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Analysis of Application of Sterilization Packaging Materials and the Influencing Factors: A Survey in 30 Chinese Hospitals

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ABSTRACT: Objective To investigate the application of sterilization packaging materials and the influencing factors in Chinese hospitals. **Methods** 30 hospitals were chosen with a typical sampling method and a structured questionnaire was developed for the investigation, based on literature review and experts consultations. The content of questionnaire included the current status of usage of sterilization packaging materials and influencing factors of decision-making. **Results** There were 4 kinds of sterilization packaging materials widely used in Chinese hospitals. For 30 surveyed hospitals, non-woven fabrics was used the most, followed by cotton fabrics, paper-plastic pouches, and rigid sterilization containers. The influencing factors of hospitals selection of sterilization packaging materials included the precision of instruments, the shape, size, weight and quantity of instruments, hospital infection risk, and the sterilization effectiveness. To choose rigid sterilization container, main considerations were instrument precision, transportation, infection control, and hospital infrastructure situation. For other three types, main considerations were shape, size, weight and quantity of instruments, infection control, and sterile barrier performance. **Conclusions** Non-woven fabrics, cotton fabrics, paper-plastic pouches, and rigid sterilization containers were major sterilization packaging materials used in Chinese hospitals and there were important influencing factors for them to be chosen by hospitals.

KEY WORDS: Sterilization packaging materials; Application; Influencing factors

1. Introduction

Sterilization packaging materials are widely used for packaging medical diagnosis and treatment instruments before sterilization, to ensure that the sterility is maintained when the package is opened during clinical surgeries[1-2]. There are two main types of sterilization packaging materials: disposable sterilization packaging materials such as non-woven fabric and paper-plastic pouches, and reusable sterilization packaging materials such as cotton fabrics and rigid sterilization containers[3-4].

Different sterilization packaging material has different efficiency, cost, and capability, which may lead to different risk of nosocomial infection in medical work[5-10]. Among sterilization packaging materials, Cotton fabric has the advantages of softness and penetration but with defects such as poor microbial barrier, frequent cotton-wetting, short validity period, and nonstandard replacement criterion[11]. Non-woven fabric has the advantages of better hydrophobicity, no static electricity, no toxicity, and

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no irritation, but its cost is high due to non-reusable characteristic[12]. The paper-plastic pouches have good antibacterial effect, with long validity period after sterilization[13], but easier to be pierced by sharp instruments. Rigid sterilization container has superior barrier to microbes, and easy to carry and store[14-15], but due to its relatively high initial purchase cost, it has not been widely used in China.

With the development of sterilization technologies, packaging materials used for sterilization preservation are abundant in the market. In hospital management nowadays, choosing suitable sterilization packaging materials is an important topic. In this study we surveyed four kinds of widely used sterilization packaging materials which are cotton fabrics, non-woven fabrics, rigid sterilization containers and paper-plastic pouches, to analyze the application status and influencing factors of decision-making in hospitals.

2. Methods

2.1 Study design

We used typical sampling method to select representative hospitals for in-depth investigation and analysis. Representative hospitals inclusion criteria were developed based on experts consultations: hospitals used at least three types of cotton fabrics, non-woven fabrics, rigid sterilization containers and paper-plastic pouches. And the selected hospitals agreed to participate in the study were finally selected. A total of 30 tertiary hospitals were included for survey in this study.

To conduct the survey, the person in charge of central sterile supply department (CSSD) from surveyed hospital was selected, and a structured questionnaire was applied for investigation. Content of survey included the current status of usage of sterilization packaging materials and influencing factors of decision-making. The survey was applied in August, 2021.

For the survey, a structured questionnaire was developed based on literature review and experts consultations[16-17]. It included 3 parts: hospitals' information, usage status of sterilization packaging materials, and decision-making considerations of sterilization packaging materials.

The hospitals' information part included the name of hospital, the types of hospital, the location, the number of surgeries performed annually, and the consumption of surgical instrument packages annually. The usage status of sterilization packaging materials part included the types and shares of sterilization packaging materials. The decision-making consideration factors part included the weights of decision-making consideration factors and the consideration factors when choosing a specific type of sterilization packaging material.

