



Literature List SmartCare®/PS

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SmartCare[®]/PS Literature List

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Categories

CLIN = Clinical Study

REV = Review

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CLIN	Lellouche F. et al.	A multicenter randomized trial of computer-driven protocolized weaning from mechanical ventilation.	<i>Am J Respir Crit Care Med.</i> 2006 Oct 15; 174(8):894-900
<p>Rationale and Objectives: Duration of weaning from mechanical ventilation may be reduced by the use of a systematic approach. We assessed whether a closed-loop knowledge-based algorithm introduced in a ventilator to act as a computer-driven weaning protocol can improve patient outcomes as compared with usual care.</p> <p>Methods and Measurements: We conducted a multicenter randomized controlled study with concealed allocation to compare usual care for weaning with computer-driven weaning. The computerized protocol included an automatic gradual reduction in pressure support, automatic performance of spontaneous breathing trials (SBT), and generation of an incentive message when an SBT was successfully passed. One hundred forty-four patients were enrolled before weaning initiation. They were randomly allocated to computer-driven weaning or to physician-controlled weaning according to local guidelines. Weaning duration until successful extubation and total duration of ventilation were the primary endpoints.</p> <p>Main Results: Weaning duration was reduced in the computer-driven group from a median of 5 to 3 d (p=0.01) and total duration of mechanical ventilation from 12 to 7.5 d (p=0.003). Reintubation rate did not differ (23 vs. 16%, p=0.40). Computer-driven weaning also decreased median intensive care unit (ICU) stay duration from 15.5 to 12 d (p=0.02) and caused no adverse events. The amount of sedation did not differ between groups. In the usual care group, compliance to recommended modes and to SBT was estimated, respectively, at 96 and 51%.</p>			
<p>Conclusion: The specific computer-driven system used in this study can reduce mechanical ventilation duration and ICU length of stay, as compared with a physician-controlled weaning process.</p>			
CLIN	Rose L. et al.	A randomised, controlled trial of conventional versus automated weaning from mechanical ventilation using SmartCare/PS.	<i>Intensive Care Med</i> 2008 DOI 10.1007/s00134-008-1179-4
<p>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.</p> <p>Patients: A total of 102 patients were equally divided between SmartCare/PS and Control.</p> <p>Interventions: The automated system titrated pressure support, conducted a spontaneous breathing trial and provided notification of success ("separation potential").</p> <p>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.</p>			
<p>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 organizational context.</p>			

CLIN	Schädler D. et al.	Automatic control of pressure support for ventilator weaning in surgical intensive care patients.	<i>January 20, 2012 as doi:10.1164/rccm.201106-1127OC</i>
<p>Rationale: Despite its ability to reduce overall ventilation time, protocol-guided weaning from mechanical ventilation is not routinely used in daily clinical practice. Clinical implementation of weaning protocols could be facilitated by integration of knowledge-based, closed-loop controlled protocols into respirators.</p> <p>Objectives: To determine whether automated weaning decreases overall ventilation time compared with weaning based on a standardized written protocol in an unselected surgical patient population.</p> <p>Methods: In this prospective controlled trial patients ventilated for longer than 9 hours were randomly allocated to receive either weaning with automatic control of pressure support ventilation (automated-weaning group) or weaning based on a standardized written protocol (control group) using the same ventilation mode. The primary end point of the study was overall ventilation time.</p> <p>Measurements and Main Results: Overall ventilation time (median [25th and 75th percentile]) did not significantly differ between the automated-weaning (31 [19–101] h; n = 150) and control groups (39 [20–118] h; n = 150; <i>P</i> = 0.178). Patients who underwent cardiac surgery (n = 132) exhibited significantly shorter overall ventilation times in the automated-weaning (24 [18–57] h) than in the control group (35 [20–93] h; <i>P</i> = 0.035). The automated-weaning group exhibited shorter ventilation times until the first spontaneous breathing trial (1 [0–15] vs. 9 [1–51] h; <i>P</i> = 0.001) and a trend toward fewer tracheostomies (17 vs. 28; <i>P</i> = 0.075).</p>			
<p>Conclusions: Overall ventilation times did not significantly differ between weaning using automatic control of pressure support ventilation and weaning based on a standardized written protocol. Patients after cardiac surgery may benefit from automated weaning. Implementation of additional control variables besides the level of pressure support may further improve automated-weaning systems.</p>			
CLIN	Jouvet PA et al.	Weaning children from mechanical ventilation with a computer-driven protocol: a pilot	<i>Intensive Care 2013 Med DOI 10.1007/s00134-013-2837-8</i>
<p>Purpose: Duration of weaning from mechanical ventilation is decreased with the use of written protocols in adults. In children, the use of written protocols has not had such an impact.</p> <p>Methods and Measurements: We conducted a single-center trial to assess the feasibility of conducting a multicenter randomized clinical trial comparing the duration of weaning from mechanical ventilation in those managed by a computer-driven explicit protocol versus usual care. Mechanically ventilated children aged between 2 and 17 years on pressure support and not receiving inotropes were included. After randomization, children were weaned either by usual care (n = 15) that was characterized by no protocolized decisions by attending physicians, or by a computer-driven protocol (Smartcare/PS™, Dräger Medical) (n = 15). Weaning duration until first extubation was the primary outcome. For comparison, a Mann-Whitney U test was employed (<i>p</i> < 0.05).</p> <p>Results: Patients characteristics at inclusion were similar. The median duration of weaning was 21 h (range 3–142 h) in the SmartCare/PS™ group and 90 h (range 4–552 h) in the usual care group, <i>p</i> = 0.007. The rate of reintubation within 48 h after extubation and the rate of noninvasive ventilation after extubation in the SmartCare/PS™ and usual care groups were 2/15 versus 1/15 and 2/15 versus 2/15, respectively.</p>			
<p>Conclusions: A pediatric randomized trial on mechanical ventilation with a computerized protocol in North America is feasible. A computer-driven protocol that also manages children younger than 2 years old would help to decrease the number of PICU admissions screened in a multicentre trial on this topic.</p>			

