

Comparison of extubation times between protocolized versus automated weaning systems after major surgery in the intensive care unit

MEHMET TURAN INAL (✉) •
DILEK MEMİŞ •
İLKER YILDIRIM
Trakya University Faculty of Medicine
Department of Anesthesiology
and Reanimation
22030 Edirne, Turkey
Phone: +902842357641
Fax: +902842357680
E-mail: mehmetturainal@yahoo.com

MEHMET TURAN INAL • DILEK MEMİŞ • İLKER YILDIRIM

ABSTRACT

Background. Prolonged mechanical ventilation is associated with adverse clinical outcomes for critically ill patients.

Objective. To assess the the extubation times of protocolised versus automated weaning systems in patients after major surgery in intensive care unit.

Design. Retrospective analysis.

Measurements and results. We analyzed 70 patients with major abdominal or pelvic surgery. Patients that were used Draeger Evita2 Dura for weaning process named as the C (control) group (n=35) and patients that were used Draeger Evita2 XL Smartcare/PS named as the SC group (n=35). A physician evaluate the patient every 5 or 10 minutes in group C. Gender, age, weight, operation time, operation type, the total volume of intravenous infusion, bleeding, total dose of propofol, fentanyl citrate, rocuronium during surgery and extubation time were all recorded. All side effects included reintubation, bleeding, stroke, death, postoperative myocardial infarction were all recorded. The partial oxygen pressure (PaO₂) and partial carbondioxide pressure (PaCO₂) were recorded before and after extubation.

Results. Demographic data and operative data were similar between groups (p>0.05). The extubation time was similar between groups (SC group versus C group: 191,14±79,1 min versus 188,29±51,47 min, p=0,534. There was significant decrease in arterial PO₂ and increase in arterial PCO₂ after extubation in all groups. No side effects were observed.

Conclusion. In conclusion, although we found no differences between SmartCare and control groups, the evaluating of the patient increased the workload in the control group. We think that SmartCare decreased the workload. Thus, it can be recommended for weaning process of patients after major surgery in intensive care unit.

Key words: weaning, smartcare, protocols

Introduction

The use of mechanical ventilation has markedly increased in the past decades and has now become a major therapeutic modality in the intensive care unit (ICU). (1,2) Despite being a major therapeutic modality, prolonged mechanical ventilation is associated with adverse clinical outcomes for critically ill patients. Patients who have difficulty in weaning frequently require longer

hospital stays, have higher morbidity and mortality. Thus, early weaning from mechanical ventilation is desirable. (2-5) The time from initiation of weaning to successful endotracheal extubation may account for as much as 40% of the overall ventilatory time. (6) Thus several modes and techniques have been tried to facilitate weaning. The optimal strategy for weaning patients from ventilation remains unclear. Compared to traditional care, several studies have shown that protocols can reduce the total duration of mechanical ventilation

and the time to mechanical ventilation discontinuation. (7,8) Automated weaning systems use closed-loop control for ventilatory management and their main mechanism is to improve adaptation of ventilatory support through intermittent monitoring. SmartCare™ (SC) (Drager Medical, Lubeck, Germany) is a automated system, specifically designed to guide weaning and has been associated with a substantial reduction in the duration of ventilation. (9-14) The aim of the study was to compare the extubation times of protocolized versus

automated weaning from mechanical ventilation in patients after major surgery in the intensive care unit.

Materials and methods

Ethical approval for this study (Ethical Committee N° 2011/13) was provided by the Ethical Committee of Trakya University Hospital, Edirne, Turkey (Chairperson Prof H. Karagol) on 26 January 2011. All new consecutive patients admitted to the general and surgical ICU after elective major abdominal or pelvic surgery, who stayed for <24 hrs during a 6 month period (from April 1, 2010, to September 30, 2010), were retrospectively enrolled. Our ICU has Draeger Evita2 Dura and Draeger Evita2 XL mechanical ventilators. In addition to the above criteria, patients weaned by Draeger Evita2 XL Smartcare/PS and Draeger Evita2 Dura were enrolled into the study. Exclusion criteria included chronic obstructive pulmonary disease, (15,16) pneumonia, neuromuscular disease and emergency operations.

