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THE EFFECTS OF SHELF LIFE OF STERILE INSTRUMENTS ON THE COLONY COUNT OF INSTRUMENTS STERILIZED IN THE AL-ZAHRA HOSPITAL AFFILIATED TO THE ISFAHAN UNIVERSITY OF MEDICAL SCIENCES

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ABSTRACT

Introduction: One of the most important sources and means of transmitting nosocomial infections is improper sterilization of surgical tools and instruments, because contamination transmission through contaminated surgical equipment and tools is one of the main causes of infection in the surgical wound. The present study aimed to investigate the effect of shelf life of sterile instruments on colony count of instruments sterilized.
Method: this study was field trial. The population included 66 surgical packs and 66 instruments sterilized in the Hospital Central Supplies. 22 of them were randomly selected according to the considered periods (3, 15 and 30 days for fabric packs and 6, 15 and 30 days for surgical instruments) and colony counting was performed. In order to perform colony counting, a sterile swab plated with normal saline was rotationally rubbed on the 5*6 cm rectangular area of the inner surface of surgical packs and 1*5 cm area of the sterilized instruments packs and then, the swab was returned to normal saline. The specimens were transferred to the laboratory and placed in a medium of Blood Agar and Eosin methylene blue at 35 ° C for 24 to 48 hours. Microorganisms were then examined in terms of type and number. SPSS V.23 Software was used to analyze the data and the data was analyzed using descriptive and analytical statistical tests.
Results: average number of colonies counted in the sterile packs opened 30 days after sterilization was greater compared to the sterile packs opened 3 and 15 days after sterilization (p-value<0.05) (3 days after sterilization: 68.18±319.80 VS 15 days after sterilization: 113.64±169.86 and 30 days after sterilization: 6527.27±21400.16). Also, no significant difference was observed among the sterilized instruments packs used 6, 15 and 30 days after sterilization (p-value>0.05) (6 days after sterilization: 45.45±147.12 VS 15 days after sterilization: 172.73±636.35 and 30 days after sterilization: 172.73±443.13). The bacteria of Coagulase-Negative Staphylococci, Staphylococcus aureus and Bacillus spp were more present in the samples.Conclusion: according to the results, it is recommended that in the studied hospital, the sterilized instruments packs are stored up to 30 days and the sterile packs are stored up to 15 days after sterilization that due to the reduction in the repetition of sterilization, this results in the economic savings and less damage to the packs and tools in the Hospital Central Supplies as well as the reduction in the workload of the personnel of this department. However, given the fact that each package has its unique half-life and number of bacteria, it is suggested to conduct the same study with greater number of specimens.

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Introduction

Hospitals are one of the important centers for patient care and treatment. In the absence of attention to health and safety issues in hospitals, nosocomial infections are created [1]. Nosocomial infections refer to a type of infection that is created at the time of hospitalization and did not exist at the time of admission or incubation period and additionally, the infections created for the personnel in the hospital should be considered as nosocomial infections. Nosocomial infections are difficulty treated and sometimes lead to death and consequently, directly and indirectly increase hospital costs and create new health hazards in different societies [2]. Prevention of an infection in a surgical patient is the primary responsibility of each member of the post-operative care team. One of the expected results for surgical interventions is that the patient has no signs and symptoms of infection. Today health-related infections are one of the 10 main causes of death in the United States today [3].

One of the most important sources and means of transmitting nosocomial infections is improper sterilization of surgical tools and instruments [4]. Reusable surgical instruments are an important and potential source of transmission of pathogenic microorganisms between patients and should be properly disinfected and sterilized. Sterilizing and disinfecting the instruments improperly can lead to the transmission of microorganisms, such as Mycobacterium tuberculosis, from the instruments to the patients [5]. In order to minimize the chance of infection and to use surgical instruments properly, the steps of cleaning, disinfecting, examining, packing, sterilizing, transferring, storing and using must be performed on them [5].

