

Assessment of a new valveless infant ventilator

K N CHAN,* M K CHAKRABARTI, J G WHITWAM, AND M SILVERMAN*

Departments of *Paediatrics and Anaesthetics, Royal Postgraduate Medical School, Hammersmith Hospital, London

SUMMARY A new valveless ventilator, which uses an air jet to provide the driving force for positive pressure ventilation, was used on 13 newborn babies (10 of very low birthweight) who had severe respiratory disease. The ventilator differs from 'true' jet ventilators in that its driving gas does not take part in gas exchange. Functionally it is a pressure pre-set, time-cycled ventilator, whose performance is characterised by the rapid and precise maintenance of both inspiratory and expiratory airway opening pressure. All the babies had progressively worsening respiratory failure (mean values of arterial pCO₂ were 9.46 kPa, with a pH of 7.14, and an inspired oxygen concentration of 92.5%) on conventional mechanical ventilation. On the new ventilator, with the same settings, there was a dramatic and highly significant improvement within 20 to 30 minutes (mean values of arterial pCO₂ were 6.45 kPa, pH 7.26, and inspired oxygen concentration 85.7%). This improvement was maintained. The new ventilator represents an important advance in the management of babies with severe respiratory failure.

A new valveless ventilator has been developed at this hospital.^{1,2} The prototype, CW200, comprises two jets in a single tube (see fig 1). The driving jet delivers intermittent pulses of unconditioned gas, which provides the driving force for positive pressure ventilation, whereas the positive end expiratory pressure (PEEP) jet provides continuous gas flow that maintains positive pressure in the breathing circuit throughout the respiratory cycle. The gas

supply for these jets can be derived from any single convenient source: from either a piped supply of commercially available cylinders (air or oxygen). It need not be conditioned as it does not enter the patient's respiratory system. A low flow of an appropriate mixture of air and oxygen (roughly 2 l/minute for general neonatal use) that has been adequately warmed and humidified enters the breathing circuit close to the endotracheal tube. The

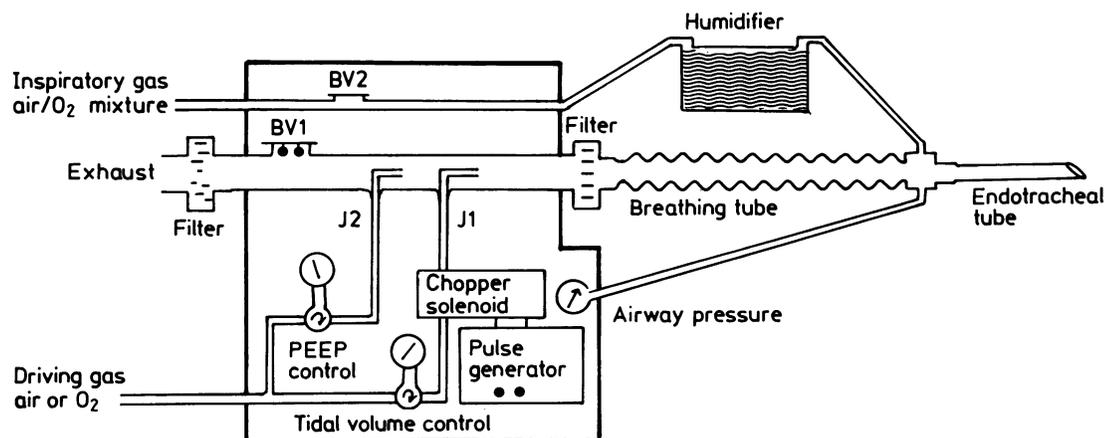


Fig 1 Schematic diagram of CW200 ventilator. J1:driving jet; J2:PEEP jet; BV1 and BV2:blow-off valves.

driving jet functions like a pneumatic piston, it raises the pressure of the airway opening and drives the desired tidal volume of fresh respiratory gas collected in the breathing circuit into the patient's airways. The lung inflation pressure, and hence the tidal volume, is controlled by adjusting the pressure of the driving jet, independent of the fresh gas flow.

