Published online 2017 July 31

Impact of Care Program on Ventilator-Associated Pneumonia Incidence: A Clinical Trial

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ARTICLEINFO ABSTRACT

Article history:	Background: Ventilator-associated pneumonia (VAP) is one of the common problems
Received: 14 April 2017 Revised: 04 July 2017 Accepted: 30 July 2017	in patients who are under mechanical ventilation and increases the hospitalization duration and treatment expenses. The current study was conducted to determine the impact of a care program on VAP. Methods: This clinical trial was performed on intubated patients who were under
Key words: Care program Intubation Intensive Care Unit Ventilator-associated pneumonia	mechanical ventilation in Intensive Care Unit (ICU) of teaching hospitals in Zahedan, Iran in 2015. Seventy patients were selected through convenience method and were assigned into two groups of 35 people as the control and intervention groups. The care program was executed for three days in the intervention group. Pneumonia incidence was evaluated by the Modified Clinical Pulmonary Infection Score (MCPIS) both pre- and post-intervention. The data were analyzed by independent t-test and Chi-square
	test. Results: Pneumonia did not occur in the intervention group, while VAP occurred in 54% of the patients of the control group. The Chi-square test demonstrated a significant difference between the two groups (P<0.001). Conclusion: Preventive interventions might be beneficial in reducing the occurrence of

Conclusion: Preventive interventions might be beneficial in reducing the occurrence of VAP when executed as a regular caring package for the patients. Therefore, these therapies are recommended as a nursing intervention in ICUs.

1. Introduction

Iatrogenic pneumonia is the second common reason for iatrogenic infections, and is known as a mortality reason in severely ill patients.¹⁻⁴ Ventilatorassociated pneumonia (VAP) is a kind of iatrogenic pneumonia, which mostly occurs happen during the first 48 hours post-reception admission in ventilated and intubated patients of intensive care unit (ICU) with tracheal tube under mechanical ventilation.^{1, 2} Most of the patients who are hospitalized in ICU have tracheal tube are intubated and are under mechanical ventilation. Tracheal tube disposes the patients to the risk of VAP due to bacterial entrance into the lower respiratory tract, simultaneous with reduced consciousness, open and dry mouth, and aspiration of the secretions.⁵ Mean incidence of the VAP in internal and surgery ICUs has been reported as 3.6 per 1000 days of ventilation, and it varies in developing countries from 10 to 41.7 per 1000 days.6

In addition to imposing high costs on health and therapeutic systems, the VAP leads in increased mortality from 5 to 65%.^{7, 8} Therefore, the important nursing point in these patients is to recognize the avoidable risk factors of pneumonia and to control them through preventive paces, so that the pneumonia incidence and the negative consequences will decline.⁹ Apostolopo et al. (2003) have studied the patients hospitalized in ICUs, and have introduced the enteral feeding, tracheostomy, bronchoscopy, and clinical status of the patient as factors effective on VAP occurrence.¹⁰ Erbay et al. (2004) have also considered the enteral feeding as the main risk factor and believe that it might increase VAP development up to three times.¹¹

Some studies have reported that pulmonary aspiration due to flow back of gastric contents, which occurs as the result of continuous gastroesophageal reflux (GER) could transfer the microbes to the pharynx and elevate increase the risk for pneumonia. It seems that enteral feeding increases the risk, because of alkalizing the gastric contents and delay in gastric evacuation which leads in higher gastric residual volume (GRV).^{2, 8, 12-14} Therefore, performing some interventions for GRV management also seems to be essential.² Some studies have suggested the abdominal massage as an approach for facilitating gastric evacuation and declining the aspiration risk.^{3, 15} They believe that the evidence revealed massage as a preventive intervention is one of the basic and major skills in nursing profession.³ Abdominal massage reduces the time needed for transfer of food from gastrointestinal tract, and improves the peristaltic movements, intestinal evacuation, and local blood circulation, all of which result in reduced intra-abdominal pressure.3, 14, 16

Sinclaie et al. (2011) have also presented abdominal massage as a reducing factor for reflux in intubated severely ill patients who are fed through the tube. These authors reported that applying these methods is remarkably beneficial in decreasing the need for prokinetic agents, which are taken to enhance gastric secretions evacuation.¹⁴ In a metaanalysis performed by Labeo et al. (2015), the antiseptics used for mouth and teeth have been found to prevent the VAP.¹⁷

Concerning the importance of iatrogenic pneumonia, especially VAP, which threatens the patients' health and leads in increased mechanical ventilation time and hospitalization duration, preventive actions seem essential. These actions should be organized and follow a specific guideline which is utilized by all the nurses of the department in different working shifts. Although some preventive modalitiesons for VAP might be executed in ICUs, the authors' experience and the results of other studies demonstrate that these actions are not taken continuously and regularly.^{3, 8, 12, 13}

Therefore, the authorwe designed a complete and organized prevention program based on the effective factors for VAP, which have been assessed in some studies. Consequently, aim of the current study was to determine the impact of care program on VAP incidence.

