Original Article

Effect of intermittent subglottic secretion drainage on ventilator-associated pneumonia: A clinical trial

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Abstract

Background: Secretions contaminated with oral, nasal, and gastric bacteria accumulate in the subglottic space, above the endotracheal tube cuff. If these secretions are aspirated into lower airways, the intubated patient will be susceptible to ventilator-associated pneumonia (VAP). The aim of this study was to investigate the effect of inspiratory pause maneuver for intermittent subglottic secretions drainage (SSD) on the incidence of VAP in patients receiving mechanical ventilation.

Materials and Methods: This randomized clinical trial was conducted in four intensive care units of educational hospital in Isfahan, Iran. A total of 76 adult patients intubated with a conventional endotracheal tube and connected to ventilators for more than 48 h were selected through convenient sampling and were randomly assigned to undergo intermittent SSD (n = 38) or not (n = 38). In this study, for SSD, we used inspiratory pause/hold key in the ventilators to hyperinflate the lungs. Pressure that produces with this maneuver could remove the secretions from the subglottic space.

Results: VAP was found in 10 (26.3%) patients receiving SSD and in 18 (47.4%) patients in the control group (P = 0.04).

Conclusions: SSD using inspiratory pause during mechanical ventilation results in a significant reduction in VAP.

Key words: Critically ill patients, intensive care unit, subglottic secretions drainage, ventilator-associated pneumonia

Introduction

Nosocomial infections (hospital-acquired infections) are becoming a major problem in the hospitals due to increase in morbidity, mortality, and cost associated with them.[1] Ventilator-associated pneumonia (VAP) is defined as hospital-acquired pneumonia which occurs within 48-72 h after endotracheal (ET) intubation.[2,3] This infection is the second most prevalent nosocomial infection in the Intensive Care Units (ICU), which increases the hospital costs, morbidity, and mortality rate of intubated, critically ill patients.[2] Incidence rate of pneumonia depends on the type of patient population (who are under examination), which is reported to be between 9 and 68%,[3,4] and may have a mortality rate up to 27%.[2]

In addition, the crude mortality rate of 20-50% has been reported.[5] This nosocomial infection increases the hospital costs from about US$ 10,000 to 13,000 per case.[6] The accumulated secretions around the endotracheal tube (ETT) cuff (subglottic space) and aspiration of them is one of the main causes of VAP. Therefore, the plan of prevention must include ways for reducing accumulation, removing (draining) secretions, and averting leakage between the tube and tracheal wall.[7] There are a few ways by which the secretions around the cuff can be cleared/removed. One of these methods is the use of "*Hi Lo evac*" ETT. Several studies have confirmed the ability of this in reducing the incidence of VAP.[7-13]

The "*Hi Lo evac*" ETT is not widely used. All over the world, many mechanically ventilated patients, before being admitted to the ICU, are intubated with standard ETT,[9] which is not able to remove the accumulated secretions in the subglottic space.[7] Also, there are two obstacles in using the "*Hi Lo evac*" ETT, including:

- The high price of the ETT and
- Identifying patients at risk for VAP (patients who need long-term ventilation).[9]

A new method was introduced in a report for controlling the subglottic secretions in patients who have standard ETT and also to protect them from VAP. Gentile and Soibal (2010) suggested this method, which is explained in the textbooks of respiratory care and anesthesia.[1] In this technique, after suctioning the oropharynx, a positive pressure which causes lung hyperinflation is applied by an inspiratory pause (use of inspiratory hold/pause key or with an ambu bag); then

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the cuff is rapidly deflated, and the air flows upward past the deflated cuff and drives the secretions toward the oropharynx where they (secretions) can be cleaned with frequent oropharyngeal suctioning.[1,14]

As one of the preventive measures of VAP, this operation could be used in order to remove or clear the subglottic secretions intermittently.[1] (Inspiratory pause key causes the ventilator to seal patient's breathing circuit at the conclusion of the gas delivery phase of designated volume- or pressure-based mandatory inspiration. This safe inspiratory pause maneuver, embedded in mechanical ventilators, maintains the inflated state of the lungs. The inspiratory pause maneuver provides the means to measure the patient's static lung–thoracic compliance, static resistance, and plateau pressure.)

