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Relationship between monitored elements and prescribed ventilator setting modifications in critically ill children

by
Kay Allen Eddington, MD, FAAP

Faculté de Médecine

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Relationship between monitored elements and prescribed ventilator setting modifications in critically ill children

Présenté par :
Kay Allen Eddington, MD, FAAP

a été évalué par un jury composé des personnes suivantes :

Yves Tremblay, président-rapporteur
Philippe Jouvet, directeur de recherche
Guillaume Emeriaud, co-directeur
Jean Paul Prauld, membre du jury

Résumé

Les pédiatres intensivistes ont plusieurs éléments disponibles pour guider leurs décisions par rapport à la ventilation mécanique. Par contre, aucune étude prospective ne décrit les éléments auxquels les intensivistes se réfèrent pour modifier les paramètres du respirateur.

Objectifs : Décrire la pratique actuelle de la modification des paramètres du respirateur aux soins intensifs du CHU Sainte-Justine, un hôpital pédiatrique tertiaire.

Hypothèse : 80% des modifications des paramètres du respirateur influant sur l'épuration du CO_2 sont liées à l'analyse de la PCO_2 ou du pH et 80% des modifications des paramètres d'oxygénation sont liés à l'analyse de l'oxymétrie de pouls.

Méthodes : En se servant d'un logiciel de recueil de données, les soignants ont enregistré un critère de décision primaire et tous les critères de décision secondaires menant à chaque modification de paramètre du respirateur au moment même de la modification.

Résultats : Parmi les 194 modifications des paramètres du respirateur influant sur l'épuration du CO_2, faites chez vingts patients, 42.3% ±7.0% avaient pour critère primaire la PCO_2 ou le pH sanguin. Parmi les 41 modifications de la pression expiratoire positive et les 813 modifications de la fraction d'oxygène inspirée, 34.1% ±14.5% et 84.5% ±2.5% avaient pour critère primaire l'oxymétrie de pouls, respectivement.

Conclusion : Les médecins surestiment le rôle de la PCO_2 et du pH sanguins et sousestiment le rôle d'autres critères de décision dans la gestion de la ventilation mécanique. L'amélioration de notre compréhension de la pratique courante devrait aider à l'éboration des systèmes d'aide à la décision clinique en assistance respiratoire.

Mots-clés : ventilation mécanique, pratique courante, soins intensifs pédiatriques

Abstract

Pediatric intensivists have a multiplicity of elements available to guide them in mechanical ventilator decision-making; however, no prospective studies describe which elements intensivists currently use to make ventilator setting changes.

Objectives: We describe the current practice of ventilator setting modification in the intensive care unit at Sainte-Justine Hospital, a tertiary care pediatric hospital.

Hypothesis: Eighty percent of ventilator settings affecting carbon dioxide clearance are based on the PCO_2 or pH while eighty percent of settings affecting oxygenation are based on pulse oximetry.

Methods: Caregivers recorded the primary element and any secondary elements leading to a ventilator setting change at the time of the change via a custom-designed data gathering software.

Results: We included twenty patients. Of a combined 194 changes affecting CO_2 clearance, 42.3% ±7.0% were in reference to blood PCO_2 or pH. Of forty-one changes to positive end-expiratory pressure, 34.1% ±14.5% were in reference to pulse oximetry, as were 84.5% ±2.5% of the 813 changes to the fraction of inspired oxygen.

Conclusion: Physicians over-estimate the role of blood pH and PCO_2 in their ventilator management, while under-estimating the role of other elements. Improving our understanding of current practice patterns can help in the development of systems to aid in clinical decision-making in mechanical ventilation, improving clinical outcomes.

Keywords : mechanical ventilation, practice patterns, pediatric intensive care

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To Mom and Dad

And to Erin, Marianna, Emily and Amberlee

Special Thanks

To my family, friends; to my co-fellows and residents; to the many nurses and respiratory therapists who participated in this study; to my patients; to my mentors (who have become my friends); and especially to Philippe for his guidance throughout this process, Thank you! Je vous remercie!

Introduction

Invasive mechanical ventilation in children is managed by attending physicians, physicians in training (fellows or residents), and respiratory therapists. [1] Little evidence is available to describe how these caregivers manage invasive mechanical ventilation on a day to day basis, and no published data exists describing the relationship between patient information available to the caregiver and how that information is processed and ultimately leads to the prescription of setting changes on the mechanical ventilator.

Caregivers have multiple variables to consider when implementing or adjusting a ventilation strategy, including the patient's age, weight, chronic illness, acute illness, level of sedation, physical exam findings, chest radiography findings, blood gas analysis, and non-invasive monitoring. Once a ventilation strategy is chosen and a mode of ventilation and settings are prescribed, changes in any of above factors can potentially lead to changes in the settings, the mode, or even the overall strategy.

It has been established in a recent point prevalence study that significant variability exists in ventilator settings currently being used in children with acute lung injury (ALI), including settings outside of current recommendations. [2] A survey of pediatric intensivists from Canada and Europe has also revealed wide variability in acceptable physiologic elements (especially respiratory rate, tidal volume, and PCO_2) during the weaning phase of mechanical ventilation. [3] The presence of this variability in ventilator settings and in acceptable physiologic elements strongly suggests that variability also exist

in which elements caregivers consider most important when prescribing changes to ventilator settings, not only in the weaning phase, but throughout the patient's entire course of mechanical ventilation.

This practice variability may be leading to sub optimal patient outcomes and is a barrier to the evaluation of different ventilation strategies and new modes of ventilation, because there is no clearly described "best practice" to use as a standard of comparison. Studying and describing how basic patient information, physiologic elements, and other information at the physician's disposition lead to ventilator setting changes has the potential of bringing about improved patient outcomes if a "best practice" can be described, accepted and implemented within the pediatric intensive care community. It may simplify patient care by focusing physician's attention on the elements which matter the most in decision-making regarding mechanical ventilation. Furthermore, it may allow for the development of computer assisted decision-making protocols (software packages in which caregivers enter a patient's pertinent clinical information and which, in turn, propose a management plan adapted for that patient's specific situation, based on a pre-defined protocol) and/or automatically adjusting ventilator modes (modes of ventilation which automatically adjust settings based on protocols integrated into the ventilator's computer and relying on information gathered directly from the patient via patient monitoring devices integrated onto to the ventilator). Such protocols and automatic ventilator modes have been developed and could potentially simultaneously improve outcomes and free caregivers to tend to other aspects of patient care, but they have not enjoyed wide spread acceptance,

perhaps in part because data concerning current practice patterns are lacking. [4] Physicians may be understandably reluctant to turn decision making over to a protocol or an automatic ventilator in an area where they do not fully understand their own decision making process.

