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Original Article

Electric Muscle Stimulation for Weaning from Mechanical Ventilation in Elder Patients with Severe Sepsis and Acute Respiratory Failure – A Pilot Study☆

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SUMMARY

Background: Patients with severe sepsis and acute respiratory failure often developed muscle weakness because of their critical illness and immobility. We hypothesized electric muscle stimulation (EMS) may prevent the weakness and shorten the duration of mechanical ventilation (MV).
Methods: Elderly patients with severe sepsis and acute respiratory failure were enrolled and randomized to EMS or control group on the third day of MV. The EMS was applied to both quadriceps 32 minutes in weekdays with minimal voltage to induce visible muscle contraction (device: HELEX 573®, programmed strength aggravating mode). Control group had passive exercise of extremities. Duration of MV support was compared.
Results: 545 patients were screened and 25 patients were randomized in 2:1 ratio. (18 patients into EMS and 7 into control group). 64% of the acute respiratory failures resulted from pneumonia. Both group had similar demographic data and median age of all participants was 78 years-old (interquartile range 72–82). The mean duration of ventilator dependence was 6 days (IQR 6–15) in control group and 6.5 days (IQR 5–10) in EMS group (P = 0.85).
Conclusion: EMS did not help critical-ill septic elderly to reduce the duration of mechanical ventilation in our pilot study. Further larger study is warranted with adequate study power and identical weaning strategy to test the EMS benefits.

1. Introduction

Critical-ill patients may have muscle wasting and general weakness when they are bed-bound in intensive care unit (ICU) with acute severe disease. The intensive care unit acquired weakness (ICUAW) typically affects proximal limb muscles symmetrically and respiratory muscles. The main risk factors for ICUAW include high severity of illness upon admission, sepsis, multiple organ failure, prolonged immobilization, and hyperglycemia, and also older patients have a higher risk[1]. After described in early 1980, critical illness polyneuropathy and myopathy (CIPM) are increasingly recognized as one of important causes in ICUAW[2]. The muscle weakness was reported in 32–100% of critically ill adult patients ventilated for longer than 3 days[3] and 69% in critical primary neurological diseases[4]. Administration of glucocorticoids and non-depolarizing muscle relaxants, sepsis and multi-organ failure per se as well as elevated levels of blood glucose and muscular immobilization are the risk factors of CIPM[5]. Diaphragm was affected in CIPM and weaning from mechanical ventilation could be delayed[4,6].

In management of CIPM and ICUAW, no specific pharmacotherapy was validated. Infection control and early mobilization are the cornerstone of the management. The earlier the physical rehabilitation started, the better improvement was observed in body functions[7,8]. However, active rehabilitation is not always

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eligible for ICU patients because of the stupor consciousness, sedation or restraint in ICU. Electric muscle stimulation (EMS) induces muscle contraction without patient's cooperation and was proposed as an adjunctive rehabilitation modality. In 2003, Zanotti et al reported EMS in addition to active limb mobilization significantly improved peripheral muscles strength in bed-bound patients with mechanical ventilation for chronic obstructive pulmonary disease[9]. For septic patients requiring mechanical ventilation and having 1 or more organ failure other than respiratory dysfunction enrolled in the intensive care unit, Rodriguez et al reported EMS was associated with an increase in strength of the stimulated muscle[10]. Further research showed early EMS applied to legs in critically ill patients with an Acute Physiology and Chronic Health Evaluation (APACHE) score $\geq$ 13 prevented the development of CIPM and also resulted in shorter duration of weaning[11]. Two system-review also reported EMS was an effective means of improving muscle weakness in adults with progressive diseases such as COPD, chronic heart and critical illness[12,13].

Previous EMS studies did not focus in acute respiratory failure following severe sepsis. However, the most acute respiratory failure acquiring mechanical ventilation in my constitution resulted from elderly patients with severe sepsis and multiple comorbidities. Mean age of the ICU patients were increasing globally, and severe sepsis and septic shock remain leading cause of respiratory failure in the elderly. Age itself may not predict mortality[14], and adequate therapy should be given to the elderly. Therefore, we conducted the pilot study to investigate the feasibility and effect of early EMS in the elderly with sepsis and acute respiratory failure. Optimal setting of EMS (muscle site, daily duration, electric voltage and frequency) was not clearly defined so far, and we also want to evaluate the effect of a programed electric stimulation device (HELEX 573®) applied in weekdays. The aim of our study was to assess the effect of EMS on muscle power preservation and duration of mechanical ventilation (MV) in critically septic patients.

