

Efficacy of Weaning Protocol in Medical Intensive Care Unit of Tertiary Care Center

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Objective: To evaluate the efficacy of the protocol-directed weaning from a mechanical ventilator compared to physician-directed weaning.

Material and Method: A comparative study between retrospective studies of physician-directed weaning as controls (N = 198) reviewed from July 2000 to July 2002 and the prospective studies of protocol-directed weaning as intervention (N = 196) enrolled from October 2002 to October 2003 in the medical ICU of Maharaj Nakorn Chiang Mai Hospital, tertiary care center of northern Thailand. Study results were concluded by Fisher's exact test.

Results: Baseline characteristics data of both groups including sex, age, illness severity which demonstrated by APACHE II score and PaO₂/FiO₂ ratio, causes of respiratory failure and mode of mechanical ventilation used were similar. The duration of mechanical ventilation before weaning was 5.89 ± 3.71 days in the protocol-directed group and 7.41 ± 5.54 days in the physician-directed group (p < 0.05). Weaning duration in the protocol-directed group was significantly shorter than the physician-directed group (14.58 ± 16.98 hours VS 47.09 ± 38.23 hours; p < 0.05). Kaplan-Meire analysis demonstrated that patients in the protocol-directed group had significantly shorter durations of mechanical ventilation compared to patients in the physician-directed group (p = 0.001, log-rank test). The ICU LOS was significantly shorter in the protocol-directed group (7.91 ± 4.71 vs 11.53 ± 7.80 days; p < 0.05). The 28 days mortality rate and the incidence of hospital acquired pneumonia seemed to be less in the protocol-directed group (4.60% vs 6.10% and 5.60% vs 10.10% consecutively) and reintubation rate seemed to be higher in the protocol-directed group (6.1% vs 4.5%) than the physician-directed group but differences were not significant (p > 0.05).

Conclusion: Protocol-directed weaning proved to have more efficacy in weaning patients from a ventilator than physician-directed weaning in terms of weaning duration and ICU length of stay without a deteriorating effect to the patients.

Keywords: Protocol-directed weaning, Physician-directed weaning

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Timing for weaning from a mechanical ventilator might be 40 percent of total ventilator used time^(1,2) or longer, depending on patients and caring team ability. Principally, weaning time should be as short as possible because of the increasing risk of ventilator associated pneumonia⁽³⁾, increasing psychic

trauma and increasing cost of hospital care. Weaning while patients conditions are not appropriate is dangerous, resulting in increasing cardiovascular stress, loss of airway protection and muscle fatigue which take 24 hours or longer to recovery⁽⁴⁾. In readiness to wean patients, weaning failure is not as harmful as not-yet-ready patients because of good monitoring and weaning failure sign detection, patients were not put in severe muscle fatigue state which made them recover faster than not-yet-ready patients⁽⁵⁾. Using clinical judgment alone, physicians do not accurately

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predict whether mechanical ventilation can be discontinued successfully, leading to delayed weaning. At tertiary care hospitals, Intensive Care Unit (ICU) beds have become a precious resource. The authors realized that the faster a patient is successfully extubated, the sooner the ICU bed can be available for the next patient waiting in the queue. Studies showed that by improving patient outcomes, ventilator-management protocols could reduce ICU costs⁽⁶⁾. Variations in weaning practice due to different physicians who have individual practice styles and vary in clinical judgment experience also have been shown to be associated with differences in patient outcomes^(7,8). Such variations in weaning practice sometimes impedes weaning. Variability in practices is diminished by standardized protocols, which are based on the best available medical knowledge, offer a systematic approach to providing less-variable medical care that can decrease errors, improve the effectiveness of the treatment, increase the accountability of medical providers, and provide a reference of measure to assess future refinements in the treatment protocol^(8,9). Weaning protocol practice by multidisciplinary team mostly respiratory therapists-driven or nurse-driven has proved to have more efficacy in weaning than physician-directed weaning practice. In the present study, the authors wanted to know whether Protocol weaning which is done in the authors' center has proved to be beneficial.

