Clinical Outcomes and Cost of Ventilator Weaning and Endotracheal Extubation Guided by An Established Ventilator Weaning Protocol in Patients Undergoing Elective Cardiac Surgery

Supanan Innok, M.N.S*, Witchuda Dokphueng, M.N.S*, Kamol Udol, M.D., M.Sc., Worawong Slisatkorn, M.D.***, Prasert Sawasdiwipachai, M.D.******

**Department of Nursing, Siriraj Hospital, Bangkok 10700, Thailand, **Department of Preventive and Social Medicine, ***Department of Surgery, ****Department of Anesthesiology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand*

ABSTRACT

Objective: To compare successful early extubation rates, complications, and cost before and after the use of an established ventilator weaning protocol in patients undergoing elective cardiac surgery.

Materials and Methods: Subjects were adult patients undergoing elective cardiac surgery who were clinically stable within 2 hours after surgery. The control group underwent conventional ventilator weaning at the discretion of their attending staff. The intervention group underwent protocol-guided ventilator weaning. The primary outcome was a successful early extubation (within 6 hours after surgery). Secondary outcomes were complications from weaning to 24 hours after surgery, and the relevant cost related to respiratory and cardiovascular care within 24 hours after admission to the postoperative intensive care unit.

Results: The primary outcome occurred in 37 out of 65 patients (56.9%) in the intervention group and in 5 out of 65 patients (7.7%) in the control group (adjusted odds ratio 20.6; 95% confidence interval 6.7–62.9, p<0.001). The complication rates were not statistically different between the intervention and control groups (26.2% vs. 20.0%, p=0.41). The relevant cost, approximated by the service charges, related to respiratory and cardiovascular care was significantly less in the intervention group than in the control group (median 2,491 vs. 2,711 Thai baht, p<0.001).

Conclusion: The use of the established ventilator weaning protocol after elective cardiac surgery was associated with a higher rate of successful early extubation and lower cost related to respiratory and cardiovascular care compared to the conventional practices of ventilator weaning and extubation. The rates of overall complications were not significantly different.

Keywords: Early extubation; cardiac surgery; ventilator weaning protocol; complication; cost (Siriraj Med J 2021; 73: 815-822)

INTRODUCTION

Open-heart surgery remains an important treatment option for patients with coronary artery disease, valvular heart disease, and congenital heart disease. After successful open-heart surgery, patients often require further ventilatory support for a period of time until the effects of general anesthesia fade and their vital signs are stable. Timely ventilator weaning and endotracheal extubation is essential in order to avoid unnecessary prolonged ventilation and, at the same time, to minimize the adverse effects of too early weaning and extubation.

Corresponding author: Kamol Udol
E-mail: kamol.udo@mahidol.ac.th
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ORCID ID: https://orcid.org/0000-0002-1508-7749
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At Siriraj Hospital, the process of ventilator weaning in elective cardiac surgery patients in the postoperative intensive care unit (ICU) has conventionally been handled primarily by the attending nurse, under the supervision of the attending ICU physician, without any specific guidance. The nurse initiates the process of ventilator weaning and regularly monitors the patient's response and weaning parameters. When the patient is considered ready for extubation, the nurse notifies the attending ICU physician to confirm the evaluation and to perform the extubation. The ventilator weaning process depends considerably on the individual nurse's experience and preference. This leads to a variation in practice and can result in an unnecessarily prolonged intubation in some patients, especially those who are ready for extubation during the night. Prolonged ventilatory support and delayed endotracheal extubation are associated with an increase in the length of ICU and hospital stay, adverse clinical outcomes, including an increase in mortality, and higher health care costs.[1,2] Previous studies found that post cardiac surgery patients with stable hemodynamics could be safely extubated within 4–6 hours after surgery.[3,4] In order to reduce variations in practice and to avoid delayed extubation, a team comprising postoperative ICU nurses, a cardiovascular-thoracic surgeon, and a cardiovascular anesthesiologist was formed to establish a protocol for ventilator weaning and extubation for postoperative cardiac surgery patients. The protocol specifies the steps and activities to be followed by the attending nurse, with an aim for early extubation within 6 hours after surgery.

We conducted this study to evaluate the effects of using the established ventilator weaning protocol in patients undergoing elective cardiac surgery compared to conventional weaning practices.

MATERIALS AND METHODS

This prospective pre-post intervention study was conducted at Siriraj Hospital in Bangkok, Thailand. The Institutional Review Board of the Faculty of Medicine Siriraj Hospital approved the study protocol. All the subjects provided written informed consent to participate in the study.

