# Clinical Evaluation of a Computer-controlled Pressure Support Mode

# MICHEL DOJAT, ALAIN HARF, DOMINIQUE TOUCHARD, FRANÇOIS LEMAIRE, and LAURENT BROCHARD

Institut National de la Santé et de la Recherche Médicale (INSERM) U 492, Département de Physiologie, and Service de Réanimation Médicale, Hôpital Henri Mondor, AP-HP, Université Paris 12, Créteil, France

We have designed a computerized system providing closed-loop control of the level of pressure support ventilation (PSV). The system sets itself at the lowest level of PSV that maintains respiratory rate (RR), tidal volume (VT), and end-tidal CO<sub>2</sub> pressure (PET<sub>CO2</sub>) within predetermined ranges defining acceptable ventilation (i.e., 12 < RR < 28 cycles/min, VT > 300 ml [> 250 if weight < 55 kg], and  $P_{ET_{CO_2}} < 55$  mm Hg [< 65 mm Hg if chronic CO<sub>2</sub> retention]). Ten patients received computer-controlled (automatic) PSV and physician-controlled (standard) PSV, in random order, during 24 h for each mode. An estimation of occlusion pressure (P<sub>0.1</sub>) was recorded continuously. The average time spent with acceptable ventilation as previously defined was 66  $\pm$  24% of the total ventilation time with standard PSV versus 93  $\pm$  8% with automatic PSV (p < 0.05), whereas the level of PSV was similar during the two periods (17  $\pm$  4 cm H<sub>2</sub>O versus 19  $\pm$  6 cm H<sub>2</sub>O). The time spent with an estimated  $P_{0.1}$  above 4 cm  $H_2O$  was 34  $\pm$  35% of the standard PSV time versus only 11  $\pm$  17% of the automatic PSV time (p < 0.01). Automatic PSV increased the time spent within desired ventilation parameter ranges and apparently reduced periods of excessive workload.

Pressure support ventilation (PSV) is a mode of partial respiratory support that is widely used, especially during gradual weaning from mechanical ventilation (1-4). Because PSV is not a volume-controled mode, any change in respiratory mechanics modifies the delivered volume. Also, changes in respiratory demand may require adjustment of the PSV level over time as the patient's respiratory function returns to normal. PSV must be individually adjusted to the level that keeps spontaneous respiratory efforts within a reasonable range (3). Because PSV adjustment is often based on objective data, automatic control of ventilator settings via a computerized system is conceivable. The expected advantages of computerized PSV control include continuous delivery of optimized mechanical assistance and rationalization of the weaning process based on predefined guidelines. We have previously described a knowledge-based, closed-loop system that uses simple indexes to evaluate the patient's needs and to adjust the level of mechanical assistance accordingly (5, 6). We have shown that this system is useful during the weaning period for determining the optimal time for extubation and can advantageously replace the standard battery of preweaning tests and the 2-h T-piece trial (7).

The objective of the present clinical study was to test, during ventilation and before weaning initiation, the effectiveness of our closed-loop system in ensuring adequate ventilation and preventing respiratory failure. To assess the potential benefits provided by automatic PSV level control, we compared our computerized closed-loop PSV system (automatic

Correspondence and requests for reprints should be addressed to Prof. Laurent Brochard, Medical Intensive Care Unit, Hôpital Henri Mondor, 51, avenue de Maréchal de Lattre de Tassigny, 94 010 Creteil, France. E-mail: laurent.brochard@ hmn.ap-hop-paris.fr

Am J Respir Crit Care Med Vol 161. pp 1161–1166, 2000 Internet address: www.atsjournals.org

PSV) with physician-controlled PSV (standard PSV). In particular, we specifically assessed the efficacy of automatic PSV in preventing periods with a high breathing workload. We used an estimation of occlusion pressure ( $P_{0.1}$ ) as a surrogate for work of breathing (8, 9).

# **METHODS**

#### Patients

Ten patients were selected for the study. All patients received PSV after recovering from acute respiratory failure. The main patient characteristics are shown in Table 1. Inclusion criteria were as follows: a high likelihood that mechanical ventilation would be required for the next 48 h; mechanical ventilation delivered by PSV alone at a level of 10 cm  $H_2O$  or more; hemodynamic stability; and informed consent obtained from the patient or next-of-kin.