The following is a pilot study which identifies the key elements among the multiplicity of invasive and non-invasive monitored data at a caregiver's disposition and describes the relationships between those elements and the specific ventilator setting changes to which they led, as reported by the caregiver at the time the change was prescribed.

Preliminary research

Review of the literature

Prior to beginning this study, I conducted an extensive literature search primarily using the US National Library of Medicine website Pubmed.com. Broad search terms were employed, aimed at identifying studies on ventilator settings, monitoring techniques, and ventilation protocols. Examples include "mechanical ventilator settings", "ventilation wean", "ventilation monitoring", "ventilation protocol", "pulse oximetry" along with multiple permutations of these terms, including adding "pediatric" to each term. Many studies have been published which establish the validity of specific monitoring techniques (both invasive and non-invasive). [5-6] And there are some studies which attempt to establish extubation readiness criteria in children and weaning protocols in the event that a patient fails extubation readiness tests. [7-8] Other studies aim to provide guidelines for ventilator settings in specific disease entities, especially guidelines to establish the role of lung protective strategies (by means of low set tidal volumes) for children with acute respiratory distress syndrome (ARDS). [9-10] Although there is a great deal of research activity on the subject of pediatric ventilation in general, there are no published studies which specifically evaluate which monitored elements caregivers rely on as they make decisions to change a patient's ventilator settings. The studies by Santschi *et al*, as well as other studies on practice variability in pediatric ventilation, which have been published since the inception of the present study, demonstrate a growing interest in the pediatric

intensive care community in understanding the current state of the art and improving our management of invasively ventilated children.[2-3,11] The present study provides valuable information on the clinical practice of the center in which it was carried out and provides a model upon which large-scale, multi-center studies can be carried out in order to understand the current clinical decision-making processes and ultimately improve upon them.

Two preliminary surveys

In the pediatric intensive care community, it is taken for granted that the majority of changes to the ventilator settings which control oxygenation (the fraction of inspired oxygen and the positive end-expiratory pressure) are based almost exclusively on pulse oximetry monitoring, and that the majority of modifications to the remaining principle ventilator settings (respiratory rate, set tidal volume, positive inspiratory pressure, and pressure support), though they are more complex, are based primarily on arterial blood pH, arterial partial pressure of carbon dioxide ($PaCO_2$), or a surrogate measure of the latter. In order to better understand local perceptions of practice patterns, and to generate necessary data to prepare for this study, we performed two informal surveys amongst the pediatric intensivists, neonatologists, pediatric intensive care fellows, and neonatology fellows of Sainte-Justine Hospital. *(See appendices 1 and 2)* In the first survey, participants were asked to identify the elements they considered when increasing or decreasing the imposed respiratory rate, positive inspiratory pressure or tidal volume (depending on the mode of

ventilation), positive end-expiratory pressure, and fraction of inspired oxygen (respectively). All questions were open-ended. The survey was distributed via e-mail and in paper format to twenty individuals, and eight surveys were completed (forty percent response rate). The results of the first survey were reviewed, and similar responses were combined. The second survey included the elements identified in the first survey, and asked respondents to estimate the frequency (in terms of a percentage) with which a particular element was included in the decision-making process amongst all of their prescriptions to change a particular ventilator setting. (e.g., Among all of your prescriptions to change the imposed respiratory rate, what percentage are based on the partial pressure of carbon dioxide from an arterial blood gas?) The format required that participants write a percentage for each of seventeen questions. Again, the survey was distributed to twenty individuals and thirteen individuals responded (sixty-five percent response rate).

The results of these surveys were consistent with the current perceptions of clinical practice in the pediatric intensive care community. The results of the first survey were instrumental in the design of a computer program used as the primary data gathering utility for this project. The results of the second survey—specifically, that seventy-eight percent of changes to the imposed rate, positive inspiratory pressure, set tidal volume, and pressure support are made in reference to arterial blood pH or arterial partial pressure or carbon dioxide and that eighty-one percent of changes to the fraction of inspired oxygen and

positive end-expiratory pressure are made in reference to pulse oximetry monitoring—served as the basis for the hypothesis of this study.

Study Objectives

The purpose of this study is to describe the current practice of ventilation management at Sainte-Justine Hospital, with respect to which elements caregivers rely on in their decisions to change the principle ventilator settings, namely, set respiratory rate, tidal volume, positive inspiratory pressure, positive end-expiratory pressure, pressure support and the fraction of inspired oxygen. This study serves as a pilot for a larger multicenter study. A novel software product was developed for this study in order to survey caregivers in a minimally labor intensive fashion at the time a decision was made to change a ventilator setting. In part, this study, as does any pilot study, serves as learning experience to improve our processes and tools, including our software product, to refine our protocol, and to identify pitfalls of the study methods prior to initiating a large-scale study. As such, the direct interpretation of the results of this study are limited, especially considering the presumed practice differences that exist from center to center and from region to region. Nevertheless, as previously mentioned, there are no prior published studies elucidating this relationship, so this publication will directly contribute to the knowledge base of the subject, and will directly inform the practitioners at Sainte-Justine Hospital—granted, in a limited fashion—of their practice.

There are several applications of the data generated from this study, and clearly to a greater extent the data anticipated from the multicenter study. First, and most simply, this data will call the pediatric critical care community's attention to their practice patterns and possibly inform caregivers of significant differences between their actual practice and perceived practice. There is a great deal of information gathering and processing in an ongoing fashion implicated in the care of critically ill children. Obtaining this information can consume time and resources and may directly negatively impact the patient (e.g. pain,

blood loss, and risks associated with indwelling angio catheters for obtaining blood gases; dead space introduced into the ventilator circuit for continuous end-tidal carbon dioxide monitoring; radiation from chest radiography, etc). Although the benefits of obtaining this information are generally perceived to outweigh the injury, the results of this study may provide a better understanding of how we actually use that information and may change clinical practice by helping us more appropriately select which information we gather. Second, an understanding our practice patterns based on evidence will help us educate young physicians about mechanical ventilation more accurately. Third, this study is a first and necessary step toward establishing standards and guidelines in pediatric mechanical ventilation, which could ultimately improve patient outcomes. And lastly, the data obtained from this study may contribute to establishing mechanical ventilation protocols, which could be integrated into computer assisted decision-making software and potentially into automatically adjusting ventilator modes, which could simplify mechanical ventilation, freeing the physician to focus on other areas of patient care.