Functionally the CW200 is a pressure pre-set, time-cycled ventilator. It has no occluding valve or 'thumb like' device to limit gas exit from the circuit during the positive pressure (inspiratory) phase of the respiratory cycle. The breathing circuit is open to atmosphere at all times. It is capable of providing continuous positive airway pressure and intermittent positive pressure ventilation at low, normal, and high frequencies (range 0–200/minute). It differs from commercially available jet ventilators in that its driving jet is not placed at or near the patient's endotracheal tube and its output does not take part in gas exchange. Therefore tracheal complications and problems with conditioning of respiratory gas associated with true jet ventilators are not likely to occur.^{3–5}

The features and versatility of this ventilator would make it suitable for neonatal use. Because there are established mechanical ventilators in use in our unit we set out to evaluate its performance by

comparison with conventional ventilators. In preliminary observations we found it to be equivalent to existing mechanical ventilators in infants whose respiratory distress was easily controlled by conventional ventilator settings. We report our experience in the management of progressive respiratory failure in infants where conventional mechanical ventilation had failed.

Patients and methods

The performance of the CW200 was compared with other ventilators: the Vickers Neovent Model 90 (Vickers Medical, Basingstoke), SLE Newborn (SLE Ltd, Croydon), and the Sechrist Model IV 100B (EME, Brighton); the Neovent 90 is the most often used currently in our unit.

LABORATORY EVALUATION

Although the efficacy of different ventilators in neonatal respiratory support is not directly measurable in the laboratory, the mechanical properties of the different systems are likely to be reflected by the pattern of gas flow and pressure output. A standard breathing circuit, like that in use in our unit, was set up. A model lung of known compliance (1 ml/cm

Table 1 Characteristics, sequelae, and outcome of infants with acute respiratory failure

Patient No	Gestational age (weeks)	Birth weight (g)	Respiratory diagnosis before using CW200	Outcome	Respiratory sequelae (or necropsy results)
1	26	480	IRDS, PIE	Died at 2 weeks	(No necropsy)
2	29	550	IRDS, PIE	Died at 1 week	(Severe BPD, alveolar haemorrhage, tracheal lesions)
3	27	640	IRDS, PIE, pneumothoraces	Alive	BPD, O ₂ dependence for 2 months
4	28	720	IRDS	Alive	BPD, O ₂ dependence for 10 weeks
5	27	750	IRDS, PIE, BPD	Died at 2 weeks	(Severe BPD, bronchopneumonia, tracheal excoriation)
6	28	780	IRDS, PIE	Alive	O ₂ dependence for 8 weeks
7	30	910	IRDS, PIE, BPD	Died at 4 months	(No necropsy)
8	26	920	IRDS, PIE, pulmonary haemorrhage	Died at 2 days	(PIE with alveolar haemorrhage, extensive tracheal excoriation)
9	28	950	IRDS	Alive	None
10	28	1000	IRDS, pneumothorax	Alive	O ₂ dependence for 6 weeks
11	31	1800	IRDS, unilateral PIE	Alive	None
12	41	2900	Meconium aspiration, Persistent fetal circulation	Alive	O ₂ dependence for 3 weeks
13	38	3190	Diaphragmatic hernia, Hypoplastic left lung, Persistent fetal circulation	Alive	None

IRDS: idiopathic respiratory distress syndrome; PIE: pulmonary interstitial emphysema; BPD: bronchopulmonary dysplasia.

H₂O) was connected in series with a resistance block (50 cm H₂O/l/second). It was filled with copper wool to ensure that changes occurring in the model were isothermal, 'intubated' with a size 2.5 mm Portex endotracheal tube, and connected to the ventilation circuit in series with an empty water trap (internal volume 55 ml) and a full humidifier (Vickers 90). The airway opening pressure and 'lung' pressure were recorded by pressure transducers (Bell Howell type 4-442, Bell and Howell Ltd, Wembley). A pneumotachograph (Godart, Cardiokinetic Ltd, Manchester) was placed at the distal end of the endotracheal tube. Recordings of flow and pressure were obtained simultaneously on a two channel recorder (Devices, INM Intermedics, Welwyn Garden City). The different ventilators were studied in turn using the same breathing circuit and identical settings, which were arbitrarily chosen as follows: peak inspiratory pressure, 20 cm H₂O; positive end expiratory pressure (PEEP), 3 cm H₂O; gas flow rate, 7 l/minute (except for CW200, which was 2 l/minute); the inspiration:expiration ratio was 1:1. The rate of ventilation was increased in steps from 30 to 150/minute, except for Neovent 90 where a maximum rate of 90/minute was used. The pressure transducers and pneumotachograph were repeatedly calibrated during recording.

