Meta-analysis of cleaning, disinfection and sterilization management of foreign medical devices and implants

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Introduction. To assess the current status of the disposal and management of foreign medical devices and implants, to provide data support for standardizing the disposal and management of foreign medical devices and implants, to reduce the incidence of hospital infections and to ensure patient safety.

Methods: Search the CNKI, Wanfang, VIP, Chinese Biomedical Literature Database, and PubMed databases for literature on the current status of disposal and management of foreign medical devices and implants in various hospitals in China before September 2023. Literature screening and data extraction were conducted strictly in accordance with the inclusion and exclusion criteria, and RevMan5.4 software was used for Meta analysis.

Results: A total of 13 Literatures and 3391 hospitals were included in the study. The combined results of meta-analysis show that the implementation rate of the foreign medical devices and implants management and disposal system is 89%, the implementation rate of the receiving location is the Chinese Hospital Sterilization Supply Center (CSSD) is 70%, and the implementation rate of delivery 1 day before surgery is 57% %, the post-operative cleaning and disinfection implementation rate was 43%, the cleaning effectiveness rate was 58%, and

the overall positive rate of sterilization quality was 7%.

Conclusion: Chinese hospitals have a low implementation rate of post-operative cleaning and disinfection of foreign medical devices and implants. They still need to standardize the disposal and management system, refine the disposal process and quality control details, and strengthen professional training. In addition, the implementation of targeted disinfection and sterilization management processes can significantly improve the cleaning quality of external medical devices and implants in hospitals, reduce the overall positive rate of sterilization quality, and has significant clinical application value.

Keyword: Foreign medical devices, Implants, Management, Current situation, Disinfection and cleaning

1. INTRODUCTION

With the rapid development of my country's medical technology and the continuous promotion of new diagnostic methods and new surgeries, the demand for hospital specialist equipment has gradually increased. Considering that there are many types of specialist equipment, they are updated frequently, and they are expensive, therefore, in order to reduce hospital financial expenditures and reduce medical expenses, many complex and advanced medical devices are rented and used in multiple hospitals. Exotic medical devices and implants are increasingly used in applications due to their sophisticated and complex design, high price, wide variety, and strong specificity of use. They are often rented by equipment companies or provided free of charge to various hospitals for reuse. While hospitals use foreign medical equipment, the management, cleaning, disinfection and sterilization of the equipment also bring challenges to hospital management. While foreign medical devices improve the therapeutic effect, the lack of targeted management models may lead to low quality disinfection and sterilization of foreign medical devices and implants, and also increase the chance of pathogenic microorganisms entering the human body, leading to the occurrence of infection (Gyan, McAuley, Strobel, Newton, et al., 2017; Gyan, McAuley, Strobel, Shannon, et al., 2017). According to surveys, surgical incisional infections account for approximately 36% of nosocomial infections, of which postoperative incisional infections in orthopedics account for 1% to 3%. In orthopedic surgery, the incidence of postoperative infection of implants is much higher than that of other ordinary surgeries. The incidence of postoperative infection of orthopedic implants in foreign countries is about 2.4% (Doi et al., 2016, 2021). Studies have shown that surgical incision infection leads to more than twice the death rate of

normal patients (Radhamony et al., 2021; Taherpour et al., 2021). Foreign medical devices and implants are frequently transferred and used across multiple hospitals and departments. How to standardize the management process is the focus and difficulty in preventing surgical site infections (SSI). It is particularly important to standardize the foreign medical device management system from the perspective of hospital management and infection control. By summarizing the management of foreign medical devices, as well as cleaning, disinfection and sterilization processes, it provides a reference for further standardized management of foreign medical devices.

The use and management of foreign medical devices in my country started later than in Western countries. In 2009, national industry standards for the first time proposed that the Sterilization Supply Center (CSSD) need to centralize the management of foreign medical devices (Ministry of Health, 2009). In 2012, the "Technical Specifications for Disinfection of Medical Institutions" (WS/T367-2012) issued by the National Health and Family Planning Commission set out technical requirements for the handling of foreign medical devices (Xi, 2020). In December 2016, the National Planning and Family Planning Commission revised and promulgated the "Hospital Disinfection Supply Center Part 1: Management Specifications" (WS310.1-2016) (National Health and Family Planning, 2016), regarding foreign medical devices and implants, it further emphasizes the responsibilities and requirements of hospitals, device suppliers and CSSD from the management and technical levels, and requires improving systems, establishing processes, setting up special posts and conducting training. In 2019, the "Operation Guidelines for Cleaning, Disinfection and Sterilization Technology of Foreign Medical Devices" (Qin, Liming, et al., 2019) (hereinafter referred to as the Guidelines) issued by the Chinese Nursing Association provides suggestions on the reprocessing of foreign medical devices in terms of operating procedures and quality management. Strengthened CSSD management of foreign medical devices and implants. In recent years, national industry standards and operating guidelines have put forward a series of requirements and guidance for the reprocessing of foreign medical devices, providing reference and basis for medical institutions to formulate foreign medical device management systems.

