APPLICATION OF A TEMPERATURE AND PRESSURE DETECTOR TO THE PREVENTIVE MAINTENANCE OF HOSPITAL AUTOCLAVES

by

Lina DING[a], Zhuoya YAO[a*], Manchun LI[a], Junhui GENG[a], Meng ZHAN[a], Junfeng WANG[a], Yue YIN[a], and Yu ZHANG[b*]

[a] Henan Provincial People's Hospital, Zhengzhou University People's Hospital, Henan Provincial Medical Key Laboratory for Quality Control of Medical Devices Sterilization Zhengzhou, Henan, China
[b] Institute of Hospital Administration, National Health Commission

Original scientific paper
https://doi.org/10.2298/TSCI2403201D

Pressure steam sterilization is the preferred sterilization method for damp-heat resistant medical devices. This study aims to reveal the risk of sterilization failure by using temperature and pressure detectors to detect changes in the performance of the sterilizer. Six autoclaves in a general hospital were selected as the research objects, and the key sterilization parameters such as sterilization temperature, sterilization time, sterilization pressure, and equilibration time were verified, and the performance of the sterilizer was evaluated. This paper provides a new way to monitor the sterilization process and to detect hidden dangers.

Key words: *autoclave, sterilization parameters, preventive maintenance, temperature and pressure detector, quality and safety*

Introduction

Pressure steam sterilization has many advantages in fast sterilization speed, strong penetration, high safety and reliability, friendly environmental protection and low cost, and it is the preferred sterilization method for damp-heat resistant medical devices [1]. There are many factors that affect the reliability of autoclaves, such as the performance of the sterilizer, the technical level of the operator, steam quality, water quality, instrument structure, *etc.* The installation of the equipment is complicated, and there are many potential safety hazards which must be detected timely. Therefore, how to ensure the sterilization reliability of the autoclave is an intractable problem in practical applications, and it has also become an important topic to reduce the risk of hospital infection prevention and control. It has been reported that hospital autoclaves are commonly used after their out-of-service, and lack of preventive maintenance always results in poor sterilization quality [2, 3]. With the increase of service time, the sterilizer is gradually aging. When the fault is not exposed timely, the sterilizer operator often can not predict the performance change of the equipment in advance, which leads to major hidden dangers in sterilization safety [4]. Preventive maintenance can ensure the normal operation of autoclaves, improve its use efficiency and prolong its service life, which is of great significance to ensure the quality and safety of sterilization and the safety of

* Corresponding authors, e-mail: yao2709@126.com, a191897@163.com

equipment use. The Asia Pacific Society of Infection Control (APSIC) [5] requires that preventive maintenance should be carried out according to the instructions of the equipment manufacturer. Fast *et al.* [6] found that the frequent use of the autoclave could easily lead to the failure of key components. In addition, the operators might not have adequate disinfection and sterilization knowledge, and the autoclave might not be tested and maintained effectively. At present, some hospitals have established the maintenance system for autoclaves, but it is aimed at the maintenance after the failure, which has obvious lag. The temperature and pressure detector has high sensitivity and can monitor key parameters such as sterilization temperature, sterilization pressure and sterilization simultaneously [7], but its role in preventive maintenance is rarely studied, and a mathematical model using genetic programming [8] is much needed in future. In this study, the temperature and pressure detector is applied to the preventive maintenance of autoclaves, and to explore the actual sterilization parameters, so as to provide a reference for improving the maintenance system of pressure steam sterilization.

