Original Article

# Effect of Oral Care Program on Prevention of Ventilator-associated Pneumonia in Intensive Care Unit Patients: A Randomized Controlled Trial

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## Abstract

**Background:** Ventilator-associated pneumonia (VAP) is one of the most common nosocomial infections that increase mortality rate and the length of hospitalization. Oral care can improve patient's oral health, however, the role of oral care in the reduction in incidence rate of VAP is indisputable. The aim of this study was to investigate the effect of oral care on the frequency of VAP of patients in intensive care unit. **Materials and Methods:** This clinical trial was conducted on 80 participants who were randomly assigned to a control group and an intervention group from 2016 to 2017. Data were collected at the first, third, and fifth days of the study using a demographic and clinical characteristics questionnaire and the Clinical Pulmonary Infection Score for detecting pneumonia. Data analysis was performed using descriptive and inferential statistics in SPSS software. **Results:** The results of this study showed that the frequency of pneumonia on the third and fifth days was 15.80% (6) and 23.70% (9) in the control group and 10.50% (4) and 7.90% (3) in the intervention group, respectively. Chi-square test did not show a significant difference ($p$ = 0.059); however, the frequency of pneumonia in the intervention group reduced compared with the control group. **Conclusions:** According to the results of this study, the oral care program could not significantly decrease the incidence of VAP in critically ill patients compared with routine oral care practices. Similar studies with a larger sample size and longer duration should be conducted for better results.

**Keywords:** *Intensive care unit, oral hygiene, ventilator-associated pneumonia*

## Introduction

One of the common problems of patients undergoing mechanical ventilation is poor oral health.[1] Patients in intensive care units (ICUs) quickly develop oral problems for various reasons such as malnutrition, presence of the tracheal tube and nasogastric tube that is placed in the mouth of patients for treatment purposes, reduced fluid intake, and reduced salivation caused by fever, diarrhea, burns, and drug usage such as opiates.[2-4]

In patients in ICUs, dental plaques are formed more and faster than other patients.[5] Oral flora changes in the course of 48 h after hospitalization in favor of gram-negative organisms, which grow in the oral cavity resulting in the formation of dental plaque.[6] Plaque mass is increased with an accumulation of aerobic and anaerobic microorganisms and its colonization by Gram-negative bacteria is an important factor in the accumulation of oral and pharyngeal bacteria.[7,8] The results of several studies have revealed that bacteria present in dental plaque are causes of ventilator-associated pneumonia (VAP).[5,9]

VAP develops within 48 h of intubation and mechanical ventilation. VAP is the second most prevalent nosocomial infection among patients in ICUs.[10] The prevalence rate of VAP in patients undergoing mechanical ventilation is 9%–68%,[11] and its resulting mortality is reported to be 30%–70%.[12] It extends hospital and ICU stay by 6–7 days, raises healthcare costs by $40,000 per patient, increases the length of mechanical ventilation, and increases morbidity, mortality, and patient suffering.[13-15] Various studies have shown that optimum oral care was accompanied by a reduction in the occurrence of VAP in ICUs.[2,16] For instance, a study showed that the implementation of an oral care program in ICUs could significantly decrease the relative risk of VAP and reduce its



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prevalence from 10.4 to 3.9 cases per 1000 ventilator days.[17]

Therefore, providing oral care and hygiene should be considered as a fundamental aspect of nursing care in ICUs.[3] However, despite the importance of oral care in patients in ICUs, some studies mainly focus on the pathophysiology of VAP and discuss the importance of oral care when examining the physiology of oral cavity.[2] Other studies have assessed nurses' performance in oral care through self-report questionnaires and investigated nurses' opinion on the number of oral care sessions through reports attached to records of patients in ICUs.[18] Some studies have investigated oral-care-related tools such as toothbrush and mouthwashes.[19] According to a meta-analysis, the use of chlorhexidine mouthwash in patients in ICUs significantly reduced the incidence of VAP.[20] Some studies show that brushing is an effective way of reducing dental plaque and VAP.[16] Therefore, studies have recommended that further researches be conducted on oral care in patients in ICUs.[21] Therefore, the aim of this study was to evaluate the effect of an oral care program on the incidence of VAP in patients in ICUs.

