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Address: Mashhad Nursing and Midwifery School, Ebn-e-Sina St., Mashhad, Iran
P.O.Box: 9137913199
Tel.: (098 51) 38591511-294
Fax: (098 51) 38539775
Email: EBCJ@mums.ac.ir

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Original Article

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Evaluation of the Effects of Oronasal Versus Oral Disinfections with Chlorhexidine on Clinical Criteria of Ventilator-associated Pneumonia

Mahdi Alimi[1], *Zahra Sadat Manzari[2], Seyedreza Mazlom[3], Ahmad Bagheri Moghadam[4], Hossein Rouhani[5]

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Abstract

Background: Ventilator-associated pneumonia (VAP) is the most prevalent and lethal form of nosocomial infections in the ICU and oral disinfection is a nursing measure to prevent this condition.

Aim: this study aimed to evaluate the effect of oronasal versus oral disinfections with chlorhexidine on the clinical criteria for diagnosis of VAP.

Method: This randomized clinical trial was conducted on 70 intubated ICU patients under mechanical ventilation at Shahid Kamyab Hospital of Mashhad, Iran in 2016. Samples were divided into two groups of intervention (mouthwash and disinfection of nostrils with 0.2% chlorhexidine every eight hours) and control (mouthwash). Clinical criteria for VAP, including pulmonary infiltration, rectal temperature, white blood cell (WBC) count and endotracheal discharge were recorded and compared between the two groups from days 1-6. Data analysis was performed in SPSS version 11.5 using Chi-square test.

Results: In this study, mean age of intervention and control groups was 44.3±19.9 and 45.9±18.2 years, respectively. The results of Chi-square test indicated no significant difference between the groups regarding rectal temperature (P=0.22), WBC count (P=0.33), purulent endotracheal discharge (P= 0.47), pulmonary infiltration (P=0.21) and incidence of VAP (P=0.21).

Implications for Practice: According to the results of this study, no statistically significant difference was observed between the two groups regarding clinical criteria and the incidence of VAP despite clinical differences. Therefore, it is recommended that further studies be conducted in this area.

Keywords: Ventilator-associated pneumonia, Mouthwash, Chlorhexidine, Mechanical ventilation

1. MS in Nursing, School of Nursing and Midwifery, Mashhad University of Medical Sciences, Mashhad, Iran
2. Evidence Based Care Research Centre, Assistant Professor of Nursing, Department of Medical-Surgical Nursing, School of Nursing and Midwifery, Mashhad University of Medical Sciences, Mashhad, Iran
3. Evidence Based Care Research Centre, Instructor of Medical-Surgical Nursing, School of Nursing and Midwifery, Mashhad University of Medical Sciences, Mashhad, Iran
4. Assistant Professor, Department of Anaesthesiology and Critical Care, Imam Reza Hospital, Mashhad University of Medical Sciences, Mashhad, Iran
5. Anesthesiologist, Shahid Kamyab Hospital, Mashhad University of Medicals Sciences, Mashhad, Iran

* Corresponding author, Email: ManzariZ@mums.ac.ir

Introduction

Nosocomial infections are some of the major and common challenges in healthcare centers and mainly lead to prolonged hospitalization, increased medical costs and patient mortality (1). Ventilator-associated pneumonia (VAP) is the most prevalent and lethal form of nosocomial infection in the ICU (2). VAP is considered as a subgroup of nosocomial pneumonia and occurs in approximately 10-20% of patients undergoing mechanical ventilation 48-72 hours after endotracheal intubation and initiation of mechanical ventilation (3, 4). In addition, this disease is responsible for 27-47% of infection in the ICU throughout the US (5). In this regard, a study was conducted in Shohadaye Tajrish hospital, Tehran, Iran in 2005 and the results portrayed VAP as the most prevalent infection (46%) in the ICU (6).

