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Original Research Article

Comparison of the Performance Test of Reusable Patient Circuit and Disposable Patient Circuit of Ventilator

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ABSTRACT

Two kinds of ventilator patient circuits are used widely in clinical routine, namely, reusable patient circuits and disposable patient circuits. Is their performance the same in clinical application? Comparison of the performance test of these two kinds of ventilator circuits with a ventilator gas flow analyzer is given in this paper. Thirty ventilators were randomly selected to test their performance with these two types of circuits. Then, the paired t-test method was used to analyze whether the difference in performance test between the two circuits was significant. For respiratory rate, tidal volume, and end airway pressure, there were no significant differences between these two circuits ($p > 0.05$). For the airway peak pressure, the reusable patient circuit was significantly higher than the disposable patient circuit ($p < 0.05$), but the actual value of the difference was very small, only about 0.2 mbar, which did not have any significant clinical meaning. Therefore, in the experimental environment, there is no difference in performance test results between disposable circuits and reusable circuits.

Keywords—*Ventilator, Reusable patient circuit, Disposable patient circuit, Performance test.*

INTRODUCTION

Medical ventilator is the most common clinical first aid and life support equipment that can replace, control, or change human respiration, increase lung ventilation, improve respiratory function, and reduce the consumption of respiratory function. It can provide respiratory support for patients with respiratory failure and play an important role in clinical treatment. Medical ventilator is also a clinical high-risk medical equipment. According to years of monitoring and analysis by the State Food and Drug Administration and the US FDA, ventilators belong to the high-risk category of medical equipment.[1] So it is necessary to arrange at least one ventilator quality control test every year.

The complete ventilator system includes five parts: air source, air oxygen mixer, main engine, humidifier, and respiratory circuit.[2] For respiratory circuits, two kinds of patient circuits are used widely in clinical routine, namely, reusable patient circuits and disposable patient circuits. The reusable patient circuit is a reusable silicone thread pipe, and the disposable patient circuit is a PVC material thread pipe. The reusable silicone circuit, after a long time of repeated disinfection, will be subjected to aging, air leakage, damage, and other problems; also, repeated use is more likely to cause cross-infection among patients. The disposable patient circuit features lightweight, sufficient length, a transparent tube body, resistance to kinking, and a well-sealed cup. Therefore, clinical preference is to use the disposable patient circuit. Although the disposable patient circuit has advantages in economy, safety, health, and other aspects, its material is inferior to the reusable patient circuit, including thickness, elasticity, etc. Thus, is it feasible to apply it in clinical settings for evaluating whether two circuits provide consistent ventilator performance and comparable clinical therapeutic outcomes. At present, there is a lot of research literature on the influence of the disposable patient circuit on clinical therapeutic effect, while there is almost no research literature on the influence of ventilator performance. This paper evaluates whether reusable patient circuit and disposable patient circuit provide the same ventilator performance.

MATERIALS AND METHODS

Quality Control Tools and Contents

The air flow analyzer (VT 650, Fluke Biomedical, America) is used in our hospital for ventilator quality control, which can detect a variety of airflow parameters, including tidal volume, respiratory rate, oxygen absorption concentration, airway peak pressure, end airway pressure, and other indicators. The analyzer itself is qualified and within the validity period.

Thirty ventilators were randomly selected, including Evita 4 (Draegerwerk AG & Co. KGaA, Germany) and Maquet Servo-i (Getinge, Sweden). For quality control of the 30 pediatric ventilators (configured for children weighing 15–30 kg), a new reusable patient circuit and a disposable patient circuit (both suitable for this weight range) were used, respectively, with quality control data recorded.[3–7] The quality control of a ventilator refers to Calibration Specification for Ventilator (JJF 1234-2018)[8], including tidal volume, respiratory rate, airway peak pressure, airway end pressure, oxygen concentration, and various alarms.