But the efficacy of this maneuver in removing the subglottic secretions and prevention of VAP is still vague and needs further studies. For this reason, a clinical trial was conducted in order to study the effectiveness of subglottic secretions drainage (SSD) by an inspiratory pause method in patients undergoing mechanical ventilation. The main objective of this study was to determine the incidence of early-onset VAP among patients who receive SSD and to compare this outcome with that of the patients who receive routine oropharyngeal suctioning without SSD.

Materials and Methods

Study protocol

The study was conducted in four ICUs of the selected educational hospital in Isfahan, Iran. These ICUs are advanced care units with 56 active beds and more than 1600 admissions per year. They are general ICUs with medical, surgical, and trauma patients, which are under 24-h on-site intensivist coverage and a nurse-to-patient ratio of 1:2 is maintained at all times. The study protocol was reviewed and approved by the medical ethical committee of Isfahan University of Medical Sciences.

Between November 2012 and February 2013, all patients admitted to the ICU were screened in order to detect those patients in the age range of 18-60 years who were intubated with single used cuffed polyvinyl chloride endotracheal tube (PVC ETT) with high-volume and low-pressure cuff and likely required mechanical ventilation for at least 48 h. In this study, the following were the exclusion criteria:[8]

- Patients who were admitted to the ICUs with tracheostomy
- Patients whose mechanical ventilation was normally shorter than 48 h (psychotropic drug overdose, etc.)
- Patients who were likely to die in the next 48 h (those who were admitted after cardiac arrest, etc.)
- Patients who were admitted to these units for treatment of pneumonia
- Others with lung complications like fibrosis or cancer

Seventy-six patients satisfied the eligibility criteria. Randomization was performed by minimization software based on age, sex, smoking, and Simplified Acute Physiology Score (SAPS) II. Patients were randomly allocated to undergo SSD (SSD group, 38 patients) or routine oropharyngeal suctioning (control group, 38 patients). Matching practices were used in both groups in order to prevent the nosocomial pneumonia, e.g. no routine change of ventilator circuit, a 30°-45° head-of-bed elevation, oral care, and peptic ulcer prophylaxis with sucralfate, ranitidine, or omeprazole and hand hygiene.

On admission to the ICU, SSD group was connected to a ventilator with inspiratory pause or inspiratory hold key. After the patient was examined by the physician and in the absence of pulmonary complications, oropharyngeal suctioning was performed every 3 h under the supervision of an intensivist and close monitoring, and then by using the inspiratory pause or inspiratory hold keys in the ventilator, an inspiratory hold was applied.

When the airway pressure was increased (in 3rd sec), the cuff was rapidly deflated by the researcher, and it was inflated immediately after 2 sec and inspiratory pause was released. Air flow rising past the deflated cuff drove the subglottic secretions toward the oropharynx from where they (secretions) were removed with repeated oropharyngeal suctioning by a nurse specialist in critical care. Then, the cuff pressure was maintained between 20 and 30 mm H_2O.

This maneuver, based on the physician's permission and after careful assessment by the intensivist in patients who had no lung complications, was performed periodically in order to clean up the subglottic secretions. This was a safe technique which must be done with the intensivist supervisor for caution. Inspiration was held in the patient for 3 sec only until the cuff of the ETT was depleted; this method is not harmful for the patient.

Routine oropharyngeal suctioning was performed in the control group (mouth and oropharyngeal suctioning before endotracheal suction with single-use catheter). Because of the type of the intervention, physicians and nurses could not be blinded to the randomization arm. Written consent was obtained from the patients or their relatives.

Data collection

The following data were recorded:

- Demographics (age, sex, etc.)
- Primary reason for ICU admission

- Smoking
- Nonsmoker
- Ventilator mode
- Level of positive end-expiratory pressure (PEEP)
- Severity of illness that was measured by the new SAPS II.