CLIN	Burns KE et al.	Wean earlier and automatically with new technology (the WEAN study). A multicenter, pilot randomized controlled trial.	<i>Jun 1, Am J Respir Crit Care Med Vol 187, Iss. 11, pp 1203–1211, 2013</i>
<p>Rationale: Automated weaning has not been compared with a paper-based weaning protocol in North America.</p> <p>Objectives: We conducted a pilot randomized trial comparing automated weaning with protocolized weaning in critically ill adults to evaluate clinician compliance and acceptance of the weaning and sedation protocols, recruitment, and impact on outcomes.</p> <p>Methods: From August 2007 to October 2009, we enrolled critically ill adults requiring more than 24 hours of mechanical ventilation and at least partial reversal of the condition precipitating respiratory failure at nine Canadian intensive care units. We randomized patients who tolerated at least 30 minutes of pressure support and either failed or were not yet ready to undergo a spontaneous breathing trial to automated or protocolized weaning. Both groups used pressure support, included spontaneous breathing trials, used a common positive end-expiratory pressure-FI(O₂) chart, sedation protocol, and criteria for extubation, reintubation, and noninvasive ventilation.</p> <p>Measurements and Main Results: We recruited 92 patients (49 automated, 43 protocolized) over 26 months. Adherence to assigned weaning protocols and extreme sedation scale scores fell within prespecified thresholds. Combined physician-respiratory therapist and nurse acceptance scores of the study weaning and sedation protocols, respectively, were not significantly different. Automated weaning patients had significantly shorter median times to first successful spontaneous breathing trial (1.0 vs. 4.0 d; P < 0.0001), extubation (3.0 vs. 4.0 d; P = 0.02), and successful extubation (4.0 vs. 5.0 d; P = 0.01), and underwent fewer tracheostomies and episodes of protracted ventilation.</p> <p>Conclusions: Compared with a standardized protocol, automated weaning was associated with promising outcomes that warrant further investigation. Minor protocol modifications may increase compliance, facilitate recruitment, and enhance feasibility.</p>			

REV	Rose L. et al.	Automated versus non-automated weaning for reducing the duration of mechanical ventilation for critically ill adults and children (Cochran Review)	<i>The Cochrane Library 2013, Issue 6</i>
<p>Background: Automated closed loop systems may improve adaptation of the mechanical support to a patient's ventilatory needs and facilitate systematic and early recognition of their ability to breathe spontaneously and the potential for discontinuation of ventilation.</p> <p>Objectives: To compare the duration of weaning from mechanical ventilation for critically ill ventilated adults and children when managed with automated closed loop systems versus non-automated strategies. Secondary objectives were to determine differences in duration of ventilation, intensive care unit (ICU) and hospital length of stay (LOS), mortality, and adverse events.</p> <p>Search Methods: We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2011, Issue 2); MEDLINE (OvidSP) (1948 to August 2011); EMBASE (OvidSP) (1980 to August 2011); CINAHL (EBSCOhost) (1982 to August 2011); and the Latin American and Caribbean Health Sciences Literature (LILACS). In addition we received and reviewed auto-alerts for our search strategy in MEDLINE, EMBASE, and CINAHL up to August 2012. Relevant published reviews were sought using the Database of Abstracts of Reviews of Effects (DARE) and the Health Technology Assessment Database (HTA Database). We also searched the Web of Science Proceedings; conference proceedings; trial registration websites; and reference lists of relevant articles.</p> <p>Selection Criteria: We included randomized controlled trials comparing automated closed loop ventilator applications to non-automated weaning strategies including non-protocolized usual care and protocolized weaning in patients over four weeks of age receiving invasive mechanical ventilation in an intensive care unit (ICU).</p> <p>Data Collection and Analysis: Two authors independently extracted study data and assessed risk of bias. We combined data into forest plots using random-effects modelling. Subgroup and sensitivity analyses were conducted according to a priori criteria.</p> <p>Main Results: Pooled data from 15 eligible trials (14 adult, one paediatric) totaling 1173 participants (1143 adults, 30 children) indicated that automated closed loop systems reduced the geometric mean duration of weaning by 32% (95% CI 19% to 46%, $P = 0.002$), however heterogeneity was substantial ($I(2) = 89\%$, $P < 0.00001$). Reduced weaning duration was found with mixed or medical ICU populations (43%, 95% CI 8% to 65%, $P = 0.02$) and SmartCare/PS™ (31%, 95% CI 7% to 49%, $P = 0.02$) but not in surgical populations or using other systems. Automated closed loop systems reduced the duration of ventilation (17%, 95% CI 8% to 26%) and ICU length of stay (LOS) (11%, 95% CI 0% to 21%). There was no difference in mortality rates or hospital LOS. Overall the quality of evidence was high with the majority of trials rated as low risk.</p>			
<p>Conclusions: Automated closed loop systems may result in reduced duration of weaning, ventilation, and ICU stay. Reductions are more likely to occur in mixed or medical ICU populations. Due to the lack of, or limited, evidence on automated systems other than Smartcare/PS™ and Adaptive Support Ventilation no conclusions can be drawn regarding their influence on these outcomes. Due to substantial heterogeneity in trials there is a need for an adequately powered, high quality, multi-centre randomized controlled trial in adults that excludes 'simple to wean' patients. There is a pressing need for further technological development and research in the paediatric population.</p>			