The anesthetic technique was performed by the anesthetist, who was unfamiliar with the study, and intraoperative analgesia was provided by fentanyl citrate alone and the dose was recorded. Muscle relaxation was achieved with rocuronium, and anesthesia was maintained with a sevoflurane, air and oxygen mixture. No fentanyl was allowed within 30 minutes of skin closure, and after skin closure, sevoflurane was discontinued. Propofol was infused during the transfer but was stopped on arrival to the ICU. All patients were returned to the ICU intubated and were maintained on mechanical ventilation. The extubation time was defined as the time from the return to the ICU to extubation. Eligible patients, identified as above, were allocated to the weaning via SmartCare/PS or Control groups. Patients that used Draeger Evita2 Dura for weaning were named as the C group (n=35). We used the extubation criteria defined by Kataoka et al. (12) for the control group: a) respiratory rate less than 30–35 cycles/min b) stable hemodynamic condition c) patient alertness (According to Ramsay score) d)

Table 1. Demographic data.

| | SC Group (n=35) | C Group (n=35) | p |
|----------------------------|--------------------|-------------------|-------|
| Gender (M/F) | 17/18 | 17/18 | 1,000 |
| Age (year) | 63,77±12,127 | 63,34±12,918 | 0,887 |
| Weight (kg) | 73,17±13,97 | 73,66±18,84 | 0,903 |
| Type of disease (n) | | | |
| Abdominal surgery | 26 | 28 | |
| Pelvic surgery | 9 | 7 | |

F, female; M, male.

Data are presented as range (mean±SD) median unless otherwise indicated.

Table 2. Operation data during surgery and extubation times.

| | SC Group (n=35) | C Group (n=35) | p |
|---|--------------------|-------------------|-------|
| Operation time (min) | 247,71±64,857 | 246,86±71,693 | 0,816 |
| Total volume of intravenous infusion (ml) | 3457,14±1058,102 | 3402,86±1183,834 | 0,920 |
| Total volume of bleeding (ml) | 837,14±732,175 | 835,71±685,412 | 0,782 |
| Total dose of propofol (mg) | 155,43± 35,342 | 153,43 ± 37,881 | 0,762 |
| Total dose of fentanyl (µg) | 55,71 ± 21,934 | 57,00 ± 19,105 | 0,667 |
| Total dose of rocuronium (mg) | 56,57 ± 17,480 | 55,43 ± 14,621 | 0,921 |
| Extubation time (min) | 191,14±79,1 | 188,29±51,47 | 0,534 |

Data are presented as range (mean±SD) median unless otherwise indicated.

Table 3. The pO₂ and pCO₂ values before and after extubation.

| | SC Group (n=35) | | C Group (n=35) | |
|-------------------------|--------------------|------------------|-------------------|------------------|
| | Before extubation | After extubation | Before extubation | After extubation |
| pO ₂ (mmHg) | 119,309 ± 14,319 | 108,29 ± 16,237* | 118,140± 17,055 | 108,13± 15,490 * |
| pCO ₂ (mmHg) | 33,77± 4,07 | 36,73 ± 3,82* | 33,21± 3,13 | 36,14± 3,56 * |

PaCO₂, partial carbon dioxide pressure; PaO₂, partial oxygen pressure.

Data are presented as range (mean±SD) median unless otherwise indicated.

* p<0,05 compared to before

body temperature and blood test values normal e) blood gas data in the permissible range f) the patient can expel sputum unassisted. The control group was weaned by changing the ventilator mode from synchronized intermittent mandatory ventilation (SIMV) to continuous positive airway pressure (CPAP). Physicians evaluate the extubation cri-

teria, as defined above, every 5 or 10 minutes in group C.

