Protocol-Directed vs. Physician-Directed Weaning from Ventilator in Intra-Abdominal Surgical Patients†

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Background: *Previous studies have demonstrated that protocol-directed weaning is better than physician-directed weaning in terms of shorter duration of mechanical ventilation in general critically ill patients. In this prospective, randomized controlled trial, the authors compared duration of mechanical ventilation between protocol based nurse-directed weaning and physician-directed weaning in patients following intra-abdominal surgery.*
Material and Method: *One hundred intra-abdominal surgical patients requiring mechanical ventilation for more than 24 hours were randomly assigned to receive either protocol-directed (n = 51) or physician-directed (n = 49) weaning from mechanical ventilation. Patients assigned to the protocol-directed weaning group underwent daily screening and a spontaneous breathing trial by nursing staff.*
Outcomes: *The primary outcome was the duration of mechanical ventilation.*
Results: *The median duration of mechanical ventilation was 40 and 72 hrs in protocol-directed and physician-directed groups, respectively ($p < 0.001$). Two patients in the protocol-directed group and three patients in the physician directed group were re-intubated within the first 72 hours after extubation ($p = 0.61$).*
Conclusion: *Daily screening of respiratory function in intra-abdominal surgical patients followed by trials of spontaneous breathing performed by nurses resulted in a shorter duration of mechanical ventilation when compared to traditional physician-directed weaning.*

Keywords: *Mechanical ventilation, Weaning, Intensive care unit, Outcomes, Protocol-directed weaning, Nursing*

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Mechanical ventilation (MV) is one of the most common forms of medical therapy administered in intensive care units (ICU). Many advances have been made regarding the optimal methods of weaning from ventilatory support and liberating patients from the ventilator because MV is associated with considerable morbidity, mortality, and cost[1-3]. However, premature discontinuation of MV can contribute to the incidence of failed extubation, nosocomial pneumonia, or increased mortality[4-6]. An early study noted that the clinical decision to discontinue MV was often based on judgment and experience[7] with increasing risks and economic consequences of prolonged ventilation.

To date, there have been studies to assess the efficacy and efficiency of using protocols to wean patients from MV compared with the traditional practice of physician-directed weaning[8-15]. Some studies[8-11,15] demonstrated that nurses or respiratory therapists could safely and effectively wean most patients from MV using protocol guidelines. Potential advantages included reducing the duration of both MV and the weaning process. In addition, this approach would free physicians for other duties that cannot be delegated to non-physicians[9].

Although some randomized, controlled trials[8-11] of weaning protocols showed a decrease in the duration of MV, others did not[12-15]. In addition, positive trials demonstrated benefits limited to only

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some participating units[10,11]. These protocols are one of several tools to recognize patients' ability to breathe and may not be the right tool in all settings especially in ICUs where the majority of patients were general surgical patients. Moreover, previous studies had focused mostly on medical, trauma, and coronary ICU[8,9,11]. The authors were interested in only patients who underwent intra-abdominal surgery comparing the duration (hours) of MV between a protocol-directed weaning performed by nurses to a traditional physician-directed weaning.

Material and Method

Patient selection

All intra-abdominal surgical patients who were admitted to a general surgical ICU and required intubation and MV greater than 24 hours, American Society of Anesthesiology (ASA) class I-III were enrolled in the present study. Exclusion criteria included age less than 18 years, requirement of mechanical ventilation due to brain death, inability to obtain informed consent, having history of mental retardation, having a diagnosis of perioperative myocardial infarction, and morbid obesity.

Random allocation

Intra-abdominal surgical patients were randomly assigned at the time of ICU admission, to receive either protocol-directed weaning implemented by nurses or physician-directed weaning implemented by six ICU's anesthesia attending. The weaning techniques were at the discretion of the managing physician for the physician-directed weaning group. The surgical ICU had 14 beds and it was a closed unit taken care of by only one team of physicians. The surgical ICU had one senior attending that was certified for critical care medicine or anesthesia board and one junior anesthesia attending who performed a ward round every day. Additionally, there were approximately 5 to 6 trainees (2 first year, 2 second year, and 1 or 2 third year anesthesia and surgical resident) working 24 hours in the ICU. Block randomization with block size of four and six was employed to ensure an equal number of subjects in the two groups at the time of interim analyses. Each assignment of weaning method was indicated on a data form that was folded and sealed in an opaque envelope and opened only after written informed consent was obtained.

