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Research Article

The Sterility of Reusable Surgical Instruments with Pouches Packaging on One of the Private Hospital in Bandung

Kurniawansyah I S[1*], Mita S R[1], Najla N[1], Nindayani E[2]

[1]*Faculty of Pharmacy, University of Padjadjaran, Sumedang, Indonesia*
[2]*Al-Islam Hospital, Bandung, Indonesia*

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ABSTRACT

Healthcare associated infection is one of the common infection that happens in Indonesia. One form control to prevent healthcare associated infection is the sterilization process of the materials and medical instruments that used for taking care of patients. At the private hospital whereas a place of research, there's never been done the study of sterility test for reusable instrument with pouches, based on previous studies showed that 8 sets from 40 sets of reusable instrument with linen were not sterile moreover there were positively influence from the amount of time to the sterility of reusable instrument. The purpose of these studies was to determining the relationship between a long storage time and the sterility of reusable instruments with pouches. The method that used in this study was the sterility testing of reusable instrument with pouches which were stored in a central operations room storage with a long storage time of 1 and 2 months. From 30 reusable instruments with pouches which were stored for nine months there were 5 instruments were not sterile. The results of statistic analysis showed that the amount of storage time not significantly associated to the sterility of reusable instrument with pouches in the operating room central storage space.

Keywords: Central Operating Room,Healthcare Associated Infection, Reusable Instrument, Pouches Packaging, Sterility Testing.

INTRODUCTION

Prevalance of Healthcare Associated Infections (HAIs) in Indonesia is very diverse. The Ministry of Health of the Republic of Indonesia study in 2004 showed that the incidence proportion of HAIs data obtained in a government hospital with a number of patients affected by the HAIs as much as 1,527 people or around 0.95% of the number of patients at risk of 160,417 people. As for the private hospital with the number of patients affected by the HAIs as much as 991 people or about 0.76% of the number of patients at risk of 130,047 people[1].

One of the factors that causes HAIs is the use of reusable surgical equipment that is not sterile. One of the activities for HAIs control is sterilization of reusable materials and instruments[2,3,4]. Reusable instrument is a set of tools that can be used in all hospital units or parts, especially used in the surgical room or operating room. These tools can be used many times, and required a sterilization process for further usage[5]. Action in the prevention of infection have a positive impact on operating costs, patient safety, satisfaction and reputation for health services at the hospital. In addition to mortality, hospital infections can cause enormous financial burden for patients and governments. Hospitalization time will become longer, besides the patients experiencing a lot of discomfort and was depressed by the situation[2,6].

The hospital has developed a method that is often referred to as The Central Sterilization Department or the system is also called as Central Sterile Supply Department (CSSD) to address the threat of hospital infections caused by pathogenic microorganisms[2]. CSSD main function is to prepare the tools clean and sterile for the purposes of patient care in the hospital[7].

Sterilization is the most commonly used in the CSSD is a steam sterilization[8]. Packaging materials in steam sterilization should facilitate the process of releasing vapor both on the packaging and its contents and should be easy to dry and easy draining of its contents. One of the frequently used on packaging in steam sterilization is sterile plastic film or bags (pouches). The advantages of the use of sterile pouch is easy to see the contents of the items in it for the front side is made of transparent films[2]. Equipment with packaging pouches sterilized distributed to several rooms, one operating room. The operating room is an intensive care unit at the hospital that play a role in the surgical operations. Storage reusable surgical instruments in the operating room is an important factor for maintaining sterility assurance surgical equipment. On this storage process, possible contamination that may occur due to the storage space does not meet the requirements. Therefore, it needs special attention, especially the cleanliness and sterility in order to always create an aseptic condition in terms of both space and the tools used in the operating room[9].

The research by Maulidya et al. in the same hospital with the study showed that 8 of the 40 sets of reusable surgical

**Author for Correspondence: insan.sunan.kurniawansyah@unpad.ac.id*

packaged with linen were not sterile. Storage time also affect the sterility of reusable instruments with linen packaging[10].

Based on the background that have been put forward, will resume research on sterility testing of reusable surgical equipment with packaging pouches contained in the storage space in the operating room of the hospital and see the effect of storage time against the sterility of reusable surgical equipment with packaging pouches.

MATERIALS AND METHODS

Chemicals and reagents

Alcohol 70% (Brataco®), phenol (Brataco®), aquadest (Brataco®), aqua pro injection (Ikhapharmindo®), trypticase soy agar(TSA) (E-Merck®), trypticase soy broth(TSB) (E-Merck®), fluid thioglycollate medium(FTM) (E-Merck®), bacillus subtilis bacteria (micro lab), candida albicans fungus (micro lab).

Instruments/equipment/apparatus

Autoclave (All American™), spirit lamp (Pyrex®), Petri dish (Pyrex®), incubator (Memmert™), test tube rack (standard), test tubes (Pyrex®), digital balance (Ohaus™), laminar air flow cabinet (Esco™).

