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Major article

# Human patient simulation education in the nursing management of patients requiring mechanical ventilation: A randomized, controlled trial

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***Background:*** Knowledge among critical care nurses and their adherence to evidence-based guidelines for preventing ventilator-associated pneumonia is reported to be low. The aim of our study was to evaluate the effectiveness of human patient simulation (HPS) education in the nursing management of patients requiring mechanical ventilation.

***Methods:*** A prospective, parallel, randomized controlled trial with repeated measurements was conducted in a 22-bed adult mixed medical-surgical intensive care unit in Finland from February-October 2012. Thirty critical care nurses were allocated evenly to intervention and control groups (n = 15 each). The effectiveness of HPS education was evaluated through the validated Ventilator Bundle Questionnaire and Ventilator Bundle Observation Schedule at baseline and repeated twice—after the clinical and simulation settings, respectivley.

***Results:*** After HPS education, the average skill scores (Ventilator Bundle Observation Schedule) in the intervention group increased significantly (46.8%-60.0% of the total score) in the final postintervention observation. In the average skill scores, a linear mixed model identified significant time ($P_t < .001$) and group ($P_g = .03$) differences and time–group interactions ($P_{t*g} = .02$) between the study groups after the HPS education. In contrast, the model did not identify any significant change over time ($P_t = .29$) or time–group interactions ($P_t = .69$) between groups in average knowledge scores (Ventilator Bundle Questionnaire).

***Conclusions:*** Our study identified significant transfer of learned skills to clinical practice following HPS education but no influence on the level of participants' factual knowledge.



Ventilator-associated pneumonia (VAP) is the most frequently encountered device-associated nosocomial infection in critical care settings.[1,2] It causes substantial morbidity, a 2-fold increase in mortality rate,[3] excess costs,[4] and prolonged lengths of ventilator days[3] and intensive care unit (ICU) and hospital stays.[3,5]

Knowledge among critical care nurses[6-9] and their adherence to evidence-based guidelines for preventing VAP[10] have been reported to be low, which may jeopardize patient safety and thus

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quality of care.[11] Previous educational interventions have been linked to significant improvements in the level of knowledge and skill in adhering to guidelines and a significant decrease in adverse clinical outcomes.[12,13]

Simulation is an exciting application of advanced technology in health care staff education[14] that offers a unique mode for experimental learning[15] and evaluation,[14-16] yet the effectiveness of human patient stimulation (HPS) education in critical care settings is poorly documented.[17] Previous prospective, experimental,[18] and quasiexperimental[19-21] studies have demonstrated statistically significant improvements in participant knowledge, teamwork, leadership,[21] and clinical skills immediately after HPS education.[18-21] However, longitudinal randomized controlled studies are lacking that evaluate the effectiveness of HPS in improving infection control practices on nursing continuing education or that identify the transfer of learned skills to clinical practice.[22]

The aim of our study was to evaluate how knowledge about and skills for managing patients requiring mechanical ventilation differ between randomly allocated intervention and control groups before and after HPS education in both the simulation environment and clinical setting. The primary outcomes measured between randomly allocated intervention and control groups were participant knowledge and skill in adhering to ventilator bundles (VBs), a package of evidence-based interventions to prevent VAP.[23-25] The hypothesis was that in the intervention group, knowledge and skills in adhering to VBs might increase compared with a control group after the HPS education.

## METHODS

### *Study design*

A single-center, prospective, parallel, randomized controlled trial with repeated measurements was conducted to evaluate the effectiveness of HPS education in the nursing management of patients requiring mechanical ventilation. The primary outcomes measured were how participant knowledge and skill in adhering to the VBs compared between randomly allocated intervention and control groups before and after an educational intervention. The reporting of this study complies with the Consolidated Standards of Reporting Trials statement.[26]

### *Sample and setting*

The study was conducted in a single academic center in a 22-bed adult mixed medical-surgical ICU in Finland between February and October 2012. According to the Medical Research Act (488/1999 and amendments 295/2004), approval of the local ethics committee is not required for studies focusing on health care staff. However, the study protocol was approved by the relevant academic center during fall 2011.

