times was empirical and was not based on evidence; it was personal observation and opinion of the cardiac catheterization supervisors, the infection control department coordinators and central sterilization and supply department staff. The decision to use the reprocessed SUDs was shared by all country cardiologists (mutual understanding), the patient consents to the procedure only, with the hospitals' administrations awareness and approval.

Reprocessing of the SUDs

After the completion of cardiac catheterization, SUDs primary cleaning and disinfection takes place in the cardiac catheterization unit. At the end of every working day, used SUDs are transported to the CSSD dirty area for additional cleaning, and disinfection process. SUDs are washed for a complete cycle in the washing machine; thin catheters, lines and tubes are cleaned by an air gun, and then transported to the clean area using another door of the washer.

Wet items like circuits or lines or tubes are placed in a dryer till they are fully dry. In the clean area, a thorough inspection process of SUDs takes place to rule out visually detected corrosions, cracks, defects or breaks, then they are marked by a black pen, items being processed more than three times should be disposed but this was not always the case. Then, SUDS were rank-colored with a mark on the items according to the order of reprocessing, and a patient chart will include a color-coded SUDs list. SUDs were being marked with colors accordingly to the number of (re)sterilization; White: initial use (company sterilization), green: first-time in-house sterilization, yellow: second time, and red: third time.

Subsequently, SUDs are placed in a surgical tray, a chemical indictor is embedded within the set, "Flat Reel" wraps are used for single items and catheters, and double layer paper wrap is used for the surgical tray and are secured using autoclave tapes. Some SUDs are sterilized using Ethylene Oxide (EO) sterilizer or plasma sterilizer depending on their material. Thereafter, the surgical sets are arranged in the autoclave basket and a biological indicator is placed in the corner of the basket far from the machine's door.

The cycle takes around 40 mints on temperature of 137°C. EO cycle needs up to 12 h on temperature 55°C. Once the cycle is completed, a print out from the machine confirms the parameters of the cycle and the machine is opened from the other door leading to the positive pressure sterile area. SUDs are kept till they cool and are inspected for integrity. All approved verified sets are placed in a clean closed cart for transportation to the cardiac catheterization laboratory.

Patients follow up

The CCL supervisor followed up the patients as they undergo CC, recorded their epidemiological data of interest, SUDs type and number, and the actual number of each SUD reuse. Patients were clinically followed up during their procedure, hospital stay and when discharged home they were contacted by phone up to 30 D after hospital discharge checking for any adverse event. Clinical outcome (adverse events) evaluation were recorded after the use of SUDs were; fever, sepsis, bleeding, and all-cause mortality. The study was conducted in a confidential manner and the treating cardiologist as well as allied medical staff were not aware of the study, except the CC supervisor who at the end of the procedure entered the number of SUDs used on every patient and their color code in the patient's chart.

Statistical analysis

Data were uploaded to an excel sheet (Microsoft corporation), then it was imported into SPSS (IBM corporation) version 20 for analysis. Outcomes were calculated with respect to ranks. The number of used SUDs on every patient were considered, and the order of the reuse for each SUD. To differentiate the effects based on the number of each SUD use order in a patient, the reuse order for SUDs in a patient were multiplied, then log-transformed and the log rank was used in analysis (see supplementary material).

Due to the low number of the clinical outcome events, they were tested by Pearson chi-square, the non-parametric Kruskal Wallis test, and ANOVA for multiple comparisons in addition to Tukey HSD (equal variances) and Tamhane test (unequal variances) to assess differences. Logistic regression analysis to evaluate the contribution of confounders on the rank versus adverse events. P<0.05 is considered statistically significant.

Results

There were 818 Patients, males 582 (71.1%), females 236 (28.9%), age (mean 61.85 years, and median 59 (IQR 49-69). The number of patients for the five analysis ranks were 111, 446, 173, 84 and 4. SUDs mean and median device used per patient were 3.41 and 2 (IQR 2-6) respectively. The patients' distribution was not symmetric and right skewed among the SUDs ranks (Table 1).

The admission diagnoses showed dominance of CAD followed by Valvular heart disease, acute coronary events (angina or acute myocardial infarct) and heart failure. Common comorbidities were hypertension and diabetes mellitus (Table 1). The sum of the used SUDs in different ranks showed that 23 of the patients were in rank one whilst one SUD was used, 75 patients used two SUDs and 13 patients used three SUDs. In rank two there were 343 patients used two SUDs and 103 patients used ≥ three SUDs. In rank three 29 patients used three SUDs and 143 patients used ≥ 5 SUDs. In rank four 84 patients used ≥ 5 SUDs. And in rank 5 only 4 patients were there, and seven SUD were used (Table 2).

Table 1: Demography and characteristics of patients who had cardiac catheterization with new and re-processed SUDs.

