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Effective Implementation of Ventilator Care Bundles in Improves Outcomes: A Multicenter Randomized Controlled Clinical Trial

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OBJECTIVES: To evaluate the effect of 17-ventilator care bundles and different training strategies for critical care nurses on clinical outcomes.

DESIGN: A randomized controlled triple-blinded clinical trial.

SETTING: The multicenter study was conducted in four academic teaching hospitals in Tehran, Iran, from October 2011 to June 2015.

PATIENTS: A total of 1,600 adult patients (age ≥ 18 yr) who were admitted to mixed medical-surgical ICUs (> 72 hr) and received invasive ventilation (> 48 hr) were included in this study. In addition, 160 critical care nurses were recruited through letters and telephone and face-to-face invitations.

INTERVENTIONS: Seventeen-ventilator care bundles applied by four different groups of nurses.

MEASUREMENTS AND MAIN RESULTS: Clinical outcomes were compared between four groups of study which include three intervention groups (who received 17-ventilator care bundles by trained nurses) and one control group (who received routine care). According to the results, ICU length of stay, non-ICU length of stay, ventilator-associated pneumonia occurrence date, ventilator-associated pneumonia, and mortality rates were significantly higher in control group compared with other groups.

CONCLUSIONS: Critical care nurses training program to accurately implement 17-ventilator care bundles improves outcomes.

KEY WORDS: education; intensive care unit; mechanical ventilation; ventilator-associated pneumonia; ventilator care bundles

To the Editor:

As a multidisciplinary approach to infection prevention, the ventilator care bundles (VCBs) could reduce the occurrence of ventilator-associated pneumonia (VAP) and improve the patient's clinical outcomes in the ICUs (1, 2). To improve healthcare quality, using care bundles is a multifaceted issue which was actively associated to incorporating staff education, adherence process, and as well as highest levels of bundle compliance (3, 4). Although the preventive measures for VAP are well documented and evidence based, they are still poorly implemented in most ICUs. Furthermore, it seemed necessary to evaluate the VCB compliance rate and effect of education on its improvement. Therefore, we undertook a study to assess whether different educational programs for critical care nurses focusing on 17-VCBs (17-VCBs) (**Supplementary file**, http://links.lww.com/CCX/A751) (5) could reduce the clinical outcomes.

This multicenter randomized controlled clinical trial at four academic teaching hospitals in Tehran, Iran, from October 2011 to June 2015 was conducted

DOI: 10.1097/CCE.0000000000000509

to evaluate the effect of 17-VCBs and different training strategies for critical care nurses on the clinical outcomes, including ICU length of stay (LOS), non-ICU LOS, VAP occurrence date, VAP, and mortality rates. One thousand six hundred adult patients (age ≥ 18 yr) who were admitted to the mixed medical-surgical ICUs (> 72 hr) and received invasive ventilation (> 48 hr) were daily enrolled and monitored for developing VAP until ICU discharge or death. Besides, 160 critical care nurses were recruited via letters and telephone and face-to-face invitations. Nurses were randomly assigned into four groups based on different education strategies. Thus, based on the type of nurses' training, we had four study groups which are as follows: 1) the first group received routine care as a control group; 2) the second group received 17-VCBs by nurses who had a self-study booklet designed by the research team; 3) the third group received 17-VCBs by nurses, in addition to the booklet, also attend training sessions (90–120 min); and 4) the fourth group received 17-VCBs by nurses who, in addition to the booklet and training sessions, also had a direct clinical observation. ICUs participating in this program contained the multidisciplinary teams providing patient care under the direction of attending physicians who are board certified in adult critical care medicine. The leadership of ICUs including unit medical directors and clinical nurse specialists remained constant during this study, and the staffing ratio of one nurse to three patients was also uniform throughout this time period. The morning shift nurses were fixed, and the noon and evening shift nurses were present every other day. In usual, there was limited turnover in the nursing staff of ICUs during the study period. The full description of method can be read in the clinical trial with identifier NCT02838160.

Clinical outcomes were compared among four groups of study: one control group (group 1) and three intervention groups (groups 2–4). The results showed statistically significant differences among the groups due to the mean ± SD ICU LOS ($p < 0.001$), non-ICU LOS ($p < 0.001$), VAP occurrence date ($p = 0.019$), VAP ($p < 0.001$), and mortality rate ($p < 0.001$). The mean ± SD ICU LOS and non-ICU LOS were the lowest in the fourth group (8.06 ± 3.435 and 8.94 ± 3.890), third group (8.23 ± 3.640 and 10.36 ± 3.357), and second group (9.53 ± 4.262 and 10.38 ± 4.105) compared with the first group (12.85 ± 3.472 and 12.29 ± 3.409) ($p < 0.0001$). Regarding the VAP occurrence date, the results showed that VAP occurrence in the control group was significantly earlier than the three intervention groups (14.86 ± 10.81 vs 16.60 ± 7.32;

TABLE 1.
Clinical Outcomes of Patients According to Four Educational Groups of Critical Care Nurses

