Original Article

# Investigation into the current status of cleaning, disinfection, and sterilization of da Vinci surgical instruments—a cross-sectional survey

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**Background:** In recent years, the use of robotic-assisted surgery has developed rapidly in China and is now widely used in many clinical fields. However, da Vinci robotic surgical instruments are more precise, expensive, and complex than ordinary laparoscopes, have less instrument configuration, involve restrictions on the duration of use, and have cleanliness requirements for supporting instruments. The purpose of this study was to analyze and summarize the current status of cleaning, disinfection, and maintenance of da Vinci robotic surgical instruments in China to improve the management of these devices.

**Methods:** A questionnaire survey on the use of da Vinci robotic-assisted surgery at medical institutions in China was designed, distributed, and analyzed. The survey included items regarding general information, management of instrument handling personnel, instrument handling techniques, guidelines, and references for instrument handling. The results and conclusions were formed from the data generated by the analysis system and the answers of respondents to the open-ended questions.

**Results:** (I) All surgical instruments used in domestic surgery practice were imported. There were 25 hospitals that conduct more than 500 da Vinci robotic-assisted surgeries every year. (II) In a relatively high proportion of medical institutions, nurses continued to be responsible for the processes of cleaning (46%), disinfection (66%), and low-temperature sterilization (50%). (III) A total of 62% of the surveyed institutions used fully manual methods for cleaning instruments, and 30% of the ultrasonic cleaning equipment in surveyed institutions did not comply with the standard. (IV) A total of 28% of surveyed institutions used only visual inspection to evaluate cleaning efficacy. Only 16–32% of surveyed institutions regularly used adenosine triphosphate (ATP), residual protein, and other methods to detect sterilization of cavities in instruments. (V) In 60% of the surveyed institutions, robotic surgical instruments have been damaged.

**Conclusions:** Cleaning efficacy detection methods of robotic surgical instruments were not uniform and standardized. The management of device protection operations should be further regulated. In addition, further study of relevant guidelines and specifications as well as the training of operators is warranted.

**Keywords:** Robotic surgical instrument; da Vinci; management of surgical instruments; detection of surgical instrument cleaning

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## Introduction

In recent years, the use of robotic-assisted surgery in China has developed rapidly. As of December 2021, 260 da Vinci robotic surgical systems had been installed in mainland China, and in 2021, more than 89,000 surgeries were completed using this technology (1). At present, the da Vinci robotic surgery system is widely used in urinary, thoracic, extra-abdominal, head and neck, and gynecology surgery, among other fields (2-5). Da Vinci robotic surgical instruments are more precise, expensive, and complex than ordinary laparoscopes, have less instrument configuration, involve restrictions on the duration of use, and have cleanliness requirements for supporting instruments. These characteristics necessitate higher requirements for the cleaning, sterilization, and maintenance of instruments (6). Therefore, a review of the cleaning, disinfection, and management of robotic surgical instruments has important clinical significance (7-9). This study analyzed and summarized the current status of cleaning, disinfection, and maintenance of da Vinci robotic surgical instruments in China to provide a reference for improving the management of these devices. We present the following article in accordance with the SURGE reporting checklist (available at https://gs.amegroups.com/article/view/10.21037/gs-23-111/rc).

## Methods

### *Study design*

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and informed consent was taken from all the patients.

**Highlight box**

**Key findings**

- Cleaning efficacy evaluation methods for robotic surgical instruments are inconsistent, and some devices are damaged.

**What is known and what is new?**

- In recent years, robotic-assisted surgery technology has developed rapidly in China.
- We conducted a cross-sectional survey of the cleaning and maintenance of robotic surgical instruments nationwide.

**What is the implication, and what should change now?**

- The cleaning and maintenance methods of robotic surgical tools need unified norms and consensus.

### *Object and scope of survey*

Nationwide, 50 medical institutions that conduct da Vinci robotic-assisted surgeries were surveyed via the head of the disinfection supply center or operating room cleaning department.