In patients that were using the Draeger Evita2 XL Smartcare/PS for weaning-named as the SC group (n=35) - the ventilator mode was changed to Smart Care if spontaneous respirations were present. SC has three main functions: automatic adjustment of pressure sup-

port, an automatic weaning strategy, and execution of an automatic weaning test. (12) The SC evaluates the values of respiratory rate, tidal volume, and end-tidal CO₂ every 2 or 5 minutes and automatically attempts to reduce the pressure support in steps of 2 or 4 cmH₂O. This reduction depends on the patient's ventilation performance. Finally, an observation phase starts as soon as the pressure support reaches a minimum level (Goal PS). At the end of the observation period, SC recommends that the patient be separated from Evita XL if the minimum PS level has been well tolerated. Both SmartCare/PS and control patients were ultimately weaned to 5 cmH₂O PS. When the computer-driven ventilation system recommends separation, extubation can be envisaged. (12,17-19). All extubation processes were performed by experienced physicians if SC recommended separation and the patient met the extubation criteria defined before. (12) Gender, age, weight, operation time, operation type, the total volume of intravenous infusion during surgery, the total volume of bleeding, the total dose of propofol, fentanyl citrate, rocuronium and extubation time was recorded for all patients. All side effects, including reintubation, bleeding, stroke, death, postoperative myocardial infarction, were all recorded. The partial oxygen pressure (PaO₂) and partial carbon dioxide pressure (PaCO₂) were recorded before and after extubation.

Statistical Analysis

Normality was tested by Kolmogorov-Smirnov test. The groups were compared using the Student t test for normally distributed data or the Mann-Whitney U test for non-normally distributed data. We compared before and after levels in each group using the Wilcoxon signed rank test. Changes from before and after levels were compared using analysis of covariance (ANCOVA) between the groups. We considered results to be significant at $p < 0.05$. Results are expressed as means (and Standard deviations; SDs) or number. We used

Statistica 7.0 (Stat-Soft Inc.) software for our analyses.

Results

We followed 70 patients with major abdominal or pelvic surgery. Hemicolectomy was the most frequent operation, followed by nephrectomy and surgery for severe abdominal infection (table 1). Gender, age, and weight of patients are shown in table 1. Between groups there was no significant difference in gender, age, height, and weight ($p > 0.05$).

Operation time, total volume of intravenous infusion during surgery, bleeding volume, total dose of propofol, fentanyl, and rocuronium of patients are shown in table 2. Between groups there was no significant difference ($p > 0.05$).

The extubation time was similar between groups (SC group versus control group: $191,14 \pm 79,1$ min versus $188,29 \pm 51,47$ min, $p = 0,534$) (table 2).

The partial oxygen pressure (PaO₂) values before and after extubation in the SC group were as follows; $119,309 \pm 14,319$ versus $108,29 \pm 16,237$ mmHg, $p = 0.00$ and in control group $118,140 \pm 17,055$ versus $108,13 \pm 15,490$ mmHg, $p = 0.00$. The decrease of pO₂ is statistically significant in the groups, but no statistically significant difference was detected between the groups (table 3).

The partial carbon dioxide pressure (PaCO₂) values before and after extubation in the SC group were as follows; $33,77 \pm 4,07$ versus $36,73 \pm 3,82$ mmHg, $p = 0.00$ and in the control group $33,21 \pm 3,13$ versus $36,14 \pm 3,56$ mmHg, $p = 0.00$. The increase of pCO₂ is statistically significant in the groups, but no statistically significant difference was detected between the groups (table 3).

No side effects were observed during the study period.

Discussion

Our aim was to evaluate the extubation times of conventional versus automated weaning from mechanical ventilation in patients after major surgery in the intensive care unit. The results of our

