

Survey and analysis of the status of performance testing of pressure steam sterilizers

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[Abstract] Objective: To understand the current status of performance testing of pressure steam sterilizers under the new National CSSD Standards and to provide basis for further implementation of standards and testing the performance of pressure steam sterilizers. **Method:** With the support of Yunnan Institute of Measuring and Testing Technology, the temperature and pressure detector was used in the evaluation of the performance of pressure steam sterilizers according to the requirements of GB 8599-2008 and the test results were then analyzed statistically. **Results:** A total of 42 sterilizers in 14 medical institutions were tested for small loads and full loads. The pass rate of small load and full load test were only 11.90% and 42.86%, respectively, and the cumulative pass rate was only 27.38%. **Conclusion:** The low pass rate of the pressure steam sterilizers under the new standard indicated that the quality of sterilization cannot be ensured and there is a high safety risk that could potentially exist in pressure steam sterilizers. Medical institutions at all levels should keep high alert to the potential high risk involved in the sterilization processes, It should highly recommend a strictly routine test the performance of pressure steam sterilizers accordance with the standard requirements, minimize the safety risks in a timely manner, and provide basic assurance for the effective supply of sterile articles in hospitals.

[key words] pressure steam sterilizer; performance test; sterilization effect

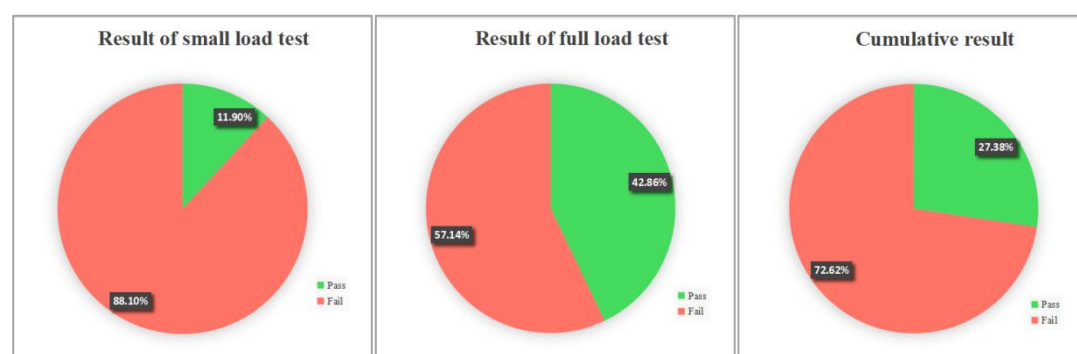
With the change of medical model and extensive research of hospital infection control, the Central Sterile Supply Department(CSSD) becomes the important source of infection control in hospitals. The level of sterilization of medical devices directly impacts on the quality of medical care, and the safety and rehabilitation of patients. Pressure steam sterilization is the preferred choice of sterilization method for preventing and controlling the occurrence of nosocomial infections. It has also the most widely used, most economical, and most reliable sterilization method in CSSDs. In order to achieve the further reduction of the hospital infections and the risks of multiplexed medical devices, as well as ensuring the absolute properties of sterile articles, it is important to put forward more rigorous and precise requirements for the performance testing of sterilizers in the final sterilization process. Correct monitoring and strict quality control management are the key factors for successful sterilization of medical products such as medical devices that are highly susceptible to risks, and should be the focus of hospital infection management. The quality monitoring methods of pressure steam sterilization include physical, chemical, and biological monitoring. Physical monitoring is the only monitoring method for sterilization process. It mainly reflects the state of the sterilizer, whether the key data meet the design or this sterilization setting requirements, is the most basic sterilization quality monitoring, can timely understand the operation of each link of the sterilizer and whether it is in the normal working range. In order to understand the current situation of using temperature and pressure detector to monitor temperature, pressure, time and other parameters of pressure steam sterilizer, this investigation and research is carried out.

1 Materials and methods

Random survey found that 14 medical institutions are interested in the project and are willing to cooperate with the test. With the support and help of metrological testing technical department, the physical properties of 42 pressure steam sterilizers in the above 14 medical institutions were tested by using temperature and pressure detector.

2 Results

The performance of 42 sterilizers in 14 medical institutions was tested by a temperature and pressure detector. Each sterilizer was tested for a small load and a full load, for a total of 84 cycles. Among them, the pass rate of small load test is only 11.90%, while the pass rate of full load test is 42.86%. The cumulative pass rate is only 27.38%.



3 Conclusion

The qualified rate of the physical properties of the pressure steam sterilizer is low, and the sterilization quality is not guaranteed effectively, and there are great safety hazards. At present, the physical monitoring of the pressure steam sterilizer mainly depends on the built-in physical parameters of the sterilizer self-test. But the physical parameters of the self-test can only indicate the temperature change of the sterilizer cavity, and cannot objectively reflect the actual parameter inside the sterilization package. The temperature and pressure detector uses high-sensitivity sensor equipment, which avoids many traditional detection problems and collects the information on temperature and pressure data real-time. It can not only accurately verify and record the entire sterilization process and detect parameter anomalies in timely fashion, but also effectively provide comprehensive analysis and determination of a sterilization process. It can show sterilizer real-time operation status and in-package sterilization process more accurately and intuitively, which is convenient for discovering the safety risks of the sterilizer and repair the sterilizer with the fail test timely, if necessary. And it can provide a basic assurance for the safe and effective supply of sterile items in hospitals.

4 Summary

In order to further strengthen hospital infection management and ensure the quality of medical care and patient safety, all medical institutions should strengthen sterilization technology training and increase in the awareness of disinfection and sterilization of the whole personnel, and clarify the importance and necessity of sterilizer performance testing. Strictly in accordance with the requirements of relevant national standards and combined with local actual conditions, we should develop a regular monitoring program suitable for pressure steam sterilizers of the region^[9]. By verifying the performance of each component of the sterilizer, the engineer will be notified of the problem in time who enforce the compliance of the standard requirements and ensure the sterilization quality of the instruments, utensils and articles, in order to achieve objectives of the prevention and control of hospital infections.