24/09/2025

INVESTIGATION OF THE EFFECT OF TWO DIFFERENT ORAL CARE METHODS ON ORAL FLORA AND VENTILATOR ASSOCİATED PNEUMONIA IN MECHANİCALLY VENTİLATED PATIENTS:

A RANDOMIZED CONTROLLED STUDY

NCT ID not yet assigned

1. Title

The Effect of Two Different Oral Care Methods (Pediatric Toothbrush and Sponge Stick) on Oral Flora and Ventilator-Associated Pneumonia in Mechanically Ventilated ICU Patients: A Randomized Controlled Trial

2. Acronym

ORAVAP-RCT

3. Background

In critically ill patients receiving mechanical ventilation, the oral microflora changes within 48 hours of intubation, with Gram-negative bacteria associated with nosocomial pneumonia replacing the normal Gram-positive flora (Miranda et al., 2016; Karateke ve Terzi, 2021). Ventilator-associated pneumonia (VAP) is associated with high mortality, prolonged hospital stays, increased antibiotic use, and healthcare costs (Ozveren., 2010).

Although both sponge sticks and toothbrushes are widely used in the ICU settings for oral care, the comparative effectiveness of these methods in preventing VAP remains unclear. Establishing evidence-based oral care practices is critical for reducing infection risk and improving patient outcomes.

4. Objectives and Hypotheses

Objective: To compare the effects of two oral care methods (pediatric toothbrush vs sponge stick) on oral bacterial colonization and the incidence of VAP in mechanically ventilated ICU patients.

Hypothesis: Oral care performed with a pediatric toothbrush is more effective than a sponge stick in reducing Gram-negative bacterial colonization and preventing the development of VAP.

5. Study Design

Type: Randomized controlled trial

Model: Parallel assignment (2 arms)

Masking: Single-blind (independent outcome assessor)

Allocation: Randomized

6. Study Setting and Participants

The study will be conducted in the Anesthesia and General Intensive Care Unit of a hospital in Türkiye between October 2025 and June 2026.

Inclusion Criteria

- Age ≥18 years,
- Receiving invasive mechanical ventilation for less than 24 hours,
- Informed consent obtained from legal guardian,

- No history of oral/maxillofacial surgery or head/neck trauma,
- No contraindications to oral care.

Exclusion Criteria

- Age <18 years,
- Diagnosed pneumonia prior to intubation,
- No informed consent,
- Contraindications to oral care.

7. Interventions

Arm 1 (Experimental): Pediatric toothbrush + 0.12% chlorhexidine oral care set

Arm 2 (Active Comparator): Sponge stick + 0.12% chlorhexidine oral care set

Both groups will receive oral care for 5 consecutive days.

8. Outcome Measures

Primary Outcome

Oral bacterial colonization (Staphylococcus spp., Pseudomonas spp., Acinetobacter spp.) will be assessed by oral swabs on Day 1 and Day 6.

Key Secondary Outcome

Incidence of VAP – will be evaulated using the Clinical Pulmonary Infection Score (CPIS ≥6) during the Day 1 and Day 6.

Additional Secondary Outcomes

Frequency and quality of oral care as will be measured by the Oral Care Assessment Scale for Intensive Care Patients developed by the researchers (daily assessments for 5 days).

9. Sample Size

Total: 72 patients (36 in pediatric toothbrush group, 36 in sponge stick group).

Based on power analysis: 80% power, 5% alpha error to detect significant differences.

10. Randomization and Masking

Randomization will be performed using computer-based block randomization.

Masking: Nurses providing oral care will not be blinded, but microbiology laboratory staff assessing bacterial cultures will remain blinded to group allocation.

11. Data Collection and Measurements

Introductory Information Form (baseline demographic and clinical data)

Microbiology Patient Follow-up Form (oral swab results on Day 1 and Day 6)

CPIS Patient Follow-up Form (VAP assessment on Day 1 and Day 6)

Oral Care Assessment Scale (daily assessments for 5 days)

12. Statistical Analysis Plan (SAP)

Descriptive statistics (mean, SD, percentages).

Between-group comparisons: Chi-square test, t-test/Mann–Whitney U test.

Within-group changes: Repeated-measures ANOVA or Friedman test.

Significance: $p<0.05$.

Analysis approach: Intention-to-treat (ITT).

13. Ethical Considerations

Approved by the Koşuyolu High Specialization Training and Research Hospital Clinical Research Ethics Committee.

Written informed consent will be obtained from the legal guardians of all patients.

14. Timeline

Data collection: October 2025 – June 2026

Analysis: July-September 2026

Publication: Late 2026

15. References

Miranda AL, et al. (2016). Oral care practices for patients in Intensive Care Units: A pilot survey. Indian J Crit Care Med, 20(5), 267-73. doi: 10.4103/0972-5229.182203. PMID: 27275074; PMCID: PMC4876647.

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Ozveren H. (2010). Oral Care in Patients Receiving Mechanical Ventilator. Hacettepe University Faculty of Health Sciences Nursing Journal, 17(2), 92-99.