Before the beginning of the present investigation, the ICU staff developed a protocol to guide the assessment of weaning readiness and the weaning process for patients in the unit. This work was done in advance to facilitate acceptance of the weaning protocols within the ICU. The nursing staff in the general surgical ICU was thoroughly trained on the weaning protocols before its implementation. A 1- month training period was used, before beginning the investigation, allowing time for nurses to become familiar with the weaning protocols. Patients randomized to the protocol-directed group were assessed for weaning readiness and were weaned from MV according to the guidelines of the ICU protocols.

Before the start of a protocol-directed weaning, each patient's attending physician was notified, and informed consent was asked from patients if they were fully conscious (in elective cases that have already reserved ICU, patients would be asked for informed consent preoperatively) or from their relatives in semi or unconscious patients.

Weaning protocols

Patients who received protocol-directed weaning entered a weaning protocol when their diseases had resolved or significantly improved, according to predetermined protocol entry criteria. Entry criteria (patient had to meet all of these criteria) included 1) the ratio of PaO_2 to FiO_2 was ≥ 200 at FiO_2 ≤ 0.4, 2) oxygen saturation $\geq 94\%$, 3) the patient was on positive end expiratory pressure (PEEP) ≤ 5 cmH_2O, 4) patients' respiratory rate were < 35 breaths/min, 5) patients' heart rate were < 120 beats/min, 6) the ratio of respiratory rate to tidal volume (Rapid shallow breathing index) was ≤ 105, 7) dopamine or dobutamine was allowed in doses ≤ 5 μg/kg/min and norepineprine in a dose of ≤ 5 μg/min, 8) pain score of the patient was < 4, 9) the patients' static lung compliance were ≥ 25 cc/cmH_2O and minute ventilation were ≤ 10 L/min and 11) the patient was awake or easily arousable and following commands. If any of the components of the daily screen were not met, the patient would not undergo a spontaneous breathing trial (SBT) on that day and continued to be screened the following morning. On the other hand, if the patients passed the screening criteria, the SBT would be performed with pressure support up to 7 cmH_2O and 5 cmH_2O of PEEP for 120 minutes. A predetermined criterion was set to define failure to tolerate the weaning trial. For SBT to be considered failed, any one of the weaning failure criteria had to be met 1) oxygen saturation $< 92\%$, 2) respiratory rate > 35 breaths/min, 3) heart rate > 120/min or heart rate changes more than 20% from baseline,

4) systolic blood pressure > 180 or < 90 mmHg or changes more than 20% from baseline, 5) the requirement of vasopressor or inotropic agents, 6) the development of diaphoresis, somnolence, dyspnea and chest pain. SBT was then terminated and mechanical ventilator was reinstituted at the original settings and the patient would be reevaluated for SBT in the next 24 hours. If SBT was considered successful, the attending was asked to approve extubation. Patients continued to be screened daily until extubation, 21 days after enrollment, performance of tracheostomy, death, or withdrawal of care.

Study outcome and variables

The primary outcome of the present study was the duration (hours) of MV defined by time from tracheal intubation to either discontinuation of MV or the continued need for MV at day 21 after randomization. The secondary outcomes were the need for re-intubation within 72 hours after extubation and the need of MV for more than 21 days.

Data collection

For all patients, the following characteristics were recorded by one of the investigators at the time of admission, age, gender, body weight, height, the severity of illness based on Sequential Organ Failure Assessment (SOFA) score and Acute Physiology and Chronic Health Evaluation (APACHE) II scores, the development of the acute respiratory distress syndrome (ARDS), types of intra-abdominal surgery, the presence of epidural catheter for postoperative analgesia, balance of fluid intake and output until the day of weaning, the mode of MV used before the beginning of weaning process, and the indication for MV. Respiratory function was measured by nurses, before the beginning of the weaning process, according to either physician orders or the guidelines of the weaning protocols. The frequency of re-intubation and the need for MV of more than 21 days were recorded. Enrolled patients were followed until they were successfully weaned from MV, died, or were transferred to a long-term care facility with MV. The individuals performing the data collection and recording patient outcomes were not involved in the medical care of the study patients.

