A Comparison of Volume Control Ventilation Delivered By the Trilogy Ventilator with a Passive Exhalation Device versus Conventional Mechanical Ventilators with an Active Exhalation Device

Study Objective
To evaluate the performance of Trilogy as compared to conventional mechanical ventilators

Study Design
Two arm, randomized study

Setting
Intensive care unit (ICU) and step down unit (University of Manitoba, Health Sciences Centre, Winnipeg, Canada)

Participants
Six (6) stable patients requiring mechanical ventilation through a tracheostomy or endotracheal tube

Measurements and Results
Blood gases, hemodynamic and respiratory variables following one-hour use periods of the participant's current ventilator and the Trilogy ventilator. There were no significant differences in any of the variables assessed between the ventilator devices.

Conclusions
When providing volume mode therapies, the Trilogy ventilator with a passive exhalation device provides equivalent therapeutic ventilation as compared with the participants' standard, approved ventilators.

Abbreviations
HR (heart rate), SpO_2 (pulse oximetry), Vte (expired tidal volume), MinVent (minute ventilation)

Key Words
Mechanical ventilation, noninvasive ventilation, invasive ventilation, passive exhalation device

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Introduction

The main purpose of a mechanical ventilator is to artificially assist or replace the patient's muscles in performing the work of breathing[1]. Mechanical ventilation was first used during the polio epidemic in Scandinavia and the United States. The most common ventilators used during that time were negative pressure ventilators, such as the iron lung. After the end of the polio epidemic, invasive mechanical ventilation via endotracheal tube or tracheostomy became more predominant largely because of a higher level of reliability and direct access to the airway. Invasive ventilation is a therapeutic methodology where an increase in positive pressure is applied to the patient's airway that causes gas to flow into the lungs until the ventilator breath is terminated. At that point, as the airway pressure drops to zero, the elastic recoil of the chest wall and lungs pushes the tidal volume out, accomplishing passive exhalation[2]. Invasive ventilation has traditionally required the use of an active exhalation device. An active exhalation device releases gas from the patient breathing circuit during the expiratory phase by creating an intermittent leak (e.g. deflating a balloon through a small opening, then re-inflating it to seal the opening during the inspiratory phase).

In noninvasive ventilation, gas is delivered to the airway via a mask or "interface", rather than an invasive conduit (endotracheal or tracheostomy tube)[3]. With noninvasive ventilation, the gases are passively released via exhalation ports on the mask or other types of passive exhalation devices (e.g. Whisper Swivel, Respironics, Pittsburgh, Pennsylvania). The passive exhalation device allows gas to continuously flush from the patient breathing circuit.

Invasive mechanical ventilation is indicated when the patient's spontaneous ventilation is not adequate to sustain life. Some common indications for employing mechanical ventilation include, but are not limited to[4]:

- Lung infections
- Acute lung injury
- Chronic obstructive pulmonary disease (COPD)
- Post-operative states
- Congestive heart failure
- Chronic restrictive pulmonary disease
- Neuromuscular disease

Individuals with one of these diseases may require mechanical ventilation outside of the hospital or institution. They may also require ventilation in the home and other transitory environments. These individuals may require mechanical aid for breathing to augment or replace spontaneous ventilatory efforts to achieve medical stability or to maintain life. An individual who requires invasive mechanical ventilation in the home may require a tracheostomy tube for ventilatory support, but may no longer require intensive medical and monitoring services[5].

Trilogy ventilator

The Trilogy ventilator is a small, lightweight, portable, invasive and noninvasive ventilator. It is intended to ventilate adult and pediatric patients weighing at least 5kg (11lbs) through their disease progression and provides both pressure- and volume-control modes of therapy, as outlined in the table below.

Pressure modes	Volume control modes
Continuous positive airway pressure (CPAP)	Synchronized intermittent mandatory ventilation (SIMV)
Spontaneous pressure support (S)	Assist control (AC)
Spontaneous/timed pressure support (ST)	Control ventilation (CV)
Pressure control pressure support (PC)	
Timed pressure support (T)	
Pressure control synchronized intermittent mandatory ventilation (PC-SIMV)	

In addition to the different modes of therapy available, the Trilogy ventilator offers user-selectable features that allow caregivers to provide mechanical ventilation with different patient circuits that may include either an active exhalation valve or a passive exhalation device. The therapy in all modalities of the Trilogy ventilator is comparable in both pressure and volume modes, regardless of the exhalation device being used.