Relevant functional departments of the hospital (such as equipment department, hospital infectious disease department, medical department, nursing department, etc.), clinical use departments, operating rooms and CSSD should all participate in the formulation of the foreign medical device system. The responsibilities in the admission, management, handover, cleaning, disinfection, sterilization and early

release of implants and foreign medical devices should be clearly defined in the form of a system (Cheng et al., 2015). Device suppliers are important participants and collaborators in the hospital's foreign medical device management plan. They need to be familiar with the hospital's requirements for applying, receiving and returning foreign medical devices, and cooperate with the hospital. Their suggestions for the hospital management process also have certain reference value (Cichos et al., 2019). A complete foreign medical device management system needs to start from the surgeon's application for the use of foreign medical devices in the system, and end with the used devices being recovered to the CSSD for cleaning and disinfection again and returned to the device supplier. Each process and link need to be managed in a standardized manner. Specific system requirements may include application for use of foreign medical devices, access, transfer, reception and first verification, equipment cleaning, disinfection, sterilization requirements, record keeping and information traceability, charging standards and methods, post-use handling, equipment return, etc.

Domestic and foreign CSSDs also use information traceability systems to ensure patient safety, minimize device assembly defects and operating room delays, and improve the overall reliability of device reprocessing (Alfred et al., 2019, 2021). The management of foreign medical devices has always been a key and difficult point in hospital management. The ultimate goal of different management methods is to eliminate safety hazards and ensure the safety of patients. In the management of foreign medical devices, it is necessary for multiple departments to jointly standardize management, conduct risk assessments, solve problems promptly and find root causes after discovering them, and promote continuous improvement of the quality of foreign medical devices. This study conducts a meta-analysis on multiple studies on foreign medical devices and implants in Chinese hospitals. In order to understand the current status of domestic management, it can provide data reference for strengthening the management of foreign medical devices and implants in a more targeted manner, reducing the risk of hospital infection, and ensuring the safety of patients.

2. MATERIALS AND METHODS

2.1 Search Strategy

From Web of Science, ScienceDirect, PubMed, China National Knowledge Infrastructure, VIP Database, Wanfang Database, China Science and Technology Journal Database and Chinese Biomedical Literature Database. The search scope is Chinese and English literature published at home and abroad on the current status of

management of foreign medical devices and implants in my country. The MeSH subject thesaurus was used as the search terms, and the Chinese search terms were foreign medical devices, implants, management, sterilization, cleaning, and current status. At the same time, manual searches will be conducted by reading relevant monographs and consulting references. The search time was until September 2023.

2.2 Inclusion and exclusion criteria

Inclusion criteria: (a) The research subjects are hospitals in various regions of my country; (b) The research content includes the current status of disposal and management of foreign medical devices and implants. Exclusion criteria: (a) Conference abstracts and reviews; (b) Documents that have been published repeatedly and where the original text cannot be obtained; (c) Documents that were of poor quality or cannot extract relevant indicators.

2.3 Quality assessment

Two researchers independently extracted information, and any disagreements were resolved through consultation or third-party adjudication. Information extraction included the name of the first author, date of publication, study type, location, sample size, follow-up time, extent of lymph node dissection, and study endpoints. When the hazard ratio (HR) is not directly recorded in the literature, Engauge Digitizer is used to extract data; for non-randomized controlled studies, the Newcastle-Ottawa Scale (NOS) is used to score, and NOS≥7 is considered a high-quality study.

