Effect of Mask Selection on the Leak Test in Ventilators Designed for Noninvasive Ventilation

Wei Tan, Hai-Jia Hou, Chang-Ling Lu, Bing Dai, Hong-Wen Zhao, Wei Wang, and Jian Kang

BACKGROUND: The mask leak test used for modern noninvasive ventilators can detect the leak characteristics of masks that are not recommended by the manufacturer, but it has not yet been determined whether this method is acceptable. METHODS: A noninvasive ventilator equipped with a single-limb circuit and an oronasal mask was connected to a lung simulator. The ventilator was set to S/T mode, and inspiratory positive airway pressure/expiratory positive airway pressure was set to 10/5, 15/5, and 20/5 cm H_2O, respectively. Eight nonmanufacturer-recommended oronasal masks were connected to the ventilator. The lung simulator was used to simulate COPD, restrictive disease, and normal lung, respectively. When switching between masks, the mask leak test was set to "Cancel" or "Start Test" in the noninvasive ventilator. The parameters displayed on the lung simulator and ventilator were recorded before and after the mask leak test. RESULTS: There were no significant difference before versus after the mask leak test for any lung simulator parameter, including trigger performance (ie, time from the beginning of the simulated inspiratory effort to the lowest value of airway pressure needed to trigger the ventilator, the magnitude of airway pressure drop needed to trigger, and time to trigger), inspiratory pressure delivery, PEEP, tidal volume, and displayed peak inspiratory pressure (all differences < 10%). At different noninvasive ventilation settings, tidal volumes displayed on the ventilator of the 3 masks were significantly different before and after mask leak test (all $P < .05$, and difference rate > 10%). CONCLUSIONS: The mask leak test had no effect on the ventilator performance when masks not recommended by the manufacturer were used, but tidal volume monitoring may be more accurate when some masks were used. *Key words:* noninvasive ventilation*; mask leak test; interface; noninvasive monitoring; tidal volume; trigger*. [Respir Care 2022;67(5):572–578. © 2022 Daedalus Enterprises]

Introduction

Noninvasive ventilation (NIV) is the administration of mechanical ventilation without using an artificial airway. It is an effective therapy for the treatment of acute and chronic respiratory failure, reducing the need for endotracheal intubation, shortening hospital stays, and decreasing mortality rates.[1-5] Different types of interfaces can be selected during NIV, including oronasal mask, nasal mask, total face mask, nose pillow, and helmet, among which the oronasal mask is most commonly used.[6,7] Most noninvasive ventilators employ single-limb breathing circuits with a passive leak port, which is located on the breathing circuit or the mask.[8] Most manufacturers have incorporated the mask and leak port into an all-in-one design (vented mask), and many different styles and models of masks are available to meet patients' needs.[9]

However, there are considerable differences in the inner volume, leakage, and leak port location of different masks.[10,11] Manufacturers often recommend using their own masks. It has been found that when using masks not recommended by the manufacturer during NIV intentional leak varies, resulting in patient-ventilator asynchrony and

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inaccurate ventilator monitoring.[12,13] The majority of manufacturers of noninvasive ventilators do not recommend using masks from other manufacturers.[14] However, due to shifting availability and other reasons, medical staff often use masks that are not recommended for use with a given ventilator during clinical NIV.

To avoid the influence of masks not recommended by the manufacturer on ventilator performance and to correctly estimate leakage and tidal volume, a noninvasive ventilator was designed to conduct a mask leak test that allows the ventilator to determine the intentional leak characteristics of the leak port of these masks and optimize the monitoring and performance of the ventilator. However, whether the mask leak test produces acceptable results in this context has not been established. Therefore, this study explored the influence of the mask leak test on ventilator performance where these masks were used under different NIV settings and lung models in vitro.

QUICK LOOK

Current knowledge

To avoid the influence of noninvasive ventilation masks not recommended by the manufacturer on ventilator performance and correctly estimate the leakage and tidal volume, a modern noninvasive ventilator is designed to conduct mask leak tests. It remains to be determined whether a ventilator mask leak test will be valuable for the use of these masks.

