Head & Face Medicine

RESEARCH

Open Access

Application of double-sleeve endotracheal tube in infection control for icu patients: a randomized controlled trial

Han Sheng[1], Linyan Wang[1,2*], Yeping Fei[1], Zhihong Zhu[1] and Ping Wang[1]

Abstract

Background Poor oral hygiene in patients with tracheal intubation will increase the occurrence of dental plaque and mucosal inflammation, resulting in oral barrier dysfunction. This study aimed to design and evaluate a novel double-lumen endotracheal tube (DETT) and explore its role in infection control, particularly its effects on the oral microenvironment and ventilator-associated pneumonia (VAP).

Methods This was a prospective, non-blinded, randomized parallel-controlled trial conducted from July 2024 to September 2024. A total of 115 patients who had been intubated for more than 3 days in a tertiary hospital ICU were enrolled and randomly assigned to either the DETT group ($n=58$) or the conventional endotracheal tube (ETT) group ($n=57$). Both groups received the same oral care protocols. The DETT group was intubated with the double-lumen endotracheal tube, which included a built-in bite block, while the ETT group used a standard endotracheal tube with a bite block. The primary outcome was the incidence of VAP, while secondary outcomes included oral bacterial colony counts, biofilm formation, BOAS oral health scores, and plaque index.

Results Compared to the ETT group, the DETT group showed a significant reduction in VAP incidence ($\chi^2=4.382$, $p<0.05$). The DETT group also had significantly lower oral bacterial colony counts ($Z=-7.362$, $P<0.05$) and biofilm formation ($\chi^2=5.472$, $p<0.05$), as well as better BOAS scores ($Z=-2.774$, $p<0.05$). However, there were no significant differences between the two groups in pathogenic bacterial presence or plaque index ($p>0.05$).

Conclusions The novel double-lumen endotracheal tube effectively reduces the total bacterial load in the oral cavity, inhibits biofilm formation, and lowers the incidence of VAP. It also improves oral function and hygiene, contributing to infection control, and holds significant clinical value.

Keywords Airway management, Endotracheal intubation, Bite block, Oral cavity, Infection, Ventilator-associated pneumonia, RCT

*Correspondence:
Linyan Wang
349930938@qq.com
[1]ICU, The Affiliated Hospital of Jiaxing University, Jiaxing, China
[2]Department of Cardiology, The Affiliated Hospital of Jiaxing University, Jiaxing, China

© The Author(s) 2025. **Open Access** This article is licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License, which permits any non-commercial use, sharing, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if you modified the licensed material. You do not have permission under this licence to share adapted material derived from this article or parts of it. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit http://creativecommons.org/licenses/by-nc-nd/4.0/.

Introduction

Endotracheal intubation is a critical medical procedure in which a tube is inserted through the mouth into the trachea to help critically ill patients maintain airway patency and respiratory function. Due to its rapid and effective application, it has become a commonly used method of assisted ventilation in emergency care, surgeries, and critical care settings. However, one of the most common complications associated with orotracheal ventilation is ventilator-associated pneumonia (VAP), which accounts for 25% of all hospital-acquired infections in intensive care units (ICUs) [1]. VAP is defined as a pulmonary infection that occurs in patients who have been on invasive mechanical ventilation for more than 48 h. Several factors contribute to its development, including altered oropharyngeal colonization, increased dental plaque, antibiotic use, and aspiration [2, 3].

The oral cavity is an open system constantly exposed to microorganisms through breathing, as well as close contact with other people, animals, and the environment. As a warm, moist, and nutrient-rich ecosystem, it provides an ideal habitat for approximately 760 species of microorganisms to thrive [4]. Prolonged intubation significantly disrupts the oral microenvironment, leading to complications such as reduced saliva secretion and decreased pH levels. These conditions promote the accumulation and proliferation of pathogenic microorganisms, increasing the risk of colonization [5]. If unmanaged, these changes may trigger the onset of VAP, prolong hospitalization, and complicate overall treatment [6].

Maintaining oral hygiene in intubated patients is more challenging than in non-intubated patients. For those on mechanical ventilation, the combination of the endotracheal tube and bite block presents dual barriers that limit the depth of oral cleaning tools, restrict movement, and reduce the overall cleaning range. The bite block is hollow and cylindrical, which results in poor compatibility with the shape of the endotracheal tube. This leads to areas that are inaccessible, particularly in gaps between the palate, inner tooth surfaces, and the tube itself. These uncleanable areas become "blind spots" for oral care, significantly increasing the risk of infection and creating opportunities for antibiotic-resistant bacteria to develop. Early-stage infection rates can reach as high as 29.5% [7].

Reducing oral infections, addressing the disruption of the oral microenvironment caused by orotracheal intubation and maintaining the barrier function of the oral cavity are critical challenges. In most cases, infections are caused by aspiration of oropharyngeal flora or pathogen colonization [3]. Poor oral hygiene in intubated and critically ill patients increases the likelihood of dental plaque accumulation and mucosal inflammation, which serve as potential sources for VAP. This condition can worsen poor oral hygiene, increase mucosal inflammation, and create a vicious cycle [8]. The cost attributable to VAP has been reported to be as high as $40,144 (95% CI, $36,286 to $44,220) [9]. In critically ill patients, dental plaque can accumulate rapidly, providing a reservoir for microbial pathogens and increasing the risk of descending infections [10, 11]. In one study, 80% of oral culture samples from mechanically ventilated patients revealed high bacterial loads [12], and VAP-associated pathogens have been strongly linked to oral colonization [13], with mortality rates ranging between 20% and 30% [14]. Therefore, understanding changes in the oral microbiota of intubated patients is crucial for preventing or managing VAP in ICU settings.

Our research team has developed a novel double-lumen endotracheal tube (DETT) aimed at improving oral hygiene and maintaining the health of the oral microbiota in critically ill patients, thereby reducing the risk of infection. The product has completed development and has been granted a patent (Utility Model Patent No. ZL 2019 2 0198455.7). In this prospective, non-blinded, randomized parallel-controlled trial, we compared the innovative DETT with conventional endotracheal tubes in ICU patients. The study aimed to evaluate the impact of the DETT on oral infections, specifically its effects on biofilm formation, bacterial colonization, and the incidence of VAP, to assess its potential for maintaining oral health in critically ill patients, and to provide new clinical practice guidelines.

