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A randomised, controlled trial of conventional versus automated weaning from mechanical ventilation using SmartCare™/PS

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This study was conducted in the Intensive Care Unit (ICU) at The Royal Melbourne Hospital, Victoria, Australia.
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Abstract *Objective:* Preliminary assessment of an automated weaning system (SmartCare™/PS) compared to usual management of weaning from mechanical ventilation performed in the absence of formal protocols. *Design and setting:* A randomised, controlled pilot study in one Australian intensive care unit. *Patients:* A total of 102 patients were equally divided between SmartCare/PS and Control. *Interventions:* The automated system titrated pressure support, conducted a spontaneous breathing trial and provided notification of success ("separation potential"). *Measurements and results:* The median time from the first identified point of suitability for weaning commencement to the state of "separation potential" using SmartCare/PS was 20 h (interquartile range, IQR, 2–40) compared to 8 h (IQR 2–43) with Control (log-rank $P = 0.3$). The median time to successful extubation was 43 h (IQR 6–169) using SmartCare/PS and 40 (14–87) with Control (log-rank $P = 0.6$). Unadjusted, the estimated probability of reaching "separation potential" was 21% lower (95% CI, 48% lower to 20% greater) with SmartCare/PS compared to Control. Adjusted for other covariates (age, gender, APACHE II, SOFAmax, neuromuscular blockade, corticosteroids, coma and elevated blood glucose), these estimates were 31% lower (95% CI, 56% lower to 9% greater) with SmartCare/PS. The study groups showed comparable rates of reintubation, non-invasive ventilation post-extubation, tracheostomy, sedation, neuromuscular blockade and use of corticosteroids. *Conclusions:* Substantial reductions in weaning duration previously demonstrated were not confirmed when the SmartCare/PS system was compared to weaning managed by experienced critical care specialty nurses, using a 1:1 nurse-to-patient ratio. The effect of SmartCare/PS may be influenced by the local clinical organisational context. *Descriptor:* 28. Mechanical ventilation: weaning.

Keywords Respiration · Artificial · Mechanical ventilation · Weaning · Automated weaning · Closed-loop ventilation

Introduction

Automated computerised systems for ventilatory management may provide improved adaptation of ventilatory support through continuous monitoring and real-time intervention [1]. The use of one such commercially available automated weaning system (SmartCare^{TM}/PS, Dräger Medical, Lübeck, Germany) was associated with a substantial reduction in the duration of ventilation and intensive care unit (ICU) length of stay when compared to physician-controlled weaning using local guidelines in five European ICUs [2].

SmartCare/PS monitors the patient's respiratory status every 2 or 5 min [frequency, tidal volume, (V_T) and end-tidal carbon dioxide ($etCO_2$) concentration] and periodically adapts pressure support (PS) aiming for a safe, efficient weaning process [1, 3]. The computerised SmartCare/PS system establishes a respiratory status diagnosis, determines an intervention and then instructs the ventilator to decrease or increase PS, or leave it unchanged to maintain the patient in a defined "respiratory zone of comfort" [4, 5]. Once SmartCare/PS has successfully minimised the level of PS, an observation period occurs, which may be followed by a recommendation to "consider separation" (proceed if clinically indicated to patient extubation).

The demonstrated ability of SmartCare/PS to reduce the duration of weaning and ventilation may vary according to local weaning practices and ICU organisational contexts, implying the desirability of further clinical validation outside Europe. This Australian pilot study aimed to estimate the magnitude of effect of SmartCare/PS compared with usual weaning methods in the absence of formalised weaning protocols. This work has been presented in abstract form [6].

Methods

Patients

Eligible patients were those admitted to the adult ICU of The Royal Melbourne Hospital between January and December 2006 who required mechanical ventilation with a volume or pressure targeted mandatory mode of ventilation for greater than 24 h. These modes included synchronised intermittent mandatory ventilation (SIMV), assist-control (A/C), or biphasic intermittent mandatory ventilation (BIPAP) (referred as Bilevel^{TM} on Puritan Bennett 840 ventilators, Puritan Bennett, CA, USA). No other restrictions were placed on the use of modes prior to randomisation once the requirement for 24 h of mandatory ventilation was met. Those patients who tolerated pressure support ventilation early (within 24 h) were excluded as this was considered an indicator of "simple weaning" patients for whom successful extubation occurs without difficulty [7].