Methods

Study design

This was a prospective observational cohort study which enrolled critically ill children admitted to the pediatric intensive care unit (PICU) of Sainte-Justine Hospital, a free-standing, tertiary care hospital for woman and children, affiliated with the University of Montreal, Montreal, Quebec, Canada. Patient enrollment took place from January 2010 to January 2011 with follow up data gathered until June 2011.

The research ethics committee of Sainte- Justine Hospital approved this study, and the need to obtain informed consent from patients or their guardians was waived due to the strictly observational nature of the study design.

During the study period, all consecutive critically ill children were considered eligible to participate in the study, regardless of their indication for mechanical ventilation (whether pulmonary, neurologic, etc) and regardless of the mode of ventilation, if they met the following inclusion criteria: 1) presence of invasive mechanical ventilation (via endotracheal tube or tracheostomy) and 2) expected duration of mechanical ventilation greater than three days. Expected duration of mechanical ventilation greater than three days was determined by the presence of one of the following three criteria that were demonstrated as risk factors for prolonged mechanical ventilation [12]: a) mean airway pressure greater than or equal to thirteen centimeters of water maintained for at least sixty

minutes at any time in the first twenty-four hours of mechanical ventilation, b) Pediatric Risk of Mortality score (PRISM) greater than or equal to ten on the day of PICU admission, or c) continuous infusion of a sedating medicine for any amount of time during the first twenty-four hours of mechanical ventilation. [12-13] Patients were excluded if they met any of the following criteria: 1) presence of a "Do not resuscitate" or "do not reintubate" order in the chart, 2) suspected or confirmed brain death, 3) history of mechanical ventilation (invasive or non invasive) at home, 4) patient ventilated with a machine other than the Servo-i (Maquet GmbH & Co. KG, Rastatt, Germany), 5) a data gathering computer required for the study was not available, or 6) permission was not granted by treating physician. *(See figure 1)* Of note, only patients ventilated with a Servo-I ventilator were included in the study, because that ventilator allows simple recording of the internal ventilator log via a memory card. That particular ventilator may be equipped to ventilate in NAVA (Neurally Adjusted Venilatory Assist) mode, a mode for spontaneously breathing patients in which breaths are triggered by and the inspiratory pressure delivered is modified as a function of the electrical activity of the patient's diaphragm as detected by a special nasogastric tube. While we were in possession of two ventilators so equipped, the use of NAVA mode at Sainte-Justine Hospital at the time of this study was limited to very brief periods for research purposes, and always under direct observation by a physician. Therefore, while there were no specific exclusion criteria for patients using NAVA, those patients were *de facto* excluded. Furthermore, provisions were made to suspend the study, should any patients be transitioned to high frequency oscillatory ventilation, and to resume

the study when the patients were returned to conventional ventilation; however, those provisions were never necessary.

Data collection

Patient characteristics including demographic data, diagnosis, severity scores, clinical data at inclusion and outcomes were collected from the charts. When a patient was selected for the study, a laptop computer was installed at the bedside. A custom-designed computer program was used to record each ventilator setting change along with one primary element which prompted the caregiver to prescribe the setting change as well as an unlimited number of secondary elements included in the caregiver's decision-making process. *(See appendix 3.)* Caregivers filled out this electronic survey while at the patient's bedside at the time of any ventilator setting modification. They had the option of selecting from a list of pre-determined ventilator setting changes and monitored elements and/or manually entering changes or monitored elements not found in the lists. The list of ventilator setting changes included the increase or decrease of the fraction of inspired oxygen (FiO_2), imposed respiratory rate (RR), tidal volume (Vt), positive inspiratory pressure (PIP), positive end-expiratory pressure (PEEP) and pressure support (PS). The list of monitored elements included pulse oximetry (SpO_2), respiratory therapy or endotracheal tube suctioning, blood pH, arterial partial pressure of carbon dioxide ($PaCO_2$), arterial partial pressure of oxygen (PaO_2), measured tidal volume, minute ventilation, end-tidal

carbon dioxide ($EtCO_2$), transcutaneous carbon dioxide ($TcCO_2$), chest radiography findings (CXR), and physical exam. If chest radiography findings or physical exam were selected, addition information could be provided to specify the findings. The role of the caregiver responsible for the setting change (nurse, respiratory therapist, resident, fellow or attending physician) was also recorded for each change.

Data collection was initially planned to proceed from study inclusion until termination of invasive mechanical ventilation; however, the first patient included remained ventilated for far greater than one month. She remained on minimal, stable settings for several days, but could not tolerate extubation. After thirty days of inclusion, the decision was made to modify the protocol to end data collection at the termination of mechanical ventilation or at twenty-eight days after inclusion. Data capture for all remaining patients ended at the termination of invasive mechanical ventilation.

Multiple training sessions were held with the various groups of caregivers to inform them of the study and to instruct them on how to use the data collection software. Sessions with nurses and respiratory therapists were approximately fifteen minutes long, while the sessions with physicians were typically thirty minutes long. Physicians tended to foresee more complicated clinical scenarios and asked more probing questions during their sessions.

The endpoint of this study was the change to the ventilator setting in reference to the primary and secondary elements included in the decision-making process. As our goal was to identify which elements were used to guide changes in which ventilator settings, determining acceptable limits of the various monitored elements and determining the magnitude of the resultant setting changes were beyond the scope of our study. Therefore, the relationship between monitored elements and ventilator setting changes are expressed as the percentage of ventilator setting changes for which a particular monitored element played a role.

During endotracheal tube suctioning, chest physical therapy, or other patient manipulation, temporary changes to a variety of ventilator settings may be made as a matter of routine, most notably to the fraction of inspired oxygen. All such temporary changes were recorded but were analyzed separately from other ventilator setting changes.