## Materials and Methods

This was a parallel randomized clinical trial (IRCT2017101631200N2) with an intervention group and a control group. The study population consisted of all intubated patients hospitalized from November 2016 to August 2017 in the ICU of hospitals affiliated to Isfahan University of Medical Sciences, Iran. The participants were selected using convenience sampling. The inclusion criteria were an age of 18–65 years, an endotracheal tube in place through the mouth, ICU hospitalization of less than 24 h, lack of hospitalization in other hospital wards before ICU admission, lack of history of autoimmune disorders, pneumonia, or sepsis, lack of pregnancy, lack of known sensitivity to herbal ingredients, lack of denture, and lack of evident oral or perioral lesions. Patients were excluded if they died, were transferred from ICU to other settings, developed severe oral lesions, or their legal guardian chose to withdraw from the study.

Using the results of an earlier study[2] and with a type II error of 0.05 and a power of 0.80, the necessary number of patients for each study group was calculated to be 35. Considering an attrition rate of 10%, 40 patients were recruited to each group. Simple randomization was performed based on a random numbers tables by an independent person who was unaware of the study. All randomization numbers were concealed in separate envelopes that were sealed, opaque, and serially numbered. However, blinding was not used because of the nature of intervention.

In the intervention group, oral care was carried out by two research assistants who had a long work experience in the ICU. They received necessary training on oral care program from the researcher. The intervention started from the first day of admission to the ICU and continued for up to 5 consecutive days. It should be noted that intervention was planned based on previous studies and arranged as follows: adjusting the pressure of the cuff of the endotracheal tube between 20 and 25 mmHg using a special manometer; Elevating the head of the bed from 30° to 45°; deep mouth and throat suctioning; brushing all internal and external surfaces of the teeth, gums, and tongue for 2 min using a baby toothbrush and antimicrobial chlorhexidine 0.2%; moisturizing all surfaces of the oral mucosa, gums, and tongue of the patient using swabs and moisturizing gel containing aloe vera and peppermint essential oil; applying a thin layer of petroleum jelly to the lip; removing and cleaning any airway obstruction; and reinserting the tube in the patient's mouth.[2,3,21-23]

In the intervention group, the patient's oral condition was scored using Beck Oral Assessment Scale, and based on the score, the frequency of care was determined every 12, 8, 6, and 4 h for patients with no, mild, moderate, and severe disorders, respectively.[22] In the control group, routine care was provided which included elevation of the head of the bed from 30° to 45° and use of swab and chlorhexidine 0.2% solution every 12 h by nurses. The data collection instruments included a demographic questionnaire and Clinical Pulmonary Infection Score (CPIS). The demographic questionnaire included age, gender, underlying diseases, reasons for hospitalization, drugs used, and history of smoking, which were measured on the first day of the study.

The CPIS is used to detect VAP. It consists of six components of temperature, volume of respiratory secretions, changes in white blood cell count, presence of infiltration in chest radiograph, hypoxemia, and secretion culture results. The overall score of this scale ranges between 0 and 10. Scores of 6 and higher indicate the presence of VAP.[17] The validity and reliability of this scale have been approved in various studies.[2,6] This scale was completed and its score was recorded by an ICU anesthetist on the first, third, and fifth days of the study in both groups.

Data analysis was performed using SPSS (version 16; SPSS Inc., Chicago, IL, USA). Fisher's exact test, Chi-square, and *t*-test were used for demographic variables. Chi-square test was used to examine the differences between the two groups in terms of qualitative variables. *t*-Test was used to examine the two groups in terms of quantitative variables. Mann–Whitney *U* test was used for comparison of CPIS between control and intervention groups. The level of statistical significance was set at $p < 0.05$.

### Ethical considerations

This study was approved by the Institutional Review Board and the Ethics Committee of Isfahan University of Medical

Sciences (code IR.MUI.REC.1395.3.361). The study aim was explained to patients' legal guardians and they were ensured that the data would be handled confidentially, participation in the study would be voluntarily, and they could withdraw from the study at any stage. All participants signed an informed consent form.

## Results

In total, 80 patients were recruited. Two were excluded from the intervention group due to death and transference from the ICU to other settings. Moreover, two were excluded from the control group due to death. Therefore, data analysis was conducted on the data retrieved from 76 patients [Figure 1].

