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Shelf Life of Sterile Small Surgical Instruments Packaged in Double Linen Versus Plastic-paper Wraps

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Abstract

Background: **In most operating theaters, unused sterile instruments have to be re-sterilized according to current practice protocols in order to guarantee that they are safe. Protocols of different institutions differ and they are hardly based on strong scientific evidence. Recently, the use of plastic-paper wrappers has been claimed to extend the sterility time significantly.**

Objective: **This study was aimed to compare safe sterility time of small stainless steel instruments packaged in plastic-paper versus linen wrappers.**

Material and Methods: **Two groups of orthopedic screws, each containing 360 screws, were sterilized by autoclaving at the same time and kept in an open shelf in the operating room . In Group 1, each screw was packaged in a double-wrapped linen pack. Screws in Group 2 were individually packaged in an inner wrap of paper and an outer plastic-paper envelope commercially available. Group 3 served as control for the reliability of the microbiology laboratory. Twenty screws were picked up from each study group for up to 52 weeks and sent for biological culture. Two screws from Group 3 were also sent to the laboratory at the same time.**

Results: **Up to the study period of 52 weeks, no growth was cultured from any sample in Groups 1 and 2. All but 4 samples in Group 3 grew several bacteria.**

Conclusion: **For small metal instruments, autoclaved packages in double wrapped linen and in double wrapped plastic-paper combination could both be stored safely for at least 52 weeks in open shelves when the storage condition was favorable in operating rooms provided that the package remained intact. Current routine practice of re-sterilization might have to be revised.**

All instruments and supplies used in surgery must be sterile. There are numerous small surgical instruments that are not frequently used and thus have to be re-sterilized again and again as scheduled by the "regulation" of the surgical department. The purpose of this practice is to guarantee that each item is sterile at the time its package is opened in the operating theater. An object is regarded as sterile when it is completely free of living microorganism.[1] Although this so-called "shelf life" for sterility of surgical instruments is an "everyday-routine" for any hospital, there has been no real scientific evidence supporting the recommendation of such "shelf life". In fact, different hospitals usually have different regulations regarding this issue. The recommendations are different even in the literatures.[2-5] In our institution,

sterile items are packed in double-wrapped linen and are considered safe when they are used within 2 weeks. Stored items must be re-sterilized every 2 weeks. This figure, again, does not comply with any recommendation from scientific studies.

It has been recognized that safe storage time depends most on the material used for packaging. Muslin or linen usually is less tolerant than plastic or plastic-paper bags completely sealed with heat.[2-4] Sterile packages stored in closed cabinets have longer shelf life than those stored in open shelves.[6] Searching from the literature, it was found that almost all of the references were very old and there was no update of such basic data.

The purpose of this study was to investigate whether a plastic-paper bag packaging could really be stored and kept sterile for a longer period than double-wrapped linen; and if so, how much longer it would be. The result would have much impact on our everyday practice in the operating theater. We would be able to calculate the cost-effectiveness and to consider whether we should switch from our routine linen wrapping re-sterilized every two weeks into plastic-paper heat-sealed bag that remains sterile for much longer period after being sterilized.

Materials and Methods

The study spanned a 52-weeks period from March 1, 1998 to February 27, 1999. Non-sterile orthopedic screws were used in this study to represent small sized surgical instruments. Seven hundred fifty-six screws were divided into 3 groups. Group 1 consisted of 360 screws, each was packaged in double linen wrappings with single-layered inner wrap and double-layered outer wrap. In Group 2, each of another 360 screws was packaged in an inner white paper wrap before being kept in a plastic-paper envelope pouch completely heat-sealed. Group 3 served as controls so that 36 screws were not wrapped at all.

The linen wrapper used were 140-thread count material, dyed green, laundered and ironed before use. The plastic-paper envelopes used were commercially available (SMS view pack®) with one side made of transparent plastic and the other of white Kraft paper. The size of each wrapper was 7.5 cm wide and 15 cm long. All samples in the 3 groups were sterilized by autoclave in the same manner as our routine sterilization for surgical instruments using Getinge autoclaving machine (Model GE 6612, Getinge AB, Sweden) with a pressure of 2.15 bar at 135°C for 5 minutes. All of them were then placed on an open shelf in the operating room, about one-foot above the floor. There was no special care for these packages. However, the keeping area was in a clean operating room that was used for most of the operations in general and abdominal surgeries. Obviously, no moisture and excessive dust was allowed in this room especially around this shelf. Samples of Group 3 were stored unwrapped in the same environment.

Packages from Groups 1 and 2 were then picked up at random according to the following protocol and sent for microbial culture. At interval of 2 weeks during the first 20 weeks, twenty packages were picked from each of Groups 1 and 2. After the 20th week, the interval was extended to every 4 weeks up to the 52nd week. All the packages picked were opened in the operating room with strict aseptic precaution and the screw in each package was transferred into a test tube containing 10 ml of Thioglycollate broth. Together with each sample of Groups 1 and 2, two screws from Group 3 were also randomly picked up. All the specimens were then sent to the microbiology department where they were incubated at 37°C. The specimens were checked daily for any bacterial growth. Whenever sign of microbial growth was observed, the broth was then sub-cultured in blood agar and also stained for any bacteria and fungi. Tubes of Thioglycollate broth that did not show sign of growth

Table 1 Type and number of microorganisms isolated from samples of Group 3.