One of the most important risk factors for the development of VAP is the duration of mechanical ventilation. While prolonged mechanical ventilation is associated with reduced risk of early-onset of VAP, the possibility of infection decreases after the fifth day admission. According to the literature, it is estimated that risk of VAP is three percent per day during the first five days of ventilation, while it reduces to two percent per day during the second five days and one percent per day thereafter. Risk for VAP is greatest during the first five days of mechanical ventilation (7, 8).

Pathogens, carried in the mouth and nose, play an important role in the incidence of VAP (9-12). Mouth and nose meet at pharynx and are important sites of pathogen colonization. These body parts harbor concavities, leading to colonization of bacteria during the times of compromised immunity (e.g., trauma and surgery) (13). On the other hand, most patients in the ICU experience endotracheal intubation during mechanical ventilation (1).

Endotracheal intubation causes dysphagia, resulting in mucus accumulation in the oral and nasal cavity and accelerated colonization of bacteria (9). However, this mucus accumulation in oral and nasal cavities cannot be avoided in patients undergoing mechanical ventilation due to their compromised consciousness, as well as disturbed cough and swallowing reflexes.

Furthermore, ineffective defense mechanisms, caused by compromised immune system in patients, lead to the colonization of microorganisms, which is carried as normal flora of nasal and oral cavities during 24 hours after admission to the ICU. These colonies, along with oral and nasal discharge, migrate through the endotracheal tube and alongside with the trachea itself toward lower airways and overcome innate host defense system, which finally leads to pneumonia (14).

According to the instructions published by the centers for disease control and prevention (CDC), the most important strategy for prevention of VAP is oral hygiene (15). Among oral rinses, chlorhexidine has been recognized as the golden standard and the most effective antibacterial oral rinse in the market (13). According to several reports, chlorhexidine decreases oral colonization (16-19), leading to reduced incidence rate of pneumonia by 10-30% (4).

Chlorhexidine (a widely used skin and mucous membrane antiseptic) is an effective, inexpensive and well tolerated solution and has sustained antibacterial activity (up to 12 hours) (20, 21). To date, there are no reports of a chlorhexidine-resistant strain of bacteria. Therefore, chlorhexidine can be considered as a proper oral rinse for hospitalized patients (6).

On the other hand, pathogens carried in nostrils have been known as the main risk factor for the incidence of nosocomial infections and VAP, especially in patients hospitalized in the ICU (5). The main entry to the nasal passageway for pathogens is through the nostrils. Moreover, this area is exposed to microbes carried in the sinus and nasal cavity mucus, which provides a desirable surface for the colonization of microorganisms (13). Aspiration of colonized nasopharyngeal discharge around endotracheal tube leads to the colonization of lower airways and subsequent VAP (16).

In a report by the national healthcare safety network (NHSN) in the US, Staphylococcus aureus was introduced during 2009-2010 as the leading cause of VAP and surgery site infection (22). Studies have shown that Staphylococcus aureus colonizes both nostrils and mouth, and nostrils are the primary reservoir for the colonization of the bacteria (13, 22). Rusha et al. (2013) demonstrated in a study that colonization of Staphylococcus aureus in nostrils was associated with increased incidence rate of VAP in patients; therefore, it is considered as a risk factor for the VAP (5).

The mupirocin nasal ointment is commonly used to eliminate nasal golden staph bacteria. However, excessive use of this substance could cause a significant resistance (22) Efforts to treat infections caused by this pathogen, made resistance to most commonly available antibiotics (23).

