Laboratory and Clinical Evaluation of a New Volume Ventilator*

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A three phase laboratory and clinical evaluation of a new fluidically controlled volume ventilator (Ohio 550) was undertaken to determine if this more compact, less complex and less costly unit retained the multiple advantages which have been established for volume ventilators in the continuous ventilatory support of patients in respiratory failure. Inspired volume, peak pressure, and flow rates were continuously monitored while a "test lung" was ventilated with its "effective compliance" reduced, and ambulatory patients with varying degrees of obstructive and restrictive ventilatory impairment were ventilated with the 550 respirator. Since adequate tidal and minute volumes were achieved under these conditions of markedly altered breathing mechanics, ten patients in acute respiratory failure requiring mechanical ventilation were managed with the 550 respirator. Aside from the absence of a sighing device, not considered by the authors to be a major disadvantage, the mechanical characteristics, inspired oxygen control and alarm systems were judged satisfactory and compared favorably with the volume ventilators currently available. The fluidic control system is expected to enhance the reliability and minimize the maintenance required of this respirator.

During the 1960s the advantages of using a volume ventilator for the continuous ventilatory support of patients in respiratory failure became apparent and widely appreciated. In addition to the capability of predetermining and maintaining tidal and minute volumes accurately, even with moderate changes in the patient's mechanics of breathing, these ventilators soon were equipped with elaborate alarm systems, precise control of inspired oxygen concentration, sighing mechanisms and, in some instances, continuously recording devices for expired volumes. Because of these obvious advantages over pressure-limited ventilators, volume ventilators are now used almost exclusively in the intensive care areas of urban hospitals. However, the cost of these units is relatively high. They are considered by some to be unduly complex and their size is occasionally a disadvantage where space around the bed is markedly limited. For these reasons, a manufacturer of respiratory support equipment designed a new volume ventilator which is smaller, less complex and less costly than the units currently on the market, while maintaining the important advantages previously indicated which are now considered essential for effective constant mechanical ventilation.

A prototype of this unit was tested in our labora-
The respirator is powered by 50 psi oxygen. This oxygen source drives the bellows up, and is also internally reduced in pressure to supply the fluidic control system. The maximum dead-ended output pressure of the respirator is 75 cm H₂O and the maximum flow is 95 lpm against 20 cm H₂O back pressure. The pressure and flow capabilities of the machine will vary slightly if supply pressure varies from 50 psi. There is an oxygen mixer in the respirator to provide continuously variable oxygen concentrations to the patient. An electrically heated water, bubble through humidifier is coupled in-line in the patient circuit. Temperature is variable from 32.2°C to 71.1°C with the humidity obtained dependent on temperature and minute volume. It is possible to deliver saturated gas to the patient. A disposable 0.5 micron filter is used to remove bacteria from the output gas before it goes to the patient. The filter is hydrophobically treated to resist water and will not become inoperative in the presence of water. Tests have shown the absence of pathogens downstream from the filter after five days but it is intended that the filter be replaced every 48 hours. The humidifier as well as the rest of the patient circuit is sterilizable.

An accessory positive end-expiratory pressure (PEEP) device for the 550 respirator is in the testing stage. It will be capable of holding a variable and controllable pressure on the exhalation valve up to 15 cm H₂O without altering the ventilator characteristics. In addition, any other commercially available PEEP device could be adapted for use with this respirator.

Air Delivery System

A schematic of the air delivery system is shown in Figure 1. The bottom of the bellows is supported by a cord. The length of this cord is variable, providing an adjustment to the extension of the bellows, and thus the tidal volume. The maximum tidal volume is 2000 ml.

At the start of inspiration, the bellows is fully extended. The interface valve receives a pressure signal from the fluidic control and opens, allowing 50 psi oxygen through the nozzle, then through the Venturi valve and into the canister. The high velocity jet of gas from the nozzle creates a negative pressure upstream of the Venturi valve which holds the relief valve closed. The nozzle and Venturi are designed to produce a flow rate of 30 lpm, and to reduce the pressure downstream of the Venturi, or in the canister, to a maximum of 75 cm H₂O. If the pressure in the canister exceeds this level, the oxygen will not flow through the Venturi, but will flow out the relief valve. If a higher flow rate is desired, the flow control valve can be adjusted to allow more oxygen to enter a chamber upstream of the Venturi. The high velocity jet from the nozzle will entrain this gas and carry it through the Venturi valve into the canister. While a maximum flow rate of 95 lpm against 20 cm H₂O back pressure is obtainable, the maximum pressure attainable will decrease as flow rate is increased, due to increased pressure drop across the Venturi.