Paired *t*-test

The t-test includes single-sample, independent-sample, and paired-sample. Single-sample refers to one sample, independent-sample refers to two groups of samples that have no correlation, and paired-sample refers to two samples that are associated according to a certain parameter. In this paper, the reusable patient circuit and disposable patient circuit of the same ventilator were compared, that is, they were paired according to the ventilator and belonged to the paired sample.[9–11]

The paired *t*-test is essentially a single-sample *t*-test. First, the difference is calculated according to the pairing, and then the difference is *t*-tested. That is, for each ventilator, quality control results of the reusable patient circuit are subtracted from quality control results of the disposable patient circuit to obtain the pairing difference X_n, as shown in Formula (1), where $n = 1, 2, 3\ldots$ represents ventilator number, R represents quality control parameters, including tidal volume, peak airway pressure, end airway pressure, respiratory rate, etc.

$$X_n = R_{reusable\ circuti} - R_{disposable\ circuit} \quad (1)$$

Then, calculate the mean value $\bar{X}$ and the sample standard deviation s of the paired difference, as shown in Formulas (2) and (3). Formulas (2) and (3) are substituted into Formula (4) to construct the *t* statistic. $\bar{X}$ refers to mean of paired differences, *s* refers to the sample standard deviation of paired differences, *t* refers to the t-statistic, and *n* refers to the number of paired samples.

$$\bar{X} = \frac{1}{n}\sum_{i=1}^{n} X_i \quad (2)$$

$$S^2 = \frac{1}{n-1}\sum_{i=1}^{n}(X_i - \bar{X})^2 \quad (3)$$

$$t = \frac{\bar{X} - 0}{\frac{s}{\sqrt{n}}} \sim t(n-1) \quad (4)$$

Finally, look up the table to obtain the P-value and calculate the confidence interval NCI of the pairing difference, as shown in Formula (5). $p < 0.05$ indicates a significant difference, and the confidence interval of paired difference is above or below the 0 scale line, where above the 0 scale line indicates that the reusable patient circuit is significantly higher than the disposable patient circuit, whereas below the 0 scale line indicates that it is significantly lower. $p > 0.05$ means that the difference is not significant, that is, there is no difference between the reusable patient circuit and the disposable circuit, and the confidence interval of the paired difference crosses the 0 scale line and has no significant positive or negative direction.

$$N_{CI} = \bar{X} \pm 2.12\frac{s}{\sqrt{n}} \quad (5)$$

Research on Quality Control Results

Thirty ventilators were randomly selected, and quality control tests were conducted on each ventilator using the reusable patient circuit and the disposable patient circuit, respectively, and quality control data were recorded. The alarms in the quality control data are qualitative indicators, and their performance is basically consistent between the two circuits. Thus, they will not be discussed in detail below. The respiratory rate is exactly the same as the ventilator setting, which will not be discussed in detail. Oxygen concentration is not discussed in detail, considering the failure of oxygen batteries in some ventilators. The remaining tidal volume, peak airway pressure, and end airway pressure are analyzed in detail below.

Tidal Volume

Under the conditions of VCV (Volume-Controlled Ventilation) mode and f = 30 times/min, *I:E* = 1:1.5, PEEP = 2 mbar (Positive End-Expiratory Pressure), and FiO_2 = 40% (oxygen concentration), two kinds of circuits were used to test the calibration points of tidal volume such as 50 mL, 100 mL, 150 mL, 200 mL, and 300 mL, respectively. The *t*-test results are shown in Figure 1. For tidal volume ranging from 200 mL to 300 mL, the confidence interval of the paired difference all cross the 0 scale line, indicating that the use of the reusable patient circuit and the disposable patient circuit has no difference. For the tidal volume = 50 mL, 100 mL, and 150 mL, the confidence interval of paired difference is above the 0 scale line, that is, the test value of the reusable patient circuit is significantly 1–2 mL higher than that of the disposable patient circuit, accounting for 2%–3%, which is within the required range of the tidal volume error. In other words, although there is a significant difference between the two circuits, the difference is very small and does not affect the quality control conclusion.