What this paper contributes to our knowledge

The mask leak test did not have an effect on the ventilator performance in the use of masks not recommended by the manufacturer. However, the test did make tidal volume monitoring more accurate when some masks were used.

Methods

Experimental Methods

The active lung simulator (ASL 5000, IngMar Medical, Pittsburgh, Pennsylvania) is a high-fidelity respiratory simulator equipped with a computer-controlled piston that moves inside the chamber. It can simulate respiratory movements for patients with lung disorders. The following lung-simulation parameters were set in this study:[15-17] The maximum inspiratory pressure drop was set to −8 cm H_2O to simulate the profile of the negative pressure created by the respiratory muscles; 5% of the respiratory cycle time was set to an active inspiration, 3% as an end-inspiratory hold, and 15% as the return of the pressure to baseline, and the breathing rate was set at 20 breaths/min. With settings adapted from previous studies,[15-19] 3 combinations of compliance and resistance were used to simulate restrictive, obstructive, and normal lung conditions: COPD: compliance = 60 mL/cm H_2O, inspiratory resistance = 10 cm H_2O/L/s, and expiratory resistance = 15 cm H_2O/L/s; restrictive disease: compliance = 30 mL/cm H_2O, inspiratory and expiratory resistance = 10 cm H_2O/L/s; and the normal lung model: compliance = 60 mL/cm H_2O, inspiratory and expiratory resistance = 10 cm H_2O/L/s.

The noninvasive ventilator (Respironics V60, Philips, Amsterdam, the Netherlands) was set to S/T mode with a backup breathing rate of 4 breaths/min and a pressure-rise slope of 1. The inspiratory positive airway pressure and expiratory positive airway pressure were set to 10/5, 15/5, and 20/5 cm H_2O.

Eight medium-size oronasal masks (A–H) were selected from different manufacturers (excluding the recommended oronasal mask from Philips Respironics). The leak ports were located in the mask, including the over nasal bridge, on the elbow, or distal to the elbow(Fig. 1).

The noninvasive ventilator was connected to the head model, and the single-limb breathing circuit was blocked by a plug behind the head model. To measure mask intentional leak, a gas analyzer (VT PLUS, Fluke Biomedical, Solon, Ohio) was connected to the breathing circuit to measure the intentional leak of test masks in CPAP mode at different pressure levels (4, 12, and 20 cm H_2O). The length of the breathing circuit (312107, Philips Respironics) was approximately 2.4 m. The mask was fixed on the head model to avoid an unintentional leak, and plasticine was placed between the mask and the head model (Fig. 1A).

During switching between masks, the mask leak test was set to "Cancel" or "Start Test" in the noninvasive ventilator. If the mask leak test was started (after test), the noninvasive ventilator was connected to the head model, and the breathing circuit was completely blocked by a plug behind the head model (Fig. 1B). Subsequently, the breathing circuit was unblocked and connected to the lung simulator for NIV (Fig. 1C). If the mask leak test was canceled (before test), NIV was directly performed.

Data Acquisition and Statistical Analyses

When the noninvasive ventilator ran for more than 3 min, the following ventilator parameters were recorded for 10 consecutive respiratory cycles (Fig. 2): T_{trig} = time to trigger, ms; TP_{min} = time from the beginning of the lung simulator's inspiratory effort to the lowest value of airway pressure needed to trigger the ventilator; P_{trig} = magnitude of airway pressure drop needed to trigger; inspiratory rising time $T_{90\%}$ = time to achieve 90% of the inspiratory target during inspiration, ms; inspiratory time; peak inspiratory

