Functional Evaluation of Bubble CPAP for Neonates Using a Leak Model

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Objective : We evaluated the influence of bias flow magnitude and leak flow on the provided CPAP level in the presence or absence of a reservoir bag.

Methods : The 500 mL soft plastic reservoir bag was connected to the bubble CPAP system. The leak pathway and a valve were prepared to simulate the function of the mouth. The pressure and flow in the regions corresponding to the lower airway (Pdistal) and the leak flow were recorded simultaneously using a flow analyzer.

Results : At a bias flow of 3 L/min, use of a reservoir bag resulted in a significant decline of the pressure swing magnitude at 60 and 90 breaths/min. A reservoir bag attenuated the rapid aspiration-induced decreases of the mean airway pressure. When bubbling disappeared due to complete opening of the leak valve, the mean airway pressure was maintained at approximately 2 cmH_2O. Additionally, the mean airway pressure increased with increasing bias flow even under 100 % leak condition.

Conclusions : Even when a large leak occurs, a low but significant airway pressure is loaded under moderate bias flow. Inclusion of a reservoir bag in the bubble CPAP may offer an effective and inexpensive option for providing respiratory support to preterm infants. *Shinshu Med J 61 : 65—73, 2013*

(Received for publication December 18, 2012 ; accepted in revised form January 8, 2013)

Key words : bubble CPAP, reservoir bag, flow analyzer, breathing simulator, leak model

I Background

Continuous positive airway pressure (CPAP) is often used to provide noninvasive respiratory support in neonates. CPAP allows better recruitment of alveoli, thereby increasing the functional residual capacity, and improves oxygenation with less imposed inspiratory work of breathing[1)-5)]. The standard treatment for very preterm infants has been mechanical ventilation and surfactant since the 1980s[6)]. Nevertheless, the incidence of chronic lung disease (CLD) has not decreased despite improvement of ventilation techniques. On the other hand, the early use of CPAP has been reported to be associated with a lower incidence of CLD[7)]. This evidence has led to an increase in the use of CPAP as an alternative to intubation and mechanical ventilation.

Bubble CPAP has been used since the 1970s[8)]. Because of its simple structure, handling of bubble CPAP is easier and it is less expensive than respirator-derived CPAP. Therefore, several investigators have recommended its use in developing countries[9)-11)].

The pressure of bubble CPAP is determined largely by resistance of the expiratory circuit due to the submersion depth and flow passing through an underwater tube, and the leak flow pathway. The flow passing through the underwater tube is determined by the bias flow in the circuit and the leak flow. In a nasal CPAP system, leakage occurs through not only the junction with the nostril but also the oral cavity. There have been several leak

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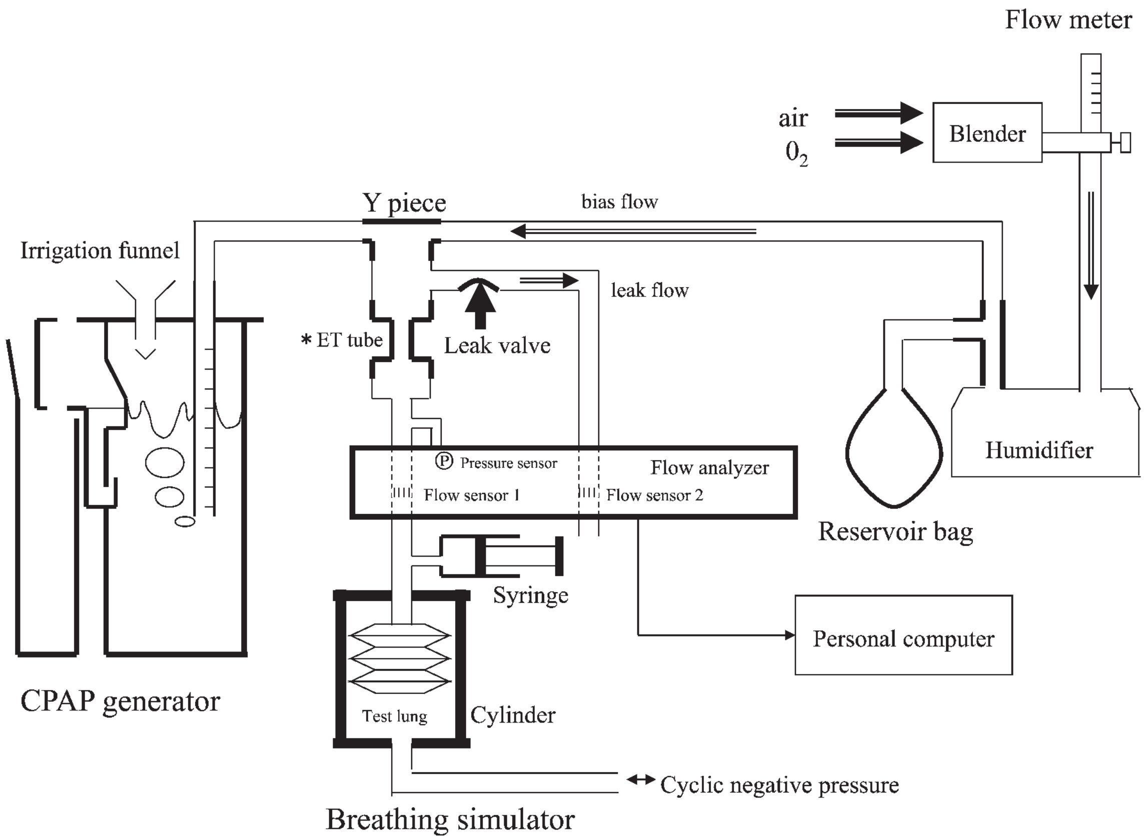