#### Material

All patients were ventilated using a Veolar ventilator (Hamilton Medical, Bonaduz, Switzerland) set to PSV mode. For computer-controlled PSV, a computer connected via two RS-232 digital outputs to the Veolar controlled the ventilator settings and received information about the patient, assessing respiratory rate (RR), tidal volume (VT), and the PSV level through the ventilator. Another serial port connected to a mainstream gas monitor (Novametrix 1260; Wallingford, CT) assessed end-tidal PCO2 (PETCO2). All data were sampled every 10 s and averaged over 2 min. Evaluation of the current respiratory status of the patient was based on these parameters as they changed over time. The functionalities of the system were developed based on clinician's knowledge modeled using forward-chaining production rules. Details on the medical knowledge representation can be found in a previous report (6). Briefly, the working principle is based on two goals: to keep ventilation within an "acceptable range" by periodically adjusting the PSV level; and to use the lowest PSV level providing acceptable ventilation defined as a RR between 12 and 28 breaths/min, VT above 250 ml (300 ml in patients weighing > 50 kg), and PET<sub>CO2</sub> below 55 mm Hg (65 mm Hg in patients with chronic CO<sub>2</sub> retention, due for instance to chronic obstructive pulmonary disease [COPD]). When the RR is 28 to 35 breaths/min with acceptable values for both  $P_{ET_{CO_2}}$  and VT (intermediate RR), the PSV level is increased by 2 cm H<sub>2</sub>O; the increase is by 4 cm H<sub>2</sub>O when the RR exceeds 35 breaths/ min (high RR). PSV is decreased by 4 cm  $\mathrm{H_2O}$  when the RR is 12 breaths/min or less (low RR). When VT or  $PET_{CO_2}$  are outside the defined limits (low VT or high PET<sub>CO2</sub>), PSV is increased by 2 cm H<sub>2</sub>O. If an apnea lasting longer than 30 s occurs, the ventilatory mode is automatically switched to assist-control as a safety feature.

PSV level modifications take into account the patient's breathing pattern history, particularly the presence of transient instabilities. For example, a PSV level below 15 cm  $H_2O$  is decreased by 2 cm  $H_2O$  if ventilation has been acceptable for the last 30 min, and a PSV level higher than 15 cm  $H_2O$  is decreased by 4 cm  $H_2O$  if ventilation has been acceptable for the last 60 min. In addition, to avoid unnecessary PSV modifications, the system tolerates transient instabilities for 2 min or 4 min according to whether PSV is lower or higher than 15 cm  $H_2O$ , respectively. In the event of tachypnea or inadequate ventilation for 2 min, a PSV level lower than 15 cm  $H_2O$  is increased by 2 cm  $H_2O$ , Patient status is evaluated at 2-min intervals. After a 4 cm  $H_2O$  change in PSV, the next patient status evaluation occurs after a 4-min observation period. The computer screen displays a message if ventilation

<sup>(</sup>Received in original form April 14, 1999 and in revised form September 21, 1999)

TABLE 1 CHARACTERISTICS OF THE 10 STUDY PATIENTS

	Age	Sex	SAPSII*	Diagnosis	Duration of Ventilation <sup>†</sup> ( <i>d</i> )	Outcome	
	0			5			
1	71	M	57	Stroke	28	D	
2	75	F	31	Cardiac surgery, DD	18	S	
3	63	F	30	Esophageal resection, pneumonia	37	D	
4	84	F	54	Obesity, chronic respiratory failure	15	S	
5	81	F	60	Obesity, chronic respiratory failure	19	D	
6	75	F	48	Cardiac surgery, obesity	70	S	
7	49	F	23	Cardiac surgery, DD	17	S	
8	76	Μ	68	Cardiac surgery, septic shock	16	D	
9	80	F	32	Cardiac surgery, pneumonia	15	S	
10	61	Μ	53	Liver transplant, DD	32	S	
Mean $\pm$ SD	72 ± 11	_	46 ± 15	_	27 ± 17	_	

Definition of abbreviations: COPD = chronic obstructive pulmonary disease; D = died; DD = diaphragmatic dysfunction; S = survived; SAPS = Simplified Acute Physiology Score.

\* Reference 28.

<sup>†</sup> Total duration of mechanical ventilation

is unacceptable at three consecutive evaluations (12 min) despite PSV level changes; this did not occur during the present study.

When the patient has tolerated a low level of PSV (9 cm  $H_2O$ , or 5 cm  $H_2O$  if the patient is tracheotomized) for 2 h, a message suggesting ventilator disconnection is displayed on the computer screen. Again, transient instabilities are tolerated. The specific efficacy of this feature of the system has been assessed previously (7).

All ventilator alarms remain enabled during automatic PSV. Before connection of the patient to the system, information on the patient (e.g., name, weight, intubation or tracheotomy, and presence of COPD) must be entered into the computer. Apart from this, the computer-controlled mode requires no external intervention. Because the system can differentiate apnea from disconnection, it does not interfere with usual patient care procedures, such as endotracheal suctioning.

In the standard (physician-controlled) PSV mode used in the present study, the same computer was connected to the ventilator but was used only for recording physiological parameters and ventilator settings, which could be modified at any time by the physician in charge. The physicians were given as little information as possible about the study to ensure that management would be performed according to standard practice in our unit. In particular, they were not aware of the details of the algorithm used by the computer-controlled system. A message displayed on the computer screen indicated whether the automatic control system was active or not. For safety reasons, when the system was active it could be inactivated at any time by the physician in charge, who could then control the ventilator manually. When the computerized system was not active, the physician in charge could modify the PSV at his or her discretion. Thus, the physicians were relatively naive about the system, and it is unlikely that the presence of the computer changed their behavior.