2.4 Statistical method

We adopted definitions used by the Cochrane Collaboration. A systematic review is a review of a well-articulated question that uses a systematic and explicit approach to identify, select and critically evaluate relevant studies, and collects and analyzes data from the studies included in the review. Cochrane Collaboration applied seven criteria: (a) random sequence generation, (b) blinding of participants and personnel, (c) allocation concealment, (d) incomplete outcome data, (e) blinding of outcome assessments, (f) selective reporting. Additionally, assessments were expressed as low risk, high risk, or unclear risk, according to the methodological description within each study. Meta-analysis may or may not have been used to summarize and analyze the results of the included studies. Meta-analysis is the use of statistical techniques to integrate the results of included studies in a series of systematic reviews.

RevMan5.4 software was used for statistical analysis, and the evaluation indicators

were expressed by weighted mean differences (WMD) and 95% confidence interval (95% CI), and the heterogeneity of the included research data was analyzed by χ^2 test and corresponding P value, P<0.05 means the difference is statistically significant, otherwise, there is no statistical significance. I^2 is used to represent heterogeneity. When I^2 >50%, it means that there is statistical heterogeneity among the studies, and the random effect model is used for analysis; when I^2 <50%, it means that there is no statistical heterogeneity among the studies. If heterogeneity exists, sensitivity analysis is used to explore the source of heterogeneity.

3. RESULTS

3.1 Literature search results

A total of 903 relevant documents were retrieved, 142 duplicate publications and cross-documents were deleted, 748 articles were excluded after reading the titles and abstracts, and 13 documents were finally included after reading the full text and quality evaluation (Figure 1). The 13 included literatures included a total of 3391 hospitals. The basic information of the included literature is shown in Table 1.

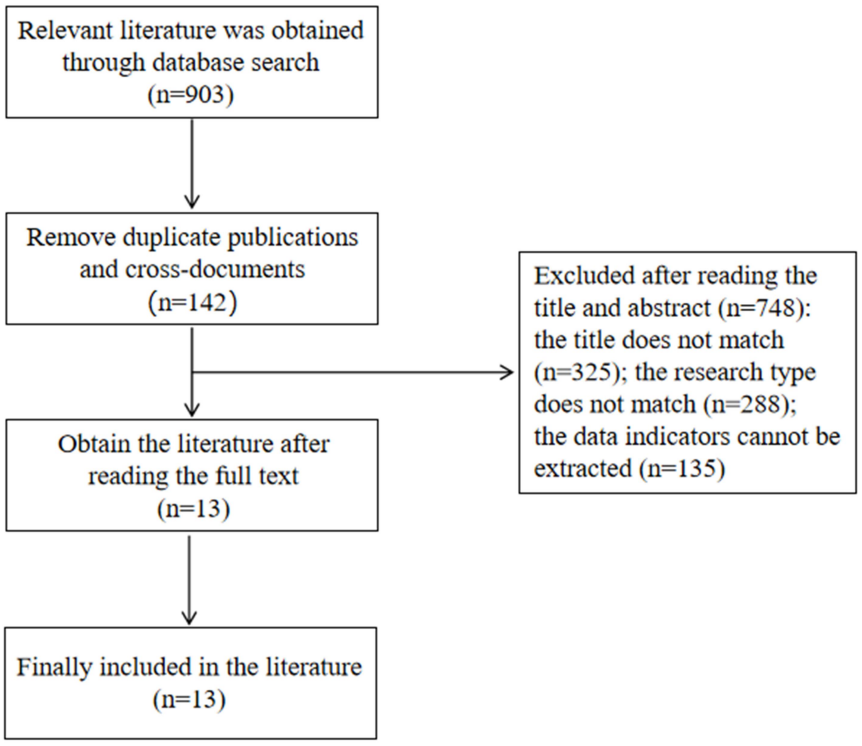

Figure 1. Current status of hospital foreign medical devices and implants management Meta analysis literature screening flow chart

Table 1. Current status of management of foreign medical devices and implants in hospitals Basic situation of literature included in Meta-analysis (n)

Included literature	Number of hospitals	Management system	The receiving location is CSSD	Delivered 1 day before surgery	Post-operative cleaning and disinfection	Cleaning efficiency	Overall positive rate of sterilization quality	NOS score
(Yanyan et al., 2022)	165	_	125	_	92	_	21	9
(Dongfang et al., 2021)	311	225	311	165	_	117	_	9
(Linghua et al., 2019)	58	55	29	50	43	57	_	7
(Yafen & Yu, 2020)	18	4	_	_	_	_	2	8
(Wang et al., 2022)	311	_	_	_	_	210	8	8
(Yuhong et al., 2019)	594	_	361	_	_	_	_	9
(Qin, Haiyan, et al., 2019)	764	742	_	429	287	419	_	7
(Kai et al., 2019)	761	_	_	_	285	479	_	9
(Yang et al., 2018)	187	_	_	_	167	_	_	8
(Bing et al., 2014)	106	89	38	_	10	_	15	9
(Yuhua et al., 2013)	32	24	_	23	_	12	_	7
(Wenjing et al., 2018)	53	_	_	38	_	28	2	8

(Ping & Tianfang, 2014)	31	30	26	10	16	—	–	9

Note: - means not reported.