Fig. 1 A schematic of the experimental system

The bubble CPAP system was connected to a breathing simulator. An underwater bubbler was set at 5 cmH_2O immersion depth. The breathing simulator was set at a tidal volume of 20 mL, and the respiratory rate was set at 30, 60, and 90 breaths/min. The leak valve was prepared to simulate the function of the mouth. A 60 mL syringe was prepared near the test lung to simulate the movement of hiccups. A 500 mL soft plastic reservoir bag was connected with the humidifier outlet. The pressure and flow in the regions corresponding to the lower airway and the leak flow were recorded simultaneously using a flow analyzer.
* Endotracheal tube.

studies in neonates, using conventional constant flow CPAP or constant pressure/variable flow CPAP[12)-15)]. Nevertheless, effects of circuit leak and a reservoir bag on breathing parameters remain unclear in neonatal bubble CPAP.

The aim of this study is to evaluate the influence of bias flow magnitude and leak flow on the provided CPAP level. We also investigate whether the addition of a reservoir can attenuate the imposed inspiratory work of breathing induced by a low flow and can reduce the pressure swing induced by rapid inspiration, such as hiccups and sighs.

II Methods

A schematic of the experimental system is shown in **Fig.1**. A Y piece connected the bubble CPAP system (Fisher & Paykel Healthcare, Auckland, New Zealand) to a breathing simulator. The distal connecting tube (internal diameter, 10 mm) was immersed under the water seal to a depth of 5 cm. Nine different flows were tested, ranging from 1 L/min to 9 L/min. The humidifier outlet was connected via a T piece to the 500 mL soft plastic reservoir bag. The breathing simulator was driven by cyclic negative pressure. The compliance of the test lung in the cylinder was set at 1.0 mL/cmH_2O, and total airway resistance from the Y piece to the test lung was adjusted to 85 $cmH_2O/L/s$ by changing the length of an endotracheal tube (Portex, Smiths Medical Japan, Tokyo, Japan ; internal diameter, 4.0 mm). The two values were confirmed using a pneumotachograph (LFM-317 Aivision

Laminar Flow Meter, Metabo, Lausanne, Switzerland). Airway occlusion pressure was 20 cmH_2O. Expiratory flow was calculated as 0.235 L/min according to the passive expiratory flow-volume method. The breathing simulator was set at a tidal volume of 20 mL and the respiratory rate was set at 30, 60 and 90 breaths/min to simulate the lung volume and mechanics of a non-intubated neonate. The leak pathway and a valve simulated the function of the mouth. To simulate hiccups, a syringe placed near the test lung in the breathing simulator circuit was aspirated rapidly. The pressure and flow in the regions corresponding to the lower airway and the leak flow were recorded simultaneously using a flow analyzer (PF-300, ImtMedical, Buchs, Switzerland), and were calculated using built-in software (FlowLab™, ImtMedical, Buchs, Switzerland). Data were collected using a computerized data accumulation system at a sampling rate of 200 samples/sec.