Materials and methods

In this study, we select six pulsating vacuum pressure steam sterilizers (MST-9618HS2) with a volume of 1.5 m^3, which have been used for eight years and the average daily working time exceeds eight hours, two temperature and pressure detectors (Big Dipper). The whole device has seven temperature probes and one pressure probe, and each temperature probe is also connected with a slender wire with length of 1.2 m, and the equipment is equipped with a data intelligent analysis system. The accuracy of the temperature and pressure detector is ±0.05 ℃, temperature resolution is 0.001 ℃, temperature range is from –60 ℃ to 150 ℃, and pressure accuracy is ±1.0 kPa. The pressure resolution was 0.001 kPa, the pressure measurement range is 0~700 kPa. The standard test package is folded into a package with sizes of 220 mm × 300 mm × 250 mm, the total weight of the package is 7 kg ±0.14 g. The standard test package meets the requirements of the GB 8599 standard. The standard test package is removed from the sterilizer after the test cycle and cooled in a room environment with temperature of 20-30 ℃ and relative humidity of 40-60%. If the weight of 250 mm thick standard test bag exceeds 7.14 kg, it cannot be used any more. After daily use, the standard test package should be cleaned in time to facilitate steam penetration and avoid affecting the test results.

Follow the WS 310.2-2016 standard to prepare the autoclave before sterilization, and the experiment process meets the requirements of health industry standards.

The performance of the sterilizer is tested by using the temperature and pressure detectors, and their distribution is in accordance with small load temperature test and full load temperature test according to the GB 8599-2008 standard. Following is the detectors distribution: No. 5 sensor is placed near the exhaust port, No. 1-No. 6 temperature sensors are placed in the bleached pure cotton cloth package of 30 cm × 25 cm × 25 cm, No. 1 temperature sensor is placed in a lower place of the package, No. 2-No. 4 temperature sensors are placed in the center, and No. 6 temperature sensor is placed in the upper place, see fig. 1. The positions of No. 1-6 sensors in full-load verification and small-load verification are the same, but the positions of No. 7 temperature sensors are different. The small-load temperature sensor No. 7 is placed at 50 mm above the vertical center of the test package, as shown in fig. 1(a). During the full-load verification test, the No. 7 temperature sensor should be placed under the first layer of cotton cloth in the test package, as shown in fig. 1(b). Put the standard test package in the exhaust port of the autoclave, select the corresponding sterilization procedure, and monitor the sterilization temperature, sterilization pressure, and sterilization time throughout the

process. After sterilization, the monitoring data are automatically obtained, and after comprehensive interpretation of the measured data, a test report combining data list and curve tables are generated. The range of sterilization parameters is evaluated according to the technical requirements of the GB 8599 standard. According to the WS 310.3-2016 standard, the sterilizer is monitored physically, chemically and biologically.

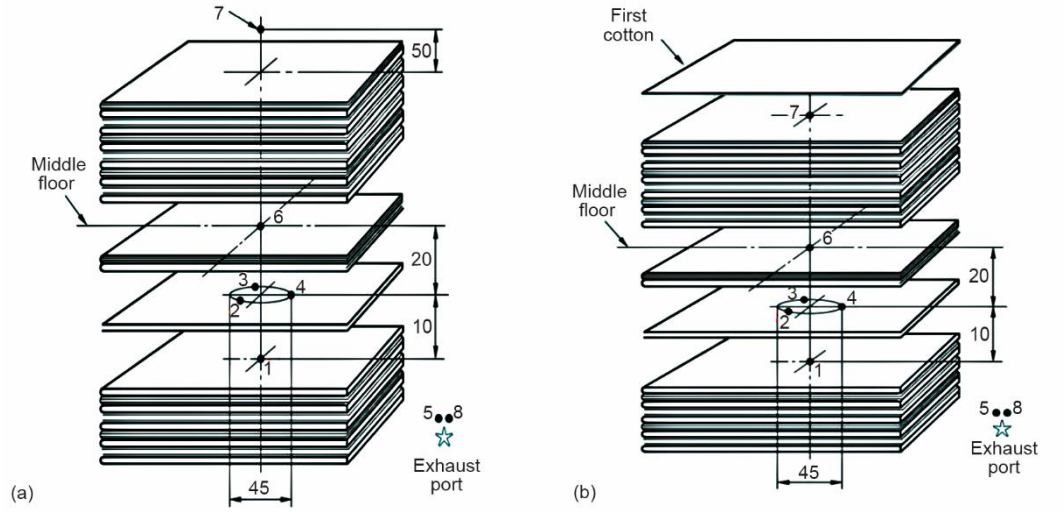

Figure 1. Schematic diagram of load distribution of temperature and pressure detector sensor; (a) small load and (b) full load