3.2 Quality assessment of literature included in the studies

Among all 13 included studies, 6 studies had an NOS score of 9, 4 had an NOS score of 8, and 3 had an NOS score of 7. It shows that the included studies are all high-quality studies (Table 1).

3.3 Foreign medical devices and implants management system

The heterogeneity test results showed that there was heterogeneity among the included literature (I^2=95%, P<0.01), so the random effects model was used for analysis. The combined implementation rate of the hospital's foreign medical devices and implant management system was 89% (95%CI [1.77; 20.06]) (Figure 2).

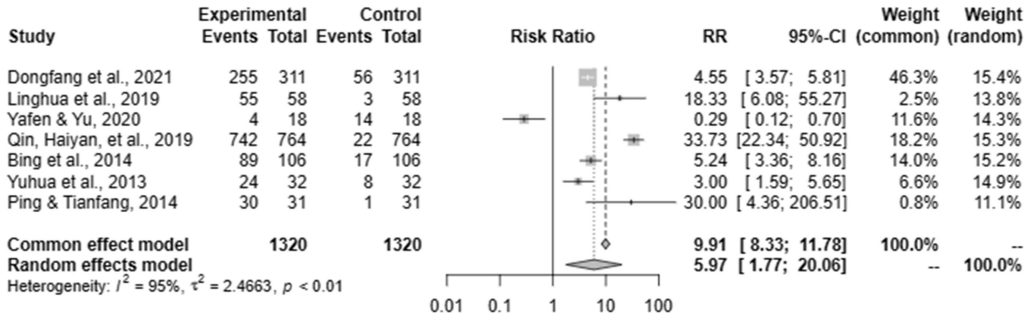

Figure 2. Forest plot of foreign medical devices and implants management system

3.4 When the receiving location is CSSD

The heterogeneity test results showed that there was heterogeneity among the included literature (I^2=95%, P<0.01), so the random effects model was used for analysis. The forest plot shows that the hospital's receiving location for foreign medical devices and implants is, and the combined value of CSSD implementation rate was 70% (95%CI [0.69; 16.08]) (Figure 3).

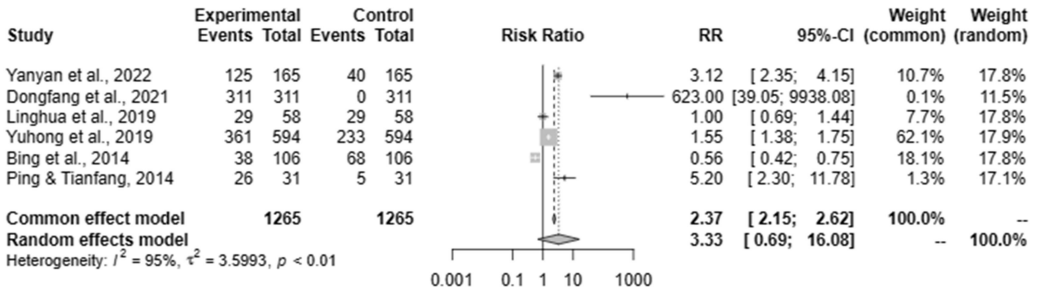

Figure 3. Forest plot of CSSD implementation rate at hospital's receiving locations for external medical devices and implants

3.5 Delivery status 1 day before surgery

The heterogeneity test results showed that there was heterogeneity among the included literature (I^2=90%, P<0.01), so the random effects model was used for analysis. The combined delivery rate of foreign medical devices and implants in the hospital 1 day before surgery was 57% (95%CI [0.87; 3.36]) (Figure 4).