2. Methods

2.1. Design

The study population of this single-blinded controlled clinical trial consisted of the intubated patients under mechanical ventilation, who were hospitalized in ICUs of Khatam and Imam Ali hospitals of Zahedan, Iran in 2015.

2.2. Participants and setting

The sample size was calculated as 70 people according to the results of the study performed by Medical - Surgical Nursing Journal 2017; 5(4): 31-37.

Kahraman (2015), with confidence level of 95% and statistical power of 80% and 35 people were assigned to each group.³

The following formula was used to calculate the sample size, in which: $P_1=6.3\%$, $1-P_1=93.7\%$, $P_2=31.3\%$, $1-P_2=68.7\%$, $Z_{1-\beta}=0.85$, and $Z_{1-\alpha}=1.96$.

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 [P_1(1-P_1) + P_2(1-P_2)]}{(P_1 - P_2)^2}$$

The patients were first selected through the convenience sampling method and were divided into the two groups of intervention and control by balance block randomization. Since two groups were needed, the patients were assigned to six conditions of four-item blocks (A as the care program group and B as the control group; for example, AABB, BBAA, ABAB, etc.). Two people subjects were included in each block of each group. The order of the blocks was random and was determined using the random numbers table. Finally, the participants entered the intervention or control groups according to the blocks.

The inclusion criteria entailed: 1) age of 16-65, 2) passing of two days after the intubation time, 3) lack of any history of pneumonia, adults respiratory distress syndrome (ARDS), and chronic obstructive pulmonary disease (COPD), 4) standard diet formula based on the protocol for patient's food, 5) lack of wound on abdominal region, 6) lack of motion limits in neck and vertebral column, and 7) not being pregnant.

The exclusion criteria included 1) discharge, transfer, or expiration of the patient, 2) weaning from the mechanical ventilation within 96 h, 3) going under tracheostomy procedure during the study, 4) initiation of prokinetic agents during the study, 5) removal or changing of the tracheal or the nasogastric tubes during the study, 6) getting NPO, and 7) occurrence of diarrhea.

2.3. Instruments

Demographic and disease data form, Richmond agitation-sedation scale (RASS), and modified clinical pulmonary infection score (MCPIS) were utilized in the present study.

The demographic and disease data form encompassed information such as age, gender, ICU hospitalization history, background disease, the type and volume of the nutritional solution, the GRV, the number of endotracheal suction times, mouth care, consciousness level based on Glasgow coma scale (GCS), size of the tracheal tube, tracheal tube cuff pressure, and the sedation level of the patient according to the RASS. RASS is a standard tool for evaluating the sedation level of the patients. This continuum consists of ten scores from -5 to +4 in three levels. The five negative scores are allocated to sedated condition (-1: drowsy, -2: light sedation, -3: moderate sedation, -4: deep sedation, and -5: unarousable sedation), the score of zero to the alert and calm condition, and the four positive scores to the agitation level (+1: restless, +2: agitated, +3: very agitated, +4: combative).¹⁸

Following the study performed by Tadrisi et al. (2009), RASS has the required validity in all the possible conditions of the patients who need sedation. It has the intragroup matching coefficient of 0.64 and the agreement coefficient of 0.95 between those who assess.¹⁹ According to Arvalo et al. (2012), RASS has the highest correlation coefficient among all the present scales for sedation level evaluation (r=0.83), and is easier, more clear, and less time-consuming compared to the other scales.²⁰

The MCPIS, which was introduced in 1990 by Pogin et al,²¹ is a standard scale including five criteria of body temperature, respiratory secretions, WBC count, PO2/FiO2 ration in mmHg, and chest radiography. Each scale gets the score of 0-2 in this tool; therefore, the maximum possible score is 10. Obtaining scores of higher than 5 in this scale is indicative of VAP^{22, 23} (Table 1). The MCPIS was used in Persian in this study. Saberi et al. calculated the test consistency as 91% using Cronbach's alpha.⁴ The consistency of the tool used in the current study was confirmed with the Cronbach's alpha coefficient of 0.88.

