

Official Title of the study:

The Impact of Different Methods of Oral Hygiene on Incidence of Ventilator Associated Pneumonia in PICU

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What is already known on this subject? What does this study add?

Ventilator associated pneumonia (VAP) is a potentially serious complication in critically ill children who are admitted to the Pediatric intensive care unit (PICU).

The Institute for Healthcare Improvement (IHI) introduced a “bundle” that collectively and reliably performs a set of evidence-based practices, which have been proven to improve patient outcomes.

The VAP bundle is composed of five major interventions which include daily oral care with chlorhexidine. (*R. Resar et al., 2005*)

In this study we will assess the effects of different methods of oral care on incidence of VAP in critically ill patients who will be admitted & mechanically ventilated in PICU Ain Shams University Children hospital and will determine its impact on length of PICU stay, days on mechanical ventilation and mortality.

1.Introduction

Ventilator-associated pneumonia (VAP) is defined by the Center for Disease Control and Prevention (CDC) and National Healthcare Safety Network (NHSN) as new and persistent radiographic infiltrates and worsening gas exchange in children who are ventilated for at least 48 hours and who exhibit at least 3 of the following criteria: temperature instability with no other recognized cause, leukopenia, change in the characteristic of respiratory secretions, respiratory distress and bradycardia or tachycardia (*Semenkovich et al., 2019*).

VAP is the second most common hospital-acquired infection among PICU patients. It accounts for 7% to 32% of healthcare-associated infections and 10% of all pediatric device-related infections reported to NHSN. (*Bhattacharya et al., 2023*).

The hypothesis of oral care regimes in PICU is to decrease infectious, inflammatory, and painful symptoms that occur in critically ill patients: mechanically (by removing the biofilm through brushing the teeth and tongue) and pharmacologically (by using antiseptic agents). (*Gomaa et al., 2017*).

Several studies were carried out in different PICUs using different oral hygiene regimes. These studies concerned with the effect of application of these regimes on the prevalence of VAP, mortality, and duration of mechanical ventilation. Most studies evaluated chlorhexidine (CHX) based regimes and its effect on incidence of VAP.

In a Cochrane Library systematic review on oral care strategies for critically ill patients to prevent VAP, the authors concluded that antiseptics and tooth brushing may be more effective than standard oral health hygiene strategies in reducing the incidence of VAP and the length of PICU stay (*Gregorczyk-Maga et al., 2023*).

2.Aim

1. To determine incidence of VAP in patients who will be admitted to PICU with routine oral hygiene in comparison to those using brushing and chlorhexidine.
2. To detect the impact of different methods of oral hygiene on mechanically ventilated patients regarding duration of mechanical ventilation, length of PICU stay and mortality rate.

3.Patients and Methods

- **Study Setting:** The study will be carried out in Ain-Shams University Children hospital, Pediatric Intensive Care Units (PICUs).
- **Study Design:** Randomized Control Trial.
- **Study Period:** until fulfillment of the study.
- **Ethical Considerations:** This study will start after approval of the " Research Ethics Committee" of Ain- Shams University Hospitals. Written consent will be obtained from the legal guardians of the patient. The guardians have the right to withdraw from the study at any time.
- **Study Population:** any patients aged from 18 months to 16 years admitted to PICU fulfilling inclusion criteria.
- **Inclusion criteria:**
 - Patients who will be on invasive mechanical ventilation.
 - Dentate patient.
 - Aged 18 months -16 years old.
- **Exclusion criteria:**
 - Patients with primary Immune deficiency.
 - Coagulation disorders.
 - Jaw fractures.
- **Sample Size:** 118 pediatric patients.
Based on the results of (**Vidal et al. 2017**) showing that among patients admitted to intensive care unit, the incidence of ventilator associated pneumonia in patients on oral care involving tooth brushing with chlorhexidine was lower than in patients on oral hygiene by chlorhexidine swab only (37,8% and 62,2% respectively).

4.Methodology:

The following assessment will be done to each patient. 1-

History:

- Demographic data: (name, age, sex).
- Medical diagnosis on admission.
- Comorbidities.
- Need for inotropic support.
- Day of worsening of respiratory symptoms after ventilation.
- Fate

Risk factors:

- Days in (PICU) until intubation. ○ Days on mechanical ventilation (MV) until infection.
- Potential risk factors: inhaled bronchodilators, proton pump inhibitors, neuromuscular blockers (doses & duration).
- Route of mechanical ventilation: Nasotracheal, endotracheal, tracheostomy. ○ Method of nutrition: Nasogastric tube, parenteral, gastrostomy.
- The antibiotic used (name, including duration, need to switch) .

1- **General examination:** Routine monitoring of Temperature, Heart Rate, Respiratory Rate, Blood Pressure.

Physical examination: Chest auscultation.

Then patients will be divided into 2 groups (59 patients in each group).

• **Sample Grouping:** VAP bundle will be applied in both groups

Intervention group: Brushing plus 0.12% chlorhexidine mouthwash.

All patients will be placed in semi recumbent position (head up position by elevating the head of their bed 30 to 45degree angle). Mouth care will be performed at least 5 minutes in each session as long as the patient is on invasive mechanical ventilation.

Patient will receive brushing by soft tooth brush and toothpaste three times daily using the Bass technique (toothbrush should be positioned at a 45 degree angle with a firm yet gentle pressure , brush back and forth or use a circular motion 15 to 20 times before moving to the next area) for one minute, plus application of 0.12% chlorhexidine mouthwash to a swab on the oral mucosa, teeth, gums, hard palate, and tongue, followed by 20 mL of normal saline , the procedure will be finished with hypo pharyngeal suctioning.

Control group: routine PICU oral care which is rinsing mouth with 0.12% chlorhexidine that is applied to a swab and rubbing it on the surface of the tongue, gum and mucosa followed by 20 mL of normal saline, three times daily, the procedure will be finished with hypo pharyngeal suctioning.

Oral Care protocol:

- Pediatric dentist will be assigned to train the PICU nurses to follow the proper Oral Care Protocol including brushing technique, mouth rinses and intraoral massaging.

2- Investigations:

a) Laboratory:

- I. CBC with differential,
- II. C- reactive Protein (CRP),
- III. Venous blood gases (VBG),
- IV. Bio-fire if available, Sputum culture, Blood culture.

The first day, the data will be collected as the pre-test data. Then the second, third- and fourth-days data will be considered as the first, second and third post-test data sets respectively. The sputum cultures will be collected on the fifth day.

- b) Radiology:** initial Chest x-ray on admission and follow up (to detect development of new infiltration or consolidation).

Microbiology: Microbiological data collected (microorganisms isolated from sputum culture and blind broncho-alveolar lavage with their antibiotic susceptibility).

5. Statistical Analysis: The data will be collected, revised, coded, and tabulated, Statistical analysis by the appropriate statistical tests will be done using SPSS (statistical package for social science) program latest version available.

6. References:

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3. **Gregorczyk-Maga I, Palka A, Fiema M, Kania M, Kujawska A, Maga P, et al. (2023):** Impact of tooth brushing on oral bacteria and health care-associated infections among ventilated COVID-19 patients: an intervention study. *Antimicrobial Resistance & Infection Control*. 2023; 12(1):17.
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