The sterilization temperature is set at 134 ℃, the upper limit does not exceed 137 ℃, and the sterilization time is set at 300 seconds. The sterilization and maintenance time of 134 ℃ should be 3 minutes. The reference range of the sterilization pressure is 201.7-229.3 kPa. The equilibration time in the small load temperature test shall require a sterilizer larger than 800 L, and the equilibration time shall not exceed 30 seconds.

The experimenters have been professionally trained to understand the parameter settings of different procedures of the pressure steam sterilizer, and can independently conduct the placement test and read and save the results. In order to ensure the accuracy of the data, the results are treated by two people and two computers.

Statistical analysis is performed using SPSS 26.0, counting data are expressed by case number and percentage, $\chi 2$ test is used for comparison between groups, and $P < 0.05$ is considered as statistically significant.

Results

Monitoring of physical parameters under different loading conditions

A total of 74 times of parameter monitoring were carried out for the preventive maintenance of the autoclave. Among them, there were 29 small load temperature tests, six of which passed the physical parameter, and the qualified rate was 20.69%. There were 45 full load temperature tests, 24 of which passed the physical parameter, and the qualified rate was 53.33%. Under the condition of full load, the qualified rate of physical parameters of sterilizer is relatively high ($\chi 2 = 7.796$, $P < 0.05$), see tab. 1.

Table 1. Comparison of physical parameters monitoring of sterilizer for preventive maintenance

Project	Qualified	Unqualified/disqualification	Percent of qualified	$\chi 2$ value	*P*
Small load	6	23	20.69%	7.796	0.005
Full load	24	21	53.33%		

Monitoring of physical parameters for preventive maintenance

During 74 times of preventive maintenance of autoclave, there were 44 unqualified physical parameters. The unqualified physical parameters mainly included six situations: prolonged equilibration time, insufficient sterilization time, minimum sterilization temperature below the lower limit, maximum sterilization temperature above the upper limit, and sterilization pressure above the upper limit. Among them, the qualified rates are relatively low in equilibration time extension, the minimum sterilization temperature being below the lower limit and the sterilization pressure being below the upper limit, which are 40.54%, 66.22% and 90.54%, respectively. See tab. 2 for the results.

Table 2. Monitoring of physical parameters of pressure steam sterilizer for preventive maintenance

Test item	Qualified times	Unqualified times	Percent of qualified
Equilibration time extension	30	44	40.54%
Insufficient sterilization time	73	1	98.65%
The minimum sterilization temperature is below the lower limit	49	25	66.22%
The maximum sterilization temperature is higher than the upper limit	73	1	98.65%
Sterilization pressure is below the upper limit	67	7	90.54%

Analysis of preventive maintenance process of No. 3 autoclave

During the preventive maintenance of No. 3 autoclave, it was found that the minimum sterilization temperature varied from 133.70~133.90 ℃, not 134.0 ℃, but the sterilizer showed that the sterilization temperature was still 134 ℃. The equilibration time varied from 30-145 seconds, and the sterilizer did not give an alarm, see fig. 2 for the sterilization operation diagram. After three days of continuous operation, it is found that the vacuum pump was damaged, which was then replaced. After replacement, the test still showed that the sterilization temperature was still unqualified, see fig. 3. We contacted the manufacturer's engineer again for maintenance, and found that the temperature sensor was abnormal. After calibrating the temperature sensor, the test continued, and the sterilization parameters became qualified, see fig. 4. The test results are shown in tab. 3.

From June 2021 to December 2022, the monthly average number of faults of the sterilizer was reduced from the original 4.5 times to 2 times, and the number of faults was significantly reduced, and the sterilizer could basically run safely and stably.

