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The Sterility of Reusable Instruments at Central Surgery Installation's Room Storage of One of The Hospital in Bandung

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Abstract

Hospital-acquired Infection (HAIs) is one thing that can increase the morbidity and mortality in hospitals. One form of action to control the (HAIs) can do with the sterilization process of medical instruments that used in patient care. Storage of reusable instruments in Central Surgery Installation was an important factor in maintaining the instrument's sterility assurance. At the hospital where the research was taken place, the sterility test of reusable instruments never been done. This study was conducted to determine the effect of the storage's time against the sterility of reusable instruments. The observational and laboratory testing were used for methods of the research. The swab method was used to find out the sterility of 30 sets of reusable instruments with time of storage at 1, 4, 8, 12, 16, and 17 days.The result showed that the storage on day of 12, there was one of reusable instruments that was not sterile. The statistical analysis showed that there was positively influenced of storage time towards the sterility of reusable instruments that stored in the storage room of the Central Surgery Installation.

Keywords: Hospital-acquired Infection (HAIs), Central Surgery Installation, Reusable Instruments, Sterility Testing, Swab Test.

INTRODUCTION

Nosocomial infections are commonly referred to as hospital acquired infection is an infection acquired within the confines of a hospital.[1] Nosocomial infections today is one of the causes of increased morbidity and mortality in hospitals, and is rapidly becoming a new health problem, both in developing countries and in developed countries.[2] Based on data from several studies in years 1995-2010, the prevalence of nosocomial infections in the countries of low and middle income ranges between 5.7% - 19.1%, including 7.1% in Indonesia.[3]

Nosocomial infection is caused by two factors, one of which is an exogenous factor. Exogenous factors are factors outside the patient's body, such as the length of the patient being treated, the treating group, as well as medical engineering equipment used.[4] The operating room is one of the most regular source of nosocomial infection. The nosocomial infection rate for surgical wound in Indonesia was reported by 2.3% - 18.3%.[5] The data show that the incidence of nosocomial infections in the operating room is moderately high.

Infection control measures need to be done to minimize the hospital's infection rate. Sterilization of medical instruments is necessary to be used for services to patients, especially patients in the operating room. Proper storage of reusable instruments is an important factor in maintaining the sterility of instruments to avoid possible contamination.[6,7] Therefore, the condition of the storage space should be in accordance with the standards required.[8]

Research conducted by Syabila in a private hospital in Bandung result of 40 sets of instruments showed there were 8 sets of instruments that were not sterile, while based on research conducted by Zahari at the CSSD private hospital in Bandung based on results of 30 sets of instruments there were 11 sets of instruments that were not sterile.[9,10]

Based on the background that has been presented, research on sterility testing instruments reusable storage room Central Surgical Installation was conducted at one hospital in Bandung to ensure the sterility of the instruments to be used, thus providing assurance of sterility and safety for said hospital patients.

MATERIAL 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 ATCC 6633 (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™).

Research samples

The sample used in this study was a reusable instrument in the storage space Installation of Central Surgical hospital in Bandung. The sample consisted of 30 sets of instruments which contained tweezers, scissors yarn, scissors nets, clamps crooked, fulder nal, anatomical tweezers, straight tweezers, tweezers sirurgis, which had be used multiple times and it had been wrapped into a set of reusable instruments.

Method

The research was used laboratory experiment that can be drawn as follows :

Preparation Tools and Materials

Tools and materials used were prepared initially prior to washing. Glass tools used were wrapped in opaque paper and sterilized by autoclaving at 121 °C for 15-30 min. After that, qualitative tools were sterilized by inserting into the oven at 150 °C for 1 h.[10]

Making the Test Media

1. Trypticase Soy Broth (TSB)
   TSB 7.5 g was weighed, and then dissolved in 250 mL of distilled water, until all were dissolved. The solution was then sterilized in an autoclave at 121 °C for 15 min.
2. Fluid Thyoglikolat Medium (FTM)
   FTM 7.5 g was weighed, and then dissolved in 250 mL of distilled water, until all were dissolved. The solution was then sterilized in an autoclave at 121 °C for 15 min.
3. Trypticase Soy Agar (TSA)
   TSA weighed 5.75 g, then dissolved in 250 mL of distilled water before boiling until dissolved. The solution was then sterilized in an autoclave at 121 °C for 15 min.