The Sechrist ventilator has an expiratory assist device. We used this to prevent high levels of circuit PEEP, with a fresh gas flow of 20 l/minute, to try to mimic the CW200.

CLINICAL EVALUATION

The criteria for trial on the CW200 ventilator included: PaCO₂ greater than 8 kPa or PaO₂ less than 4 kPa despite an inspired oxygen concentrations approaching 100%. Of the 13 babies studied consecutively on 15 occasions, 11 were preterm (gestational age 26-31 weeks) with respiratory distress syndrome and its complications, 10 had a birth weight under 1 kg, and two were term infants with severe pulmonary illness (table 1). All had been paralysed with pancuronium because of their severe respiratory failure. When the criteria for a trial on the CW200 were reached a change from the conventional ventilator was made. The ventilator settings were initially kept identical in order to facilitate comparison of ventilator performance. The pressure gauges of different models had previously been shown to give identical readings for pressures up to 50 cm H₂O with a water manometer. Arterial blood gases were measured immediately before and 20 minutes after the change.

Statistical analysis was by the paired sample *t* test.

Table 2 Ventilator settings, mean arterial pH, PaCO₂, and PaO₂/FiO₂ ratio in the hour before and after changing to the CW200 ventilator

Patient	Ventilator settings			pH	PaCO ₂ (kPa)		PaO ₂ /FiO ₂ (kPa)		
	PIP* (cm H ₂ O)	PEEP† (cm H ₂ O)	Rate (minute)		Neovent	CW200	Neovent	CW200	Neovent
				Neovent	CW200	Neovent	CW200	Neovent	CW200
3	28	3	60	7.2	7.3	9.5	6.3	10.0	11.6
4	27	4	70	7.1	7.2	10.3	7.5	13.3	24.4
5 (b)‡	32	3	70	7.2	7.24	8.6	6.9	10.1	13.7
6	26	4	70	7.1	7.3	9.0	5.7	12.0	12.9
7	30	2	75	7.0	7.05	10.5	7.7	3.6	7.0
8	28	2	60	7.34	7.41	5.3	4.2	4.0	4.6
9	24	3	52	7.0	7.0	10.9	8.9	21.9	17.8
11	30	4	75	7.0	7.15	14.2	9.3	17.0	22.2
12	26	3	40	7.24	7.5	6.3	3.7	3.3	5.5
13	24	2	70	7.25	7.46	6.9	4.9	3.4	7.1
				SLE	CW200	SLE	CW200	SLE	CW200
2 (a)‡	22	3	70	7.06	7.24	11.0	5.5	5.0	8.7
2 (b)‡	30	2	80	7.0	7.1	11.3	8.3	3.1	5.1
10	37	4	90	7.15	7.29	10.1	6.8	11.6	12.1
				Sechrist	CW200	Sechrist	CW200	Sechrist	CW200
1	26	2	85	7.19	7.26	8.4	7.1	8.0	11.5
5 (a)‡	32	4	100	7.24	7.42	9.6	4.0	6.7	4.8
Mean	28.1	3	71.1	7.14	7.26	9.46	6.45		
Probability				<0.001		<0.001		<0.01	

*PIP=peak inspiratory pressure; †PEEP=positive end expiratory pressure.

‡Patients 2 and 5 were studied twice.