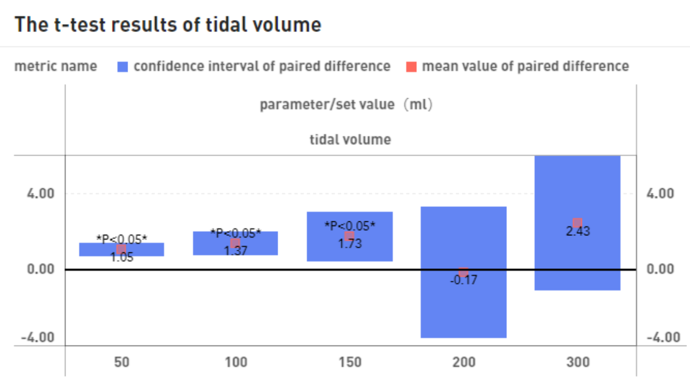

FIGURE1. The t-test results of tidal volume (mL).

Peak Airway Pressure

Under the conditions of PCV mode and f = 15 times/min, *I:E* = 1:2, PEEP = 0 mbar, and FiO_2 = 40%, two kinds of circuits were used to test the calibration points of airway peak pressure such as 10 mbar, 15 mbar, 20 mbar, 25 mbar, and 30 mbar, respectively. The *t*-test results are shown in Figure 2. The confidence interval of the paired difference is above the 0 scale line, that is, the airway peak pressure of the reusable patient circuit is significantly higher than that of the disposable patient circuit, which indicates that the sealing performance of the reusable patient circuit is better than that of the disposable patient circuit. Zheng Kun's paper also has a similar research description.[12] They found that the reusable silicone threaded circuit is made of silicone, featuring a thick tube wall, slow heat dissipation, excellent thermal insulation performance, and good compliance. The material of the disposable PVC circuit is PVC, which has a thin pipe wall, fast heat dissipation, poor thermal insulation performance, and poor compliance. The peak airway pressure measured by the reusable patient circuit is about 0.2 mbar higher on average than that of the disposable patient circuit, accounting for 1%–2%. The difference is very small, that is, although there is a significant difference between the two kinds of circuits, the difference is small and does not affect the quality control dimension.

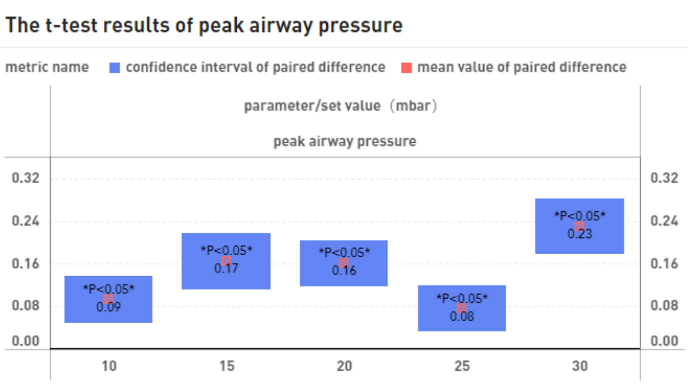

FIGURE 2. The *t*-test results of peak airway pressure (mbar).

End Airway Pressure

Under the conditions of the VCV mode and VT = 400 mL, f = 15 times/min, $I:E$ = 1:2, and FiO_2 = 40%, two kinds of circuits were used to test the end airway pressure calibration points, such as 2 mbar, 5 mbar, 10 mbar, 15 mbar, and 20 mbar, respectively. The *t*-test results are shown in Figure 3. The confidence interval of the paired difference is across the 0 scale line, that is, there is no statistically significant difference in the end airway pressure measured by the reusable patient circuit and the disposable circuit. And, the average difference in the measured end-airway pressure between the two circuits is about 0.02 mbar, which is very small.