Study participants

Patients were potentially eligible if they had coronary artery disease, valvular heart disease, or adult congenital heart disease that required elective cardiac surgery for the first time, were aged 18–75 years old, and had a left ventricular ejection fraction (LVEF) of ≥ 45%, and an echocardiographically estimated right ventricular systolic pressure (RVSP) of ≤ 60 mmHg. After the surgery, patients were admitted to the postoperative ICU. At 2 hours after surgery, the patients were assessed for their final eligibility. Patients were excluded if they met at least one of the following exclusion criteria at 2 hours after surgery: a Richmond Agitation and Sedation Scale (RASS) of < –2; pulse oximetry oxygen saturation (SpO_2) of < 95%; serious cardiac arrhythmia [symptomatic bradycardia with a heart rate of < 50 beats per minute (BPM), second- or third-degree atrioventricular block, atrial fibrillation with a ventricular rate of > 120 BPM, atrial flutter, supraventricular tachycardia, sustained ventricular tachycardia, ventricular fibrillation, or pulseless electrical activity]; unstable hemodynamics [sustained hypotension (mean arterial pressure (MAP) of < 65 mmHg or systolic blood pressure (SBP) of < 90 mmHg) for longer than 10 minutes, at least 2 episodes of hypotension (MAP of < 65 mmHg or SBP of < 90 mmHg) within the previous 2 hours, receiving at least 5 microgram/kg/min of dopamine or dobutamine, or at least 0.1 microgram/kg/min of adrenaline or norepinephrine, requiring mechanical circulatory support (intra-aortic balloon pump, ventricular assist device, or extra-corporeal membrane oxygenation), or had a urine output of < 1 mL/kg/hour]; chest drain content of > 100 mL/hour for 2 consecutive hours; and the occurrence of new stroke. Patients with a documented difficulty in intubation were also excluded.

Study procedures

Patients enrolled before implementation of the established ventilator weaning protocol (i.e., the conventional weaning group) were managed conventionally regarding ventilator weaning and extubation by the attending nurse in consultation with the attending ICU physician in the postoperative ICU. Patients were put on mechanical ventilation upon ICU admission, usually in the assist/control mode. The weaning process started with a gradual reduction of the fraction of inspired oxygen (FiO_2) to 0.4-0.5 while maintaining the SpO_2 at 95% or higher. When this level of FiO_2 was achieved and the patient was clinically stable and conscious, the ventilator mode was then switched to synchronized intermittent mandatory ventilation (SIMV) with pressure support (PS). When the attending staff were confident that the patient could tolerate this ventilator mode well and was clinically stable, the patient was put on spontaneous ventilation with either T-piece or continuous positive airway pressure (CPAP) with PS. When the patient's respiratory and clinical conditions were ready, the attending ICU physician performed the extubation. The specific details and timing of each step

were not specified and were left to the discretion of the attending nurse in consultation with the attending ICU physician. During the process, the patient's conditions were regularly monitored and management was provided accordingly.

The established ventilator weaning protocol was implemented in April 2016, and patients enrolled in the study thereafter comprised the protocol weaning group. The protocol provides details of and timing for the activities at each step, together with the criteria for the assessment of patients during the weaning process. The protocol aims for extubation to be performed within 6 hours after surgery if the patients are stable and do not have major complications. The protocol is summarized in Fig 1.

Outcomes

The primary outcome was a successful extubation within 6 hours after the surgery. Extubation was considered successful if there were no respiratory, cardiovascular, or neurological complications until 24 hours after surgery, and no re-intubation within 48 hours after extubation. Secondary outcomes were complications recorded from the beginning of ventilator weaning to 24 hours after surgery, and the relevant cost related to respiratory and cardiovascular care within 24 hours after admission to the ICU. Respiratory complications included new or worsening atelectasis, pneumothorax, re-intubation within 48 hours after extubation, and moderate or severe acidosis or alkalosis. Cardiovascular complications included postoperative myocardial infarction, significant arrhythmias (atrial flutter, atrial fibrillation with rapid ventricular rate, supraventricular tachycardia, sustained ventricular tachycardia, ventricular fibrillation, pulseless electrical activities), and hypotension (MAP < 65 mmHg or SBP < 90 mmHg for longer than 10 minutes). Neurological complication was reflected by a Glasgow coma scale of < 13. The cost considered in this study was limited to that related to inotropic agents, antiarrhythmic agents, procedures related to respiratory care (endotracheal intubation, ventilator use, suction, chest x-ray, arterial blood gas analyses, and intercostal drainage), and cardiovascular care (intraarterial blood pressure monitoring, use of infusion pumps, electrocardiography, analyses of cardiac biomarkers, and electrical cardioversion). For each service item, we used the service charge determined by Siriraj Hospital as a proxy for its cost. The service charge for each service item was fixed throughout the study period.