Characteristic	Rank of the Log-product of the Reprocessed SUDs in Patients				
	1	2	3	4	≥ 5
Age mean for all (years)	61.85				
Age mean per rank (years)*	58.85	61.49	64.02	62.98	67.75
Total number of patients (818)					
Number of patients per rank	111	446	173	84	4
Gender					
Males (total 582)	64	310	140	64	4
Females (total 236)	47	136	33	20	0
Admission Diagnosis					
CAD	101	435	168	82	4
Acute coronary event	1	1	3	2	0
Heart failure	1	1	0	0	0
Valvular heart disease	8	9	2	0	0
Comorbidities	68	308	319	61	4
Hypertension	52	265	108	54	3
Diabetes mellitus	36	161	65	41	3
Bronchial asthma	1	3	1	0	0
COPD	1	3	2	0	0
Solid malignancy	0	2	0	0	0
Hematological malignancy	1	1	0	0	0
Chronic liver disease	1	2	0	0	0

Chronic kidney disease	0	4	0	1	0
Cerebrovascular disease	1	5	1	0	0

SUD: Single Use Devices; CAD: Coronary Artery Disease; COPD: Chronic Obstructive Pulmonary Airway Disease.

Table 2: Frequency of patients in different ranks and the corresponding total number of SUDs used per patient.

Total SUDs	Ranks				
	R1	R2	R3	R4	R ≥ 5
SUM1	23	0	0	0	0
SUM2	75	343	0	0	0
SUM3	13	73	29	0	0
SUM4	0	10	1	0	0
SUM5	0	11	16	4	0
SUM6	0	9	93	50	0
SUM7	0	0	34	30	4

Note that as ranks increase, there are more SUDs used per patient (the non-shaded areas). SUD: Single Use Device. R: Rank of the SUD used in patients. SUM: Number of devices used in patients

The outcome of interest (fever, sepsis, bleeding, and all-cause mortality) revealed no fevers (Table 3), all added up to 15 events: 7 cases of sepsis in rank two, 2 in ranks three, and 1 in rank four ($p>0.2$). Bleeding from the puncture site occurred in ranks one and two, with 2 cases in each rank ($p>0.2$). And all-cause mortality up to one month of follow up was distributed on the five ranks as 1, 2, 1, 1, and 0 mortality ($p>0.2$).

Logistic regression analysis for the outcomes demonstrated no significant differences among the SUDs ranks ($p>0.05$), and it was not explained by ranks (Nagelkerke pseudo-R2=0.038); sepsis ($p=0.543$), bleeding ($p=0.29$), and all-cause mortality ($p=0.923$). The contribution of age to the model was not significant ($p=0.838$) as well as the comorbidities ($p=0.421$). The univariate analysis of the outcome based on ranks layered by age groups demonstrated some significance ($p=0.034$) between rank one (relatively younger age group) and the other ranks, but no significant differences among the other ranks ($p>0.2$). Each of the admission diagnoses (CAD, acute coronary event, valvular disease and heart failure) did not significantly affect the outcome measure ($p>0.20$).

Table 3: The differences for the clinical outcomes in patients with various ranks of the reprocessed SUDs.

The outcome measure	The use rank of the reprocessed SUD in patient					
	1	2	3	4	≥ 5	P value
Fever	0	0	0	0	0	-
Sepsis**	0	7	2	1	0	0.265
Bleeding (Puncture site)	2	2	0	0	0	0.261
All-cause mortality+	1	2	1	1	0	0.35

SUD: single use device; p value by Pearson Chi-square.

Also, due to the low events in the outcomes, they were tested by the non-parametric Kruskal Wallis test, and were all ≥ 0.265. One-way ANOVA for multiple comparisons in addition to Tukey HSD was also calculated $p>0.2$.

**Sepsis: including blood, skin and elsewhere.

+All-cause mortality: up to one-month follow-up.

