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Validation of effectiveness of sterilization for different weighted surgical instrument packages and their impacts on operators.

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Abstract

Objective: To investigate the effectiveness of sterilization of different weighty surgical instrument packages and their effect on packing experience such as operators' working satisfaction and acceptance.
Methods: Orthopedic surgical instruments of the same material were grouped into 8 different weight groups: 7 kg, 9 kg, 11 kg, 13 kg, 15 kg, 17 kg, 19 kg, 21 kg. Class 4 multi-variable CI, Class 5 integrating indicator and biological indicators were put at the least favorable position for sterilization within the packages and the monitoring results were interpreted after normal sterilization cycle to assess the sterilization performance. The operators packed the instrument with the same packaging materials, and then investigators evaluated the acceptability of the instrument package weights to the operators.
Results: Instrument packages weighing between 7 kg and 11 kg produced acceptable results in chemical and biological monitoring using the normal sterilization procedure. Package weight exceeding 11 kg indicated uneven color change in Class 4 multi-variable CI, while Class 5 integrating indicator and biological monitoring produced acceptable results only with some wet packs. Instrument packages exceeding 11 kg made packing difficult for operators and resulted in low satisfaction.
Conclusion: Package weights not exceeding 11 kg were associated with effective sterilization in normal sterilization procedures, and with good operator satisfaction.

Keywords: Weighty orthopedic surgical instruments, Sterilization effectiveness, Packaging operation experience.

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Introduction

Medical equipment have gradually developed into complex and high-tech instruments with the rapid development of medical technology. Orthopedic surgery equipment such as those used for joint replacement and internal fixation, are weighty, high-risk machines due to combination of multiple instruments, heaviness and varied shapes. The heaviest instrument set may weigh up to 21 kg. According to Chapter 5.7.6 of Healthcare Standard WS 310.2-2009 promulgated by Chinese Ministry of Health, the weight of instrument pack under steam sterilization should not exceed 7 kg, while dressing package should not exceed 5 kg [1]. However, instrument set for surgery cannot be split into smaller units. Complications arising from implants have increased over the years [2]. These implant complications are associated with hospital infection due to exogenous bacteria contamination arising from instrument sterilization defects [3].

The present study was aimed at investigating the effectiveness of sterilization of different heavy surgical instrument packages (7-21 kg), and the acceptability of the packages to the operators. This was with a view to ensuring high quality of sterilization so as to control hospital infection and decrease operator dissatisfaction.

Materials and Methods

Materials

Orthopedic surgical instruments of same material (periosteal stripping, bone knives, bone hammer, rongeur, holding bone and marrow filing) were grouped into eight categories: 7 kg, 9 kg, 11 kg, 13 kg, 15 kg, 17 kg, 19 kg, 21 kg (numbered 1 to 8, with only one instrument set in each group. Class 4 multi-variable CI, Class 5 integrating indicator and biological indicators were used as monitoring indicators in the sterilization process with MST 9-6-18HS2 steam sterilizer. The study recruited 15 male operators of age range 30~50 years, mean height of 175 ± 5 cm and mean weight of 70 ± 5 kg. Fifteen female operators of age range 30~50, mean height is 160 ± 3 cm, and mean weight of 50 ± 5 kg were also recruited.

Sterilization monitoring

The monitoring indicators were put at the three positions least accessible to steam penetration in the package, i.e. diagonal points and geometric center of pack [4]. One Class 4 multi-variable CI, one Class 5 integrating indicator and one biological indicator were put on every single point.

The operators chose normal sterilization cycle, which was for 4 min at 134°C, 205.8 Kpa, and drying time of 15 min. The eight groups were processed under the same conditions three times. The results were observed after cooling for 30 min. All results were interpreted by physical monitoring, chemical monitoring and biological monitoring after the sterilization process.

Survey of operators' working satisfaction

The 30 operators used the same medical nonwoven size 100*100 cm to pack the 8 different groups of instruments. The operators scored based on comfortability and complexity. The operators' working satisfaction with packaging instruments was divided into five grades, with the indicated scores: very satisfied (5 points), satisfied (4 points), less satisfied (3 points), unsatisfied (2 points), and very unsatisfied (1 point) [5-7]. The degree of satisfaction was calculated according to statistical score in each group out of a maximum score 150. The formula used was:

Degree of satisfaction=(actual score by each group/150 × 100)%.

Results

Evaluation of sterilization effect

All the eight BIs gave negative results. Class 5 integrating indicators provided acceptable result. Class 4 multi-variable CIs indicated unacceptable result in groups 4, 6, 7 and 8. The appearance of the instrument basket indicated that groups 1~4 (7~13 kg) was completely dry, group 5 (15 kg) was a little humidified at the right corner of the pack; group 6 (17 kg) was wet at right corner of the pack, while group 7 (19 kg) and group 8 (21 kg) contained water drops at center of bone hammers. There were wet packs in groups weighing more than 13kg. These results are summarized in Table 1.

Table 1. *Appearance of instruments and interpretation of sterilization.*

	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7	Group 8
Class 4 CI	-	-	-	+	-	+	+	+
Class 5 CI	-	-	-	-	-	-	-	-
BI result	-	-	-	-	-	-	-	-
Instruments	-	-	-	-	+	+	+	+
Qualified (-); failure (+)								

Survey of satisfaction

The packing operating experience was assessed in terms of operator satisfaction. Operators had different degrees of acceptances to weight, but they had the same trend of satisfaction. However, the satisfaction of operators sharply declined with increasing weight of the instrument packs, both of which were negatively correlated (Tables 2 and 3).