The Institutional Review Boards of both the participating hospital and The University of Melbourne approved the study. Informed consent was obtained from the participant's next of kin prior to enrolment and later from those participants who regained competency to consent in accordance with Victorian State law.

Study protocol

In addition to the requirement for a minimum of 24 h of mandatory ventilation as described above, eligibility criteria were: a Dräger EvitaXL (Dräger Medical, Lübeck, Germany) ventilator with SmartCare/PS software version 1.1 available for use immediately prior to randomisation (4 such ventilators available in a 24-bed ICU), PEEP $\leq$ 8 cmH_2O, PaO_2/FiO_2 ratio $>$ 150 (mmHg) or $SaO_2 \geq 90\%$ with $FiO_2 \leq 0.5$, plateau pressure $\leq$ 30 cmH_2O, haemodynamic stability (inotrope infusions of noradrenaline or adrenaline $\leq$ 16.5 μg/min, or dopamine $\leq$ 500 μg/min [2]), body temperature 36–39°C peripherally, stable neurological status with a Glasgow coma score (GCS) $>$ 4, and no anticipated requirements (within 2 h) for transport or surgery. The final criterion for study entry was successful completion (maintenance of respiratory and cardiovascular stability) of a 30-min spontaneous breathing test using PS (maximum 20 cmH_2O) to achieve $V_T > 200$ mL. If automatic tube compensation was in use this was turned off prior to selection of an appropriate PS level. If the PS test was failed, it was repeated at the earliest discretion of the treating clinicians. If no Dräger EvitaXL ventilator was available an otherwise eligible patient could not be randomised. Patients were also excluded if suffering from central nervous system disorders with an anticipated poor outcome including stroke, meningitis, cardiac arrest with neurologic sequelae, or neuromuscular disease.

Eligible patients identified as above were allocated randomly to wean via SmartCare/PS or usual (Control) methods according to a computer-generated block randomisation (block size of 4) administered through a sequential opaque envelope technique. In the Control group, clinicians were instructed to wean PS and PEEP according to usual local practice of the participating ICU in the absence of formal guidelines. Clinicians were instructed to wean PS as able with no constraints as to the frequency or size of PS adjustment while maintaining the patient in the same "respiratory zone of comfort" as used by the SmartCare/PS program. As SmartCare/PS has the potential to wean PS every 2 or 4 min, dependent on whether a change to PS has just been made [5] it was considered unnecessary to limit the frequency or size of PS adjustments to PS in the Control group.

The respiratory zone of comfort was defined as a respiratory frequency between 12 and 30 breaths per minute (<34 if a neurologic disorder resulting in tachypnoea were present); $V_T > 300$ mL (>250 mL if <55 kg); and $etCO_2 < 55$ mmHg (<65 mmHg if the patient had a documented history of CO_2 retention during the current episode of illness). Both SmartCare/PS and Control patients were ultimately weaned to 7 cmH_2O PS in the presence of an endotracheal tube or 5 cmH_2O if a tracheostomy was used. If necessary, PS was also increased to maintain the respiratory zone of comfort. The lower PS goal in tracheostomy patients was based on the SmartCare/PS algorithm. In addition, PEEP was reduced to 5 cmH_2O in both SmartCare/PS and Control patients prior to a 1-h monitoring period for assessment of "separation potential". Weaning endpoints in the Control group (7 cmH_2O PS; 5 cmH_2O PEEP) were stipulated to ensure parity with SmartCare/PS.

Weaning in the study ICU was performed by experienced and relatively autonomous nurses, the majority (70%) of whom held a graduate critical care specialty qualification, using a 1:1 nurse-to-patient ratio maintained over all shifts. Respiratory therapists are not employed in the Australian context. A team of nine intensivists directed overall patient care through twice-daily structured ICU ward rounds with an overnight on-call roster. Reporting to these intensivists, and providing 24-h in-ICU medical staff, were a team of 26 hospital medical officers representing a balanced mix of senior (registrar) and junior (resident) levels of post-graduate training.

