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Computer-driven management of prolonged mechanical ventilation and weaning: a pilot study

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Abstract *Objective:* To evaluate the ability of a computer-driven system (CDS) to manage pressure-support ventilation over prolonged periods and to predict weaning readiness compared to intensivists. The system continuously adapts pressure support, gradually decreases ventilatory assistance when possible, and indicates weaning readiness. *Design and setting:* A two-center, prospective, open, clinical, pilot study in medical ICUs of two university hospitals. *Patients and participants:* 42 consecutive mechanically ventilated patients (60±14 years, SAPS II 39±15), 9 of whom were excluded. *Interventions:* As soon as patients could tolerate pressure support, they were ventilated with the CDS. The times of weaning readiness determined by the intensivists and CDS were compared. *Measurements and results:* Weaning was successful in 25 patients and failed in 7; unplanned extubation occurred in 1 patient. Time on CDS ventilation was 3±3 days (maximum,

12 days). The CDS detected weaning readiness earlier than the intensivists in 17 patients, and intensivists earlier than the CDS in 4; in 11 patients detection times coincided. *Conclusions:* A CDS was successful in fully managing pressure-support ventilation over prolonged periods and often proposed weaning readiness earlier than the intensivists did. Use of this CDS may reduce the duration of mechanical ventilation.

Keywords Mechanical ventilation · Weaning · Closed-loop ventilation · Automatic weaning

Introduction

After an episode of acute respiratory failure requiring mechanical ventilation, weaning the patient off the ventilator may be difficult. Approximately two-thirds of patients can be separated from the ventilator after a simple spontaneous breathing test [1, 2, 3, 4]. Prolongation of mechanical ventilation may increase the risk of adverse events such as infections [5, 6]. Reintubation after failed

weaning is associated with increased morbidity and mortality rates [7, 8, 9]. Identifying weaning readiness early and reliably is therefore crucial. Weaning protocols, or at least a systematic approach developed to assist in identifying weaning readiness, have been shown to shorten the duration of mechanical ventilation, most notably the weaning period [10, 11, 12]. Implementation of protocols or guidelines may be difficult in routine practice. Closed-loop knowledge-based systems should be

Table 1 Main admission characteristics and outcomes in the nine excluded patients

No.	Age (years)	Sex	Diagnosis	SAPS II	Criteria for exclusion	Outcome
1	60	M	Sepsis	58	Switch to ACV >48 h	Died while on MV
2	64	M	COPD	71	Switch to ACV >48 h	Died while on MV
3	63	F	COPD	34	Switch to ACV >48 h	Alive, weaned after 8 months on MV
4	62	F	COPD	42	Switch to ACV >48 h	Died while on MV
5	59	F	Sepsis	28	Switch to ACV >48 h	Died while on MV
6	65	M	COPD	52	Frequent instabilities	Alive, weaned after 4 months on MV
7	79	M	COPD	70	Switch to ACV >48 h	Died while on MV
8	67	M	COPD	19	Switch to ACV >48 h	Died while on MV
9	72	M	COPD	37	Switch to ACV >48 h	Died while on MV
Mean \pm SD	65 \pm 6	–	–	47 \pm 19	–	–

COPD chronic obstructive pulmonary disease, *SAPS II* Simplified Acute Physiology Score II, *MV* mechanical ventilation, *ACV* assist-control ventilation

able to serve as continuously applied weaning protocols that automatically reduce ventilatory assistance when possible and indicate when criteria for weaning readiness are achieved. However, few data on this use of closed-loop knowledge-based systems have been reported [13, 14, 15, 16, 17, 18, 19, 20, 21].

A previous study evaluated a computer-driven system (CDS) that continuously adapts the level of pressure support (PS) to the patient's needs, manages a strategy of gradually decreasing ventilatory assistance, and indicates when the patient is ready to be weaned off the ventilator [19]. The CDS performed well during this short-term (24-h) study [19]. In the open pilot study reported here we evaluated the ability of the CDS to manage pressure-support ventilation (PSV) over prolonged periods and to compare the prediction of weaning readiness made by the system to the clinical judgment of intensivists [20].