In preliminary experiments, we examined whether the humidifier chamber affected the pressure of the circuit. There was no Pmean difference in the presence or absence of the humidifier chamber probably due to its very hard structure.

Ⅲ Statistical Analysis

In **Table 1** and **2**, five breaths located in the middle of the record were selected from each experimental series, and values were expressed as mean (Pmean) ± SD (pressure swing magnitude). Analysis was performed using SPSS v. 18 (IBM corporation, Chicago, IL, USA). To determine the significance of the difference between two independent groups, we used the unpaired t-test or Mann-Whitney-U test when the data were not normally distributed. To compare the difference of SD between the two samples, we used the F-test. The level of significance was defined as a P-value of less than 0.05.

Table 1 Effects of bias flow magnitude on mean airway pressure under no-leak condition

V'bias (L/min)		9	8	7	6	5	4	3	2	1
Pdistal (cmH_2O)	mean	5.95 #	5.81 #	5.76 #	5.65 #	5.55 #	5.5 #	5.44 #	4.98	3.42 #
	SD	1.41 *	1.28 *	1.24 *	1.1 *	0.95 *	0.83 *	0.63 *	0.76	2.01 *

Five breaths located in the middle of the record were selected from each experimental series, and values were expressed as mean ± SD.
The values were compared with those obtained by 2 L/min of bias flow.
Significant difference via unpaired t-test.
* Significant difference via F-test.

Table 2 Effects of a reservoir bag on pressure swing magnitude at 1 to 7 L/min of bias flow rate under no-leak condition

Respiratory rate (breaths/min)	Reservoir bag	V'bias (L/min)			
		7	5	3	1
30	(+)	5.5±1.31	5.34±0.93	4.96±0.67 #	2.80±1.37 *#
	(−)	5.54±1.43	5.35±1.10	5.25±0.7	3.45±1.73
60	(+)	5.49±1.32	5.31±1.03	4.55±1.15 *	3.02±1.65 *#
	(−)	5.51±1.43	5.31±1.12	4.55±1.39	2.78±2.34
90	(+)	5.57±1.48	5.17±1.31 *	4.41±1.35 *	3.25±1.82 *#
	(−)	5.60±1.61	5.43±1.55	4.35±1.97	2.27±2.74

The Pdistal data (cmH_2O) of five breaths are expressed as mean ±SD.
Significant difference via unpaired t-test.
* Significant difference via F-test.

Ⅳ Results

A Effects of bias flow magnitude on mean airway pressure under no-leak condition

When the bias flow was between 9 L/min and 2 L/min, the mean delivered pressure was 5 cmH_2O or higher (**Fig. 2** and **Table 1**). It should be noted that the difference between the mean delivered pressure and the intended pressure was only approximately 1 cmH_2O at a bias flow of 9 L/min. When the bias flow was 1 L/min, the mean delivered pressure decreased to 3.42 cmH_2O. In addition, bubbling disappeared and the aqueous column in the underwater tube flowed back in the inspiratory phase.

B Effects of a reservoir bag on pressure swing magnitude under no-leak condition

Under no-leak condition, the Pmean and SD (as pressure swing magnitude) of 5 breaths located in the middle of the record were statistically analyzed in the presence or absence of a 500 mL soft reservoir bag. The results are presented in **Table 2**. There was no substantial difference in Pmean in the presence or absence of a reservoir bag at a bias flow of 3 L/min and a respiratory rate of 60 or 90 breaths/min. However, use of a reservoir bag resulted in a significant decline of the SD at 60 breaths/min and 90 breaths/min. A reservoir bag-mediated decrease in the SD was larger at a bias flow of 1 L/min, as compared with the values at a bias flow of 3 L/min. On the other hand, SD as well as the mean in the presence of a reservoir bag were similar to the values in the absence of a reservoir bag at a bias flow of 7 L/min and a respiratory rate of 30, 60 or 90 breaths/min.