In addition to the above-mentioned parameters, P<sub>0.1</sub> was recorded continuously to provide an indirect assessment of patient's effort (8, 9). P<sub>0.1</sub>, defined as the airway pressure (Paw) generated 100 ms after the onset of an occluded inspiration, has been used previously as an estimate of the neuromuscular drive of respiration (10). Recently developed ventilators or monitors are capable of measuring P<sub>0.1</sub>, usually during an on-demand end-expiratory pause. Although this measurement method is reliable, it is not convenient for on-line monitoring. We elected to use a direct method applicable in patients receiving PSV. With a closed triggering system, a short pause occurs during the patient's effort to trigger the ventilator.  $P_{0.1}\,\text{can}$  be estimated from the negative Paw generated by the patient's inspiratory effort during this pause (11, 12). Because the pause is often shorter than 100 ms, we obtained P<sub>0.1</sub> from an extrapolation of Paw measured during the 50-ms period preceding the opening of the ventilator demand valve. In our study, P<sub>0.1</sub> (called the "estimated P<sub>0.1</sub>") was measured using the computerized B-analyzer system (Hamilton). This system uses pressure and flow analog signals measured by sensors attached to the ventilator as inputs, and a  $P_{CO_2}$  analog signal measured directly by the mainstream gas monitor. It calculates in real time the estimated  $P_{0.1}$  based on an algorithm that uses the flow and  $P_{CO_2}$  signals to accurately determine the end of expiration. Six Paw values are used for linear regression, and the value at 100 ms is then determined by extrapolation. Similarly to the other study parameters, estimated  $P_{0.1}$  was sampled every 10 s and averaged over 2 min. Estimated  $P_{0.1}$  could not be recorded in one patient (Patient 9) for technical reasons. Estimated  $P_{0.1}$ was used as a surrogate for work of breathing (8, 9). We compared the time spent with high  $P_{0.1}$  values during each PSV mode. For this comparison, we defined "high  $P_{0.1}$ " as an estimated  $P_{0.1}$  value greater than 4 cm  $H_2O$ , as proposed by Conti and coworkers during PSV (13).

#### Protocol

The protocol was approved by our institutional review board. Each patient was consecutively ventilated for 24 h with the computer-controlled PSV mode (automatic PSV) and for 24 h with the physician-controlled PSV mode (standard PSV), in random order. In the standard PSV mode, the physician in charge modified the PSV level at his or her discretion. With both modes, the initial PSV level was set by the physician in charge.

## Statistics

Wilcoxon's test for paired values was used to look for differences between the two PSV modes regarding study parameter values and the time spent with these parameters outside predefined ranges. p Values lower than 0.05 were considered significant.

## RESULTS

All ten patients were ventilated using both PSV modes. Table 1 summarizes the patient characteristics. Mean total ventilation duration was  $27 \pm 17$  d.

Mean durations of standard PSV and automatic PSV were  $23 \pm 3$  h and  $24 \pm 4$  h, respectively. Table 2 reports the mean values of the physiological parameters recorded with the two PSV modes, as well as the mean PSV level. No significant differences (all p values > 0.05) between the two PSV modes were found for any of the parameters shown in Table 2, and the mean PSV level was also similar with the two modes ( $17 \pm 4$  cm H<sub>2</sub>O and  $19 \pm 6$  cm H<sub>2</sub>O for standard and automatic PSV, respectively).

In each individual patient, automatic PSV was associated with a longer time spent with acceptable ventilation and a shorter time spent in critical situations, as shown in Table 3. The mean time spent with acceptable RR, VT, and PET<sub>CO2</sub> val-

TABLE 2 MEAN VALUES OF THE PHYSIOLOGICAL PARAMETERS AND PSV LEVEL DURING AUTOMATIC PSV AND STANDARD PSV\*

Patient	RR (breaths/min)		VT ( <i>ml</i> )		RR/VT (breaths/min/L)		Рет <sub>СО2</sub> ( <i>cm H<sub>2</sub>O</i> )		Estimated P <sub>0.1</sub> ( <i>cm H<sub>2</sub>O</i> )		Mean PSV level ( <i>cm H<sub>2</sub>O</i> )	
No.	sPSV	aPSV	sPSV	aPSV	sPSV	aPSV	sPSV	aPSV	sPSV	aPSV	sPSV	aPSV
1	23	23	471	406	49	59	32	37	-1.2	-1.7	19	12
2	24	23	418	439	59	54	39	35	-4.2	-4	17	17
3	14	21	508	434	30	48	30	32	-3	-3.7	10	10
4	27	20	341	434	82	51	52	46	-4.5	-2.9	25	22
5	23	19	440	631	55	31	38	28	-2.1	-2.2	15	24
6	33	23	379	463	91	56	35	34	-6.2	-3.5	11	13
7	35	27	398	665	94	44	NA	NA	-1	-1.3	18	27
8	28	27	638	813	45	34	NA	NA	-1.7	-1	17	24
9	21	23	658	659	36	36	25	31	NA	NA	17	21
10	29	23	607	687	48	36	24	24	-3.8	-3	19	22
$\text{Mean} \pm \text{SD}$	$26\pm 6$	$23\pm3$	486 ± 113	564 ± 144	$59\pm23$	$45\pm10$	$34\pm9$	$33\pm7$	$-3.1\pm1.7$	$-2.6\pm1.1$	$17 \pm 4$	19 ± 6