Previous studies have shown that the shelf life of sterile instruments and packs depends on sterilization process, half-life of the sterilized instruments and packs and the storage conditions and if the conditions of storage, transportation and packaging are favorable, the sterile instruments and packs will remain uninfected for a period more than 30 days, or 6 months, and even 12 months [6-8].

Most hospitals rely on older recommendations when adopting policies about the shelf-life of instruments and in the studied hospital, the instruments and packs are sterilized again 3 and 6 days after sterilization, respectively. So, this is done earlier than recommended by the Centers for Disease Control and Prevention (30 days after sterilization).

Not complying with any of the standards of the Center for Disease Control and Prevention, which is associated with the maintenance of sterile instruments can cause the transmission of infection and the disease caused by the transmission of microorganisms from packs and instruments infected to personnel and patients, and on the other hand, reducing the shelf time will impose economic burden, human costs and damage to the instruments. Regarding the importance of monitoring and inspection from the viewpoint of managers as an important control tool, this study aimed to investigate the effects of shelf-time of sterile instruments on the colony count of instruments sterilized in the Al-Zahra hospital.

Method

This study was field trial and aimed to investigate the effects of shelf-time of sterile instruments on the colony count of instruments sterilized in the al-Zahra hospital. Research environment included CSSD ward of Al-Zahara hospital affiliated to the Isfahan University of Medical Sciences and population included all the surgical packs and instruments sterilized in this ward. The samples were 66 surgical packs and instruments which were selected according the inclusion criteria, including the sterility of instruments and packs, being closed and sterilized until the onset of colony count, stable storage conditions (the same temperature and humidity during the sampling days) and non-wetting. Exclusion criteria were including non-sterilization of instruments in an unintentional manner during sampling and opening of instruments packs.

Researcher wrapped the surgical packs (including 4 100*100 drapes, 1 perforated drape and 1 gown and towel) and instruments (including one reciver, gallipot, needle holder, mayo scissors, Allis clamp, Kocher clamp, Babcock, Farabeuf retractor and six hemostats) in 4 layers (two double layers) and sterilized them along with other existing instruments required to be sterilized and randomly grouped them in three periods (3, 15 and 30 days for surgical packs and 6, 15 and 30 days for instruments) and placed them in the sterile area. The instruments were kept at 22°C and the humidity of %55. Also, researcher was taught how to sample by laboratory expert. 22 packs and instruments wrapped were sampled in three periods.

After performing sterilization process and learning how to sample, in order to count the colonies, researcher opened the sets of instruments and surgical sterile packs of the three groups on the given days. In order to count the colonies, a sterile swab plated with normal saline was rotationally rubbed on the 5*6 cm rectangular area of the inner surface of packs and different part of drapes and on 1*5 cm area of the sterilized instruments packs and then, the swab was placed in 1 ml normal saline. Then, the specimens were transferred to the laboratory and placed in a medium of Blood Agar and Eosin methylene blue at 35 ° C for 24 to 48 hours. Then the number of colonies of microorganisms and their type were investigated through conventional microbiological methods by laboratory expert and Ph.D. in microbiology.

Data collection tool was researcher-made checklist in which average number of colonies counted in the sterile surgical packs was recorded at 3, 15 and 30 days after sterilization and average number of colonies counted in the surgical instruments was recorded at 6, 15 and 30 days after sterilization. Its content validity was approved by 10 faculty member of departments of operating room and nursing, the School of Midwifery and Nursing, Isfahan. Swabs, blood agar culture media, Eosin methylene blue (EMB), Muller Hinton Agar (MHA) and normal saline were used to sample from surgical packs and instruments. In order to determine the reliability of the results of culture and colony count (sampling tool), two sets of instruments and two packs were sampled and the specimens were transferred to the laboratory. Two laboratory experts cultured each of specimens and performed colony count and Cronbach's alpha was estimated 0.94 and this confirms its reliability.