Caregiver compliance with the protocol was estimated by recording the internal ventilator log of ventilator setting modifications using a compact flash reader connected to the ventilator (Servo-I, Maquet GmbH & Co. KG, Rastatt, Germany). The ventilator setting changes recorded by the ventilator log were then matched with the ventilator setting changes recorded by caregivers. The number of setting changes in the ventilator log with a corresponding entry in the study software was divided by the total number of setting changes in the ventilator log to yield a percent compliance. The compliance was measured in two (ten percent) of the patients.

Sample size

Based on an average prevalence of monitored elements leading to ventilator setting prescription changes equal to fifty percent (P_0) and a ninety-five percent confidence interval, measurement of 384 ventilator changes would be required to reach a level of precision of plus or minus five percent around the estimate. Also, based on an expected mean length of mechanical ventilation of three days and an average of seven ventilator setting changes per day, a sample-size of twenty subjects (approx. 420 measurements) was targeted. The average of seven ventilator changes per day was obtained by a reviewing the data of a prior study carried out at Sainte-Justine Hospital amongst a similar patient population. [12]

Results

Twenty patients were included, with both medical and surgical indications for admission to the intensive care unit, including post operative patients with congenital heart disease. The patient ages ranged from two days to sixteen years (mean 2.4 years, standard deviation 2.0). Half were boys. The mean length of PICU stay was twenty-nine days (standard deviation sixty-nine days). Of note, one patient remained admitted to the PICU upon completion of the follow-up period; however, he was no longer mechanically ventilated. The mean duration of invasive ventilation was twenty-eight days, with a standard deviation of seventy days. The twenty-eight day mortality was fifteen percent. The mean duration of electronic capture of ventilator setting changes was six days. There were six patients admitted to the PICU for primary respiratory diagnoses, four for post-operative care after surgery for congenital cardiopathy, four for sepsis, and one each for liver transplant, multiple trauma, meningitis, major burns, hemolytic-uremic syndrome, and acute lymphoblastic leukemia (with sepsis). The initial modes of ventilation at the time of inclusion were as follows: pressure control (without pressure support), seven patients; pressure regulated volume control with pressure support, seven patients; pressure control with pressure support, four patients; and volume control with pressure support, two patients. The mode of ventilation did change occasionally in some patients. Of note, use of pressure support ventilation at Sainte-Justine Hospital is routine practice as a test for extubation readiness and as the final mode of ventilation just prior to extubation; however,

even spontaneously breathing patients are not routinely initially ventilated with that mode. Furthermore, patients are routinely weaned *to* pressure support ventilation but very rarely are settings changed when a patient is using that mode (i.e. patients deemed successful are extubated rather than decreasing their settings, and patients deemed unsuccessful are placed on a different mode of ventilation). Therefore, very little data from this study was captured from patients being actively ventilated in pressure support mode. (Table 1)

Eighty caregivers participated in the study; forty-three nurses, fifteen respiratory therapists, eight residents, six fellows, and eight attending physicians. The median caregiver compliance with the protocol was 74.5% with a median duration of observation of 16.5 days per patient. No trends in compliance were found between the different shifts nor over the days of observation for each patient. The median number of setting changes per patient per day was 19.6 with twenty-fifth and seventy-fifth percentiles of 13.3 and 26.6, respectively. Excluding changes to the fraction of inspired oxygen, the median number of setting changes per patient per day was 2.5 with twenty-fifth and seventy-fifth percentiles of 2.0 and 4.3, respectively.

After exclusion of temporary changes made during endotracheal tube aspiration and other patient manipulation, pulse oximetry was identified as the primary monitored element for 84.5% (±3.0%) of changes to the fraction of inspired oxygen (Table 2). Physical exam (1.0 ±0.4 %) and arterial partial pressure of oxygen (0.9 ±0.4 %) were also identified as elements influencing FiO_2 changes, but in much smaller proportions. Pulse oximetry was

identified as the primary reason for 34.1% ±14.5% of changes to positive end-expiratory pressure, followed by physical exam (12.2% ±10.0%), arterial partial pressure of oxygen (9.8% ±9.1%), and chest radiography findings (9.8% ±9.1%). One notion which was not included in the list of factors leading to ventilator setting changes, but which was expressed by several participants via free text was the idea that a patient was expected to tolerate the step-wise weaning of a given setting. Participants seemed to struggle to identify any given monitored element which they were following; rather, they expected to be able to successfully wean a given setting over time without significant changes to ANY of the monitored elements or to the physical exam. These changes tended to be discussed on morning rounds, mentioned in the daily progress notes, and carried out over a number of days. A common example was the plan to wean the PEEP by one centimeter of water per day until a setting of five was achieved. I refer to this notion as planned, step-wise weaning. Planned, step-wide weaning and measured tidal volume were identified as primary reasons for 7.3% ±8.0% of PEEP modifications, each.

The blood partial pressure of carbon dioxide (pCO_2)—including arterial, capillary and venous blood—was only identified as the primary factor for 47.9% ±11.5% of changes to the imposed respiratory rate, with blood pH (9.9% ±6.5%) and increase in patient work of breathing (7.0% ±5.6% each) as the next most frequently cited factors. The pCO_2 was similarly influential for changes to the tidal volume at 47.4% ±21.9%, followed by the patients' spontaneous respiratory rate (21.1% ±17.0%), blood pH (5.3% ±9.2%), and the measured inspiratory pressure (5.3% ±9.2%). pCO_2 was cited much less frequently for

changes to the positive inspiratory pressure (23.9% ±8.1), with measured tidal volume being the most commonly recorded primary monitored factor at 31.8% ±9.0%. Planned, stepwise weaning (9.1% ±5.3%) and pulse oximetry (8.0% ±5.0%) were also significant factors. Blood pH, pCO_2, spontaneous respiratory rate, and minute ventilation were all cited as primary factors for 2-5% of tidal volume changes. pCO_2 was also the most commonly recorded factor influencing changes to the level of pressure support at 31.3% ±21.2%, followed by increased patient work of breathing (12.5% ±14.7%).

Though seven patients (thirty-five percent) had $EtCO_2$ monitors at some point during the study, only two decisions to modify settings were based on that criterion, one for the set respiratory rate, 1.2% ±2.4% of RR changes, and one for the PIP, 0.9% ±1.7% of those changes.