Methods

Study design

This study was a prospective, single-center, non-blinded, randomized controlled clinical trial. Informed consent was obtained from all participants or their authorized representatives.

Participants

The subjects of this study were all patients from the ICU of Jiaxing University Affiliated Hospital in China, who underwent mechanical ventilation via ventilators and met the inclusion criteria between July and September 2024. Inclusion criteria were age ≥ 18 years, admission to the ICU with mechanical ventilation for ≥ 3 days, no significant oral injuries or bleeding, presence of ≥ 15 natural teeth, no contraindications to elevating the head of the bed to 30° or performing oral care. Exclusion criteria were fever of 238.5 °C within 24 h after intubation, patients with a pre-existing clinical diagnosis of VAP, history of oropharyngeal, tracheal, or esophageal trauma or surgery, severe immunosuppression, including organ transplant recipients, patients with neutropenia, or those with advanced-stage malignant tumors.

Sample size

The sample size was calculated using the G*Power (version 3.1) software program [15]. Based on the incidence of ventilator-associated pneumonia (VAP) reported in relevant RCT studies [14], the observation group had 17 patients and the control group had 35 patients, with 84 patients in each group. With an alpha level of 0.05 and statistical power of 90%, the power analysis indicated that at least 103 patients should be included in each group. Considering a 15% dropout rate, a total of 115 patients were required for this study.

Randomization

The 115 patients included in this study were randomly assigned to two groups by an individual not involved in the research. Randomization was conducted using software-generated random numbers (from 1 to 115) (http://www.randomizer.org/form.htm), with a 1:1 allocatio n ratio to the observation group (DETT group) and the control group (ETT group). Both the researchers and ICU nurses were blinded to group assignments. The study adhered to the CONSORT guidelines throughout the process.

Design structure

The double-sleeve endotracheal tube (Fig. 1-B) is an improved version of the traditional endotracheal tube, consisting of an endotracheal tube (1) and a bite block (2). Its key feature is the modification of the positional relationship between the endotracheal tube and the bite block, from parallel alignment to a nested configuration. The bite block (2) is a short tube that fits over the outside of the endotracheal tube. The design also includes a buckle (10) and a fixation strap (4). The buckle (10) is connected to the upper edge of the bite block via a strap (8), and its inner diameter matches the outer diameter of the endotracheal tube. The upper ends of the bite block feature two ear slits (6, 11), with one end of the fixation strap (4) attached to one ear slit (6) and the other end serving as the tail. The tail end of the strap has a Velcro patch (5).

The endotracheal tube and its cuff are made of polyvinyl chloride (PVC), while the bite block and tube connector are made of polypropylene. Each unit is individually packaged, sterilized using ethylene oxide, and intended for single-use only.

Data collection instrument

Data were collected using a demographic questionnaire, and disease severity was measured using the Acute Physiology and Chronic Health Evaluation II (APACHE II) score. Oral hygiene status was assessed through biofilm formation, microbial analysis, dental plaque measurement, and the modified Beck Oral Assessment Scale (BOAS). Ventilator-associated pneumonia (VAP) was diagnosed based on the Modified Clinical Pulmonary Infection Score (MCPIS).

General information questionnaire

The general information questionnaire included the following items: indication for intubation, mechanical ventilation (MV) mode, positive end-expiratory pressure (PEEP) parameters, gender, age, occupation, body mass index (BMI), APACHE II score, consciousness assessment, smoking history, comorbidities, length of ICU stay, duration of MV, duration of antibiotic use, saliva volume, and oral bacterial count.

Acute physiology and chronic health evaluation II (APACHE II)

Disease severity was assessed using the APACHE II scoring system [16] at the time of ICU admission. The APACHE II is one of the most widely used scoring systems in the ICU for grading disease severity and predicting in-hospital mortality. It evaluates patients' acute physiological status and chronic health conditions, with a total score ranging from 0 to 71. The score is composed of three categories: an acute physiology score (12

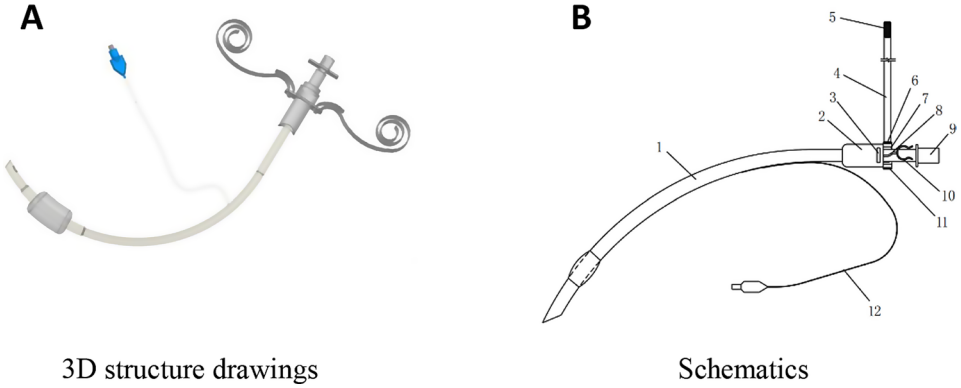

Fig. 1 Double-sleeve endotracheal tube model. (1) Tracheal tube (2) Bite block (3) Bite block stop (4) Fixation strap (5) Nylon adhesive strip (6) Ear slit (7) Semicircular tube (8) Strap (9) Tracheal tube interface (10) Buckle (11) Ear slit (12) Cuff inflation tube

parameters), a chronic health score, and an age factor, which are summed to produce the final score. A higher score indicates more severe illness, worse prognosis, and a higher likelihood of mortality [17].

Biofilm detection

After extubation, the endotracheal tubes were sent to the laboratory for examination. Laboratory personnel used scanning electron microscopy (SEM) to observe the surfaces of the endotracheal tube or bite block for the presence of extensive fibrous membrane-like structures, which served as the basis for determining biofilm formation [18]. Biofilm was confirmed if the surface of the endotracheal tube or bite block was covered with a substantial amount of fibrous membrane, with visible reticular cracks, a three-dimensional structure, and a significant bacterial attachment.