Test Media Evaluation

The test media evaluation was conducted, namely fertility test media. *Bacillus subtilis* bacteria were implanted into two test tubes containing sterile media FTM each, then incubated at 30-35 °C for not less than 7 d. While fungus *Candida albicans* were each implanted into two tubes containing TSB sterile media, then incubated at 20-25 °C for not less than 7 d. Data was collected for turbidity that occurred in a test tube.

Contamination Testing of Installation Space Central Surgery

Test Installation of Central Surgical room contamination was carried by said plate method. A total of 4 fluid-filled Petri dishes were prepared in aseptic TSA media, then one Petri dish placed in a storage closet of Central Surgery Installation and 3 Petri dishes were placed in the area of storage space. Petri dishes were placed in an open state for 15-30 min. Then resealed and placed in an incubator for 24 h at 37°C. The number of colonies formed were calculated.

Sterility Testing of Reusable Instruments

Aseptic sampling inspection was conducted in the LAF. Sterility testing of reusable instruments was performed by the swab method, using a sterile swab transport beforehand moistened with sterile Aqua bidestilata pro injectionum (pyrogen free) which was then rubbed in the sample study. Then transport swab immediately put into sterile Aqua bidestilata pro injectionum which had been prepared in a test tube. Aseptically each test sample was inoculated directly into a test tube containing FTM and TSB media. Then each of the media incubated at 30-35 °C for FTM media and 20-25 °C to TSB media during the last 14 d the turbidity observed on days 1, 3, 5, 7 and 14. Tests were conducted on the day 1, 4, 8, 12, 16 and 17 of the storage time.

Data analysis

The data obtained from the test instrument sterilization of reusable storage from the Installation of Central Surgical was processed and interpreted in two stages, namely descriptive analysis and statistical analysis.

Descriptive analysis

Descriptive analysis was done by describing or depicting the result of collected data as it is.

Statistical analysis

Statistical analysis was performed using logistic regression analysis to find the amount of time needed for the effect of sterilization on reusable instruments. Stages of logistic regression were performed as follows:[11]

1. Significance
   Significance testing was done using a significant test on hypotheses to be tested. Hypothesis was a tentative conclusion, benchmark with provisional estimates that the truth would be proven in research. The hypothesis for effect of the amount of time:
   H0: There is no longer the effect of storage time of sterilization on the results of reusable instruments.
   H1: There is a long effect of storage time of sterilization on the results of reusable instruments.
2. The coefficient of determination
   The coefficient of determination is the proportion of the variability in the data that is calculated based on statistical models. The coefficient of determination used was Nagelkerke, conducted to seek the contribution of long storage time of the sterilization of reusable instruments.
3. Odds ratio
   The odds ratio is defined as the ratio of the value of the independent variable and the dependent variable. The odds ratio which was the ratio between the odd one with odd reference variable or control.

RESULTS AND DISCUSSION

The results and discussion obtained during testing in the laboratory will be described in this chapter. The results covered include contamination test chamber Laminar Air Flow (LAF), the test contamination Central Surgery Installation of storage space, test of medium fertility and the sterility test of instruments in the storage room.

Preparation Tools and Materials

The equipment used was cleaned and sterilized using an autoclave. It was done to avoid any contamination coming from the equipment. Furthermore, the growth media used were also sterilized using an autoclave.

Microbial Contamination Testing on Space Laminar Air Flow (LAF)

The test was conducted to determine the number of microbes in the testing room, in this case LAF, sterilized and ready for use. Alcohol 70% was used in the process of disinfection and sterilization. Then the blower tool LAF was lit with ultraviolet irradiation for 1 h. Microbial

contamination testing was done using the plate method which was also called as Settling Plate method. By way of a Petri dish, which was filled with media TSA, was placed in the LAF for 15-30 min in an open state. It was then incubated at 37° C for 18-24 h. The test results of microbial contamination in the LAF can be seen in Table 1.