Definition of abbreviations: RR/VT = rapid shallow breathing;  $P_{0,1} =$  estimated occlusion pressure; NA = not available continuously; sPSV = standard pressure support ventilation; aPSV = automatic pressure support ventilation.

\* No statistical differences were found between aPSV and sPSV for any of the study parameters.

ues, expressed as the percentage of total ventilation duration, was  $66 \pm 23\%$  with standard PSV and  $93 \pm 8\%$  with automatic PSV (p = 0.003). Three patients had a twofold or greater increase in the acceptable ventilation time during automatic PSV as compared with standard PSV. The number of PSV level changes was considerably higher with automatic PSV (56 ± 40) than with standard PSV (1 ± 2).

The time spent with unacceptable ventilation was broken down into periods of intermediate RR, low RR, high RR, low VT, and high  $PET_{CO2}$ , according to the definitions in the METH-ODS and the last four represented the critical ventilation. The percentage of time spent with critical ventilation was 23% with standard PSV versus 3% with automatic PSV (p < 0.05). The unacceptable ventilation criterion met most often was a RR value outside the predefined range. The percentage of to-tal ventilation spent with RR values between 28 and 35 was 12% with standard PSV versus 4% with automatic PSV (p = 0.02). Corresponding figures for the time spent with RR values greater than 35 breaths/min were 14% and 1% (p = 0.03). In each individual patient, automatic PSV was associated with

less time spent with a high RR. These results are displayed in Figures 1 and 2.

The time spent with an estimated  $P_{0.1} \ge 4 \text{ cm } H_2\text{O}$  was lower with automatic PSV than with standard PSV in eight of the nine patients in whom it was measured. Mean percentage of total ventilation time spent with an estimated  $P_{0.1} \ge 4 \text{ cm} H_2\text{O}$  was  $34 \pm 35\%$  with standard PSV versus  $11 \pm 17\%$  with automatic PSV (p < 0.01) (Table 4).

### DISCUSSION

One of the main goals of mechanical ventilation is to reduce the patient's effort or work of breathing. Our computer-controlled PSV system uses three parameters to automatically control the level of assistance: RR, VT, and  $Pet_{CO2}$ , RR, which seems to reflect how well the respiratory muscles adapt to the workload (14), is the main parameter, while VT and  $Pet_{CO2}$  are used to improve safety. With standard PSV, most periods of unacceptable ventilation were so classified based on an RR value above the predefined range, consistent with the results

TABLE 3 TIME SPENT WITH AN ACCEPTABLE VENTILATION\* DURING AUTOMATIC PSV AND STANDARD PSV<sup>†</sup>

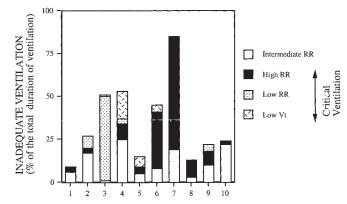
AUTOWATIC F3V AND STANDARD F3V												
	Duration of Ventilation ( <i>min</i> )		Period with Acceptable Ventilation		Period with Acceptable RR		Period with Acceptable VT		Period with Acceptable Pet <sub>CO2</sub>		Changes in PSV Level	
	sPSV	aPSV	sPSV	aPSV	sPSV	aPSV	sPSV	aPSV	sPSV	aPSV	sPSV	aPSV
1	1,483	1,441	91	94	91	94	100	100	100	100	3	67
2	1,437	1,281	73	90	74	90	99	100	100	100	0	87
3	1,441	902	49	100	50	100	99	100	100	100	4	10
4	1,420	1,681	47	74	63	79	84	91	100	100	0	120
5	1,542	1,345	85	94	90	94	95	100	100	100	2	41
6	1,485	1,433	54	97	59	97	96	100	100	100	0	41
7	1,039	1,445	15	99	15	99	100	100	100	100	0	20
8	1,465	1,582	88	100	87	100	100	100	100	100	0	9
9	1,160	1,703	78	86	78	87	100	100	100	99	1	110
10	1,409	1,468	76	100	76	100	100	100	100	100	4	58
$\text{Mean} \pm \text{SD}$	$1,388\pm159$	$1,428\pm229$	$66\pm24^{\ddagger}$	$93\pm8$	$68\pm23^{\ddagger}$	$94\pm7$	97 ± 5	99 ± 3	100	100	$1\pm2^{\ddagger}$	$56\pm40$

Definition of abbreviations: aPSV = automatic pressure support ventilation; sPSV = standard pressure support ventilation.