Material and Method

Patients

The study was approved by the ethics committee and conducted in the medical ICU in two phases. Because of the method selection bias if the same caring team knew about the weaning protocol, they would un-intentionally use the protocol in some part of the weaning procedure, caused the authors to use retrospective patients for comparison instead of a prospective randomized control trial. Retrospective or physician-directed weaning patients were reviewed from July 2000 to July 2002, only 198 complete medical records were collected. The demographic data, diagnosis, APACHE II score, duration of ventilator used, duration of weaning, weaning method, complications, ventilator-associated pneumonia rate and 28-day ICU mortality were analyzed. The prospective or protocol-directed weaning, totally 196 patients, were enrolled to the study from October 2002 to October 2003. The study was explained to ready-to-wean patients and enrollment of patients who gave informed consent.

Weaning protocol

The authors used the Saundok weaning protocol as shown in Diagram 1. Weaning readiness was screened daily in the morning by respiratory care nurses. Patients who met all weaning readiness criteria were asked to enroll in the study. For patients who did not meet all the weaning readiness criteria, physician adjustment was needed before enrolling the patient. Spontaneous breathing trial (SBT) with once daily T-piece, low level pressure support (PS) or continuous positive airway pressure (CPAP) was initiated to the patient depending on the ventilator setting before the trial. Patients who passed 2 hours of spontaneous breathing trial were declared as weaning success and extubation was considered in patients who had good spontaneous cough and ability to protect their airway. Weaning procedure was termi-

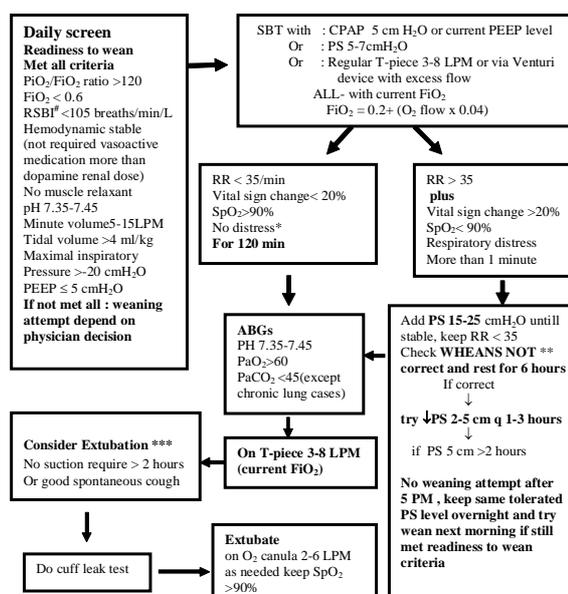


Diagram 1. Saundok weaning protocol

RSBI (Rapid shallow breathing index) = respiratory rate (F)/tidal volume (Vt) = respiratory rate²/minute volume (L)

* Respiratory distress

2 or more of : marked use of accessory muscle
: abdominal paradox
: diaphoresis
: marked compliant of dyspnea

** WHEANS NOT

W: wheeze; H: heart, hypertension; E: electrolyte; A: airway, anxiety, aspiration, alkalosis; N: neuromuscular; S: sepsis, sedation; N: nutrition (over/under); O: opiate, obesity; T: thyroid disease

*** physician adjustment

nated in patients who could not tolerate spontaneous breathing trial and pressure support level was increased to 15-25 cmH₂O to comfort the patient. The causes of weaning failure were evaluated and the problems were corrected. After a period of rest for at least 6 hours, patients were evaluated for weaning readiness and spontaneous breathing trial were done in ready- to- wean patients on the same day before 5 pm or next morning.

Statistical analysis

The statistical analysis was performed with commercially available computer software (SPSS version 10.0). Continuous variables were expressed as mean \pm SD and Unpair t-test was used to analyze. Categories variables were expressed as percentage and Chi-square test or Fisher's exact test was used to analyze depending on data size. A p-value $<$ 0.05 was considered to indicate statistical significance. Kaplan-Meier analysis was used to demonstrate the probability of successful weaning over time for each treatment group.

Results

Baseline characteristics data of both groups are shown in Table 1. The two groups were similar in

sex, age and illness severity which was demonstrated by APACHE II score and PaO₂/FiO₂ ratio. The causes of respiratory failure had similar distribution between the groups. The mode of mechanical ventilation used in both groups did not differ significantly.