Results

LABORATORY EVALUATION

All three conventional ventilators produced similar pressure waveforms at frequencies of up to 90/minute. The inspiratory gas flow through the endotracheal tube and into the model lung was distinctly higher for the CW200 than for the other ventilators at identical settings (fig 2). Because of its design the CW200 produced a peak inspiratory gas flow rate of 6 l/minute, which was much higher than the fresh gas flow (2 l/minute). For the other conventional ventilators the peak inspiratory flow rate did not exceed 3 l/minute and was less than the fresh gas flow (7 l/minute). The high inspiratory gas flow for the CW200 meant that the time required to reach the target lung pressure, and therefore to deliver the desired tidal volume, was less than for conventional ventilators. This is reflected in the slope of the 'lung' pressure profile, giving it a 'square' pressure plateau at low frequencies and higher 'lung' pressure at high frequencies. The higher 'lung' pressure meant that,

for the same airway opening pressure, the CW200 delivered larger tidal volumes to the model lung at frequencies over 60/minute.

When we tried to mimic the CW200 by using a Sechrist ventilator at a fresh gas flow of 20 l/minute (with expiratory assist), although the circuit and 'lung' waveforms improved, they remained inferior. In particular, the pressure plateau was less 'square' and at 'lung' level, the fall in peak pressure at high frequencies was still greater than with the CW200.

CLINICAL EVALUATION

The CW200 ventilator was easily adapted to a standard breathing circuit as used on our ward. The mean arterial pH, carbon dioxide tension (PaCO₂) and ratio of oxygen tension to inspired oxygen fraction (PaO₂/FiO₂) in the hour before the change from conventional ventilation to the CW200 was an index of the severity of respiratory failure (table 2). Using identical settings the change resulted in lowering of PaCO₂ and improvement in pH on every occasion, and increase in PaO₂/FiO₂ ratio on 13 out