Modified clinical pulmonary infection score (MCPIS)						
Scale	Range	Score				
	≤38.4 and ≥36.5	0				
Body temperature	≤38.9 and ≥38.5	1				
	≤36.4 and ≥39	2				
Blood	≤11000 and ≥4000	0				
leukocyte/mm3	>11000 or <4000	1				
	Low	0				
Tracheal secretions	Moderate	1				
Tracheal secretions	High	2				
	Purulent	+1				
Oxygenation	>240 or presence of ARDS	0				
(PaO2/FiO2 mmHg)	≤240 or lack of ARDS	2				
Thoracic	Without infiltration	0				
	Diffuse infiltration	1				
radiography	Focal infiltration	2				

2.4. Data Collection

The patients entered the study based on the inclusion criteria and the pneumonia status was evaluated using the MCPIS by one of the

researchers and only the patients with scores of higher than 5 were included in the study.

After inclusion in the intervention and control groups, the demographic characteristics form was evaluated and filled since the second day after intubation for three days in the both groups according to the patient's observations, the present data in the documents, and RASS. It should be mentioned that since the consciousness level of the patients was obtained based on the information recorded in the documents before the research, the assessment method for consciousness level was checked by the personnel and supervisor nurse of the departments to be consistent with Marino book.⁷

The patients in the intervention group, received cares as the designed care program for reducing the pneumonia incidence in addition to the routine cares, while the control group just received the rutin cares of the unit.

The care program was designed by the research through the related references team and articles,3, 12, 13, 24-27 and was confirmed by the ICU doctor. The program was designed as a combination of standard cares and abdominal massage for increasing the peristaltic movements and accelerating the gastric evacuation, which finally leads in reduced aspiration incidence. It was executed within 3 days on days 2, 3, and 4 postintubation in the intervention group by one of the researchers.

The designed care program consisted of four parts. At the first step, the bed head was elevated to 30 degrees or more, except for the cases with medical prohibition. Afterwards, the daily GRV was determined and managed at 10 a.m. and 10 p.m., and gastric contents lavage was then performed by a 60-mililiter (ml) syringe. The total volume of the extracted fluid from the tubes was reported as milliliters. If the refluxed fluid was more than 200 ml, the next gavage was delayed according to the policies. The third step was the abdominal massage as follow: the patient was in back-laying position while the bed head was 30 degrees up and the knees were bent when possible. A researcher stood on the right hand of the patient, and the massage procedure was began with superficial effleurage (a type of massage including circular stroking movements made with the palm of the hand), followed by deep effleurage, petrissage (a massage technique that involves kneading the body), and clockwise vibration massage techniques around the intestines.²⁸ The whole abdominal massage duration was 15 min, and was performed twice a day at 10:30 a.m. and 10:30 p.m.

The fourth and final step consisted of oral care including mouth washing, which was performed as a part of care program by a researcher and his/her colleague one hour post-gavage in all shifts using a swab soaked with chlorhexidine.

The patients of control group just received the unit routine cares, which were performed by the nurses. The patients were introduced to the supervisors of all the shifts in order to conduct the procedures uniformly and monitor the proper execution of the designed care programs in absence of the researchers. Therefore, correct execution of all the procedures including pharyngeal-oral suction, oral cares, gavage, and position changing were controlled by the supervisor when the researchers were not present. Besides, two research assistants were also recruited for controlling during the morning and night shifts.

The MCPIS was completed and recorded at the end of the third day of the intervention (four days after intubation). The study was single-blinded, so that the doctor, who interpreted the chest radiograph as a part of MCPIS tool, was unaware of the patients' groups and confirmed the presence or absence of infiltration.

2.5. Ethical Considerations

According to the ethical terms of the Ethical Committee of Zahedan University of Medical Sciences, written consent for participation in the study was taken from the people who were accompanying the patients. Additionally, the accompanying people were assured that the treatment procedure would be the same whether they participate in the study or not. Moreover, confidentiality of the patients' information was warrantied. This studv has the code of IR.ZAUMS.REC.1395.124 the Ethical from

Committee of the Zahedan University of Medical Sciences.

2.6. Statistical Analysis

Data analysis was performed by descriptive indices, independent T-test (for comparing the quantitative variables between the two groups), and Chi-square test (to compare the difference in pneumonia incidence between the two groups of intervention and control). All the analysis was completed using the SPSS version 15.