Extubation always remained the decision of the attending clinicians. Readiness for extubation was determined by assessment of the patient's ability to safely maintain a patent airway, satisfactory gas exchange and neurological status, and respiratory and cardiovascular parameters within normal limits. Extubation greater than 1 h after first achieving "separation potential" was defined as delayed extubation, and the reason for this delay (pathophysiologic or organisational) was recorded. In both study groups the need to discontinue weaning was based on the same criteria (recurrent apnoea or worsening clinical condition as evidenced by worsening gas exchange, persistent tachypnoea or hypoventilation warranting reinstatement of mandatory ventilation).

Statistical analysis

The time to separation, defined as time in hours from randomisation (immediately following successful completion of the 30 min spontaneous breathing PS test) to the time of declaration of "separation potential" was the primary outcome of interest as this variable was considered to be the least confounded measure of the SmartCare/PS effect. Secondary outcomes included the total duration of weaning (randomisation to successful extubation), time from intubation to first extubation, time from intubation to successful extubation, and overall length of ICU and hospital stay.

The primary and secondary outcomes were determined using Kaplan–Meier estimates, with deaths regarded as censored observations. Following the intention-to-treat principle, all randomised patients were included in these analyses. Treatment groups were initially compared by log-rank tests. Subsequently, multivariate Cox proportional hazards modelling was performed to estimate the adjusted effect of selected covariates on the probability of remaining on mechanical ventilation. The Cox model included covariates representing patient demographics, severity of illness indices, and selected other variables showing univariate associations ($P < 0.10$) with the primary outcome. First level interactions between selected covariates and the weaning method were explored during model development, and the global test of Schoenfeld residuals described by Grambsch and Therneau [8] was used to assess the final model's specification.

Comparison of continuous variables between groups was performed by the Mann–Whitney test, while categorical variables were compared using the chi-squared or Fisher's exact tests. All P values were two-tailed with values of <0.05 considered statistically significant. All analyses were performed using Minitab 14 [9] or Stata version 9.2 [10].

Results

Participants

During the 12-month trial, a total of 988 ventilated patients were screened, of whom a total of 102 patients were randomised and received the intended treatment (51 in each study group, Fig. 1). The most common reason for exclusion ($n = 792$) was a duration of mechanical ventilation with a mandatory mode for less than 24 h. Only four patients were excluded due to the unavailability of a Dräger EvitaXL ventilator.

The characteristics and primary indication for ventilation of study patients are summarised in Table 1. Both SmartCare/PS and Control groups were similar in terms of age, gender, severity of illness, indication for mechanical ventilation, and its duration prior to randomisation.

Study outcomes

The probability of remaining ventilated according to the time from randomisation to first meeting criteria for separation potential is shown in Fig. 2. The relationship between SmartCare/PS and the primary and secondary outcomes of the trial are summarised in Table 2.

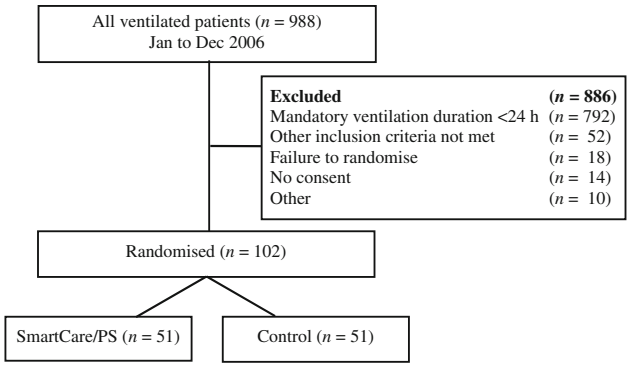

Fig. 1 Trial diagram

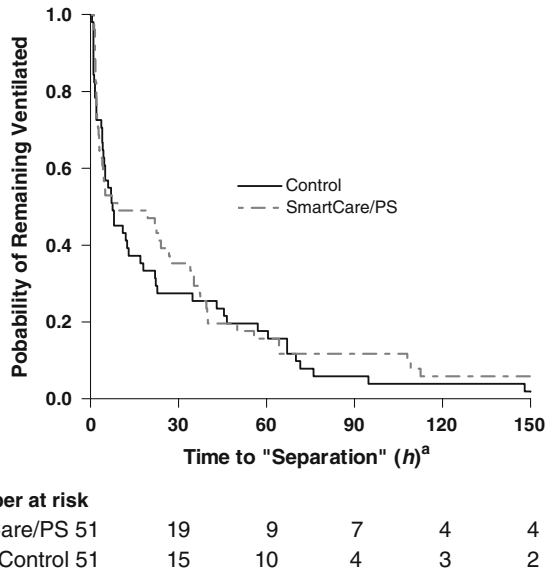

Fig. 2 Kaplan–Meier estimated probability of remaining ventilated. Log-rank test $P = 0.3$. Plot truncated at 150 h due to small numbers of patients beyond that point. [a] Time in hours from randomisation to the time of declaration of "separation potential"