Statistical analyses

On the basis of our local ICU statistics, the rate of successful extubation within 6 hours after cardiac surgery was approximately 25%. To demonstrate a doubling of the successful extubation rate after the use of the established ventilator weaning protocol with the power of 80% at a two-sided significance level of 0.05 and the assumption of a 10% loss of subjects, it was determined that a sample size of 65 subjects in each group would be required.

The patients' characteristics were summarized with the median and interquartile range (IQR), or number and percentage, and were compared between groups using the Mann–Whitney U test, chi-square test, or the Fisher's exact test as appropriate. The primary outcome was analyzed using multiple logistic regression analysis, adjusted for imbalances in the baseline characteristics (characteristics with a p-value of < 0.2 in comparisons between groups). The magnitude of the effect is presented as an adjusted odds ratio (OR) and its 95% confidence interval (CI). The complication rates were compared between groups using the chi-square test. The cost was compared using the Mann–Whitney U test.

RESULTS

In total, 130 patients participated in the study: 65 in the conventional weaning group and 65 in the protocol weaning group. All the patients completed the study protocol and were included in the analyses. The median age was 61.5 years old and 61.5% were male. Comorbidities were prevalent; almost 40% of the study participants had diabetes, about three-quarters had hypertension, and slightly more than half had dyslipidemia. Coronary artery bypass graft (CABG) surgery was performed, as a single procedure or combined with other procedures, in 74% of the subjects. Valve surgery, alone or combined with other procedures, was done in 32% of the subjects. The patients' baseline characteristics were not statistically significantly different between the groups (Table 1).

Primary outcome

The median (IQR) duration of intubation was 5.8 (5.3–6.0) hours in the protocol weaning group and 9.0 (7.4–11.1) hours in the conventional weaning group (p < 0.001). The primary outcome (successful extubation within 6 hours after surgery) occurred in 37 patients (56.9%) in the protocol weaning group and in 5 patients (7.7%) in the conventional weaning group (Table 2). The OR for the primary outcome, adjusted for sex, the presence of diabetes mellitus, and the presence of coronary artery disease, was 20.6 (95% CI 6.7–62.9, p < 0.001) for the intervention group compared to the control group.

