

## Original Article

# Application and effectiveness of Plan-Do-Check-Action cycle method for quality control in rigid container handling

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Received September 25, 2020; Accepted October 21, 2020; Epub February 15, 2021; Published February 28, 2021

**Abstract:** Objective: To explore the quality control and application effects of a Plan-Do-Check-Action (PDCA) cycle in rigid container sterilization in a central sterile supply department. Methods: A total of 2,422 pieces of minimally invasive surgical instruments went through rigid container disinfection from our disinfection supply room, and the quality control results, sterile barrier damage rate, wet package rate, as well as the satisfaction rate of clinical departments for rigid container disinfection were compared before and after the application of a PDCA cycle. Results: After the application of PDCA cycle, the sterile barrier damage rate and wet package rate were significantly lower than those before PDCA cycle application. The comparison between groups was significantly different ( $P < 0.05$ ). The quality control scores and satisfaction rate of clinical departments for rigid container sterilization were significantly higher than those before the application of PDCA cycle ( $P < 0.05$ ). Conclusion: PDCA cycle can reduce the sterile barrier damage rate and wet package rate, ultimately improving the quality control results of rigid container sterilization and the satisfaction rate of clinical departments.

**Keywords:** Disinfection supply center, Plan-Do-Check-Action cycle, rigid containers, clinical department satisfaction, quality control

## Introduction

The department supply room is responsible for the management of medical instruments, including instrument recovery, cleaning, disinfection and reapplication in the clinical departments [1, 2]. With the rapid development of modern surgical technology, various minimally invasive techniques have gradually replaced traditional open surgery due to the advantages of less wounds, quick postoperative recovery, and safety and precision in operation [3-5]. At present, minimally invasive technology is applied in various surgeries, such as thoracic surgery, general surgery, gynecological surgery and others [6, 7]. However, compared with the traditional open surgery, endoscopic surgery entails more surgical instruments with high mechanical precision and the instruments are more expensive and easily damaged. Therefore, special tools for cleaning, disinfection and preservation of such surgical instruments are quite necessary [8, 9].

Previous studies have confirmed that rigid containers have become the main packing containers for disinfecting endoscopy surgical instruments because they are strong, durable, stable, inexpensive, and simple in operation as well as the fact that they can be used repeatedly [10]. Meanwhile, some scholars compared the rigid containers with the traditional textile wrapping cloth, non-woven fabric and paper plastic packing materials for disinfection of endoscopy surgical instruments, and the results showed that rigid containers did better in disinfection, which reduced the wet package rate and increased the intact rate of the instruments [11]. However, there remains a wet package rate (about 0.8%) and sterile barrier damage rate (about 3.0%). So, reducing the wet package rate and the sterile barrier damage rate is essential for widespread use of rigid containers in disinfection [12].

Plan-Do-Check-Action (PDCA) cycle, also known as the Deming cycle, which includes four stag-

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es with each stage following one another and are repeated from the start. The four stages are plan, do, check and action. The cycle can improve work quality and help to finally reach the goal [13, 14]. Because of its good clinical effect, it is widely used in hospital management but seldom used in the quality control of rigid containers handling [15, 16]. This study focused on the instruments packed and disinfected by rigid containers handling in our center, and explored the role of PDCA cycle, so as to improve the effect of rigid containers.

### Materials and methods

#### *Baseline information*

A total of 2,422 instruments were disinfected in rigid containers in The First Affiliated Hospital with Nanjing Medical University from January 2019 to December 2019. The control group included 1,189 instruments before the application of PDCA cycle (from January to April, 2019). The observation group included 1,233 instruments and the disinfection effect was evaluated during and after the implementation of PDCA cycle (from August to December, 2019).

#### *Methods*

Both groups used rigid containers (Shanghai Suning Medical Devices Co., Ltd., China) for disinfection. The specific use procedures included rigid container recovery, cleaning, inspection, packing, sterilization, regular record of the wet package rate and damage package rate of aseptic barrier without any other intervention. The observation group adopted PDCA cycle for quality control which differed from the control group [17, 18]. The specific measures of PDCA cycle included: (1) Plan: In accordance with the relevant disinfection rules and regulations, the disinfection center staff formulated the plan for improving the quality control of the supply department by brainstorming discussion of the staff. They analyzed the reasons of the wet package and aseptic barrier damage in their work, and came up with the corresponding solutions. (2) Do: This stage mainly included selecting container boxes to match the size of the instrument. During the process, the overlapping of metal instruments must be avoided. The instrument couplings were opened to improve the contact area in disinfection and, reduce condensed water, and at the same time put the container on the carrier to facilitate

drainage. Set up sufficient drying time and avoid cooling directly under the air conditioner. (3) Check: The staff would regularly check the sterilization records, container position and biochemical test, record the conditions of wet package and damaged package, and then analyze the possible causes. (4) Action: Address the problems in a timely manner according to the PDCA cycle and form standards to solve problems. Regular meetings were carried out once a week. During the meeting, the effect and problems in the work were summarized and fully discussed. Any unsolved problems that remained were moved into the next PDCA cycle until the solution for them.

