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Risk Assessment of Hydrogen Peroxide Low-Temperature Plasma Sterilization Using Different Monitoring Methods

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Abstract: *Objective:* This study aims to evaluate the application value of biological monitoring and different types of chemical indicator cards in batch monitoring of hydrogen peroxide low-temperature plasma sterilization. The goal is to standardize the selection of loading conditions for this sterilization method and avoid positive biological monitoring results. *Methods:* Physical monitoring, Class I chemical indicator card monitoring, Class IV chemical indicator card monitoring, and biological monitoring were used to monitor the hydrogen peroxide low-temperature plasma sterilization process. The sterilization effect on instruments inside the Johnson & Johnson 100S plasma sterilizer was monitored and the qualification of various monitoring methods was compared. *Results:* The comparison showed that when non-standard or adsorption-prone packaging materials were used, the interception rate of biological monitoring and Class IV chemical indicator cards was significantly higher than that of physical monitoring and Class I chemical indicator cards. These methods more intuitively and effectively detected sterilization failures. *Conclusion:* Biological monitoring and Class IV chemical indicator cards are safe, fast, accurate, and easy to interpret in hydrogen peroxide low-temperature plasma sterilization, especially for monitoring instruments inside packages. They provide a reliable basis for the release of sterilized instrument packages. Identifying the reasons for positive biological monitoring results in hydrogen peroxide low-temperature plasma sterilization and taking effective measures promptly can minimize associated risks.

Keywords: Hydrogen peroxide sterilization; Chemical monitoring; Biological monitoring

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1. Research background

With the development of medicine, minimally invasive surgery is widely carried out, and the number of medical devices that are not resistant to high temperature and humidity is increasing. Under normal operating conditions, the hydrogen peroxide plasma low-temperature sterilization system has a safe and reliable sterilization effect. It offers advantages such as a low sterilization temperature, fast sterilization speed, dry sterilized items, non-toxicity, environmental friendliness, no damage to instruments, and long storage life. Therefore, using a hydrogen peroxide low-temperature plasma sterilizer has become the best choice. Research has confirmed that

low-temperature sterilization is fast and efficient, and is mostly used for hard lumen medical devices that are not heat-resistant or moisture-resistant [1-3]. This technology is commonly used in clinical practice to sterilize luminal medical devices. However, due to the complex structure and narrow pipes of luminal instruments, low-temperature sterilization is prone to some package sterilization failures, resulting in incomplete disinfection and increasing the risk of hospital infection [4,5]. Therefore, monitoring the effectiveness of low-temperature sterilization is significant for ensuring the safety of device use.

There are many factors influencing low-temperature plasma gasification hydrogen peroxide sterilization [6,7]. Packaging materials, concentration of sterilizer, sterilization time, loading capacity, and instrument dryness may all cause low-temperature hydrogen peroxide plasma sterilization failure. Compared to pressure steam sterilization, one of the most significant differences is that the hydrogen peroxide low-temperature plasma sterilization process provides a fixed amount of sterilization agent for each cycle. In contrast, steam sterilization requires continuous provision of sterilization agents (steam) during the exposure phase to maintain the specified sterilization parameters and reach the sterilization temperature and pressure. Therefore, hydrogen peroxide sterilization has a higher risk compared to high-pressure high-temperature steam sterilization. Improper operation by the operator can easily lead to sterilization failure and affect the smooth progress of surgery. For example, if the operator places very little load in the hydrogen peroxide sterilization pot, or if the load exceeds the weight limit or contains incompatible materials, the hydrogen peroxide sterilizer can still only provide the same fixed amount of sterilization agent. Conversely, steam sterilization cycles may use steam to compensate for heavier and denser loads by using more sterilizing agents (steam). Each hydrogen peroxide cycle can be compared to an oven, with only one temperature set for each baking. The amount of loading directly affects the sterilization temperature of the equipment [8,9]. Additionally, the use of non-essential packaging materials also impacts the success of hydrogen peroxide sterilization.

In summary, different types of cycles, fixed sterilization doses, relatively unstable molecules, residual moisture, and the use of non-essential materials create a sensitive technological environment. In this environment, changes in the composition and weight of the load introduced by the user will greatly affect the results of the hydrogen peroxide sterilization process. Therefore, controlling the hydrogen peroxide sterilization process is very important. In current clinical operations, monitoring methods for low-temperature sterilization include physical monitoring, chemical monitoring, and biological monitoring to evaluate the sterilization effect of hydrogen peroxide low-temperature plasma [9,10].

In hydrogen peroxide plasma sterilization, the STORAD® 100S hydrogen peroxide low-temperature plasma sterilizer is frequently used, mainly for sterilizing endoscopes and precision instruments that are not resistant to high temperature and humidity. The sterilization effect is verified through three monitoring methods: physical, chemical, and biological. After sterilization, the sterilization effect of the item must be confirmed before use. If one of the items is unqualified, it is recommended to conduct emergency follow-up on the instrument and patient after surgery, and evaluate the sterilization results from different perspectives [11-15]. This study compares the sterilization monitoring effects of physical monitoring, Class I chemical indicator card monitoring, Class IV chemical indicator card monitoring, and biological monitoring. It also analyzes the sterilization monitoring effects of the four types of chemical indicator cards and biological monitoring in non-standard loading or packaging materials with adsorption, providing a theoretical basis for clinical analysis of positive sterilization monitoring.