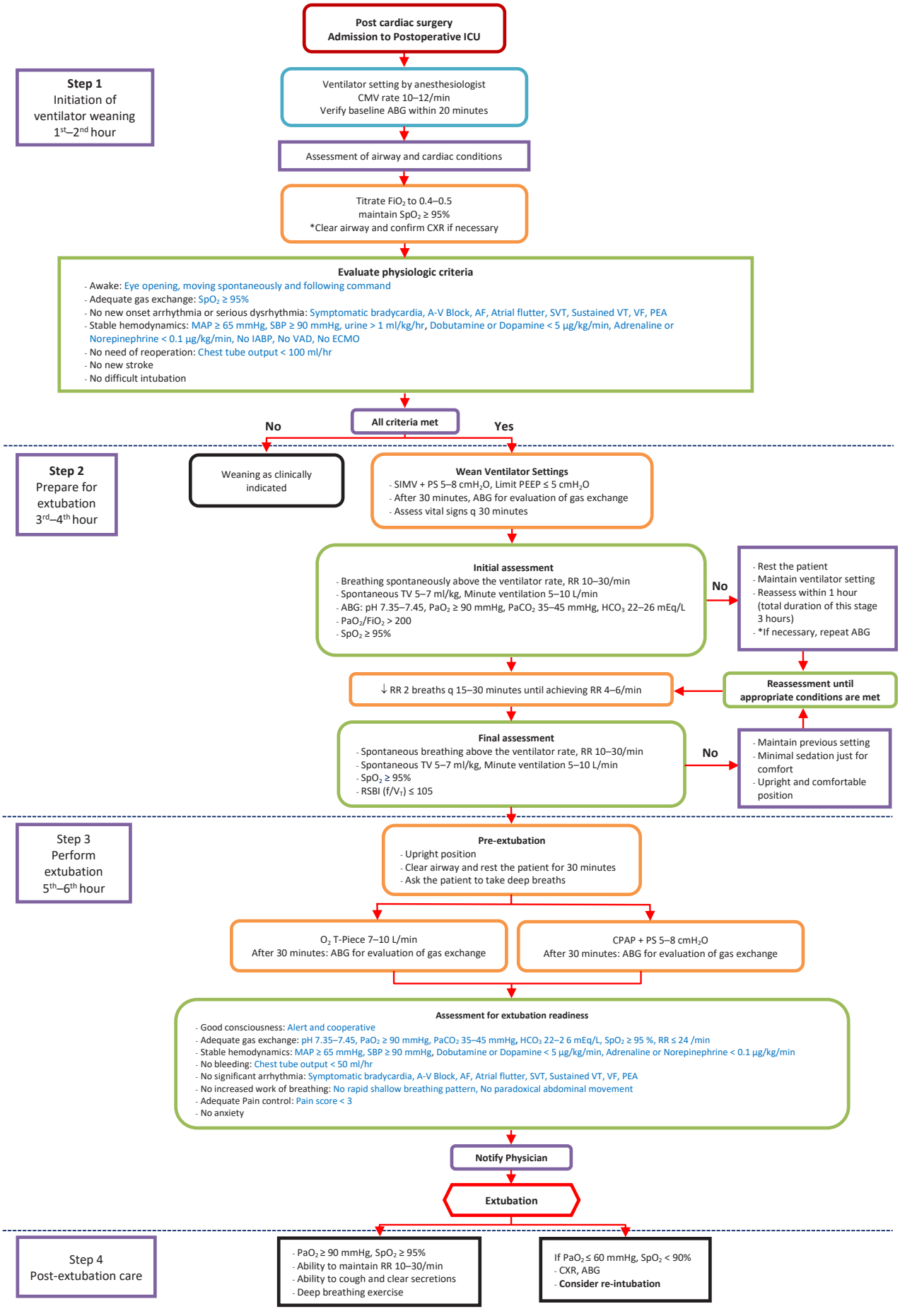

Fig 1. Ventilator weaning and extubation protocol after elective cardiac surgery

TABLE 1. Characteristics of the study participants at enrolment.

Characteristic	Total (n = 130)	Protocol weaning (n = 65)	Conventional weaning (n = 65)	p-value[a]
Age (year) – median (IQR)	61.5 (54.0–6 7.0)	60.0 (52.5–67.0)	62.0 (55.0–67.0)	0.537[b]
Male – no. (%)	80 (61.5)	45 (69.2)	35 (53.8)	0.071
Comorbidities – no. (%)				
Diabetes mellitus	48 (36.9)	20 (30.8)	28 (43.1)	0.146
Hypertension	99 (76.2)	52 (80.0)	47 (72.3)	0.303
Dyslipidemia	70 (53.8)	36 (55.4)	34 (52.3)	0.725
Chronic kidney disease	8 (6.2)	2 (3.1)	6 (9.2)	0.273[c]
COPD/Asthma	5 (3.8)	1 (1.5)	4 (6.2)	0.365[c]
eGFR[d] (mL/min/1.73 m^2) – median (IQR)	75.4 (62.6–91.8)	75.8 (65.2–91.6)	75.1 (60.8–91.8)	0.524[b]
Smoking status – no. (%)				0.639
Current smoker	11 (8.5)	7 (10.8)	4 (6.2)	
Ex-smoker	31 (23.8)	15 (23.1)	16 (24.6)	
Non-smoker	88 (67.7)	43 (66.2)	45 (69.2)	
ASA class – no. (%)				1.000[c]
2	5 (3.8)	2 (3.1)	3 (4.6)	
3–4	124 (96.2)	63 (95.4)	62 (93.8)	
Cardiac condition[e] – no. (%)				
Coronary artery disease	96 (73.8)	52 (80.0)	43 (66.2)	0.075
Valvular heart disease	43 (33.1)	19 (29.2)	24 (36.9)	0.351
Congenital heart disease	8 (6.2)	4 (6.2)	5 (7.7)	0.730[c]
Type of surgery – no. (%)				0.367[c]
Single procedure				
CABG surgery	83 (63.8)	44 (67.7)	39 (60.0)	
Valve surgery	25 (19.2)	8 (12.3)	17 (26.2)	
Closure of septal defect	4 (3.1)	2 (3.1)	2 (3.1)	
Combined procedures				
CABG and valve surgery	13 (10.0)	8 (12.3)	5 (7.7)	
Valve surgery and closure of septal defect	4 (3.1)	2 (3.1)	2 (3.1)	
Other	1(0.8)	1 (1.5)	0 (0.0)	
Operation time (minutes) – median (IQR)	155 (120–216)	150 (120–199)	170 (120–235)	0.257[b]