Prevention is a priority to improve the quality of patient care because of serious consequences and complications of VAP (17).
It is obvious that preventing these infection, not only may reduce costs but also improve the results related to patient and patient safety and even increase the quality of patient care (24).
According to the literature, nurses play an important role in prevention of VAP (9).
Diagnosis ability of healthcare teams for VAP is extremely limited despite its clinical importance (4). Several intensive care researchers have tried to establish criteria for a more precise diagnosis of pneumonia for more than 50 years (2). In this regard, Johanson et al. described clinical criteria for diagnosis of VAP to facilitate this process (25). Literature review revealed only two studies with the aim of evaluating the effects of chlorhexidine solution in mouth and nostrils on reduced respiratory infections, both carried out in patients after cardiac surgery. In a study by Segers et al. (2006), a significant decrease was observed in the incidence of pulmonary complications after open heart surgery (21). On the other hand, the results obtained by Rostami et al. (2011) were indicative of no significant reduction in spite of decreased respiratory infection after open heart surgery (26).
To the best of our knowledge, there has been no research on the effect of simultaneous disinfection of mouth and nostrils on the incidence of VAP. Prevention of ventilator-associated respiratory infections is of paramount importance and nurses have a key role in this regard. In addition, it has been confirmed that nasal pathogens are recognized as risk factors for VAP and chlorhexidine has a significant role in disinfection of mucous membrane for VAP prevention. Given the fact that the effects of nasal disinfection with chlorhexidine has not been thoroughly studied, compared to mouth rinsing, the present study aimed to compare the effects of oronasal versus oral disinfections with chlorhexidine on the clinical criteria for the diagnosis of VAP.

Methods

This randomized clinical trial was conducted on 70 intubated patients under mechanical ventilation in the ICU of Shahid Kamyab hospital, Mashhad, Iran in 2016. Participants were divided into two groups and post-test was used to evaluate the results. Due to the lack of similar studies and qualification of dependent variables based on Johansson's criteria, sample size was estimated based on the results obtained from a pilot study (on 10 cases in each group) and the comparison of two ratios formula with 95% confidence level and 80% test power. Subsequently, the criterion used to estimate the highest sample size was pulmonary infiltration in this study. In total, sample size was calculated at 29 in each group; however, 45 individuals were assigned to each group for more accuracy and due to possible sample loss.
Exclusion criteria were unplanned endotracheal extubation (UE) on day one or two of mechanical ventilation (elimination of four and five individuals from intervention and control group, respectively), patient mortality on day one and two of mechanical ventilation (elimination of two patients in each group) and meeting at least two out of three criteria of Johansson's criteria (e.g., rectal temperature, WBC count and purulent endotracheal discharge) on day one or two of mechanical ventilation (elimination of four and five patients in intervention and control group, respectively), which led to a total elimination of 10 patients from the study and conduction of data analysis on 35 individuals per each group. Other exclusion criteria were allergy to chlorhexidine, observation of obvious aspiration and probable presence of pneumonia prior to intubation and mechanical ventilation (6, 12, 17, and 27).
Participants were among the eligible patients hospitalized in the Shahid Kamyab hospital at the time of research and were selected through convenience sampling. Afterwards, patients were assigned to the intervention and control groups using random number table. Accordingly, random numbers (0-9) were drawn and then allocated to each group. Subsequently, the tip of a pen was placed on a number with closed eyes in the random numbers table and the following numbers were recorded in the table. The sequence of numbers determined the sequence of individuals enrolled in each group based on the previous assignment of numbers to individuals. Since individuals were allocated to groups before the start of the experiment, the minimum level of bias was achieved.
Inclusion criteria were agreement of patient's relatives (because of compromised consciousness of patients), aged ≥18 years, orotracheal intubation, at least 48 hours of expected mechanical ventilation, lack of proper nasogastric intubation for nasal disinfection by swab, lack of immunodeficiency or underlying lung diseases and lack of symptoms of respiratory infection upon admission to the ICU

(i.e., lack of pulmonary infiltration in chest radiography and lacking at least two out of three clinical criteria of VAP).

Data collection tools were checklist of VAP predisposing factors and daily patient examination checklist using clinical criteria of VAP. In this regard, VAP risk factors included the level of consciousness upon admission to the ICU (based on Glasgow coma scale), cause of hospitalization, severity of disease (based on APACHE II scoring system), history of underlying diseases, antibiotic consumption during hospitalization, smoking habit, bed head position, surgical operation during hospitalization, enteral nutrition and use of sedative agents during mechanical ventilation (1, 4, 6, 28). These confounding variables were controlled by randomized distribution and close monitoring of participants in the study groups.

