Animal and Clinical Trials on a Prototype, Pressure Limited, Time Cycled Philippine Ventilator (PhilVent ™)

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ABSTRACT

Objective. To test the efficacy and safety of PhilVent™, a pressure limited, time cycled, Philippine ventilator through animal and clinical studies.

Methods and Results.
Animal study: Term, newborn piglets (N=8) were intubated and alternately cycled to the PhilVent™ or to a pressure limited, time cycled, commercial ventilator (Sechrist) at peak inspiratory pressures of 10, 13 and 15 cm H20 and rates of 15, 20, 25 breaths per min and constant FiO2 (0.40) and positive end expiratory pressure (+4). Blood gases and adverse events (pneumothorax, sudden deterioration, death) were monitored. Results show no significant difference in blood gases on either machine at the various ventilator settings. No adverse events occurred.
Clinical study: Prospective, randomized, controlled trial of 90 preterm infants with respiratory distress, randomized either to PhilVent ™ (N=45) or Sechrist (N=45). Ventilator settings were adjusted to achieve predetermined range of blood gases. Arterial blood gases and any adverse events e.g., pneumothorax, pulmonary hemorrhage were monitored. There were no clinically significant differences in the ventilator settings or blood gases of the infants on the PhilVent™ or Sechrist. No increase in adverse events were noted with the PhilVent™.

Conclusion. In animal and clinical studies, the efficacy and safety of the PhilVent were comparable to the Sechrist. The PhilVent™ is an effective, alternative ventilator for the treatment of respiratory insufficiency in newborn infants.

Key Words: ventilator, neonate, respiratory distress

Presented as a poster at the Philippine Society of Newborn Medicine Annual Convention, February 5-6, 2010, Crowne Plaza Hotel, Ortigas, Mandaluyong City.

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Introduction

The treatment of infants with significant respiratory problems, especially from hyaline membrane disease, requires the use of a ventilator. Unfortunately, commercial ventilators are expensive; thus the number of ventilators available in any neonatal intensive care unit (NICU) is limited by the budget constraints of the hospital for the purchase and maintenance of such equipment. Often, this is the situation in government hospitals in the Philippines (personal communication). Alternative measures to meet the ventilator needs of the nurseries in these hospitals have been adopted, which include (1) ventilator rental and (2) manual hand bagging of the infant. Unfortunately, for ventilator rental, the infant's family is asked to pay for the rented equipment which often is beyond their financial means. Thus, in many instances, the alternative measure of hand bagging of the infant becomes the only recourse (personal communication). A caregiver, usually a family member or member of the hospital staff is asked to provide for manual ventilation of the infant by the use of an Ambu bag. This is a dangerous and relatively ineffective method of ventilation since the required tidal volume and peak inspiratory pressure that are needed to ventilate the infant are not adequately nor uniformly delivered leading to more respiratory failure or complications, such as pneumothorax. Similarly, the hand bagger may eventually tire or fall asleep which leads to the demise of the infant. Thus, alternative means to provide for effective, yet low cost ventilator are needed to meet the ventilatory needs of many neonatal intensive care units in the Philippines. The pressure limited and time cycled ventilator has been a standard ventilator in many intensive care nurseries and has been used for more than 2 decades. It is simple in its mechanism and can be easily developed at low cost and with minimal maintenance.

PhilVent ventilator:

The PhilVent™ ventilator (Figure 1) is an assembly of tubes, fittings, valves, and sensors that permit the regulation of the pressure and flow of the air to the infant (1) connected to the machine. This is achieved by the periodic opening and closing of as Asco low pressure solenoid valve (McMaster Carr, New Jersey, USA) (2) that alternates the flow of oxygen/air gas mixture (3) through the machine

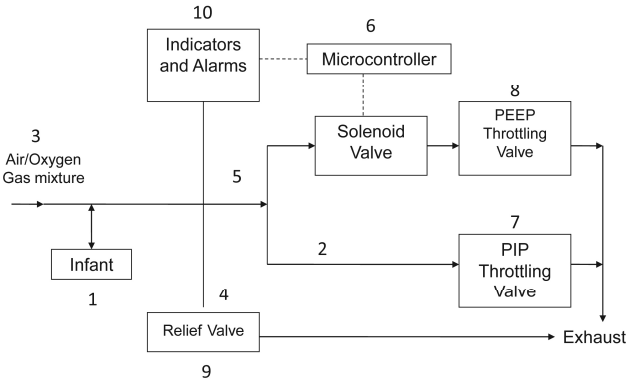

Figure 1. Schematic diagram of Philvent.