In order to analyze the data, SPSS V.3 software, descriptive statistics (average and standard deviation), non-parametric Kruskal-Wallis test and Mann-Whitney post hoc test were used.

Results

In the present field trial study performed in the Hospital Central Supplies at Al-Zahra Hospital, the surgical packs were randomly divided into three groups of 3, 15 and 30 days after sterilization (in each group, n=22) and the instruments were randomly divided into three groups of 6, 15 and 30 days after sterilization (in each group, n=22). Then, colony counting was performed on them.

The results of the present study showed that there were significant differences among the sterile packs opened 3, 15 and 30 days after sterilization in terms of average number of colonies counted (p-value<0.05) so that the average number of colonies counted in the sterile packs opened 30 days after sterilization was greater than the sterile packs opened 3 and 15 days after sterilization (p-value<0.05) (3 days after sterilization: 68.18±319.80 vs 15 days after sterilization: 113.64±169.86 and 30 days after sterilization: 6527.27±21400.16). Also no significant difference was observed between the sterile packs opened 15 and 30 days after sterilization in terms of the average number of colonies counted (p-value>0.05) (15 days after sterilization: 113.64±169.86 and 30 days after sterilization: 6527.27±21400.16) **[Diagram 1]**. The results were presented based on the results of non-parametric Kruskal-Wallis test and Mann-Whitney post hoc test**.**

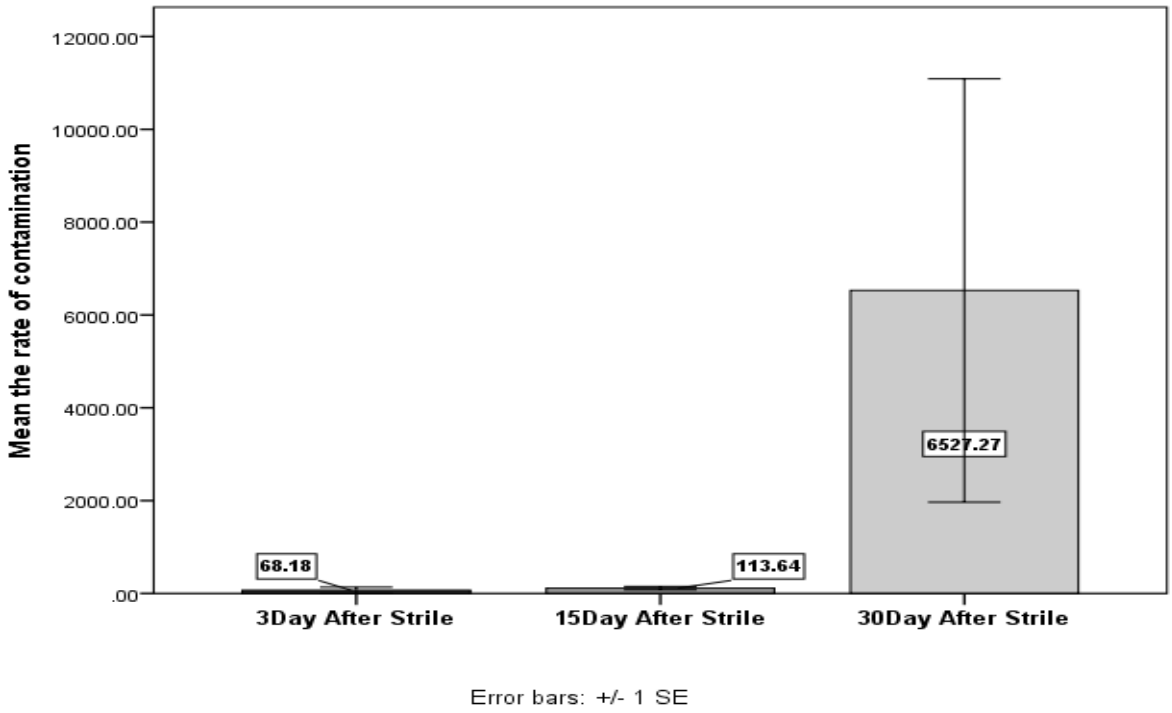

Diagram 1. Average number of colonies counted in the sterile packs opened 6, 15 and 30 days after sterilization