Clinical Outcomes	Group 1 (*N* = 400)	Group 2 (*N* = 400)	Group 3 (*N* = 400)	Group 4 (*N* = 400)	Total (*N* = 1,600)	*p*[a]
ICU LOS, median (IQR)	13 (10–16)	10 (5–13)	8 (5–11)	8 (5–11)	10 (6–13)	< 0.001
Mean ± SD	12.85 ± 3.47	9.53 ± 4.26	8.23 ± 3.64	8.06 ± 3.43	9.67 ± 4.18	
Non-ICU LOS, median (IQR)	12 (9–15)	10 (6–13)	9 (8–13)	8 (5–12)	10 (7–13)	< 0.001
Mean ± SD	12.29 ± 3.41	10.38 ± 4.10	10.36 ± 3.35	8.94 ± 3.89	10.49 ± 3.88	
VAP occurrence date, median (IQR)	13 (5–17)	18 (19–26)	16 (13–21)	16 (10–21)	10 (6–13)	0.019
Mean ± SD	14.86 ± 10.81	16.32 ± 8.61	16.72 ± 6.90	16.77 ± 6.47	16.01 ± 8.39	
VAP, yes, *n* (%)	135 (33.8)	81 (20.3)	69 (17.3)	35 (8.8)	320 (20)	< 0.001
Mortality, yes, *n* (%)	150 (37.5)	92 (23)	82 (20.5)	62 (15.5)	386 (24.1)	< 0.001

IQR = interquartile range, LOS = length of stay, VAP = ventilator-associated pneumonia.

[a]$p < 0.05$ was considered statistically significant. In addition, the mean score of ICU LOS, non-ICU LOS, and VAP occurrence date was compared between the groups two by two in which (Tukey) post hoc test; Group 1: received routine care (control group), Group 2: received 17-ventilator care bundles (17-VCBs) by nurses who received a booklet, Group 3: received 17-VCBs by nurses who, in addition to the booklet, also attend training sessions, and Group 4: received 17-VCBs by nurses who, in addition to the booklet and training sessions, also had direct clinical observation.