2. Research objectives

According to the provisions of WS310.3-2016 “Hospital Disinfection Supply Center Part 3: Cleaning, Disinfection, and Sterilization Effect Monitoring Standards” for hydrogen peroxide low-temperature plasma

sterilization, the chemical monitoring method uses external chemical indicators outside each sterilization item package as a symbol of the sterilization process. Chemical indicators inside each package should be placed at the most challenging location for sterilization, and their color changes should be observed to determine whether they meet the sterilization qualification requirements. The biological monitoring method requires at least one sterilization cycle of biological monitoring during daily use, following the requirements of Appendix D [8]. Each hydrogen peroxide low-temperature plasma sterilizer in the hospital undergoes biological monitoring in the first sterilization cycle every day.

After thorough cleaning, disinfection, and drying of all items to be sterilized, a dedicated instrument box is used to load the rigid endoscope. Two disposable medical instruments are packaged in two layers of non-woven fabric, or in appropriately sized special hygiene strong packaging bags. Other small instruments are packaged in special hygiene strong packaging, and the items to be sterilized are placed in two layers on the loading rack to avoid touching the cabin walls and doors. The loading capacity of the items should not exceed 80% of the entire sterilization chamber volume [9].

Before sterilization, according to the manufacturer's instructions, place the rapid biological indicator naked on the sterilization tray and position it on the bottom shelf near the front of the sterilization chamber in the Johnson & Johnson 100S plasma sterilizer. After the bacterial cycle is completed, remove the biological indicator from the sterilizer and press the bottle cap completely until the ampoule bottle breaks. Shake quickly to ensure that the liquid flows into the growth pool and activates the biological indicator. Place the activated biological indicator in the selected reader culture well for cultivation, and read the results after cultivation.

This research aims to study the application of chemical and biological monitoring in the batch monitoring of hydrogen peroxide low-temperature plasma sterilization effects and to standardize the operation of hydrogen peroxide sterilization monitoring to avoid the impact of positive biological monitoring and recall [16,17]. Physical monitoring, Class I chemical indicator card monitoring, Class IV chemical indicator card monitoring, and biological monitoring are used in the monitoring of hydrogen peroxide low-temperature plasma sterilization. The sterilization effect of instruments inside the Johnson & Johnson 100S plasma sterilizer is monitored, comparing the sterilization qualifications of different monitoring methods to provide a reliable basis for the release of hydrogen peroxide low-temperature plasma sterilization packages.

3. Research methods

3.1. Factors affecting sterilization effectiveness

The hydrogen peroxide low-temperature plasma sterilizer (model 100S) from the Second Affiliated Hospital of Wenzhou Medical University, imported from abroad, was selected. The monitoring materials included Class I chemical indicator cards, Class IV chemical indicator cards, and rapid biological indicators for thermophilic fatty acid bacteria spores. A biological reader compatible with the biological indicator was also used. Packaging materials compatible with hydrogen peroxide gasification sterilization, such as sterilized paper plastic packaging bags, medical non-woven fabric packaging materials, and instrument boxes, were selected.

The four types of chemical indicator cards and one type of biological indicator were placed in the packaging equipment to be sterilized, with the biological indicator in a sealed packaging bag of Teweiqiang, positioned behind the lower shelf of the sterilizer. The selected sterilization cycle was a 100S sterilization cycle.

The effect of loading capacity on sterilization effectiveness was studied. Although there is no specified weight limit for the 100S sterilizer, the ASP sterilizer model 100NX specifies the load capacity for different cycles. Based on the maximum load capacity of 9.7 kg for the 100NX standard cycle (as detailed in the 100NX

sterilizer manual), the loading capacity of 100S sterilized items was divided into three different scenarios: approximately 60% (9.7 kg × 60%) of the maximum load capacity, approximately 80% (9.7 kg × 80%), and approximately 120% (9.7 kg × 120%). After sterilization, the results of the three different monitoring methods were judged and recorded.

The effect of adsorbed sterilized instruments on sterilization effectiveness was also studied. This included instruments without hydrogen peroxide adsorption, such as silicone pads without hydrogen peroxide adsorption in the instrument box, and instruments with adsorption properties, such as silicone pads below the instrument box, to simulate instruments with adsorption properties in the instrument box. Recent research has been conducted on the impact of adsorption properties on the sterilization effect of hydrogen peroxide.

3.2. Evaluation method for sterilization effect

After sterilization, according to the product instructions of different monitoring indicators, the sterilization results were evaluated using the three different monitoring methods mentioned above: physical monitoring, chemical monitoring, and biological monitoring. The evaluation results were divided into qualified and unqualified. The qualified standard for hydrogen peroxide type chemical indicator cards is that the color of the sterilization indicator strip changes from blue to light pink uniformly. The qualified standard for the four types of chemical indicator cards is that the color change block changes from blue to pink, and the pink enters the Accept range. The rapid biological indicator evaluation method considers a sterilization process qualified if the reader displays a negative result after reading for 24 minutes.