Microbial colony count

Before oral cleaning, 1 mL of saliva was collected post-extubation and sent to the laboratory for analysis. The samples were obtained by nurses from between the canine and first molar of the lower arch of each patient. Laboratory personnel used sterile pipettes to inoculate the saliva samples onto culture media for bacterial isolation, followed by qualitative and quantitative microbial assessments. A 0.1 mL sample was taken each time for semi-quantitative comparison. The culture medium used was CHROMagar Orientation (PLASTLABOR), a widely applied general-purpose medium for isolating various microorganisms, with microbial identification based on colony count comparisons.

Dental plaque index

The dental plaque index is an indicator used to assess the cleanliness of teeth and the degree of plaque accumulation [19]. After patients underwent suctioning and extubation, a plaque disclosing agent was applied to detect plaque across all tooth surfaces, with fluorescent spots indicating plaque presence.

The scoring system designed by Turesky et al., commonly used internationally, was adopted. The index grades plaque accumulation from 0 to 5, with the following scale:

0: No plaque on the tooth surface.

1: Small spots of plaque at the gingival margin of the tooth.

2: Plaque width at the gingival margin ≤ 1 mm.

3: Plaque staining band > 1 mm but covering less than 1/3 of the tooth surface.

4: Plaque covering 1/3 to 2/3 of the crown surface.

5: Plaque covering ≥ 2/3 of the tooth surface.

The dental plaque index is calculated by dividing the total plaque score by the number of teeth examined. The plaque removal rate is calculated using the formula: (pre-experiment plaque index - post-experiment plaque index) / pre-experiment plaque index.

Beck oral assessment scale (BOAS)

The modified Beck Oral Assessment Scale (BOAS) was used to evaluate oral health in intubated patients after they had undergone suctioning and extubation. In a pilot study with 60 questionnaires, the BOAS demonstrated a good reliability with a Cronbach's alpha of 0.791. This scoring system is specifically designed for assessing oral health, particularly in critically ill patients, including those receiving mechanical ventilation in the ICU [20].

BOAS evaluates five independent aspects of oral health: lips, gums and oral mucosa, tongue, teeth, and saliva. Each aspect is scored through visual inspection, with scores ranging from 1 to 4. The total score ranges from 5 to 20, where higher scores indicate poorer oral health conditions.

Modifed clinical pulmonary infection score (MCPIS)

The Modified Clinical Pulmonary Infection Score (MCPIS) was utilized to diagnose ventilator-associated pneumonia (VAP) in this study. This scoring system is widely used in ICU settings to facilitate early diagnosis and management of VAP, enabling clinicians to adjust interventions accordingly. ICU physicians assessed patients on day 1 and day 3 following intubation. MCPIS is specifically designed to evaluate the likelihood of VAP in mechanically ventilated patients. The total score ranges from 0 to 10, with a score below 6 indicating the absence of VAP, and a score of 6 or higher suggesting the presence of VAP [21].

The scoring system consists of five parameters: body temperature, white blood cell count, secretions, PaO2/FiO2 ratio, and chest X-ray findings (Table 1).

Table 1 The modified clinical pulmonary infection score

CPIS Points	0	1	2
Tracheal secretions	Rare	Abundant	Abundant + purulent
Chest X-ray infiltrates	No infiltrate	Diffused	Localized
Temperature, ℃	≥ 36.5 and ≤ 38.4	≥ 38.5 and ≤ 38.9	≥ 39 or ≤ 36
Leukocytes count, per mm^3	≥ 4,000 and ≤ 11,000	< 4,000 or > 11,000	< 4,000 or > 11,000 + band forms ≥ 500
PaO_2 /FiO_2, mmHg	> 240 or ARDS	-	≤ 240 and no evidence of ARDS
Microbiology	Negative	-	Positive

ARDS = acute respiratory distress syndrome; CPIS = clinical pulmonary infection score

Protocol

All intubations were performed by a team of experienced intensivists, each with at least 300 successful intubations. The observation group (DETT group) used the double-sleeve endotracheal tube device, while the control group (ETT group) used conventional endotracheal tubes. After intubation, oral care procedures were identical in both groups, with intermittent subglottic suctioning. Oral care involved using compound chlorhexidine mouthwash (1.2 mg/mL) every 6 h (Q6H). During care, the head of the bed was elevated to 30°–45°, and a disposable negative pressure suction toothbrush was used for both rinsing and brushing the oral cavity.

Patient demographic information was collected from family members using a general information questionnaire after intubation. To ensure the accuracy and completeness of the dataset, strict quality control measures were applied throughout the data analysis process. All researchers underwent standardized training and assessment before participating in the study. Additionally, a double-entry system with two rounds of data verification was employed, with any errors or discrepancies immediately reported to the relevant researchers for correction and clarification.

Data analysis

The data were analyzed using SPSS version 25 (SPSS Inc., Chicago, IL, USA). Continuous variables with a normal distribution were expressed as mean ± standard deviation, while non-normally distributed variables were expressed as median. Qualitative variables were presented as percentages. For comparisons of continuous variables, either the t-test or non-parametric tests were applied. Categorical variables were summarized as numbers and percentages, and compared using the χ^2 test or Fisher's exact test.

Ethical considerations

The ethical guidelines for this study were registered and approved by the Human Ethics Research Committee of Jiaxing University Affiliated Hospital (EC Nr: LS2021-KY-201-02). Before initiating the study procedures, the research objectives and processes were briefly explained to the patients, and a written informed consent form was provided. All patients who participated in the study signed the informed consent form prior to enrollment.

Results

Outcome measures

Comparison of patient characteristics

After applying the inclusion, exclusion, and elimination criteria, a total of 58 patients were included in the DETT group and 57 in the ETT group (Fig. 2). There were no significant differences in baseline characteristics between the two groups (Table 2), and 115 patients successfully completed the study. No intubation failures occurred during the procedure. Two patients in the DETT group and three patients in the ETT group did not complete the observation due to changes in their clinical conditions. The baseline characteristics of both groups were comparable ($p > 0.05$) (Table 3, 4 and 5).