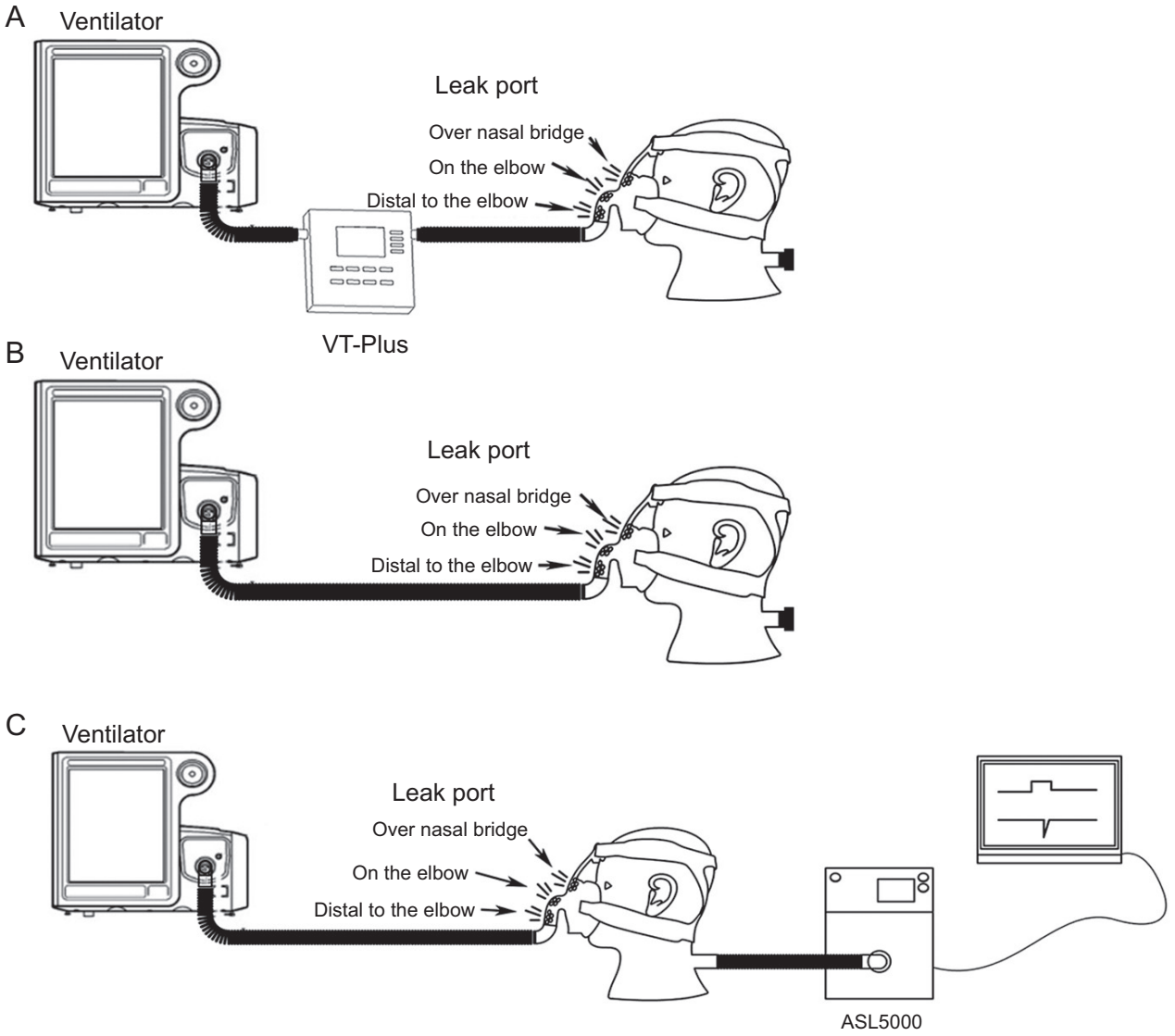

Fig. 1. Illustration of the experiment. A: Measuring the intentional leak of the test masks. B: Beginning the mask leak test. C: Noninvasive ventilation simulation.

pressure; peak inspiratory flow; mean inspiratory flow; actual tidal volume = tidal volume displayed on the lung simulator; monitored peak inspiratory pressure/tidal volume = peak inspiratory pressure/tidal volume displayed on the ventilator; auto-triggering and ineffective triggering were also recorded.