2. Materials and methods

2.1. Study design

The study was a prospective randomized control study approved by institutional Review Board in Mackay Memorial hospital (13MMHIS060) in June, 2013 (ClinicalTrials.gov ID: NCT01895647A). Informed consent was explained and obtained from all of the participants' surrogates before the enrollment. The primary end-point was duration of mechanical ventilation. Successful weaning was defined as spontaneous breath without inspiratory pressure support more than 6 hours. The second outcomes were mortality after randomization and hand grip strength measured by digital handgrip dynamometer every three day after randomization.

Mackay Memorial Hospital is a teaching hospital in Taipei, and the adult medical ICU had 28 beds. The ICU had patient—nurse ratio 2:1, patient—respiratory therapist ration 10:1, and patient—physician ratio 8:1. The weaning strategy was driven by the critical care physicians.

2.2. Participants

Adult patients (20—90 years-old) admitted with mechanical ventilator were daily screened and recorded as eligible If they fulfilled criteria of sepsis according to definition of 1992 American College of Chest Physicians and the Society of Critical Care Medicine[15]. The randomization was performed when the eligible patients required mechanical ventilation longer than 72 hours (defined as need of inspiratory mechanical support in ventilator setting). They were randomly assigned to electric muscle stimulation (Intervention group, arm biceps or thigh quadriceps) or passive arm biceps or thigh quadriceps limb mobilization (Control group) in 1:1:1 ratio.

The exclusion criteria were following:

1. Skin defect or infection around the thighs
2. Acute myocardial infarction within one week
3. Life-threatening cardiac arrhythmia
4. Pregnancy
5. Dying patient with life expectance shorter than one month.
6. Severe encephalopathy with coma and no spontaneous breath drive
7. Uncontrolled seizure
8. Patient is fully awake and has adequate muscle power to cooperate active limb exercise
9. Air-born contagious diseases. eg. Tuberculosis and Influenza virus infection
10. Moderate to severe adult respiratory distress syndrome with requirement of neuromuscular blocker.
11. Patients with Extracorporeal Membrane Oxygenation

2.3. Intervention protocol

The patients in the intervention group received EMS on both quadriceps (vastus medialis) and biceps, 32 minutes per day, 5 days per week (Monday to Friday). EMS was conducted with a commercial stimulator (HELEX 573®, EverProsperous company, Taiwan) with adhesive electrode (4.7 cm $\times$ 4.7 cm). The stimulator output current was 0—75 mA in biphasic waves with carrier frequency of 1500 Hz. We used its strength aggravation mode which protocol consisted with warm-up, exercise and cool-down. The lowest stimulation current was given to induce visible muscle contraction.

Bilateral hands grip strengths were measured and recorded by digital hand dynamometer (CAMRY, model: EH101, China, (range 0—90 Kg)) before EMS and every 3 days. The test was performed with the arm at right angles and the elbow by the side of the body. Three trials were allowed for each hand alternatively, with a pause of 60 seconds between each test.

The control group had active or passive exercise of extremities. the extent of exercise was decided and performed by the physical rehabilitation therapist after the consultation. The actual exercise was individualized clinically.

2.4. Statistical analyses

All continuous variables were presented by median (25—75% quartile range). Categorical data were presented in exact ratio. The differences between groups were evaluated by nonparametric test (Two-sample Wilcoxon rank-sum (Mann—Whitney) test) for continuous variable and Fisher's exact test for categorical variables. The statistical significance of P value was set at 0.05. The Kaplan—Meier method was used to compare the duration of ventilator support between patients assigned to the EMS and control groups. All analyses were done with small STATA 12.1 (StataCorp, Texas USA).

3. Result

From 1st Aug, 2013 to 30 Sept 2015, 545 patients were screened as eligible at their ICU admission. The major cause of their sepsis and acute respiratory failure resulted from pneumonia and urinary tract infection. After three days of mechanical ventilation, 288 patients (52.84%) could be weaned from bi-level ventilator support, 17