Discussion

Research studies both domestically and internationally have shown that the incidence of ventilator-associated pneumonia (VAP) ranges from 5 to 55.26% [14, 23, 24]. In this study, the proportion of patients who developed VAP was 8.62% in the DETT group and 22.81% in the ETT group, with the ETT group having 2.6 times the risk of developing VAP compared to the DETT group, consistent with findings worldwide. Current nursing research primarily focuses on improving VAP rates through the use of modified mouthwashes, oral care tools, intubation methods, and head-of-bed elevation [25]. However, studies on endotracheal tubes and bite blocks mainly focus on reducing pressure injuries, with few attempts to reduce VAP by optimizing the overall structure and spatial relationship between the endotracheal tube and bite block [26].

The findings of this study suggest that the double-sleeve endotracheal tube offers advantages in controlling oral infections in ICU patients, primarily by improving the design to minimize hygiene dead spaces. Maintaining oral hygiene in mechanically ventilated patients has been shown to reduce VAP incidence [14]. The double-sleeve endotracheal tube addresses the limitations of traditional tubes in oral cleaning and monitoring, reducing bacterial adhesion and biofilm formation on the tube surface. This, in turn, lowers the risk of infection, providing a novel approach to infection control.

First, the double-sleeve tube design effectively prevents bacterial adhesion and biofilm formation. Biofilms form on endotracheal tubes, especially in patients with prolonged intubation, sheltering pathogens and making it difficult for antibiotics to eradicate infections [24]. Research shows that biofilm and oral bacteria accumulate rapidly in patients intubated for more than 48 h, significantly increasing VAP risk [27]. This study supports that finding: the total bacterial count in the ETT group was 7.16 × 10^8 CFU/mL, significantly higher than in the DETT group, and biofilm incidence in the ETT group was 54.39%, 1.7 times higher than in the DETT group. Inhibiting biofilm formation may play a critical role in reducing VAP incidence. By modifying the arrangement of the bite block and tube, the double-sleeve tube reduces the surface area exposed to the oral cavity, decreasing microbial adhesion and controlling bacterial load.

Secondly, the study found that patients using the double-sleeve endotracheal tube had better oral hygiene

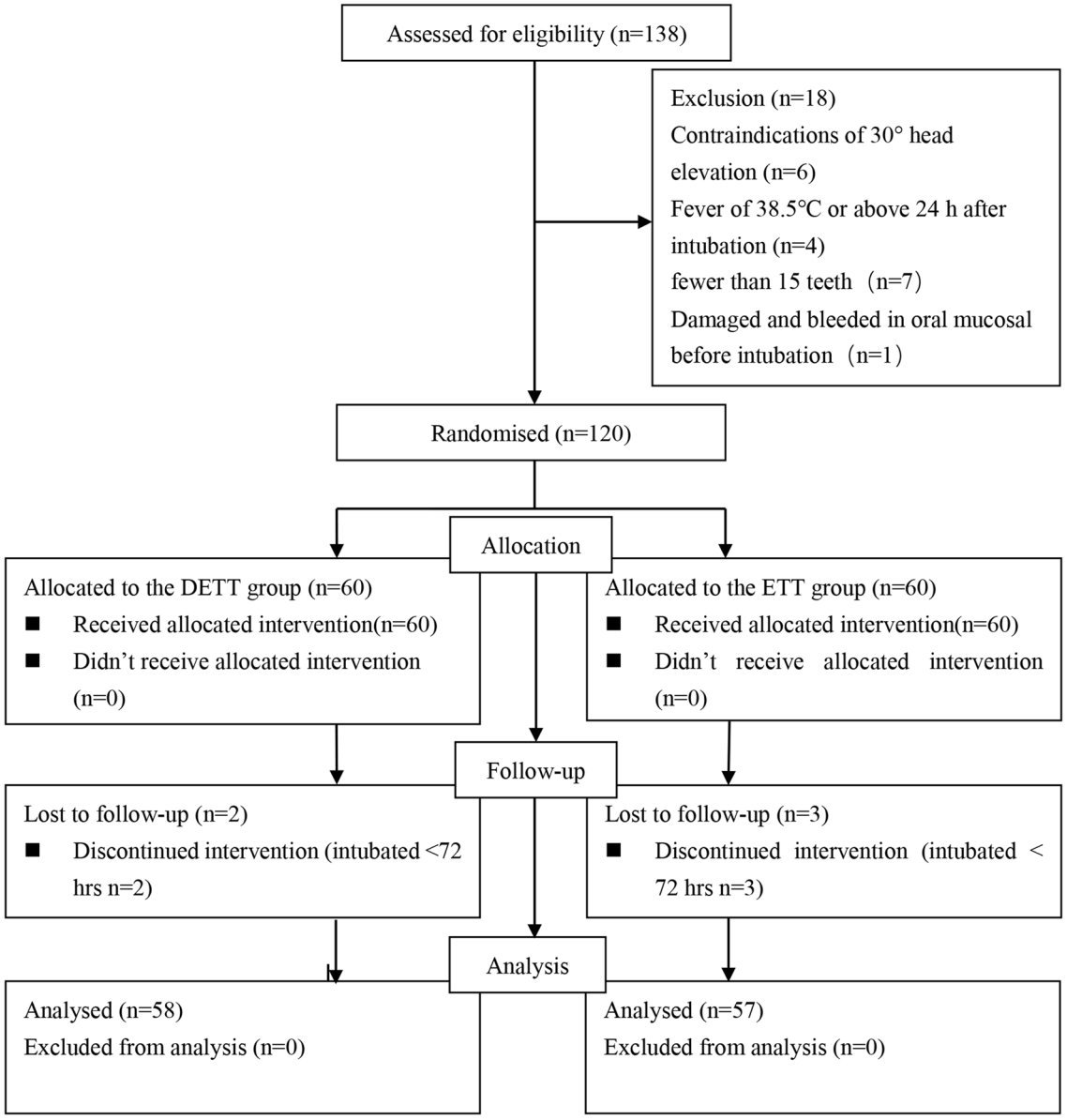

Fig. 2 Patient inclusion and exclusion flowchart

outcomes. The BOAS score in the DETT group was significantly lower than in the ETT group (Z = -2.774, $p < 0.05$), positively impacting overall oral health and further reducing the risk of lung infections. The double-sleeve tube allows more space in the oral cavity, enhancing tongue mobility and improving oral environment and function. Intubated patients often have multiple open pathways, leading to impaired mucosal hydration and reduced antimicrobial substance production. This study may help mitigate these issues by reducing excessive air exposure from dual channels [28].

