Impact of a Systematic Oral Care Program in Post-Mechanically Ventilated Intensive Care Patients

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Funded by Medline Industries: Prevention Above All Discovery Grants Program
<table>
<thead>
<tr>
<th>Conflict of Interest</th>
<th>Within the study I used the following commercial products:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Oral-B Pro-Health Type 3744™ -Proctor &amp; Gamble</td>
</tr>
<tr>
<td></td>
<td>Colgate Total Clean Mint Paste ™ -Colgate-Palmolive,</td>
</tr>
<tr>
<td></td>
<td>Crest Pro-Health™ -Proctor &amp; Gamble</td>
</tr>
<tr>
<td></td>
<td>Medline Remedy Phytoplex™ lip balm –Medline Incorp</td>
</tr>
<tr>
<td>Employer</td>
<td>The Ohio State University</td>
</tr>
<tr>
<td>Sponsor/Commercial Support</td>
<td>Funding was provided by Medline Incorp ($78,000). Researchers selected all products independently. Medline lip balm was used.</td>
</tr>
</tbody>
</table>
Goals and Objectives

- **Session Goal:**
  - The goal of this session is to disseminate the results of our randomized control trial on the impact of an oral care program on post mechanically ventilated patients, and to promote the development of evidence-based oral care practice guidelines in the immediate care period following extubation from mechanical ventilation.

- **Session Objective:**
  - The learner will be able to describe the current state of the science related to oral care.
  - The learner will be able to describe the results of a randomized control trial that aims to develop an evidence-based protocol for providing oral care to post-mechanically ventilated patients.
Interdisciplinary Research Team

- Michele Carr MA, RDH
- Rachel Kearney, MS, RDH
- Timothy Landers, PhD, RN, CNP, CIC
- Jennifer MacDermott, MS, RN ACCNS-BC, NP-C, CCRN
- Tania Von Visger, MS, APRN, CCNS, PCCN
- Kristin Calvitti, MS, RN, ACNS-BC, CMSRN
- Brenda Vermillion, DNP, RN, ACNS-BC, ANP-BC, CCRN
- Michele Weber, DNP, RN, CCRN, ANP-BC
- Cheryl Newton, MSN, RN, CCRN, CNRN
- Jamie St Clair, MS, RN ACNS-BC, CCRN
- Naeem Ali, MD
- Amando Hoet, DVM, PhD, DACVPM
- Joany Van Ballen, DVM, PhD
- Christopher Holloman, PhD
Who We Are

- The Ohio State University
- The Ohio State University Wexner Medical Center
- 5 Hospital System 1246 bed
  - University Hospital *Flagship*
  - James Cancer Hospital
  - Harding Behavior Health
  - Dodd Rehabilitation
  - University Hospital East
  - Ross Heart Hospital
- Ranked 3rd among the 104 academic medical centers by the University Health System Consortium
Safe, High-quality, Patient-centered Care
Background

- Oral care protocols in the ICU shown to reduce the risk of infection—particularly VAP—part of the standard of care bundle for ICU patients who are mechanically ventilated.

- Post mechanical ventilation, these patients continue to be at high risk for medical complications, yet oral care protocols dissipate from post mechanical ventilation.

- Many HAIs originate with bacteria which are normal residents of the patient’s own skin and mucous membranes, including Staphylococcus aureus (SA).
Specific Aims

To determine the efficacy of implementing a systematic oral care program in post-mechanically ventilated post-intensive care patients on:

- Overall oral cavity health
- Acquisition of SA and SA/MRSA colonization in post-mechanically ventilated patients

Additionally, we examined the impact of the oral care protocol on:

- Patient satisfaction and
- Patient symptom burden
Methods

▪ This study is a prospective, randomized clinical trial enrolling patients who met ventilator liberation criteria with anticipated extubation and with no plans for further ventilator support.