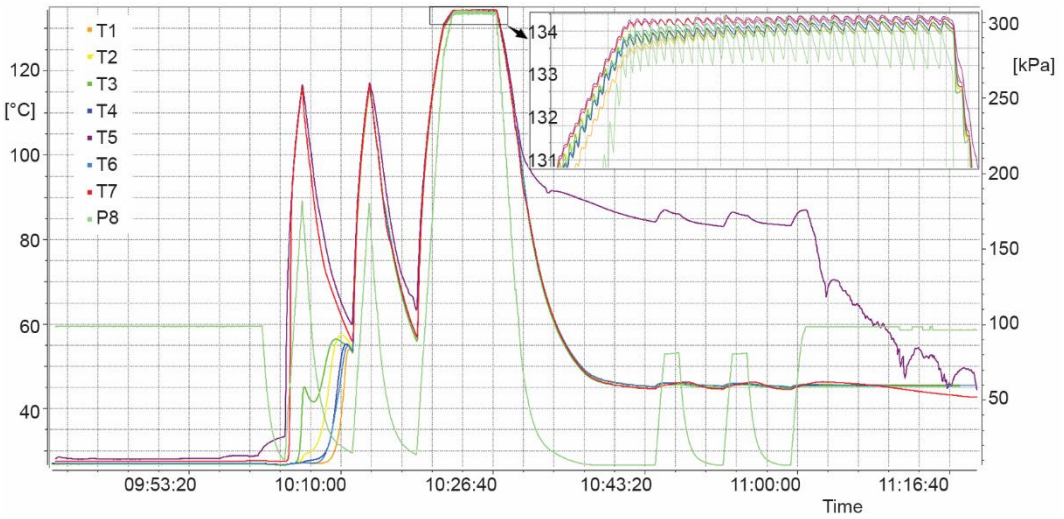

Figure 2. Sterilization operation diagram before maintenance

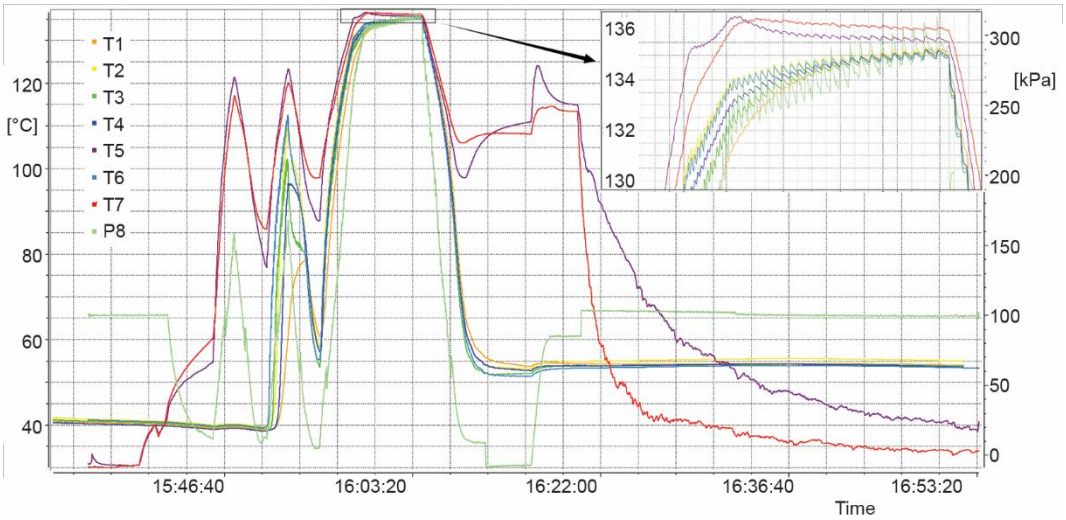

Figure 3. Sterilization operation diagram after replacing vacuum pump

Discussion

Preventive maintenance refers to the inspection, maintenance and necessary debugging of the equipment, which is a necessary means to ensure the normal operation of the equipment and the qualified sterilization quality of medical instruments [9-11]. The physical parameters of the sterilizer are not only the basis to ensure the qualified sterilization effect, but also the key indicators of the performance of the sterilizer itself. *National Health and Family Planning Commission of People's Republic of China* (WS 310.3-2016) clearly requires that parameters such as sterilization temperature, pressure, and time should be monitored with a temperature and pressure detector every year, and the detector probe should be placed in the most difficult sterilization position.