Moreover, intubated patients often face challenges in oral hygiene due to incomplete oral wiping and insufficient secretion removal, which leads to bacterial growth. Various deposits in deep and hidden areas of the oral cavity are difficult to clean, resulting in bacterial adhesion [24]. The endotracheal tube and bite block create "blind spots," complicating the cleaning of areas like the sublingual, tongue base, oropharynx, and both sides of the cheeks [29]. The double-sleeve endotracheal tube developed in this study reduces oral care difficulties by providing more space for tools like toothbrushes and swabs, facilitating thorough rinsing, improving secretion drainage, and reducing dental plaque and bacterial accumulation.

Nevertheless, this study found no significant difference in the number of patients carrying pathogenic bacteria between the two groups ($p > 0.05$), indicating

Table 2 Characteristics of patients at baseline

Characteristics	DETT group ($n=58$)	ETT group ($n=57$)	Z/χ^2	*p* value
Indication for intubation, n(%)				0.861[a]
Respiratory failure	27(46.55)	30(52.63)		
Altered mental status	22(37.93)	18(31.58)		
Airway obstruction	6(10.34)	7(12.28)		
Haemodynamic instability	3(5.17)	2(3.51)		
Type of mechanical breaths, n (%)			1.465	0.226
Volume control	36(62.07)	29(50.88)		
Pressure control	22(37.93)	28(49.12)		
PEEP[cmH_2O, $M(P_{25}, P_{75})$**]**	4.00(4.00,5.25)	5.00(4.00,5.50)	-0.669	0.504
Sex, n(%)			0.076	0.783
Male	46(79.31)	44(77.19)		
Female	12(20.69)	13(22.81)		
Age[year, $M(P_{25}, P_{75})$**]**	68.50(55.00,77.00)	71.00(62.50,79.00)	-1.548	0.122
Occupation, n (%)				0.513[a]
Farmer	30(51.72)	27(47.37)		
Worker	3(5.17)	6(10.53)		
Retired	15(25.86)	18(31.58)		
Freelance	10(17.24)	6(10.53)		
BMI[kg/m^2, $M(P_{25}, P_{75})$**]**	22.92(18.65,24.16)	22.49(20.72,24.46)	-0.523	0.601
APACHE II[scores, $M(P_{25}, P_{75})$**]**	16.00(12.00,22.00)	15.00(11.00,20.00)	-0.462	0.644
Consciousness, n (%)			0.450	0.502
Conscious	31(53.45)	34(59.65)		
Unconscious	27(46.55)	23(40.35)		
Smoking status, n (%)			0.028	0.866
Yes	44(75.86)	44(77.19)		
No	14(24.14)	13(22.81)		
Comorbidities *, n (%)			2.708	0.100
Yes	44(75.86)	50(87.72)		
No	14(24.14)	7(12.28)		
ICU Length of Stay[d, $M(P_{25}, P_{75})$**]**	7.50(6.00,9.00)	8.00(6.00,10.00)	-0.254	0.800
The number of days of intubation[d, $M(P_{25}, P_{75})$**]**	6.00(4.75,7.00)	5.00(4.00,7.00)	-1.762	0.078
Antibiotic days[d, $M(P_{25}, P_{75})$**]**	7.00(4.50,9.00)	6.00(0.00,8.00)	-0.953	0.341
Saliva volume[ml, $M(P_{25}, P_{75})$**]**	2.90(2.24,3.50)	2.86(2,21,3.27)	-0.655	0.512
Bacterial count[CFU/mL, $M(P_{25}, P_{75})$**]**	$0.98(0.89,1.11)\times10^8$	$1.02(0,90,1.17)\times10^8$	-0.907	0.365

*Comorbidities include diabetes, hypertension, and coronary artery disease

[a] indicates Fisher's exact test

Table 3 Outcomes of oral infection indicators

Outcome	DETT group ($n=58$)	ETT group ($n=57$)	Z/χ^2	*p* value
Primary outcome				
VAP, n(%)	5(8.62)	13(22.81)	4.382	0.036
Secondary outcomes				
Total number of biofilm formation, n(%)	19(32.76)	31(54.39)	5.472	0.019
Biofilm formation: Endotracheal intubation, n(%)	12(20.69)	21(36.84)		
Biofilm formation: Bite block, n(%)	7(12.07)	10(17.54)		
Bacterial count **[**CFU/mL, $M(P_{25}, P_{75})$**]**	$4.27(3.63,5.31)\times10^8$	$7.16(6.05,7.67)\times10^8$	-7.362	<0.001
BOAS **[**scores, $M(P_{25}, P_{75})$**]**	5.00(5.00,5.00)	5.00(5.00,6.00)	-2.774	0.006
Plaque Index **[**scores, $M(P_{25}, P_{75})$**]**	0.00(0.00,1.00)	0.00(0.00,1.50)	-0.195	0.845

Table 4 Comparison of the number of patients with Pathogenic Bacteria in the oral cavity

Outcome	DETT group($n=58$)	ETT group ($n=57$)	χ^2	*p* value
Total number of patients, n(%)	10(17.24)	18(31.58)	3.208	0.073
Streptococcus pneumoniae, n(%)	0	0	-	-
Haemophilus influenzae, n(%)	0	0	-	-
Staphylococcus aureus, n(%)	5(8.62)	8(14.04)	0.841	0.359
Pseudomonas aeruginosa, n(%)	4(6.89)	7(12.28)	0.963	0.326
Enterobacter cloacae, n(%)	0	0	-	-
Escherichia coli,, n(%)	0	0	-	-
Candida albicans, n(%)	1(1.72)	2(3.51)	-	0.618[a]
Acinetobacter Baumannii, n(%)	0	1(1.75)	-	0.496[a]

[a] indicates Fisher's exact test

Table 5 Stratified Analysis of Total Bacterial Count, BOAS Score, and VAP in patients with different disease risk levels. Stratified analysis was performed based on the median APACHE II score of 16, following methods used in other studies [22]. Patients were divided into subgroups: low-risk (APACHE II < 16) and medium-to-high risk (APACHE II ≥ 16)