▪ Inclusion Criteria:
  - Age 18 years or older
  - Has required mechanical ventilation for at least 48 hours
  - Meets ventilator liberation criteria (PEEP ≤ 8 and FiO₂ ≤ 50%)
  - Must have ≥3 teeth
  - Able to provide informed consent / LAR
Enrollment

Assessed for eligibility \( (n = 85) \)

Excluded \( (n = 11) \)
- Not meeting inclusion criteria \( (n = 8) \)
- Died \( (n = 2) \)
- Discharged \( (n = 1) \)

Randomized \( (n = 74) \)

Allocated to control \( (n = 41) \)
- Received standard care \( (n = 32) \)
- Did not receive intervention
  - Withdrawal \( (n = 5) \)
  - Reintubation \( (n = 3) \)
  - Discharged \( (n = 1) \)

Allocated to intervention \( (n = 33) \)
- Received intervention \( (n = 24) \)
- Did not receive intervention
  - Reintubation \( (n = 3) \)
  - Discharged \( (n = 5) \)
  - Died \( (n = 1) \)

Follow-up

R-THROAT completed \( (n = 28) \)
- Cultures completed \( (n = 32) \)

Analysis

R-THROAT completed \( (n = 21) \)
- Cultures completed \( (n = 24) \)

Analyzed with imputation \( (n = 39) \)

Analyzed with imputation \( (n = 30) \)
Oral Hygiene Protocol

Screen for inclusion/exclusion

Obtain informed consent; Screen daily for SBT/Extubation

Extubation

Rescreen for inclusion/exclusion

Intervention group

Assessment (THROAT #1) Within 24 hrs after extubation

Oral Care Intervention

Assessment (THROAT #2) Within 24 hrs after day 4 intervention

Culture 1

Randomization

Control group

Assessment (THROAT #1) Within 24 hrs after extubation

Standard Oral Care

Assessment (THROAT #2) Within 24 hrs after day 4 intervention

Culture 1

Culture 2

Culture 2
<table>
<thead>
<tr>
<th>Component</th>
<th>Frequency</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teeth brushing</td>
<td>Twice a day</td>
<td>Oral-B Pro-Health Type 3744™ (Proctor &amp; Gamble, Cincinnati, OH)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Colgate Total Clean Mint Paste™ (Colgate-Palmolive, New York, NY)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Each quadrant of the mouth was brushed for 30 seconds (Total time: 2 min)</td>
</tr>
<tr>
<td>Tongue care</td>
<td>Twice a day</td>
<td>Tongue scraped from posterior to anterior using a tongue scraper</td>
</tr>
<tr>
<td>Flossing</td>
<td>Twice a day</td>
<td>Flossing between teeth using floss holder</td>
</tr>
<tr>
<td>Mouth rinse</td>
<td>Twice a day</td>
<td>Swish and spit using Crest Pro-Health™ mouthwash</td>
</tr>
<tr>
<td>Lip care</td>
<td>Twice a day</td>
<td>Medline Remedy Phytoplex™ lip balm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Medline Industries, Mundelein, IL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Application of lip balm to lips</td>
</tr>
<tr>
<td>Outcome Measure</td>
<td>Instrument/Measures</td>
<td>Frequency</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Assessment of Oral Cavity</td>
<td>Revised-THROAT Assessment: 7-items-(lips, gums, teeth, tongue, saliva, smell, mouth comfort). Items scored 1-3 for total 7-21</td>
<td>Day 1 (+ 24 hours) and Day 4 (+ 24 hours)</td>
</tr>
<tr>
<td>Oral/Nasal Colonization of MSSA and MRSA</td>
<td>Oral/Nasal Cultures (Swabs)</td>
<td>Day 1 (+ 24 hours) and Day 4 (+ 24 hours)</td>
</tr>
<tr>
<td>Patient Satisfaction</td>
<td>Patient Satisfaction Survey/Interview</td>
<td>Day 4</td>
</tr>
<tr>
<td>Symptom Burden</td>
<td>Edmonton Symptom Assessment System</td>
<td>Day 4</td>
</tr>
</tbody>
</table>
Data Analysis

- Independent student t tests, chi-square, and Fisher exact tests were used to summarize and compare the standard and intervention groups on the age, gender, race, baseline R–Throat and culture result.

- A repeated-measures model was used with time as within-subjects effect and group as the between-subjects effect for R–Throat. Imputation was used for missing data.