between a "high" pressure path (4) and a "low" pressure path.(5) The solenoid valve is controlled by a microcontroller (University of the Philippines, College of Engineering, Department of Electronic) (6) which can bet set to determine the number of breaths per minute and the length of the inspiratory time. The PIP (Peak Inspiratory Pressure) is adjusted by a throttling valve (McMaster Carr, New Jersey, USA) (7) installed in the "high" pressure path while the PEEP or Positive End Expiratory Pressure (8) is adjusted by a similar valve installed in the "low" pressure path. For safety against over-pressure, a mechanical poppet or pressure relief valve (9) is also installed in the system. A visual indication of the pressure by LED bar graph (10) is provided to assist the operator in adjusting the PIP and PEEP. An alarm system (10) is integrated in the machine. The alarm system sends out both visual and audible alerts whenever the following conditions exist: pressure too high, pressure (PEEP) too low and pressure is not cycling (Pressure Sensors 26PC Series Honeywell). The machine is downstream of the infant and no gases from the machine flows back into the infant at any time.

Animal study:

The safety and efficacy of the PhilVent™ were initially tested in 8 newborn piglets and its performance was simultaneously compared to the Sechrist. Both are time cycled and pressure limited ventilators. Full term, newborn piglets were obtained within 24 hours of birth from a commercial pig farm. The piglet was premedicated with intramuscular atropine (0.01 mg/kg) and anesthetized with ketamine HCL (3-4 mg/kg). The piglet was intubated using a 2.5 endotracheal tube and then connected to a Sechrist ventilator at an initial setting of: oxygen concentration (FiO2) = 0.40, peak inspiratory pressure (PIP) = 13 cm H2O, intermittent mandatory ventilator rate (IMV) = 20 breaths per minute and positive end expiratory pressure (PEEP) = + 5 cm H2O. An umbilical venous catheter was inserted for intravenous fluid administration and an umbilical arterial catheter was inserted for blood gas determinations and continuous measurement of blood pressure through a pressure transducer. A 5% dextrose solution containing 0.3% sodium chloride was administered intravenously through the umbilical vein line at a rate of 4 mL/kg/h. To maintain anesthesia in the piglet, sodium pentothal was initially given at a loading intravenous dose of 8 mg/kg, followed by a maintenance dose of 50-100 mcg/kg/min.

After initial stabilization of the piglet on the Sechrist ventilator, the piglet was alternately switched from the Sechrist to the PhilVent or vice versa after the following changes on the ventilator settings: IMV (rates of 15, 20 and 25) and PIP (10, 13 and 15 cm H2O). The FiO2 and PEEP were maintained constant at 0.40 and +5 cm H2O, respectively. The heart rate and blood pressure of the piglet were continuously monitored. Blood was drawn through the umbilical artery 30 minutes after each change in IMV or PIP setting in the Sechrist or PhilVent™ for blood gases determinations on a Radiometer blood gas machine.

Clinical study:

The objective of this study was to determine, in a randomized controlled trial, the safety and efficacy of the PhilVent™ as compared to the Sechrist in infants with respiratory failure requiring ventilator support. Excluded were infants with severe asphyxia or major congenital malformations. A total of 90 infants were enrolled in the study (45 infants each for PhilVent™ and Sechrist) in a randomized, control manner. The power of the study was calculated on the basis of pneumothorax as a ventilator complication. The incidence of pneumothorax in infants on standard ventilator in the Philippine General Hospital nursery was 26%. Assuming that the frequency of pneumothorax will increase twofold (26% to 52%) with the use of the PhilVent™, a sample size of 45 infants in each arm of the study provided a power of 0.82, at an alpha = 0.05 (1 tailed analysis) for the study. A one tailed analysis was used because we were only interested in the increase in the incidence of pneumothorax with the use of the PhilVent™.