	Low risk APACHE II<16($n=54$)		Moderate and high risk APACHE II≥16($n=61$)	
Characteristics	**DETT group ($n=25$)**	**ETT group ($n=29$)**	**DETT group ($n=33$)**	**ETT group ($n=28$)**
Bacteria count (CFU/mL,$\bar{x}\pm s$)	$4.50\pm1.26\times10^8$	$7.09\pm1.37\times10^8$	$4.33\pm1.42\times10^8$	$6.72\pm1.29\times10^8$
t	-7.158		-6.842	
***p*value**	<0.001		<0.001	
BOAS [scores, M(P_{25}, P_{75})]	5.00(5.00,5.00)	5.00(5.00,6.00)	5.00(5.00,5.50)	5.50(5.00,6.00)
Z	-1.899		-2.339	
***p*value**	0.058		0.019	
VAP, n(%)	3(12.00)	4(13.79)	2(6.06)	9(32.14)
χ^2	-		6.972	
***p*value**	0.100[a]		0.008	

[a] indicates Fisher's exact test

the intervention did not significantly reduce pathogen presence. The primary oral pathogens identified in both groups were Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, and Candida tropicalis. Research has shown that the oral microbiome structure of intubated patients differs significantly from healthy individuals, with intubated patients exhibiting a distorted microbiome [30]. These pathogens are either absent or present in minimal quantities in healthy individuals [31]. In intubated patients, Staphylococcus aureus and Acinetobacter baumannii are opportunistic pathogens that primarily infect critically ill patients, leading to nosocomial infections, most commonly VAP or central venous catheter-related bloodstream infections [32]. These bacteria are major VAP pathogens in some Asian countries [33, 34].

Identifying the appropriate target population for the double-sleeve endotracheal tube is a key issue. Stratified analysis based on risk revealed that as APACHE II scores increased, so did VAP incidence and patient mortality rates [25, 35]. Compared to the low-risk group, medium-to-high risk patients (APACHE II score ≥ 16) using the double-sleeve endotracheal tube had significantly lower oral bacterial counts, BOAS scores, and VAP incidence. This suggests that the double-sleeve endotracheal tube holds promise for critically ill patients.

While the double-sleeve tube does not have strong antimicrobial properties on its own, combined with effective oral care, it can significantly reduce oral pathogen load. This intervention plays a role in minimizing infection sources and interrupting transmission chains. Studies have shown that endotracheal tubes often act as vectors for infection, with the highest VAP risk occurring between 48 h post-intubation and 48 h post-extubation [36]. A review of previous research shows that standard ICU care for mechanically ventilated patients often focuses on basic nursing, neglecting oral and oropharyngeal hygiene [20, 37, 38]. Providing easily cleaned endotracheal tubes and bite blocks offers an effective non-pharmacological intervention, addressing the limitations of conventional oral care in ICU patients. This approach presents a practical solution for improving oral hygiene in mechanically ventilated patients and reducing infection risks.

Despite the demonstrated effectiveness of the double-sleeve endotracheal tube in this study, several limitations

should be noted. First, the study was conducted at a single center with a relatively small sample size, which may limit the generalizability of the findings. Second, the use of antibiotics could have significantly reduced species diversity and increased the relative abundance of certain bacterial groups. Since most patients were receiving antibiotic therapy, the impact of antibiotics on oral microbiome diversity may have influenced the results, necessitating further investigation. Additionally, while the study showed a significant reduction in total bacterial load, it did not significantly reduce the number of pathogenic bacteria. Future improvements, such as the development of antimicrobial coatings on the endotracheal tube, may enhance the product's efficacy. Furthermore, the study primarily focused on short-term outcomes. The long-term safety and efficacy of the double-sleeve endotracheal tube still require validation through larger-scale studies and extended follow-up.

Conclusions

This study is the first to confirm the potential benefits of the double-sleeve endotracheal tube in reducing oral infections, inhibiting biofilm and dental plaque formation, and lowering the incidence of ventilator-associated pneumonia (VAP) in ICU patients. Its innovative design not only improves the quality of endotracheal tube-related oral care but also provides a novel intervention for healthcare providers. The clinical application of the double-sleeve endotracheal tube offers a new approach for protecting the oral microenvironment, enhancing care quality, and promoting oral health in patients. Additionally, subgroup analysis demonstrated that its use is particularly advantageous in patients with higher disease severity, highlighting its greater clinical value for critically ill populations.

Abbreviations

VAP	ventilator-associated pneumonia
ICU	intensive care unit
APACHE	Acute Physiology and Chronic Health Evaluation
BOAS	Beck Oral Assessment Scale
MCPIS	Modified Clinical Pulmonary Infection Score
MV	mechanical ventilation
PEEP	positive end-expiratory pressure
BMI	body mass index
SEM	scanning electron microscopy

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13005-025-00488-8.

Supplementary Material 1

Acknowledgements

We thank all study participants who joined this study.

Author contributions

H. S. and L. Y. W. contributed to the study conception and design. Data collection were performed by D. Y. Z. and P. W. Statistical analysis were done by L. Y. W. Writing the article were performed by H. S. and L. Y. W. Planning and supervision were done by Y. P. F. and Z. H. Z. All authors read and approved the final manuscript. The authors declare no competing interests.

Funding

This research was funded by Jiaxing Science and Technology Program under Grant Nos. (2022AY30015) and Jiaxing Key Discipline of Medicine on Nursing (2023-ZC-007).

Data availability

Data is provided within supplementary information files.(data.sav).

Declarations

Ethics approval and consent to participate

The trial was approved by the Human Ethics Research Committee of the Affiliated Hospital of Jiaxing University (LS2021-KY-201-02).

Consent for publication

We adhered to ethical guidelines by obtaining approval from the Human Ethics Research Committee of the Affiliated Hospital of Jiaxing University (LS2021-KY-201-02). All participants were given a detailed explanation of the study's objectives and signed informed consent forms before enrollment, ensuring voluntary participation and confidentiality.

Competing interests

The authors declare no competing interests.