Preparation of apparatus and materials

The apparatus and materials were sterilized first for sterility assurance and not to affect the results of the experiment. The apparatus used in this research were the autoclave, spirit lamp, Petri dish, incubator, test tube rack, test tubes, digital balance, and glassware. The whole research procedure conducted in the laminar air flow cabinet which has been sterilized with alcohol 70 % and exposed to UV rays for 2 hours before starting any work and the floor of the laminar air flow room was cleaned with phenol solution[11].

Preparation of reusable surgical instruments with pouches

As many as 20 reusable surgical instruments used in the central operations room set up, then washed with soap and dried using the next lap packaged using pouches. Sets of instrument that have been packed, taken to the installation of the CSSD to be sterilized by autoclaving. Reusable surgical instruments that have been sterilized and then distributed to the storage operating room. Each set of reusable surgical instrument stored for sampling at month 1, 3, 5, 7, and 9.

Microbial contamination testing of laminar air flow and central operating rooms

A sterile petri dish containing trypticase soy agar were placed into the laminar air flow cabinet and central operating room. The lid of the petri dish were removed, and the petri dish were left exposed for 15 min. After that, they were covered, labeled and incubated at 37 °C for 18-24 hours[12].

Sterility testing of reusable surgical instruments with pouches

Sterility testing of reusable surgical instruments made by soaking method. Samples were taken from the central operating room storage space, reusable surgical instruments that will be examined were removed from the packaging pouches and then soaked with FTM and TSB media were then taken across the media the results of soaking and put into a sterile erlenmeyer flask that had been prepared. Then, media immersion results inserted into three sterile test tube aseptically. Then each of the media incubated at 30-35^{0}C for FTM media and for media TSB 20-25^{0}C for 7-14 days. The occurrence of turbidity in a test tube was observed and recorded on days 1, 3, 5, 7, and 14[13]. Tests were conducted at months 1, 3, 5, 7 and 9 of storage time, the number of samples tested per month test was four packaging pouches.

Data Analysis

Analysis of data using a computer device performed by using logistic regression analysis to find the influence of storage time against the sterility of reusable surgical instrument with pouches and using the chi square to determine the relationship between storage time against the sterility of reusable surgical instrument with pouches, following stages[7]:

Logistic regression analysis

Regression significance

The significance of regression was done with test of significance to know the influence of independent variable i.e., the influence of the length of time against the sterility of reusable surgical instrument. With the proviso p-value > α, so H0 was accepted, the hypothesis to be tested were as follows:

H0: there was no significant influence between prolonged storage time against the sterility of reusable surgical instrument with pouches.

H1: there was significant influence between prolonged storage time against the sterility of reusable surgical instrument with pouches.

Coefficient of determination

The coefficient of determination using Nagelkerke, a value that indicates the magnitude of the variability of the dependent variable (the sterility of reusable surgical instrument with pouches) that can be explained by the independent variable (retention) were studied. The coefficient of determination was used to find the contribution of storage time against the sterility of reusable surgical instrument with pouches.

Odds ratio

Odds ratio is the ratio of the opportunities being made to interpret the data results of a relationship between the length of storage against the sterility of reusable surgical instrument with pouches.

Analysis of Chi Square

Chi square analysis is one of the association test to determine whether or not the relationship between the two nominal and nominal variables, which in this study to determine the relationship of the amount of time and sterility of reusable surgical instrument with pouches. With the proviso p-value ≤ α then H0 is rejected, the hypothesis to be tested were as follows:

H0: There was no relationship between the storage time and the sterility of reusable surgical instrument with pouches.

H1: There was a relationship between the storage time and the sterility of reusable surgical instrument with pouches.

RESULTS AND DISCUSSION

Table 1: Fertility and Sterility Testing Media Test.

Observation days	Fertility testing		Sterility testing	
	FTM + *Bacillus subtilis*	TSB + *Candida albicans*	FTM	TSB
1	+	+	-	-
2	+	+	-	-
3	+	+	-	-
4	+	+	-	-
5	+	+	-	-
6	+	+	-	-
7	+	+	-	-

Description : (+) = microbial growth
(-) = no microbial growth

Table 2: Microbial contamination test of laminar air flow space.

Petri dish	Result
1	-
2	-
control (-)	

Description : (+) = microbial growth
(-) = no microbial growth

Results and discussion of the research described the results obtained from laboratory testing. Storage reusable instruments in the operating room is one of the important factors for maintaining sterility assurance of reusable surgical instruments. At the hospital where the research was still a non-sterile surgical equipment was stored space of the central operating room.

Medium Test Evaluation

On testing the sterility of reusable devices, the sample was immersed in the media. Media can be either liquid or solid. Liquid medium used was Tryptone Soy Broth (TSB) as a medium for bacterial growth of mold and Thyoglikolat Fluid Media (FTM) as a medium for bacterial growth. While the solid medium Trypticase Soy Agar (TSA) was used to isolate a wide variety of aerobic microorganisms[14]. Before performing reusable sterility test equipment, test media to be used need to be evaluated first. Test media evaluation stage includes fertility test FTM against Bacillus subtilis and media TSB of the fungus Candida albicans, and the results that can be seen in Table 1.