study show that the extubation times were similar in both the conventional and automated weaning groups. Blood gases, before and after extubation, and side effects were also similar between the groups. Weaning is a process which has traditionally required clinicians to evaluate objective parameters and subjective assessments. (10) Several methods and techniques have been used to facilitate the weaning process. Compared with traditional care, weaning protocols have been shown to decrease the weaning time. (7,8) In a study made by Chaiwat and colleagues (7) the authors assessed the duration of mechanical ventilation in 100 intra-abdominal surgical patients requiring mechanical ventilation for more than 24 hours. The patients were randomly allocated to receive either protocol-directed or physician directed weaning. The authors demonstrated that the median duration of mechanical ventilation was 40 and 72 hours in protocol-directed and physician-directed groups, respectively, and concluded that daily screening of respiratory functions resulted in a shorter duration of ventilation. Another study made by Kollef et al. (8) demonstrated the effectiveness of protocol directed weaning. Similar weaning protocols were used in these studies. We used the criterias described by Kataoka (12) because these are very similar to our protocol used in our intensive care unit. Even though there are advantages of protocol based weaning, many barriers exist to implementing weaning protocols in clinical practice, (16) and because of these barriers researchers have focused on automated weaning systems. Automated weaning systems evaluate clinical data intermittently and arrange interaction between patient and the ventilator. SmartCare™ is a unique automated system, specifically designed to guide weaning, that incorporates a closed-loop knowledge based system into an automated protocol that adapts the level of pressure support provided to individual patient needs by predetermined algorithms based upon respiratory rate, tidal volume and end-tidal carbon dioxide. (12,17-19) Smar-

tCare™ has been evaluated in previous studies. (11,13,18,19) Lellouche et al. (11) made a preliminary randomized controlled trial study in 5 European centres involving 144 patients and demonstrated that SmartCare™ decreased the median duration of ventilation, total duration of ventilation and median ICU stay. Rose et al. (13) composed a preliminary study in 102 critically ill patients. The patients were equally divided between SmartCare and usual management control groups. They found that the median time to successful extubation was 43 h using SmartCare and 40 h with usual management. The authors concluded that the most common reason for delayed extubation was a low Glasgow Coma Scale in patients. The authors also did not demonstrate any reductions in complication rates. They concluded that the effect of SmartCare may be influenced by the local clinical organisational context. Dojat and colleagues (18) demonstrated that the SmartCare™ evaluates patients' ability to breathe spontaneously and decreases work of breathing. Another study made by the same author (19) also demonstrated that periods of res-

piratory distress during weaning was decreased with the SmartCare system. Kataoka et al. (12) performed a study to compare the intubation time using SmartCare with conventional physician controlled weaning in patients after off-pump coronary artery bypass surgery. They found that the intubation times were $172,6 \pm 51,6$ min in the SmartCare group and $342,0 \pm 239,0$ min in the control group. Similar to this study, Naritaka et al. (15) conducted a study on patients after esophageal surgery and found that the extubation time was $104,4 \pm 42,8$ minutes. Similar to these studies, we found extubation times of $191,14 \pm 79,1$ min for SmartCare and $188,29 \pm 51,47$ min for the control group. Kataoka et al. (12) and Naritaka (15) showed that the reason for their study findings was that SmartCare estimated respiratory state every 2 or 5 minutes, to make progress with active weaning, and it was difficult for intensive care staff to observe the respiratory state more carefully than SmartCare. In our study, a physician evaluated respiratory parameters every 5 or 10 minutes. This situation may explain our study results. Kataoka et al. (12) found

no difference in arterial pO₂, pCO₂ before and after extubation. This finding may be due to frequent estimation of the SmartCare during the weaning process. In our study we found statistically significant differences in pO₂, pCO₂ before and after extubation, but the decrease in pO₂ and increase in pCO₂ after extubation did not affect the patient clinical status for the worse. No side effects, including reintubation, bleeding, stroke, death, postoperative myocardial infarction, were observed during the study period. In Kataoka's and Naritaka's study (12,14) the authors found no side effects either. These findings were probably due to the frequent observations of SmartCare and the great experience of the physicians during and after the weaning process.

In conclusion, although we found no differences between SmartCare and control groups, evaluating the patient every 5 or 10 minutes increased the workload in the control group. We think that SmartCare decreased the intensive care workload. Thus, it can be recommended for weaning of patients in the intensive care unit after major surgery.