Passive exhalation device

As previously stated, invasive ventilation has traditionally required the use of an active exhalation device with a volume control mode of therapy. Volume control therapy is divided into two parts: 1) the inspiratory phase when the precise amount of flow is controlled until the prescribed volume has been delivered, and 2) the expiratory phase, when a set pressure is delivered according to the positive end expiratory pressure (PEEP) set point.

The standard practice has been that an active exhalation device is needed when ventilating volume control modes of therapy. No ventilator in the past has offered volume mode therapy with a passive exhalation device. In those therapy modes, the passive exhalation device complicates the control algorithms for both measurement and delivery of the set volume. Leak flow during the inspiratory phase changes with the pressure at any given instant, which is not typical compared to circuits with a closed active exhalation valve. The Trilogy ventilator has been designed to model the leak characteristics of the passive exhalation device to provide a flow waveform that, when measured at the patient, is indistinguishable from that provided by an active exhalation device. The set volume is maintained on a breath-by-breath basis regardless

of the exhalation device being used. Furthermore, the flow sensing technology can accurately account for additional leaks and provide automatic leak detection and compensation. The Trilogy ventilator is currently the only ventilator on the market capable of delivering volume ventilation with a less complicated passive exhalation circuit.

Therapy provided by the Trilogy ventilator, with either an active or passive exhalation device, has been independently shown to be equivalent through bench testing utilizing a manometer (gauging the patient applied pressure) and flow meter positioned at the "patient" for all patients listed in ASTM-F1100 (90). See the Demographic Data table on the next page.

Philips Respironics sponsored a study comparing current conventional ventilators to the Trilogy ventilator. For the purposes of this analysis, data were only included from those participants who used the Trilogy ventilator in the passive-volume configuration. The aim of the study was to determine if the therapy provided with the Trilogy ventilator would achieve comparable levels of gas exchange, SpO_2, breathing patterns, hemodynamics, and breathing comfort, as that of the participant's current ventilator.

Methods

Seventeen mechanically ventilated participants were recruited into this study. Six participants (five adults and one child) used the Trilogy ventilator with the passive exhalation device in a volume mode (synchronized intermittent mandatory ventilation (SIMV), assist control (AC), or control ventilation (CV)). For the purposes of this report, only the adult participants' data were analyzed and are presented here. The pediatric data were not included due to the small sample size and inability to make comparisons with the adult participants.

The one pediatric participant was a male, age 23 months. The participant's current device was the LTV950, assist-control mode of therapy. The pediatric physiologic data collected while using both the Trilogy ventilator and the participant's current ventilator demonstrated equivalency for blood gases (PCO_2, pH, and HCO_3), hemodynamic variables (HR and SpO_2), and respiratory variables (Vte and MinVent) sampled.

Participants underwent two separate one-hour treatment sessions; one with their current ventilator and one with the Trilogy ventilator. Each participant served as his/her own control in this within-subjects trial. During each one-hour session, data was collected by the NICO Respiratory Management System (Respironics, Wallingford, Connecticut) after 15, 30, and 60 minutes of use. The NICO measurements included heart rate (HR), pulse oximetry (SpO_2), exhaled tidal volume (Vte), and minute ventilation (MinVent). In addition to the NICO measurements, blood gases were collected at the end of each one-hour of use. The blood gases were obtained via arterial or venous blood draw using standard clinical methods. All participants were studied in an attended hospital setting and the research was approved by the institution's Research Ethics Board. All participants provided written, informed consent prior to undergoing any study-related procedures; parental consent was obtained for the pediatric participant.

Participants were randomized to either their current ventilator or the Trilogy ventilator for the first hour and switched to the alternate for the second hour in this crossover design. The Trilogy ventilator was set up in accordance with the participant's current ventilator prescription. On the Trilogy ventilator, participants used the passive exhalation device and all were prescribed their same volume modes of therapy as their standard, approved ventilators.

The statistical analysis compared the performance of the Trilogy ventilator to the current ventilator using the following variables: PCO_2, pH and HCO_3 (arterial or venous), SpO_2, heart rate, exhaled tidal volume, and minute ventilation. For each variable, the distributions of the paired differences were inspected for normality. None of the distributions was significantly asymmetric per the Shapiro-Wilk test and treatments were compared using paired t-tests. All comparisons were two-tailed with the p-value set at 0.05.