3. Results

The age mean and standard deviation were 48.54 ± 14.01 and 51.97 ± 8.44 years in intervention and control groups, respectively. 54.3% (19 people) in the intervention group and 51.4% (18 people) in the control group were men. The most frequent reason for hospitalization was trauma (63.3%) in the intervention group, and cardiopulmonary diseases and cancer (81.8% and 64.3%, respectively) in the control group. The mean and standard deviation of tracheal tube size was 7.6 ± 0.35 and 7.57 ± 0.54 in intervention and control groups, respectively. The clinical characteristics of the participants are shown in Table 2. No significant difference was observed regarding the demographic and clinical data of the patients between the two groups (P < 0.05).

The results of pneumonia incidence in the two groups indicated that none of the patients in the intervention group got affected by VAP after execution of the program, while 54.3% of the control group was affected. This difference between the two groups was statistically significant (P<0.001) (Table 3).

Time		Day one	Day two	Day three
Variable		Mean±SD	Mean±SD	Mean±SD
Nutritional solution volume (mL)	Intervention	53.57±10.74	72.85±19.52	83±16.63
	Control	57.14±21.49	70.71±22.26	83.71±21.6
	P-value*	0.384	0.67	0.877
Endotracheal suction	Intervention	5.4±1.06	5.48±1.03	5.91±1.09
times	Control	5.88±1.36	5.74±1.44	6.42±1.61
	P-value*	0.1	0.39	0.12
	Intervention	3.34±0.59	3.11±0.4	3.25±0.44
Mouth care times per day	Control	3.11±0.58	3.37±0.54	3.54±0.85
	P-value*	0.1	0.06	0.08
	Intervention	6.54±2.25	7.17±2.24	7.43±2.3
Consciousness level	Control	7.69±2.98	7.8±2.81	8±3.09
	P-value*	0.07	0.3	0.38
Tracheal tube cuff pressure (mmHg)	Intervention	24.71±7.11	22.4±4.46	23.2±4.07
	Control	22.57±3.95	22±5.65	22.74±5
	P-value*	0.12	0.74	0.67
	Intervention	-3.54±1.09	-3.17±1.09	-2.91±1.35
Sedation level	Control	-3.09±1.19	-2.63±1.35	-2.46±1.91
	P-value*	0.1	0.7	0.25
Contria regidual valuma	Intervention	9.64±24.41	23.85±25.71	12.96±24.61
Gastric residual volume	Control	11±29.14	40.71±43.09	26.57±42.59
(mL)	P-value*	0.83	0.06	0.1

Table2. Clinical characteristics of the participants

*Independent T-test

Table 3. Comparison of ventilator associated pneumonia incidence between the intervention and control groups

Group	Intervention		Сог	P-value*	
Pneumonia incidence	Frequency	Percentage	Frequency	Percentage	F-value
Positive	0	0	19	54.3	<0.001*
Negative	35	100	16	45.7	

4. Discussion

Findings of the current study demonstrated that execution of a designed care program including elevating the bed's head, abdominal massage, GRV management, and mouth care reduces the incidence of VAP. Eom et al. (2014) indicated that proper execution of VAP prevention program decreased pneumonia occurrence remarkably in patients under mechanical ventilation,29 which is consistent with the results of the present study. Two interventions in the study performed by Eom et al. including elevating the bed's head to 30-45 degrees and mouth washing by chlorhexidine were similar to this study. The reason for reduced pneumonia incidence in the two studies might be the similarity of these two interventions that affect aspiration reduction and sufficient oral hygiene. Results of the study conducted by Hellyer et al. (2016) on the impact of care interventions package proposed by the association of special cares for VAP prevention also confirmed this finding.³⁰

Furthermore, Azab et al (2015) demonstrated that using a designed care program could notably decline the VAP incidence, ICU hospitalization duration, and mortality rate,²⁴ which is also consistent with the results of present study. The effect of elevating the bed's head on prevention from aspiration incidence showed that it may result in lower VAP occurrence. The latter indicates that elevating the head of bed between 30-45 degrees plays such an important role in prevention from VAP in patients, who are under ventilator and receive enteral feeding. Many guidelines have recommended elevating the bed's head to more than 30 degrees to prevent reflux, aspiration, and pneumonia occurrence.³¹⁻³³

Another part of the designed care program in the current study included management of GRV in intubated patients, who were hospitalized in ICU. It can prevent aspiration of patient's gastric contents as a reason for VAP. Based on the findings of the present study, the mean GRV on the study days was not significantly different between the intervention and control groups. Metheny et al. (2010) showed that the protocol for assessing GRV could have a remarkable role in decrease of VAP.¹³ Although in the current study there was not a significant difference regarding GRV on days one, two, and three of the study between the two groups, the intervention reduced the GRV in the intervention group compared to the controls. The mentioned decline might be one of the effective factors on decreasing the pneumonia incidence in the intervention group.