Through preliminary literature research and experts consultation, we covered 11 decision-making consideration factors in this study: 1. the precision of the packaged surgical instruments; 2. the shape, size, weight and quantity of the packaged surgical instruments; 3. nosocomial infection control; 4. sterilization effect of sterilized packaging materials (such as whether the wet pack is easy to occur); 5. the usage frequency of packaged surgical instruments; 6. the influence of sterilization packaging materials on the optimization of CSSD's process, (e.g. the management complexity of different sterilization packaging materials, such as the validity period, expiration rate, and turnover rate of sterilization packages, whether the CSSD has enough staff to manage the process of sterilization packaging materials); 7. the cost of the sterilization packaging materials (costs that incurred in whole work process including material costs, labor costs, infection treatment costs, cleaning and disinfection costs, sterilization cost and so on.); 8. hospital infrastructure (such as storage space, cleaning capacity); 9. whether the surgical instrument packages need to be transferred; 10. the total time consumption of sterilization packaging materials (calculate the total time consumption on each process for one sterilization package with different wrappings); 11. disposal of medical waste, such as the cost, and the impact on the environment.

The weights of these factors ranged from 0 to 10, with 0 indicating that the factor was not considered and 10 indicating very important. The respon-

dents scored the importance of each factor.

2.2 Data analysis

Descriptive statistical analysis was conducted for hospitals' information, the usage status of the sterilized packaging materials, the weights of influencing factors when choosing packaging materials. Hospitals were grouped by the scale of annual surgeries quantities. Measurement data conformed for the normal distribution were expressed as mean（standard deviation）[Mean（SD)] and the difference between groups was tested by t-test or analysis of variance. For variable with skew distribution, median and interquartile range were used for statistical description and Wilcoxon rank sum test and Kruskal-Wallis H test were applied. Categorical variables were expressed in frequency (n) and percentage (%) and chi-square test was applied. The difference was statistically significant with $P<0.05$.

To control data quality, two research assistants entered the data individually and double checked. Database was built in MS Excel 2019. STATA 12.0 and MS Excel were used for data coding and statistical analysis.

3. Results

3.1 Hospitals' characteristics

In this study, 87% hospitals surveyed were general hospitals and 13% were specialized hospitals. 53% hospitals were located in eastern China, 23% in the west, 17% in the middle, and 7% in the northeast. The median number of surgical operations performed of these hospitals was 33, 424.8 per year. The median number of surgical instrument packages used was 800 per year.

These hospitals were divided into 3 groups according to amount of surgical operations each year. Hospitals with surgeries quantities in the upper tertile were categorized as large-volume group; hospitals in the lower tertile were categorized as small-volume group, and the rest categorized as medium-volume group. 33% of the hospitals were in the large-volume group, 30% in medium-volume group, and 37% in small-volume group. Detailed data please see table 1.

3.2 Usage status of sterilization packaging materials

For the usage of sterilization packaging materials in surveyed hospitals, all hospitals used non-woven fabrics and paper-plastic pouches(100%), 28 hospitals used cotton fabrics (93%), and 25 hospitals used rigid sterilization containers (83%).

Overall, non-woven fabrics were the most widely used, followed by cotton fabrics, paper-plastic pouches, and rigid sterilization containers (Table 2). The share of sterilization packaging materials was different in hospitals with different surgical operation scales. In large-volume group, the largest share of materials was non-woven fabric, followed by rigid sterilization containers, cotton fab-

Table 1 the hospital baseline characteristics

Baseline Characteristics	*n*(%)
Type	
Specialized hospital	4 (13%)
General hospital	26 (87%)
Located area	
Northeast	2 (7%)
East	16 (53%)
Middle	5 (17%)
West	7 (23%)
Number of surgeries performed annually, median (IQR)	33 424. 8 (19 000. 0, 86 000. 0)
The groups divided by annual surgery	
Large-volume group	10 (33%)
Medium-volume group	9 (30%)
Small-volume group	11 (37%)
Number of surgical instrument packages, median (IQR)	800. 0 (500. 0, 3 000. 0)

rics, and paper-plastic pouches. In medium-volume group, cotton fabrics accounted for the largest proportion, followed by non-woven fabrics, paper-plastic pouches, and rigid sterilization containers. In small-volume group, non-woven fabrics occupied the largest share, followed by cotton fabrics, paper-plastic pouches, and rigid sterilization containers.

3.3 Weights of influencing factors on choosing sterilization packaging materials

The influencing factors, with weights, for sterilization packaging material selection were shown in Table 3. According to the survey results, precision of packaged surgical instruments was the most important factor (weight 9.6), followed by the shape, size, weight and quantity of the surgical instruments (weight 9.2), nosocomial infection control(weight 9.2), the sterilization effect of the sterilization packaging materials(weight 9.0), the usage frequency of packaged surgical instruments (weight 8.0) and the influence of sterilization packaging materials on the optimization of CSSD's process (weight 8.0), the cost of sterilization packaging materials(weight 7.8), the requirements for hospital infrastructure (weight 7.7), whether the surgical instrument packages need to be transferred(weight 7.3), the total time consumption of sterilization packaging materials (weight 7.0), and the disposal of medical waste (weight 6.9).