C A reservoir bag attenuates rapid aspiration-induced decrease of the mean pressure at a low bias flow under no-leak condition

To simulate hiccups, using a syringe, 60 mL of air was aspirated rapidly and synchronously with the inspiration phase, and was returned to the circuit in the expiratory phase. When the bias flow was 3 L/min, rapid aspiration decreased the mean airway pressure to 1.21 cmH_2O in the absence of the reservoir bag, as shown in **Fig. 3**. In the CPAP with a reservoir bag, rapid aspiration-induced decrease of the mean airway pressure was attenuated (3.03 cmH_2O). When the bias flow was 1 L/min, rapid aspiration caused negative mean airway pressure in the absence of a reservoir bag (−1.43 cmH_2O), whereas the mean airway pressure was 2.01 cmH_2O in the presence of a reservoir bag. On the other hand, a reservoir bag-mediated decline of the mean airway pressure was inferior at a bias flow of 5 L/min (data not shown).

D Influence of leak flow on the mean airway pressure

We examined the effects of leak on the mean airway pressure at 5 L/min of bias flow. When the leak valve was completely opened, bubbling disappeared, and the mean V'leak revealed approximately 5 L/min, as shown in **Fig. 4**. According to the formula reported by Fischer et al.[16], we defined it as 100 % of a leak. The airway pressure swing decreased with increasing leak flow. During moderate leakage, intermittent bubbling and a suboptimal mean airway pressure were observed. When bubbling disappeared due to complete opening of the leak valve, the mean airway pressure was maintained at approximately 2 cmH_2O.

E Effects of bias flow magnitude on the mean airway pressure under 100 % leak condition

We examined whether an increase in the bias flow could secure the intended CPAP level of 5 cmH_2O even under 100 % leak condition. As shown in **Fig. 5**, the mean airway pressure increased with increasing bias flow. When the bias flow was 9 L/min, approximately 5 cmH_2O mean airway pressure was obtained.

Ⅴ Discussion

Oxygenation is tightly linked to the mean airway pressure applied to the lung. On the basis of the results reported by Kahn et al.[17], the mean airway pressure in bubble CPAP is generated mainly by the submersion depth of the CPAP generator and the bias flow. They reported, using a static lung model, that the pressure delivered in a bubble CPAP system was >2 cmH_2O higher than the immersion

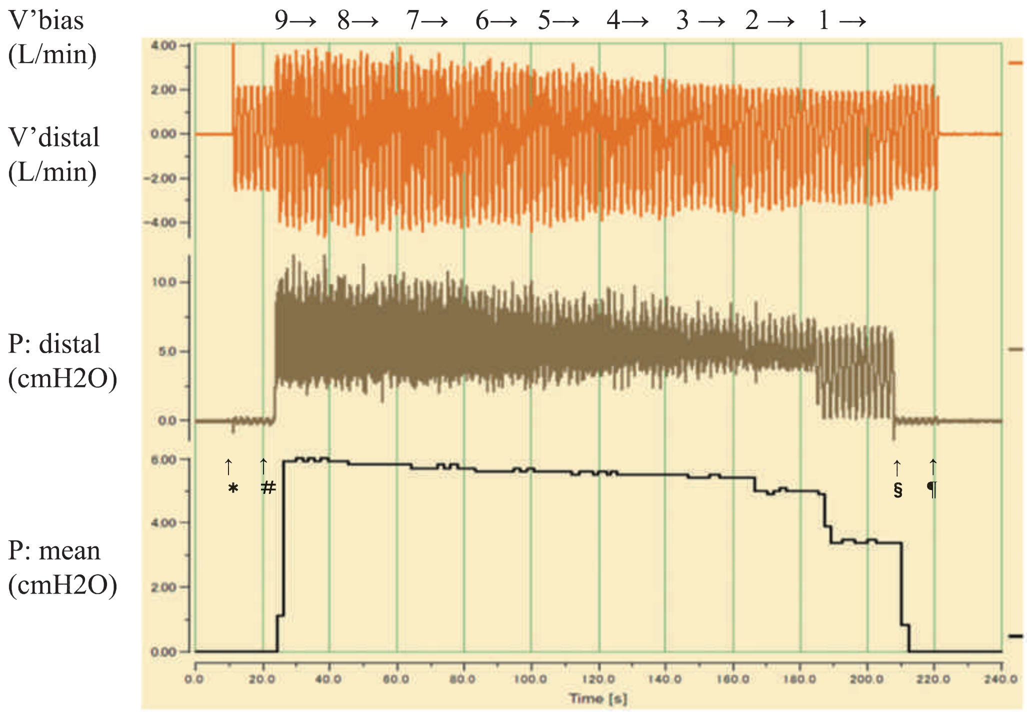

Fig. 2 Effects of bias flow magnitude on mean lower airway pressure under no-leak condition
Effects of bias flow rates ranging from 9 L/min to 1 L/min were examined under the condition of no leak.
* Simulator on ; # Start CPAP ; § Stop CPAP ; ¶ Simulator off.