The gas entering the canister will cause the bellows to collapse upward forcing the gas trapped inside the bellows into the patient circuit. A second signal from the fluidic control will close the exhalation valve on the patient circuit, so that gas will be directed to the patient. The flow rate entering the canister will be the same as the flow rate out of the bellows, while the pressures inside the bellows will be nearly the same as the pressure in the canister, differing by about 2 cm H₂O, due to the weight of the bellows. Thus, since the pressure in the canister is limited to 75 cm H₂O, the maximum pressure to the patient is also approximately 75 cm H₂O. A pressure gauge measures the pressure in the patient airway, upstream of the filter and humidifier. There is a small difference, depending on flow rate, between the patient and gauge pressure.

When the bellows is fully collapsed, a magnet in the bottom of the bellows actuates a sensor in the top of the canister. This sensor sends a pressure signal to the fluidic control to start an exhalation phase. The signals to the interface valve and the exhalation valve in the patient circuit are removed and the exhalation valve opens so that the patient can exhale to atmosphere. The interface valve closes, and flow no longer enters the canister. Since no flow is going through the nozzle, there is no longer a negative pressure to hold the relief valve closed. This relief valve can open, and the weight of the bellows will force oxygen out of the canister, back through the Venturi, and out to the relief valve. The bellows will drop until it is caught by the cord.

A new inspiratory phase can be started in one of three ways. If the patient tries to inhale, he will create a slight negative pressure in the patient airway. This negative pressure can switch a fluidic amplifier in the control system, which starts another inspiratory phase. The negative pressure at which this amplifier switches is variable from 5 to 0.5 cm H₂O. A visual indicator shows if a breath has been patient-triggered. If the patient does not initiate a breath, a fluidic timer will time out and start an inspiration.Expiration time is adjustable from 1 to 17 seconds. There is no pure assist mode on this respirator. There is also a manual pushbutton that will start on inspiration at any point in a cycle. If this button is held down, the respirator will remain in the inspiration phase, even after the set tidal volume has been delivered.

Oxygen Mixing System

A schematic of the oxygen mixer is shown in Figure 2. The threaded control shaft changes the position of the ball with respect to the two seats so that the relative areas of the oxygen and air inlet passages are changed, but the sum of the two areas is constant. The ball is shaped to make the area change linear with position change. The inlet allows room air to be drawn in through a filter. The oxygen comes from the valve on the bellows driving Venturi system, i.e., oxygen exhausting from the canister goes through the Venturi, out the relief valve, into the standpipe area to ensure that it is at atmospheric pressure, then into the mixer.
Thus, air and oxygen at atmospheric pressure enter the two sides of the mixer. The middle leg is connected to the inside of the bellows and, as the bellows drops, it creates a slight negative pressure inside the bellows, which is transmitted to the third leg of the mixer. Air and oxygen are drawn into the bellows; the proportion of each is determined by the area of each inlet passage, since the pressure drop across each is equal.

Alarms and Safety Systems

The respirator has two alarms: a low pressure (patient disconnect), and a fail-to-cycle alarm. The low pressure alarm has a line that is connected to the patient delivery line. If a pressure greater than 8 cm H2O does not reach the fluidic control through the signal line in 15 seconds, a fluidic timer will time out. Both visual and audible signals will result; the audible signal can be turned off.

The fail-to-cycle alarm can be actuated in one of two ways. If an inspiration does not start at least 15 seconds after the last inspiratory cycle has ended, or an inspiration phase does not end at least five seconds after it begins, fluidic timers will actuate the alarm. Both visual and audible signals will occur; again, the audible signal may be turned off. The fail-to-cycle alarm will also open the exhalation valve on the patient circuit. This is to ensure that if the respirator does not finish its inspiration phase (e.g., if the pressure capabilities of the machine are exceeded and the full tidal volume cannot be delivered), the patient will not be pressurized for more than five seconds. Additionally, there is an adjustable pressure relief valve.

If the respirator should fail, its design will allow a patient who is not apneic to inhale through the check valves on the bellows system, and exhale past the deflated patient circuit exhalation valve.