Clinical criteria of VAP (Johnson criteria) were pulmonary infiltration in chest radiography and meeting at least two out of three criteria (e.g., rectal temperature <35 or >38°C, WBC count <4000 or >12000/mm3 and purulent endotracheal secretion). Presence of each of the above-mentioned criteria leads to VAP diagnosis (7).

These tools were prepared according to experimental methodology, previous studies and review of the latest literature, validity of which have been confirmed by numerous studies inside and outside the country. (7, 29, 30). Application of these criteria for VAP diagnosis is recommended by the American Thoracic Association (25). In this study, the validity of study tools was evaluated and confirmed one more time by 10 faculty members of the Department of Nursing and Midwifery of University of Mashhad, Iran.

Mobile X-ray equipment (Siemens, Germany) was used for all the patients, validity of which was confirmed based on its reputable brand and the reliability of this scale was assessed by regular quality controlling by a radiologist. In addition, an anesthesiologist and ICU specialist checked chest radiographs for pulmonary infiltration and rectal temperature was measured by a glass thermometer with the aid of a nurse with five years of experience in the ICU. Validity (since it was brand-new and belongs to a reliable company) and reliability (by regular comparison to similar tools) of thermometer were also confirmed. WBC count of blood samples was measured by the author using Sysmex K-1800 (Japan). Validity and reliability of the counter was confirmed based on its brand and the lab technician who regularly calibrated the device with standard blood tubes. Endotracheal discharge was assessed based on color, odor and viscosity with the aid of the nurse taking care of patients. Validity and reliability of this method was confirmed by 10 experts and the assessor agreement method (r=0.82), respectively.

Checklist of VAP risk factors consisted of objective and clear questions, which have been frequently used in similar studies and their validity was already confirmed. The reliability of daily checklist of patient examination of clinical criteria of VAP was assessed using assessor agreement method on 15 patients, which was confirmed with the coefficient of 0.85.

A form, consisting of demographic characteristics (e.g., age, gender and marital status) and risk factors of VAP, was completed for all the participants by the researcher through interviews with relatives, referring to medical histories and observing clinical criteria in the patients. In addition, the severity of patients' disease was evaluated based on APACHE II scale 24 hours after admission to the ICU.

In the present study, respiratory infection indices were assessed based on Johnson's criteria with the aid of two physicians, who were not aware of the order of assignment of experimental units to intervention and control groups. According to previous studies, examination of patients was continued until day six due to the fact that daily risk of VAP is at its peak on day five of mechanical ventilation and starts to decline thereafter.

Upon admission to the ICU and daily assessment until day six of mechanical ventilation (at 6-7 am), all the participants were evaluated for three clinical criteria of VAP. In addition, presence of at least two out of three criteria on day one or two could lead to sample exclusion due to probable pneumonia before intubation and mechanical ventilation. If two criteria were observed through day 3-6 of mechanical ventilation, patients were examined for pulmonary infiltration using portable chest radiography. In case of presence of clinical criteria of VAP, intervention terminated and patients were diagnosed with VAP. Otherwise, examination would continue until day six of mechanical ventilation and on day six (in case of absence of at least two out of three clinical criteria of VAP) pulmonary infiltration was considered to be negative (Figure 1).

The first intervention was performed for all the participants after 12 hours of connection to the ventilator. Intervention process continued until the end of day five of mechanical ventilation or until all clinical criteria of PAV became positive. Mouthwash (disinfection of vestibules, gums, palate, the tongue and teeth) with chlorhexidine was performed every eight hours by the researcher for 30 seconds using applicator in both groups (6, 14, and 22).
In the intervention group, an additional disinfection was performed on nostrils immediately after disinfection of mouth using a cotton swab dipped in 2% chlorhexidine.