\* Acceptable ventilation is defined as: 12 < RR < 28 breaths/min, VT > 300 ml (250 if weight < 55 kg), and PETCO2 < 55 mm Hg (65 if COPD).

<sup>†</sup> Periods are expressed as the percentages of the total duration of ventilation with the corresponding mode.

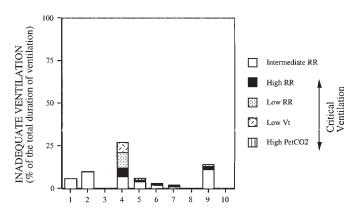
 $^{\ddagger}$  Significant difference (p < 0.05) between aPSV and sPSV.



*Figure 1.* Contributions to unacceptable ventilation of intermediate RR (28 < RR  $\leq$  35 breaths/min), high RR (RR > 35 cycles/min), low RR (RR  $\leq$  12 breaths/min), low VT (VT < 300 ml, or 250 ml if weight > 55 kg), and high PET<sub>CO2</sub> (PET<sub>CO2</sub>  $\geq$  55 mm Hg, or 65 if COPD) during 24 h of standard PSV in the 10 study patients. With standard PSV, unacceptable ventilation represented 36% of the total ventilation duration in this mode, of which 24% was spent with critical ventilation.

of our preliminary study (5). The computer-controlled system responded to high RR values by increasing the PSV level. This led to an increase in VT in Patients 5, 7, and 8. When ventilation remained acceptable for 30 or 60 min (depending on whether PSV was below or above 15 cm H<sub>2</sub>O, respectively), the system automatically decreased the level of PSV. The PSV level was also decreased if hyperventilation occurred (RR  $\leq$ 12 cycles/min). Because the system is designed to use the lowest level of PSV tolerated by the patient, our patients had fewer critical situations while in automatic PSV mode. Mean PSV level, however, was not significantly different between automatic and standard PSV, because in some patients the computer system increased PSV in response to episodes of tachypnea. However, specific additional automatic responses could perhaps be introduced into the system to allow intermittent testing of whether a faster PSV level decrease would be tolerated, the goal being to expedite weaning if possible.

The hypothesis that drove us to design our computer-controlled PSV system was that continuous PSV adjustment to



*Figure 2.* Contributions to unacceptable ventilation of intermediate RR (28 < RR  $\leq$  35 breaths/min), high RR (RR > 35 cycles/min), low RR (RR  $\leq$  12 breaths/min), low VT (VT < 300 ml, or 250 ml if weight > 55 Kg), and high PET<sub>CO2</sub> (PET<sub>CO2</sub>  $\geq$  55 mm Hg, or 65 if COPD) during 24 h of automatic PSV in the 10 study patients. With automatic PSV, unacceptable ventilation represented 9% of the total ventilation duration in this mode, of which 5% was spent with critical ventilation.

WITH AUTOMATIC PSV AND STANDARD PSV							
Patient	Period with Estimated $P_{0,1} \ge 4 \text{ cm H}_2O$						
No.	sPSV	aPSV					
1	2	0					
2	64	48					
3	27	22					
4	61	0.1					
5	2	2					
6	95	22					
7	0.1	1					
8	4	0.1					
10	52	1					
Mean $\pm$ SD	$34 \pm 35^{*}$	11 ± 17					

TABLE 4

PERCENTAGE OF THE TOTAL DURATION OF VENTILATION SPENT WITH A HIGH LEVEL OF ESTIMATED  $P_{0.1}$  ( $\geq$  4 cm  $H_2O$ )

\* p < 0.01 versus aPSV.

the level ensuring acceptable ventilation may facilitate respiratory function recovery and weaning from mechanical ventilation (5, 7). High values of  $P_{0,1}$  and RR/VT have been shown to predict a high rate of weaning failure. In at least two of our patients (Patients 4 and 6), the work of breathing as evaluated based on the estimated P<sub>0.1</sub> was substantially higher with standard PSV (4.5 cm H<sub>2</sub>O and 6.2 cm H<sub>2</sub>O, respectively) than with automatic PSV (2.9 cm H<sub>2</sub>O and 3.5 cm H<sub>2</sub>O, respectively). The rapid shallow breathing index in these two patients was 82 and 91 breaths/min/L with standard PSV versus 51 and 56 breaths/min/L with automatic PSV, respectively. Thus, in these two patients, automatic PSV reduced the overall breathing workload. As another example, with standard PSV, Patient 3 exhibited hyperventilation during 49% of the total ventilation time; the automatic system decreased the PSV level by 4 cm H<sub>2</sub>O as soon as hyperventilation was detected.