Eligible infants were randomized to either the PhilVent™ or Sechrist ventilator based on randomization via preshuffled cards contained in a sealed envelope. Informed consent was obtained from the infant's parents. The initial setting on the ventilator was Fi02 = 0.6, IMV = 40, PIP = 20 cm H2O, PEEP = +4 cm H2O, inspiratory time = 0.4 sec . The ventilator settings were then adjusted to achieve the following range of blood gases: pH = 7.25-7.35, PC02 = 45-55 mm Hg and P02 =55-60 (or 90% saturation) mm Hg. Inspired oxygen concentration in the ventilator was determined by an oxygen analyzer. The infant's blood pressure and 02 saturation by pulse oximeter, were monitored, as well as adverse events such as pneumothorax and pulmonary hemorrhage as determined by clinical signs or chest X-ray. The duration of ventilator use for the purpose of the study was 3 days. Thereafter, the infant was switched to a conventional Sechrist ventilator for the remainder of its

ventilator needs. The study was approved by the Human Investigation Committee (Research Implementation and Development Office) of the UP College of Medicine.

Data analysis

Univariate analyses were done on continuous and categorical variables. For continuous variables, analysis between independent groups was done by the Student "t" test and for categorical variables, comparison between groups was done by Pearson Chi square analysis. The incidence of adverse events, e.g. pneumothorax and pulmonary hemorrhage were categorized as dichotomous (yes/no) variables and were related to the type of ventilator used. A p value of <0.05 will be taken as the level of statistical significance in all statistical analyses.

Results

Animal study

There was no significant difference in the blood gas pH, PCO2, HCO3 and PO2 between the PhilVent™ and Sechrist at different PIP and ventilator rates (Tables 1-3). There were no adverse events noted that were directly associated with the PhilVent™ or Sechrist ventilator use. However, a piglet death occurred secondary to mechanical problems encountered during a change in oxygen gas tanks.

Table 1. Philvent versus Sechrist at Peak Inspiratory Pressure = 10 CM H20 and Ventilator rates from 15-25 breaths per minute (PIGLET STUDY).

	Ventilator	N	IMV	Mean	Std. Deviation	p *
pH	PhilVent	13	15	7.3562	.20723	
	Sechrist	13	15	7.4277	.06772	NS
PCO2	PhilVent	13	15	53.00	35.162	
	Sechrist	13	15	40.00	6.390	NS
PO2	PhilVent	13	15	147.85	79.307	
	Sechrist	13	15	189.62	35.082	NS
HCO3	PhilVent	13	15	25.92	4.112	
	Sechrist	13	15	26.15	1.994	NS
pH	PhilVent	9	20	7.4933*	.09734	
	Sechrist	10	20	7.3800	.12649	<0.05
PCO2	PhilVent	9	20	36.56	10.333	
	Sechrist	10	20	50.30	17.645	NS
PO2	PhilVent	9	20	162.89	69.252	
	Sechrist	10	20	152.90	60.953	NS
HCO3	PhilVent	9	20	26.89	1.269	
	Sechrist	10	20	27.60	1.647	NS
pH	PhilVent	10	25	7.4390	.16703	
	Sechrist	10	25	7.3560	.13842	NS
PCO2	PhilVent	10	25	43.20	19.275	
	Sechrist	10	25	51.00	15.811	NS
PO2	PhilVent	10	25	156.30	64.883	
	Sechrist	10	25	152.00	57.797	NS
HCO3	PhilVent	10	25	26.40	1.430	
	Sechrist	10	25	27.80	3.706	NS

** Comparison of independent sample means by the Student "t" test*

Clinical study

There were 90 infants enrolled in the study (PhilVent™ = 45; Sechrist = 45) - Table 4. The mean gestational age was slightly higher (32.7 ± 3.2 versus 31.5 ± 2.6 wks, p<0.038) in the PhilVent™ infants, but birth weight was not significantly

Table 2. Philvent versus Sechrist at Peak Inspiratory Pressure = 13 CM H20 and Ventilator rates from 15-25 breaths per minute (PIGLET STUDY)