Statistical data analysis

Previous data[8] showed that mean $\pm$ SD of the duration of MV was 108 ± 126 and 144 ± 144 hours in the protocol-directed weaning and physician-directed weaning, respectively. Based on these figures, a sample size of 176 subjects per group was required to guarantee a power of 80% at 2-sided type I error of 0.05 to test the mean difference in duration of MV between two groups of 36 hours with SD of 120 hours. O'Brien-Flemming procedure was applied to control for overall type I error due to repeated data analyses. To account for four looks of the data using O'Brien-Flemming method, the sample size required then becomes 176 multiplied by adjusting factor of 1.024, which is 180 subjects per group.

Since it will take about a year to recruit all 370 patients, four interim analyses are planned at fixed calendar time of month 4, 6, 8, and the end of the present study. The stopping boundaries of O'Brien-Flemming are applied to control for the overall type I error at 0.05. Decision to terminate the present study early based on both statistical data analysis result and other factors was done by an independent committee.

Primary analysis of duration of MV based on intention-to-treat (ITT) population and the secondary (supporting) analysis was on per-protocol (PP) population.

The primary outcome (duration of mechanical ventilation) was compared by using Mann-Whitney-Wilcoxon test. Data was presented as median (inter-quartile range).

Analysis of secondary endpoints, the proportion of re-intubation within three days among extubated patients, and the proportion of the need of MV more than 21 days in the two arms were compared using Chi-square or Fisher's exact test as appropriate. All statistical procedures were performed using SAS 8.0. A 2-sided p-value of ≤ 0.05 was considered statistical significance.

Definitions

APACHE II scores and SOFA scores were calculated in a standard manner, APACHE II using clinical data available from the first 24 hrs of intensive care[16] and SOFA score was calculated on admission and every 48 hrs until ICU discharge[17]. ARDS was defined on the basis of the following criteria: a) chest radiograph showing bilateral pulmonary infiltrates; b) PaO_2/FiO_2 ratio ≤ 200, regardless of the level of PEEP; and c) a pulmonary artery occlusion pressure of ≤ 18 mmHg or no clinical evidence of left atrial hypertension[18]. Morbid obesity was defined as body weight greater than two times of ideal weight, ideal body weight = body mass index [weight (kg)/height^2 (m^2)] of 22-28, morbid obesity defined as BMI > 35.

Finally, re-intubation was defined as the requirement of intubation within three days after extubation.

Results

During the present study period, 472 patients required invasive MV more than 24 hours. Some of patients satisfied exclusion criteria or informed consent could not be obtained. Nevertheless, the present study was early terminated after the second interim analyses at 6 months. One hundred patients were enrolled in the present study. There were 51 patients enrolled in the protocol-directed weaning group and 49 patients enrolled in the physician-directed weaning group.

Demographic variables

Demographic data are shown in Table 1. There were 36 men in the protocol group (70%) and 26 men in the physician-directed group (53%). The mean age of the present study participants was 57.7 $\pm$ 12.9 years in the protocol group and 60.3 $\pm$ 13.8 years for the physician-directed group. The majority of type of operation was general surgery, 76.5% in the protocol and 85.7% in the physician-directed group. There were 11 patients in the present study group and 12 patients in the control group who had epidural catheter for post-operative pain control. At the time of enrollment, a variety modes of MV were used, SIMV (simultaneous intermittent mechanical ventilation) was used more than other modes (86.3% in the protocol and 79.6% in the control group). The SOFA score was approximately 3.0 in both groups. The balance of fluid before weaning was not significantly different between groups.

The majority of patients required MV for the reason of post-operative respiratory support. However, there were two patients in the protocol group that had to be intubated because of aspiration and pulmonary effusion and one patient in the control group required intubation because of sepsis and respiratory failure. None of the patients in the present study was diagnosed with ARDS.

Duration of Mechanical Ventilation

The median duration of MV before a successful screening test was 2.0 (1, 5) days in the protocol group and 2.5 (1, 6) days in the control group

Table 1. Baseline Characteristics of the study patients*. Data presented as n (%), mean $\pm$ SD or median (interquartile range, IQR)

