RESEARCH ARTICLE

COMPARING SAFEKEEPING PRACTICES IN PREVENTING MICROBIAL CONTAMINATION OF OPENED SINGLE-USE AMPULES

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Abstract

As observed in today's health care setting, ampules, which are designed for single-use are still persistently reused when there is a drug left-over, in order to aid the patients lessen the cost of health care. Leaving the ampules exposed, covered with a micropore or cotton plug in the patient's immediate bedside are believed to be beneficial in controlling contamination. This study aimed to compare the practices in safekeeping of opened single-use ampules in a closed plastic container in two environments utilizing a 2 x 3 experimental factorial research design. The specimens were collected from 180 ampules' neck after 6 hours of exposure, which were then cultured; the resultant colony forming units were counted expressed in CFU/mL. The use of various practices in safekeeping, use of a closed plastic container and two environments were not significant in preventing contamination. Results demonstrated that none of the current practices in safekeeping was effective in controlling the number of microbial contaminants. Hence adherence to their nature, "single-use" must be advocated despite circumstance of having a drug left over.

Keywords: safekeeping practices, closed plastic container, microbial contamination

Introduction

The practice of reprocessing single-use devices (SUDs) for reuse has begun in hospitals as early as the 1970s and that is justified on the basis of economic and environmental benefits. Reuse of single-use devices (SUDs) was a common practice in many health care centers in the United States (Stokowski, 2012; Alfa & Castillo, 2004; Reichert, 1993). The Food Drug Authority (FDA) policy on instrument reuse from 1987 states that, "*reuse decision belongs to the hospital and practitioner".* Over the years, this policy guideline had been argued and debated by authorities, which led to the 2000 guidance document that reuse of SUDs is only safe if it is well supported by sound theoretical principles (Oberoi & Wattal, 2014). Observed in today's health care setting, reuse of the left over drug content of opened single-use ampules is evident, due to economic reasons. These ampules are left exposed, covered with a micropore and plugged with cotton in the immediate bedside of a patient, tagged as safekeeping practices, either of the two environments, supplied with environmental air, with the use of an air conditioning unit (AC) or none (nAC). Covering the opened neck of the ampule, either with a micropore or a cotton plug can form a seal from the natural environment where the contaminants are evidently present, since microorganisms are ubiquitous (Black, 2013; Morse &Meitzner, 2013; Tortora, Funke & Case, 2013; Wessner, Dupont & Charles, 2013; Engelkirk & Duben-Engelkirk, 2011; Health and Safety Department of the University of Edinburgh [HSDUE], 2009) and the health-care setting is not spared from this truth (Booty & Barraclough, 2010), which includes all of the physical surrounding and staff (Ayliffe, Babb & Taylor, 2000) and is extended to even fomites as vehicles of transport, by way of medical and non-medical devices (Vickery, Jacombs, Bradshaw, & Dava, 2013; Flodgren, Conterno, Mayhew, Omar, Pereira, & Shepperd, 2013; Samuel, Gopalan, Coodavia, & Samuel, 2013; Crinch&Drinka, 2012; De Oliveira, Damasceno, Piscoya & Nicoli, 2012; Jhung et.al., 2007; NSW Department of Health [NSW-DOH], 2007; Rosenthal et.al., 2006 ;von Eiff, Jansen, Kohnen, & Becker, 2005; Vickery, Pajkos, Cossan, 2004; Lofgren, MacPherson, Granieri, Myllenbeck, & Sprafka, 1989).

These observed practices are not well supported by empirical evidence that these are effective measures in preventing possible contamination, which in the latter, can compromise the health of the patients, leading to more serious complications and illnesses. Diseases, in particular, infectious processes, acquired in the hospital are labeled as either nosocomial or hospital acquired infections or health-facility acquired infection (Shiferaw, Beyene, Kasa & Sewunet, 2013; Zagaria, 2004) that has been concluded