REFERENCES

1. Esteban A, Alía I, Ibañez J, Benito S, Tobin MJ. Modes of mechanical ventilation and weaning. A national survey of Spanish hospitals. The Spanish Lung Failure Collaborative Group. *Chest* 1994;106:1188-93.
2. Esen S, Leblebicioglu H. Prevalence of nosocomial infections at intensive care units in Turkey: a multicentre 1-day point prevalence study. *Scand J Infect Dis* 2004;36:144-8.
3. Cook DJ, Walter SD, Cook RJ, Griffith LE, Guyatt GH, Leasa D, et al. Incidence of and risk factors for ventilator-associated pneumonia in critically ill patients. *Ann Intern Med* 1998;129:433-40.
4. Dries DJ. Weaning from mechanical ventilation. *J Trauma* 1997;43:372-84.
5. Esteban A, Anzueto A, Frutos F, Alía I, Brochard L, Stewart TE, et al; Mechanical Ventilation International Study Group. Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study. *JAMA* 2002;287:345-55.
6. Tonnelier JM, Prat G, Le Gal G, Gut-Gobert C, Renault A, Boles JM, et al. Impact of a nurses' protocol-directed weaning procedure on outcomes in patients undergoing mechanical ventilation for longer than 48 hours: a prospective cohort study with a matched historical control group. *Crit Care* 2005;9:83-9.
7. Chaiwat O, Sarima N, Niyompanitpattana K, Komoltri C, Udomphorn Y, Kongsayreepong S. Protocol-directed vs. physician-directed weaning from ventilator in intra-abdominal surgical patients. *J Med Assoc Thai* 2010;93:930-6.
8. Kollef MH, Shapiro SD, Silver P, St John RE, Prentice D, Sauer S, et al. A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation. *Crit Care Med* 1997;25:567-74.
9. Rose L, Presneill JJ, Cade JF. Update in computer-driven weaning from mechanical ventilation. *Anaesth Intensive Care* 2007;35:213-21.
10. Burns K, Lellouche F, Lessard M. Automating the weaning process with advanced closed-loop systems. *Intensive Care Med* 2008;34:1757-65.
11. Lellouche F, Mancebo J, Jolliet P, Roeseler J, Schortgen F, Dojat M, et al. A multicenter randomized trial of computer-driven protocolized weaning from mechanical ventilation. *Am J Respir Crit Care Med* 2006;174:894-900.
12. Kataoka G, Murai N, Kodera K, Sasaki A, Asano R, Ikeda M, et al. Clinical experience with Smart Care after off-pump coronary artery bypass for early extubation *J Artif Organs* 2007;10(4):218-22.
13. Rose L, Presneill JJ, Johnston L, Cade JF. A randomized, controlled trial of conventional versus automated weaning from mechanical ventilation using SmartCare/PS. *Intensive Care Med* 2008;34(10):1788-95.
14. Naritaka Y, Shimakawa T, Asaka S, Isohata N, Yamaguchi K, Murayama M, et al. Clinical experience with Smart Care for respiratory management after esophageal cancer surgery *Ann Cancer Res Thera* 2009;17:11-3.
15. Pauwels RA, Buist AS, Calverley PM, Jenkins CR, Hurd SS. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Workshop summary. *Am J Respir Crit Care Med* 2001;163:1256-76.
16. Ely EW, Bennett PA, Bowton DL, Murphy SM, Florance AM, Haponik EF. Large scale implementation of a respiratory therapist-driven protocol for ventilator weaning. *Am J Respir Crit Care Med* 1999 Feb;159(2):439-46.
17. Burns KE, Meade MO, Lessard MR, Keenan SP, Lellouche F. Wean Earlier and Automatically with New technology (the WEAN study): a protocol of a multicentre, pilot randomized controlled trial. *Trials* 2009;10:81.
18. Dojat M, Harf A, Touchard D, Laforest M, Lemaire F, Brochard L. Evaluation of a knowledge-based system providing ventilatory management and decision for extubation. *Am J Respir Crit Care Med* 1996;153:997-1004.
19. Dojat M, Brochard L. Knowledge based systems for automatic ventilatory management. *Respir Care Clin N Am* 2001;7(3):379-96.