Received: 26 October 2024 / Accepted: 6 February 2025
Published online: 26 February 2025

References

1. Nusrat T, Akter N, Rahman NAA, Godman B, DT DR, Haque M. (2020) Antibiotic resistance and sensitivity pattern of Metallo-β-Lactamase Producing Gram-Negative Bacilli in ventilator-associated pneumonia in the intensive care unit of a public medical school hospital in Bangladesh. Hospital practice (1995) 48:128–136. https://doi.org/10.1080/21548331.2020.1754687
2. Dalben YR, Pimentel J, Maifrede SB, Carvalho JA, Bessa-Neto FO, Gomes JFS, Leite GR, Rodrigues AM, Cayô R, Grão-Velloso TR, Gonçalves SS. Early Candida colonisation impact on patients and healthcare professionals in an intensive care unit. Mycoses. 2024;67:e13786. https://doi.org/10.1111/myc.13786.
3. Fally M, Haseeb F, Kouta A, Hansel J, Robey RC, Williams T, Welte T, Felton T, Mathioudakis AG. Unravelling the complexity of ventilator-associated pneumonia: a systematic methodological literature review of diagnostic criteria and definitions used in clinical research. Crit Care (London England). 2024;28:214. https://doi.org/10.1186/s13054-024-04991-3.
4. Mark Welch JL, Ramírez-Puebla ST, Borisy GG. Oral Microbiome Geography: Micron-Scale Habitat and Niche. Cell Host Microbe. 2020;28:160–8. https://doi.org/10.1016/j.chom.2020.07.009.
5. Chang Y, Jeon K, Lee SM, Cho YJ, Kim YS, Chong YP, Hong SB. The distribution of Multidrug-resistant microorganisms and treatment status of Hospital-acquired Pneumonia/Ventilator-associated Pneumonia in Adult Intensive Care units: a prospective cohort Observational Study. J Korean Med Sci. 2021;36:e251. https://doi.org/10.3346/jkms.2021.36.e251.
6. Barbier F, Dupuis C, Buetti N, Schwebel C, Azoulay É, Argaud L, Cohen Y, Hong Tuan Ha V, Gainnier M, Siami S, Forel JM, Adrie C, de Montmollin É, Reignier J, Ruckly S, Zahar JR, Timsit JF. Single-drug versus combination antimicrobial therapy in critically ill patients with hospital-acquired pneumonia and ventilator-associated pneumonia due to Gram-negative pathogens: a multicenter retrospective cohort study. Crit Care (London England). 2024;28:10. https://doi.org/10.1186/s13054-023-04792-0.
7. Xie J, Yang Y, Huang Y, Kang Y, Xu Y, Ma X, Wang X, Liu J, Wu D, Tang Y, Qin B, Guan X, Li J, Yu K, Liu D, Yan J, Qiu H. The current Epidemiological Landscape of Ventilator-associated Pneumonia in the Intensive Care Unit: a Multicenter prospective observational study in China. Clin Infect Diseases: Official