The data in Table 1 showed that there was the growth of bacillus subtilis in FTM and candida albicans in TSB media. These mean that both of the growth media were good for microbial growth and could be used for sterility test[13].

Microbial contamination test of laminar air flow space and central operating rooms

The microbial contamination test was usually conducted using settling plate method. The aim of the test was to ensure that the laminar air flow and central operating rooms were free from all forms of living organism that could cause contamination. The result of this test showed that the laminar air flow space fulfilled the sterility condition (Table 2).

The laminar air flow space was an area for testing of sterile product and categorized as class 1 or white area and has to meet the total number of microbes allowed requirement. According to the good manufacturing practice guidelines, the growth limit of microbes in class 1 area is less than 1 cfu and it turns out that based on the results obtained in table 2 showed that the growth of bacteria was 0 cfu[11]. In order to obtained a sterile room/space and meet the number of microbes and particle's requirement, the inner and outer parts of the laminar air flow cabinet had disinfected first with alcohol 70 % and phenol to clean the floors, walls, and ceiling of the room. The mechanism of action of alcohol was by penetrating the bacterial cell wall with the help of water and cause denaturation of the cell wall protein, causing cell lysis. Alcohol 70 % was used for the disinfection of laminar air flow cabinets because it did not corrosive towards metal and evaporates easily thus minimizing the time of contact with the surface of the laminar air flow cabinet. Phenol works by coagulating proteins, which led to the leakage of the bacterial cell membrane. Phenol is commonly used for the disinfection of floors, walls and tabletops and so on. Phenol is unsuitable for cleaning the inner surface of the laminar air flow cabinet due to its longer contact time with the surface compared to that of alcohol and its more corrosive property[2,12,15]. And for central operating rooms, the result can be seen in Table 3.

Based on the data in Table 3 can be seen that there were 4-36 colonies grown on a test plate. This showed that the central operating room storage room was not meet the standards of a sterile room that is <10 CFU / m3, and it is feared may play a role in the spread of the HAIs[2]. Therefore reusable instrument sterility testing that was in the storage space needs to be done to determine the influence of storage space against the sterility of instruments was kept.

Sterility testing of reusable surgical instruments with pouches

The result of **s**terility testing of reusable surgical instruments with pouches can be seen in Table 4.

The data were showed in Table 4, in the central operating room storage space, on first month storage, there were four non-sterile surgical instruments. On 3rd month of storage, there were 3 non-sterile surgical instruments. At 5th month of storage, there were four non-sterile surgical instruments. The 7th month storage, there were two non-sterile surgical instruments. And 9th month of storage, there were two non-sterile surgical instruments.

Data Analysis

The influence of storage time against the sterility of reusable surgical instrument with pouches

To find the influence of storage time (months) against the dependent variable in the form of the sterility of reusable instrument in the form of data categories and is dichotomous (it has only two variables: sterile / not sterile), analysis was performed using logistic regression. From the test results obtained p-value of 0.069 where the value was greater than alpha 0.05 and cause H0 were accepted. This means that prolonged storage for 1, 3, 5, 7, and 9 months did not have a significant influence on the sterility of

Table 3: Microbial contamination test of central operating room.

Petri Dish	Place	Number of colony
I	Storage Cabinet	21
II	Around Area of Storage Cabinet	26
III	Patient Area	4
IV	Public Area	36

Table 4: Sterility testing of reusable surgical instruments with pouches.

Month of	Number of sterile instrument	Number of non-sterile instrument
1	-	4
3	1	3
5	-	4
7	2	2
9	2	2

reusable instruments were stored in a central storage space the operating room, so no need to proceed to the calculation of large contribution to influence. Therefore, advanced further tests ie the coefficient of determination and interpretation of the data using odds ratio, can not be done.

Furthermore, the association test to determine the relationship between the storage time and the sterility of reusable surgical equipment packaging pouches in the central operating room storage room on the condition that if the p-value ≤ α, then H0 was rejected. After testing with α = 5%, was obtained p-value of 0.255. The greater value of α = 5%, so that H0 was accepted. So, there was no relationship between prolonged storage for 1, 3, 5, 7, and 9 months and the sterility of reusable surgical instrument packaging pouches were stored in a central storage space the operating room.

The results of this study do not fitted with previous studies in which, long storage had an influence on the sterility of surgical instruments. This occurs due to the possibility of factors that lead to inaccuracy of the test results, namely, the condition of the sample packaging, succeeding indicator sterilization, and sterilization programs were used.

CONCLUSION

Sterility testing results of reusable surgical instrument in the central operating room storage space, it can be concluded as follows:

The reusable surgical instrument storage in the central operating room storage space of 20 sets of reusable surgical there were 15 sets of reusable surgical equipment that were not sterile.

Long storage time does not affect the sterility of reusable surgical instruments. And there was no relationship between the length of time storage against the sterility of reusable surgical instrument packaging pouches.

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