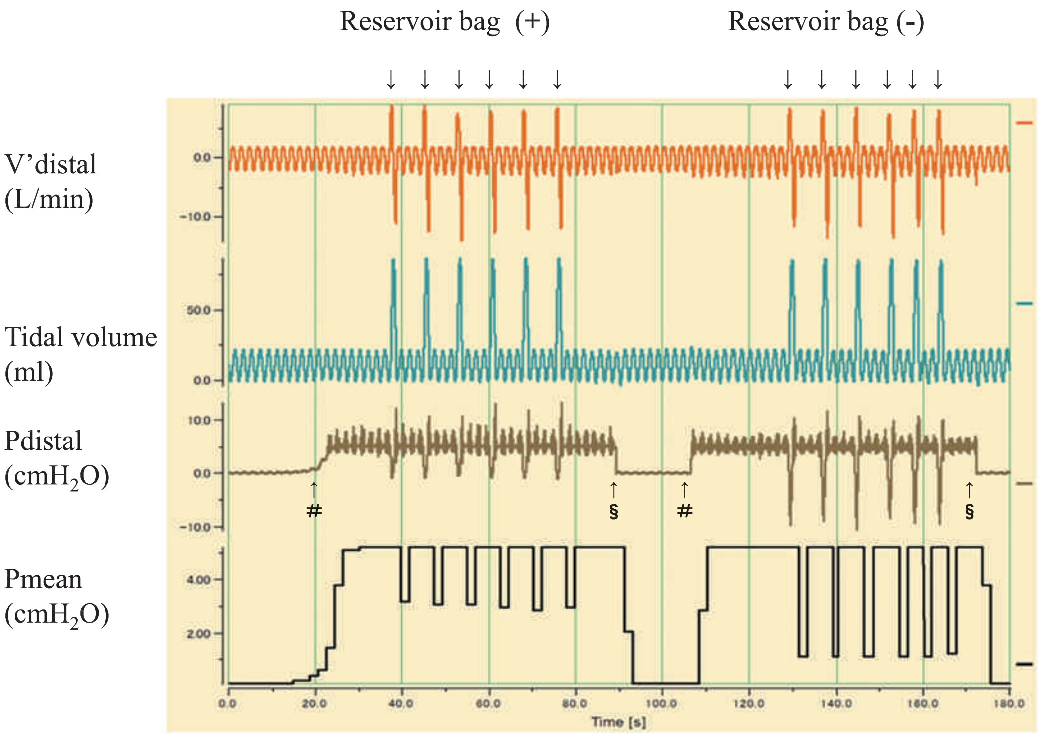

Fig. 3 A reservoir bag attenuates rapid aspiration-induced decrease of the mean airway pressure
To simulate hiccups, 60 mL of air was aspirated rapidly and returned to the circuit synchronously with the inspiration phase and expiratory phase, respectively, using a syringe. The bias flow was set at 3 L/min.