Material and methods

Patients

This study was conducted in two medical intensive care units (ICUs) in two teaching hospitals, in Créteil, France, and Barcelona, Spain. The local ethics committees of both centers approved the study. Written informed consent was obtained from the patient or family. The 42 consecutive patients who were admitted between 1 March 2001 and 31 December 2001, and who met our inclusion criteria were included in the study after stabilization of the acute health problem that prompted ICU admission. Inclusion criteria were invasive assist-control ventilation (ACV) for at least 24 h, plateau pressure less than 30 cmH₂O, PEEP less than 8 cmH₂O, PaO₂/FIO₂ ratio greater than 150 or SaO₂ of 90% or higher with FIO₂ less than 60%, epinephrine or norepinephrine not higher than 1 mg/h, body temperature higher than 36°C and lower than 39°C, sedative drugs stopped or decreased, stable neurological status with a Glasgow Coma Score (GCS) greater than 4, and availability of the CDS at the time of switching to PSV. We excluded patients younger than 18 or older than 85 years of age, patients on chronic ventilatory assistance at home, pregnant patients, and patients with decision to limit life-sustaining treatments.

Of the 42 original patients 9 were excluded (Table 1), including 7 with chronic obstructive pulmonary disease; none of the 9 patients had neurological disorders. A single patient was excluded because the CDS was unable to manage PSV; high levels of PS were reached repeatedly because of frequent breathing pattern instabilities due to copious tracheal secretions. This patient was successfully weaned after 4 months on mechanical ventilation. The other 8 patients were switched back to ACV because of clinical deterioration; 7 died while on mechanical ventilation and one was weaned after 8 months on mechanical ventilation.

In the 42 study patients, in compliance with the written ventilation protocols used routinely in the two study centers, tolerance of PSV was tested daily by switching from ACV to PSV and setting the PS level to keep the tidal volume (V_t) higher than 6 ml/kg and the respiratory rate (RR) below 35 breaths/min. The maximal inspiratory pressure allowed was 30 cmH₂O (PS plus PEEP). The PSV test was considered positive if the following criteria were met after 60 min: stable condition with a heart rate less than 130/min, systolic arterial pressure greater than 80 mmHg, RR less than 40 breaths/min, V_t of 6 ml/kg or higher, SaO₂ of 90% or higher with FIO₂ 50% or lower, and pH above 7.32. Patients who met these criteria were left on PSV managed by the CDS.

Description of the computer-driven system

The CDS is a knowledge-based system embedded in a ventilator [19, 21, 22]. It achieves three main goals. First, the CDS continuously adjusts the PS level based on RR, V_t, and end-tidal partial pressure of CO₂ (PETCO₂) acquired from the ventilator in real time and averaged over 2 min. Adjustment is such that the patient is kept within a "comfort zone" defined as RR in the 15–30 range (up to 34 in patients with neurological disorders), V_t greater than 300 ml (>250 ml if body weight <55 kg), and PETCO₂ less than 55 mmHg (<65 mmHg in patients with chronic obstructive pulmonary disease). Second, the CDS manages a strategy of gradually decreasing ventilatory assistance by reducing the PS level after at least 30 min of stable ventilation within the comfort zone; the reduction is 2 or 4 cmH₂O depending on whether the initial level is below or above 20 cmH₂O, respectively. Third, the CDS evaluates weaning readiness: when the PS level reaches the preset minimal value (with a heated humidifier or a filter, respectively, 5 or 9 cmH₂O in tracheotomized patients and 7 or 12 cmH₂O in intubated patients), the CDS starts an observational period, which serves as an automatic "spontaneous breathing" test. After uninterrupted ventilation at the minimal PS level for 1 or 2 h (depending on whether the initial PS

Table 2 Main admission characteristics and results in the 33 patients who completed the study

Age (years)	60±14
Sex: F/M	9/24
Diagnosis	
Acute COPD exacerbation	4
Neurological disorder	7
Other	22
SAPS II score	39±15
Time on ventilation before CDS (days)	
Mean ±SD	8±6
Median, IQR	7, 2–13
Time on ventilation with CDS (days)	
Mean ±SD	3±3
Median, IQR	2, 2–3
Time on ventilation with CDS ≥3 days	13
Weaning readiness detection	
Physician before CDS	4
CDS before physician	17
Physician and CDS contemporaneously	11
Unplanned extubation	1
Noninvasive ventilation after extubation	6
Extubation failure	7

SAPS II Simplified Acute Physiology Score, *COPD* chronic obstructive pulmonary disease, *IQR* interquartile range

level was above or below 15 cmH₂O, the CDS displays a message that the patient is ready for weaning).