It should be noted that among 22 sterile packs opened 6 days after sterilization, positive culture was observed in 2 cases (%9.1), among 22 sterilized instruments packs used 15 days after sterilization, positive culture was observed in 8 cases (%36.4) and among 22 sterilized instruments packs used 30 days after sterilization, positive culture was observed in 11 cases (%50) and significant differences were observed between them in terms of positive culture (p-value<0.05). The frequency of incidence of positive culture in the sterile packs opened 3 days after sterilization was significantly lower than the sterile packs opened 15 and 30 days after sterilization **(Diagram 2)** shows the frequency of incidence of various microorganism types in the sterile packs opened 6, 15 and 30 days after sterilization.

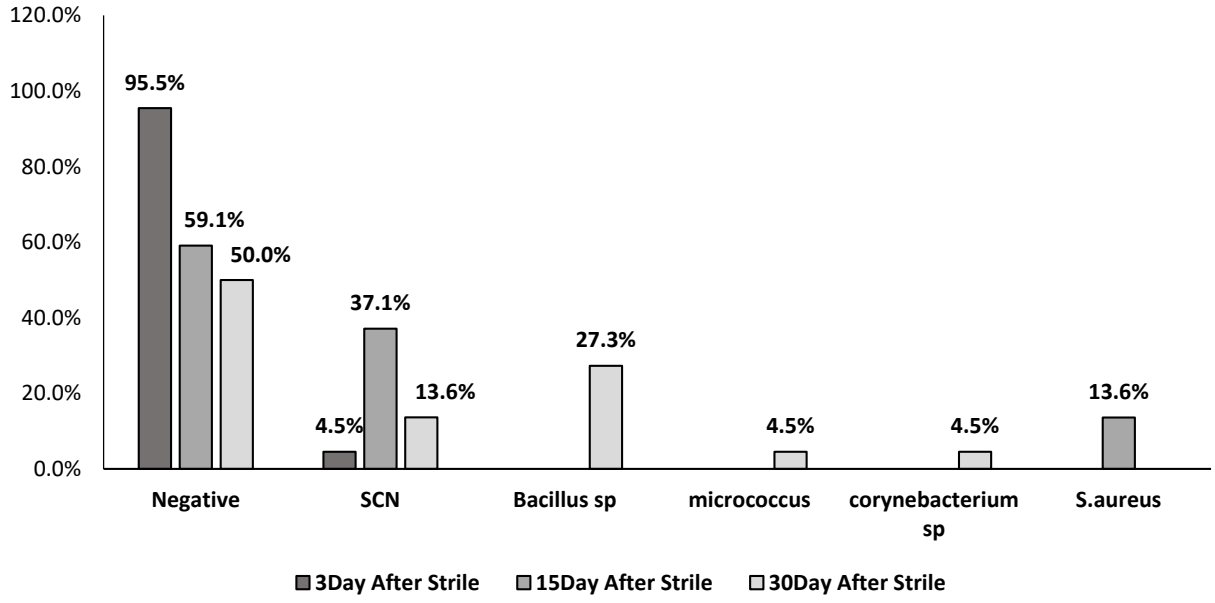

Diagram 2. The frequency of incidence of various microorganism types in the sterile packs opened 6, 15 and 30 days after sterilization

Also, it was observed that there were no significant differences between the sterilized instruments packs used 6, 15 and 30 days after sterilization in terms of average number of colonies counted (p-value>0.05). Average number of colonies counted in the sterilized instruments packs used 6 days after sterilization was less compared to the sterilized instruments packs used 15 and 30 days after sterilization (6 days after sterilization: 45.45±147.12 vs 15 days after sterilization: 172.73±636.35 and 30 days after sterilization: 172.73±443.13). The results were presented based on the results of non-parametric Kruskal-Wallis test **(Diagram 3)**.