Data were analyzed using GraphPad Prism (GraphPad Software, San Diego, California). All data are expressed as means ± SD. The difference between the lung simulator parameters before and after the mask leak test was calculated as follows: difference rate = (before mask leak test − after mask leak test)/after mask leak test. A paired *t* test was used to compare the difference before and after the mask leak test. One-way analysis of variance was used to compare the differences in parameters before and after the mask leak test, whereas Mann-Whitney test was used to compare the intentional leak of those masks that had significant differences before and after the mask leak test with the remaining masks. When the difference rate was > 10% and statistically significant difference ($P < .05$), the change was considered clinically important.[15]

Results

The 8 oronasal masks were different from each other in terms of leaks and positions of the leak port. The leak ports of masks A–C, D–F, and G–H were located on the elbow, over the nasal bridge, and distal to the elbow, respectively. The comparison of leaks between masks showed a linear correlation with CPAP pressure ($P = .031$, r = 0.99)

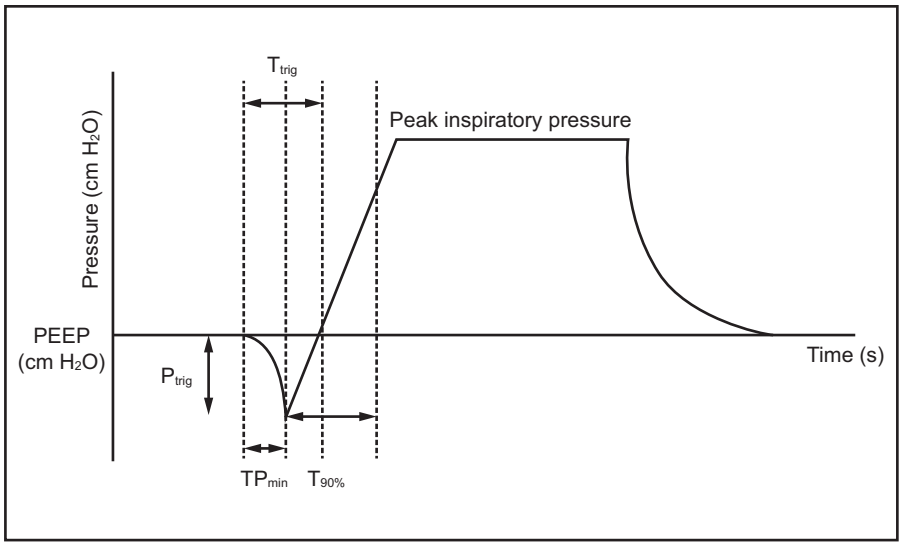

Fig. 2. Graphic explanation of the variables. TP_{min} = time from the beginning of the lung simulator's inspiratory effort to the lowest value of airway pressure needed to trigger the ventilator. P_{trig} = magnitude of airway pressure drop needed to trigger. T_{trig} = time to trigger.

described by the equation y = 1.86x + 12.54 (R^2 = .99) (Table 1).

No auto-triggering or ineffective triggering was observed during NIV for any oronasal mask. In addition, no significant differences in any lung simulator parameters were detected before and after the mask leak test, including in trigger performance (T_{trig}, TP_{min}, P_{trig}), inspiratory pressure delivery (inspiratory rising time $T_{90\%}$, inspiratory time, peak inspiratory pressure, peak inspiratory flow, or mean inspiratory flow), PEEP, and tidal volume (tidal volume displayed on the lung simulator) (all $P > .05$ and difference rate $< 10\%$) (Table 2).

Before and after mask leak test, no significant differences in monitoring peak inspiratory pressure were detected (all $P > .05$ and difference rate $< 10\%$), but significant differences in monitoring tidal volume were detected in 3 masks (A, C, and H) under different NIV settings and lung models (all $P < .05$ and difference rate $> 10\%$; Fig. 3). A comparison between these 3 masks and the other 5 revealed a significant difference in the intentional leak (CPAP 4 cm H_2O: 16 ± 1 L/min vs 21 ± 3 L/min, $P < .0001$; CPAP 12 cm H_2O: 33 ± 3 L/min vs 39 ± 2 L/min, $P < .0001$; CPAP 20 cm H_2O: 46 ± 6 L/min vs 51 ± 4 L/min, $P = .042$).