	Ventilator	N	IMV	Mean	Std. Deviation	p *
pH	PhilVent	18	15	7.5078	.12022	
	Sechrist	19	15	7.4684	.10489	NS
PCO2	PhilVent	18	15	35.50	14.018	
	Sechrist	19	15	38.53	14.061	NS
PO2	PhilVent	18	15	186.56	32.876	
	Sechrist	19	15	177.05	38.302	NS
HCO3	PhilVent	18	15	26.39	2.090	
	Sechrist	19	15	26.26	4.161	NS
pH	PhilVent	18	20	7.5417	.16314	
	Sechrist	18	20	7.5233	.12829	NS
PCO2	PhilVent	18	20	33.94	16.548	
	Sechrist	18	20	34.06	14.002	NS
PO2	PhilVent	18	20	195.17	61.028	
	Sechrist	18	20	186.33	33.264	NS
HCO3	PhilVent	18	20	26.39	2.330	
	Sechrist	18	20	26.06	2.600	NS
pH	PhilVent	19	25	7.5684	.13631	
	Sechrist	19	25	7.5400	.12640	NS
PCO2	PhilVent	19	25	29.84	12.339	
	Sechrist	19	25	28.89	11.742	NS
PO2	PhilVent	19	25	189.11	58.070	
	Sechrist	19	25	167.37	44.242	NS
HCO3	PhilVent	19	25	25.32	2.689	
	Sechrist	19	25	23.42	5.135	NS

** Comparison of independent sample means by the Student "t" test*

Table 3. Philvent versus Sechrist at Peak Inspiratory Pressure = 15 CM H20 and Ventilator rates from 15-25 breaths per minute (PIGLET STUDY)

	Ventilator	N	IMV	Mean	Std. Deviation	p *
pH	PhilVent	20	15	7.5405	.16593	
	Sechrist	21	15	7.4767	.10224	NS
PCO2	PhilVent	20	15	33.45	12.906	
	Sechrist	21	15	37.38	9.962	NS
PO2	PhilVent	20	15	165.25	42.922	
	Sechrist	21	15	171.43	36.276	NS
HCO3	PhilVent	20	15	26.35	2.852	
	Sechrist	21	15	26.76	3.833	NS
pH	PhilVent	17	20	7.5529	.17860	
	Sechrist	19	20	7.5468	.16439	NS
PCO2	PhilVent	17	20	29.76	12.039	
	Sechrist	19	20	30.26	13.642	NS
PO2	PhilVent	17	20	155.88	47.396	
	Sechrist	19	20	172.21	46.019	NS
HCO3	PhilVent	17	20	24.53	3.223	
	Sechrist	19	20	24.89	4.267	NS
pH	PhilVent	18	25	7.5911	.18613	
	Sechrist	19	25	7.5889	.19799	NS
PCO2	PhilVent	18	25	25.78	10.914	
	Sechrist	19	25	28.16	16.774	NS
PO2	PhilVent	18	25	157.61	60.749	
	Sechrist	19	25	160.00	57.505	NS
HCO3	PhilVent	18	25	23.94	4.940	
	Sechrist	19	25	24.11	5.141	NS

** Comparison of independent sample means by the Student "t" test*

different (1382.7 ± 464.4 versus 1325.7 ± 354.4 g, p<0.518). The diagnosis of hyaline membrane disease, transient tachypnea, early or late pneumonia as cause of respiratory insufficiency was comparable in both groups (Table 4). Although the mean PIP, PEEP, IT and flow rate to achieve the desired blood gases were slightly higher in the Sechrist than PhilVent™ group, the difference was not of clinical significance (Table 5). Similarly, the arterial blood pH, PCO2, and HCO3 were slightly lower in the PhilVent group but again, were not of clinical significance (Table 6). The mortality rate and the incidence of air leak and pulmonary hemorrhage were not significantly different between the 2 groups (Table 7).