The weights of influence factors were different in different hospitals. As indicated in Table 4, for hospitals in large-volume group the precision of instruments, the sterilization effect, and nosocomial infection control were the top three concerns. For hospitals in medium-volume group, the shape, size, weight, and quantity of the surgical instruments packaged, the precision of instruments and nosocomial infection control were the top three concerns. For hospitals in small-volume group, the most concerned three factors were the precision of instruments, nosocomial infection control, and the sterilization effect of sterilization packaging materials.

3.4 Influencing factors for each kind of material

According to the survey, different kinds of sterilization packaging materials have different considerations, and the influencing factors in different surgical scales hospitals were also different (Table 5).

Table 2 The share of sterilization packaging materials used in hospitals with different surgical operation group[mean(SD)]

Type	All	Different surgical operation scale			F-value	*P*
		large-volume group	medium-volume group	small-volume group		
N	30	10	9	11		
Rigid sterilization container	15. 90 (20. 73)	27. 54 (26. 77)	5. 56 (9. 19)	13. 78 (17. 23)	3. 17	0. 06
Cotton fabric	29. 91 (26. 26)	20. 26 (16. 98)	37. 73 (26. 93)	32. 27 (31. 73)	1. 13	0. 34
Non-woven fabric	32. 30 (21. 84)	33. 14 (25. 55)	29. 02 (10. 24)	34. 20 (26. 42)	0. 14	0. 87
Paper-plastic pouch	21. 89 (18. 26)	19. 05 (15. 13)	27. 67 (23. 29)	19. 75 (16. 85)	0. 63	0. 54

* Excluding the extreme in the calculation

Table 3 The weights of decision-making factors [mean (SD)]

Factors	Weight
The precision of the packaged surgical instruments	9. 6 (0. 9)
The shape, size, weight and quantity of the packaged surgical instruments	9. 2 (1. 6)
Nosocomial infection control	9. 2 (1. 4)
Sterilization effect of sterilized packaging materials	9. 0 (1. 6)
The usage frequency of packaged surgical instruments	8. 0 (2. 2)
The influence of sterilization packaging materials on the optimization of CSSD's process	8. 0 (1. 9)
The cost of the sterilization packaging materials	7. 8 (1. 6)
Hospital infrastructure	7. 7 (2. 4)
Whether the surgical instrument packages need to be transferred	7. 3 (2. 8)
The total time consumption of sterilization packaging materials	7. 0 (1. 8)
Disposal of medical waste	6. 9 (2. 1)

Table 4 Weights of decision-making factors in hospitals of different group [mean (SD)]

Factors	Large-volume group	Medium-volume group	Small-volume group	F-value	*P*
N	10	9	11		
The shape, size, weight and quantity of the packaged surgical instruments	9. 1 (1. 6)	9. 9 (0. 3)	8. 6 (2. 0)	1. 70	0. 20
Usage frequency of packaged surgical instruments	7. 2 (2. 9)	8. 2 (2. 0)	8. 5 (1. 6)	0. 91	0. 42
The precision of the packaged surgical instruments	9. 7 (0. 7)	9. 4 (1. 3)	9. 7 (0. 5)	0. 30	0. 74
Sterilization effect of sterilized packaging materials	9. 4 (1. 3)	8. 7 (2. 2)	9. 0 (1. 4)	0. 47	0. 63
The total time consumption of sterilization packaging materials	7. 2 (1. 9)	6. 6 (2. 0)	7. 2 (1. 6)	0. 38	0. 69
The cost of the sterilization packaging materials	8. 1 (1. 6)	7. 0 (1. 0)	8. 1 (1. 9)	1. 55	0. 23
The influence of sterilization packaging materials on the optimization of CSSD's process	8. 8 (1. 5)	7. 2 (2. 0)	7. 8 (1. 8)	1. 85	0. 18
Hospital infrastructure	8. 6 (1. 4)	6. 8 (2. 9)	7. 5 (2. 7)	1. 38	0. 27
Nosocomial infection control	9. 5 (0. 8)	9. 0 (1. 6)	9. 2 (1. 7)	0. 31	0. 74
Disposal of medical waste	7. 1 (2. 4)	7. 2 (2. 6)	6. 5 (1. 6)	0. 28	0. 76
Whether the surgical instrument packages need to be transferred	7. 3 (3. 2)	8. 1 (2. 0)	6. 6 (2. 9)	0. 69	0. 51

For cotton fabric, the shape, size, weight and quantity of instruments, the usage frequency of instruments, and the total time consumption were the most important factors when selecting cotton fabric for all surveyed hospitals. In addition, hospitals with a large number of surgeries usually concerned more about whether the surgical instrument packages need to be transferred. While hospitals with a small number of surgeries were more concerned about the optimization to the process of the CSSD and sterilization effect.