Characteristic	Protocol group (n = 51)	Control group (n = 49)
Sex		
Male	36 (70)	26 (53)
Female	15 (29)	23 (46)
Age (years)	57.5 $\pm$ 12.9	60.3 $\pm$ 13.8
Types of surgery		
General	40 (78)	42 (85)
Urological	6 (11.8)	4 (8)
Gynecology	3 (5.9)	2 (4)
Obstetric	2 (4)	1 (2)
Epidural catheter	11 (21)	12 (24)
Mode of mechanical ventilator		
SIMV	44 (86)	39 (79)
A/CMV	4 (7.8)	6 (12)
PS	3 (6)	3 (6)
BIPAP	0 (0)	1 (2)
Fluid balance (cc)	4,623 $\pm$ 4246	5,306 $\pm$ 3936
SOFA score	3.06 $\pm$ 2.7	3.06 $\pm$ 1.8
APACHE II score	8.5 $\pm$ 3.8	8.8 $\pm$ 3.5
Median duration before weaning** (days)(IQR)	2 (1-5)	2.5 (1-6)

* SOFA score = sequential organ failure assessment; APACHE II scores = acute physiology and chronic health evaluation II scores; SIMV = simultaneous intermittent mandatory ventilation; A/CMV = assist control mandatory ventilation; PS = pressure support; BIPAP = bi-level positive airway pressure

** Duration before weaning was defined as the number of days between intubation and a successful screening test

($p = 0.06$). The median duration of MV was 40 (25, 125) hours in the protocol group and 72 (26, 220) hours in the physician-directed weaning group ($p < 0.001$).

Complication

No complications occurred during the screening tests or the trials of spontaneous breathing with pressure support. None of the patients required MV > 21 days. There was no difference between the groups regarding re-intubation rate, two patients (3.9%) in the protocol group and three patients (6.1%) in the control group were re-intubated within the initial 72 hours after extubation ($p = 0.61$). Pulmonary edema was the major reason for re-intubation.

Discussion

The weaning process may account for 56-92% of the total duration of MV[19]. Therefore, recognizing weaning readiness and managing the weaning process are important. Several studies[8-11] demonstrated that weaning protocols improve outcomes over decisions made by clinicians. In 2001, the collective task force facilitated by the American College of Chest Physicians, the American Association for Respiratory Care, and the American College of Critical Care Medicine developed evidence-based guidelines for weaning and discontinuing ventilatory support. The guidelines recommended that weaning/discontinuation protocols that are designed for non-physician health-care professionals should be developed and implemented in ICUs[20]. Nevertheless, ICUs are complex places. The problem is how to implement this protocol and have a high rate of adherence in various institutions that are different in resources and systems.

The present study was a randomized, controlled study designed to examine the effect of weaning protocols on the duration of MV in the intra-abdominal surgical patients. The authors demonstrated that nurses, using protocol guidance, could wean patients from MV safely and more quickly than physicians in intra-abdominal surgical patients. The baseline characteristics were not significantly different between the two groups. The majority of patients in the present study was postoperative and had mild severity of illness scores (SOFA 4 3). The median duration of MV, the primary outcome, was significantly shorter in the protocol-directed weaning group than the physician-directed group (40 and 72 hours, $p < 0.001$). However, the authors recruited only 100 participants in the present study, apparently the overall sample size should be 360 patients. The authors did the first and second interim analysis of 100 patients and found significant outcomes so the authors decided to stop the present study earlier. Furthermore, the duration of MV of both groups was shorter than other previous studies[8,10,11] that might have resulted from postoperative, mild severity of illness in the population. Additionally, the majority of patients in the physician-directed weaning group were ventilated with SIMV (79%) and IMV was traditionally used for weaning. Given that IMV weaning had previously shown to take approximately two days longer than weaning with SBT[21], the results from the present study was consistent with the study of Esteban et al. Although SBT is usually the final test of adequate patients ventilation, there are many variations on the actual process of conducting an SBT, for example, the duration might range from 30 to 120 min, the level of mechanical support intended to overcome the work of breathing through the endotracheal tube varying among various modes of ventilator and the different criteria to identify SBT failure. Any of these factors might influence the outcome of the trail. In the present study, the authors used pressure support up to 7 cmH_2O and 5 cmH_2O of PEEP for 120 minutes. Although none of the patients had complications from SBT, there might be some patients ready to be extubated earlier. However, more work is required to confirm the adequacy of shorter SBT[22] and to compare various ventilatory support methods for SBT.