Discussion

Mechanical ventilation has become the mainstay of treatment in infants with severe respiratory failure. Prior to the advent of ventilators, the standard treatment of newborn infants with severe lung disease, principally from respiratory distress syndrome, consisted merely of supportive measures of supplemental oxygen and correction of metabolic acidosis and the mortality rate was high. With the introduction of mechanical ventilation in the neonate, the mortality rate was significantly reduced, but most marked in larger infants with birth weight of >2000 g.[1] The first ventilators that became widespread in use were continuous flow, pressure limited, time cycled ventilators and had become the preferred method of mechanical ventilation for nearly 25 years.[2,3] Subsequent improvements in the ventilators have allowed the neonatologist to further control target modality, the mode of ventilation, tidal volume delivery, minute ventilation, the cycling mechanism, assist sensitivity and even real time pulmonary graphic monitoring.[4,5] Although more sophisticated and newer types of ventilators have been subsequently introduced that allowed the fine tuning of many modalities of ventilation of the infant, there have been no large, randomized, controlled trials comparing past and newer ventilator models that provide evidence that the improvements in ventilator modalities have increased survival rate of infants nor lowered complications rates of mechanical ventilation. In fact, despite major advances in neonatology, which includes newer modalities of ventilation treatment and strategy, the incidence of chronic lung disease which is a consequence of mechanical ventilation has not significantly improved in the surviving premature infants.[6]

As a device, the neonatal ventilator can be classified as either a device that delivers tidal ventilation (referred to as the conventional mechanical ventilator) or a device that delivers small gas volumes at high rates (referred to a high frequency ventilator). A ventilator breath is also classified according to three features: trigger, limit and cycle. The trigger refers to the mechanism that initiates the breath, which may be time, change in airway pressure or flow. For

Table 4. Patient Characteristics

		PhilVent (n=45)	Sechrist (n=45)	p
Gestation	Mean (SD)	32.7 (3.2)	31.5 (2.6)	0.038 *
	95% CI	31.8-33.7	30.7 – 32.2	
Weight (g)	Mean (SD)	1382.7 (464.4)	1325.7 (354.4)	0.518 *
	Median	1350	1300	
	Range	600-3000	800-2100	
Diagnosis				
Hyaline membrane disease		25 (55.6%)	30 (66.7%)	0.280 **
Transient tachypnea of newborn		7 (15.6%)	4 (8.9%)	0.265 **
Early pneumonia		4 (8.9%)	3 (6.7%)	0.500 **
Late pneumonia		2 (4.4%)	7 (15.6%)	0.079 **
Others		7 (15.6%)	1 (2.2%)	0.026 **

** Student "t" test*

*** Pearson chi square analysis*

Table 5. Ventilator Settings: = MEAN (SD)

	PhilVent (n=45)	Sechrist (n=45)	p*
FiO2	62.3 (25.4)	64.4 (29.9)	0.178
IMV	44.6 (17.4)	46.3 (17.9)	0.070
PIP (cm H2O)	19.1 (4.6)	20.2 (6.8)	0.001
PEEP (cm H2O)	4.1 (0.4)	4.0 (0.3)	0.001
IT (sec)	0.46 (0.07)	0.43 (0.05)	0.001
Flow rate (L/min)	11.1 (2.0)	10.6 (1.7)	0.001

** Student "t" test*

FiO2 – fractional concentration of inspired oxygen

IMV – intermittent mandatory ventilator rate

PIP – peak inspiratory pressure

PEEP – peak end expiratory pressure

IT – inspiration time

Table 6. Arterial Blood Gases = MEAN (SD)

	PhilVent (n=45)	Sechrist (n=45)	p*
pH	7.30 (0.14)	7.32 (0.13)	0.001
PCO2	43.4 (15.5)	44.0 (16.3)	0.351
PO2	105.5 (61.1)	126.8 (88.0)	0.001
HCO3	20.6 (6.3)	21.9 (7.0)	0.001

** Student "t" test*

Table 7. Mortality and Morbidity of infants in the study

	PhilVent (n=45)	Sechrist n=45)	Risk estimate ****	p
Mortality	6 (13.3%)	6 (13.3%)	1.000 (0.297-3.372)	0.500 **
Morbidity				
Air leak	10 (22.2%)	9 (20.0%)	1.143 (0.415-3.149)***	0.796 **
Pulmonary hemorrhage	0	1 (2.2%)	2.023 (1.639-2.496)	0.500 ***
Heart rate (bpm)	148 (12.7)	151.1 (13.9)		0.001*
Systolic BP (mm Hg)	55.1 (10.9)	56.4 (10.1)		0.018*
Diastolic BP (mm Hg)	29.4 (7.4)	27.6 (6.6)		0.001*