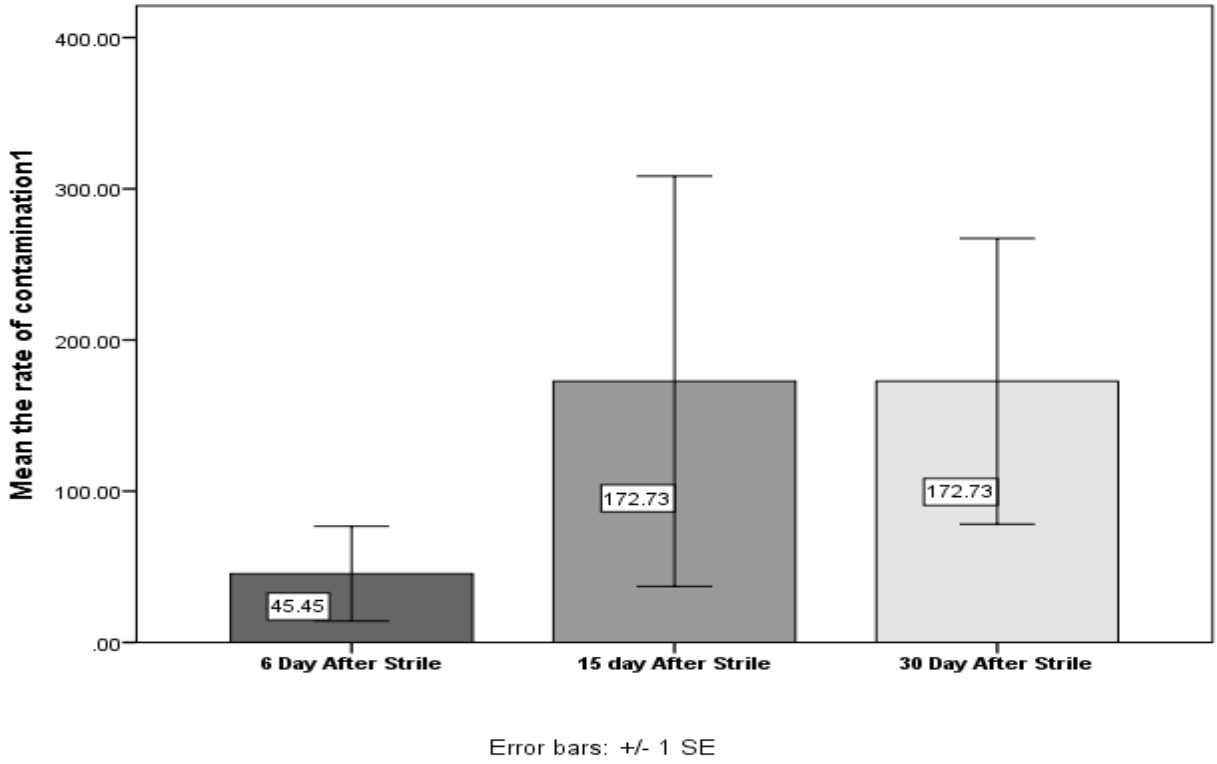

Diagram 3. Average number of colonies counted in the sterilized instruments packs used 6, 15 and 30 days after sterilization

It should be noted that among 22 sterilized instruments packs used 6 days after sterilization, positive culture was observed in 2 cases (%9.1), among 22 sterilized instruments packs used 15 days after sterilization, positive culture was observed in 5 cases (%22.7) and among 22 sterilized instruments packs used 30 days after sterilization, positive culture was observed in 4 cases

(%18.2) and no significant difference was observed between them in terms of positive culture (p-value>0.05). **[Diagram 4]** shows the frequency of incidence of various microorganism types in the sterilized instruments packs used 6, 15 and 30 days after sterilization.