Overall, the time spent with high estimated  $P_{0,1}$  values was significantly decreased with automatic PSV. The overall percentage of the total ventilation time spent with an estimated  $P_{0.1}$  value higher than 4 cm  $H_2O$  was substantially influenced by the data from four patients (Patients 2, 4, 6, and 10), in whom this percentage was > 50% with standard PSV. Had we used  $-3 \text{ cm } H_2O$  as the  $P_{0.1}$  cutoff, the difference would not have been significant (51  $\pm$  43% with standard PSV versus  $34 \pm 41\%$  with automatic PSV). However, reducing the cutoff decreases the likelihood of finding a significant difference because the system is not designed to constantly reduce RR (and presumably respiratory effort) as compared with standard PSV, but only to avoid unnecessary episodes of tachypnea and high  $P_{0.1}$ . It follows that differences are likely to be found only when out-of-range periods are considered. Both Alberti and coworkers (8) and Mancebo and coworkers (9) reported close correlations between P<sub>0.1</sub> and the work of breathing. Thus, automatic PSV may have prevented prolonged periods of excessive work of breathing in our patients. This may have important implications for facilitating recovery from or avoiding respiratory muscle fatigue (15).  $P_{0,1}$  could be used to improve the PSV regulation loop. This parameter was introduced in a servo-controlled system by Iotti and coworkers (16). Determining the optimal  $P_{0,1}$  value for an individual patient is still empirical, however, and optimal threshold values for weaning are still a matter of debate (17-20). Whether P<sub>0.1</sub> could be used as a second-line parameter for safety purposes needs to be determined.

The comparison between the days with and without automatic PSV allows one to understand why the system increased the PSV level and VT in some patients. It is interesting to see that the system succeeded in reaching the predefined goals. For instance, Figure 3 shows the time-course of the breathing pattern and PSV level in Patient 7. The RR/VT ratio in this patient was often around or above 100 (a very high value under PSV) without the system and, intuitively, the response of the automatic PSV system, which was to increase PSV, seems to have been very appropriate. In Patient 8, frequent episodes of transient tachypnea were avoided by automatic PSV. Patient 5 was very often at the upper limit for RR without automatic PSV, a fact that probably explains the higher PSV and  $V_T$  levels with automatic than with standard PSV. In addition, very short periods of tachypnea (RR > 35 cycles/min) also resulted in PSV increases in this patient. One could argue that in such a patient the threshold for RR could have been raised slightly and the level of PSV decreased. Conceivably, the upper limit for RR could be determined case-by-case on the basis of the patient's history and clinical tolerance.

Mean PETCO2 was not different between standard and automatic PSV despite differences in the amount of time spent with rapid shallow breathing. We offer at least two explanations for the similar mean  $P_{ET_{CO_2}}$  values with the two systems despite the difference in the amount of time spent with rapid shallow breathing. First, our system assesses the ventilatory status of the patient based primarily on RR. VT and  $P_{ET_{CO2}}$  serve mainly to improve safety. No target range is set for  $\ensuremath{\mathsf{Pet}_{\text{CO}_2}}$ , for which the only requirement is that the value be no higher than 55 mm Hg (65 in patients with COPD). Second, and more importantly, in a number of situations our system can help to avoid hypocapnia, for instance by decreasing the PSV level in response to an RR decrease below the acceptable range or by responding to an apnea with a high VT and a low PET<sub>CO2</sub> value. In some patients, these responses of the system may result in a higher  $\ensuremath{\mathsf{PET}_{\text{CO}_2}}$  value compared with standard PSV.

The use of computers for automatic patient monitoring is increasing in hospitals, especially in intensive care units. Few closed-loop systems for controlling ventilator settings have been reported. Recent knowledge-based systems for patient monitoring analyze the time-course of ventilation and advise physicians about the best treatment response. They usually deal with complex problems-such as the ventilation of neonates (21) or the design of general architectures for intensive care monitoring (22, 23)-and explore sophisticated techniques coming from the area of artificial intelligence. They do not act on the ventilator and are difficult to evaluate clinically. Another avenue of research is the development of new ventilation modes based on algorithms that integrate physiological models to facilitate the weaning process. ARIS (24) and ALV (25), which are used in prototype ventilators, are good examples of the fruits of this approach. In ALV, automatic ventilation adjustments are based on measurements of the patient's lung mechanics and series dead space, with the goals of achieving the lowest possible work of breathing and avoiding intrinsic positive end-expiratory pressure. ARIS is designed primarily to avoid hyperinflation and to gradually restore spontaneous ventilation by allowing the patient to determine his or her RR, VT, and inspiratory/expiratory ratio values compatible with an optimal level of minute ventilation and a minimal VT determined by the physician. Because the introduction into the clinical environment of a new mode of ventilation is a time-consuming process, we chose to ventilate patients with PSV, a mode widely used during weaning, and to use specific empirical knowledge with the goal of improving PSV use and of facilitating the weaning process. Based on our extensive clinical