LABORATORY EVALUATION

Methods

A polygraph recorder with appropriate amplifiers and preamplifiers, pressure transducers, a Lilly-type pneumotachograph screen and electrical integrator are used for continuous recording of "airway" pressure, inspiratory and expiratory air flow and tidal volume. The "test lung" is simply an inflatable rubber bag connected in series to the pneumotachograph and the patient circuit of the respirator. A needle sensing "airway" pressure is inserted into the connecting piece between the pneumotachograph head and respirator tubing. The test lung is considered to have "standard" mechanical characteristics when it is allowed to fully inflate. A clamp is used to exclude portions of the inflatable bag or test lung volume, thereby causing increased "stiffness" of the test lung. "Effective compliance" is calculated as the ratio of tidal volume to peak airway pressure and is used as a general index of the mechanical characteristics of the test lung, being dependent upon both elastic and nonelastic resistance. Oxygen concentration of the delivered gas is measured with a paramagnetic oxygen analyzer and results compared with the indicated values.

Results

Figure 3 illustrates the data from a typical series of experiments with the use of the test system described above. Under "standard" test lung conditions (Fig 3-A), pressure, flow and volume characteristics of normal lungs are reasonably well simulated. At the maximum inspiratory flow setting of the respirator (95 liters per minute), a large tidal volume is generated with a system pressure of only 15 cm H2O. Inspiratory time is slightly less than one second. When the effective compliance is halved by clamping off a portion of the test lung, a normal tidal volume is delivered at moderate flow rate with pressure and inspiratory time unchanged (Fig 3-B). When effective compliance is again half of standard, delivery of a large tidal volume at moderate flow is now associated with a doubling of system airway pressure. There is minimal but insignificant lengthening of the inspiratory time to slightly over one second (Fig 3-C). When effective compliance is halved and an attempt is made to deliver a large tidal volume using maximum inspiratory flow rate (in order to reduce inspiratory time), system pressure of 30 cm is reached and there is early loss of the square waveform for flow, indicating that the maximum mechanical characteristics of the respirator have been reached (Fig 3-D). Further reduction of the effective compliance or increase of inspired volume would prolong the inspiratory phase to an unacceptable time and eventually produce an "inspiratory hold" terminated by opening of the exhalation valve after five seconds (see section on ventilator description). It was considered at this stage of the evaluation that the output characteristics of the ventilator were probably sufficient to effectively ventilate most patients with severe airways or alveolar disease.

Figure 4 displays measured inspiratory oxygen concentration plotted against the oxygen setting indicated on the respirator control panel. The determined oxygen concentration was within 5 percent of the setting indicated at all oxygen levels and in most instances agreement was within 4 percent. This precision is considered adequate for most clinical circumstances.

Clinical Evaluation

Methods

The performance of the ventilator was evaluated in two groups of patients. Initially, airway pressure, flow and tidal volume were monitored, as described previously, while ambulatory patients with several types and levels of severity of respiratory disease were being ventilated. These patients rapidly became accustomed to being connected to the ventilator by way of a mouthpiece while a nose clamp was in place, and after a suitable period of relaxed passive ventilation, the records were considered representative of the performance of the ventilator in these patients with the indicated disorders.

During the next phase of this evaluation ten consecutive patients admitted to the intensive care unit of the Veterans Administration Hospital with acute respiratory failure and who were initially placed on mechanical ventilation during the day shift, are included in this trial. Only patients admitted during this shift were ventilated with the 550 respirator because the nursing staff was initially unfamiliar with this new ventilator and, therefore, it was felt necessary that the investigators assist the technical and nursing staff in the monitoring and close supervision of these patients. The period of mechanical ventilation with this respirator was generally dictated by the clinical situation.

Figure 4. Measured inspired oxygen concentration plotted against indicated setting.

Results

The polygraph recordings for several of the ambulatory patients taken while they were being ventilated by the 550 respirator are displayed in Figure 5. In Figure 5-A, the curves of a patient with moderate obstructive ventilatory impairment are shown with large tidal volume delivered at relatively high flow and modest airway pressure. Data on a patient with moderately severe obstruction to air flow and obesity are shown in Figure 5-B, with a very large tidal volume being easily delivered at near maximum inspiratory flow and moderate airway pressure. In Figure 5-C, a patient with very severe airways obstruction is shown to have delivery of a large tidal volume at submaximal inspiratory flow but with a greater airway pressure than in the previous, less severely obstructed patients. Inspiratory time is acceptably short. Finally, in Figure 5-D, curves from a patient with severe pulmonary fibrosis show adequate tidal volume delivered at near maximum inspiratory flow with generation of moderately elevated pressure. In these patients, who range from those with moderate to very severe obstructive or restrictive ventilatory impairment, fully adequate ventilatory volumes were achieved with maintenance of square wave inspiratory flow, short inspiratory time, and reasonable airway pressures. These results led to the final phase of the investigation of this ventilator.