3.3. Statistical analysis

The evaluation results were organized and collected, non-conformance detection rates (number of non-conformance detection batches/total number of batches) of each evaluation method under different sterilization procedures and loading conditions were calculated, and the chi-squared test method was used to compare the differences in non-conformance detection rates of different evaluation methods under different sterilization procedures and loading conditions. The inspection level was set at $\alpha = 0.05$.

4. Research results

(1) Evaluation of sterilization effects of non-standard loaded instruments using different monitoring methods: During the experimental process, a total of 15 cycles of hydrogen peroxide low-temperature plasma sterilization were carried out. Of these, 5 cycles were performed with a maximum load capacity of about 60%, another 5 cycles with a maximum load capacity of 80%, and 5 cycles with a maximum load capacity of 120%.

(2) Evaluation of sterilization effectiveness of instruments with adsorption properties using different monitoring methods: During the experiment, a total of 10 cycles of hydrogen peroxide low-temperature plasma sterilization were conducted, including 5 cycles with instruments without hydrogen peroxide adsorption and 5 cycles with instruments featuring silica gel adsorption in the instrument box.

4.1. Evaluation of sterilization effects of different monitoring methods on different loading capacities

After the instruments were completely dried, they were sterilized using an ASP 100s low-temperature plasma sterilizer with loading capacities of about 60%, 80%, and 120%, respectively. A total of 30 sterilization cycles

were performed, with 10 cycles for each loading method. The results showed that when the loading capacity was around 60%, all three methods produced qualified monitoring results. When the loading capacity was around 80%, the four types of chemical indicator cards for hydrogen peroxide showed positive results in monitoring. When the loading capacity was above 120%, all sterilization monitoring methods showed positive results, except for the Class I chemical indicator card sterilization monitoring, which showed negative results. Refer to **Table 1** for the monitoring results of plasma sterilization effects with different loading capacities.

Table 1. Monitoring effects of plasma sterilization with different loading amounts

Monitoring methods	Loading capacity					
	60% loading		80% loading		120% loading	
	Unqualified batch	Positive rate (%)	Unqualified batch	Positive rate (%)	Unqualified batch	Positive rate (%)
Physical monitoring	0	0	0	0	0	0
Class I card	0	0.00	0	0	0	0
Four types of cards	0	0.00	5	50	6	60
Biological indicator	0	0.00	6	60	8	80

Note: n = 15 batches

4.2. Evaluation of sterilization effects of different monitoring methods on silicone pad adsorption materials

After the instruments were completely dried, they were sterilized using an ASP100s low-temperature plasma sterilizer. An evaluation of the sterilization effect of different monitoring methods on sterilized instruments was conducted. During the experiment, a total of 10 cycles of hydrogen peroxide low-temperature plasma sterilization were carried out, including 5 cycles with instruments without hydrogen peroxide adsorption. All three different types of sterilization monitoring methods produced qualified results. The sterilization instrument box with silicone pad adsorption showed positive results in two sterilization monitoring methods, except for one sterilization chemical indicator card that showed negative results in sterilization monitoring. Refer to **Table 2** for details on the impact of silicone pads on the sterilization effect monitoring results in the instrument box.

Table 2. Influence of silicone pads in the instrument box on the monitoring results of sterilization effectiveness

Monitoring methods	Sterilization instrument box without silicone pad adsorption		Instrument box with silicone pad adsorption	
	Unqualified batch	Positive rate (%)	Unqualified batch	Positive rate (%)
Physical monitoring	0	0	0	0
Class I card	0	0.00	0	0
Four types of cards	0	0.00	4	80
Biological indicator	0	0.00	5	100

5. Conclusion

The evaluation of the sterilization effect of hydrogen peroxide low-temperature plasma involves three types of monitoring: physical, chemical, and biological. In chemical monitoring, according to the requirements of ISO 11140-1:2014, the hydrogen peroxide low-temperature plasma Type I chemical indicator card only represents

the sterilization process and is not used as a definitive sterilization standard. However, the four types of chemical indicator cards can simultaneously monitor temperature, concentration, and sterilization time, better reflecting the actual sterilization effect inside the package.

Biological monitoring can indicate the actual sterilization effect of the entire sterilization chamber, but it should be noted that the concentration of hydrogen peroxide inside the package is lower than the actual concentration within the chamber. Therefore, using biological monitoring alongside the four types of hydrogen peroxide cards provides enhanced protection for low-temperature sterilization monitoring.

In summary, biological monitoring and Class IV chemical indicator sterilization monitoring produce more reliable results and better represent the actual sterilization effect compared to Class I chemical indicator cards. These methods can promptly reflect the sterilization status of clinical items, intercept unqualified items, and play a significant role in controlling hospital infections and reducing recall risks.

Disclosure statement

The authors declare no conflict of interest.

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