The duration of mechanical ventilation before weaning was 5.89 ± 3.71 days in the protocol-directed group and 7.41 ± 5.54 days in the physician-directed group ($p < 0.05$). The majority of weaning mode in the physician-directed group was synchronized intermittent mandatory ventilation (SIMV) with PS \pm CPAP (48%). In the protocol-directed group, spontaneous breathing trial was done by different methods as shown in Table 2. Weaning time in the protocol-directed group was significantly shorter than the physician-directed group (14.58 ± 16.98 hours vs 47.09 ± 38.23 hours; $p < 0.05$). The length of stay in the ICU was significantly shorter in the protocol-directed group (7.91 ± 4.71 days vs 11.53 ± 7.80 days; $p < 0.05$). The 28 days mortality rate and the incidence of hospital acquired pneumonia in the protocol-directed group were not significantly different from the physician-directed group (4.60% vs 6.10% and 5.60% vs 10.10% consecutively; $p > 0.05$). The reintubation rate was

Table 1. Baseline characteristics and clinical status

	Protocol-directed n = 196	Physician-directed n = 198	P value
Sex (Male/Female)	97/99	85/113	0.192
Age (years)	53.34 \pm 15.77	52.19 \pm 16.69	0.483
APACHE II score	15.91 \pm 3.51	15.82 \pm 3.46	0.809
PaO ₂ /FiO ₂	267.47 \pm 42.60	273.54 \pm 41.41	0.153
Mode of MV			
VC-ACV or CMV	168	173	0.571
PCV	20	16	
SIMV with PS \pm CPAP	3	6	
PS \pm CPAP	5	3	
Cause of respiratory failure			
COPD/asthma/bronchiectasis	38	30	0.306
Pneumonia	32	28	
ARDS	26	30	
Sepsis	23	29	
Renal failure	25	20	
COPD with Pneumonia	9	10	
Neuromuscular diseases	14	16	
CVA/meningitis	9	7	
Pulmonary embolism	4	2	
Congestive heart failure	8	4	
Other	8	12	

MV=mechanical ventilation; VC-ACV=volume control-assist control ventilation; CMV=continuous mandatory ventilation; PCV=pressure control ventilation; SIMV=synchronized intermittent mandatory ventilation; PS=pressure support; CPAP=continuous positive airway pressure; COPD=chronic obstructive pulmonary disease; ARDS=acute respiratory distress syndrome; CVA=cerebrovascular accident

Table 2. Weaning outcome

	Protocol-directed n = 196	Physician-directed n = 198	p value
MV duration before weaning (days)	5.89±3.71	7.41±5.54	0.001
Weaning Mode			
SIMV with PS ± CPAP	0	95	0.000
PS ± CPAP	75	45	
CPAP	61	4	
T-piece	60	54	
Weaning duration (hours)	14.58±16.98	47.09±38.23	0.000
ICU-LOS (days)	7.91±4.71	11.53±7.80	0.000
28 day mortality rate (%)	4.60%	6.10%	0.516
HAP rate (%)	5.60%	10.10%	0.098
Reintubation rate (%)	6.10%	4.50%	0.486

not significantly higher in the protocol-directed group (6.1% vs 4.5%). Kaplan-Meier curves of the probability of successful weaning over time between patients receiving protocol-directed weaning and physician-directed weaning are shown in Fig. 1. Statistical tests suggested that the survival function were different between the two groups, favoring a shorter duration of mechanical ventilation for the protocol-directed weaning patients ($p = 0.001$, log-rank test).