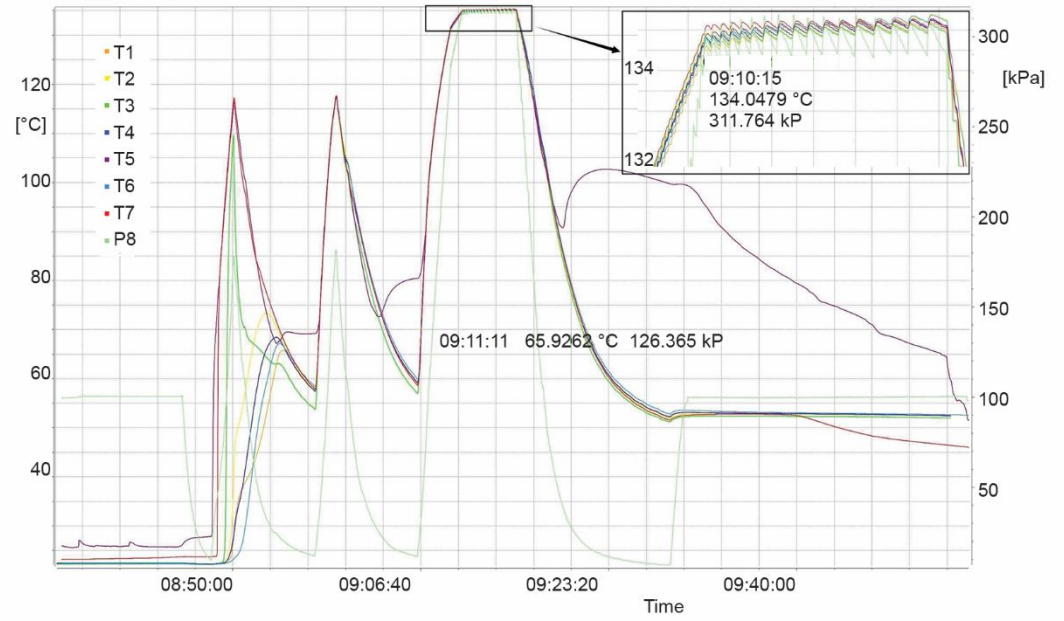

Figure 4. Normal sterilization operation diagram of autoclave

Chen *et al.* [3] found that according to the investigation in Guangdong Province, 84.86% of CSSD hospitals did not use temperature and pressure detectors to monitor the performance of autoclave regularly. It was reported that most of the CSSD autoclaves in domestic hospitals were overloaded, and faults occurred from time to time, which affected the normal development of medical work [12]. Therefore, preventive maintenance of autoclave should be implemented to ensure the quality and safety of autoclave. The results of this study show that the qualified rate of small load test is 20.69%, and the qualified rate of full load test is 53.33%. The qualified rate of full load test is higher than that of small load test, and the difference between them is significant ($\chi^2 = 7.796$, $P < 0.05$). The reason is that when the sterilized articles are covered with the cavity, there is no space for the cold air masses, which minimizes the influence of cold air masses on the temperature in the sterilization chamber, so the qualified rate of full load is high. During the small load test, there is excessive cold air in the cavity, and the temperature probe of the temperature and pressure detector is placed in the standard test package. When the steam penetration ability decreases and there is residual non-condensing gas in the standard test package, the parameters such as sterilization temperature and sterilization time in the standard test package will be unqualified, revealing the risk of sterilization failure.

