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An open-loop, physiological model based decision support system can reduce pressure support while acting to preserve respiratory muscle function

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ABSTRACT

Purpose: To assess whether a clinical decision support system (CDSS) suggests PS and FIO_2 maintaining appropriate breathing effort, and minimizing FIO_2.
Materials: Prospective, cross-over study in PS ventilated ICU patients. Over support (150% baseline) and under support (50% baseline) were applied by changing PS (15 patients) or PEEP (8 patients). CDSS advice was followed. Tension time index of inspiratory muscles (TTies), respiratory and metabolic variables were measured.
Results: PS over support (median 8.0 to 12.0 cmH_2O) reduced respiratory muscle activity (TTies 0.090 ± 0.028 to 0.049 ± 0.030; $p < .01$), and tended to increase tidal volume (VT: 8.6 ± 3.0 to 10.1 ± 2.9 ml/kg; $p = .08$). CDSS advice reduced PS (6.0 cmH_2O, $p = .005$), increased TTies (0.076 ± 0.038, $p < .01$), and tended to reduce VT (8.9 ± 2.4 ml/kg, $p = .08$). PS under support (12.0 to 4.0 cmH_2O) slightly increased respiratory muscle activity, (TTies to 0.120 ± 0.044; $p = .007$) with no significant CDSS advice. CDSS advice reduced FIO_2 by 12–14% ($p = .005$), resulting in median $SpO_2 = 96\%$ ($p < .02$). PEEP changes did not result in changes in physiological variables, or CDSS advice.
Conclusion: The CDSS advised on low values of PS often not prohibiting extubation, while acting to preserve respiratory muscle function and preventing passive lung inflation. CDSS advice minimized FIO_2 maintaining SpO_2 at safe and beneficial values.

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1. Introduction

Management of mechanical ventilation can be considered a process of balancing competing goals. Inspired oxygen should be set to avoid hypoxaemia, without elevated values causing hyperoxaemia [1], and in patients with respiratory muscle activity and ventilated in pressure support (PS) mode, levels of PS should be selected which prevent excessive work of breathing while maintaining the strength of respiratory muscles [2]. Over-support, and minimal work of breathing (WOB) by the patient, may result in depression of respiratory drive and the development of ventilator induced diaphragmatic dysfunction (VIDD) [3]. Under support, and excessive patient WOB, may result in rapid shallow breathing [4], elevated muscle work and consequent muscle fatigue [5]. A complete understanding of the effects of changes in PS requires esophageal pressure (Peso) [5], which is not routinely measured.

Recently, a computerized clinical decision support system (CDSS), based on mathematical models of physiology, has been shown to provide appropriate advice on mechanical ventilation for a period of 4–8 h [6]. Changes in ventilator settings were evaluated from current clinical conditions, with physiological changes in PS evaluated using clinical variables.

This paper prospectively evaluates the ability of this CDSS to select appropriate ventilator settings in patients with spontaneous breathing activity following systematic over and under support. The ability of CDSS advice on PS to preserve respiratory muscle function is assessed from esophageal pressure measurements.

2. Materials and methods

2.1. Patients

Twenty-three patients were included from July 2015 to January 2017 at one university hospital general ICU (Ferrara, Italy). Patients were considered eligible if: on invasive mechanical ventilation;

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recovering from ARF; triggering the ventilator; and having Richmond Agitation Sedation Scale score between −1 and + 1. Patients were excluded if: contraindicated for esophageal catheter insertion; cardiac instability (heart rate > 120 beats/min, systolic blood pressure < 90 or > 160 mmHg and vasopressor infusion (i.e., dobutamine >5 μg/kg/min or noradrenaline >0.1 μg/kg/min)); neurological or neuromuscular pathology; elevated intracranial pressure; <18 years and pregnancy. This was a prospective single-center crossover study. The study was approved by the local ethics committee and informed consent obtained.

2.2. Clinical decision support system

An open-loop CDSS (Beacon Caresystem™, Mermaid Care A/S, Nørresundby, Denmark) was connected to the patient by pulse oximeter and respiratory tube including pneumotach measurement and side stream gas analysis. This allows measurement of oxygenation (SpO_2), RR, minute ventilation (VMIN), VT, fraction of end-tidal carbon dioxide ($FetCO_2$), fraction of end tidal oxygen ($FetO_2$), oxygen consumption (VO_2), carbon dioxide production (VCO_2) and respiratory exchange ratio (RER). The CDSS registers ventilator settings by serial communication with the ventilator. The CDSS was set to provide advice on FIO_2 and PS. For a more detailed description of the CDSS see the electronic supplementary material (ESM) and [7].

2.3. Procedure

The study was designed to investigate the CDSS response to systematic over and under support. Patients were studied semi-recumbent, and ventilated with a Servo i ventilator (Maquet Critical Care, Solna, Sweden) in PS mode. As support for respiratory muscles is a combination of levels of PS and PEEP, patients were randomized to receive over support (150% baseline) and under support (50% baseline), either with changes in PS or PEEP, with baseline settings those of the attending physician. Patients were randomized to receive over or under support first, with baseline ventilation for 15 min between phases (Fig. 1). Randomization was performed using closed envelopes.

CDSS advice was followed from baseline, and from over and under support. Advice was followed for maximum 1 h or five pieces of advice per phase, with a maximum duration of 6 h. Advice was followed if considered safe by the clinician, with unsafe advice documented.