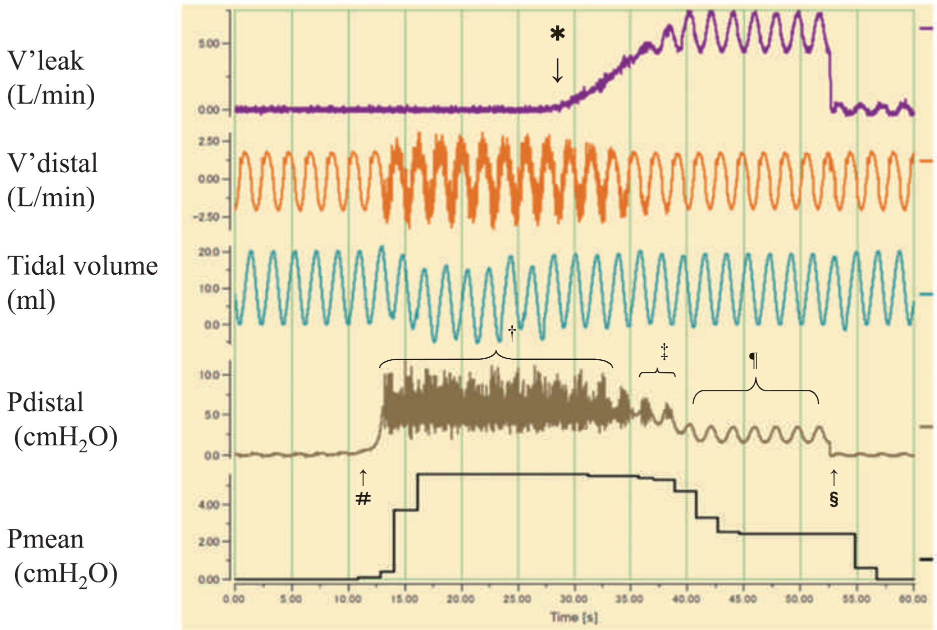

Fig. 4 Influence of a leak flow on the mean airway pressure

We examined the effects of leakage on the mean airway pressure. The leak was changed from 0 % to 100 % using a leak valve. When bubbling disappeared, we defined it as representing 100 % of leak. The bias flow was set at 5 L/min.

† continuous bubbling ; ‡ intermittent bubbling ; ¶ no bubbling.

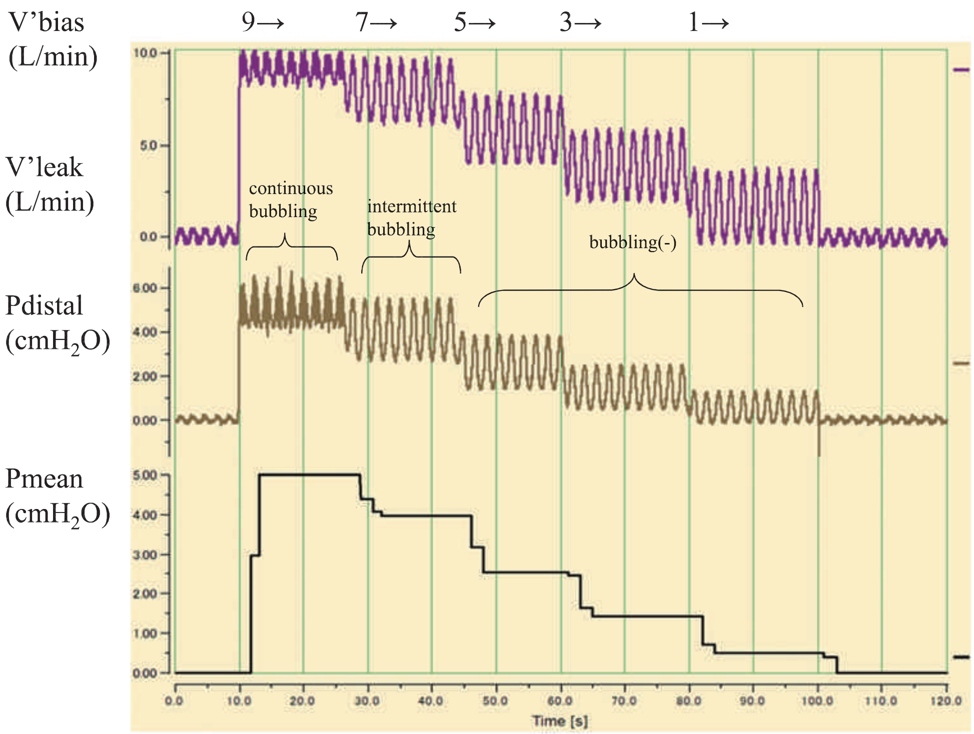

Fig. 5 Effects of bias flow magnitude on the mean airway pressure under 100 % leak condition

We examined whether an increase in the bias flow could get close to the intended CPAP level of 5 cmH_2O under 100 % leak condition. The bias flow was changed from 9 L/min to 1 L/min.