experience and on data in the literature, we designed a computer-controlled PSV system to be used at the bedside. Our work is similar to that by Strickland and Hasson (26, 27), who developed a closed-loop system that modifies the setting of synchronized intermittent mandatory ventilation and of PSV for intervening breaths based on RR, VT, and pulse oximeter oxygen saturation measurements. One important technical difference between their system and ours is that our system uses specific temporal reasoning (6) to adjust PSV according to the patient's ventilation history. Our system is designed to adjust the PSV level whatever the stage of the weaning process. In the present study, we investigated patients receiving PSV before the initiation of weaning. In contrast, Strickland and Hasson (27) studied only candidates for weaning.

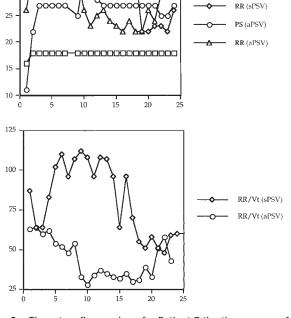
Our main finding was that the automatic system was able to keep the patients within predefined ranges for physiological respiratory parameters. Our estimated  $P_{0.1}$  data suggest that this may provide benefits in terms of breathing workload and energy expenditure. We used the same predefined ranges in all our patients. It could be argued that individually tailored ranges may provide better results. Because the basic rules of knowledge-based systems are easy to grasp by users, individual tailoring of ranges is probably feasible. In the present study, the upper limit of the acceptable range for RR was 35 breaths/min but the system started to react when RR exceeded 28 breaths/min. These cutoffs could perhaps be increased in some situations, for instance in patients with chronic respiratory disorders associated with habitually high RRs.

The automatic PSV system used in this study was more effective in maintaining RR, VT, and  $P_{ET_{CO2}}$  within acceptable

PS (sPSV

35

30



*Figure 3.* These two figures show for Patient 7 the time-course of PSV and RR (*top panel*), and the time-course of RR/V<sub>T</sub> (*bottom panel*) over the two 24-h periods of ventilation with (aPSV) or without (sPSV) the automated system. Note that very high values of the rapid shallow breathing index (RR/V<sub>T</sub>) were found during sPSV but not during aPSV = automatic pressure support ventilation (computer-controlled); sPSV = standard pressure support ventilation (physician-controlled).

ranges than physician-controlled PSV. It would be of interest to conduct a large, randomized, controlled trial investigating the effects on weaning duration and outcomes of automatic versus standard PSV used early in the course of respiratory failure.

*Acknowledgment*: The authors thank Josef X. Brünner and Hamilton Medical AG for supplying the B-analyzer system and Florence Picot for typing the manuscript.

#### References

- Brochard, L. 1994. Pressure support ventilation. *In* M. J. Tobin, editor. Principles and Practice of Mechanical Ventilation. McGraw-Hill, New York. 239–257.
- Brochard, L., F. Pluskwa, and F. Lemaire. 1987. Improved efficacy of spontaneous breathing with inspiratory pressure support. *Am. Rev. Respir. Dis.* 32:1110–1116.
- Brochard, L., A. Harf, H. Lorino, and F. Lemaire. 1989. Inspiratory pressure support prevents diaphragmatic fatigue during weaning from mechanical ventilation. *Am. Rev. Respir. Dis.* 139:513–521.
- MacIntyre, N. R. 1986. Respiratory function during pressure support ventilation. *Chest* 89:677–683.
- Dojat, M., L. Brochard, F. Lemaire, and A. Harf. 1992. A knowledgebased system for assisted ventilation of patients in intensive care units. *Int. J. Clin. Monit. Comp.* 9:239–250.
- Dojat, M., F. Pachet, Z. Guessoum, D. Touchard, A. Harf and L. Brochard. 1997. NeoGanesh: a working system for the automated control of assisted ventilation in ICUs. *Artif. Intell. Med.* 11:97–117.
- Dojat, M., A. Harf, D. Touchard, M. Laforest, F. Lemaire, and L. Brochard. 1995. Evaluation of a knowledge-based system providing ventilatory management and decision for extubation. *Am. J. Respir. Crit. Care Med.* 153:997–1004.
- Alberti, A., F. Gallo, A. Fongaro, S. Valenti, and A. Rossi. 1995. P0.1 is a useful parameter in setting the level of pressure support ventilation. *Intens. Care Med.* 21:547–553.
- Mancebo, J., P. Albaladejo, E. Bak, S. Elatrous, D. Touchard, M. Subirana, F. Lemaire, A. Harf, and L. Brochard. 1996. Use of the occlusion pressure (P0.1) to titrate the level of external PEEP in patients with dynamic hyperinflation (abstract). *Am. J. Respir. Crit. Care Med.* 153: A368.
- Whitelaw, W. A., J. P. Derenne, and J. Milic-Emili. 1975. Occlusion pressure as a measure of respiratory center output in conscious man. *Respir. Physiol.* 23:181–199.
- Fernandez, R., S. Benito, J. Sanchis, J. Milic Emili, and A. Net. 1988. Inspiratory effort and occlusion pressure in triggered mechanical ventilation. *Intens. Care Med.* 14:650–653.
- Conti, G., G. Cinnella, E. Barboni, F. Lemaire, A. Harf, and L. Brochard. 1996. Estimation of occlusion pressure during assisted ventilation in patients with intrinsic PEEP. *Am. J. Respir. Crit. Care Med.* 154:907–912.
- 13. Conti, G., R. A. De Blasi, P. Pelaia, S. Benito, M. Rocco, M. Antonelli,