Means, standard deviations (SD) and p-values are presented in the data below. Standard deviation is a measure of the variability of the data set. A low standard deviation indicates that the data points tend to be very close to the same value (the mean), while a high standard deviation indicates that the data are spread out over a large range of values. When looking at the p-value, one must remember that it directly relates to the null hypothesis, which is always 'no difference'. If the p value is > .05, the null hypothesis stands (there is no difference between the two samples); if the p value is < .05, the null hypothesis must be dismissed (there is a difference between the two samples). For this data set, a p-value of <0.05 was considered significant. We recognize that with an n of only 4-5, statistical significance is unlikely. However, we still believe that such assessments have value.

Results

Demographic data						
ID number	Gender	Age (years)	Height (cm)	Weight (kg)	Mode of ventilation	Current ventilator
A005	Male	41	178	87	Assist - Control	LP10
A007	Male	55	170	47	Assist - Control	PB 840
A008	Male	51	180	108	Assist - Control	PB 840
A010	Female	63	152	157	Assist - Control	LP6
A011	Female	60	157	139	Assist - Control	LP6

There were a total of five adult participants. The current ventilators that were being used included the Puritan Bennett LP10, LP6, and 840 (Tyco Healthcare, Pleasanton, California). All participants were using mechanical ventilation prior to enrolling in the study.

Blood gases				
Blood gas variables at 60-minutes post therapy	Current ventilator (mean ± SD)	Trilogy ventilator (mean ± SD)	N	p-value (2-sided)*
PCO_2	36.8 ± 4.79	34.3 ± 5.91	4**	0.4287
pH	7.46 ± 0.04	7.48 ± 0.03	4**	0.2010
HCO_3	25.75 ± 2.06	25.00 ± 3.16	4**	0.3910

Blood gases for each one hour of ventilator use were analyzed. The blood gases were obtained after treatment.
There were no significant differences in PCO_2, pH, or HCO_3 between devices.

*Paired t-test

**Only 4 out of the 5 total participants' data were used for blood gases due to one participant's arterial line failing.

Hemodynamic data				
Hemodynamic variables at 60-minutes post therapy	Current ventilator (mean ± SD)	Trilogy ventilator (mean ± SD)	N	p-value (2-sided)*
HR	81.4 ± 15.99	80.0 ± 14.07	5	0.4310
SpO_2	95.75 ± 2.06	97.0 ± 1.22	4 / 5**	0.2522
BP - systolic	123.2 ± 22.17	132.4 ± 29.81	5	0.1778
BP - diastolic	72.2 ± 9.26	71.2 ± 10.99	5	0.6993
Mean BP	92.4 ± 13.81	95.8 ± 21.70	5	0.5358

Heart rates, SpO_2, and blood pressures were collected at 15, 30, and 60 minutes during each session of ventilator use.
Only the final measurements (60 minutes) are presented in this analysis; however, the analyses at 15 and 30 minutes showed similar results.
There were no significant differences in these variables between devices at any time interval.

*Paired t-test

**Only 4 out of the 5 total participants' data were used for the SpO_2 current ventilator analysis due to missing data.

Respiratory data				
Respiratory variables at 60-minutes post therapy	Current ventilator (mean + SD)	Trilogy ventilator (mean + SD)	N	p-value (2-sided)*
MinVent	8.83 ± 1.55	9.56 ± 1.59	4 / 5**	0.3086
Vte	574.8 ± 95.22	594.2 ± 194.54	4 / 5**	0.2743

Vte and MinVent measurements were collected after one hour of ventilator use. There were no significant differences in Vte or MinVent.

* Paired t-test

**Only 4 out of the 5 total participants' data were used for the MinVent and Vte current ventilator analysis due to missing data.

Discussion

This initial evaluation demonstrates that the Trilogy ventilator with a passive exhalation device provided equivalent therapy in a group of five mechanically-ventilated participants. Comparable outcomes were observed between the Trilogy ventilator with a passive exhalation device and the participants' current active-exhalation devices. There were no significant differences ($p \geq 0.18$) and no real trends between devices with respect to blood gases, hemodynamic variables, or respiratory measurements. These data suggest that the Trilogy ventilator with passive exhalation offers an adequate alternative to currently marketed ventilators with an active exhalation device.

Conclusion

The Trilogy ventilator with a passive exhalation device provided equivalent therapy in this group of five mechanically-ventilated participants. The statistically validated measurements including blood gases, hemodynamic variables, and respiratory variables demonstrate that the Trilogy ventilator with a passive exhalation device offers an effective alternative to ventilation using an active exhalation device. This initial evaluation demonstrates that the Trilogy ventilator with a passive exhalation device, in volume modes of therapy, is able to equivalently ventilate patients who require mechanical ventilation.

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