Randomly selected critical care nurses were invited to participate via letter and electronic mail. In addition, nurse managers informed critical care nurses at staff meetings of study availability and encouraged completion. Inclusion criteria were: holding a degree qualification as a registered nurse and being a direct care provider (bedside). Written informed consent from participants was obtained before inclusion in the study (Declaration of Helsinki 2008).

A sample size of 40 was calculated to detect a 20% difference between the study groups (mean [SD], 2.74 [2.66] points) in the average skill score[27] with significance level $\alpha = .05$; power $1\text{-}\beta = 90\%$; dropout level = 20%. Participants were allocated to intervention (n = 20) and control (n = 20) groups according to a computer-generated randomization list separately in 2 age-based strata ($\leq$35 and >35 years) according to the median age of the study population.

### *Intervention and study protocol*

HPS education began with a brief bedside introduction (20 minutes) from the simulation educators, giving a hands-on explanation of the simulation process (ie, briefing, simulated scenario, and debriefing) and use of the HPS mannequin (HAL, Gaumard, Miami, FL). During the 10-minute scenario, participants were asked to engage in all of the essential nursing interventions to prevent VAP in a patient being enterally fed and requiring mechanical ventilation with an artificial airway, starting from respiratory management. During the simulations, the software of the HPS mannequin was programmed to cough and change vital signs (eg, heart and respiratory rates, blood and airway pressures, and peripheral oxygen saturation).

Participants had access to all necessary equipment used in the ICU environment (eg, patient monitors, respirator, oxygen, endotracheal suctioning device, and oral care equipment) and could ask the facilitator questions. Only the intervention group received verbal feedback and participated in a 60-minute structured debriefing based on the effectiveness of the VBs. During the debriefing, participants could ask questions and engage in discussion with the simulation educators.

The measurements were completed three times for both groups. After the baseline measurement, the intervention group underwent HPS education. Then the measurements were performed similarly for the intervention and control groups. The initial postintervention measurements (3 months after the intervention) were conducted in the simulation environment (follow-up I), and the final postintervention measurements (6 months after the intervention) were made during the morning shift (7 AM-3 PM) in clinical practice (follow-up II). Participants were evaluated while managing adult patients requiring mechanical ventilation using a direct, structured, nonparticipatory method of observation, which is a purposeful data collection method, particularly for recording participant behavior.[28]

Participant knowledge and skills in adhering to VBs were evaluated through the validated 49-item multiple-choice Ventilator Bundle Questionnaire (VBQ) and 86-item Ventilator Bundle Observation Schedule (VBOS), whose overall content validity have ranged from 0.99-1.0 and the overall intraclass correlation coefficient of the VBOS have ranged from 0.93-1.0.[29] The content of the VBQ and VBOS consisted of a list of pharmacologic and nonpharmacologic nurse-led interventions aimed at preventing VAP: intubation and mechanical ventilation (eg, daily sedation vacations and assessment of readiness to extubate, facilitate accelerated weaning) and prevention of airway colonization (eg, respiratory therapy equipment, appropriate enteral nutrition, adequate hand hygiene, daily oral care, and updated endotracheal suctioning recommendations).[29]

### *Statistical analysis*

SPSS 18.0 for Windows (IMB SPSS Inc, Armonk, NY) and SAS for Windows (version 9.2, SAS Institute Inc, Cary, NC) were used for data analyses. Analyses were conducted by a biostatistician who was unaware of group identity. All participants were included in the analysis in the groups to which they were originally assigned (intention-to-treat analysis).[26]

The repeatedly measured data were analyzed using a linear mixed model with a covariance pattern model. *P* values reported for repeatedly measured data are as follows: *P* for time ($P_t$), the overall change over time; *P* for group ($P_g$), the average