For non-woven fabrics, the shape, size, weight and quantity of instruments and sterilization effect were two most important factors. The hospitals with large-volume and small-volume were all concerned the sterilization effect, the shape, size, weight and quantity of instruments, and the usage frequency. Hospitals with medium-volume paid more attention to the optimization to the process of the CSSD, nosocomial infection control, and medical waste disposal.

For rigid sterilization containers, 90% surveyed hospitals took the precision of instruments as the most important factor which followed by whether the instrument needed to be transferred, nosocomial infection control, and hospital infrastructure. The large-volume hospitals considered the precision, the shape, weight, size and quantity of instruments mostly. The medium-volume hospitals considered more about hospital infrastructure, total time consumption, and cost of sterilization packaging materials. For small-volume hospitals, they concerned more about the precision of instruments and whether the instrument packages need to be transported.

For paper-plastic pouches, all surveyed hospitals considered the shape, size, weight, and quantity of instruments and optimization to process of CSSD. In addition, hospitals with large and medium number of surgeries also paid attention to nosocomial infection control.

4. Conclusion & discussion

In this study, 30 hospitals used a large number of surgical instrument packages and varieties of sterilized packaging materials were selected for investigation. Through a structured questionnaire survey, four widely used sterilized packaging materials (cotton fabric, non-woven fabric, rigid sterilized container and paper-plastic pouch) were covered, and their usage status and the influencing factors for decision-making have been investigated.

The results showed that non-woven fabric and

Table 5 Decision-making factors for the use of sterilization packaging materials in of different surgical scales hospitals [Factors (*n*/ %)]

	All surveyed hospitals	Large-volume group	Medium-volume group	Small-volume group
Cotton fabrics	the shape, size, weight and quantity of the packaged surgical instruments(19/63%) usage frequency packaged surgical instruments(18/60%) the total time consumption of sterilization packaging materials(17/57%)	the shape, size, weight and quantity of the packaged surgical instruments(7/70%) the total time consumption of sterilization packaging materials(5/50%) whether the surgical instrument packages need to be transferred(5/50%)	the shape, size, weight and quantity of the packaged surgical instruments(6/67%) usage frequency packaged surgical instruments(6/67%) the total time consumption of sterilization packaging materials(6/67%)	frequency of use of packaged surgical instruments(8/73%) The influence of sterilization packaging materials on the optimization of CSSD's process(8/73%) sterilization effect of sterilized packaging materials(7/64%)
Non-woven fabrics	the shape, size, weight and quantity of the packaged surgical instruments(26/87%) sterilization effect of sterilized packaging materials(26/87%)	sterilization effect of sterilized packaging materials(10/100%) the size, weight and quantity of the packaged surgical instruments(9/90%) frequency of use of packaged surgical instruments(9/90%)	the shape, size, weight and quantity of the packaged surgical instruments(8/89%) sterilization effect of sterilized packaging materials(8/89%) The influence of sterilization packaging materials on the optimization of CSSD's process(8/89%) nosocomial infection control (8/89%) Disposal of medical waste(8/89%)	The shape, size, weight and quantity of the packaged surgical instruments(9/82%) frequency of use of packaged surgical instruments(9/82%) the total time consumption of sterilization packaging materials(9/82%) the cost of the sterilization packaging materials(9/82%) The influence of sterilization packaging materials on the optimization of CSSD's process(9/82%) Disposal of medical waste(9/82%)
Rigid sterilized containers	the precision of the packaged surgical instruments(27/90%) whether the surgical instrument packages need to be transferred(25/83%) nosocomial infection control (24/80%) hospital infrastructure(24/80%)	the precision of the packaged surgical instruments(10/100%) the shape, size, weight and quantity of the packaged surgical instruments(9/90%)	hospital infrastructure(8/89%) the precision of the packaged surgical instruments (7/78%) the total time consumption of sterilization packaging materials(7/78%) the cost of the sterilization packaging materials(7/78%) The influence of sterilization packaging materials on the optimization of CSSD's process(7/78%) nosocomial infection control (7/78%) whether the surgical instrument packages need to be transferred(7/78%)	the precision of the packaged surgical instruments(10/91%) whether the surgical instrument packages need to be transferred(10/91%)
Paper-plastic pouches	the shape, size, weight and quantity of the packaged surgical instruments(26/87%) nosocomial infection control (24/80%) The influence of sterilization packaging materials on the optimization of CSSD's process(24/80%)	nosocomial infection control(8/80%) the shape, size, weight and quantity of the packaged surgical instruments(7/70%) usage frequency packaged surgical instruments(7/70%) sterilization effect of sterilized packaging materials(7/70%) The influence of sterilization packaging materials on the optimization of CSSD's process(7/70%)	the shape, size, weight and quantity of the packaged surgical instruments(8/89%) nosocomial infection control (8/89%)	the shape, size, weight and quantity of the packaged surgical instruments(11/100%) The influence of sterilization packaging materials on the optimization of CSSD's process (10/91%)