For the different ventilator settings, there were between 3.4% and 16.1% of changes for which respondents recorded a setting change, but did not record their motivation for making the change. The frequency with which respondents identified secondary monitored elements assuming a primary element was identified varied as follows: imposed respiratory rate 19.8%, tidal volume 4.3%, positive inspiratory pressure 22.6%, pressure support 15.0%, positive end-expiratory pressure 17.1%, and fraction of inspired oxygen 0.9%. (Table 3)

In order to estimate the potential gains of employing either computer assisted ventilation management protocols or ventilator modes with automatic setting adjustment, we categorized the reasoning for any given setting change (including the primary and all secondary elements) as readily incorporatable into an automatic protocol based on current technology or non-incorporatable. For this analysis, an element is considered incorporatable into an automatic protocol if data can be gathered from the patient and digitized without further human intervention for data entry via equipment which is commonplace in most pediatric intensive care units. The list of elements considered as readily incorporatable into an automatic protocol is shown in Table 4. When multiple elements were reported for one ventilator setting change, if any one element was considered non-readily incorporatable into an automatic protocol, that ventilator setting change was considered to be based on non-incorporatable elements. Temporary changes for respiratory therapy and suctioning were again excluded, as were survey entries in which no reason for the setting change was reported.

Of the sixty changes to the imposed respiratory rate, fourteen (23.3%) were based on elements which are potentially incorporatable into automatic protocols. Such was also the case for five (33.3%) of the fifteen tidal volume changes, forty-seven (56%) of the eighty-four positive inspiratory pressure changes, five (41.7%) of the twelve pressure support changes, nineteen (51.4%) of thirty-seven positive end-expiratory pressure changes, and 659 (97.1%) of 679 fraction of inspired oxygen changes.

Discussion

Contrary to the results of our preliminary surveys in which caregivers estimated that roughly eighty percent of their prescribed setting changes to the imposed respiratory rate, positive inspiratory pressure, tidal volume and pressure support were motivated by pCO_2 or blood pH, those elements were only cited as primary elements in 35.1% of setting changes when caregivers recorded their motivation at the time the prescription was made. The common perception among pediatric intensivists is that most changes to the settings listed above are made either because the level of carbon dioxide or pH is outside of an acceptable target range or because targets are being met, and physicians feel that the patient could be weaned without those elements going out of target range. But according to this study, such is only the case in roughly a third of the setting changes we make. Rather, other considerations are driving us to modify ventilator settings, specifically peak or plateau pressures, measured tidal volumes, and spontaneous respiratory rates. If we use the presence or absence of recorded secondary factors as an indirect measure of the complexity of decision making, the majority of the prescriptions made during this study were lower complexity, as 80.7 percent of the changes to respiratory rate, tidal volume, positive inspiratory pressure and pressure support were made in reference to a single primary monitored element.

These results provide new insight into our daily practice and into our ability to correctly perceive our daily practice. The imposed respiratory rate, tidal volume, positive inspiratory

pressure and pressure support are the settings that primarily determine a patient's partial pressure of carbon dioxide and, along with metabolic and renal factors, the patient's blood pH. But those settings are also important in determining patient synchrony and comfort on the ventilator and determining the risk of lung injury secondary to mechanical ventilation. Perhaps, then, when questioned retrospectively, pediatric intensivists lend greater importance to the role of those settings in maintaining carbon dioxide level and blood pH, than to the other outcomes determined by those settings, leading to a very significant recall bias. The complexity (or simplicity) of our decision-making may also be difficult for physicians to perceive accurately. With eighty percent of changes to these four ventilator settings based on a single element, it seems feasible to develop guidelines and ventilation strategy protocols which could reduce the practice variability both within and across centers, allowing the pediatric intensive care community to measure pertinent outcomes and determine a best practice. When considering secondary elements, and categorizing the monitored elements as incorporatable or non-incorporatable into automatic ventilator modes as described in Table 4, 41.5% of the setting changes to imposed respiratory rate, positive inspiratory pressure, tidal volume and pressure support could have been managed by use of automatic ventilator modes using readily available technology. Of note, end-tidal carbon dioxide monitoring is not standard practice in our ICU. Seven of the twenty patients had end-tidal carbon dioxide monitors attached during our observation period, and only two setting changes were made primarily in response to their readings. This could be interpreted in two ways: either ventilator setting changes are not often based on $EtCO_2$ monitoring because few patients have the monitor at Sainte-Justine Hospital, or,

conversely, physicians seldom request that the monitor be installed, because it does not influence their clinical decision-making. It remains to be seen if other centers where end-tidal carbon dioxide monitors are used as a matter of routine for all intubated patients see higher proportions of prescribed ventilator changes based on that technology.

While our results for imposed respiratory rate, tidal volume, etc, diverged from physician's perceptions, the results for the fractions of inspired oxygen were consistent with perceived clinical experience. Changes to the fraction of inspired oxygen were the most numerous, were almost uniformly associated with pulse oximetry (84.5% of changes), and were the least complex. Less than one percent of changes were associated with multiple elements. Lack of complexity is demonstrated by the fact that the routine management of the fraction of inspired oxygen has been largely delegated to bedside nurses, who are instructed to adjust it in order to maintain target pulse oximetry readings and in accordance with the patient's skin coloration and general status. Our findings show that 97.1% of fraction of inspired oxygen setting changes in our center could potentially be managed by automatically adjusting ventilator modes. Such technology is currently under development, and is of particular interest in neonatal intensive care units. [14]

Changes to positive end-expiratory pressure were made with reference to various elements; however, multiple elements were only recorded for 17.1% of modifications. In other words, several elements were tracked, but usually, only one of these elements became clinically significant at a time. These findings may be explained by considering the clinical

scenarios that might develop during the course of mechanical ventilation and that influence the preferred level of PEEP (although the "preferred" level of PEEP for some situations remains controversial). For example, the development of a pneumothorax (diagnosed on physical exam or by chest radiography) may lead physicians to decrease the PEEP in a patient who might otherwise benefit from higher levels, or a patient with poor pulmonary compliance who develops increasing levels of CO_2, and who is experiencing very high inspiratory pressures may require a reduction in PEEP to improve CO_2 removal via a relative increase in PIP without actually increasing the inspiratory pressure. The development of bronchospasm might lead some physicians to increase PEEP, some to decrease PEEP, and others may not adjust PEEP in light of bronchospasm. Pulse oximetry was by far the most frequently cited element at about one third of the changes, while physical exam, arterial partial pressure of oxygen, chest radiography findings, planned, step-wise weaning and measured tidal volume were all identified at similar frequencies (7.3% to 12.2%). Assuming that an adaptable weaning plan can be incorporated into computer assisted decision-making protocols and/or automatically adjusting ventilator modes, about half of the changes to positive end-expiratory pressure which we observed could have been managed by such methods. [4]