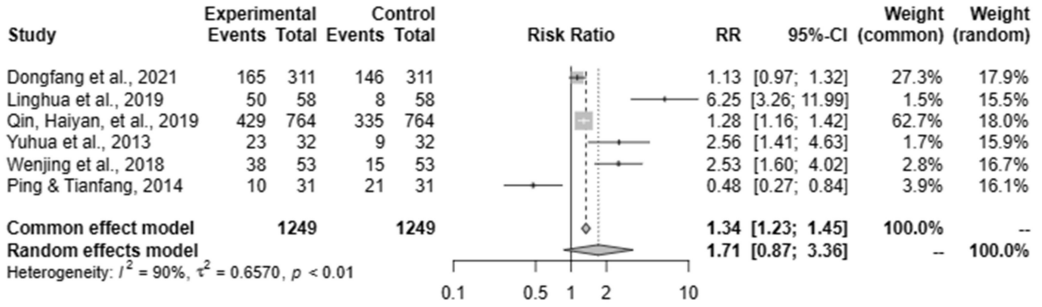

Figure 4. Forest plot of hospital delivery implementation rate of foreign medical devices and implants 1 day before surgery

3.6 Implementation of cleaning and disinfection after surgery

The heterogeneity test results showed that there was heterogeneity among the included literature (I^2=97%, P<0.01), so the random effects model was used for analysis. The combined value of the implementation rate of cleaning and disinfection of external medical instruments after surgery was 43% (95%CI [0.36; 3.52]) (Figure 5).

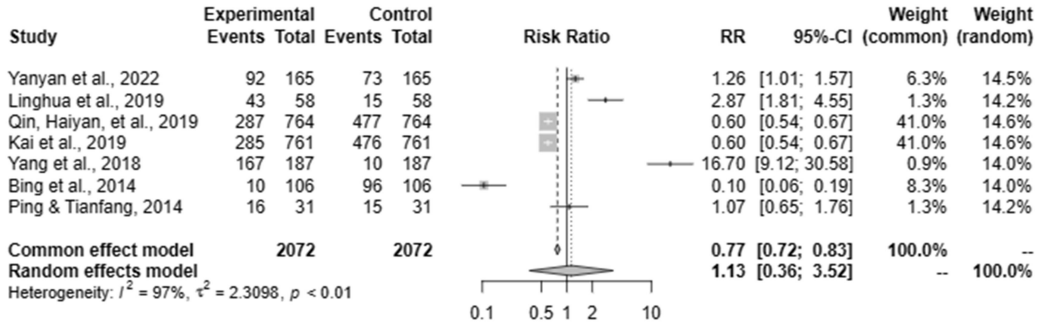

Figure 5. Forest plot of implementation rate of cleaning and disinfection of foreign medical devices after surgery

3.7 Cleaning effectiveness

The heterogeneity test results showed that there was heterogeneity among the included literature (I^2=96%, P<0.01), so the random effects model was used for analysis. The implementation rate of cleaning and disinfection after surgery was 58% (95%CI [0.11; 2.41]) (Figure 6).

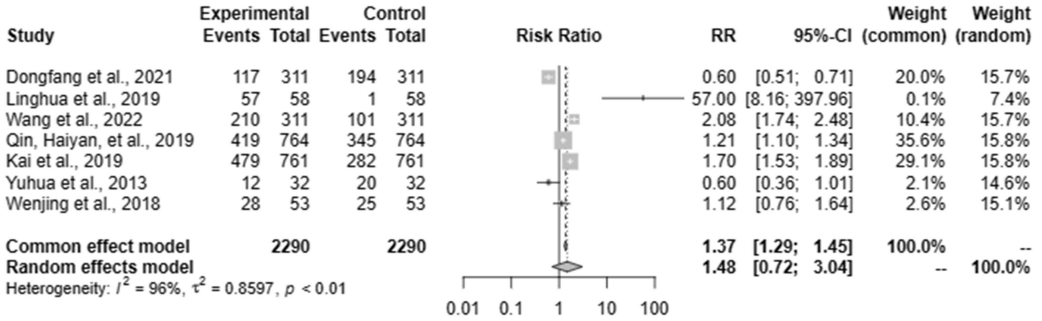

Figure 6. Cleaning efficient forest plot

3.8 Overall positive status of sterilization quality

The heterogeneity test results showed that there was heterogeneity among the included literature (I^2=83%, P<0.01), so the random effects model was used for analysis. The overall positive rate of sterilization quality is 7% (95%CI [0.04; 0.18]) (Figure 7).