Through analyzing the physical parameters of the 74 times preventive maintenance monitoring of autoclaves, there are mainly problems such as prolonged sterilization equilibration time, insufficient sterilization maintenance time, and the minimum sterilization temperature lower than the set temperature, and there are potential safety hazards of sterilization failure. The experimental results of Meng *et al.* [4] showed that during the full load dressing, the actual test temperature of the sterilizer used for eight years is lower than that of the sterilizer used for one year, and its average deviation from the setting temperature is 3.10%. The unqualified parameters may be related to the aging of some sterilizers, which is close to the deadline of the performance of some sterilizers, resulting in the decline of the sterilizer perfor-

Table 3. Monitoring results of physical parameters of No. 3 autoclave for preventive maintenance

Detection opportunity	Detection type	Maximum temperature [°C]	Minimum temperature [°C]	Equilibration time [second]	Maintenance time [second]	Mean pressure [kPa]	Three major monitoring
Preventive maintenance	Full load	135.50	133.80	125.00	210.00	303.0	qualified
	Small load	135.00	133.70	104.0	219.00	301.0	qualified
	Full load	135.20	133.70	49.00	272.00	302.0	qualified
	Small load	134.85	133.71	145.00	210.00	297.35	qualified
	Full load	134.90	133.90	24.00	285.00	304.00	qualified
	Small load	134.60	133.70	127.00	180.00	304.00	qualified
	Full load	136.93	133.85	30.90	284.00	302.13	qualified
	Small load	134.59	133.72	71.00	230.00	305.96	qualified
	Full load	134.93	133.77	105.00	212.00	301.24	qualified
	Small load	135.79	133.71	118.00	256.00	301.29	qualified
	Full load	135.27	133.80	86.00	247.00	304.45	qualified
	Small load	134.55	133.71	122.00	190.00	305.28	qualified
	Full load	134.40	133.79	76.00	226.00	301.45	qualified
	Small load	134.93	133.77	138.00	199.00	300.06	qualified
Detection after overhaul (Replace vacuum pump)	Full load	134.45	133.81	92.00	199.00	306.27	qualified
	Small load	134.56	133.79	20.00	188.00	306.38	qualified
	Full load	134.45	133.79	137.00	153.00	305.82	qualified
	Small load	134.69	133.77	158.00	162.00	305.34	qualified
Detection after calibrating the temperature sensor	Full load	134.48	134.82	26.00	191.00	305.82	qualified
	Small load	134.69	134.77	24.00	187.00	305.34	qualified

Note: The sterilization temperature is set at 134 °C, the upper limit does not exceed the sterilization temperature +3 °C, the equilibration time is ≤ 30 seconds, and the reference range of sterilization pressure is 201.7-229.3 kPa.

mance. According to the investigation in hospitals of low- and middle-income countries, none of most-used autoclaves reached acceptable physical parameters, and all autoclaves had been used for over 16 years, with an average working life of 25.3 years, which are lack of preventive maintenance and performance testing [13]. The CSSD managers should focus on sterilizers with long service life (>5 years) and heavy workload, strengthen their preventive maintenance, and find out the existing problems in time, so as to avoid major failures. When the autoclave reaches the service life recommended by the equipment manufacturer, it should be scrapped. If it is to continue to use, it should be reported to the special equipment inspection and testing institution for inspection, and the performance of no major defects can be used, otherwise there will be double safety risks of pressure vessel accident and unqualified sterilization.