Of note, heart-lung interactions were never specifically reported as a reason to modify the level of positive end-expiratory pressure. This could be explained first by assuming that when physicians cited the physical exam as a reason for making a change, that heart-lung interactions were considered as part of that assessment, and second, by recalling that we

only observed changes to ventilator settings as opposed to initial settings and/or magnitude of change. Therefore, patients whose initial assessment included cardiovascular reasons to limit positive end-expiratory pressure may have had their level modified as a function of pulse oximetry and the other elements mentioned above, but with smaller increments of change and lower total values throughout their entire course of ventilation than those without special heart-lung considerations.

As one would expect, by selecting intubated patients with a projected duration of mechanical ventilation of greater and three days, the patients included in this study had longer lengths of stay, higher severity of illness scores (PRISM and PELOD), and a higher mortality rate than the average for our ICU. [13,15] One may also suppose that the ventilation management of these patients is more complex than the average pediatric ICU patient.

By virtue of the survey method we used, we were able to achieve higher response rates than we would have expected using a survey given periodically, after a call night, for example. One of the strengths of this technique is that it reduces caregivers' recall bias and eliminates the bias created by allowing caregivers to observe the results of the ventilator changes they prescribe prior to filling out the survey. Special care was also taken in the design of the software to ensure ease of use and a minimal amount of computer navigation in an effort to increase compliance.

Caution should be used when interpreting our data because it represents the practice of a single center in an area of medicine with few standards or guidelines. In addition, we remind the reader that we only identified monitored elements that led to ventilator changes. If the default position of a ventilation management plan was to change (wean) a setting, and a monitored parameter prevented that change, we did not capture such information. Also, as is the case with any study attempting to understand clinical reasoning, our observations are limited to what caregivers reported, and may therefore be inherently oversimplified. For standards and guidelines to be established, data must be gathered from multiple centers representative of pediatric intensive care as a whole and should represent the full range of mechanical ventilation. To that end, in preparing for a multi-centered study, there are modifications to this pilot study which would improve the quality of data. First, for ease of patient inclusion by a single researcher, we allowed data capture after several hours of mechanical ventilation. In doing so, we failed to capture the acute—and in terms of ventilator settings, rapidly escalating—phase of ventilation some patients. A future, multi-center study should attempt to initiate data capture from the time of intubation, or from the time of transfer to the PICU. Second, controversy surrounding the management of the fraction of inspired oxygen is much less than the management of the other settings. While the target of oxygen saturation may be debated in particular situations, most agree that the adjustment up or down of the fraction of inspired oxygen is almost exclusively based on pulse oximetry. This study confirmed that assumption, and most PICUs have a policy delegating that management to nurses with specific guidelines, so further studies of that particular setting could be omitted from future studies. Finally, we gathered data regarding

the role of the caregiver prescribing each setting change; however, the number of settings changes we gathered were far too small to perform any sort of analysis stratifying by caregiver role. There may be significant practice differences between physicians in training, attending physicians, and respiratory therapists, and elucidating those differences may prove particularly beneficial to ventilator management education.

Conclusions

This pilot study demonstrates that observation and surveying of clinical decision making in mechanical ventilation at the time decisions are being made is feasible and that the results may lead to a more accurate and objective understanding of our own practice. The methods used are easily transportable to other intensive care units and do not require special equipment, other than a computer. Staff training sessions were brief, and compliance was high. The results obtained using the bedside computerized survey varied greatly from results obtained from a preliminary paper/e-mail survey, which demonstrates the significance of recall bias in studies of practice patterns and the benefit of using a methodology similar to ours.

The data obtained in this study reveal that physicians in our center do not use end tidal pCO_2 to modify ventilator settings and over-estimate the role of blood pH and carbon dioxide in their ventilator management, while the role of elements such as the patient's spontaneous respiratory rate, measured tidal volume, and peak pressure were under-estimated. This discrepancy between perceived practice patterns and actual practice patterns and the relatively low-complexity of the decisions made may be a reflection of physicians' priorities with regards to ventilation; specifically, assuring an acceptable blood pH and carbon dioxide level takes priority over limiting the risk of secondary pulmonary lesions due to mechanical ventilation, maximizing patient synchrony with the ventilator, and assuring patient comfort. Caregivers are more concerned about assuring adequate blood pH and carbon dioxide, so they believe the majority of their prescriptions to change

ventilator setting are to achieve that goal, when in fact, even among the sickest patients, those goals are often met, but "fine tuning" to meet secondary objectives leads to the majority of setting changes.

Roughly half of the changes to the positive end-expiratory pressure, forty percent of the changes to the imposed respiratory rate, tidal volume, positive inspiratory pressure, and pressure support, and ninety-seven percent of changes to the fraction of inspired oxygen which we observed could have potentially be managed by automatic ventilator modes based on technology which already exists. This serves as evidence that establishing standards and practice guidelines (if not protocols and automatic ventilation modes) in pediatric mechanical ventilation is feasible, and the current level of practice variability as can be surmised from the available studies suggests that patient outcomes would improve as a result of such endeavors. Furthermore, caregiver efficiency and the education of medical students, respiratory therapy students, nurses, residents and fellows would benefit from clearly established "best practice" guidelines. However a multicenter observational study is necessary to generalize our results and I am currently collecting data with the same methodology from two sites in US (University of Virginia and Children Hospital of Los Angeles) and plan to include more centers.