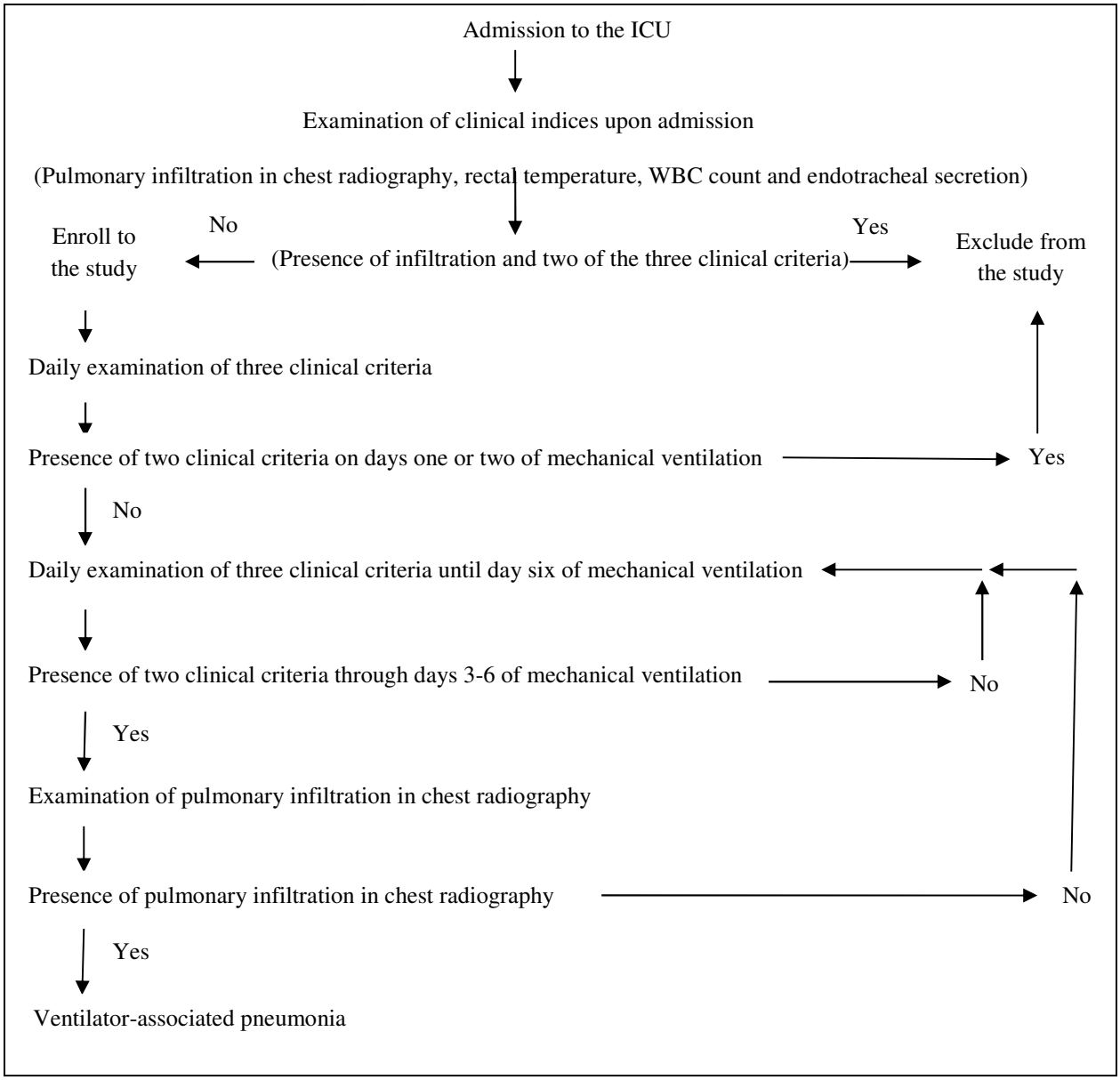

Figure 1. Approaches used for the diagnosis of ventilator-associated pneumonia

Reachable areas of nasal cavity were also disinfected for two consecutive times with separate swabs to ensure complete disinfection of nostrils. However, this process was not performed for the control group. All disinfections were performed only with chlorhexidine and by our researcher. In this regard, disinfection of mouth and nostrils with other antiseptics, such as normal saline, resulted in exclusion from the study. Discharge suction was performed prior to disinfection and at times needed in case of accumulation of nasal and oral discharge. Moreover, endotracheal tube cuff pressure was kept within an optimal range in all patients by the responsible nurse, checking the signs every four hours.
This study was approved by Ethics Committee of Mashhad University of Medical Sciences before the initiation of intervention. In addition, necessary approvals were obtained from the hospitals'