Significant differences in the tidal volume were not detected for all the test masks between the ventilator and the lung simulator ($P = .29$ and difference rate $< 10\%$).

Discussion

We investigated the effects of mask leak test on ventilator performance in vitro. Under different NIV settings and simulated lung mechanics, we used masks not recommended by the manufacturer with different leak and leak port locations. Our results showed that the mask leak test had no effect on lung simulator parameters (including trigger performance, controlling performance, PEEP, and tidal volume) or monitoring peak inspiratory pressure. However, when some masks not recommended by the manufacturer

Table 1. General Characteristics of the Eight Oronasal Masks

Test Mask	Model	Manufacturer	Leak Port Location	Leak1, L/Min	Leak2, L/Min	Leak3, L/Min
A	Skynecor	Tianhui (Jiangsu, China)	On the elbow	16 ± 1	30 ± 1	41 ± 1
B	Full face series	ResMed (San Diego, California)	On the elbow	21 ± 1	41 ± 1	50 ± 2
C	JOYCE Full Face	Weinmann (Hamburg, Germany)	On the elbow	16 ± 1	36 ± 1	533 ± 1
D	FreeMotion 2	Fisher & Paykel (Auckland, New Zealand)	Over nasal bridge	19 ± 1	38 ± 1	47 ± 2
E	Mirage Quattro	ResMed (San Diego, California)	Over nasal bridge	20 ± 1	37 ± 1	49 ± 2
F	BestFit II	Curative Medical (Santa Clara, California)	Over nasal bridge	18 ± 0	40 ± 1	55 ± 0
G	FreeMotion 1	Fisher & Paykel (Auckland, New Zealand)	Distal to the elbow	26 ± 1	38 ± 1	48 ± 1
H	BestFit I	Curative Medical (Santa Clara, California)	Distal to the elbow	16 ± 0	33 ± 1	45 ± 1

1CPAP 4 cm H_2O; 2CPAP 12 cm H_2O; 3CPAP 20 cm H_2O.

Table 2. Difference Rates in Lung Simulator Parameters Before and After Mask Leak Test

Oronasal Mask	T_{trig}	TP_{min}	P_{trig}	Inspiratory Rising Time $T_{90\%}$	Inspiratory Time	Peak Inspiratory Pressure	Peak Inspiratory Flow	Mean Inspiratory Flow	PEEP	Actual Tidal Volume
A	−5.9 ± 8.0	−3.2 ± 11.1	−4.2 ± 3.9	−2.9 ± 7.9	2.8 ± 3.9	−0.8 ± 2.4	3.3 ± 8.2	1.8 ± 8.5	−2.0 ± 2.5	1.5 ± 2.3
B	1.5 ± 2.9	0.6 ± 1.7	0.6 ± 3.3	0.2 ± 2.1	−0.2 ± 1.2	−0.2 ± 0.5	−0.7 ± 1.5	2.3 ± 1.4	1.4 ± 1.6	−0.2 ± 0.5
C	5.8 ± 9.5	2.6 ± 5.9	−1.7 ± 4.5	9.0 ± 5.3	8.1 ± 5.7	0.3 ± 0.4	−7.0 ± 4.7	1.6 ± 0.7	1.0 ± 1.0	0.6 ± 1.5
D	−1.0 ± 7.2	−0.8 ± 4.6	2.8 ± 3.7	−2.1 ± 3.8	−1.9 ± 1.6	−0.1 ± 0.8	3.6 ± 3.5	−2.1 ± 1.1	−1.7 ± 1.4	0.3 ± 0.9
E	1.9 ± 2.8	−0.3 ± 2.0	−0.6 ± 2.9	2.5 ± 1.9	2.3 ± 2.3	0.2 ± 0.4	−1.8 ± 1.5	−1.2 ± 1.2	−2.1 ± 1.1	0.4 ± 0.6
F	6.0 ± 12.3	4.2 ± 11.1	0.5 ± 2.7	3.3 ± 7.8	2.3 ± 1.8	0.8 ± 0.8	−3.4 ± 3.6	2.7 ± 3.7	4.6 ± 5.9	0.4 ± 2.3
G	−2.5 ± 5.7	−1.0 ± 2.5	−1.6 ± 5.9	0.9 ± 3.3	1.8 ± 2.4	0 ± 0.4	−1.5 ± 2.1	−1.6 ± 0.8	−0.8 ± 1.0	0.3 ± 0.6
H	2.3 ± 5.4	2.0 ± 4.5	−2.6 ± 6.4	5.6 ± 5.4	7.8 ± 5.6	−0.1 ± 1.1	−5.7 ± 5.1	−1.0 ± 1.2	−1.4 ± 1.3	1.6 ± 1.3