depth of the expiratory tubing with an inner diameter of 10 mm when the bias flow was 8 L/min under no-leak condition. The pressure overshoot became greater as the flow magnitude increased. This pressure overshoot was also observed in preterm infants[18]. In the present study, the difference between the mean delivered pressure and the intended pressure (5 cmH_2O) at a bias flow of 9 L/min was only approximately 1 cmH_2O. Mestriner et al.[19] pointed out that the inner diameters of both expiratory tube and air-escape orifice are important to obtain an exact airway pressure : the tubing must be 8 mm or larger in inner diameter, and the air-escape orifice should be 8 mm or larger. The CPAP generator used in our study had an irrigation funnel on the cap, which might function as a sufficient air-escape orifice. Additionally, the inner diameter of the expiratory tube of the CPAP circuit was 10 mm. Therefore, these two factors may account for the smaller difference between the mean delivered pressure and the intended pressure. When the bias flow is set between 2 L/min and 9 L/min, the Fisher & Paykel Healthcare bubble CPAP system may safely support the breathing of neonates with closed mouths at rest.

A reservoir bag is a traditional device to stabilize the pressure in a respiratory circuit[20]. Nevertheless, it remains unclear whether the addition of a reservoir can clinically attenuate the imposed inspiratory work of breathing and reduce the pressure swing induced by hiccups or sighs. In the present study, there was no substantial difference in Pmean in the presence or absence of a reservoir bag at a bias flow of 3 L/min and a respiratory rate of 60 or 90 breaths/min. However, use of a reservoir bag resulted in a significant decline of the SD at both 60 breaths/min and 90 breaths/min. On the other hand, the mean and SD in the presence of a reservoir bag were similar to the data in the absence of a reservoir bag at a bias flow of 7 L/min and a respiratory rate of 30, 60 or 90 breaths/min. In the CPAP with a reservoir bag, rapid aspiration-induced decreases of the mean airway pressure were attenuated at a bias flow of 3 L/min, whereas a reservoir bag-mediated decline of the mean airway pressure was smaller at a bias flow of 5 L/min. Accordingly, a bias flow of 6-9 L/min is generally used for neonates with respiratory distress in the developed countries. Given the present results, use of a reservoir bag plus the bubble CPAP system may be clinically anticipated to improve the inspiratory work of breathing imposed at a low flow, particularly in neonates with tachypnea. Additionally, it is expected that a reservoir bag attenuates momentary and sequential decreases of the mean airway pressure induced by hiccups at a low flow.

Neonatal vital capacity is almost 40 mL/kg. In a neonate with 3 kg of body weight, 120 mL of medical gas was necessary in the appearance of a sudden hiccup. Since several hiccups occur sequentially, we set 500 mL as the capacity of the reservoir bag in this study. In the case of an infant, a larger reservoir bag may be required.

Unlike test lungs or intubated neonates, leaks are clinically problematic for the employment of nasal CPAP. In addition to leakage through the junction between the device and the nostril, mouth opening causes a markedly high level of leakage[21]. A chin strap has been used to close the mouth, but long-term fixation of the lower jaw is unfavorable for neonates. The latest model of the CPAP generator can cope with varying leaks and adjust the bias flow to maintain the desired pressure for neonates using a computer-controlled feedback system. In developing countries, a low flow setting is desirable to save medical gas. In the present study, we examined the effects on the airway pressure of the leak flow produced by opening a leak valve. Although the airway pressure swing decreased with increasing leak flow, intermittent bubbling and a suboptimal mean airway pressure were observed during moderate leakage at a bias flow of 5 L/min. Mean airway pressure of approximately 2 cmH_2O was retained at a bias flow of 5 L/min when the leak valve was completely opened. This finding may be model-dependent, because the possibility of the resting pressure caused by the flow resistance of the valve and the pneumotachograph can not be excluded.

Our findings may be related to evidence that 5 cmH_2O of the set pressure at the prongs dropped to approximately 2-3 cmH_2O at the pharynx when preterm infants opened their mouths[21]. Leak appears to be generated by a difference between airway pressure and atmospheric pressure. The absence of a difference in the mean pressure with or without the reservoir bag suggests that the reservoir bag does not influence leak volume.

In conclusion, inclusion of a reservoir bag in the bubble CPAP may offer an effective and inexpensive option for providing respiratory support to preterm infants.

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(2012. 12. 18 received ; 2013. 1. 8 accepted)