2.4. Data collection and analysis

Patient characteristics (age, height, weight, sex, reasons for admission and intubation, morbidity, heart rate, MAP, adjunctive therapies, comorbidities, outcome and length of stay) were registered on inclusion. The CDSS registered advice, changes in settings and resulting changes in SpO_2, $FetCO_2$, RR and VT. Predicted body weight (PBW) and VT per PBW (VT/PBW) were calculated as previously [8]. VMIN and rapid shallow breathing index (RR/VT) were calculated from VT and RR. Each measurement represented a 2-min average.

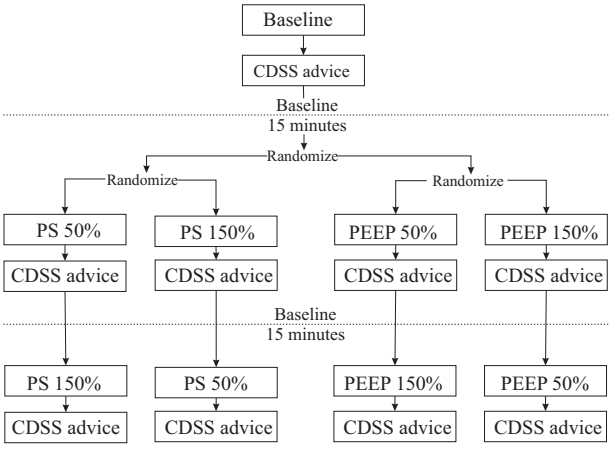

Fig. 1. Protocol flowchart.

Esophageal pressure (Pes) was measured using a standard air-filled balloon catheter (Microtek, Zutphen, The Netherlands). Proper positioning was verified by end expiratory occlusion (Baydur test) [9]. Airflow (V′) was measured with a heated pneumotachograph (3700, 0–160 l/min, Hans Rudolf, Kansas City, Mo., USA) placed between y-piece and endotracheal tube connected to a differential pressure transducer (DP55 ± 3.5 cmH_2O Raytech Instruments, B.C., Canada). Airway pressure (Paw) was measured through a side port on the pneumotachograph using a differential pressure transducer (DP55 ± 100 cmH_2O Raytech); and esophageal pressure (Pes) was measured by direct connection of a similar transducer to the catheter. Transpulmonary pressure (PL) was obtained by subtracting Pes from Paw.

VT, inspiratory time (Ti), RR, and the "duty cycle" (Ti/Ttot) were calculated offline as averages from flow traces. PL was used to calculate dynamic lung elastance ($E_{L,dyn}$) and pulmonary resistance ($R_{L,dyn}$) according to the Neergaard-Wirtz elastic subtraction technique [10].

The values for Pes at zero flow were assumed to be the beginning and end of inspiration. The theoretical value for chest wall compliance, i.e. 4% of the predicted value of the vital capacity per cmH_2O, was used, assuming no abnormal chest wall compliance [11]. Dynamic intrinsic PEEP ($PEEPi_{,dyn}$) was computed as the negative deflection in Pes from the onset of inspiratory effort to the point of zero flow during spontaneous inspiratory activity. The onset of inspiratory effort was determined as the beginning of the esophageal pressure decay at the end of expiration. The pressure time product (PTP) of the inspiration was calculated as the area subtended by Pes and the chest-wall static recoil pressure time, taking into account $PEEPi_{,dyn}$ [12].

Maximum inspiratory pressure (MIP) was obtained from the negative deflection in Paw during a maneuver of maximum inspiratory efforts against occluded airways for 20 s [20]. The Tension Time index of the inspiratory muscle (TTies) was calculated as described previously, i.e. $TTies = \frac{mean\ Pes}{MIP} * \frac{Ti}{Ttot}$ [13].

The waveforms of Paw, Pes and V′ were recorded continuously (Dyrec System, Raytech Instruments, B.C., Canada) at 100 Hz for offline data analysis. Paw, Pes and V′ were calculated as averages of 20 breaths immediately prior to ventilator change and 5–10 min after change. A customized version of software was used to analyse esophageal signals (ICU Lab software; Kleistek Engineering; Bari, Italy).

2.5. Statistical analysis

Statistical analysis was performed with SPSS (SPSS Statistics 22.0, IBM). Normality was tested using the Shapiro Wilk test. Descriptive statistics are reported as mean ± SD for normally distributed data and as median [interquartile range] for non-normally distributed data.

Values of ventilator settings and physiological variables were compared at baseline, over and under support, and before and after CDSS advice using either two-way repeated measures ANOVA for normally distributed measurements; or two way repeated measures nonparametric Friedman analysis. For variables with significance on ANOVA or Friedman analysis, post-hoc analysis was performed for differences between baseline values and over and under support; and differences due to CDSS advice from baseline, over and under support. Post-hoc comparisons were performed using paired *t*-test for normally distributed variables, or Wilcoxon, both with Bonferroni correction.

To investigate whether low values of PS advised by the CDSS were consistent with subsequent rapid extubation, a post-hoc analysis was performed comparing the subsequent clinical management of patients where advice following under-support resulted in low PS levels (PS ≤ 4 cmH_2O), or otherwise (PS > 4 cmH_2O).

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