Data are expressed as %.
T_{trig} = time to trigger
TP_{min} = time from the beginning of the lung simulator's inspiratory effort to the lowest value of airway pressure needed to trigger the ventilator
P_{trig} = magnitude of airway pressure drop needed to trigger A = Skynecor; B = Full face series; C = JOYCE Full Face; D = FreeMotion 2; E = Mirage Quattro; F = BestFit II; G = FreeMotion 1; H = BestFit I.

were used, the mask leak test made the monitoring of tidal volume more accurate.

Clinicians often mix masks from different manufacturers during NIV. However, different masks can affect ventilator performance and monitoring.[12] To avoid the influence of ventilator performance and correctly estimate the leak and tidal volume, modern noninvasive ventilators are designed to conduct a mask leak test using any interface. The ventilator

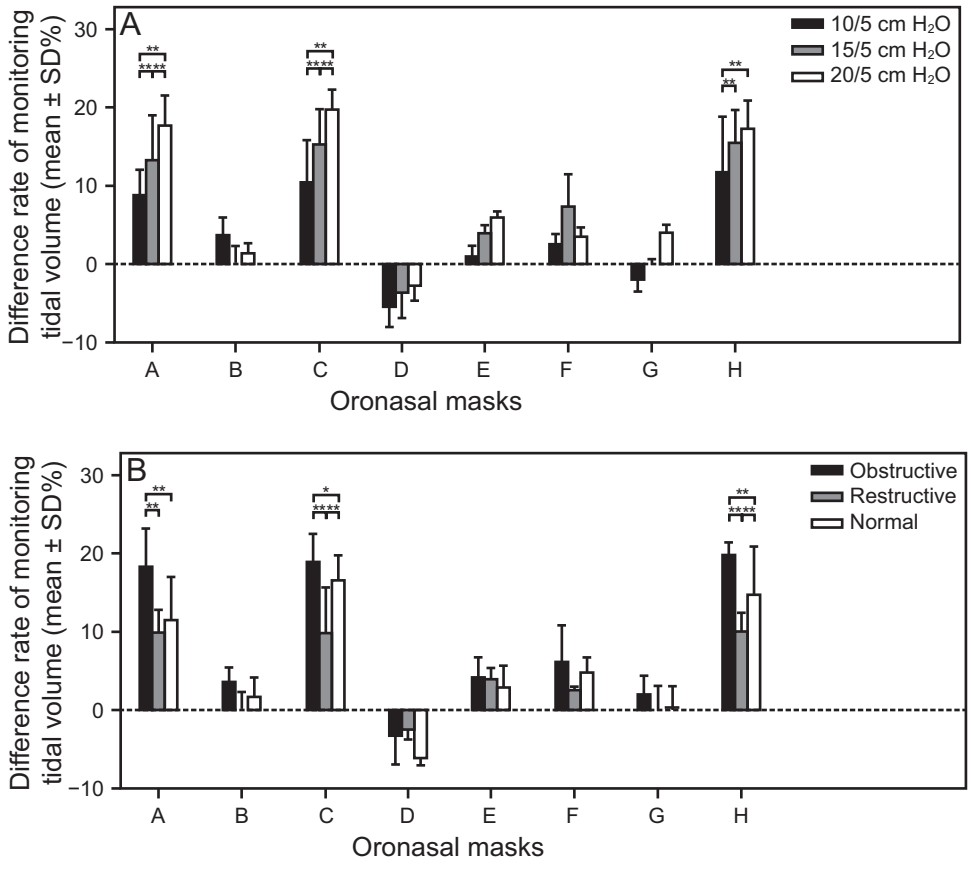

Fig. 3. Comparison of monitoring tidal volume with oronasal masks A–H before and after mask leak test. A: Inspiratory positive airway pressure/expiratory positive airway pressure were set to 10/5, 15/5, and 20/5 cm H_2O. B: COPD, restrictive disease, and normal lung conditions were simulated, respectively. *P < .05, ***P < .001. A = Skynecor; B = Full face series; C = JOYCE Full Face; D = FreeMotion 2; E = Mirage Quattro; F = BestFit II; G = FreeMotion 1; H = BestFit I.

recognizes the intentional leak characteristics of manufacturer-recommended masks when they are used, so there is no need to perform a mask leak test after a mask is properly set on the ventilator. However, when using nonmanufacturer-recommended masks, the mask leak test is required. If an intentional leak of these masks is found, the monitored tidal volume can be estimated from the delivered flow and change in the unintentional leak. The ventilator can then test and identify the leak characteristics of the masks, thereby optimizing the monitoring of tidal volume. This study demonstrated that the mask leak test had no effect on ventilator performance and made the monitoring more accurate when these nonmanufacturer-recommended masks were utilized.

Different masks with different intentional leaks may affect the ventilator performance. A previous study found that, under different NIV settings (pressure support/PEEP: 10/4 cm H_2O, 15/4 cm H_2O, or 20/4 cm H_2O) in different lung models (obstructive and restrictive lung models), different masks had an influence on certain trigger parameters (time from inspiration onset to airway pressure above PEEP) and control parameters (peak inspiratory pressure, inspiratory time, and tidal volume).[12] However, we only focused on the influence of the mask leak test on ventilator performance. The trigger parameters (T_{trig}, TP_{min}, and P_{trig}) and control parameters (inspiratory time, peak inspiratory pressure, peak inspiratory flow, and mean inspiratory flow), PEEP, and delivered tidal volume were not affected by the mask leak test when using the test masks, irrespective of the NIV settings and lung models.