Eight of the ten patients who were continuously ventilated in the intensive care unit with the 550 respirator had chronic obstructive airways disease, usually with infection as a precipitating event in the development of acute respiratory failure. Pertinent data on these patients are shown in the accompanying table. As can be appreciated by review of the ventilatory function data, often obtained some months prior to the acute episode, these patients had marked impairment of ventilatory function and variable but usually severe disturbance of arterial blood gases. No difficulties in regard to performance of the ventilator were encountered in any of these patients, and adequate tidal volumes were achieved in each of them. The humidifier was clinically judged to be adequate and the alarms worked well. After becoming familiar with the respirator, the nursing personnel felt comfortable while it was being used on their patients. The only
FIGURE 5. A. Patient with moderate obstruction to air flow (FEV₁ between 55 percent and 70 percent of predicted). B. Patient with moderately severe obstruction to air flow (FEV₁ between 45 percent and 55 percent of predicted) and obesity. C. Patient with very severe obstruction to air flow (FEV₁ below 35 percent of predicted). D. Patient with severe restriction of lung volume secondary to pulmonary fibrosis (VC below 50 percent of predicted).

minor complaint was that the patients had to be manually "sighed" because of the absence of a sighing mechanism in the respirator. This presented no significant problem, however, and the sighing was usually performed at the same time that the patient's airways were suctioned. The general assessment of the 550 respirator by both medical and nursing staff was favorable.

**DISCUSSION**

Since the role of a volume ventilator has been established in the effective management of patients in acute respiratory failure in whom mechanical ventilation is necessary, consideration should be given to those features of such a ventilator which are either desirable or necessary. Tidal volume and respiratory frequency must be easily controlled so that adequate alveolar ventilation can be achieved in the wide spectrum of patients whose breathing mechanics vary considerably. Inspiratory flow rate should be separately adjustable and will influence delivery of the predetermined tidal volume in the time interval allowed for the inspiratory phase. It is obvious that a high inspiratory flow will be necessary to deliver a large tidal volume in a short time period. The pressure-flow capabilities of the ventilator must be sufficient to adequately ventilate even those patients with severely disordered respiratory mechanics but there will always be a small proportion of patients with a strikingly abnormal

| Table 1—Clinical and Physiologic Data in Patients Ventilated with 550 Respirator |
|-----------------------------------|------------------|-----------------|-------------------|-------------------|------------------|------------------|------------------|------------------|
| Patient                          | Pat 1—56 M      | Pat 2—53 M      | Pat 3—49 M       | Pat 4—56 M       | Pat 5—79 M       | Pat 6—53 M       | Pat 7—54 M       | Pat 8—60 M       | Pat 9—53 M       | Pat 10—61 M      |
| Diagnosis and Precipitating Event| C Br            | C Br            | Pneum            | C Br             | C Br             | C Br             | C Br             | C Br             | CVA              | C Br             |
| Arterial Blood Gases             | Inf             | Inf             | Meningitis       | Inf              | CVA              | CVA              | Inf              | Inf              | Inf              | Inf              |
| (Initial-Other-Stable)           |                 |                 | Shock            |                 |                 |                 |                 |                 |                 |                 |
| PaO₂ (mm Hg)                     | 35-250-68       | 35-67            | 41-136           | 33-57-53        | 41              | 57-600           | 38-255-60        | 51-436-58        | 46-78-48         | 47-69-48         |
| PaCO₂ (mm Hg)                    | 78-52-64        | 83-42            | 22-25            | 115-54-53       | 60              | 53-32            | 72-48-68         | 58-43-57         | 57-48            | 74-54-56         |
| Peak Pressure (cm H₂O)           | 10              | 8               | 10               | 10              | 10              | 10              | 10              | 10              | 10              | 10              |
| Tidal Volume (ml)                | 750             | 700             | 800              | 800             | 800             | 850             | 750             | 800             | 800             | 800             |
| Ventilatory Period (hrs)         | 12              | 46              | 54               | 24              | 3               | 55               | 53              | 17              | 48               | 24              |
| Ventilatory Function             |                 |                 |                  |                 |                 |                 |                 |                 |                 |                 |
| VC in ml (Percent Pred)          | 1980 (47%)      | 2772 (67%)      | 3036 (72%)       | 2068 (46%)      | 1300 (31%)      | 2156 (48%)       | 4185 (104%)      | 2294 (56%)       |                 |                 |
| FEV₁ in ml (Percent Pred)        | 616 (18%)       | 1700 (54%)      | 836 (26%)        | 484 (12%)       | 800 (25%)       | 484 (20%)        | 1156 (31%)       |                 |                 |                 |
| FEF 25-75 in L/sec (Percent Pred)| 9%              | 44%             | 11%              | 22%             | 19%             |                 |                 |                 |                 |                 |