Chi-square test, independent *t*-test, and Fisher's exact tests revealed no significant differences between the groups ($p > 0.05$) [Table 1]. The mean (standard deviation) score of pneumonia on the first, third, and fifth days was 4.13 (0.84), 4.45 (1.17), and 4.65 (1.02) in the control group and 4.18 (0.69), 4.28 (0.95), and 4.31 (0.93) in the intervention group, respectively. The results of Mann–Whitney *U* test revealed that there was no significant difference between the two groups on days 1, 3, and 5 in terms of mean CPIS ($p > 0.05$). In addition, the frequency of pneumonia on the third and fifth days was 6 (15.80%) and 9 (23.70%) in the control group and 4 (10.50%) and 3 (7.90%) in the intervention group, respectively. Chi-square test did not show a significant difference between control and intervention groups ($p > 0.05$) [Tables 2 and 3].

## Discussion

The aim of this study was to determine the effect of an oral care program on VAP in patients in ICUs. The results of this study showed that oral care program did not affect the incidence of VAP; there was no significant difference in the two groups regarding the incidence of VAP. However, as can be seen, the incidence of pneumonia in the intervention group was lower than that of the control group. Haghighi *et al*.[2] also showed that the use of chlorhexidine and tooth brushing twice a day had no effect on the incidence of VAP. Kaya *et al*.[6] also stated in their study that chlorhexidine mouthwash, in comparison with glutamine, had no effect on the incidence of VAP.

The results of this study differ from those of the study by Hutchins *et al*.[5] They showed that oral care can reduce the incidence of VAP.[5] This difference may be attributed to the type of oral care protocol and the duration of the study. In this study, children's toothbrush and chlorhexidine were used twice a day. Nevertheless, in addition to using chlorhexidine and toothbrush, Hutchins *et al*.[5] used hydrogen peroxide every 8 h to clean the oral cavity. The duration of the study was also 2 years. On the other hand, El Azab *et al*.[24] reported that oral care, along with controlling other effective factors such as elevating the head of the bed, interruption of daily sedation, and early weaning from the ventilator, can reduce the incidence of VAP.

This study had several limitations. One limitation was the limited setting of the study, that is, an ICU; therefore,