When all the three routine monitoring are qualified, the monitoring results of temperature and pressure detector are unqualified, and there are potential safety hazards in sterilization quality. According to the thorough analysis of No. 3 autoclave, it can be known that the test result of temperature and pressure detector was unqualified before the sterilizer broke down. The sterilizer gave an alarm to indicate that the vacuum pump was damaged. The vacuum pump is used to pump out cold air, steam, and condensed water from the cabin during exhausting. The autoclave is overloaded for a long time, and the sterilizer is close to the scrap use period, resulting in the performance of the vacuum pump, unable to fully withdraw non-condensable gas, resulting in the decline of steam penetration capacity. After replacing the vacuum pump, the monitoring results of the temperature and pressure detector are still unqualified, while the routine monitoring results are qualified. We contacted the equipment engineer to find the reason again. After calibrating the temperature sensing probe of the sterilizer, the monitoring results of the temperature and pressure detector is qualified. But in the routine of practical work, such problems cannot be found. It can be seen that the daily physical monitoring is not consistent with the actual sterilization parameters in the package. The temperature probe of the sterilizer is directly exposed to the pipeline, which can only indicate the temperature change of the sterilizer cavity, and cannot objectively reflect the actual parameters inside the sterilized package. He *et al.* [14] pointed out that by simulating the leakage fault of pulsating vacuum steam sterilizer in the heating stage, it is also found that the traditional three monitoring methods can not find the risk of sterilization failure in time, and the risk of sterilization failure increases obviously with the increase of the proportion of non-condensed gas or the extension of air leakage time. Wu *et al.* [15] proposed that after a new installation, displacement and overhaul are insufficient and problems cannot be found in time, and the sterilizer should be tested by temperature and pressure detector. Therefore, temperature and pressure detector detection should be included in the preventive maintenance and overhaul routine testing of autoclaves, and the detection items and frequency should be defined to strengthen the standard management of autoclaves.

Preventive maintenance includes daily maintenance and periodic maintenance, which is not only low in cost, but also will not affect the continuous function of equipment and reduce the economic losses caused by major faults of sterilizers. It takes an average of five working days to solve the problems in the sterilization cycle of autoclave. After the equipment breaks down, it needs to be overhauled or replaced on a large scale, which takes a long time and seriously affects the normal medical work. Through the temperature and pressure detector, the performance change of sterilizer can be found early, and preventive maintenance can be carried out in time. The average monthly failure rate of the sterilizer is reduced from 4.5 times to 2 times, which greatly reduces the downtime and economic cost. Van Wezel *et al.* [16] proposed that the current preventive maintenance of sterilizer is based on time, and the change of sterilizer performance is not considered. What is worth considering in the future is whether preventive maintenance should be based on the process of events to respond to the changing trend of key performance indicators of equipment. In order to reduce the occurrence of unexpected faults, Musagil *et al.* [17] established an algorithm to predict the sterilization performance change of small pressure steam based on the vacuum pump and steam generator to accurately evaluate the performance change of the sterilizer. Sudden temperature changes or heat-shock response during operation should be also considered in the prediction [18, 19]. With the wide applications of evidence-based medicine, the safety early warning model of autoclave can be established based on sterilization parameters, and the scientific maintenance scheme can be constructed according to the working years of sterilization equipment, and pas-

sive failure maintenance can be changed into active preventive maintenance, so as to ensure the quality and safety of pressure steam sterilization and the use safety of autoclaves.

Conclusion

The application of a temperature and pressure detector to preventive maintenance of autoclaves can monitor the key parameters in the operation process of autoclave in real time, ensure the accuracy and effectiveness of the sterilization process, predict the sterilization performance of the autoclave prospectively, avoid the disadvantages of routine three monitoring, and intervene as early as possible to effectively reduce the risk of sterilization failure, ensure the optimal operating condition of autoclaves, so as to further improve the quality control system of pressure steam sterilization, prevent and control hospital infection from the source, and improve the quality and safety level of sterilization.