Table 1 Patient characteristics

Characteristic	SmartCare/PS ($n = 51$)	Control ($n = 51$)
Age (years)[a]	51 (29–68)	54 (38–65)
Ventilation prior to randomisation (h)[a]	68 (40–114)	66 (42–133)
Severity of illness scores[a]		
APACHE II	17 (14–48)	18 (11–32)
SAPS II	38 (24–49)	41 (27–54)
Admission SOFA	6 (4–9)	6 (4–9)
SOFAmax	10 (8–12)	9 (7–12)
PaO_2/FiO_2 ratio[b]	226 (197–297)	234 (169–283)
Male gender *n* (%)	36 (71)	32 (63)
Admission type *n* (%)		
Trauma	24 (47)	24 (47)
Surgical	16 (31)	13 (26)
Medical	11 (22)	14 (27)
Indication for ventilation, *n* (%)[c]		
Trauma	24 (47)	24 (47)
Coma	10 (20)	9 (18)
Postoperative	5 (10)	4 (8)
Pneumonia	5 (10)	3 (6)
Sepsis	3 (5.5)	4 (8)
Heart failure	1 (2)	5 (10)
Other	3 (5.5)	2 (4)

APACHE Acute physiology and chronic health evaluation, *SAPS* simplified acute physiology score, *SOFA* sequential organ failure assessment, *SOFAmax* maximum organ failure score during ventilation [11]

Log-rank test $P = 0.3$. Plot truncated at 150 h due to small numbers of patients beyond that point

[a] Median (interquartile range, IQR)

[b] Worst PaO_2/FiO_2 ratio recorded on the day of study inclusion

[c] Though not an exclusion criteria, no patients with chronic obstructive pulmonary disease met the entry criteria for the study

In addition to the above univariate analyses, multivariate Cox proportional hazards analyses was performed with the study primary outcome, time from randomisation to reaching the state of "separation potential" and the secondary outcome, time from randomisation to successful extubation. As shown in Table 3, the adjusted probability of reaching separation potential was estimated to be 31% lower with SmartCare/PS compared to Control (95% CI, 56% lower to 9% greater). Use of SmartCare was not associated with time to successful extubation either alone or when adjusted for other potentially relevant covariates ($P = 0.57$ and $P = 0.69$, respectively). Notably, greater age, male gender, elevated maximum SOFA scores and prior receipt of neuromuscular blocking drugs were independently associated with a reduced chance of successful extubation (Table 3).

The number of deaths prior to declaration of separation potential (2 vs. 1 patient, $P = 0.4$) and successful extubation (5 vs. 0 patients, $P = 0.06$) was similar in both the SmartCare/PS and Control groups. Likewise the rates of reintubation within 48 h (5 SmartCare/PS patients vs. 6 Control patients, $P = 1.0$), use of non-invasive ventilation post-extubation (8 vs. 6, $P = 0.8$), requirement for tracheostomy (6 vs. 8, $P = 0.8$) or prolonged episode of mechanical ventilation >14 days (5 vs. 7, $P = 0.8$) were similar between study groups.

Compared to Control, more participants in the SmartCare/PS group experienced a delay in extubation >1 h (31/51 vs. 22/51 participants, $P = 0.07$). The most frequent reason for delayed extubation was a low GCS [SmartCare/PS 12 (24%) patients, Control 9 (18%) patients] followed by respiratory failure as evidenced by worsening chest X-ray or gas exchange [SmartCare/PS 8 (16%) patients, 3 (6%) Control patients]. Organisational factors such as unavailability of senior staff highly