Table 2. *Statistics of operator satisfaction with different instruments weights.*

Experimental group (kg)	Score 5	Score 4	Score 3	Score 2	Score 1	Total Score
No.1 (7 kg)	24	6	-	-	-	144
No.2 (9 kg)	18	12	-	-	-	138
No.3 (11 kg)	-	22	8	-	-	112
No.4 (13 kg)	-	-	15	12	3	72
No.5 (15 kg)	-	-	-	24	6	52
No.6 (17 kg)	-	-	-	1	29	31
No.7(19 kg)	-	-	-	-	30	30
No.8 (21 kg)	-	-	-	-	30	30

Table 3. *Operator satisfaction with different weights.*

Experimental group (kg)	Total score (30)	Average Score	Degree of satisfaction (%)
1 (7 kg)	144	4.8	96
2 (9 kg)	138	4.6	92
3 (11 kg)	112	3.73	75
4 (13 kg)	72	2.4	48
5 (15 kg)	52	1.73	35
6 (17 kg)	31	1.03	20.7
7 (19 kg)	30	1	20
8 (21 kg)	30	1	20

Discussion

Studies have revealed steady annual increases in cases of complications in orthopedic implants due to implant-related instrument contamination as a result of defective sterilization which led to exposure to exogenous bacteria. The packing of orthopedic instruments and sterilization should strictly follow the manufacturer's written recommendations under experimental validation. If it cannot be provided by the instrument vendor, CSSD should verify the sterilization effectiveness of the instruments or split the packs and establish a scientific packaging operation and process in order to ensure

effective sterilization quality. The heaviest orthopedic instrument set weighed about 21 kg. Therefore, the instruments were divided into 8 groups within the range of 7~21 kg.

In the experiment, physical monitoring, chemical monitoring and biological monitoring were applied to assess the effectiveness of sterilization. The Class 4 multi-variable CIs reacted to the key variables such as saturated steam, sterilization temperature and time by color change of dye strip or block. It was cheap and easy to use. Class 5 integrating indicator identified the sterilization effectiveness by movements in the position of a color bar. It was also easy to use, but more precise than Class 4 multi-variable CI, and equivalent in performance to biological indicator. The waterproof design was also very suitable for packaging many instruments [8]. The chemical indicators just responded to the sterilization process-related variables. Biological indicators containing spores could provide specific resistance to effective sterilization. Thus, multiple methods should be used in sterilization monitoring. Besides, the positions of indicators could affect the effect of monitoring. For baskets, chemical indicators should be placed in the geometric center of the pack. For rigid containers surrounded by inside dead corner structure, chemical indicators should be placed in the diagonal corner of the pack. Therefore, the indicators were placed as 1.2.1.1 mentioned in packages to ensure accurate and reliable monitoring results.

The results showed acceptable biological monitoring and Class 5 chemical monitoring in the sterilization of the different weight categories of instruments. However, in groups 4, 6, 7 and 8 there was one unacceptable Class 4 chemical monitoring result. The reason for this failure was most likely due to fact that the orthopedic surgical instruments were too big, overweight and hard to split into smaller units. This resulted in blockage of penetration of saturated steam. The indicator was attached on the metal surface because water condensed easily there. Due to the effect of the condensed water, the color of the chemical indicator turned to light white or silver, instead of black, which made the result inaccurate. Instrument packages cannot be used if physical monitoring, chemical monitoring or biological monitoring fails [9]. Packages should not be used if they contain wet packs or if chemical indicators fail. In this study, the instruments in basket were observed for 30 min at the end of sterilization. Groups 1~4 were completely dry, group 5 was a little humidified at right corner of the pack, group 6 was wet at right corner of the pack, while groups 7 and 8 contained water droplets at the center of bone hammers. It was concluded that effective sterilization could be ensured under normal sterilization cycle, i.e. for 4 min at 134°C, 205.8 Kpa and drying time of 15 min. Moreover, the weight of instrument packages should be less than 11 kg.

In this study, 30 operators was selected by age, height, and weight to reduce the affect of these factors on the result of the experiment. Statistics of satisfaction evaluated from the 30 operators showed that most operators accepted packages weighing less than 11 kg. If the weight exceeded 11 kg, the operator experienced pain in the shoulder, elbow and finger, and the packaging integrity decreased significantly, which may result in low efficiency.

Conclusion

Sterilization quality control of different instrument weight packages is the major objective of sterilization work, and an issue that will continue to attract research attention. It is important to strengthen quality control with respect to cleaning, packaging, sterilization and drying, especially in the sterilization of heavy and oversized instrument packages which play vital roles in professional development. The present study revealed that effective sterilization can be ensured and the operators satisfied under normal sterilization cycle i.e. for 4 min at 134°C, 205.8 Kpa and drying time of 15 min. In addition, the weight of instrument packages should be less than 11 kg. For instruments exceeding 11 kg, it was suggested that manufacturer's written recommendations for use should be strictly followed to validate sterilization, otherwise the instrument package should be split.

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