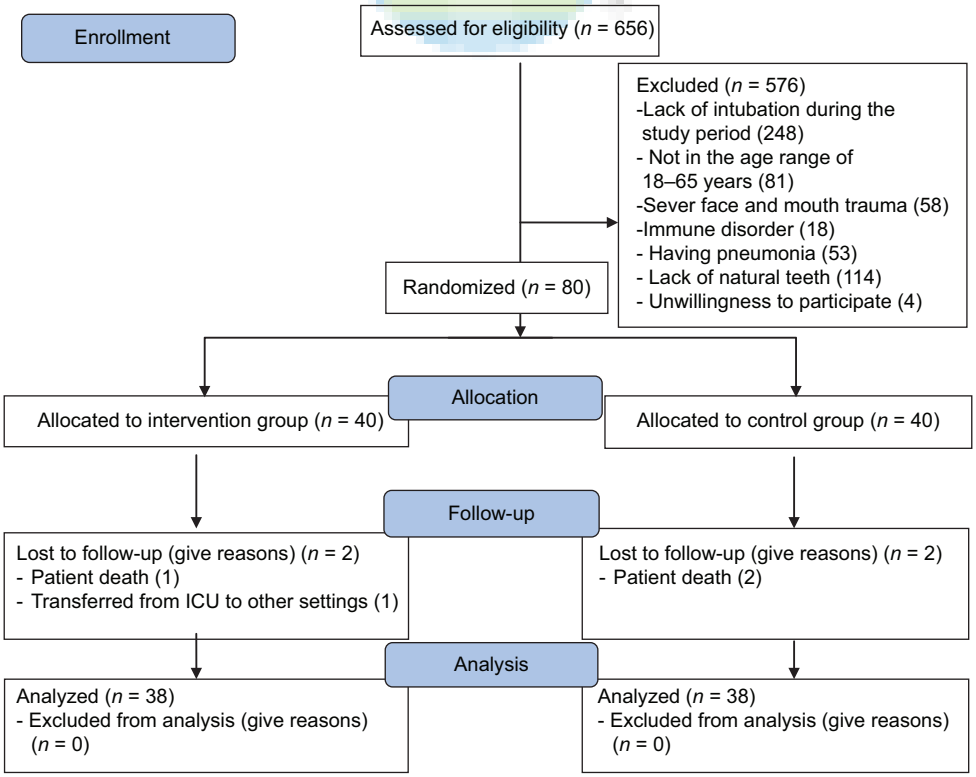


**Figure 1: CONSORT flow diagram**

**Table 1: Between-group comparisons with respect to patients' demographic characteristics (*n*=38)**

| Groups characteristics | Mean (SD) | | *p* |
|---|---|---|---|
| | Placebo (*n* [38]) | Intervention (*n* [38]) | |
| Age (years) | 52.44 (14.88) | 45.55 (17.06) | 0.065[a] |
| APACHE II | 18.29 (6.64) | 19.02 (6.59) | 0.629[a] |
| Gender | *n* (%) | *n* (%) | |
| Male | 27 (71.10) | 25 (65.80) | 0.622[b] |
| Female | 11 (28.90) | 13 (34.20) | |
| Cigarette smoking | | | |
| Used | 12 (31.60) | 11 (28.90) | 0.803[b] |
| Not used | 26 (68.40) | 27 (71.10) | |
| Underlying diseases | | | |
| Yes | 23 (60.50) | 18 (47.40) | 0.250[b] |
| No | 15 (39.50) | 20 (52.60) | |
| Antacid consumption | | | |
| Yes | 37 (97.40) | 36 (97.40) | 0.999[c] |
| No | 1 (2.60) | 2 (3.50) | |
| Feeding route | | | |
| NPO | 25 (65.80) | 26 (68.40) | 0.372[c] |
| TPN | 0 (0) | 2 (5.30) | |
| NGT or OGT | 13 (34.20) | 10 (26.30) | |

SD: Standard deviation; NPO: Nothing by mouth; TPN: Total parenteral nutrition; NGT: Nasogastric tube; OGT: Orogastric tube. [a]Independent *t*-test, [b]Chi-square test, [c]Fisher's exact test

**Table 2: Comparison of Clinical Pulmonary Infection Score between the intervention and control groups on the first, third, and fifth days**

| Group time | Mean (SD) | | Mann-Whitney *U* | *p* |
|---|---|---|---|---|
| | Control | Intervention | | |
| Day 1 | 4.13 (0.84) | 4.18 (0.69) | 0.16 | 0.872 |
| Day 3 | 4.44 (1.17) | 4.28 (0.95) | 0.49 | 0.624 |
| Day 5 | 4.65 (1.02) | 4.31 (0.93) | 1.79 | 0.073 |

**Table 3: Comparison of frequency of ventilator-associated pneumonia between intervention and control groups on the third and fifth days**

| Group time | VAP | Control *n* (%) | Intervention *n* (%) | $\chi^2$ | *p* |
|---|---|---|---|---|---|
| Day 3 | Yes | 6 (15.80) | 4 (10.50) | 0.46 | 0.497 |
| | No | 32 (84.20) | 34 (89.50) | | |
| Day 5 | Yes | 9 (23.70) | 3 (7.90) | 3.56 | 0.059 |
| | No | 29 (76.30) | 35 (92.10) | | |

VAP: Ventilator-associated pneumonia

it is suggested that further studies be carried out in different ICUs. Another limitation of the study was lack of sufficient supervision on nurses' performance regarding oral care implementation in the control group; therefore, we cannot confirm the accuracy of their practices, neither can we confirm that all patients received the same oral care.

## Conclusion

Based on the findings of this study, the incidence of pneumonia in the intervention group was lower than that of the control group; however, there was no significant difference between the two groups. According to different guidelines for prevention of VAP, the combination of preventive measures of VAP, such as head of bed elevation by 30°–45°, sedation reduction, assessment of patient's readiness for extubation, peptic ulcer and deep vein thrombosis prevention, oral care, hand hygiene, and subglottic suctioning, can more effectively prevent VAP. Thus, it is recommended that care providers consider the impact of oral care along with other preventive measures for VAP.

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### Conflicts of interest

Nothing to declare.

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