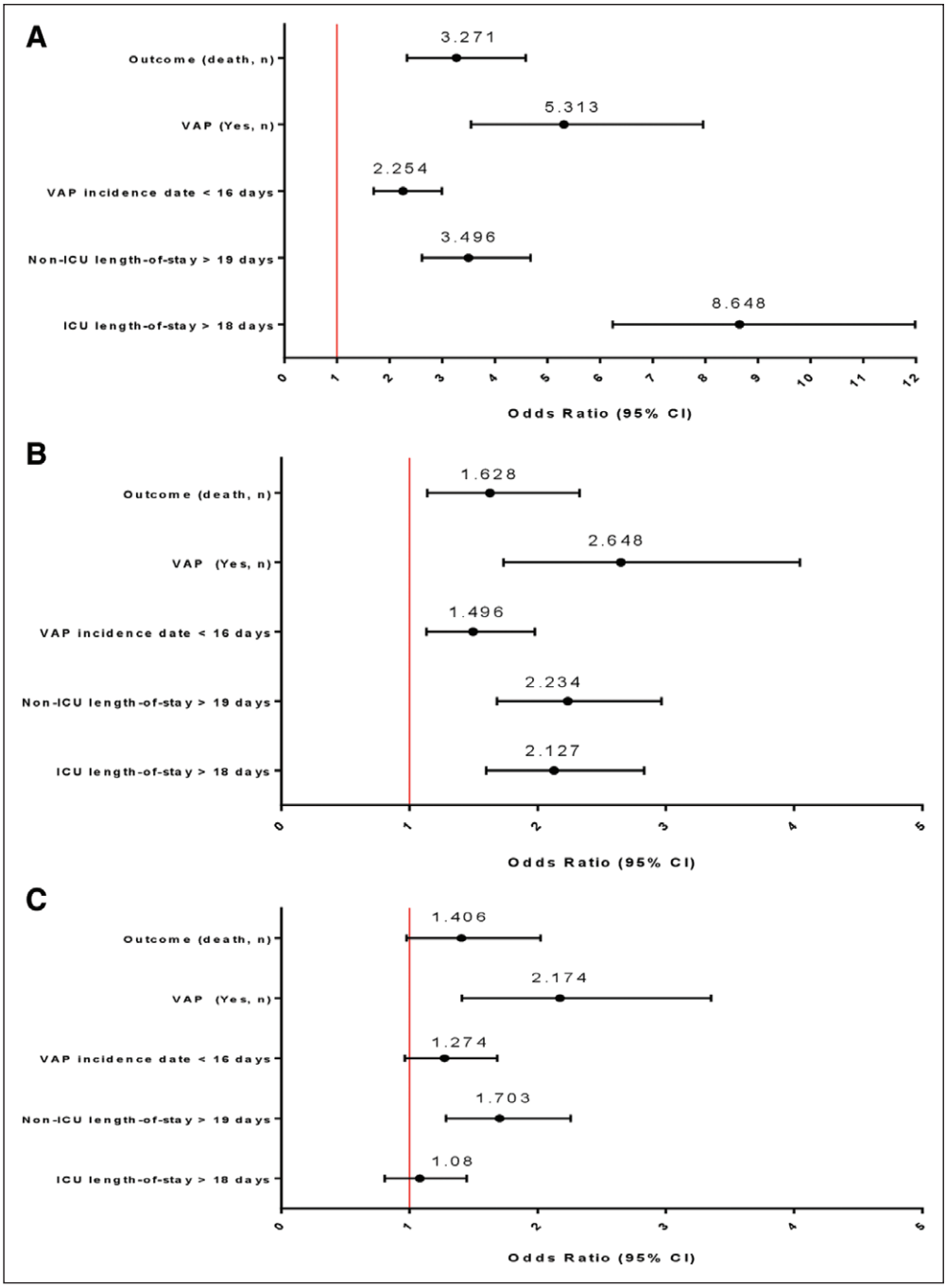

Figure 1. Clinical outcomes compared between (**A**) first (control) group and the fourth group, (**B**) second group and the fourth group, and (**C**) third group and the fourth group. VAP = ventilator-associated pneumonia.

p = 0.019). However, the highest percent of VAP and mortality rates were observed in the control group than the other groups (33.8% and 37.5%) ($p < 0.001$) (**Table 1**). Logistic regression (**Fig. 1*A***) indicated that the higher risk for ICU LOS greater than 18 days (odds ratio [OR], 8.64; 95% CI, 6.26–12.01), non-ICU LOS greater than 19 days (OR, 3.49; 95% CI, 2.46–4.89), VAP occurrence date less than 16 days (OR, 2.25; 95% CI, 1.78–3.36), VAP (OR, 5.31; 95% CI, 3.51–8.12), and mortality rates (OR, 3.27; 95% CI, 2.23–4.78) in the control group compared with the other groups. Besides, the results among the intervention groups elucidated that all outcomes had higher ORs in the second and third groups compared with the fourth group which received 17-VCBs through nurses who, in addition to the booklet and training sessions, also had direct clinical observation (**Fig. 1**, ***B*** and ***C***).

According to the results, all intervention groups had accomplished the goal to decrease VAP occurrence. However, the important point which should not be forgotten is that among the intervention groups, in the fourth group compared with the third and second groups, VAP occurrence rate and mortality rates were significantly decreased ($p < 0.05$). Therefore, more training via the booklet and training sessions and also had a direct clinical observation for group 4 really warranted. Our findings indicated that multifaceted training for nurses was more effective in the ICU. Furthermore, adherence to the VAP care bundle was low (< 25%) in the control group. However, more than 90%, from 70–80% to 50–60% of VCB compliance were reported in groups 4, 3, and 2, respectively. Obviously, training for nurses and raising their awareness of VCB is a momentous effort, and after educated, most of them become more committed (6, 7).

Besides, using 17 elements of VCBs in this study is one of the most important points which should not be overlooked. It should be emphasized that each of the VCB elements is individually supported by empirical evidence, and when all 17 elements, not some of them, are bundled together as a set of actions, it will lead to significantly improved outcomes.

The present study has several strengths. First, we assessed the baseline status of patients before intervention, and all groups were completely matched due to the demographic characteristics (age and sex) and clinical data (severity of illness based on Acute Physiology and Chronic Health Evaluation, Simplified Acute Physiology Score, and Sequential Organ Failure Assessment scores). Second, all nurses had a previous ICU history, and there was no difference in work experience among them. Hence, there was no difference among them for better and more efficient use of bundles. Third, we undertook a multicenter clinical trial study to evaluate different training strategies for critical care nurses to accurately implement 17-VCB. While, the most prior studies were observational and because of the limitations of observational design, a definitive causal relationship between the VCB and VAP occurrence and ICU LOS cannot be proved. Despite all these strengths, there may be other limitations such as the occurred possible factors coincidence with the intervention in ICU patients which may change the patient's condition, increase infection, prolong ICU LOS, and use mechanical ventilation.

ACKNOWLEDGMENTS

The author would like to acknowledge Vice chancellor of Research and Technology, Hamadan University of Medical Sciences for approval of this study. Moreover, we thank guidance and advice from the "Clinical Research Development Unit of Baqiyatallah Hospital."

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Before the trial commenced, the protocol was reviewed by the investigational review boards at the participating medical centers in Tehran, Iran, in 2010 including Baqiyatallah Hospital, Besat Hospital, Loghman-e Hakim Hospital, and Shariati Hospital, and these ethics committees waived the need for approval.

The trial was registered with ClinicalTrials.gov (identifier NCT02838160).

The study was funded by the Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences. Also, the study protocol was approved by the Ethics Committee of Hamadan University of Medical Sciences, Hamadan, Iran (Approval No: IR.UMSHA.REC.1400.443).

Written informed consent was obtained from the nurses and patient prior to intubation and inclusion in the study. Consent covered both study participation and consent to publish the findings. Surrogate consent from the patient's legal guardian or healthcare proxy was permitted in cases where the patient did not have decision-making capacity.The authors have disclosed that they do not have any potential conflicts of interest.

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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