Based on data in Table 1, it can be seen that the LAF has been sterilized. It was indicated by the absence of microbial growth in the cabin LAF. LAF space meets the requirements according to the GMP sterile room, where the number of colonies of bacteria for space LAF ie <1 cfu / m3 so it can be used as a test sample.[13]

Table 1. Microbial Contamination of LAF Cabinet

Place	Colony (CFU/m^3)
LAF Cabin Area	0
LAF Outer Area	0
LAF Around Area	3

Table 2. Microbial Contamination in The Storage Room of The Central Surgical Installation

Place	Colony (CFU/m^3)
Storage Cupboard	2
Storage Room 1	8
Storage Room 2	7
Storage Room 3	13

Microbial Contamination Test on Storage Installation Central Surgery

Testing of microbial contamination of storage space Installation Central Surgery was performed to determine the number of microbes in the storage room of reusable instruments. Microbial contamination testing was done by using the plate method explained called as Settling Plate method. By way of a Petri dish filled with media TSA was placed in the storage space of the Central Surgical Installation for 15-30 min in an open state. Then incubated at 37°C for 18-24 h. The test results of microbial contamination in the storage room of the Central Surgical Installation can be seen in Table 2.

Data in Table 2 showed that the results of microbial contamination tests carried in a storage cupboard and storage space of Installation of Central Surgical still meets the requirements, whereby the average number of colonies was 9.3 cfu/m3. The number of colonies which meets the requirements of storage space reusable instruments surgical installation is <10 cfu / m3. So it can be said that the storage space was still feasible to be used. It has to be said that the cleanliness and sterility of storage space is an important instrument to inhibit the growth of microorganisms.[13]

Media Test Evaluation of FTM and TSB

Before performing sterility tests of reusable instruments, it is necessary to evaluate the test medium to be used first. Evaluation conducted was a fertility test. This test was conducted to see the media's ability to grow microbes. Test medium used were Trypticase Soy Broth (TSB) and Thioglycolate Fluid Medium (FTM) for fungus and bacterial growth media.

Medium fertility testing was performed by implanting Candida albicans in TSB media and embed Bacillus subtilis on FTM media. The result of the fertility test of both media seen in Table 3.

Based on the data in Table 3, there were growth of bacteria *Bacillus subtilis* in the media FTM and fungus *Candida albicans* in TSB media. As for the sterility test, there were no microbial growth in both media. This suggests that the TSB and FTM media meet the requirements of fertility and sterility test so it can be used for sterility testing sampling.

Table 3. The Fertility Test of FTM and TSB

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

Description :
(+) = Growth of microorganism
(-) = No Growth of microorganism

Descriptive Analysis Results for Sterility Testing of Reusable Instruments

Sterility testing of reusable instruments made to the instruments contained in the Central Surgery Installation of storage space with a total sample of 30 sets of instruments. The analysis presented consists of two parts; namely descriptive and statistical analysis. Discussion on the descriptive data analysis will be done before hand in this section.

Reusable instrument sterility testing was conducted using a swab. Samples tested include reusable instrument sets stored in the storage room of the Central Surgical Installation with storage time variation 1, 4, 8, 12, 16, and 17 d. Results of testing the sterility of reusable instruments can be seen in Table 4 and Table 5.

Table 4 showed that the sterility of aqua bidestilata and swab were sterile. The testing was done to ensured that the aqua bidestilata and the swab were void from contamination of microorganisms.

Table 5 showed that on day 1 of storage, from 5 tested reusable instruments not one instrument was found to be not sterile. Likewise on day 4 and day 8 of storage, of 10 instruments that were tested not one reusable instrument was found to be not sterile. The growth of microorganisms was first found on day 12, namely from the storage of five instruments only 1 instrument was found to be not sterile. On the 16th day of storage, there was a decrease of the number of reusable sterile instruments, namely out of five instruments tested, three instruments that were found to be not sterile. While on the 17th day of storage, the amount of

sterile instruments decreased, from 5 instruments there were four instruments found to be not sterile.

A large number of reusable instruments in Central Surgery Installation of storage space that was not sterile can be caused by various factors, such as environmental factors and factors of personnel. The number of officers who were around the sterile instrument storage space can lead to microbial contamination and can contaminate sterile instruments stored.

Another factor that can affect the sterility of reusable instruments was packaging of instruments. To prevent contamination, the instruments were washed and wrapped in linen or pouch prior to sterilization. This wrapping should be able to inhibit the entry of microorganisms into the instrument that has been sterilized, moreover, this wrapper also must be able to be penetrated by penetrating tool that is within sterile instruments.