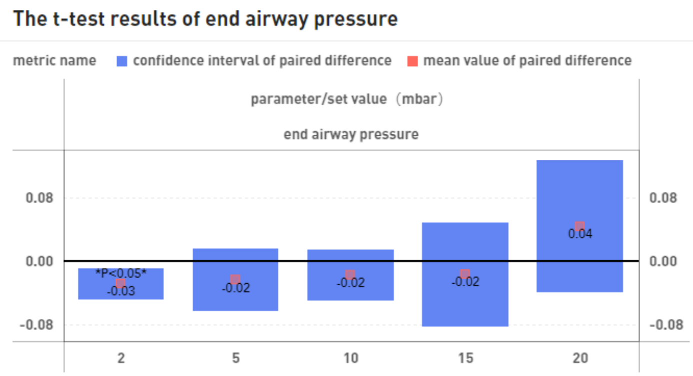

FIGURE 3. The *t*-test results of the end airway pressure (mbar).

DISCUSSION

This study found that the reusable patient circuit and the disposable patient circuit do not affect the quality control results. For respiratory rate, tidal volume, and end airway pressure, there were no statistically significant differences between the two kinds of circuits ($p > 0.05$). For airway peak pressure, the reusable patient circuit was significantly higher than the disposable patient circuit ($p < 0.05$), but the difference was very small, only about 0.2 mbar, accounting for 1%–2%, within the error range, which did not affect the quality control results.

Yang Qiuyue et al.[13] found that the treatment effect of the disposable patient circuit of a noninvasive ventilator was significantly better than that of the reusable patient circuit and could significantly reduce the nursing workload, which was reflected in the number of calls to the nursing staff, the amount of humidification fluid used, and the number of suction times of the disposable patient circuit group being significantly lower than that of the reusable patient circuit group. Xiao Chunlian et al.[14] found that the disposable circuit system could reduce the workload of the ventilator circuit care, reduce the viscosity of airway sputum, and reduce the incidence of ventilator-related pneumonia, which is worthy of widespread clinical application.

The disposable circuit has fine heating wires built inside, which communicate with the temperature control module of the humidifier through a dedicated interface to achieve real-time temperature compensation. Reusable circuits have no built-in heating wires, or their interfaces are not compatible with the temperature control systems of mainstream humidifiers. Repeated disinfection may damage the electronic components. Therefore, they cannot participate in the dynamic regulation of humidity. The heaters utilize disposable heated wire circuits to provide 100% humidity and rainout prevention. Rainout in a circuit can be a major cause of desaturation in a patient when the excess water in a circuit is inadvertently dumped down the ET tube (Endotracheal Tube) and aspirated by the patient. This can cause adverse effects to the patient.

According to our studies and those of our peers, the disposable circuit provides the same ventilator performance as the reusable patient circuit, with advantages in the clinical treatment effect. These results show that the disposable circuit can be used in clinical practice. Obviously, we simulate the response of the membrane lung to two kinds of circuits, which has some limitations. In complex cases, especially in young infants, further evaluation is needed to better realize the compliance of the circuits to the function of the relevant ventilation pattern, especially the tidal volume compensation. The advantages of the disposable circuit in clinical treatment effect also need to be verified by subsequent multidimensional analysis, especially for the study of the clinical treatment effect in children.

SUMMARY

This study found that the reusable patient circuit and the disposable patient circuit do not affect ventilator quality control results, that is, two kinds of ventilator patient circuits provide the same ventilator performance. Combined with the peer's research on the therapeutic effect of two kinds of ventilator patient circuits, the disposable circuit can be used in clinical practice.

AUTHOR CONTRIBUTIONS

Conceptualization, L.B. and S.W.X.; Methodology, L.B and S.W. X; Software, L.B. and S.W.X.; Hardware, L.B. and S.W.X.; Validation, L.B.; Formal Analysis, L. B.; Investigation, L.B.; Resources, Y.M.S and K.Z.; Data Curation, L.B.; Writing–Original Draft Preparation, L. B.; Writing–Review & Editing, L.B.; Visualization, L.B.; Supervision, Y.M.S. and K. Z.; Project Administration, L.B.; Funding Acquisition, Y.M.S and K.Z.

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Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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