References

[1] Panta, G., *et al.*, Effectiveness of Steam Sterilization of Reusable Medical Devices in Primary and Secondary Care Public Hospitals in Nepal and Factors Associated with Ineffective Sterilization: A Nation-Wide Cross-Sectional Study, *Plos One*, *14* (2019), 11, pp. 1-14
[2] Cuncannon, A., *et al.*, Sterile Processing in Low- and Middle-Income Countries: An Integrative Review, *Journal of Infection Prevention*, *22* (2021), 1, pp. 28-38
[3] Chen, A. Q., *et al*., Investigation on Current Situation of Steam Sterilizer Monitoring of Part Health Institutions in Guangdong Province (in Chinese), *Chinese Journal of Disinfection*, *35* (2018), 2, pp. 102-104
[4] Meng, X. Y., *et al*., Monitoring and Analysis of Quality Control Indexes of Pressure Steam Sterilizer (in Chinese), *Chinese Medical Equipment*, *14* (2017), 3, pp. 46-48
[5] Ling, M. L., *et al*., APSIC Guidelines for Disinfection and Sterilization of Instruments in health Care Facilities, *Antimicrob Resist Infect Control*, *7* (2018), Feb. Article No. 25
[6] Fast, O., *et al*., Limited Sterile Processing Capabilities for Safe Surgery in Low-Income and Middle-Income Countries: Experience in the Republic of Congo, Madagascar and Benin, *BMJ Global Health*, *2* (2017), Suppl, 4, e000428
[7] Puttaiah, R., *et al.*, A Preliminary Evaluation of a Reusable Digital Sterilization Indicator Prototype, *The Journal of Contemporary Dental Practice*, *15* (2014), 5, pp. 626-635
[8] Madic, M., *et al.*, Mathematical Modelling of the CO_2 Laser Cutting Process Using Genetic Programming, *Facta Universitatis-Series Mechanical Engineering*, *20* (2022), 3, pp. 665-676
[9] Chen, Z. X., *et al*., Analysis of the Necessity of Preventive Maintenance of Autoclaved Steam Sterilizer (in Chinese), *Chinese Medical Device Information*, *25* (2019), 16, pp. 166-167
[10] Basu, D., Reason Behind Wet Pack After Steam Sterilization and Its Consequences: An Overview from Central Sterile Supply Department of a Cancer Center in Eastern India, *Journal of Infection and Public Health*, *10* (2017), 2, pp. 235-239
[11] Rajic, M., *et al*., Experimental and Numerical Stress and Strain Analysis of the Boiler Reversing Chamber Tube Plate, *Thermal Science*, *26* (2022), 3A, pp. 2135-2145
[12] Panta, G., *et al*., Effectiveness of Autoclaving in Sterilizing Reusable Medical Devices in Healthcare Facilities, *Journal of Infection in Developing Countries*, *13* (2019), 10, pp. 858-864
[13] O'Hara, N. N., *et al.*, Sterile Reprocessing of Surgical Instruments in Low- and Middle-Income Countries: A Multicenter Pilot Study, *American Journal of Infection Control*, *43* (2015), 11, pp. 1197-2000
[14] He, H. Y., *et al*., Risk Study by Fault Simulation of Entering Air at Heating-up Stage in Pulsating Vacuum Autoclave (in Chinese), *Chinese Journal of Nosocomial Infection*, *29* (2019), 24, pp. 3830-3835
[15] Wu, J. W., *et al*., Application of Sterilization Parameter Detection in the New Installation, Displacement and Major Repair of Sterilizers (in Chinese), *Chinese Journal of Infection Control*, *18* (2019), 7, pp. 680-683
[16] van Wezel, R. A. C., *et al*., Following Trends in Steam Sterilizer Performance by Quantitative Monitoring of Non-Condensable Gases, *Journal of Hospital Infection*, *97* (2017), 4, pp. 1-6
[17] Musagil, M., *et al*., Classification Model for Predictive Maintenance of Small Steam Sterilisers, *IET Collaborative Intelligent Manufacturing*, *2* (2020), 1, pp. 1-13

[18] Liu, F. J., *et al.*, Thermal Oscillation Arising in a Heat Shock of a Porous Hierarchy and Its Application, *Facta Universitatis Series: Mechanical Engineering*, *20* (2022), 3, pp. 633-645
[19] Lindquist, S., The Heat-Shock Response, *Annual Review of Biochemistry*, *55* (1986), pp. 1151-1191

Paper submitted: February 26, 2023
Paper revised: May 17, 2023
Paper accepted: May 18, 2023