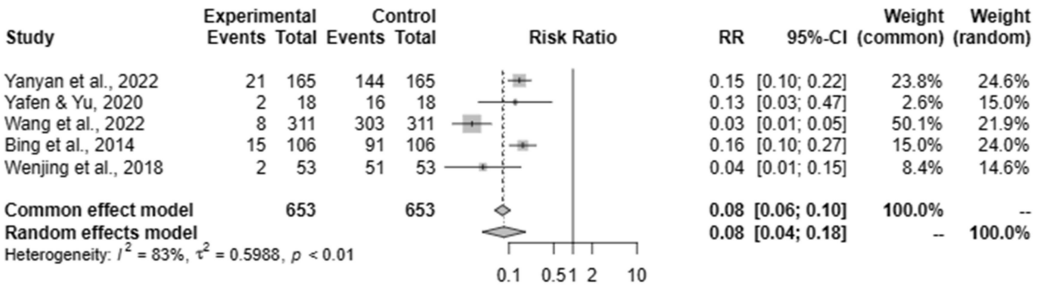

Figure 7. Forest plot of overall positive rate of sterilization quality

3.9 Publication bias

The publication bias of the implementation rate of various indicators for the disposal and management of foreign medical devices and implants in hospitals was analyzed, and a funnel plot was drawn. The results show that the funnel plot has poor symmetry and may have publication bias (Figure 8).

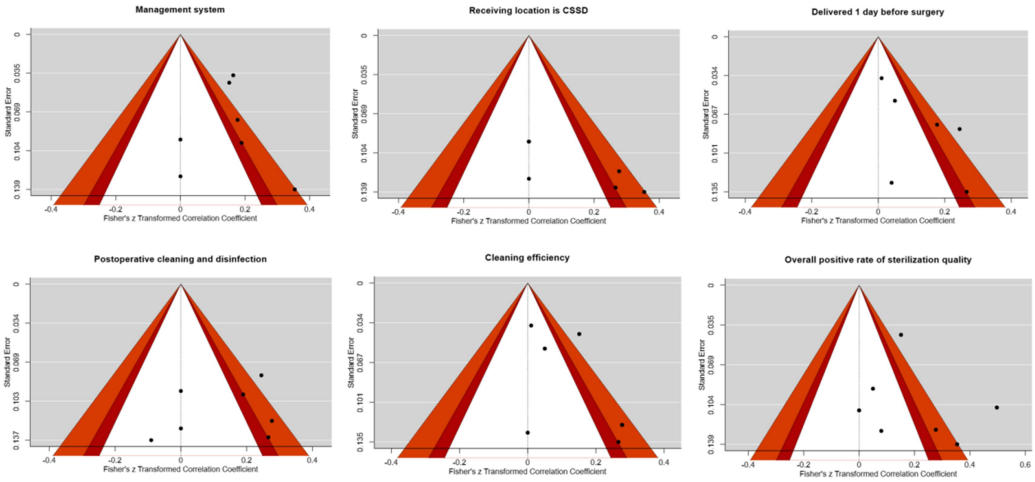

Figure 8. Funnel chart of the implementation rate of each indicator in the included literature

4. DISCUSSION

Exotic medical devices are reusable surgical instruments that the hospital rents from device suppliers (Seavey, 2010). An implant is an implantable medical device that is placed in a body cavity formed by surgical operation or exists physiologically and remains for more than 30 days. Foreign medical devices and implants have a wide variety, complex structures, and special materials. They are also seriously contaminated after use and flow among various medical institutions. Therefore, management and cleaning, disinfection and sterilization technology are more difficult. The results of this study show that the implementation rate of postoperative cleaning

and disinfection of foreign medical devices and implants is low, and some manufacturers do not provide correct sterilization procedures and parameters, etc., which reduces the quality of medical care and increases patient safety risks. Therefore, it is necessary to strengthen standardized management to effectively prevent and control the occurrence of hospital infections and ensure patient safety.