Prediction of weaning

Weaning readiness as evaluated by the CDS and by the intensivists was recorded daily, i.e., every morning. The decision was considered to be taken by the CDS before the physician when it was taken 1 day in advance, i.e., the preceding morning. Physicians were aware of the PS level delivered by the CDS and could take this level into account in their evaluation; however, they did not have access to the weaning readiness message displayed by the CDS. Weaning protocols used routinely in both centers recommended a daily “spontaneous breathing” test similar to that used by the CDS. Patients were extubated as soon as the physician or CDS predicted weaning readiness, provided the following criteria were fulfilled: SaO₂ of 90% or higher with FIO₂ at 50% or below and PEEP at 5 cmH₂O or below, cough and secretions present, epinephrine and norepinephrine 1 mg/h or less, GCS higher than 8, and either minimal sedation or no sedation. Use of noninvasive ventilation and extubation failure (reintubation within 48 h) were recorded.

Results

Table 2 and Fig. 1 show the main results in the 33 patients. Mean time on CDS-managed ventilation was 3±3 days; 13 patients were ventilated using the CDS for 3 days or more (up to 12 days). The time spent in the comfort zone was 64%. Weaning readiness was detected earlier by the CDS in 17 patients and by the intensivists in 4 patients; in 11 patients, weaning readiness was identified simultaneously by the CDS and the intensivists. Of the 33 patients, 25 were successfully weaned and 7 were reintubated within 48 h after extubation; unplanned extubation occurred in the remaining patient.

Discussion

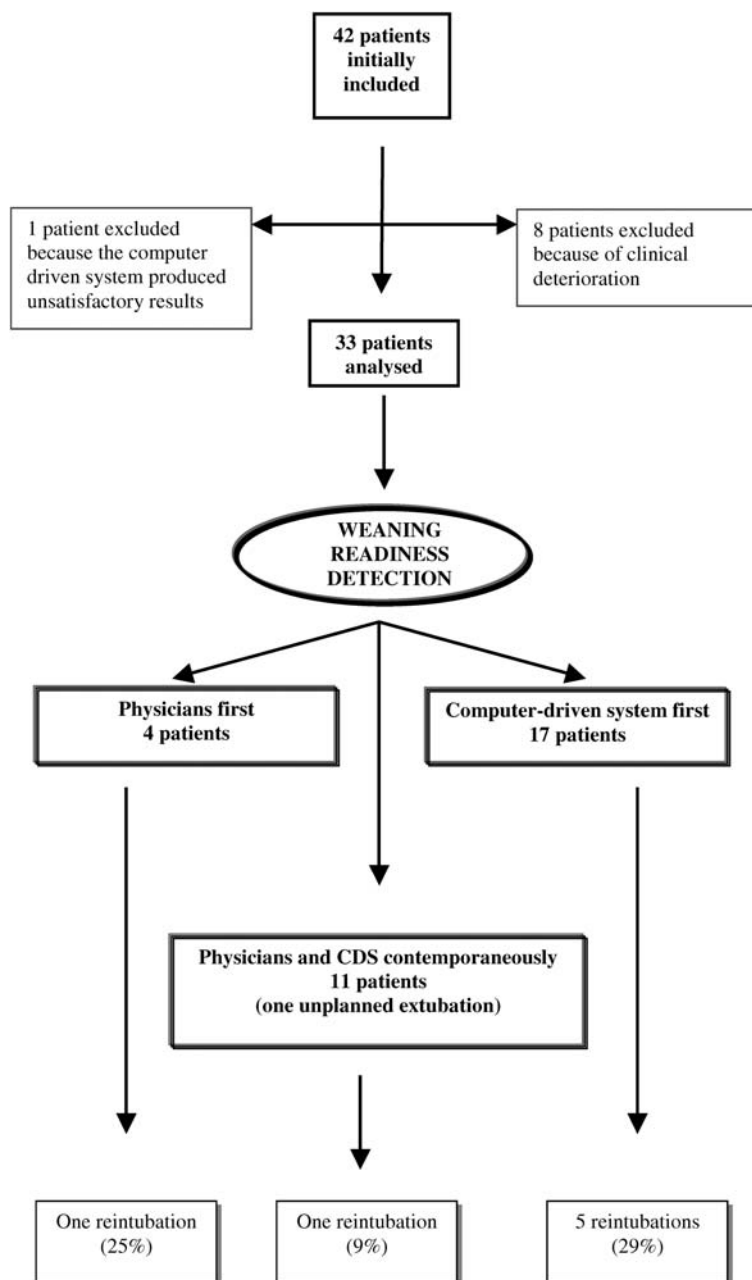
The main findings of this study are that the CDS ensured acceptable PSV over prolonged periods and frequently detected and thus proposed to the clinician weaning readiness earlier than did the intensivists. The CDS is designed to work only with PSV, a widely used mode of partial ventilatory support, frequently used during gradual weaning from mechanical ventilation. In theory, changes in respiratory demand throughout the 24-h cycle require frequent adjustment of the PS level. Because the appropriate PS level is often determined from objective data (RR, V_I), computerized control of ventilator settings in real time should be feasible. Protocols and guidelines has been shown to shorten the duration of the weaning phase, perhaps at least by introducing standardization and a systematic approach. However, presence of a physician at the bedside 24 h a day to apply a protocol continuously is not feasible in clinical practice. Continuous automatic protocol application by a CDS that manages PSV and evaluates weaning readiness, in contrast, should be possible and may reduce the duration of mechanical ventilation. Several automated systems have been described, but most of them were designed to make recommendations about ventilator settings [13, 18]. Few systems incorporated a weaning strategy [16, 14, 15, 17].