In contrast to invasive ventilation, NIV is characterized by an open-circuit design that is inherently leaky.[20] Leaks pose a challenge because they create a mismatch between the air flow supplied by the ventilator and the flow actually delivered to the patient.[11,21] During NIV, the monitored tidal volume displayed on the ventilator is an estimated value. The flow at the patient is not the same as that measured at the ventilator outlet, which is mainly caused by intentional leak (such as leakage ports) and unintentional leak (for example, around the mask).[22] In many cases, the ventilator could correctly estimate the tidal volume. However, we found that when 3 masks (A, C, and H) were used the ventilator could not estimate the tidal volume accurately, which might be related to the large amount of intentional leak of the masks. For these masks, the monitored tidal volume was more accurate following the mask leak test. The mask leak test allowed the ventilator to estimate the intentional leak characteristics of the test masks, optimizing the monitoring tidal volume displayed on the ventilator.

Our study had some limitations. The results were obtained from an in vitro study, and further clinical research is needed to validate the findings. Our results demonstrated that there was a significant difference in monitored tidal volume among some masks before and after the mask leak test, suggesting that the use of masks not recommended by the manufacturer could affect certain aspects of ventilator performance. Thus, the use of these masks should be avoided if possible. Our results support the contention that the mask leak test makes tidal volume monitoring more accurate. However, to the best of our knowledge, there was only one ventilator that had this function; further, we did not test all commercial interfaces. At the same time, whether the function is acceptable in the presence of unintentional leak remains to be further studied.

Conclusions

When using nonmanufacturer-recommended masks with different leakage and leak port locations, the mask leak test had no effect on ventilator performance under different NIV settings and lung models in vitro, but tidal volume monitoring was more accurate following the mask leak test in some masks.

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