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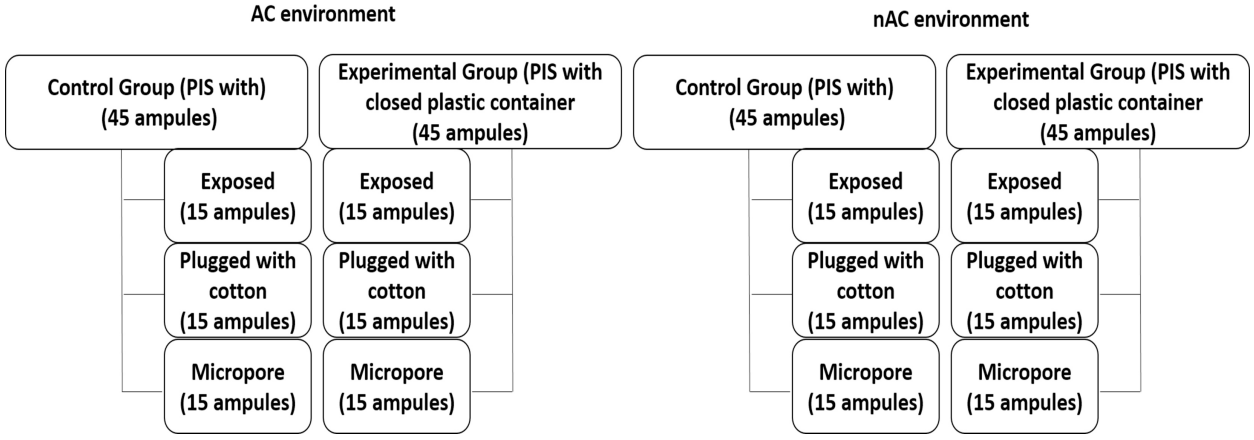
Figure 1. Random allocation of the opened single-use ampules among the various practices in safekeeping in two environments



as an additional reason for prolonged hospital stay, long-term disability, massive additional source of expense (Ray & Singhal, 2014), and increased microorganism resistance to certain treatments, such as antibiotics, was associated with increased morbidity, mortality, and of course, higher healthcare-related costs (Fortier & Khardori, 2014; Ray & Singhal, 2014). The increasing toll of Hospital-Acquired Infection (HAI) is documented by the Centers for Disease Control and Prevention [CDC] (2009) accounts to two million infections, 90,000 deaths, and $4.5 billion dollars in healthcare costs annually. Tayh (2011) noted that *Staphylococcus aureus* as one of the leading hospital-acquired pathogens that contribute to the ill-health condition of patients, which is the same organism that has been regarded with resistance to certain antibiotics (Tayh, 2011).

The main aim of the study is to generate empirical evidence by testing the effect of the safekeeping practices (PIS) and two environments (AC and nAC), in preventing microbial contamination on the neck of opened single-use ampules. Furthermore, it sought to determine the same outcome when ampules were kept in a closed plastic container that in theory can reduce contamination by achieving a seal away from the natural environment (Black, 2013; Morse & Meitzner, 2013; Tortora et. al, 2013; Wessner, Dupont & Charles, 2013; Pitt & Barer, 2012; Engelkirk & Duben-Engelkirk, 2011).

Methodology

A 2x3factorial experimental research design was utilized in comparing the effects of the PIS, two environments and use of a closed plastic container in preventing microbial contamination of opened single-use ampules. Two hospitals were duly selected, one with an AC equipped unit and the other has none (nAC). A total of 180 ampules (75, 101 and 4 ampules with a corresponding volume of 1 mL, 2 mLs and 3 mLs) were collected in the hospital. These were mostly anti-spasmodics, anti-pyretics, and histamine-2 receptor blockers, pain relievers, anti-infectives, anti-seizures, anti-inflammatory agents, antihistamines, pro-coagulants, and anti-cholinergics. Ampules were randomly allocated in their respective groups, either control or experimental in two environments with PIS by fishbowl technique as denoted in Figure 1. Each of the safekeeping practices in two environments received 15 ampules, which were left at the bed side for a period of 6 hours.

After 6 hours, trained Medical Technologists collected the specimens from the neck of all the opened single-use ampules (control and experimental) by using a sterile cotton swab; consequently, it was soaked in 2 cc of sterile normal saline solution (NSS) enclosed in a sterile vacutainer, and were transported to the laboratory for culture and growth. Following strict flame sterilization in handling test tubes with specimens, a sterile inoculating loop was used to collect 10 uL of the NSS in the vacutainer and was streaked on a nutrient agar plate (NAP). After incubation, the NAPs were placed in a Colony Forming Unit counting device for the proper counting and notation of the colonies formed, expressed in CFU/mL. Data collected after the meticulous counting was logged on an observation checklist for proper notation.

Kolmogorov Smirnov test yielded a score of 0.000, which denoted that the data collected were not normally distributed, hence, suggesting that the non-parametric tests Man-Whitney U (comparing two groups) and Kruskall-Wallis (comparing three groups) were employed to determine and compare the effects of PIS, two environments and use of a closed plastic container in preventing microbial contamination. The Statistical Package for Social Sciences version 21 was used.