The CDS used in our study was developed by engineers, physiologists, and intensivists at the medical ICU of the Henri Mondor Teaching Hospital, Créteil, France. Clinical studies have established that the CDS can maintain acceptable ventilation in the short term (<24 h) [19] and predict successful extubation [22]. Here we showed that the same CDS successfully managed PSV over a long period in patients with a variety of disorders. Although 9 of the 42 patients were excluded, a single exclusion was related to inability of the CDS to ensure an appropriate level of PS.

The time spent by patients within the comfort zone was only 64%. This is lower than the 93% rate in a previous study [19]. The discrepancy is chiefly ascribable to inaccurate PETCO₂ measurements in the present study when heated humidifiers were used; water droplet deposition on the sensor led to spuriously low recorded PETCO₂ values, and therefore periods within the comfort zone were misclassified as being outside the comfort zone. New sensors have solved this problem. Nevertheless, we decided to use only heat and moisture exchangers in future studies.

Other modifications were decided based on the results of this study. First, to improve CDS performance in patients with normal respiratory mechanics the minimal PS level was allowed to decrease to 5 cmH₂O for patients with a low respiratory rate and no PETCO₂ elevation. Second, because secretions induce high resistance, to which the CDS responds by a rapid PS increase, a modification was introduced. With this modification, a rapid

Fig. 1 Diagram showing the study results



increase in PS followed by automatic recognition of suctioning prompts an attempt by the CDS to rapidly decrease the PS level immediately after the end of suctioning. Suctioning is recognized either via a specific sequence of alarms generated by disconnection or via activation by the nurse of a special ventilator function (pre- and postsuctioning oxygenation with 100% FIO₂ during 120 s). Suctioning can be performed as often as needed with no special maneuver on the computer.

The nonrandomized open design is a major limitation of our study. However, this work is intended as a pilot study to prepare larger prospective, randomized studies.

The number of patients with chronic obstructive pulmonary disease was too small to allow an assessment of the long-term efficacy of our CDS in this population.

In conclusion, potential benefits of the CDS include improved matching of ventilatory assistance to patient needs and earlier detection of weaning readiness. This study, however, was not able to determine whether this detection by the system was correct, and a randomized trial is needed. In addition, the decision for extubation needs a careful clinical assessment by the physician. These benefits, if confirmed, may translate into shorter times on mechanical ventilation and better patient outcomes.

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