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List of abbreviations

ALI	Acute lung injury
ARDS	Acute respiratory distress syndrome
CXR	Chest radiograph
$EtCO_2$	End-tidal carbon dioxide
FiO_2	Fraction of inspired oxygen
$PaCO_2$	Arterial partial pressure of carbon dioxide
PaO_2	Arterial partial pressure of oxygen
PCO_2	Partial pressure of carbon dioxide (of blood from any source)
PEEP	Positive end-expiratory pressure
PELOD	Paediatric logistic organ dysfunction score
PICU	Pediatric intensive care unit
PIP	Positive inspiratory pressure
PRISM	Pediatric risk of mortality score
PS	Pressure support
RR	Respiratory rate
SpO_2	Oxygen saturation measured by pulse oxymetry
$TcCO_2$	Transcutaneous carbon dioxide
Vt	Tidal volume

Figure 1: Patient enrolment

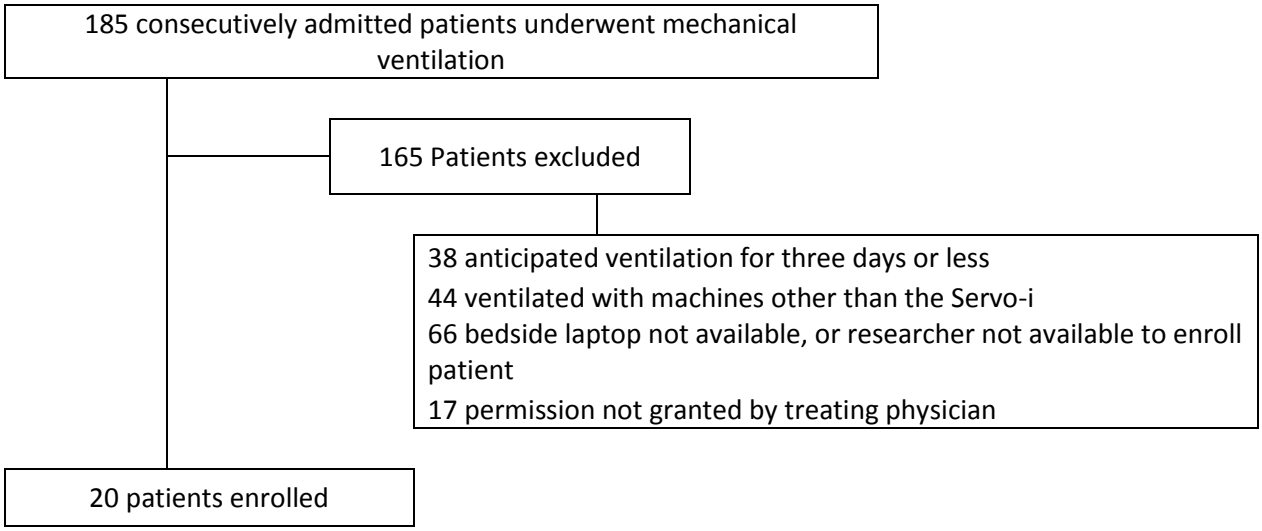

Table 1: Patient Characteristics

	n=20	
	(Mean ± STD or %)	(Range)
Age (years)	2.4 ± 2.0	2 days to 16 years
Male gender	50%	
Weight (kg)	12.1 ± 7.1	2.6 to 63
PRISM	10 ± 6	0 to 22
PELOD	8 ± 6	1 to 22
PICU length of stay*	29 ± 69	3 to 209
Duration of ventilation (days)	28 ± 70	2 to 211
Duration of electronic capture (days)	6.0 ± 9.8	1 to 30
Twenty-eight-day mortality	15%	
Reasons for PICU admission	(number)	(percentage)
Primary respiratory disease	6	30%
Cardiac surgery	4	20%
Sepsis	4	20%
Liver transplant	1	5%
Multiple trauma	1	5%
Meningitis	1	5%
Burn (20% total body surface area)	1	5%
Hemolytic-Uremic syndrome	1	5%
Acute lymphoblastic leukemia (with sepsis)	1	5%
Additional clinical information		
Acute Respiratory Distress Syndrome	4	20%
Acute Lung Injury	2	10%
Multiple Organ Dysfunction	14	70%

PRISM Pediatric risk of mortality score

PELOD Pediatric logistic organ dysfunctions score

*One patient remained admitted to the PICU after the follow-up period of this study ended; however, he was no longer mechanically ventilated. His length of stay was truncated at 201 days for calculation purposes.

Table 2: Modes of Ventilation Employed at Inclusion

	(number)	(percentage)
Pressure Control (without pressure support)	7	35%
Pressure Regulated Volume Control with pressure support	7	35%
Pressure Control with pressure support	4	20%
Volume Control with pressure support	2	10%

Table 3: Proportion of all changes of a given ventilator setting due to a given primary element. Given as percentage with 95% confidence interval given in *italics*

	Respiratory rate		Tidal volume		Positive inspiratory pressure		Pressure support		Positive end-expiratory pressure		Fraction of inspired oxygen	
Primary element	**(n=81)**		**(n=23)**		**(n=115)**		**(n=20)**		**(n=41)**		**(n=2616)**	
Blood pH	8.6%	*6.1%*	4.3%	*8.3%*	3.5%	*3.3%*	5.0%	*9.6%*	2.4%	*4.7%*	0.0%	*0.0%*
PCO_2	42.0%	*10.7%*	39.1%	*19.9%*	18.3%	*7.1%*	25.0%	*19.0%*	0.0%	*0.0%*	0.0%	*0.0%*
PaO_2	0.0%	*0.0%*	0.0%	*0.0%*	1.7%	*2.4%*	0.0%	*0.0%*	9.8%	*9.1%*	0.3%	*0.2%*
Spontaneous RR	1.2%	*2.4%*	17.4%	*15.5%*	2.6%	*2.9%*	5.0%	*9.6%*	0.0%	*0.0%*	0.0%	*0.0%*
Measured tidal volume	0.0%	*0.0%*	0.0%	*0.0%*	24.3%	*7.8%*	5.0%	*9.6%*	7.3%	*8.0%*	0.1%	*0.1%*
Measured peak pressure	0.0%	*0.0%*	4.3%	*8.3%*	0.9%	*1.7%*	0.0%	*0.0%*	0.0%	*0.0%*	0.0%	*0.0%*
$EtCO_2$	1.2%	2.4%	0.0%	0.0%	0.9%	1.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Physical Exam	4.9%	*4.7%*	0.0%	*0.0%*	3.5%	*3.3%*	5.0%	*9.6%*	12.2%	*10.0%*	0.3%	*0.2%*
Chest radiography findings	0.0%	*0.0%*	0.0%	*0.0%*	0.0%	*0.0%*	0.0%	*0.0%*	9.8%	*9.1%*	0.0%	*0.0%*
Pulse oximetry	2.5%	*3.4%*	0.0%	*0.0%*	6.1%	*4.4%*	0.0%	*0.0%*	34.1%	*14.5%*	26.3%	*1.7%*
Planned, stepwise weaning	3.7%	*4.1%*	0.0%	*0.0%*	7.0%	*4.6%*	0.0%	*0.0%*	7.3%	*8.0%*	0.0%	*0.0%*
Per protocol (temporary)*	12.3%	*7.2%*	17.4%	*15.5%*	23.5%	*7.7%*	20.0%	*17.5%*	0.0%	*0.0%*	68.9%	*1.8%*
Minute ventilation	0.0%	*0.0%*	0.0%	*0.0%*	1.7%	*2.4%*	0.0%	*0.0%*	0.0%	*0.0%*	0.0%	*0.1%*
Other	23.5%	*9.2%*	17.4%	*15.5%*	6.1%	*4.4%*	35.0%	*20.9%*	17.1%	*11.5%*	4.1%	*0.8%*