Ethical clearance was expedited since the research protocol did not include any human subjects to be involved in the entire process of experimentation; the ampules used were provided and were not taken from actual medications of the patients; and trained personnel ascertained the conduct of the research adhering on standards of preventing cross contamination.

Results

In preventing microbial contamination on the neck of opened single-use ampules, use of closed plastic container (MW=0.000 <

Table 1. Comparison on the Effects of the Safekeeping Practices, Use of a Closed Plastic Container and Two Environments in Preventing Microbial Contamination of Opened Single-use Ampules

	Mean	*SD*	*Mdn*	IQR	p-value
Practices in Safekeeping					
Exposed[a]	1566.7	4537.3	450.0	775	0.656[K]
Micropore[b]	2685.0	6583.3	450.0	1075	
Cotton Plug[c]	3928.3	8378.4	500.0	1100	
Various use of a Closed Plastic Container					
With a closed plastic container[d]	1838.9	5483.1	300.0	625	0.000*[MW]
Without a closed plastic container[e]	3614.4	7690.1	600.0	1100	
Environments					
AC[d]	886.67	2224.5	200.0	725	0.000*[MW]
nAC[e]	4566.7	8888.2	500.0	1325	

α) and AC environment compared to nAC (MW=0.000 <*α*) favorably demonstrated reduced number of microbial colonies, which was neither observed among the safekeeping practices, keeping the ampules exposed, covered with a micropore or cotton plug (K=0.656 >*α*).

Discussion

Evidently, the number of microbial colony forming units was reduced when kept in a closed plastic container and when exposed in an AC environment. The number of colony forming units were reduced among the ampules enclosed in a closed plastic container which may be related to the double barrier protection that separated the natural environment of microbes and the scarcity of the needed requirements for microbial multiplication (Tortora et.al., 2013; Wessner et.al., 2013). Microbes in ampules in the AC environment were noted to be lesser because most microbes would require warm temperature, as noted in Thompson (2013) and Tortora et.al. (2013), as an auspicious and promising requirement that augments microbial activity in terms of growth, multiplication and proliferation. A colder environment, on the other hand, promotes lesser metabolic activities of microorganisms, hence limiting growth and reproduction (Roberts, 2015; Engerlkirk & Duben-Engelkirk, 2011). However, these did not totally prevent microbial contamination, which contradicts the claim of most literatures cited in Black (2013), Morse and Meitzner (2013), Tortora et.al. (2013), Wessner et.al. (2013), Engelkirk and Duben-Engelkirk (2011) and HSDUE (2009).

In terms of the safekeeping practices, none was able to depict the effect of preventing microbial contamination. The hands of the health-care provider, used in manipulating the ampule, and application of the micropore and cotton plug were essentially known to be reservoirs of microorganisms, which may be considered potential sources of contamination (Kapil, 2014; Oberoi &Wattal, 2014; Bhatta, GoKhale, Ansari, Tiwari, Gaura, Mathuria, & Ghosh, 2011; McDonnell & Russel, 1999). Additionally, Wessner et.al. (2013) and Bauman (2012) observed microorganisms have the capacity to create biofilms, which enabled them to find attachment on surfaces of fomites (Vickery et.al., 2013; Talsma, 2007; Vickery et.al., 2004; Rioufol,Deyvs, Meunier, Perraud, & Goullet,1999). The adhesiveness of the micropore tape was a potent source of contamination (Venkateswaran et.al., 2001) possibly collecting surface microorganism on the hands of the health care provider. Ampules which were merely exposed in the health care environment with omnipresent microorganisms (Booty & Barraclough, 2010), can be contaminated readily (Black, 2013; Morse & Meitzner, 2013; Tortora et.al., 2013; Wessner et.al., 2013).

Conclusions and recommendations

Safekeeping practices that are observed in today's health care setting were not effective in preventing microbial contamination. Despite the result of reduced number of microbial colony forming units using a closed plastic container and AC environment, these are not recommended. Nurses, who are advocates of the patients, should prioritize safety and maintain quality care as they execute their duties and responsibilities. Minimizing health care cost by reusing opened single-use ampules may be beneficial, but, learning that none of the safekeeping practices currently employed was effective in preventing microbial contamination, reuse may place more harm on the health of the patient, which may consequentially lead to a more expensive health care. Nurses should actively be involved in promoting none reuse of drug-left over for these might also be contaminated since the neck portion was noted to bear colonies of microorganisms. Adherence to the principles of medical asepsis in the preparation and administration of medications should be strictly observed. Identification of the specific organisms that thrived on the neck of the ampules may be a direction for future research.

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