Discussion

Weaning patients from the mechanical ventilation using protocol has been demonstrated to be safe and effective in reducing mechanical ventilation time, length of stay in the intensive care unit from many studies⁽¹⁰⁻¹³⁾. In the present study the authors also wanted to know the efficacy of protocol-directed weaning compared to physician-directed weaning whether it also proved to be beneficial in our ICU. The patients in the present study were medical patients who had severe illnesses and substantial underlying conditions which the demographic and clinical status for two groups were no statistically different. The physicians who spent time in the care the patients were mostly internal medicine training residents who have different levels of experience and clinical decision making under the supervision of attending physicians who rotate in the ICU on a monthly basis. The nurses in the ICU had between a high and low level of experience in ICU nursing practice. The authors' finding demonstrated that weaning the patients with protocol in this ICU situation was superior to the physician-directed weaning approach in terms of

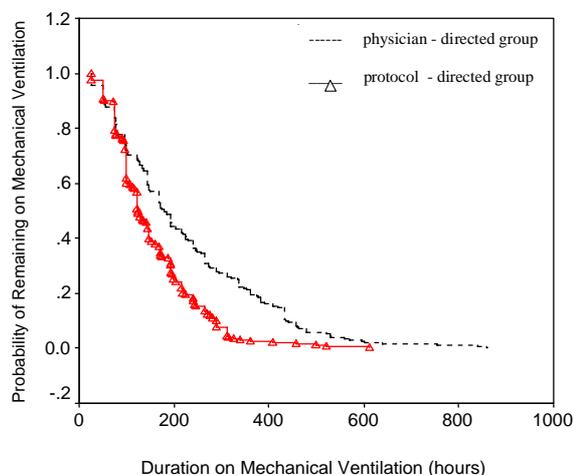


Fig. 1 Kaplan-Meier curves of the probability of remaining on mechanical ventilation over time between patients in the protocol-directed weaning group (solid line) and the physician-directed weaning group (dashed line)

weaning duration and ICU length of stay (ICU-LOS). Although the re-intubation rate was higher, the 28 day mortality rate and the incidence of hospital acquired pneumonia (HAP) were lower in the protocol-directed group. These findings had no statistical difference. The mechanical ventilation duration before weaning initiation in the physician-directed group was longer than the protocol-directed group because of a lack of standardized criteria in patients' screening, weaning initiation depended on physician decision making which was judged by the clinical criteria and a few respiratory mechanic parameters including maximal inspiratory pressure > 20 cmH₂O, tidal volume > 4 ml/kg and vital capacity > 10 ml/kg. In the protocol-directed group, screening was done daily systematically and ready to wean patients were identified by clinical criteria, pulmonary mechanics and rapid shallow breathing index. Modes of weaning used in both groups were quite different. In the physician-directed group, 48 percent (95/198) of the patients used SIMV with PS ± CPAP and the rest used PS ± CPAP 22.7%, CPAP 2% and T-piece 27.3% as the weaning mode. In the protocol-directed group, ventilator weaning was done with spontaneous breathing trial⁽¹⁴⁾ by different methods including low level PS ± CPAP 38.3%, CPAP 31.1% and once daily T-piece 30.6% of the patients, depending on the previous ventilator setting, endotracheal tube size and type of ventilator. The majority of patients in the physician-directed group were weaned with SIMV mode which is inferior to the T-piece and PSV mode in terms of weaning time. These findings could explain the longer duration of weaning

in this group. Kollef et al⁽¹⁰⁾ demonstrated that simply introducing a protocol or guideline to the weaning process lead to a decrease in weaning time independent of the mode used. *Krishnan et al*⁽¹⁵⁾ found that the protocol-directed weaning was not superior to the physician-directed weaning. The authors agreed that protocol-directed weaning is not superior to physician-directed weaning if the weaning process was done in a closed ICU of a tertiary care center by the same internal medical residents under the supervision of the same attending physician. In the present study, the authors wanted to know the efficacy of protocol-directed weaning by avoiding physician bias, the authors designed the study by using retrospective data for comparison instead of a prospective randomized control trial as in the study of *Krishnan et al*. In Thailand, the ICUs in many hospitals are open ICU models in which ventilator weaning practice depends on the service physician who has different practice styles, patients in this ICU situation would benefit from a protocol-directed weaning guideline.

In conclusion, protocol-directed weaning by using spontaneous breathing trial as a weaning technique proved to have more efficacy in weaning patients from the ventilator than physician-directed weaning previously performed in our ICU in terms of weaning duration and ICU length of stay without a deteriorating effect to the patients.