#### *Outcome measures*

*Main outcome measures:* Main outcome measures included sterile barrier damage rate (the outermost layer of the package was punctured) and wet package rate (after sterilization, water stains could be seen on the outer package or water drops appeared in the sterilized instrument in the container below the wet surface). The damage package rate equals damaged package/total number of pieces \* 100% and the wet package rate equals wet package/total number of pieces \* 100%.

*Secondary outcome measures:* Secondary outcome measures included work quality score (disinfection, isolation and pack quality of instruments and items) and clinical satisfaction score on disinfection evaluated by a self-made satisfaction questionnaire.

#### *Statistical analysis*

All the data were analyzed by SPSS 22.0 statistical analysis software. The measurement data were expressed by mean  $\pm$  standard deviation ( $\bar{x} \pm sd$ ) and compared by independent t-test. The count data were expressed as the number of cases/percentage (n/%), and the comparison of the rates between groups was conducted by  $\chi^2$  test with  $\alpha=0.05$  as the reference standard.  $P<0.05$  was considered as a statistically significantly difference.

### Results

#### *Comparison of the baseline data of the staff from our supply department*

The results showed that there were no significant differences in gender, age, working years

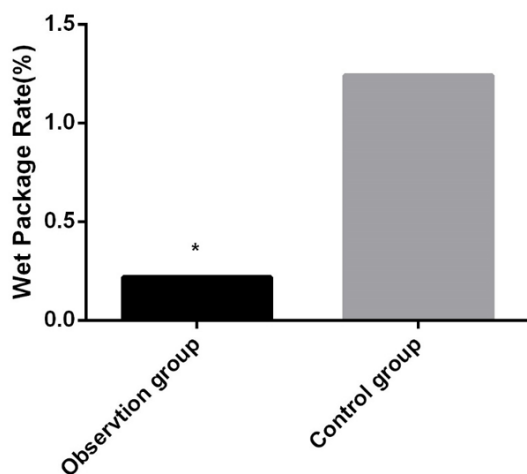
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**Table 1.** Comparison of the baseline data of the staff from our supply department

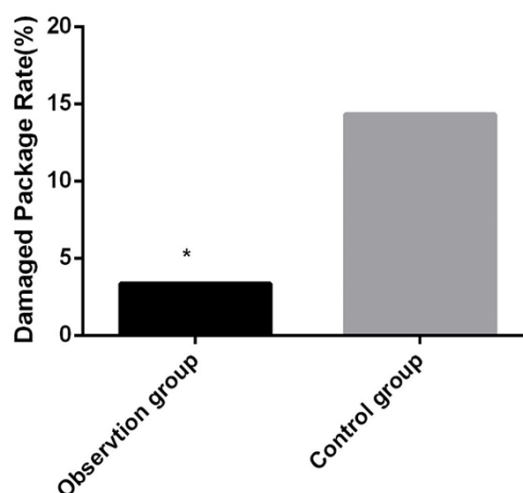
Group	Age (years)	Working years (years)	Gender (male/female)	Educational level			
				Technical secondary school	Junior college	Undergraduate	Postgraduate
Control group	43.5±3.7	15.3±3.6	8/16	2	10	10	2
Observation group	44.0±3.6	14.9±4.2	10/14	2	9	11	2
t/ $\chi^2$	0.458	0.354	0.089			0.100	
P	0.649	0.725	0.766			0.992	

**Table 2.** Comparison of instruments

Group	Ordinary instruments	Minimally invasive instruments			
		Department of Cardiothoracic surgery	Department of obstetrics and gynecology	Department of General surgery	Department of Orthopedics
Control group (n=1,189)	211	200	108	320	350
Observation group (n=1,233)	235	208	90	340	360
t/ $\chi^2$	3.164			2.338	
P	0.075			0.505	



**Figure 1.** Comparison of wet package rate. Compared with the control group, \* $P < 0.05$ .



**Figure 2.** Comparison of the sterile barrier damage rate. Compared with the control group, \* $P < 0.05$ .

and educational levels between the two groups ( $P > 0.05$ ). See **Table 1** for details.

### Comparison of instruments between the two groups

The results showed that the proportion of ordinary instruments was low. The proportion of both ordinary instruments and minimally invasive instruments didn't have significant change between the two cleaning phases ( $P > 0.05$ ). There was no significant difference in the instrument types of rigid containers in disinfection ( $P > 0.05$ ). See **Table 2** for details.