authorities and the researcher was introduced to hospital officials. Due to compromised consciousness of the patients, written informed consents were obtained from relatives of patients prior to the study. Samples were homogenous in terms of demographic characteristics, and Kolmogorov–Smirnov and Shapiro-Wilk tests were used to evaluate normal distribution of quantitative variables. Data analysis was performed in SPSS version 11.5 using independent t-test (to compare normally distributed quantitative variables), Mann-Whitney U (to assess other quantitative variables), as well as Chi-square and Fisher's exact test (to compare qualitative variables). P-value less than 0.05 was considered statistically significant.

Results

In this study, results of Chi-square and independent t-test revealed no significant difference between the study groups regarding demographic characteristics. In this regard, mean age of patients was 44.3±19.9 and 45.9±18.2 years in the intervention and control groups, respectively. According to the results of Mann-Whitney U, independent t-test, Chi-square and Fisher's exact test, no significant difference was observed between the two groups in terms of risk factors of VAP (Table 1).

Table 1. Comparison of demographics of the participants and risk factors of ventilator-associated pneumonia in the intervention and control groups

Variable		Intervention	Control	P-value
Age (year)		44.3±19.9	45.9±18.2	0.73*
Gender	Female	6 (17.2)	11 (31.4)	0.16**
	Male	29 (82.8)	24 (68.6)	
Marital status	Married	25 (71.4)	25 (71.4)	1.00**
	Single	10 (28.6)	10 (28.6)	
Level of consciousness upon admission to the ICU		8.2±4.2	8.1±3.6	0.91***
Causes of hospitalization	Multiple trauma	22 (62.9)	19 (54.2)	0.25**
	Head trauma	9 (25.7)	7 (20)	
	Intracranial hemorrhage (non-traumatic)	2 (5.7)	8 (22.9)	
	Other	2 (5.7)	1 (2.9)	
Severity of disease		21.5±7.8	18.3±6.5	0.07*
Underlying disease	Yes	14 (40)	11 (31.4)	0.45**
	No	21 (60)	24 (68.6)	
Antibiotic administration during hospitalization	Yes	31 (88.6)	34 (97.1)	0.36****
	No	4 (11.4)	1 (2.9)	
Smoking status	Yes	10 (28.6)	13 (37.1)	0.45**
	No	25 (71.4)	22 (62.9)	
Bed head position (≥30 degrees)	Yes	27 (77.1)	30 (85.7)	0.36**
	No	8 (22.9)	5 (14.3)	
Enteral nutrition during mechanical ventilation	Yes	19 (54.3)	26 (74.3)	0.08 **
	No	16 (45.7)	9 (25.7)	
Use of sedative agents	Yes	22 (62.9)	26 (74.3)	0.3**
	No	13 (37.1)	9 (25.7)	
Surgical operation	Yes	21 (60.0)	25 (71.4)	0.31**
	No	14 (40.0)	10 (28.6)	

*Independent t-test **Chi-square test *** Mann-Whitney U test ****Fisher's exact test

In post-test, rectal temperature was at the normal range in 22 (62.9%) and 17 (48.6%) cases in the intervention and control groups, respectively. Chi-square revealed that no significant difference was found between the groups regarding rectal temperature (P=0.23). While WBC count was within the normal range in 17 (48.6%) and 13 (37.1%) patients of the intervention and control groups, respectively, no statistically significant difference was observed between the groups according to the results of Chi-square (P=0.33).