paper-plastic pouch were used in all the surveyed hospitals, 93% hospitals used cotton fabrics, and 83% hospitals used rigid sterilization container. In term of market share, among the 30 surveyed hospitals, non-woven fabrics were the most widely used one, followed by cotton fabrics, paper-plastic pouches, and rigid sterilization containers.

For the hospital decision-making of sterilization packaging materials, the most concerned factors were the precision of instruments, the shape, size, weight and quantity of instrument, nosocomial infection control, and the sterilization effect. The influencing factors for hospitals with different surgery scales were consistent with the results. Precise surgical instruments are delicate, expensive, and their quantity are limited in the hospital. Once damaged, the maintenance is usually costly and the process is long, which may affect the normal operation arrangement. Therefore, protective measures should be concerned for precision instruments. Different packaging materials have different loading capacities, cotton and non-woven fabrics packages should be less than 7 kg, paper-plastic pouches can only be used for lighter and smaller instruments, and rigid sterilization containers can be loaded up to a maximum of 10 kg. Therefore, to choose a more suitable packaging material, hospitals will consider the characteristics of the surgical instruments themselves. The sterility of clinical diagnosis and treatment instruments is related to medical safety and is the key concern for hospitals. Materials with good microbes barrier and low risk of nosocomial infection were given priority. The sterilization packaging material with good sterilization effect, low wet pack rate, and low re-sterilization rate are conducive to reducing the workload of medical staff, reducing hospital consumption and controlling costs. Therefore, when hospitals choose sterilization packaging materials, they will also focus on the factor: sterilization effect of sterilization packaging materials.

Most previous studies have compared the use of packaging materials based on cost, sterilization effectiveness, characteristics, etc. to select suitable sterilization packaging materials. These researches showed that on decision of selecting cotton fabric, non-woven fabric, rigid sterilized container paper-plastic pouch or other materials, hospital staffs would consider the patients' safety, durability, ease of use, compatibility with the intended method of sterilization, and the surgical instruments to be sterilized[16-18]. Based on previous researches, we summarized a total of 11 factors for decision-making including the influence of sterilization packaging materials on the optimization of CSSD's process, hospital infrastructure, nosocomial infection control, disposal of medical waste. We thought that our study was valuable for hospital administrators and the staff of CSSD to understand the decision-making of sterilized packaging materials in Chinese hospitals. Based on comprehensive consideration of all factors, the decision-makers should choose the most suitable packaging material with good protective measures for precise surgical instruments, and according to the different shape, size, weight and quantity of instrument to choose packaging material, and select the materials with good sterilization effect and low risk of hospital infection which beneficial to hospital safety management.

The results were consistent with those of the qualitative research which showed that when choosing packaging materials factors such as the types and characteristics of the items to be sterilized, the sterilization methods used, the characteristics of packaging materials, and the sterilization validity period should be fully considered, and different packaging materials were used for different medical devices[19]. And the results were also compatible with the sterilization packaging materials using recommendation[20].

This study also had limitations. There were a large number of hospitals in China, and in this study we just selected 30 surveyed hospitals via a typical sampling method, which might cause selection bias. Also, this study used a questionnaire to investigate the person in charge of CSSD. They filled the questionnaire base on their own preferences, and it might still be subjective. Therefore, in future research we should increase the number of surveyed hospitals

and expand the scope of surveyed people to obtain more information.

In short, sterilization packaging materials are important tools in the medical work. They can help improve the quality of medical care and reduce risk of adverse events such as surgical site infections. This study investigated and analyzed the status of sterilization packaging materials used in Chinese hospitals and factors affecting decision-making. The results of this study will be valuable for hospitals administrators and sterilization materials manufactures to make wise decision in medical work.

Contributorship

All authors participated in the process of the initial drafting of the article, review, presentation of the initial idea and design, and contributed significantly to the collection of the data, analysis and interpretation of the data. All authors read and approved the final manuscript.

Ethics approval and consent to participate

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Data availability

Data are available upon reasonable request from the corresponding author.

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