### *Survey methods*

The content of the questionnaire included 5 dimensions: general information, related personnel, cleaning methods, cleaning efficacy detection methods, and instrument damage. The questionnaires were distributed by the Nursing and Materials Branch of the Chinese Medical Equipment Association.

### *Statistical analysis*

Continuous variables conforming to normal distribution were expressed by mean ± standard deviation (SD), and *t*-test was used for comparison between the two groups, otherwise, rank sum test was used. Two categorical variables were expressed by values and percentages, and chi square test or Fisher exact probability test is used for comparison between the two groups where appropriate. A two tailed P value of <0.05 was considered as statistical significance. All the statistical analyses were performed by using IBM SPSS Statistics version 26.

## Results

### *General data analysis*

All 50 questionnaires in this survey were collected from the main tertiary hospitals in large and medium-sized cities, including Beijing, Shanghai, Guangzhou, Wuhan, Shenzhen, Chengdu, and Fuzhou. Among them, there were 25 hospitals that conduct more than 500 da Vinci robotic-assisted surgeries every year, accounting for 50%. All surgical instruments used in domestic surgery were imported. Currently, there is no formal application of domestic surgical instruments for use on humans. Handling specifications for instruments came only from the manufacturer's instructions. Most of the cleaning, disinfection, and sterilization of such devices were conducted by the hospital disinfection supply center. Some procedures were conducted by the operating room cleaning department, or the disinfection supply center stationed in the operating room cleaning department (*Table 1*).

**Table 1** Ratio of department types in medical institutions managing da Vinci robotic surgical instruments

| Items | Disinfection supply center | Operating room cleaning department | Disinfection supply center for surgical treatment |
|---|---|---|---|
| Number of hospital rooms | 44 | 5 | 1 |
| Proportion (%) | 88 | 10 | 2 |

**Table 2** The composition ratio of types of personnel performing cleaning, inspection of packaging, and low-temperature sterilization operations on da Vinci robotic surgical instruments

| Items | Cleaning | | | Inspection of packaging | | | Low-temperature sterilization | | |
|---|---|---|---|---|---|---|---|---|---|
| | Nurse | Nurse + worker | Worker | Nurse | Nurse + worker | Worker | Nurse | Nurse + worker | Worker |
| Number of hospital rooms | 23 | 20 | 7 | 33 | 14 | 3 | 25 | 16 | 9 |
| Proportion (%) | 46 | 40 | 14 | 66 | 28 | 6 | 50 | 32 | 18 |

**Table 3** Composition ratio of different types of detection methods for cleaning efficacy

| Items | Visual inspection only | Visual inspection + periodic residual protein | Visual inspection + periodic ATP | Visual inspection + periodic residual protein + periodic ATP |
|---|---|---|---|---|
| Number of hospital rooms | 14 | 8 | 12 | 16 |
| Proportion (%) | 28 | 16 | 24 | 32 |

ATP, adenosine triphosphate.

### *Personnel*

A high proportion of cleaning and disinfection, inspection of packaging, and low-temperature sterilization of da Vinci robotic instruments in the surveyed hospitals was carried out by nurses. Only a small proportion of the hospitals utilized skilled workers for these tasks, and the majority involved cooperation between nurses and skilled workers (*Table 2*).

### *Cleaning methods*

According to the survey data, only 19 medical institutions (38%) used fully automatic mechanical cleaning of da Vinci robotic equipment (except optical eyepieces). The majority (62%) cleaned the instruments manually.

### *Cleaning efficacy detection method*

Some respondents used only visual inspection of robotic instruments as a method for detecting the cleaning efficacy, and the proportion of respondents who regularly monitored blood or dirt residues on devices using adenosine triphosphate (ATP), residual protein, and other chemical indicators was low. In addition, 30% of the surveyed institutions did not comply with the requirements for the use of robotic equipment (*Table 3*).