### Comparison of wet package rate and sterile barrier damage rate

The results showed that the wet package rate (12/978 vs. 2/898,  $P = 0.024$ ) and sterile barrier damage rate (14/978 vs. 3/898,  $P = 0.014$ ) in the observation group were significantly lower than those in the control group ( $P < 0.05$ ). This indicated that PDCA cycle could reduce the wet pack rate and sterile barrier damage rate in instrument disinfection. See **Figures 1** and **2** for details.

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**Table 3.** Comparison of quality control scores

Groups	Instrument management	Items management	Disinfection and isolation	Package quality
Control group	95.59±2.54	96.77±2.55	97.88±1.27	96.43±1.38
Observation group	92.85±2.06	91.93±1.96	94.43±3.15	91.78±1.57
t	25.524	45.797	31.571	68.257
P	0.000	0.000	0.000	0.000

**Table 4.** Satisfaction rate of clinical departments on instrument disinfection

Groups	Number of questionnaires	Very satisfied	Satisfied	Not satisfied	Satisfaction rate
Control group	60	25	25	10	50/60
Observation group	60	34	24	2	58/80
$\chi^2$			4.537		
P			0.033		

### Comparison of quality control scores

The results showed that the quality control scores of rigid containers after PDCA cycle application were higher than those before ( $P < 0.001$ ), which suggested that PDCA cycle could improve the quality control scores of rigid containers. See **Table 3** for details.

### Satisfaction rate of clinical departments on instrument disinfection

The results showed that the satisfaction rate score of the observation group was higher than that before the application ( $P < 0.05$ ). See **Table 4** for details.

### Discussion

The work of cleaning and disinfection of various precision instruments has been increasing on a daily basis. The cleaning and disinfection of precision and expensive minimally invasive instruments, has currently become an important part of work in the central sterile supply department. Meanwhile, the integrity of surgical instruments after disinfection directly affects the safety and efficiency of operation, and finally influences the surgical treatment effect of patients. A scientific and reasonable management method can reduce the damage package rate and prolong the service life of surgical instruments [19, 20]. In addition, the choice of sterilization packaging is related to potential contamination. Sterilization failure and repeat-

ed disinfection increase the consumption of resources. Compared with the previous sterilization package, the rigid container is much safer and more protective, so it has been widely favored in clinical departments. How to further improve the clinical effect of rigid containers is a current research hotspot [21].

The PDCA cycle, a method based on cycle management, gives feedback to workers and helps them analyze the principles of the management mode,

and it has achieved good results in nursing work [22]. In many disinfection centers, the application of rigid container combined with the PDCA cycle is an important measure to improve the effectiveness in disinfection. The wet package rate and the sterile barrier damage rate are important outcome measures for evaluating the quality of package disinfection. Once the package gets wet, it means that the instrument may be damaged due to contamination, so the instrument may be forbidden from use clinically. The results of this study showed that the wet package rate and the sterile barrier damage rate were significantly reduced after applying the PDCA cycle, which has a good exclusion system and can better prevent water drop formation. Besides, the hard texture of the rigid container can provide high-quality protection, facilitate stacking, keep surgical instruments sterile before use, and help reduce the sterile barrier damage rate. The results of our study were consistent with previous relevant research conclusions [23, 24].

Effective quality control is an important guarantee for high efficiency management. This study explored the correlation between PDCA cycle and quality control of rigid containers. It showed that the PDCA cycle could significantly improve the quality control score of rigid containers as a disinfection carrier, which attributes to its effective working principle. It can timely and effectively give feedback on the problems in work and help to take effective

measures to solve them. Previous studies have also proved this [24, 25].

Satisfaction rate of clinical departments, a standard for evaluating the department supply room, can effectively help to evaluate the combination efficiency of the PDCA cycle with rigid container disinfection. It has shown that using rigid containers combined with PDCA cycle could effectively improve the clinical satisfaction rate. It has the advantages of repeated use, easy cleaning, drying, packing and unpacking, cutting down the preparation time for operation and temporary instruments use. Besides, a rigid container plays a pivotal role in protecting the professional instruments from relevant departments, which can prevent instrument damage, improve the quality, increase the service life, and ultimately improve the satisfaction rate of clinical departments. Previous studies have also confirmed this [26].

In conclusion, the PDCA cycle can effectively improve the quality control scores of rigid containers as disinfection carrier, reduce the wet package rate and sterile barrier damage rate, and help to improve clinical satisfaction. It is worthy of wide use in disinfection rooms. However, this study was a single-center study with a small sample size, which needs to be further confirmed by studies with multi-centers and larger sample. Besides, more research is also needed to elaborate whether there are differences in disinfection efficacy of different materials of rigid containers.

### Disclosure of conflict of interest

None.

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