Results of a review study performed by Bing et al. on 17 articles from 2000 to 2013 revealed that measuring the GRV alone cannot be a suitable criterion for predicting aspiration occurrence in the severely ill patients, and aspiration has also happened in patients with low GRV. However, GRV monitor and control is still required regarding its possible role in preventing pulmonary aspiration.²⁵

In those severely ill patients who are under mechanical ventilation, the peristaltic movements of the intestines decrease due to the position of sleeping on back. Considering the initiation of feeding by tube in these patients during the first 24 hours of hospitalization, the risk for aspiration incidence is high in these patients.

In the current study, the third part of the designed care program was abdominal massage, effective on decreasing which was the intraabdominal pressure and facilitation of enteral movements leading in reduced GRV in patients of the intervention group. Moreover, it managed to reduce the VAP incidence in the test group. Pyszora et al. (2010) stated that abdominal massage could accelerate the blood flow and peristaltic movements of the intestines, increase absorption, facilitate transition of food from intestines, and decrease the intraabdominal pressure.¹⁶ Kahraman et al. (2014) showed in a study that abdominal massage could be performed twice a day with the aim of reducing the GRV in severely ill patients, who are under mechanical ventilation and receive enteral feeding. It might be performed in order to prevent the VAP and decrease the GRV.3 Tekgunduz et al. have also mentioned the positive influence of this method on neonates, who receive enteral feeding.34

Another component of the care program in this study was oral hygiene using chlorhexidine, which could besides other interventions affect reduction of pneumonia incidence. In a meta-analysis performed by Labeau et al. in 2015, it has been stated that using oral antiseptics has an important role in the VAP prevention.¹⁷ On the other hand, Ranjbar et al. (2011) suggested that the most important method being used in mouth washing is applying chlorhexidine solution.³⁵ However, Seyedoshohadayi et al. (2012) presented in their study that using the chlorhexidine 0.12% solution

neither was effective on pneumonia incidence, nor altered the types of microbes isolated from the samples. Consequently, it is of no preference for usage compared to the normal saline.³⁶ However, Panchabhai et al. demonstrated in their study that using chlorhexidine twice a day in patients of openheart surgery from two days before the operation results in reduced incidence of pneumonia.³⁷

5. Conclusion

According to the clinical findings of this study, performing preventive nursing cares for reducing the risk of VAP occurrence as a designed care program could have more remarkable effects. Furthermore, performing abdominal massage as a simple, safe, and cost-efficient care method might be of benefit in decreasing the intraabdominal pressure in critically ill patients who are fed through the tracheal tube. Additionally, it reduces the aspiration risk as well as the VAP occurrence.

The tracheal tubes in the current study were placed in different shifts and places, and by different people, which might affect the results. Therefore, it was not under the control of the researchers and could be considered as a limitation for this study.

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Conflicts of interest

The authors declare no conflicts of interest.

Authors' contributions

Fariba Yaghoubinia: was responsible for the study design, drafting, and final approval of the article. Seyed Mohammad Nasir-al-din Tabatabaei: contributed to the study design and drafting. Mojgan Jahantigh: contributed to the study design, and drafting of the manuscript. Parastoo Mohammadi: was responsible for the study design, data collection, and drafting of the manuscript.

Acknowledgments

This article is a part of the thesis for master of nursing in the faculty of nursing and midwifery of Zahedan University of Medical Science, Iran with the number of 7753. It has been registered in the Iranian Registry of Clinical Trials with the code of IRCT2016072729100N1. We would like to acknowledge the kind cooperation of the ICU personnel of the Imam Ali and Khatam hospitals of Zahedan, Iran, the professors, ICU doctors, and anesthetics specialists, and also all the patients who assisted in conduction of this study.

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How to cite: Yaghoubinia F, Nasir-al-din Tabatabaei SM, Jahantigh M, Mohammadi P. Impact of Care Program on Ventilator-Associated Pneumonia Incidence: A Clinical Trial. Medical - Surgical Nursing Journal 2017; 5(4): 31-37.