The incidence of early-onset VAP in the case and control groups was the outcome measure and was compared between them. VAP consistent with the clinical pulmonary infection score (CPIS) was diagnosed. Scores in this scale are between 0 and 12; scores equal to or greater than 6 are considered as the diagnostic cut-off.[15] This is a validated scale with sensitivity and specificity more than 90% for VAP diagnosis, and has been agreed upon by the doctors and nurses in the ICUs[16] [Table 1].

Incidence of pneumonia within the first 48 h of mechanical ventilation was not thought to be ventilator associated.

A threshold of 5 days after initiation of mechanical ventilation was used to distinguish early-onset (≤5 days) VAP and assessed in all randomized patients with a blinded method by an intensivist physician who was not a member of the research team.

Statistical analysis

Analysis was performed with SPSS software Version 20.0. Means of continuous variables were compared using Student's *t*-test and categorical variables were compared using Chi-square test and Fisher's exact test, as appropriate. All statistical tests were two tailed. The level of significance was set at $P < 0.05$ for all the tests.

Table 1: CPIS point score

Item	Scales	Point
Temperature (°C)	36.5-38.4	0
	38.5-39.0	1
	<36 or >39.0	2
Leukocytes	4000-11,000/mm^3	0
	11,000-17,000/mm^3	1
	>17,000/mm^3	2
Secretions	None	0
	Yes	1
	Copious purulent secretions	2
PaO_2/FiO^2 in kPa	>33	0
	<33	2
	>33 with ARDS[1]	0
Chest radiograph infiltrates	Clear	0
	Patchy	1
	Localized	2

[1]: Acute respiratory distress syndrome, CPIS: Clinical pulmonary infection score

Results

Patients

Between November 2012 and February 2013, 408 patients were admitted in the ICUs in the participating center. At ICU admission, 162 patients were not intubated. Among the 246 remaining patients, 150 met the exclusion criteria. Finally, 96 patients were included: 50 in the control arm and 46 in the SSD arm. Among the included patients, 11 patients died before the end of the study: 5 patients in the intervention group and 6 in the control group.

Nine patients required mechanical ventilation for less than 48 h, 6 in the control group and 3 in the SSD group, and they were excluded because of the unavailability of complete data. Therefore, the analysis was limited to 76 patients: 38 in the control group and 38 in the intervention group. On the whole, the mean age of the patients was 42 ± 14.66 years (range 18-60 years). There were 53 male (69.7%) and 23 female (30.3%) patients. The PEEP level in the control and intervention groups was 9 ± 4 and 10 ± 4 cm H_2O, respectively, and the mean SAPS II score was 28.29 ± 2.08. In addition, there were no significant differences in the other features (ventilator mode, peptic ulcer prophylaxis, etc.) between the patients undergoing SSD and the control patients [Table 2].

VAP incidence

Within 5 days of mechanical ventilation, 28 patients developed pneumonia: 10 (26.3%) in the intervention group and 18 (47.4%) in the control group (Risk Ratio (RR) 36.85, 95% confidence interval, 0.26-0.47, $P = 0.04$). [Table 3]

Discussion

Aspiration of subglottic secretions is an important pathophysiologic mechanism for both early- and late-onset VAP.[8] In our study, intermittent SSD with inspiratory pause maneuver resulted in a significant reduction in the incidence of early-onset VAP (26.3% vs. 47.4%) in an unselected population of ICU patients.

It is difficult to compare the results of the present study with those of other studies regarding the effect of SSD on VAP incidence rate because SSD with inspiratory pause maneuver is a new method used to remove or clean up the subglottic secretions and there is no similar study to compare the results. However, our results are congruent with the studies about the effects of "*Hi Lo evac*" ETT and the influence of oral suctioning on VAP incidence.