### *Damage to devices and causes*

A total of 60% of the respondents reported damage to robotic surgical instruments, and in 70% of the medical institutions that reported damage, this occurred 1–3 times/year. The type or location of damage included: the optical mirror (20%), the working end of the robotic arm (60%), the water injection port of the robotic arm (30%), and the connecting cable (20%).

The causes of damage included: improper use by doctors during surgery (58%); improper use in the operation procedures of instrument cleaning, disinfection, packaging, and sterilization (16%); accidental damage (16%); and production quality issues of equipment (10%).

### *Existing issues*

For survey items relating to the management of robotic surgical instruments, an open-ended question method was adopted. The respondents reported that the following issues required urgent action: accurate and comprehensive guidance on cleaning efficacy detection methods could not be obtained for the instruments, which are complex in structure and difficult to clean; there was a discrepancy between turnover efficiency of the equipment and demand for use in Linchuan; and there were difficulties obtaining protective equipment, tools, baskets, and other necessary items during the device cleaning processing.

## Discussion

As seen in *Table 3*, the majority of respondents used only visual methods to detect cleaning efficacy of da Vinci surgical instruments. However, only surface pollutants >50 micrograms can be observed by visual inspection (10). It is impossible to observe the cleaning effect on the shaft cavity of the robotic arm, the gap at the working end, and other complex structural locations. In recent years, the cleaning efficacy of these devices has been monitored by experts using successively more scientific methods, including ATP detection and residual protein detection, among others (11,12). However, the shaft cavity of the da Vinci system has its own unique lumen structure. Thus, the volume of the inner cavity should be calculated during ATP detection, residual protein detection, and other tests so that the amount of neutralizing liquid or rinse solution used in the cleaning efficacy test can be calculated, and the threshold of detection can be further determined. Therefore, these detection methods should be further studied and standardized.

At present, most medical institutions still use a manual standard cleaning process that complies with the manufacturer's user guide for the da Vinci robotic system (13,14). As domestic-made robotic surgical instruments have entered the development and clinical trial stage in China, it is worth giving attention to structural or specification differences between domestic robotic products and the da Vinci system that could impact instrument treatment.

In addition, the shaft cavity of the robotic arm has a unique structure, and the specification is longer than other laparoscopic surgical instruments. Medical institutions could standardize the use of compliant and verified equipment when performing cleaning operations. Survey data demonstrated that some medical institutions (30%) used ultrasonic cleaning machines beyond the suggested scope for robotic surgical instruments. Moreover, the hidden danger of incomplete cleaning is also a concern.

Regarding the issue of personnel, in a large proportion of medical institutions surveyed, nurses were responsible for robotic surgical instrument processing (*Table 2*). Since the disinfection supply center is a nonclinical department within a medical institution, the use of nurses in this role is not conducive to implementation of the National Health Commission's guidance that nonclinical conditions should account for no more than 5% (15). Therefore, it is necessary to revise the unified norms or guidelines and train non-nursing staff to take up the relevant operational positions, which could reduce the proportion of nurses.

Limitations of study: first, as a cross-sectional survey, the simple randomization sampling method may have contributed to selection bias and information bias. Second, because the sample size was not estimated in advance, the statistical power of the results may not be strong enough. Third, the dimensions and items of the questionnaire in this study should be further optimized.

## Conclusions

Cleaning efficacy detection methods of robotic surgical instruments were not uniform and standardized. The management of device protection operations should be further regulated. In addition, further study of relevant guidelines and specifications as well as the training of operators is warranted.

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## Footnote

*Reporting Checklist:* The authors have completed the SURGE reporting checklist. Available at https://gs.amegroups.com/article/view/10.21037/gs-23-111/rc

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*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at https://gs.amegroups.com/article/view/10.21037/gs-23-111/coif). XW is an employee from Shanghai Ruipu Medical Technology Co., Ltd. The other authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and informed consent was taken from all the patients.



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