** Student "t" test*

*** Pearson chi square analysis*

**** Fisher's Exact test*

***** Odds ratio (95% confidence interval)*

the conventional ventilator, there are 4 modes of trigger: intermittent mandatory ventilation (IMV), synchronized IMV, assist/control and pressure support ventilation. The IMV is the prototype trigger and are predetermined breaths set on the ventilator. Further modifications on the triggering mechanisms are designed to synchronize the machine and the infant's spontaneous breath. The limit refers to the targeted variable, whether pressure or volume limited. It is beyond the scope of this discussion to present the pros and cons of pressure versus volume limited ventilators and for more information on the issues, the following studies can be reviewed.[7,8,9] Finally, the cycling mechanism is what causes the ventilator breath to end, or to cycle from inspiration to expiration. Time cycling is the oldest mechanism and the inspiration ends after a pre-set inspiratory time has elapsed. Most clinicians are familiar with time-cycled, pressure-limited ventilation, in which mechanical breaths are initiated and terminated by time, and which are limited by a pre-set inspiratory pressure limit that cannot be exceeded. The inspiratory flow is constant and the delivered tidal volume is related to pulmonary compliance. The Sechrist and PhilVent™ that were used in this study are both pressure limited, time cycled ventilators.

Unlike most published clinical studies on mechanical ventilators that have dealt on comparing the performance of different models or types of ventilators, this paper addresses a different issue – the serious problem of lack of mechanical ventilators in many neonatal intensive care units in the Philippines brought about by the high incidence of prematurity and low birth weight infants[10] and the high cost and maintenance of mechanical ventilators for these infants. Prematurity and low birth weight are the major causes of respiratory problems in newborn infants, mostly due to hyaline membrane disease and many of these infants require mechanical ventilators to survive. Unfortunately, in the Philippines setting, the lack of ventilators has led to unacceptable alternative modes of treatment, particularly the use of continuous, manual bagging of the infant. What is therefore needed is a ventilator that is comparatively low in procurement and maintenance cost and has undergone animal and clinical tests to prove its efficacy and safety. The PhilVent™ is presented in this paper as a prototype of this ventilator and its efficacy and safety are tested and compared with the Sechrist, a standard, commercial ventilator. Both PhilVent™ and Sechrist are pressure limited and time cycled and is the type of ventilator that most clinicians are familiar with since this ventilator has been used extensively for more than 25 years.

In the animal (piglet) studies, the PhilVent™, under different settings of IMV (15, 20, 25 breaths per min) and PIP (10, 13, 15 cm H20) showed blood gases comparable to those obtained with the animal on the Sechrist (Tables 1-3). To allow for paired comparison, the animals were tested on both ventilators for each change in IMV or PIP. To avoid selection bias, the change in ventilator setting did not always start on the same ventilator but alternated between the Sechrist and the PhilVent™. No adverse events were encountered from the direct use of the PhilVent™ or Sechrist. A single adverse event of piglet death was not related to the ventilator but occurred from mechanical problem encountered during an oxygen gas tank change. One limitation of the animal study is that full term, instead of preterm, piglets were used, whereas most newborn infants that are placed on ventilators are preterm. The use of preterm piglets was not feasible because these animals do not survive when born premature. The piglets were born in distant areas and transport of any premature piglet to the laboratory soon after birth precluded any survival in these animals. Likewise, since the lungs of the animals were not diseased after birth, the ventilator settings that were used in the study were lower that what are normally used in sick animals to avoid hyperventilation.

The clinical study was conducted on a total of 90 infants half of whom were on the PhilVent™ or Sechrist. No baseline blood gases were taken prior to placing the infant on the ventilator and most infants came from the delivery floor already intubated. Criteria for placement on a ventilator was made on clinical presentation such as significant respiratory distress and low oxygen saturation. Although randomization was attempted, it was not always possible to follow such a procedure since there was only one PhilVent machine and if an infant was admitted and randomized to the PhilVent and the PhilVent was still in use by another infant, the infant was placed on the Sechrist or a regular ventilator. The respiratory diseases in the infants that required ventilator treatment were essentially similar in both groups (Table 4). There was a slightly higher gestational age, but similar birth weight in the PhilVent™ compared to the Sechrist group. However, we do not feel that the difference in gestational age was of clinical significance since the machines performed with comparable PIP, PEEP, IMV and I-time to achieve similar blood gases based on desired blood gas levels. Although there were statistically significant differences in the ventilator settings and blood gases in the 2 ventilator groups (Tables 5-6), these differences did not have any clinical importance. The incidence of complications that are commonly associated with ventilator use, such as pneumothorax and pulmonary hemorrhage was not significantly different between the PhilVent™ and Sechrist groups (Table 7).