Discussion

Earlier studies focused on the cost and the environmental effects for the use of the reprocessed SUDs, while fewer studies focused on the clinical effects of using the reprocessed SUD. An earlier study observed some complications like pseudoaneurysm repair, retroperitoneal bleed, repeat catheterization, repeat PTCA, myocardial infarction, CABG and death, no significant differences were found between the new and the reprocessed SUDs [10]. Our study measured the effects of SUDs in a patient when they were used in various reprocessing combinations ranks and correlated with the clinical outcome, they did not reveal significant differences; all patients in all ranks did not have fever, and the other outcome measures (bleeding, sepsis and all-cause mortality) were not statistically different among the various new/reprocessed SUDs. Possibly, we may have needed larger population to increase the power of measuring the outcomes difference "if there were any" among the different SUDs ranks. The contribution of age, comorbidities and the admitting diagnoses did not have impact on patients' outcome in all reprocessed SUDs ranks. However, univariate analysis revealed significant differences for age groups when the other ranks were contrasted with rank one where younger age groups dominated. This may be interpreted as younger patients with less reprocessed SUDs did not affect the outcome differently from the older patients with higher SUDs ranks, this finding may be in support of the safety of the reprocessed SUDs in the more comorbid elderly patients. Our data suggest that reprocessed SUDs may be used more than once, possibly safe up to four times. Although these results must be interpreted with caution, which requires supervision and without extrapolation, also, the number of cases were small for higher ranks. Furthermore, the application of such results should be within a context of an organizational structure that closely monitor the CCL with a precise procedure through trained staff on how to perform a thorough on-site cleaning, CSSD proper segregation and recleaning, inspection for devices defects, proper re-sterilization procedure for different SUDs materials, wrapping single items and re-packaging as a whole set [11,12]. If the procedure was implemented properly, the benefit would be lowering costs without compromising the quality of care and decreasing the medical wastes and their environmental effects [13-15]. Our study did not have a control over the study patients, whether a patient was included in the all-new, reprocessed or a mixture of SUDs. This resulted in the complexity of measuring each SUD reprocess-rank effect within total SUDs used in a patient which dictated using a method to account for measuring the different effects of mixed SUDs ranks in a patient (see supplementary material).

Conclusion

In conclusion, reusing the reprocessed SUDs would be beneficial, especially in resources-limited countries where cost is of "great" concern and possibly underdeveloped waste disposal system. Hitherto, many hospitals in affluent countries like the USA, Canada and Europe practice the reprocessing and the reuse of the SUDs despite the continuing debate on this issue. The use of the reprocessed SUDs did not demonstrate a significant difference in the measured clinical outcomes (fever, sepsis, bleeding and all-cause mortality). Those results should not be extended to higher use ranks, or in the absence of a rigorous control over the process.

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References

1. Rutala WA, Weber DJ. Gastrointestinal endoscopes: A need to shift from disinfection to sterilization. JAMA. 2014;312:1405-06.
2. Sabnis RB, Bhattu A, Mohankumar V. Sterilization of endoscopic instruments. Curr Opin Urol. 2014;24:195-202.
3. Tessarolo F, Caola I, Caciagli P, Guarrera GM, Nollo G. Sterility and microbiological assessment of reused single-use cardiac electrophysiology catheters. Infect Control Hosp Epidemiol. 2006;27:1385-92.
4. Collignon PJ, Graham E, Dreimanis DE. Reuse in sterile sites of single-use medical devices: how common is this in Australia. Med J Aust. 1996;164:533.
5. Polisena J, Hailey D, Moulton K, Noorani HZ, Jacobs P. Reprocessing and reuse of single-use medical devices: a national survey of Canadian acute-care hospitals. Infect Control Hosp Epidemiol. 2008;29:437-39.
6. Amarante JMB, Toscano CM, Pearson ML, Roth V, Jarvis WR. Reprocessing and reuse of single-use medical devices used during hemodynamic procedures in Brazil: a widespread and largely overlooked problem. Infect Control Hosp Epidemiol. 2008;29:854-58.
7. https://books.google.co.in/books/about/Proceedings_of_the_International_Confere.html?id=qay2GQAACAAJ&redir_esc=y
8. Hogan JM, Colonna TE. Products liability implications of reprocessing and reuse of single-use medical devices. Food Drug LJ. 1998;53:385.
9. Shaw JP, Eisenberg MJ, Azoulay A, Nguyen N. Reuse of catheters for percutaneous transluminal coronary angioplasty: effects on procedure time and clinical outcomes. Catheter Cardiovasc Interv. 1999;48:54-60.
10. Popp W, Rasslan O, Unahalekhaka A, Brenner P, Fischnaller E. What is the use? An international look at reuse of single-use medical devices. Int J Hyg Environ Health. 2010;213:302-07.
11. Crawford TC, Allmendinger C, Snell J, Weatherwax K, Lavan B. Cleaning and sterilization of used cardiac implantable electronic Devices with process validation: the next hurdle in Device Recycling. JACC: Clinical Electrophysiology. 2017;3:623-31.
12. Renton D, Denk P, Varban O. Reprocessed single-use devices in laparoscopy: Assessment of cost, environmental impact, and patient safety. Surg Endos. 2018;1-4.
13. Unger S, Landis A. Assessing the environmental, human health, and economic impacts of reprocessed medical devices in a Phoenix hospital's supply chain. J Cleaner Prod. 2016;112:1995-2003.
14. Garay OU, Elorrio EG, Rodríguez V, Spira C, Augustovski F. Single-use devices in Argentina: Cost comparison analysis of a "Re-Use" versus a "Single-use" Policy for trocars, endocutters, linear cutters, and harmonic scalpels. Value Health Iss. 2017;14:89-95.
15. Jacobs P, Akpinar I. Single-use medical devices: Economic issues. Heart Asia. 2018;10: e011034.