M. Bufi, C. Mattia, and A. Gasparetto. 1992. Early prediction of successful weaning during pressure support ventilation (PSV) weaning in chronic obstructive pulmonary disease (COPD) patients. *Crit. Care Med.* 20:366–371.

- 14. Tobin, M. J., W. Perez, S. H. Guenther, B. J. Semmes, M. J. Mador, S. J. Allen, R. F. Lodato, and D. R. Dantzker. 1986. The pattern of breathing during successful and unsuccessful trials of weaning from mechanical ventilation. *Am. J. Respir. Crit. Care Med.* 134:1111–1118.
- Laghi, F., N. D'Alfonso, and M. J. Tobin. 1995. Pattern of recovery from diaphragmatic fatigue over 24 hours. J. Appl. Physiol. 79:539–546.
- Iotti, G. A., J. X. Brunner, A. Braschi, T. Laubscher, M. C. Olivei, A. Palo, C. Galbusera, and A. Comelli. 1996. Closed-loop control of airway occlusion pressure at 0.1 second (P. 01) applied to pressure-support ventilation: algorithm and application in intubated patients. *Crit. Care Med.* 24:771–779.
- Sassoon, C. S. H., T. T. Te, C. K. Mahutte, and R. W. Light. 1987. Airway occlusion pressure: an important indicator for successful weaning in patients with chronic obstructive pulmonary disease. *Am. Rev. Respir. Dis.* 135:107–113.
- Sassoon, C. S. H., C. K. Mahutte, T. T. Te, D. H. Simmons, and R. W. Light. 1988. Work of breathing and airway occlusion pressure during assist-mode mechanical ventilation. *Chest* 93:571–576.
- Montgomery, A., R. H. O. Holle, S. R. Neagley, D. J. Pierson, and R. B. Schroene. 1987. Prediction of successful ventilator weaning using airway occlusion pressure and hypercapnic challenge. *Chest* 91:996–999.
- Fernandez, R., J. Cabrera, N. Calaf, and S. Benito. 1990. P0.1/PIMax: an index for assessing respiratory capacity in acute respiratory failure. *Intens. Care Med.* 16:175–179.
- Miksch, S., W. Horn, C. Popow, and F. Paky. 1997. Utilizing temporal data abstraction for data validation and therapy planning for artificially ventilated newborn infants. *Artif. Intell. Med.* 8:543–576.
- Larsson, J. E., B. Hayes-Roth, D. M. Gaba, and B. E. Smith. 1997. Evaluation of a medical diagnosis system using simulator test scenarios. *Artif. Intell. Med.* 11:119–140.
- Rutledge, G. W., G. E. Thomsen, B. R. Farr, M. A. Tovar, J. X. Polaschek, I. A. Beinlich, L. B. Sheiner, and L. M. Fagan. 1993. The design and implementation of a ventilator-management advisor. *Artif. Intell. Med.* 5:67–82.
- Chambrin, M.-C., C. Chopin, and K. H. Mangalaboyi. 1992. Autoregulated inspiratory support system. 14th IEEE Engineering in Medicine and Biology Annual International Conference. Institute of Electrical and Electronics Engineers, Piscataway, NJ. 2419–2420.
- Laubscher, T. P., W. Heinrichs, N. Weiler, G. Hartmann, and J. X. Brunner. 1994. An adaptive lung ventilation controller. *IEEE Trans. Biomed. Eng.* 41:51–58.
- Strickland, J. H., and J. H. Hasson. 1991. A computer-controlled ventilator weaning system: a clinical trial. *Chest* 100:1096–1099.
- Strickland, J. H., and J. H. Hasson. 1993. A computer-controlled ventilator weaning system: a clinical trial. *Chest* 103:1220–1226.
- Le Gall, J. R., P. Loirat, A. Alperovitch, P. Glaser, C. Granthil, D. Mathieu, P. Mercier, R. Thomas, and D. Villers. 1984. A simplified acute physiology score for ICU patients. *Crit. Care Med.* 12:975–977.