Table 2 Primary and secondary outcomes

	SmartCare/PS	Control	*P* value
Primary outcome			
Time to "separation" (h)[a]	20 (2–40)	8 (2–43)	0.3
Secondary outcomes			
Time to successful extubation (h)[b]	43 (6–169)	40 (14–87)	0.6
Ventilation to first extubation (h)[c]	119 (66–218)	128 (54–218)	0.9
Total duration of ventilation (h)[d]	119 (69–226)	129 (62–243)	0.9
Length of ICU stay (h)[e]	146 (106–286)	196 (97–293)	0.7
Length of hospital stay (h)[f]	445 (301–788)	532 (334–791)	0.9

Data denote estimated median (IQR) time in hours according to Kaplan−Meier methods with Log-rank *P* values. Deaths were treated as censoring events

[a] Time in hours from inclusion in the study to the time of declaration of "separation potential"

[b] Time in hours from randomisation at study commencement to successful extubation. Denoted as primary outcome in previously reported randomized, controlled trial of SmartCare/PS [2]

[c] Time in hours from commencement of ventilation in ICU to first extubation. Time in hours from commencement of ventilation in ICU to discontinuation from positive pressure ventilation (if sustained for ≥24 h) for patients who required tracheostomy

[d] Time in hours from commencement of ventilation in ICU to successful extubation. Time in hours from commencement of ventilation in ICU to successful discontinuation from positive pressure ventilation for patients who required tracheostomy

[e] Time in hours from ICU admission to ICU discharge

[f] Time in hours from hospital admission to hospital discharge

experienced at intubation, as required by unit policy, accounted for extubation delay in seven (14%) SmartCare/PS patients and in six (12%) Control patients. The median time elapsed from first achievement of the separation criteria to the clinical decision to proceed to first extubation was 19 (IQR 5–60) hours in the SmartCare/PS group and 31 (IQR 5–60) hours in the Control group ($P = 0.04$).

Sedation administered to each trial group was similar, both prior to and after inclusion on the study protocol (Table 4). The frequency of exposure to corticosteroids was also comparable between the two groups ($P = 0.5$).

The median highest level of PS used was 13 cmH_2O (IQR 10–19 cmH_2O) in the SmartCare/PS group and 15 cmH_2O (IQR 10–15 cmH_2O) in the Control group. Compared to Control, the SmartCare/PS group had a greater median number of PS changes (34 vs. 7 changes, $P < 0.001$). The maximum PEEP settings were similar between SmartCare/PS (10 cmH_2O, IQR 10–12 cmH_20) and Control (10 cmH_2O, IQR 10–15 cmH_2O).

Patient extubation occurred prior to achievement of the criteria for separation (PS 7 cmH_2O and PEEP 5 cmH_2O), in 20% of the SmartCare/PS group and 39% of Control ($P = 0.03$). In the SmartCare/PS group, non-compliance with the study protocol was mainly due to a clinical assessment of patient–SmartCare/PS incompatibility, such as occurred in 14% of patients where high levels of PS were reached repeatedly due to unstable breathing patterns, or a clinical decision to proceed to extubation prior to reaching a declaration of separation potential (6% of patients). In the Control group, non-compliance was entirely due to a clinical decision to extubate prior to a reduction of PEEP to 5 cmH_2O.

Discussion

In this first Australian pilot study, the unadjusted chance of reaching "separation potential" was estimated to be 21% lower (95% CI, 48% lower to 20% greater) with SmartCare/PS compared to Control. Following adjustment for age, gender, severity of illness, use of neuromuscular blockade or use of corticosteroids, maximum blood glucose during ICU admission, and presence of coma, the estimated probability of reaching "separation potential" remained 31% lower (95% CI, 56% lower to 9% greater) with SmartCare/PS. Likewise, use of SmartCare was not associated with a decreased time to successful extubation using either unadjusted or adjusted analyses.

To the present, there has been only one published large randomised study of SmartCare/PS. In the recent study of 144 patients admitted to five European ICUs, SmartCare/PS was demonstrated to reduce the median duration of weaning from 5 to 3 days ($P = 0.01$) and the median total duration of ventilation by 4.5 days ($P = 0.003$) with no differences in ventilatory complications between the two groups [2]. In the current Australian study the returned upper limits of the estimated likely benefit from SmartCare/PS for the time to successful weaning were 70% (unadjusted) or 43% (adjusted), with a multivariate point estimate of effect actually unfavourable to SmartCare/PS.