[a] Conventional weaning vs. Protocol weaning, Chi-square test unless indicated otherwise.
[b] Mann–Whitney U test.
[c] Fisher's exact test.
[d] Calculated using the CKD–EPI creatinine equation.
[e] Listed conditions are not mutually exclusive.
IQR: Interquartile range, COPD: Chronic obstructive pulmonary disease, eGFR: Estimated glomerular filtration rate, CABG: Coronary artery bypass graft, ASA: American Society of Anesthesiologists.

TABLE 2. Primary outcome.

	Protocol weaning (n = 65)	Conventional weaning (n = 65)	Adjusted OR[a] (95% CI)	p-value
Successful extubation within 6 hours after surgery – no. (%)	37 (56.9)	5 (7.7)	20.6 (6.7–62.9)	< 0.001

[a] Adjusted for sex, presence of diabetes mellitus, presence of coronary artery disease.
OR: odds ratio, CI: confidence interval.

Secondary outcomes

Overall, 30 subjects suffered at least 1 complication from the beginning of ventilator weaning to 24 hours after the surgery: 17 (26.2%) in the protocol weaning group and 13 (20.0%) in the conventional weaning group (p = 0.405) (Table 3). Atrial fibrillation developed more frequently in the protocol weaning group than in the conventional weaning group (8 vs. 3 subjects respectively). Two subjects in the protocol weaning group required inotropic agents. In both groups, no subject required re-intubation within 48 hours.

The service charges related to respiratory and cardiovascular care within 24 hours after admission to the ICU were significantly less in the protocol weaning group than in the conventional weaning group [median (IQR) 2,491 (2,308–2,652) Thai baht (THB) vs. 2,711 (2,479–2,945) THB, p < 0.001] (Table 3).

TABLE 3. Secondary outcomes.

	Protocol weaning (n = 65)	Conventional weaning (n = 65)	p-value
Complications[a] – no. (%)	17 (26.2)	13 (20.0)	0.405
Respiratory – no. (%)			
Atelectasis	4 (6.2)	4 (6.2)	
Pneumothorax	1 (1.5)	1 (1.5)	
Acidosis (arterial pH < 7.25) or alkalosis (arterial pH > 7.5)	1 (1.5)	1 (1.5)	
Cardiovascular – no. (%)			
Atrial fibrillation	8 (12.3)	3 (4.6)	
Supraventricular tachycardia	1 (1.5)	0 (0.0)	
Hypotension	3 (4.6)	2 (3.1)	
Requirement of inotropic agents	2 (3.1)	0 (0.0)	
New pathological Q wave or new LBBB in ECG – no./total (%)	1/52 (1.9)	3/44 (6.8)	
Costs[b] (THB) – median (IQR)	2,491 (2,308–2,652)	2,711 (2,479–2,945)	< 0.001

[a] Complications recorded from the beginning of ventilator weaning to 24 hours after surgery.
[b] Approximated by the service charges related to respiratory and cardiovascular care within 24 hours after admission to the postoperative intensive care unit.
LBBB: left bundle branch block, ECG: electrocardiography, THB: Thai baht, IQR: Interquartile range.

DISCUSSION

In this prospective pre-post intervention study among patients undergoing elective cardiac surgery, the implementation of the established ventilator weaning protocol led to a remarkable increase in the rate of successful extubation within 6 hours after surgery and a decrease in service charges related to respiratory and cardiovascular care within 24 hours after admission to the postoperative ICU, when compared to the conventional weaning practices. There was no statistically significant increase in the rates of respiratory and cardiovascular complications.

Early extubation in stable postoperative cardiac patients, when compared to late extubation, was shown in previous studies to shorten the length of ICU and hospital stay, and to reduce healthcare costs.[3,5-9] Strategies that enhance early extubation would, therefore, be beneficial for both patients and the healthcare system. A number of studies have found that ventilator weaning guided by an established weaning protocol shortens the time to extubation and increases the rate of early extubation when compared to weaning without a guide among cardiac patients in a coronary care unit or post cardiac surgery patients.[10-12] Moreover, early extubation in cardiac surgery patients was found to lead to a reduction in costs and an improvement in health resource utilization.[5,9] The results of our study confirm the clinical and cost benefits of protocol-guided ventilator weaning in post cardiac surgery patients.