The Sechrist is a low maintenance, pressure limited, time cycled ventilator machine that essentially operates through a continuous flow of gas, a valve that opens and closes at preset time to redirect the gas mixture either into the patient or to an exhaust to which some resistance to gas flow can be applied to deliver the PEEP and relief valves with variable resistances to gas flow to generate varying peak pressures. Unlike volume ventilators, the Sechrist has

no moving piston like parts which accounts for its low maintenance requirement. Thus, the Sechrist belongs to the generation of pressure limited, time cycled ventilators that have been extensively used for the past 25 years. The PhilVent™ operates on the same principle as the Sechrist. As evidenced by the animal and clinical studies, its efficacy and safety compares to that of the Sechrist and presumably it is low maintenance. The simplicity of the PhilVent™ contributes further to its low production cost as compared to current commercial ventilators. The cost of the PhilVent is approximately one-fifth that of a regular, commercial ventilator.

In summary, we have compared the performance of the PhilVent™ to a standard, commercial ventilator (Sechrist) in both animal and clinical studies. Both ventilators are time cycled and pressure limited. The safety and efficacy of the PhilVent™ have been demonstrated in paired studies with the Sechrist at varying IMV and peak pressures. We conclude that the PhilVent™ is an effective and safe ventilator for use in the neonatal intensive care nurseries in the Philippines.

Acknowledgments

We gratefully acknowledge the contributions to this research of Manuel Hernandez, PhD, Alexander Paran, PhD and Carl Odulio, MS from the University of the Philippines, College of Engineering, and Carmen Briones, MD, Karen Cruz, MD, Harold Sia, MD, Angelina V. Tomas MD, Lolit Bravo, MD, Patrick M. Ostrea, Honey Raborara, MD, Monina Quiambao, Rachelle Perez, MD, Lieza Sahi, MD, Resti Bautista MD, Jeffrey Masilungan MD, from the University of the Philippines, College of Medicine and Philippine General Hospital.

References

1. Henderson-Smart DJ, Wilkinson AR, Raynes-Greenow CH. Mechanical ventilation for newborn infants with respiratory failure due to pulmonary disease: Review. The Cochrane Collaboration. John Wiley & Sons, Ltd. 2009.
2. Donn SM. Neonatal ventilators: how do they differ? J Perinatol. 2009; 29:S73–8.
3. Delivoria-Papadopoulos M, Levison H, Swyer PR. Intermittent positive pressure respiration as a treatment in severe respiratory distress syndrome. Arch Dis Child. 1965;40:474–9.
4. Sinha SK, Donn SM. Newer forms of conventional ventilation for preterm newborns. Acta Paediatr. 2008;97:1338–43.
5. Becker MA, Donn SM. Real-time pulmonary graphic monitoring. Clin Perinatol. 2007;34:1–17.
6. Aly H. Is there a strategy for preventing bronchopulmonary dysplasia? Absence of evidence Is not evidence of absence. Pediatrics. 2007;119:818-820.
7. Sinha SK, Donn SM, Gavey J, McCarty M. Randomised trial of volume controlled versus time cycled, pressure limited ventilation in preterm infants with respiratory distress syndrome. Arch Dis Child Fetal Neonatal Ed. 1997;77:F202–5.
8. Lista G, Castoldi F, Bianchi S, Battaglioli M, Cavigioli F, Bosoni MA. Volume guarantee versus high-frequency ventilation: lung inflammation in preterm infants. Arch Dis Child Fetal Neonatal Ed. 2008;93:F252–6.
9. Singh J, Sinha SK, Clarke P, Byrne S, Donn SM. Mechanical ventilation of very low birth weight infants: is volume or pressure a better target variable? J Pediatr. 2006;149:308–13.
10. Department of Making Pregnancy Safer. Country Profile Philippines. WHO. [online]. [cited 2006 January]. Available from http://www.who.int/making_pregnancy_safer/countries/phl_rev.pdf.