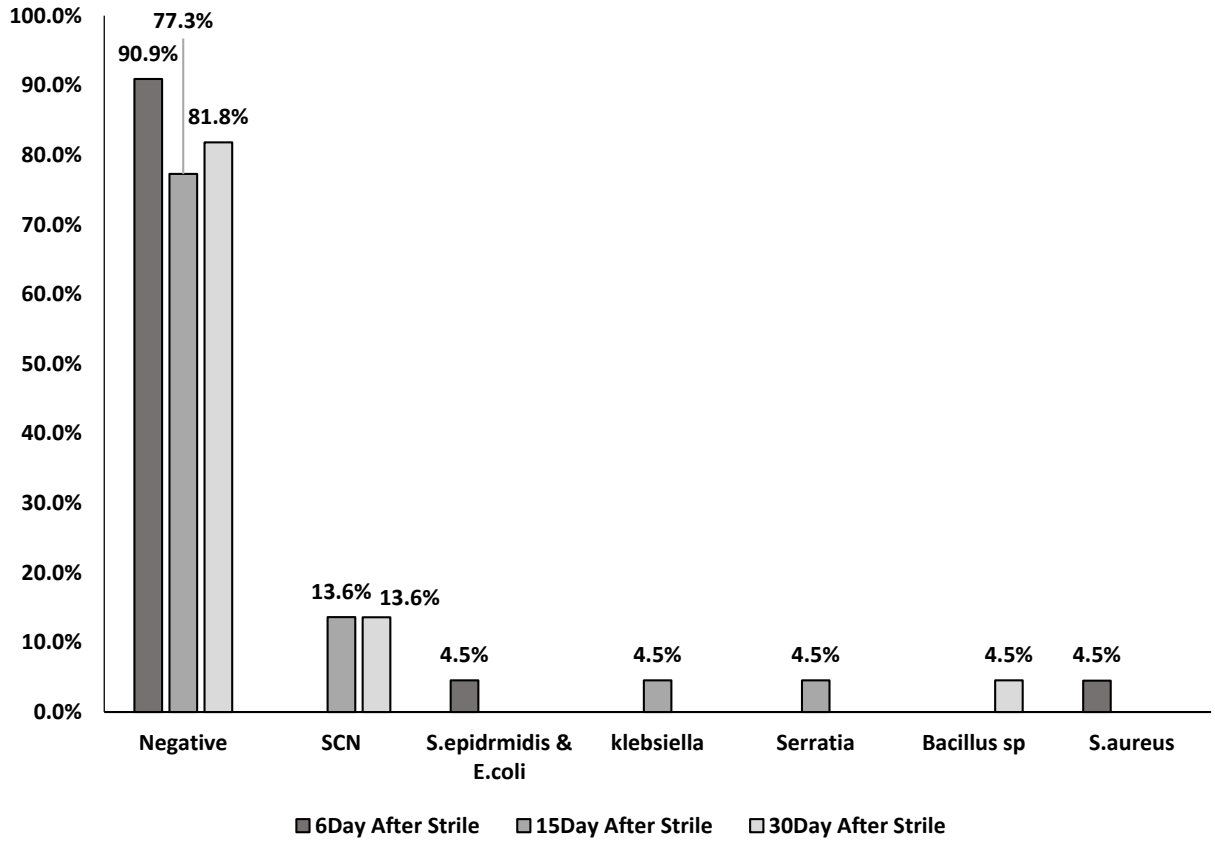

Diagram 4. The frequency of incidence of various microorganism types in the sterilized instruments packs used 6, 15 and 30 days after sterilization