Implementing the established ventilator weaning protocol appeared to be safe. In this study, no patients required re-intubation within 48 hours after extubation. The rates of respiratory and cardiovascular complications were similar between the 2 groups, except for atrial fibrillation, which was higher in the protocol weaning group. Previous studies did not observe an increased rate of atrial fibrillation in patients with early extubation. It is still not clear whether this increase in atrial fibrillation in our study was true or just a chance finding. Additional information is required before a definite conclusion regarding this issue can be made.

The established ventilator weaning protocol clearly specifies the steps to take and time frames to follow during the weaning process; thereby reducing the variations in practice, hastening the process of weaning, and enhancing the success rate of early extubation. In addition, the protocol also provides monitoring criteria to determine the progression of the patients and the actions to be taken if the patients do not progress as expected. In conventional weaning practices, extubation in some patients who are ready during the night may be delayed until the next morning due to concerns about safety, as the number of staff during the night may be less than that during the day. Moreover, it might be perceived that night staff may not be as vigilant as day staff in detecting complications after extubation. Our study provides assurances that following the established weaning protocol does not increase the risk of complications after extubation, regardless of the time of extubation.

Experts have suggested that a ventilator weaning protocol should be developed using a multidisciplinary team approach.[13] The ventilator weaning protocol implemented in this study was developed by a team of postoperative ICU nurses, a cardiovascular-thoracic surgeon, and a cardiovascular anesthesiologist. In our institution, and in this study, the attending nurse plays a primary role in the process of ventilator weaning, in consultation with the attending ICU physician when necessary. Nurses have important roles to play in various strategies essential for successful ventilator weaning, including enhancing the readiness to wean, frequent assessment of the readiness to wean, encouraging spontaneous breathing during weaning, and the use of spontaneous breathing trials.[14] Other studies support the success of ventilator weaning and early extubation when directed by a nurse using a pre-specified protocol.[12,15]

Employing the result of our study to clinical practice has potential implications for post cardiac surgery patients and for health care system. For patients, early ventilator weaning and endotracheal extubation is likely to reduce discomfort and anxiety associated with mechanical ventilation and the endotracheal tube. The length of postoperative ICU stay is likely to be shortened. Mechanical ventilators and ICU beds could therefore be utilized more efficiently as they become more readily available to other patients in need. In Thailand, about 11,000 adults underwent CABG and/or valve surgery in 2019.[16] Applying the protocol-guided early ventilator weaning and extubation could lead to millions of Thai baht being saved each year.

However, our study had some limitations to note. Group allocations for each subject did not follow a process of randomization. Thus, selection bias and some effects of unmeasured or unknown confounding factors could not be entirely excluded. The successful extubation rate within 6 hours after surgery in the conventional weaning group (7.7%) was much lower than that estimated in our sample size calculation (25%). This would indicate bias in the study and may have led to an overestimation of the effect of protocol weaning compared to conventional weaning. The unadjusted OR estimated from the result of the study was 15.9 (95% CI 5.6–44.7, $p < 0.001$).

However, if we assume an approximate 25% successful extubation rate in the conventional weaning group (16 subjects out of 65), the result would still be statistically significant in favor of protocol weaning, but the effect would be less pronounced, with an unadjusted OR of 4.0 (95% CI 1.9–8.6, $p < 0.001$). Also, we used relevant service charges related to respiratory and cardiovascular care in each group as proxies for the cost data. However, for any particular service in our institution, cost is a primary determinant of its service charge. Therefore, a comparison of service charges would provide a similar conclusion as the comparison of costs between groups. Last but not least, this study was conducted in a single university hospital in patients with elective cardiac surgery; the results may not be applicable to other care settings or to other groups of patients.

CONCLUSION

In conclusion, ventilator weaning and extubation guided by an established weaning protocol in patients undergoing elective cardiac surgery was found to be associated with a higher rate of successful extubation within 6 hours after surgery and lower cost related to respiratory and cardiovascular care within 24 hours after admission to the postoperative ICU, compared to conventional practices of ventilator weaning and extubation. The rates of overall complications from the initiation of ventilator weaning to 24 hours after surgery were not significantly different.

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