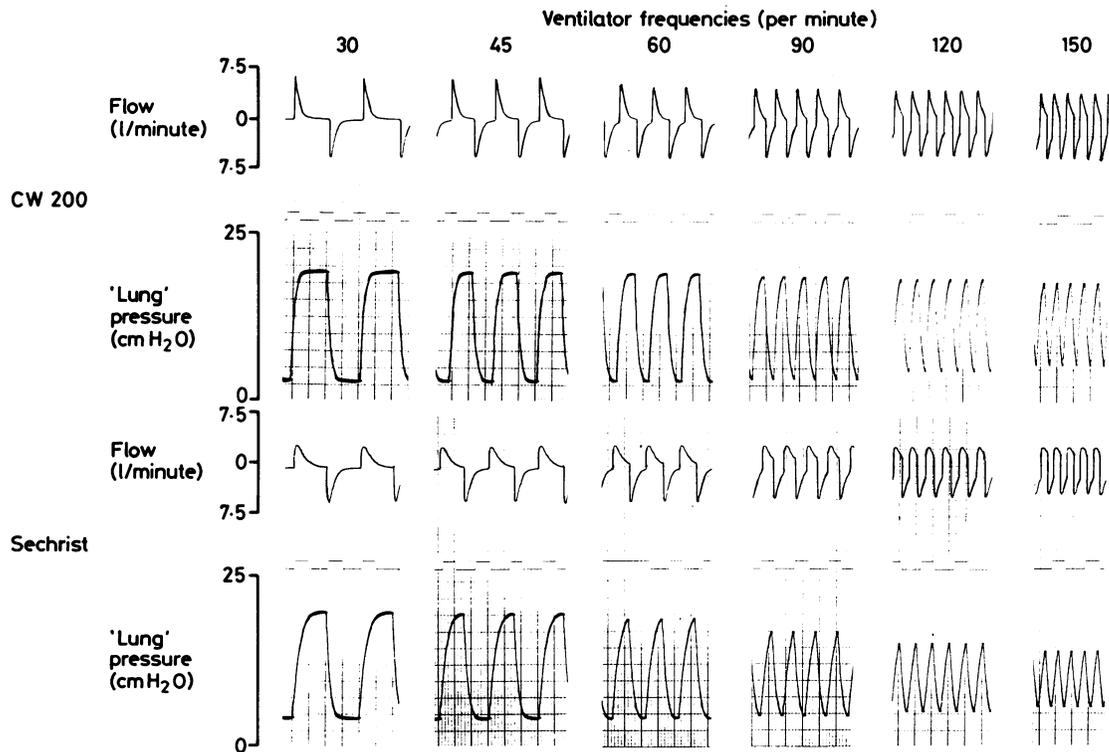


Fig 2 Gas flow and pressure in the model lung at several frequencies for the CW200 and Sechrist mechanical ventilators. The conventional ventilator failed to deliver the pre-set peak inspiratory pressure at a frequency of about 60/minute, the CW200 began to fail at about 90/minute. Inspiratory flow rate was higher at all frequencies with the CW200; expiratory flow rates were similar for both ventilators.

of 15 occasions. One of the two infants whose $\text{PaO}_2/\text{FiO}_2$ ratio fell had been hyperoxic (as well as hypercapnic) on conventional ventilation. In the other infant the small decline in oxygenation had to be compared with an appreciable improvement in PaCO_2 . The mean changes in PaCO_2 and $\text{PaO}_2/\text{FiO}_2$ were highly significant ($p < 0.001$ and < 0.01 , respectively). In the three cases in which the indication for change was persistent hypoxia (patients 8, 12, 13), improvement in oxygenation and $\text{PaO}_2/\text{FiO}_2$ ratio occurred in all three.

Five infants died, four in the neonatal period and one several months later due to chronic lung disease (bronchopulmonary dysplasia) (table 1). Necropsy performed on three infants showed evidence of hyaline membrane disease with interstitial emphysema (PIE); it confirmed alveolar haemorrhage in one infant (patient 8), and severe bronchopulmonary dysplasia with alveolar haemorrhage in the other two (patients 2 and 5). Tracheal lesions were evident in all three, ranging from partial desquamation and squamous metaplasia (patient 2) to severe excoriation (patients 5 and 8).

Eight infants developed signs of pulmonary air leaks (PIE and pneumothoraces). The occurrence of seven of them preceded the use of the CW200. A single pneumothorax occurred while patient 7 was being weaned off the CW200 ventilator. In addition, five infants developed chronic oxygen dependency for three weeks to four months after treatment on a ventilator. At the time of writing the youngest of the survivors in our series was 3 months old whereas the oldest was 13 months. None of them required ambulant oxygen treatment at home. There was no clinical evidence of upper airway problems among the survivors.

Discussion

This valveless ventilator is novel in that the driving force for lung inflation is provided for by a pneumatic piston. Provided that the fresh respiratory gas flow is more than twice the minute volume (greater than about 500 ml/kg/minute even at the highest frequencies of ventilation) and the internal volume of the breathing circuit between the driving jet and the endotracheal tube is more than the patient's tidal volume, the driving gas does not enter the patient's pulmonary system and therefore need not be conditioned. With the high peak inspiratory gas flow the CW200 is particularly advantageous at high frequencies of ventilation over 60/minute when the inspiratory time is inevitably short. In this study, it was assessed at relatively high frequencies (table 2), at which our laboratory studies had shown conventional ventilators to be failing (fig 2). At lower

frequencies the CW200 ventilator was no more effective than the existing ventilators.

For conventional ventilators the driving force for lung inflation is derived from the build up of pressure in the breathing circuit due to obstruction of the gas exit during the inspiratory phase while respiratory gas flow continues. During this time the gas in the breathing circuit is compressed, and then is discharged during the expiratory phase without actually contributing to the tidal gas exchange. This part of 'wasted' tidal volume is known as compressible volume. Its presence reduces the rate at which the target inspiratory pressure is reached at the onset of the inspiratory phase and therefore reduces the time available to deliver the tidal volume. Any leaks in the circuit will reduce the filling rate even more. Our experimental results suggested that the CW200 behaved as if the compressible volume were low. Its mode of operation would be more capable of overcoming minor leaks in the breathing circuit that were due to worn humidifier seals or endotracheal tube leakage. On the other hand, if there is a major leak in the fresh gas supply limb, or if the latter becomes accidentally disconnected, the unconditioned driving gas can inadvertently reach the patient's pulmonary system.