PCO_2 blood partial pressure of carbon dioxide; PaO_2 arterial partial pressure of oxygen; RR respiratory rate ; $EtCO_2$ End-tidal carbon dioxide

*Temporary modifications carried out per protocol for endotracheal tube aspiration, chest physical therapy, or other patient manipulation

Table 4: Proportion of ventilator setting changes in which secondary elements were identified

	Respiratory rate	Tidal volume	Positive inspiratory pressure	Pressure support	Positive end-expiratory pressure	Fraction of inspired oxygen
Total number of changes	81	23	115	20	41	2617
Changes excluding temporary*	71	19	88	16	41	813
Changes with secondary elements listed	16	1	26	3	7	23
Total percentage with secondary elements	19.8%	4.3%	22.6%	15.0%	17.1%	0.9%
Percentage with secondary elements, excluding temporary changes	*22.5%*	5.3%	29.5%	18.8%	17.1%	2.8%

*Temporary modifications carried out per protocol for endotracheal tube aspiration, chest physical therapy, or other patient manipulation

Table 5: Categorization of elements which could be incorporated into automatically adjusting ventilator modes based on current ventilator technology.

Could readily be incorporated	Cannot currently be incorporated
Pulse oximetry	Blood pH
End-tidal carbon dioxide	Blood pCO_2
Spontaneous respiratory rate	PaO_2
Measured peak pressure	Physical exam
Measured tidal volume	Chest radiography findings
Minute ventilation	Planned, stepwise weaning

Appendix 1: Preliminary survey number 1

Le 12 février 2009

Bonjour à tous!

Pour mon projet de recherche, on va investiguer quels sont les critères sur lesquels les intensivistes augmentent ou diminuent certains paramètres ventilatoires. (Est-ce que c'est plus sur le monitoring non invasif, sur les gaz de sang, les radiographies, les données provenant du ventilateur, la pression artérielle, ... etc.).

Je demande donc, votre participation dans un sondage qui servira comme première étape de cette investigation.

Dessous, vous trouverez une liste de paramètres ventilatoires. S'il vous plaît, indiquez à droite tous les critères sur lesquelles vous augmentez ou diminuez le paramètre nommé. Soyez exhaustifs et spécifiques (par exemple pCO_2, *pH*, etc.; et non pas *gaz sanguin*.) Le nombre de pages n'est pas limité.

Je vous remercie d'avance de votre participation,

Allen

Fréquence respiratoire du respirateur: _____

_____

Pression inspiratoire ou volume courant (selon le mode ventilatoire): _____

_____

PEEP: _____

_____

FiO_2: _____

Appendix 2: Preliminary survey number 2

Le 7 avril 2009

Bonjour à tous!

Merci beaucoup de votre participation dans le sondage des critères de changement de paramètres ventilatoires.

Les critères que vous avez indiqués dans le premier sondage sont indiqués dessous. Je vous demanderais encore votre participation pour identifier de manière quantitative le rôle que jouent, selon votre opinion, ces critères dans les changements de paramètres de ventilation.

S'il vous plaît, parmi l'ensemble des changements d'un paramètre de ventilation, estimez le pourcentage lié à chaque critère.

Considérer tout patient sous ventilation invasive.
Ne considérer que les changements effectués après l'installation initiale du patient dans l'unité.

____% des changement de **fréquence respiratoire** sont basés sur la **$PaCO_2$**.
____% des changement de **fréquence respiratoire** sont basés sur le **ratio Ti/Te voulu**.
____% des changement de **fréquence respiratoire** sont basés sur le **pH**.
____% des changement de **fréquence respiratoire** sont basés sur la **compliance pulmonaire (volume obtenu en mode pression ou pression obtenue en mode volume)**.
____% des changement de **volume courrant ou pression inspiratoire** sont basés sur la **$PaCO_2$**.
____% des changement de **volume courrant ou pression inspiratoire** sont basés sur le **pH**.
____% des changement de **volume courrant ou pression inspiratoire** sont basés sur la **SpO_2**.
____% des changement de **volume courrant ou pression inspiratoire** sont basés sur la **compliance pulmonaire (volume obtenu en mode pression ou pression obtenue en mode volume)**.
____% des changement de **volume courrant ou pression inspiratoire** sont basés sur la **RxP.**
____% des changement de **PEEP** sont basés sur la **SpO_2**.
____% des changement de **PEEP** sont basés sur la **RxP**.
____% des changement de **PEEP** sont basés sur la **PaO_2.**
____% des changement de **PEEP** sont basés sur la **FiO_2**
____% des changement de **PEEP** sont basés sur la **présence de PEEP intrinsèque.**
____% des changement de **PEEP** sont basés sur la **fonction cardiaque.**
____% des changement de **FiO_2** sont basés sur la **SpO_2**.
____% des changement de **FiO_2** sont basés sur la **PaO_2**.

(Exclure augmentation temporaire de FiO_2 pour instrumentation des voies aériennes—aspiration, réintubation, bronchoscopie, etc.—et physiothérapie respiratoire.)

Merci encore de votre participation!
Allen

Appendix 3: Screen shot of the data-gathering software