- Patient satisfaction and symptom burden measures were computed using independent student t tests and analysis of variances.
## Baseline Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Standard</th>
<th>Intervention</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>56.10 (SD 15.9)</td>
<td>52.12 (SD 15.5)</td>
<td>.28</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Male: 56.1%</td>
<td>Male: 60.6%</td>
<td>.81</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td>Caucasian: 97.5%</td>
<td>Caucasian: 84.8%</td>
<td>.09</td>
</tr>
<tr>
<td><strong>Baseline</strong> R-THROAT</td>
<td>11.4 (SD, 2.40)</td>
<td>11.5 (SD, 2.40)</td>
<td>.96</td>
</tr>
<tr>
<td><strong>S. aureus</strong></td>
<td>6 (18.8%)</td>
<td>2 (8.3%)</td>
<td>.27</td>
</tr>
<tr>
<td>MSSA</td>
<td>2 (6.3%)</td>
<td>0 (0%)</td>
<td>.62</td>
</tr>
<tr>
<td>MRSA</td>
<td>4 (12.5%)</td>
<td>2 (8.3%)</td>
<td>.21</td>
</tr>
</tbody>
</table>
## R-Throat Scores: Usual vs Intervention

<table>
<thead>
<tr>
<th>Body Part</th>
<th>Usual Care Day</th>
<th>Intervention Day</th>
<th>Group effect (p)</th>
<th>Time effect (p)</th>
<th>Group * Time Interaction (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lips</td>
<td>2.02</td>
<td>1.70</td>
<td>.56</td>
<td>.00</td>
<td>.48</td>
</tr>
<tr>
<td>Gums</td>
<td>1.48</td>
<td>1.45</td>
<td>.08</td>
<td>.02</td>
<td>.12</td>
</tr>
<tr>
<td>Teeth</td>
<td>2.12</td>
<td>2.02</td>
<td>.18</td>
<td>.00</td>
<td>.22</td>
</tr>
<tr>
<td>Tongue</td>
<td>2.07</td>
<td>2.0</td>
<td>.11</td>
<td>.00</td>
<td>.02</td>
</tr>
<tr>
<td>Saliva</td>
<td>1.51</td>
<td>1.41</td>
<td>.22</td>
<td>.16</td>
<td>.06</td>
</tr>
<tr>
<td>Smell</td>
<td>1.05</td>
<td>1.08</td>
<td>.97</td>
<td>.49</td>
<td>.49</td>
</tr>
<tr>
<td>Comfort</td>
<td>1.15</td>
<td>1.26</td>
<td>.64</td>
<td>.07</td>
<td>.001</td>
</tr>
<tr>
<td>Total</td>
<td>11.44</td>
<td>10.57</td>
<td>.33</td>
<td>.07</td>
<td>.04</td>
</tr>
</tbody>
</table>
Oral Colonization with *Staphylococcus aureus*

- There were no significant differences between overall SA colonization, MSSA, or MRSA at the end of the 4-day intervention.

- There were no statistically significant differences between the groups in the number of usual care versus intervention patients who acquired new colonization, those who cleared, or those who were persistently colonized.
Patient Satisfaction

- Small sample size (n=45), as many patients could not communicate.
- Subjects in intervention group reported higher staff attention to oral care by staff (p=.05).
- Overall, intervention group rated toothbrushes, toothpaste, mouthwash and lip balm higher than usual care.
- Received positive comments: “Just a good cleaning of my mouth alone greatly improved my well-being.”
Edmonton Symptom Assessment Scores

- No statistical difference in nausea, tiredness, appetite, SOB, depression, anxiety or well being.

- There was a difference in drowsiness with intervention group reporting < drowsiness than on day 4.
Study Limitations

- Investigated only one pathogen
- Did not collect the frequency and type of oral care in the usual care group.
Implications

▪ Both groups showed improvement in their oral cavity post-intubation. However, the intervention group demonstrated a nearly 2-point reduction.
▪ Tongue scraping is particularly effective.
▪ A standardized, evidenced based protocol specifically addressing patients in the post-intubation period is imperative.
▪ Patient satisfaction is high with oral care in the post-intubation period.
Thank you!