First-time Sterilization Effectiveness Test Study of Foreign Device Implants

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Abstract

Objective: To explore the first sterilization parameters and sterilization effectiveness of foreign medical devices and implants. **Methods:** 300 pieces of foreign medical devices and implants were randomly divided into four groups, 75 pieces in each group. The incidence rate of wet package, sterilization physical, chemical and biological monitoring compliance rates of the four groups were observed and compared. **Results:** in the four groups of foreign instruments and implants, the incidence rate of wet package in the four groups was 5.3%, 8.0%, 13.3% and 20.0% respectively; the qualified rate of sterilization physical monitoring in each group was 100%; the qualified rate of sterilization chemical monitoring in each group was 100%; the qualified rate of sterilization biological monitoring in each group was 100%. **Conclusion:** the use of equipment basket and cotton cloth assembly packaging of foreign devices and implants can effectively reduce the incidence rate of wet package, reduce the incidence of hospital infection, and ensure the safety of patients.

Keywords

Foreign Instruments, Implants, Sterilization Parameters

1. Introduction

With the rapid development of surgical technology, complex and difficult surgical procedures have been carried out more and more in the clinic, and these highly advanced and complex procedures often require supporting new and sophisticated exotic surgical instruments to complete. However, foreign instruments and implants are mobile and are frequently transferred to different hospitals and operating rooms, making cleaning and disinfection more difficult and leading to an increased risk of nosocomial infections [1]. We need to establish effective management systems in all aspects of distribution channels, cleaning, disinfection, sterilization, and use in order to ensure the safe use of foreign instrument implants [2].

The annual volume of orthopedic surgery in our hospital can be more than 2000, and most of the surgical procedures

need to be completed with foreign surgical instruments and implants. For foreign medical devices and implants, we rent them from foreign instrument companies by temporary leasing, which do not belong to our hospital and are not stored in our hospital, and foreign instrument companies provide the same set of surgical instruments to several hospitals in order to save costs. If they are not handled properly, they may induce medical risks and are potential risk factors for medical disputes [3].

At present, there is no unified standard for the assembly method, packaging material and sterilization parameters of foreign device implants in China. By using different assembly methods and packaging materials for sterilization under the sterilization parameters of manufacturers, we compared the incidence rate of wet packets, sterilization physical, chemical and biological monitoring rates of different assembly and packaging methods for first time exotic device implants, and analyzed the sterilization quality of different assembly and packaging methods. This study can solve the problem of wet pack and sterilization failure due to complex structure, different weight and volume, different assembly and different packaging materials, and provide a basis for ensuring the safe use of surgical instruments, reducing the occurrence of nosocomial infection and ensuring the safety of patients' lives. It also provides some reference significance for the promotion of the standardized research on the assembly and packaging sterilization of foreign instrument implants.

2. Materials and methods

2.1. General information

In this study, a total of 300 pieces of foreign device implants disposed of in our hospital from January 2020 to December 2020 were selected as the study objects, and the samples were divided into four groups in the form of randomized groups: device basket + cotton packaging group, device basket + non-woven packaging group, rigid device box + cotton packaging group and rigid device box + non-woven packaging group, with 75 pieces in each group.

2.2. Research method

2.2.1. Inclusion criteria and exclusion criteria for exotic device implants in the study population.

Inclusion criteria: (1) foreign instruments and implants that can be recycled repeatedly; (2) sterilization and supply center can be disposed of by physical moist heat sterilization; (3) sterilization and supply center can be disposed of by steam autoclaving sterilization; (4) hospital unified transportation and storage of foreign instruments and implants used in the operating room sterilization items storage room, select instruments, instruments and items that meet the inclusion criteria for orthopedic surgery foreign instrument implants in the operating room. A variety of types and structures are complete.

Exclusion criteria: (1) foreign instruments using powered instruments; (2) patients using the previous surgery as special infection contacts (for example: gas gangrene, prions and infections of unknown origin, etc.).

2.2.2. Methods

Exotic device implants were cleaned after pre-soaking in neutral machine washing enzyme solution for 5 minutes, followed by inspection of the cleaning quality of the exotic device implants, and after passing the inspection the exotic device implants were entered into assembly and packed ready for sterilization to avoid the cleaning quality of the exotic device implants affecting the subsequent study.