The present study had several potential limitations. It is rarely possible to blind clinicians in the study to treatment assignment. Therefore, bias from differential use of co-interventions or assessment of outcomes can never be completely excluded. Given this design limitations, it is not surprising that clinical trials of protocols generate a great deal of debate. Although the present study demonstrated that duration of MV was shorter in the protocol-directed weaning group, other more meaningful outcomes such as ICU stay, hospital stay, hospital costs, and mortality were not presented. Consequently, the clinical importance of the results is not clear and doubt on the generalization of the present findings still exists. However, the present study was the first study regarding the implementation of clinical protocol in the presented ICU and the first study to demonstrate the use of a weaning protocol by non-physician in this particular group of patients. Furthermore, more research with rigid methodology is required in order to disseminate and implement this protocol.

The introduction of protocols into an institution or ICU did not guarantee that the protocol would be used, or used correctly. The initial obstacle for the implementation of the weaning protocol in our ICU was a shortage of nursing staff (one nurse per two or three patients at study period), performing the protocol has consumed their time from their daily work. In addition, there have not been respiratory therapists in our institution, the responsibility of patients' respiratory care was taken by nurses, residents and attending physicians. Other problems related to the propagation of protocol are that therapies that are inherently appealing become institutionalized before they are rigorously proven to improve outcomes, and they become a "standard of care" that is difficult to reverse such as weaning patients from a ventilator can be performed only by physicians or using IMV for weaning. From our ICU system, the authors do believe that the protocol must be initiated by a clinician. Furthermore, if the intent of the protocol is to improve patient outcomes, intense education and monitoring are necessary to achieve even minimal protocol adherence[23].

Conclusion

The authors have shown that protocol-directed weaning of MV is safe and resulted in a shorter duration of MV compared with the traditional practice of physician-directed weaning in intra-abdominal surgical patients. Although implementation of a protocol-directed weaning resulted in the initiation of the weaning process earlier and a more rapid progression of weaning to the point of discontinuation of MV, their implementation should be based on local clinical characteristics and needs, accompanied by an intensive education effort and measurement of adherence and outcomes.

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การหย่าเครื่องช่วยหายใจในผู้ป่วยที่มาทำการผ่าตัดในช่องท้อง

อรอุมา ชัยวัฒน์, นิยมพร สาริมา, กัสมา นิยมพานิชพัฒนา, จุฬาลักษณ์ โกมลตรี, ยุทธนา อุดมพร, สุณีรัตน์ คงเสรีพงศ์

ภูมิหลัง: *จากการศึกษาที่ผ่านมา การหย่าจากเครื่องช่วยหายใจสำหรับผู้ป่วยวิกฤตทั่วไปโดยวิธี protocol-directed ใช้ระยะเวลาสั้นกว่าวิธี physician-directed การศึกษาแบบไปข้างหน้าโดยการสุ่มนี้เพื่อเปรียบเทียบระยะเวลาที่ผู้ป่วยใช้เครื่องช่วยหายใจระหว่างวิธี protocol based nurse-directed กับวิธี physician-directed ในผู้ป่วยที่ได้รับการผ่าตัดช่องท้อง*

วัสดุและวิธีการ: *ผู้ป่วยที่ต้องช่วยหายใจหลังการผ่าตัดช่องท้อง 100 คน ถูกสุ่มแยกเป็น 2 กลุ่ม 1) protocol-directed 51 คน 2) physician-directed 49 คน โดยกลุ่ม protocol-directed ได้รับการทำ daily screening และ spontaneous breathing trial โดยพยาบาล*

การวัดผล: *ระยะเวลาที่ผู้ป่วยใช้เครื่องช่วยหายใจ*

ผลการศึกษา: *ระยะเวลาที่ผู้ป่วยใช้เครื่องช่วยหายใจโดยวิธี protocol-directed กับวิธี physician-directed มีค่ามัธยฐาน 40 และ 72 ชั่วโมง ตามลำดับ ($p < 0.001$) ผู้ป่วย 2 ราย ในกลุ่ม protocol-directed และ 3 ราย ในกลุ่ม physician-directed ได้รับการใส่ท่อช่วยหายใจซ้ำภายใน 72 ชั่วโมง หลังการถอดท่อ ($p = 0.61$) ไม่มีผู้ป่วยที่ต้องช่วยหายใจนานกว่า 21 วัน*

สรุป: *การทำ daily screening และ spontaneous breathing trial โดยพยาบาลในผู้ป่วยหลังการผ่าตัดช่องท้อง มีระยะเวลาที่ผู้ป่วยใช้เครื่องช่วยหายใจสั้นกว่าวิธี physician-directed*