Similar to our finding, Lacherde *et al.*, in their study about intermittent SSD with "*Hi Lo evac*" ETT, reported

Table 2: Baseline characteristics of the study patients

Patient characteristics	*n* (%)		*P* value
	Group intervention	Control	
Sex			
Male	27 (71)	26 (68)	0.8
Female	11 (29)	12 (32)	
Smoking			
Smoker	12 (31.58)	17 (53.12)	0.23
Nonsmoker	26 (68.42)	21 (55.26)	
Ventilator mode			
SIMV	26 (68.4)	30 (78.9)	0.52
Assist control A/C	10 (26.3)	6 (15.8)	
CMV	2 (5.3)	2 (5.3)	
Peptic ulcer prophylaxis			
Omeprazol	11 (28.9)	12 (31.6)	0.88
Sucralfate	13 (34.2)	11 (28.9)	
Ranitidine	14 (36.8)	15 (39.5)	
PEEP level			
Mean	10 cm H_2O	9 cm H_2O	0.07
SD	4	4	
Age			
Mean	42.76	41.24	0.67
SD	15.89	14.54	
SAPS II			
Mean	36.8	25.42	0.25
SD	32.61	14.6	

SIMV: Synchronized intermittent mandatory ventilation, CMV: Controlled mandatory ventilation, PEEP: Positive end-expiratory pressure, SAPS II: Simplified acute physiology score II, SD: Standard deviation

Table 3: Clinical outcome

Outcome	*n* (%)		*P* value
	Group intervention	Control	
VAP	10 (26.3)	18 (47.4)	0.04

VAP: Ventilator-associated pneumonia

VAP reduction.[8] Also, Liu *et al.* and Smulders *et al.*, in their studies about continuous and intermittent SSD with "*Hi Lo evac*" ETT, showed VAP reduction in the intervention group versus control group.[3,17]

Muscedere *et al.*, in their systematic review and meta-analysis of 13 randomized clinical trials, have reported 50% reduction in VAP incidence by using the "*Hi Lo evac*" ETT.[9] Also, studies about oral suctioning in intubated patients show the reduction in VAP incidence. Oral suctioning reduces accumulated secretions in the subglottic space. Chao *et al.*, in a study on removal of oral secretion prior to changing position, showed a significant reduction of VAP incidence in the intervention group versus control group.[18]

Similarly, Chow *et al.*, in their pilot randomized trial about the effect of continuous oral suctioning on the development of VAP, found a significant reduction in VAP incidence.[19] These three methods (SSD with inspiratory pause maneuver, "*Hi Lo evac*" ETT, and oral suctioning) operate by a similar mechanism in preventing VAP by removing the accumulated secretions in the subglottic space and reducing their amount, but their methodologies are different. We suppose that the reduction of pneumonia rate in the present study is due to the removal of accumulated secretions from the subglottic space as done by "*Hi Lo evac*" ETT and oral suctioning, but by a different method.

An exceptional outcome in the present study is the 20% reduction of VAP incidence, which was achieved with less cost. In addition, this technique is applicable in all intubated patients, as it was tolerated by all patients in the intervention group and no adverse effect was found. The results of this study support the protective effect of SSD with inspiratory pause maneuver on early-onset VAP in intubated patients.

The outcome that we evaluated was the early-onset VAP, because this was a new technique and its impact on the occurrence of VAP was unknown. One limitation of the study is its small sample size and inability to compare the effectiveness of two methods ("*Hi Lo evac*" ETT and SSD with inspiratory pause maneuver). Currently, SSD by using inspiratory pause maneuver is an investigational intervention, and further research with a larger sample size is needed to prove its effects.

Conclusion

In conclusion, a significant reduction in the incidence of early-onset VAP by using SSD with inspiratory pause maneuver among intubated patients was demonstrated. Future clinical trials with a larger sample size are needed to strengthen these results and to verify the general impact of SSD with inspiratory pause maneuver as part of the care plan for the prevention of VAP. Till such data are obtained, clinicians must learn to make the best use of innovative methods like inspiratory pause maneuver to prevent VAP.

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