Furthermore, 20 (57.1%) and 17 (48.6%) patients had non-purulent endotracheal discharge in intervention and control groups, respectively, which indicated no significant difference in this regard (P=0.47). Pulmonary infiltration was not observed in 25 (71.4%) and 20 (57.1%) participants in

intervention and control groups, respectively. According to the results of Chi-square test, no significant difference was found between the two groups in terms of observation of pulmonary infiltration in chest radiography (P=0.21) (Table 2). In total, 10 (28.6%) cases of intervention and 15 (42.9%) samples of control groups were diagnosed with VAP (based on clinical criteria of VAP); however, no significant difference was observed between the groups in this regard (Figure 2).

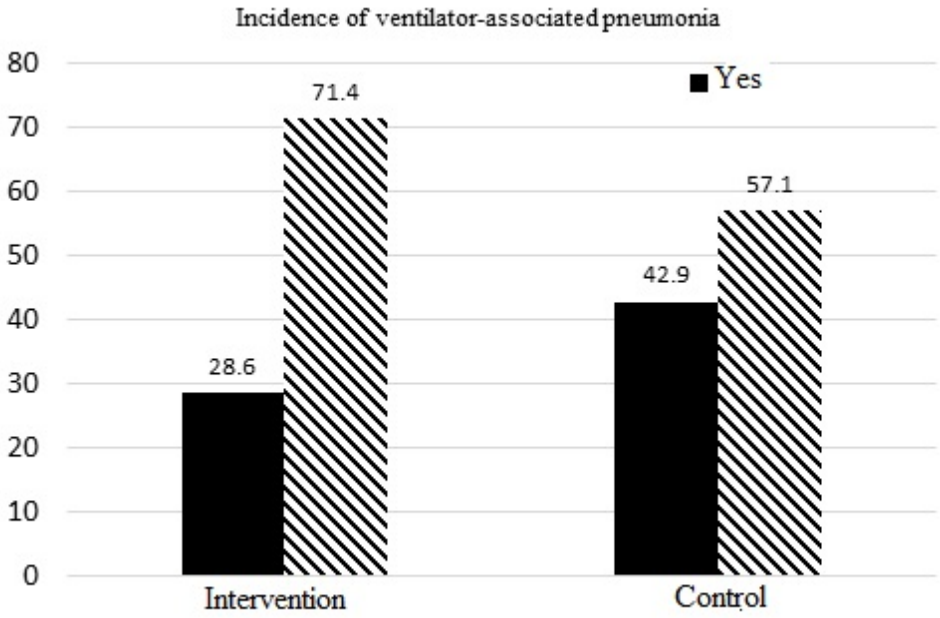

Figure 2. Incidence rate of ventilator-associated pneumonia in the intervention and control groups

Table 2. Comparison of clinical criteria of ventilator-associated pneumonia in the study groups

Clinical criteria		Intervention N (%)	Control N (%)	Chi-square test
Rectal temperature (°C)	35-38	22 (62.9)	17 (48.6)	X^2=1.4, df=1, P=0.23
	<35 or >38	13 (37.1)	18 (51.4)	
WBC (count/mm^3)	4,000-12,000	17 (48.6)	13 (37.1)	X^2=0.9, df=1, P=0.33
	<4,000 or >12,000	18 (51.4)	22 (62.9)	
Endotracheal discharge	Purulent	20 (57.1)	17 (48.6)	X^2=0.5, df=1, P=0.47
	Non-purulent	15 (42.9)	18 (51.4)	
Pulmonary infiltration	Positive	10 (28.6)	15 (42.9)	X^2=1.6, df=1, P=0.21

Discussion

According to the results of the current research, simultaneous oronasal disinfection with chlorhexidine resulted in no significant outcomes, compared to independent use of oral disinfection, in spite of clinical differences observed in the final results. Accordingly, the participants of intervention group were in better condition regarding clinical criteria of VAP, compared to the samples of control group. All the studied variables (e.g., hyper/hypothermia, leukocytosis or leukopenia, purulent tracheal discharge and pulmonary infiltration in chest radiography) were less frequently observed in the intervention group, compared to the control group. Moreover, no significant difference was observed between the study groups regarding the incidence of VAP despite clinical differences.