In addition to the sterilization process, the distribution process was also an important thing in determining the sterility of reusable instruments, especially the distribution of reusable instruments when moving from room Central Sterile Supply Department (CSSD) to the Central Surgery Installation of storage space. There should not be a big difference between the space within the CSSD and sterile instrument storage space and the path should not often be bypassed by visitors of the hospital, including patients of the hospital. All phases of the sterilization process must be adapt to the requirements of the standards set by the hospital so that the sterility of reusable instruments stored can be assured and protected from contamination of microorganisms.[13]

Table 4. The Sterility of *Aqua Bidestilata Sterile Pro Injectionum* and *Swab* as Control

Sample	Sterility
Sample 1	Sterile
Sample 2	Sterile
Sample 3	Sterile

Table 5. The Sterility of Reusable Instruments

Day	Amount of Sterile Instrument	Amount of Non Sterile Instrument
1	5	0
4	5	0
8	5	0
12	4	1
16	2	3
17	1	4

Table 6. Interpretation of *Odds ratio*

Storage Time (Day)	*Odds ratio*
1	1
4	1
8	1
12	0,27
16	0,064
17	0,030

Results of Statistical Analysis for Sterility of Instrument Testing

To determine the effect of storage time on the sterility of reusable instruments that have been tested, statistical analysis using logistic regression method was performed.

Significance of Old Time Sterility of Reusable Instruments

To determine the effect of storage time on the sterility of the instruments, analysis on the reuse of the impacts on the independent variable independent variable (independent), ie the amount of time, and the dependent variable (dependent) which was the result of sterility. The hypothesis was as follows:

H0: There is no effect of the amount of time against the sterility of reusable instruments.

H1: There is the influence of the amount of time the sterility of reusable instruments.

Statistical analysis used to see the relationship between the two variables was based on logistic regression. The test rejected H0 if the significance value <5%. Based on the results obtained, a score of significance or probability of testing is 0.02. This result was smaller than the significance level of 5%. It can be concluded that there were significantly long storage time of the sterility of reusable instruments stored in the storage room of the Central Surgical installation.

Contributions Old Time against Sterility of Reusable Instruments

Coefficient of determination coefficient analysis *Nagelkerke* was used to find out how much influence the amount of time contributed to the sterility of the instruments used. Based on the calculation coefficient *Nagelkerke*, a value of 0.649 was obtained. This shows that the influence of the amount of time against the sterility of reusable instruments have contributed as much as 64.9% while the remaining 35.1% is influenced by other factors which were not included in the calculation of this logistic regression. For example, direct contamination of human resources or in the distribution process.

Odd Ratio Interpretation of the Old Time against Sterility of Reusable Instruments

The results of logistic regression equation was a form that is not linear, so as to make an interpretation it cannot be done directly as a simple linear regression model, but must use the value of the odds ratio by comparing the odd one with odd reference variable or control.

The interpretation of the amount of time against the sterility of the instrument by using the opportunities Day 1 as the control can be seen in Table 6.

Based on data in Table 6, for the duration of storage on day 4 and day 8 shows the value obtained odds ratio which was the same as the day-1 or it can be concluded that the storage time on day-1 has same level of sterility as day 4 and 8. For the duration of storage on the 12^{th} day, the value of odds ratio was 0.27 or it can be

concluded that the storage time on day-1 result was 3.70 times more sterile than the 12th day of storage.

For the duration of storage on the 16th day, the values obtained odds ratio of 0.064 or it can be concluded that the storage time on day-1 result is 15.625 times more sterile than the 16th day of storage. As for the duration of storage on the 17th day, the values obtained odds ratio of 0.030 or it can be concluded that the storage time on day-1 results are 33.33 times more sterile than the 17th day of storage.

CONCLUSION

Based on research that has been done, some conclusions can be drawn as follows:

1. The reusable instrument storage in the storage room of the Central Surgical Installing hospital in Bandung, which was packed using pouches, on the 12th day, one reusable instrument was unsterile among 5 reusable instruments being tested. On the 16th day, 3 reusable instruments were not sterile and the 17th day of storage there were 4 reusable instruments that were not sterile.
2. Long storage time has an effect on sterility of reusable instruments stored in the storage room of the Central Surgical Installing of one hospital in Bandung, where the longer the storage time, the number of instruments that remain sterile reusable was reducing.

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