Table 3 Variables associated with time from randomisation to reaching "separation potential" and successful extubation

	Reference	Time to separation potential				Time to successful extubation			
		Univariate[a]		Multivariate[b]		Univariate[a]		Multivariate[b]	
		Hazard ratio (95% CI)	*P* value	Hazard ratio (95% CI)	*P* value	Hazard ratio (95% CI)	*P* value	Hazard ratio (95% CI)	*P* value
SmartCare/PS	Control	0.79 (0.52–1.20)	0.27	0.69 (0.44–1.09)	0.12	1.13 (0.75–1.70)	0.57	0.91 (0.58–1.43)	0.69
Age, ≥median (years)[c]	<Median	0.95 (0.90–1.00)	0.06	0.99 (0.92–1.05)	0.67	0.60 (0.40–0.92)	0.02	0.49 (0.29–0.80)	0.005
Male gender	Female	1.63 (1.04–2.56)	0.03	1.81 (1.03–3.19)	0.04	1.86 (1.20–2.89)	0.006	1.87 (1.09–3.20)	0.02
APACHE II ≥ median[c]	<Median	0.90 (0.77–1.06)	0.21	0.98 (0.80–1.19)	0.82	0.73 (0.48–1.11)	0.14	1.07 (0.60–1.91)	0.81
SOFAmax	Per 5 points	0.57 (0.42–0.77)	<0.0005	0.83 (0.54–1.26)	0.38	0.48 (0.34–0.66)	<0.0005	0.48 (0.31–0.74)	0.001
NMBs[d]	No NMBs	0.76 (0.51–1.15)	0.20	0.65 (0.40–1.07)	0.09	0.60 (0.39–0.91)	0.02	0.50 (0.31–0.81)	0.005
Corticosteroids	No corticosteroids	0.35 (0.17–0.72)	0.004	0.57 (0.25–1.31)	0.19	0.42 (0.22–0.82)	0.01	1.07 (0.48–2.39)	0.86
Glucose (maximum) (mmol/L) ≥ overall median[c]	<Overall median	0.68 (0.51–0.91)	0.008	0.73 (0.53–0.99)	0.04	0.61 (0.40–0.92)	0.02	0.81 (0.49–1.34)	0.41
Coma	No coma	1.40 (0.84–2.33)	0.19	1.53 (0.82–2.88)	0.19	1.61 (0.97–2.68)	0.07	1.71 (0.91–3.23)	0.10

APACHE Acute physiology and chronic health evaluation, *SOFAmax* sequential organ failure assessment maximum, *NMBs* neuromuscular blockers, *Glucosemax* maximum plasma glucose (mmol/L) recorded during ICU admission

[a] Univariate Cox proportional hazards model with only the indicated covariate

[b] Multivariate Cox proportional hazards models adjusted for all other variables in the table. Tests of proportional hazards assumptions, $P = 0.97$ (time to separation potential) and $P = 0.88$ (time to successful extubation), used global tests of Schoenfeld residuals [8]. Overall goodness of fit was also confirmed by graphical methods using Cox−Snell residuals

[c] Model diagnostics indicated three continuous covariates did not support the proportional hazard assumption and were therefore included in the model as binary categorical covariates according to their respective medians (age 53 years; APACHE II score 18; maximum glucose 11 mmol/L

[d] Use of NMBs prior to commencement of weaning phase

Table 4 Use of sedation and neuromuscular blockade

	Before inclusion		*P* value[a]	After inclusion		*P* value[a]
	SmartCare/PS	Control		SmartCare/PS	Control	
Propofol (mg)	1,665 (523–6,485)	1,630 (400–5,078)	0.8	1,515 (35–3,783)	705 (25–4,579)	0.7
Midazolam (mg)	156 (39–418)	166 (55–399)	0.8	0 (0–25)	0 (0–25)	0.3
Morphine (mg)	143 (44–407)	165 (48–387)	0.9	0 (0–25)	0 (0–7)	0.5
Fentanyl (μg)[b]	0 (0–0)	0 (0–0)	0.5	0 (0–0)	0 (0–0)	0.9
Vecuronium (mg)	10 (0–30)	10 (0–32)	0.8	0 (0–0)	0 (0–0)	0.9

Data denote median (IQR) of total quantity of each drug administered in ICU divided according to time of randomisation