To the best of our knowledge, no direct study has been conducted on clinical criteria of VAP; therefore, we compared our results with studies, in which the incidence of respiratory infections and VAP were evaluated. Our findings are in line with the results obtained by Rostami et al. (2011) and Fraser et al. (2010). Rostami et al. (2011) conducted a study to evaluate the effects of oronasal disinfection with 0.2% chlorhexidine on reduced surgical site infections and respiratory infection after

cardiac surgery. According to the results of the aforementioned study, no significant decrease was observed in post-surgical respiratory infection (26). Meanwhile, Fraser et al. (2010) evaluated the effects of nasal disinfection with mupirocin, along with body wash with chlorhexidine, on VAP. According to their results, no significant difference was found regarding the diagnosis of VAP (31), which is consistent with the results of the present study. The mentioned study is similar to the present research due to the use of antiseptics for nasal disinfection and chlorhexidine for reducing the incidence of VAP.

Inconsistent with our results, Segers et al. (2006) evaluated the effects of pre-surgery oronasal disinfection with chlorhexidine on nosocomial infections after cardiac surgery and reported a significant reduction in respiratory infections (21). This discrepancy might be due to difference in sample size, which was 954 in the mentioned study. The same results could be obtained in the present study if a greater sample size was used. According to the results of the present study, 35.8% of all the participants were diagnosed with VAP. Similar results (31.3%) were obtained in a study by Li et al. (2011), in which chlorhexidine was used as oral rinse three times a day for five days.

Ozkaka et al. (2012) reported 55.1% incidence rate of VAP, which was higher than the present study (17). This inconsistency between the results might be due to the fact that VAP data was obtained for 14 days of mechanical ventilation in the study of Ozkaka et al., while this process lasted for six days in our study. In this regard and according to the results of most of studies, prolonged duration of mechanical ventilation could lead to increased possibility of VAP (7, 8).

A study was conducted by Seyedoshohadayee et al. (2010) in Rasool Akram hospital, Tehran, Iran. According to the results of the mentioned study, the incidence rate of VAP was reported to be 23.1%. In addition, Lin et al. (2015) reported 16% incidence rate of VAP (18, 27). However, both of these study results were lower than the present study. Most patients in our experiment were hospitalized due to trauma to various organs of the body, which could justify the higher incidence rate of VAP due to the fact that VAP is reported to be more prevalent in trauma patients and those undergone surgical operations (32).

Some of the major drawbacks of this study were small sample size and short duration of intervention. While the number of participants was calculated based on reasonable confidence coefficient and power, lack of significance is probably caused by variability of data and characteristics of participants. If intervention was performed on a greater sample size for a longer period (until the patients were connected to ventilator and mechanical ventilation), oronasal disinfection with chlorhexidine might have yielded significantly different results on the clinical criteria of VAP, compared to independent use of oral disinfection.

Implications for Practice

According to the results of the present research, it could be concluded that frequency of clinical criteria of VAP, including pulmonary infiltration in chest radiography, abnormal rectal temperature, WBC count outside normal range, purulent endotracheal discharge and incidence of VAP, were lower in the intervention group, compared to the control group. However, this difference between the groups was not statistically significant. The final results were indicative of relative effectiveness and clinical significance of oronasal disinfection with chlorhexidine. Therefore, it is recommended that this method be used to reduce respiratory infections in intubated patients under mechanical ventilation. Due to the effectiveness of oronasal disinfection with chlorhexidine on clinical criteria for diagnosis of VAP, it is suggested that further studies be conducted to evaluate the effects of this method on the duration of intubation, mechanical ventilation and admission to the ICU. In addition, it is recommended that future studies be performed on greater sample sizes for a longer period to obtain more accurate results.

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Conflict of interest

The authors declare that there is no conflict of interest.

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