When attempts are made to use a conventional ventilator circuit at high frequencies, a higher gas flow into the breathing circuit is often used in order to compensate for large compressible volumes. This manoeuvre creates two further problems. Firstly, a high gas flow may exceed the output of the humidifier for conditioning of the respiratory gas; this leads to adverse consequences in the patient's airways.⁶ Secondly, the resistance to high gas flow through the exit valve may result in unacceptably high PEEP with its attendant undesirable effects. Although this circuit PEEP can be eliminated by an expiratory assist device, this has little effect on intrinsic PEEP at alveolar level.

With the CW200 ventilator the inflation pressure is not dependent on the flow rate of the fresh respiratory gas. Changes in ventilator pressure and frequency to meet the changing conditions of the baby can be made easily without any need for adjustment of fresh gas flow rate. The low fresh gas requirement means there is less wastage of respiratory gas and its conditioning is less dependent on the output of the humidifier, which may be less than adequate.⁷ Unlike the blow off valves of conventional ventilators whose escape pressure is not always precise the CW200 is open to atmosphere throughout the respiratory cycle. It is therefore intrinsically very safe, as the driving gas always flows back to atmosphere once the pre-set pressure in the breathing circuit is reached.

There are practical and ethical difficulties in designing a clinical trial of mechanical ventilation in conditions of acute respiratory failure. A cross over study was not possible as the response to the CW200 ventilator was so obvious in all cases that it would have been unethical to return these infants immediately to the conventional ventilation. Under these circumstances statistical analysis is of less value than the power of clinical observation. We cannot say whether, by using the CW200 from the outset, it might have been possible to prevent the development of severe respiratory failure. These infants, having shown improvement in blood gases, were kept on the CW200 until the ventilatory requirements could be sufficiently reduced and conventional ventilation was considered adequate, though two infants subsequently developed respiratory failure again after returning to conventional ventilation.

Our study has clearly shown that this new ventilator is superior to that of conventional pressure-limited time-cycled mechanical ventilators for infants with severe lung disease, especially when relatively large compressible volumes are present in the circuitry. The improvement in blood gases brought about by this ventilator was often followed by improvement in the patient's general condition, although five out of the 13 infants subsequently died. A further five who developed chronic oxygen dependency all had evidence of pulmonary interstitial emphysema before they were put on the CW200 ventilator. The high pulmonary complication and mortality rate in our series reflects the severity of their underlying lung disease. Only one new episode of air-leak occurred during the trial of this ventilator: as patient 7 was being weaned off the ventilator.

There have been numerous reports of local tracheal complications with neonatal high frequency jet ventilators.³⁻⁵ These are thought to be related to the fact that the 'jet' was close to the patient's airway and that adequate conditioning of the respiratory gas was difficult to maintain. Although the CW200 utilises an air jet to provide the force for lung inflation, it functions as a pneumatic piston. The output from the jet only pushes humidified respiratory gas into the breathing circuit and not directly into the patient's airway. Tracheal lesions, nevertheless, were observed in all three infants who underwent necropsy examination. This suggests that mechanical factors other than the inadequate conditioning of respiratory gas alone have a role in the aetiology of these lesions.

The improvement in blood gases brought about by the use of this new ventilator seems likely to be due to delivery of larger tidal volumes in these infants who, in general, had low lung compliance and high airways resistance.⁸ The waveforms shown in fig 2 suggest that at higher frequencies the mean 'lung' pressure was higher with the CW200; this could contribute to better oxygenation. It is also possible that high initial inspiratory gas flow rates, which we observed in the model lung, lead to improved CO₂ scavenging from the lungs.

In conclusion, our preliminary uncontrolled study has shown that this new valveless infant ventilator was more effective than conventional ventilators in providing mechanical ventilation to newborn babies in severe respiratory failure. Prospective, controlled studies will be needed to ascertain whether deteriorating respiratory failure can be prevented by its use, and to determine what influence it has on airway complications and mortality rate in such infants.

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Correspondence to Dr M Silverman, Department of Paediatrics, Royal Postgraduate Medical School, Hammersmith Hospital, Ducane Road, London W12 0HS.

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