The exotic device implants are assembled using rigid device boxes or device baskets with the weight incorporated into the total weight of the device package, the total weight$\leq$ 7 kg, the packaging material is non -woven fabric or medical cotton, the packaging method uses sterile package envelope type packaging method, the sterilization physical monitoring probe, chemical and biological monitoring indicators are placed in the most difficult sterilization position of the device, 5 monitoring points are placed in the southeast, northwest and middle according to one layer of the device, the sterilization equipment is fixed using D sterilizer No. 3 (sterilization parameters can be adjusted), using the sterilization parameters required by the manufacturer's instructions to sterilize the instruments program, and unloading after 30 minutes of cooling after sterilization according to the new specifications, and conducting statistics on the wet packet rate, sterilization physical parameters, and chemical and biological monitoring pass rate to check the sterilization quality performance.

2.2.3. Quality control standards for cleaning quality of foreign instrument implants

Cleaning quality passing judgment standards refer to WS310.3-2016 "Sterilization Supply Center Part III: Cleaning Disinfection Sterilization Effect Monitoring Standards" in 4.2.1.1 Daily inspection standards in monitoring the cleaning

quality of instruments, appliances and articles; (1) should be visually inspected and/or checked with the help of a magnifying glass with light source. (2) carry out ATP testing on research instruments.

2.2.4. Wet pack quality control standards

Wet pack quality control qualification criteria refer to WS310.3-2016 "Sterilization Supply Center Part 2: Cleaning and Disinfection and Sterilization Technical Practice" in 3.14 After sterilization and cooling, (1) sterilized packets with dampness and water droplets inside or outside the packet; (2) sterilized packets removed after complete cooling of sterilization and the weight of the sterilized items exceeds 3% before sterilization, meeting any of these conditions are wet packets.

2.2.5. Qualified quality control standards for sterilization monitoring

After sterilization, check the integrity of the package, check the actual changes of the physical, chemical and biological monitoring indicators parameters of the sterilized package in the case of qualified closure, and count the sterilization qualification rate monitored by physical monitoring method, chemical monitoring method and biological monitoring method respectively.

2.3. Data processing and statistical analysis

The raw data were checked and entered into an Excel sheet, and SPSS25.0 software was used for statistical analysis, and the count data were expressed as rate (%); 2 test was used for comparison between groups; $P < 0.05$ was considered as a statistical difference.

3. Results

3.1. Comparison of the incidence of wet bags in the four groups

The experimental results showed that the incidence rate of wet pack was 7.7%, 6.0%, 11.1% and 8.9% in the instrument basket + cotton packing group, instrument basket + non-woven packing group, rigid instrument box + cotton packing group and rigid instrument box + non-woven packing group, respectively. Among them, the incidence rate of wet pack was the lowest in the group using instrument basket + nonwoven packaging and was significantly lower than the other groups ($P = 0.027$). (See Table 1)

Table 1. Comparison of the incidence of sterilized wet packs in four groups [cases (%)]

Grouping Categories	Numbers	Incident Rate of Wet Packs
Equipment basket + cotton packing set	75	4(5.3)
Equipment basket + non-woven packing set	75	6(8.0)
Rigid instrument box + cotton packing set	75	10(13.3)
Rigid instrument box + non-woven packing set	75	15(20.0)
χ^2Value	-	9.154
P Value	-	0.027

3.2. Comparison of sterilization quality pass rates of the four groups

Then, we studied the physical, chemical and biological monitoring sterilization qualification rates of four groups of exotic device implants with different packaging, and the study results showed that the physical monitoring qualification rate of all four groups reached 100%, and the chemical monitoring qualification rate of the four groups of instrument basket + cotton packaging, instrument basket + non-woven packaging, rigid instrument box + cotton packaging and rigid instrument box + non-woven packaging all reached The pass rate of sterilization biological monitoring all reached 100%. The differences were not statistically significant.

Combining the above two parts of the study, it can be concluded that for the first sterilization of foreign instrument implants, the lowest wet pack rate was achieved in the instrument basket + cotton packaging, provided that the sterilization quality was qualified.

4. Discussion

With the development of medical technology in China and the promotion and application of new types of surgery, the demand for instruments for specialized surgery has increased year by year. In view of the wide variety of specialist instruments, the rapid update frequency and the high price, these instruments are generally flowing in various hospitals in the form of leasing [6]. This not only poses a great challenge to the work of the sterile supply room, but also demands higher professional quality from the personnel working in this department. How to improve the skills of sterile supply room personnel in handling foreign instruments and implants, ensure their safe use in our hospital, effectively reduce the infection rate of surgical procedures, and guarantee medical safety has become an urgent problem and focus of work in sterile supply rooms.

In conclusion, exploring the first sterilization parameters and effectiveness of foreign instrument implants can actively optimize the management of foreign instrument implants in sterile supply centers, improve the quality of safety management, and ensure the smooth development of medical care.

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