Publication Infect Dis Soc Am. 2018;67:S153–61. https://doi.org/10.1093/cid/ciy692.
8. Cooper AS. Oral Hygiene Care to Prevent Ventilator-Associated Pneumonia in critically ill patients. Crit Care Nurse. 2021;41:80–2. https://doi.org/10.4037/ccn2021314.
9. Papazian L, Klompas M, Luyt CE. Ventilator-associated pneumonia in adults: a narrative review. Intensive Care Med. 2020;46:888–906. https://doi.org/10.1007/s00134-020-05980-0.
10. Bostanghadiri N, Kouhzad M, Taki E, Elahi Z, Khoshbayan A, Navidifar T, Darban-Sarokhalil D. Oral microbiota and metabolites: key players in oral health and disorder, and microbiota-based therapies. Front Microbiol. 2024;15:1431785. https://doi.org/10.3389/fmicb.2024.1431785.
11. Karimi S, Kolyaei E, Karimi P, Rahmani K. Effectiveness of supervised implementation of an oral health care protocol on ventilator-associated pneumonia patients in intensive care units: a double-blind multicenter randomized controlled trial. Infect Prev Pract. 2023;5:100295. https://doi.org/10.1016/j.infpip.2023.100295.
12. Kitsios GD, Fitch A, Manatakis DV, Rapport SF, Li K, Qin S, Huwe J, Zhang Y, Doi Y, Evankovich J, Bain W, Lee JS, Methé B, Benos PV, Morris A, McVerry BJ. Respiratory microbiome profiling for Etiologic diagnosis of Pneumonia in mechanically ventilated patients. Front Microbiol. 2018;9:1413. https://doi.org/10.3389/fmicb.2018.01413.
13. Emonet S, Lazarevic V, Leemann Refondini C, Gaïa N, Leo S, Girard M, Nocquet Boyer V, Wozniak H, Després L, Renzi G, Mostaguir K, Dupuis Lozeron E, Schrenzel J, Pugin J. Identification of respiratory microbiota markers in ventilator-associated pneumonia. Intensive Care Med. 2019;45:1082–92. https://doi.org/10.1007/s00134-019-05660-8.
14. Jahanshir M, Nobahar M, Ghorbani R, Malek F. Effect of clove mouthwash on the incidence of ventilator-associated pneumonia in intensive care unit patients: a comparative randomized triple-blind clinical trial. Clin Oral Invest. 2023;27:3589–600. https://doi.org/10.1007/s00784-023-04972-w.
15. Amrani G, Gefen A. Which endotracheal tube location minimises the device-related pressure ulcer risk: the centre or a corner of the mouth? Int Wound J. 2020;17:268–76. https://doi.org/10.1111/iwj.13267.
16. Knaus WA, Draper EA, Wagner DP, Zimmerman JE. An evaluation of outcome from intensive care in major medical centers. Ann Intern Med. 1986;104:410–8. https://doi.org/10.7326/0003-4819-104-3-410.
17. Troisi F, Guida P, Vitulano N, Argentiero A, Passantino A, Iacoviello M, Grimaldi M. Clinical complexity of an Italian cardiovascular intensive care unit: the role of mortality and severity risk scores. J Cardiovasc Med (Hagerstown Md). 2024;25:511–8. https://doi.org/10.2459/jcm.0000000000001632.
18. Jakubovics NS, Goodman SD, Mashburn-Warren L, Stafford GP, Cieplik F. The dental plaque biofilm matrix. Periodontol 2000. 2021;86:32–56. https://doi.org/10.1111/prd.12361.
19. Ren X, He J, Cheng R, Chen Y, Xiang Y, Zhang Y, Jiang S, Li J, Cheng L, Hu T. The efficacy and safety of oral irrigator on the Control of Dental Plaque and Gingivitis: a Randomized, Single-Blind, parallel-group clinical trial. Int J Environ Res Public Health. 2023;20. https://doi.org/10.3390/ijerph20043726.
20. Winning L, Lundy FT, Blackwood B, McAuley DF, El Karim I. Oral health care for the critically ill: a narrative review. Crit Care (London England). 2021;25:353. https://doi.org/10.1186/s13054-021-03765-5.
21. Fartoukh M, Maitre B, Honoré S, Cerf C, Zahar JR, Brun-Buisson C. Diagnosing pneumonia during mechanical ventilation: the clinical pulmonary infection score revisited. Am J Respir Crit Care Med. 2003;168:173–9. https://doi.org/10.1164/rccm.200212-1449OC.
22. Santhakumaran S, Gordon A, Prevost AT, O'Kane C, McAuley DF, Shankar-Hari M. Heterogeneity of treatment effect by baseline risk of mortality in critically ill patients: re-analysis of three recent sepsis and ARDS randomised controlled trials. Crit Care (London England). 2019;23:156. https://doi.org/10.1186/s13054-019-2446-1.
23. Lei S, Liu Y, Zhang E, Liu C, Wang J, Yang L, Zhang P, Shi Y, Sheng X. Influence of oral comprehensive nursing intervention on mechanically ventilated patients in ICU: a randimized controlled study. BMC Nurs. 2023;22:293. https://doi.org/10.1186/s12912-023-01464-w.
24. Thorarinsdottir HR, Kander T, Holmberg A, Petronis S, Klarin B. Biofilm formation on three different endotracheal tubes: a prospective clinical trial. Crit Care (London England). 2020;24:382. https://doi.org/10.1186/s13054-020-03092-1.
25. Nair GB, Niederman MS. Ventilator-associated pneumonia: present understanding and ongoing debates. Intensive Care Med. 2015;41:34–48. https://doi.org/10.1007/s00134-014-3564-5.
26. Zhang X, Zhang Q, You J, Xu R, Zhang Z, Shi Y, Han C, Zhao S, Yao B, Geng Y, Liu S. Effect of a self-developed fixation device on preventing endotracheal intubation-related pressure injury: a randomised controlled trial. Crit Care (London England). 2024;28:87. https://doi.org/10.1186/s13054-024-04874-7.
27. Gil-Perotin S, Ramirez P, Marti V, Sahuquillo JM, Gonzalez E, Calleja I, Menendez R, Bonastre J. Implications of endotracheal tube biofilm in ventilator-associated pneumonia response: a state of concept. Crit Care (London England). 2012;16:R93. https://doi.org/10.1186/cc11357.
28. Wittekamp BH, Plantinga NL. Less daily oral hygiene is more in the ICU: no. Intensive Care Med. 2021;47:331–3. https://doi.org/10.1007/s00134-021-06359-5.
29. Dale CM, Angus JE, Sutherland S, Dev S, Rose L. Exploration of difficulty accessing the mouths of intubated and mechanically ventilated adults for oral care: a video and photographic elicitation study. J Clin Nurs. 2020;29:1920–32. https://doi.org/10.1111/jocn.15014.
30. Kelly BJ, Imai I, Bittinger K, Laughlin A, Fuchs BD, Bushman FD, Collman RG. Composition and dynamics of the respiratory tract microbiome in intubated patients. Microbiome. 2016;4:7. https://doi.org/10.1186/s40168-016-0151-8.
31. Takahama A Jr., de Sousa VI, Tanaka EE, Ono E, Ito FAN, Costa PP, Pedriali M, de Lima HG, Fornazieri MA, Correia LS, Cardoso LTQ, de Maio Carrilho CMD. Analysis of oral risk factors for ventilator-associated pneumonia in critically ill patients. Clin Oral Invest. 2021;25:1217–22. https://doi.org/10.1007/s00784-020-03426-x.
32. Harding CM, Hennon SW, Feldman MF. Uncovering the mechanisms of Acinetobacter baumannii virulence. Nat Rev Microbiol. 2018;16:91–102. https://doi.org/10.1038/nrmicro.2017.148.
33. Song JH. Treatment recommendations of hospital-acquired pneumonia in Asian countries: first consensus report by the Asian HAP Working Group. Am J Infect Control. 2008;36. https://doi.org/10.1016/j.ajic.2007.01.015. S83-92.
34. Choi JY, Kwak YG, Yoo H, Lee SO, Kim HB, Han SH, Choi HJ, Kim HY, Kim SR, Kim TH, Lee H, Chun HK, Kim JS, Eun BW, Kim DW, Koo HS, Cho EH, Lee K. (2016) Trends in the distribution and antimicrobial susceptibility of causative pathogens of device-associated infection in Korean intensive care units from 2006 to 2013: results from the Korean nosocomial infections Surveillance System (KONIS). The Journal of hospital infection 92:363– 71. https://doi.org/10.1016/j.jhin.2015.12.012
35. He Q, Wang W, Zhu S, Wang M, Kang Y, Zhang R, Zou K, Zong Z, Sun X. The epidemiology and clinical outcomes of ventilator-associated events among 20,769 mechanically ventilated patients at intensive care units: an observational study. Crit Care (London England). 2021;25:44. https://doi.org/10.1186/s13054-021-03484-x.
36. Marjanovic N, Boisson M, Asehnoune K, Foucrier A, Lasocki S, Ichai C, Leone M, Pottecher J, Lefrant JY, Falcon D, Veber B, Chabanne R, Drevet CM, Pili-Floury S, Dahyot-Fizelier C, Kerforne T, Seguin S, de Keizer J, Frasca D, Guenezan J, Mimoz O. Continuous pneumatic regulation of Tracheal Cuff pressure to decrease ventilator-associated Pneumonia in Trauma patients who were mechanically ventilated: the AGATE Multicenter Randomized Controlled Study. Chest. 2021;160:499–508. https://doi.org/10.1016/j.chest.2021.03.007.
37. Roberts N, Moule P. Chlorhexidine and tooth-brushing as prevention strategies in reducing ventilator-associated pneumonia rates. Nurs Crit Care. 2011;16:295–302. https://doi.org/10.1111/j.1478-5153.2011.00465.x.
38. Asadi N, Jahanimoghadam F. Oral care of intubated patients, challenging task of ICU nurses: a survey of knowledge, attitudes and practices. BMC Oral Health. 2024;24:925. https://doi.org/10.1186/s12903-024-04652-5.

Publisher's note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.