CSSD recommends that foreign medical devices and implants should be delivered at least 2 days before surgery. Allow sufficient time for CSSD staff to carry out standardized cleaning, inspection, packaging, sterilization, monitoring, recording and traceability. In accordance with the requirements of WS310-2016, hospitals should sign agreements with device manufacturers to strictly regulate the delivery time of foreign medical devices. CSSD is implemented in accordance with regulations to ensure that foreign medical devices and implants have sufficient processing time, and the devices should undergo biological monitoring after sterilization, and can only be released after passing the test (Barneschi et al., 2021). In order to effectively ensure the sterilization quality of foreign medical devices and implants, foreign medical devices and implants used in the operating room should be delivered to the hospital at least 1 day before surgery and sterilized at the CSSD. When receiving foreign medical devices and implants for the first time, the hospital CSSD should first evaluate whether the equipment has the conditions for cleaning, disinfection and sterilization, and test the sterilization parameters and effectiveness before use. Since the delivery time of foreign medical devices and implants is generally determined by the hospital itself, the delivery time varies greatly, and there is a phenomenon that it cannot be delivered within the specified time. If the delivery time is late, the quality of sterilization cannot be guaranteed, which will increase the risk of hospital infection. The analysis of this study shows that the delivery implementation rate of foreign medical devices and implants 1 day before surgery is 57% (95% CI [0.87; 3.36]). The reason for the low implementation rate of this is that the advance delivery time of foreign medical devices and implants is generally set by the hospital itself, which varies greatly, and there are cases where delivery cannot be made on time despite regulations. Therefore, hospitals should strengthen the management and requirements of device manufacturers and emphasize the delivery time of foreign medical devices and implants.

WS310.2-2016 (National Health and Family Planning Commission of the People's Republic of China, 2017) stipulates that CSSD must clean and disinfect used foreign medical devices before returning them to the device manufacturer. Due to their complex structures and materials, foreign medical devices and implants are difficult to clean and disinfect. If they are not cleaned properly, contaminants such as blood and

body fluids on the surface of the devices can easily cause corrosion of the devices and biofilm is formed, causing equipment damage and sterilization failure. Research (Browne et al., 2023) shows that the qualification rate for cleaning and disinfection of foreign medical devices and implants is only 91.50%. The analysis results of this study show that the implementation rate of cleaning and disinfection of foreign medical equipment after surgery is only 43% (95%CI [0.36;3.52]). The reason for this low implementation rate lies in the operating procedures, different conditions of each hospital, and different usage conditions of each department. During the turnover process of instruments, it is difficult to ensure that the instruments arrive at the supply room for cleaning within 2 hours after use. In addition, some medical staff may lack knowledge and skills in cleaning and disinfection, or may not have received adequate training and guidance. Therefore, management should be further standardized, cleaning and disinfection should be carried out by trained CSSD staff, and full-process quality traceability management should be achieved (Ying et al., 2022).

In actual work, some foreign medical device manufacturers do not provide correct sterilization procedure parameters, which brings many difficulties to the CSSD work (Jing et al., 2018). It may result in substandard sterilization quality, increase the risk of hospital infection, threaten the life safety of patients, and even cause damage to precision and valuable medical equipment, resulting in high medical costs. Develop operating procedures in accordance with relevant requirements, choose appropriate methods to clean, disinfect and sterilize foreign medical devices and implants, and evaluate whether the devices are functioning well to ensure the quality of foreign medical devices and implants and patient safety. The analysis results of this study show that the cleaning effectiveness rate is 58%, and the overall positive rate of sterilization quality is 7%. There are many reasons for the low efficiency of cleaning and disinfection of medical devices, some of which may include: not paying enough attention to cleaning, not brushing carefully enough, difficult-to-clean parts being ignored and missed, improper detergents or cleaning methods used, etc. In addition, some medical institutions may not have a cleaning machine for cleaning medical devices, but rely solely on manual cleaning. It is suggested that the implementation of targeted disinfection and sterilization management processes can significantly improve the cleaning quality of external medical devices and implants in hospitals and reduce the overall positive rate of sterilization quality.

The total number of hospitals included in this study is large and the scope is wide. It has important guiding significance for understanding the current situation and existing problems of foreign medical devices and implants management in my country, and further standardizing the management of foreign medical devices and implants.

However, the heterogeneity among studies is large, which may be related to the large gap in the number of samples included in the studies. It is recommended that further nationwide surveys and studies be conducted in the future to conduct a more comprehensive analysis. To sum up, the implementation rate of the dedicated post responsibility system for the disposal and management of foreign medical devices and implants in hospitals in my country needs to be further improved. The implementation rate of postoperative cleaning and disinfection is low. The disposal and management system also needs to be standardized and strengthened. Strengthen supervision, implement the dedicated post responsibility system, strengthen professional training, increase management of device manufacturers, require them to provide correct sterilization procedures and parameters, strictly regulate delivery time, and further refine the disposal process and quality control details to ensure the quality of foreign medical devices and implants and ensure patient safety.

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