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**ประสิทธิภาพของการหย่าเครื่องช่วยหายใจโดยการใช้วิธีปฏิบัติตามเกณฑ์ที่วางไว้ในหออภิบาล
แผนกอายุรกรรมของศูนย์การแพทย์ตติยภูมิ**

ชัยวัฒน์ บำรุงกิจ, เฉลิม ลีวีศรีสกุล, อรรถวุฒิ ดิสมโชค, อีกรร อีกริตติกุล, ชายชาญ โพธิรัตน์

วัตถุประสงค์: เพื่อประเมินประสิทธิภาพของการหย่าเครื่องช่วยหายใจโดยปฏิบัติตามเกณฑ์ที่วางไว้เปรียบเทียบกับ
การหย่าเครื่องช่วยหายใจโดยแพทย์ตามอิสระ

วิธีการศึกษา: โดยการศึกษาเปรียบเทียบการหย่าเครื่องช่วยหายใจโดยใช้แนววิธปฏิบัติตามเกณฑ์ที่วางไว้
(prospective) ในช่วงเดือนตุลาคมปี พ.ศ. 2545-2546 จำนวน 196 คน กับการหย่าเครื่องช่วยหายใจโดยแพทย์ตามอิสระ
จากรายงานของผู้ป่วยย้อนหลัง (retrospective) ในช่วงเดือนกรกฎาคมปี พ.ศ. 2544-2546 จำนวน 198 คน

ผลการศึกษา: ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติในผู้ป่วยทั้ง2กลุ่มในเรื่องของข้อมูลพื้นฐาน สาเหตุ
และความรุนแรงของภาวะการหายใจล้มเหลว และวิธีการช่วยหายใจ ระยะเวลาที่ใช้เครื่องช่วยหายใจก่อน
ที่จะหย่าเครื่องโดยในกลุ่มที่ใช้แนววิธปฏิบัติเท่ากับ 5.89 ± 3.71 วัน ซึ่งจะสั้นกว่ากลุ่มที่หย่าเครื่องช่วยหายใจโดย
แพทย์ตามอิสระ (7.41 ± 5.54 วัน) อย่างมีนัยสำคัญทางสถิติ ระยะเวลาที่ใช้ในการหย่าเครื่องในกลุ่มที่ใช้แนววิธ
ปฏิบัติจะสั้นกว่า (14.58 ± 16.98 ชั่วโมง vs 47.09 ± 38.23 ชั่วโมง $p < 0.05$) ระยะเวลาที่นอนในหออภิบาลก็น้อยกว่า
กลุ่มที่หย่าเครื่องช่วยหายใจโดยแพทย์ตามอิสระ (7.91 ± 4.71 วัน vs 11.53 ± 7.80 วัน $p < 0.05$) อย่างมีนัยสำคัญ
ทางสถิติ อัตราการเสียชีวิตที่28วันและอุบัติการณ์ของการเกิดปอดอักเสบในโรงพยาบาล. ในกลุ่มที่ใช้แนววิธปฏิบัติ
จะน้อยกว่ากลุ่มที่หย่าเครื่องโดยแพทย์ตามอิสระ (4.60% vs 6.10% และ 5.60% vs 10.10% ตามลำดับ) แต่ไม่มี
นัยสำคัญทางสถิติ ถึงแม้ว่าอัตราการใส่ท่อหายใจซ้ำหลังจากที่ถอดท่อไปแล้วในกลุ่มที่ใช้แนววิธปฏิบัติจะมากกว่า
กลุ่มที่หย่าเครื่องช่วยหายใจโดยแพทย์ตามอิสระ แต่ไม่พบว่ามีนัยสำคัญทางสถิติ (6.1% vs 4.5%) ($p > 0.05$)

สรุป: การหย่าเครื่องช่วยหายใจโดยการใช้วิธีปฏิบัติตามเกณฑ์ที่วางไว้มีประสิทธิภาพสูงกว่าการหย่าเครื่องช่วย
หายใจที่ทำโดยแพทย์ตามอิสระ ในด้านระยะเวลาที่ใช้ในการหย่าเครื่อง ทำให้จำนวนวันนอนในหออภิบาลลดลง
และไม่มีผลเสียต่อผู้ป่วย