Types of organisms	Number of specimens isolated
- Micrococcus species	2
- Staphylococci coagulase negative	11
- Micrococcus luteus	2
- Clostridium perfringens	2
- Bacillus species	8
- Bacillus cereus	3
- Propionibacterium acnes	2
- Corenebacterium species	2
- No growth	4

after 5 days were picked up for subculture and staining before being discarded.

Results

All specimens of Group 1 showed no microbial growth in 52 weeks. Similarly, all specimens of Group 2 also showed no growth in 52 weeks of observation. All but 4 screws in Group 3 (control) showed heavy bacterial growth. The species of growth was shown in Table 1.

Discussion

The length of time that sterilized supplies will remain sterile and safe for use is important in planning the protocol for routine re-sterilization of packaged surgical instruments, especially for those items that are not used frequently. To quote Dyer and colleague,[3] "...existing policy was based to a great extent on experience, tradition, and intellectualizations". Few studies had been devoted to answer this problem specifically[2,3,6] and most of them were published more than two decades ago. In our hospital, all autoclaved instruments are packaged in double wraps of linen consisting of an inner single-layered and outer double-layered 140-threaded linen. They are usually stored in open shelves. These packaged instruments have to be re-autoclaved every 2 weeks if unused. Using this storage condition, the safe sterile time has been recommended in the literature to range from 21 days to at least 60 days.[2,3,6] In fact, in at least one study was it shown that if it were not because of the accidental technical error in handling of specimens, the packages should have been safe up to one year of their study period.[3]

The methods of wrapping and packaging also have been shown to affect the shelf life of sterilized packs. Plastic wrappers, double-layered two-way crepe paper wrappers and the combination of paper-in-plastic bag were frequently considered to result in longer storage time than linen packs.[7] The use of impervious plastic bags was safe for up to nine months in one study[2] and one year in another.[5]

Considering all the above-mentioned information and the fact that, if we could prove that packaging in plastic-paper bags can result in significantly longer storage time, we might, based upon such data, modify our protocol of package re-sterilization and benefit from the cost-saving. This would certainly have great impacts on our health economy and manpower utility.

It was our purpose to compare safe storage times between double-wrapped linen packaging, which was our current type of packaging, and double-wrapped inner paper and outer plastic-paper bag, which was commercially available. We chose to limit our study only for small metal surgical items, which were the most frequent items that needed re-sterilization because of their infrequent usage. The end point was the appearance of positive bacterial and fungal cultures in any of the packaged instruments.

To our surprise, all the autoclaved instruments packaged in either type of wrappers showed no growth for up to 52 weeks in our experimentation. We were opted to conclude that double-wrapped linen packaging could be stored up to at least 52 weeks in open shelves, as was the double-wrapped inner paper and outer plastic-paper envelope, provided that the storage area was at least one foot above the floor and without excessive dust and moisture. Within this period of storage time there was no difference in the safety between these two types of wrappings.

In order to confirm our findings, we initiated a second experiment. This time, we used only the double-layered linen wrappers that we had been using in our operating theater. We wished to know how much longer small items packaged in such wrappers could be stored. At the time of this report, it was beyond the 64th week, we found preliminarily that all the packaged screws still remained sterile. The final outcome would be reported in due time.

Our finding actually agreed with that of Dyer and colleague.[3] However, in most textbooks and literature of operative nursing, it was usually regarded that double-wrapped linen packaging could only be sterile for about 3 to 7 weeks.[2,5] The difference of this study to other studies, especially those recommended in most textbooks required an explanation. In some studies, the samples were transferred from the storage institution to the laboratory in another institution.[2,6] It was still uncertain whether this study design of transfering specimens had contributed to the different outcome.

Another factor that might affect the difference in outcomes of our study and other studies was the fact that in our study the samples were orthopedic screws,

which were made of high quality stainless steel. This type of samples resembled the real situation and the purpose of instrument wrapping in the operating room. In contrast, all other studies used "gauze sponges" or "cotton buds" or "applicator sticks", all of which were more prevalent to harboring infection than polished metal. Besides, it was the small metal instruments that we needed to store for long period of time, and not those gauze sponges or applicator sticks. We thus believed that our result was at least as reliable as in other studies. It is noteworthy to stress the fact that the issue addressed in this study is only for small metal instruments that are stored individually for occasional usage, and not the big trays' collection of surgical instruments.

The clinical application of this finding allows a change in hospital's protocol. Autoclaved metal small instruments can be kept in open shelves under good conditions for at least one year. It needs to be stressed that the keeping conditions are very important in this regard since the duration is rather long. In order to avoid unexpected moisture, several packages may be kept in a big plastic bag after sterilization.

Regular monitoring might be necessary to verify the safety of these packages. This can be carried out by random culture of the stored packages at a preset period. Alternatively, a piece of small stainless steel screw can be co-packaged with the instrument in the same wrapping and then autoclaved together. When the instrument is used, the screw is randomly sent for culture. This is probably not necessary, but it is used just to verify its sterility. The possibility of positive culture should be none if the result of this study is accurate.

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