Discussion

The present study aimed to investigate the effect of shelf life of sterile instruments on colony count of instruments sterilized. Devices, medical equipment and packs used in patients to prevent infection should be sterilized accurately. Before using each pack for the patient, its instruments must be checked in terms of being sterilized. Shelf-life of instruments is determined based on different factors. If storage conditions are not appropriate, their shelf life must be checked before using them and it is ensured that they are sterile [9]. According to the Center for Disease Control and Prevention, the instruments wrapped in two layers remain sterile for at least 30 days [10]. The results of the present study showed that there were significant differences among the sterile packs opened 3, 15 and 30 days after sterilization in terms of average number of colonies counted (p-value<0.05) so that the average number of colonies counted in the sterile packs opened 30 days after sterilization was greater than the sterile packs opened 3 and 15 days after sterilization (p-value<0.05). In the studied hospital, the sterile packs are used up to 3 days after sterilization while the results of the present study showed that given the current conditions in the hospital, sterile packs can be kept for up to 15 days but they cannot be stored for up to 30 days (recommended by the Center for Disease Control and Prevention). DE ARAÚJO MORIYA et al. (2012) have studied on 175 specimens with different woven fabric, v-pack and crepe paper packages and concluded that the packs remain free of contamination for more than 6 months (6) and this result is not consistent with the results of the present study and this inconsistency can be due to the effects of different environmental factors and the difference between the temperature and humidity of their study and the present study and since the sterilized packs are cooled quickly, the moisture remains inside them.

Also, it was observed that there were no significant differences between the sterilized instruments packs used 6, 15 and 30 days after sterilization in terms of average number of colonies counted (p-value>0.05). Average number of colonies counted in the sterilized instruments packs used 6 days after sterilization was less compared to the sterilized instruments packs used 15 and 30 days after sterilization (6 days after sterilization: 45.45±147.12 vs 15 days after sterilization: 172.73±636.35 and 30 days after sterilization: 172.73±443.13). In the studied hospital, the sterilized instruments packs are used 6 days after sterilization while the results of the present study showed that that given the current conditions in the hospital, sterilized instruments pack scan be kept for up to 1 month. MORIYA& GRAZIANO (2010), in their study, have concluded that the

presence of moisture inside the perforated surgical instruments box sterilized by steam and then wrapped in SMS sheets (Spunbound, Metblouwn, Spunbound) cannot prevent the instruments from being sterile even after 30 days and so, they can be kept for 30 days [7]. This result is consistent with the result of the present study. Also, Bhumisirikul et al. (2003) has reported that if the storage conditions are appropriate, the packs of small surgical instruments wrapped in two-layer linen (fabric) package would remain sterile for at least 12 months [8]. These results show the effects of current storage conditions of sterile instruments on the shelf life of sterile instruments.

Also the results showed that the bacteria of Coagulase-Negative Staphylococci, Staphylococcus aureus and Bacillus spp were more present in the specimens.

In a study by Owens & Stoessel (2008), it was reported that the bacteria of Coagulase-Negative Staphylococci, Staphylococcus aureus, Escherichia coli and Bacillus spp have been isolated as the bacteria present in the surgical wound [11].

Uncontrollable environmental factors such as air circulation, humidity in the space, microbial flora caused by the presence of individuals (respiration of people, sneezing, coughing, etc.) cause a minimum number of microbes in the results of microbial culture [12]. This can justify the minimum number of microbes in the microbial culture results of the present study.

Limited number of specimens and conducting a research in an environment can be mentioned as the limitations of the present study that lead to caution in generalizing the findings.

Conclusion

According to the results, it is recommended that in the studied hospital, the sterilized instruments packs are stored up to 30 days and the sterile packs are stored up to 15 days after sterilization that due to the reduction in the repetition of sterilization, this results in the economic savings and less damage to the packs and tools in the Hospital Central Supplies as well as the reduction in the workload of the personnel of this department. However, given the fact that each package has its unique half-life and number of bacteria, it is suggested to conduct the same study with greater number of specimens.

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