C Br—Chronic Bronchitis  Inf—Infection  CVA—Cerebrovascular Accident

18 WEILL, WILLIAMS, BURK  CHEST, 67: 1, JANUARY, 1975
respiratory apparatus who cannot be effectively ventilated (and oxygenated) by any mechanical respirator. A ventilator will only be useful, however, if the number of patients who cannot be effectively managed is kept very low. Airway pressure is the dependent variable in a volume ventilator-patient system, but peak pressures attainable must be high enough to assure adequate delivery of inspired volume at sufficiently high flow rates in patients with increased elastic or inelastic resistance or both. Finally, the mechanical characteristics of a volume respirator must provide sufficiently high flow rates in order to permit the delivery of a predetermined inspired volume in one second or less, should a high respiratory frequency be necessary.

Inspired oxygen concentration must be adjustable with reasonable accuracy so that delivery of adequate oxygen levels is assured but with the avoidance of an excessively high inspired oxygen concentration. Alarms should primarily indicate when the patient has become disconnected from the respirator, usually by way of low pressure sensing, and if there is failure of the respirator to cycle. In our view, a high pressure alarm is much less important. Inspired air must be adequately humidified and provision must be made for adequate cleaning and sterilization of the humidifier and patient breathing circuit, but this will not be further discussed here.

The 550 respirator meets the requirements outlined above. This conclusion is based on results of a three phase testing program beginning in the laboratory with the use of a “test lung” system and progressing to ambulatory patients and finally to individuals hospitalized with acute respiratory failure. If an automatic sighing mechanism is considered an essential feature of a respirator, the 550 will not be considered adequate, since such a feature is not included. It is our view, however, that sighing capability is not essential and its absence may, in fact, promote closer nursing care at intervals where chest physical therapy or airways suctioning or both will ordinarily be required anyway. It could even be argued that the efficacy of sighing patients who are being mechanically ventilated has not been convincingly established in terms of preventing atelectatic complications. There may be those who prefer a ventilator powered electrically instead of by a pressurized oxygen source but this will depend on local circumstances and eliminating the need for an electrical power source may in many situations be an advantage.

It should be pointed out that our clinical trial with this ventilator has been limited primarily to patients with chronic obstructive airways disease, but in our experience, these patients have been among the most difficult to ventilate. There is no reason to believe that equally favorable results would not be achieved in patients with diffuse alveolar consolidations (called by some the “adult respiratory distress syndrome”) as seen in such conditions as “shock lung,” fat embolism and diffuse pulmonary contusion. In order to confirm this impression, trial with this ventilator should be carried out in a surgical intensive care unit where such patients are likely to be treated.

Although the reliability of the 550 respirator can only be established by longterm clinical use, there is a reasonable prospect that reliability will be good because of the fluidic controller used in this unit. The pneumatic input of a ventilator makes it ideal for a fluidic control system. This system gathers information, makes appropriate decisions based on predetermined requirements and then instructs the machine components when to act. In replacing electronic devices, a fluidic system has the great advantage of reliability because of the absence of moving parts, giving excellent shock and vibration resistance as well as easy maintenance. The cost is low in large quantities since simplicity allows injection molding from plastic or by metal die casting. It can be anticipated that fluidic control systems will find increasing use in this type of application in the future.

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CHEST, 67: 1, JANUARY, 1975

EVALUATION OF A NEW VOLUME VENTILATOR 19