Drugs used in <10 patients overall included diazepam, olanzapine, clonidine, pethidine, fentanyl, ketamine, dexemetomidine, haloperidol, and rocuronium

[a] Difference in total dose calculated using Mann−Whitney test. Analysis of sedation administered per hour of ventilation produced similar results (data not shown)

[b] Maximum dose of Fentanyl used before study inclusion was 1,028 μg in the SmartCare/PS group (920 μg after inclusion) and 1,030 μg in Control (555 μg after inclusion)

The current Australian study showed a number of differences in baseline patient characteristics compared to the European study [2]. These differences included lower median ages and SAPS II scores, a larger proportion of trauma patients, and the absence of COPD patients. These differences imply that SmartCare/PS may be of most use with patients who are more difficult to wean, and further studies are required to define the characteristics of ventilated patients best suited to the application of SmartCare/PS.

Further, in the European study the median duration of weaning and ventilation were comparatively prolonged in both the SmartCare/PS (wean 3.0 days, ventilation 7.5 days) and Control groups (wean 5.0 days, ventilation 12.0 days) compared to those reported in this Australian study. In the Control group of the European study, assessment of criteria to determine extubation readiness was performed daily in one institution or two-to-three times a day in the other participating ICUs [2]. In comparison, weaning management in the current Australian study involved unlimited assessment of weaning and extubation readiness performed by experienced and relatively autonomous critical care nurses using a 1:1 nurse-to-patient ratio, supported by 24-h house medical staff and twice-daily rounds by intensivists. These organisational features are common to Australian ICUs in which ICU nurses commonly titrate ventilation and manage respiratory therapy according to physician-set physiologic targets [12–14].

The lack of a clear association between SmartCare/PS and a substantial reduction in the duration of weaning also may have been due to locally specific weaning practices and organisational structure of the study ICU, such that the present study results may not necessarily be reproduced in other ICUs. In this regard, some evidence suggests a shorter duration of weaning and overall ventilation compared to previously reported international norms [15, 16] in the study ICU prior to the evaluation of the SmartCare/PS system [17].

Studies of weaning protocols conducted in ICUs with high staffing levels, such as those present in the current Australian hospital, may not demonstrate the same advantage as those performed in ICUs with lower staffing levels [18]. The ability of SmartCare/PS to effect a reduction in the duration of ventilation may differ substantially in an ICU that does not normally provide frequent titration of ventilation instituted by trained and specialised medical and nursing staff.

Although randomised, this study was potentially limited due to the difficulty of conducting a blinded assessment of ventilatory or weaning methods, making it possible that clinical staff may have introduced bias by conscious or unconscious actions or decisions. No attempt was made to measure these possible influences on ICU weaning behaviour in the presence of the SmartCare/PS system. However, some evidence against a large bias of this type was provided by comparison with the duration of ventilation previously observed in the same Australian ICU 1 year prior to commencement of the SmartCare/PS trial [17]. Data from that study, for the patient subgroup who received some form of mandatory ventilation for a minimum of 24 h prior to the commencement of weaning, showed an overall duration of mechanical ventilation (median 117 h (IQR 54–207 h) closely comparable to those observed in the Control group of the present study.

An important aim of SmartCare/PS is the maintenance of each patient in a proprietary "respiratory zone of comfort" by continuous monitoring and real-time interventions [5]. In the current study, a notable observation was the substantially greater number of changes to the PS level in the SmartCare/PS group compared to Control patients. An assessment of any consequence of this greater frequency of PS manipulation on a patient's

experience of SmartCare/PS weaning, relative to more conventional methods, has not yet been reported.

Conclusion

This pilot study represented the first randomised evaluation of the SmartCare/PS system in an Australian ICU. In this clinical context, SmartCare/PS did not reduce substantially the duration of weaning, in marked contrast to its previously demonstrated success in Europe. The performance of SmartCare/PS in this Australian study showed no obvious advantage over existing weaning methods, which comprised frequent assessment of weaning readiness and titration of ventilatory support performed by registered nurses qualified and experienced in ventilatory management, in collaboration with trained medical specialists working in a closed ICU model. A large multi-centre study may be required to more clearly estimate the magnitude of any advantage of SmartCare/PS on the duration of weaning from mechanical ventilation in Australian ICUs, where experienced critical care specialty nurses manage ventilated patients using a 1:1 nurse-to-patient ratio.

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