

Effects of a Standard Versus Comprehensive Oral Care Protocol Among Intubated Neuroscience ICU Patients: Results of a Randomized Controlled Trial CE

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ABSTRACT

The purpose of the study was to compare changes in oral health during intubation until 48 hours after extubation in neuroscience intensive care unit (ICU) patients enrolled in a standard or a comprehensive oral care protocol. The effects of manual toothbrushing (standard group, $n = 31$) were compared with those of tongue scraping, electric toothbrushing, and moisturizing (comprehensive group, $n = 25$) in intubated patients in a neuroscience ICU in a 2-year randomized clinical trial. Oral health was evaluated based on the Oral Assessment Guide (OAG) on enrollment, the day of extubation, and 48 hours after extubation. There were no significant differences in the frequency of the oral care protocol. Protocol compliance exceeded 91% in both groups. The total OAG score and all eight categories significantly deteriorated (Friedman test, $p < .001$, Bonferroni corrected) in the standard oral care group and did not return to baseline after extubation. Large effect sizes were present at all three points in this group. The total OAG score deteriorated during intubation within the comprehensive protocol group (Friedman test, $p < .004$) but returned to baseline status after extubation. In four categories, the ratings on tongue, mucous membranes, gingiva, and teeth did not deteriorate significantly over time. Published oral care protocols are substandard in promoting and maintaining oral health in intubated patients. A comprehensive oral care protocol, using a tongue scraper, an electrical toothbrush, and pharmacological moisturizers, was more effective for oral hygiene throughout intubation and after extubation than manual toothbrushing alone.

Although providing oral hygiene to intubated patients is a technical challenge, doing so is vital for both patients' oral health and overall systemic health and disease prevention. However, data on how to most effectively provide oral care to this patient population are lacking. In the absence

of adequate oral hygiene, the composition of dental plaque changes (Terezakis, Needleman, Kumar, Moles, & Agudo, 2011). Mature dental plaque harbors gram-negative anaerobic bacteria and contributes to an environment rich in pathogenic bacteria. This environment combined with the reduced salivary flow associated with prolonged endotracheal intubation can result to mucositis (Dennesen et al., 2003). As the duration of oral intubation lengthens, dried secretions and debris consolidate at the dorsum of the tongue and hard palate and contribute further to pain and halitosis. This multifactorial process suggests that oral care should be addressed using a comprehensive approach. Oral care is difficult to perform in intubated patients because of the artificial airways and the patients' underlying critical condition. Because oral health worsens during intubation, the clinical challenge is to prevent deterioration by addressing, for example, the development of dental plaque, xerostomia, and bacterial growth. Before an effective, comprehensive protocol for oral care can be established, how oral health changes over time and the impact of different oral care methods must first be understood.

The use of a manual toothbrush has been emphasized as part of standard oral care (American Association of Critical-Care Nurses, 2010; Ames, 2011). Although intensive care unit (ICU) nurses may

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perceive oral hygiene as a priority, few appear to conduct routine oral assessments or to brush their patients' teeth regularly (Rello et al., 2007). Barriers to providing adequate oral care in hospitalized patients, for example, lack of time and inadequate knowledge of oral health, have been identified. Such obstacles can result in incomplete assessments of oral health to guide oral care practices (Berry, Davidson, Masters, & Rolls, 2007; McNeill, 2000). Although providing oral care is a standard of practice within ICUs, oral assessment scales to indicate oral health, evaluate effectiveness of oral care, and serve as a guide for how frequently oral care should be performed are needed (McNeill, 2000; Munro, Grap, Jablonski, & Boyle, 2006; O'Reilly, 2003). Eilers' Oral Assessment Guide (OAG), originally developed for oncology patients, has been used to determine oral health status and frequency of oral hygiene measures (Munro et al., 2006). The instrument consists of eight categories for evaluating oral health: swallow, lips, tongue, saliva, mucous membranes, gingiva, teeth, and voice. These categories are graded 1 (*best*), 2, or 3 (*worst*). A total score of 8 indicates normal findings, whereas a total score of 24 reflects the worst possible score in all eight categories. Early studies reported a nurse-to-nurse interrater reliability coefficient of 0.912 and robust content validity among experts for the OAG. (Andersson, Persson, Hallberg, & Renvert, 1999; Eilers, Berger, & Petersen, 1988) The OAG and slight modifications thereof have been applied to several patient populations to reflect response to oral care and the need for additional intervention (Andersson et al., 1999; Andersson, Hallberg, & Renvert, 2002; Ross & Crumpler, 2007).

Scant literature describes changes in oral health over time among ICU patients receiving mechanical ventilation. The decline of oral health related to poorly performed oral care is reflected in the development of dried mucous membranes, gingivitis, and periodontal disease (Paju & Scannapieco, 2007; Shay, 2002). Physical barriers such as an endotracheal tube, oral gastric tubes, and bite blocks hamper access to the oral cavity and have been described as the main barriers to providing oral care in the ICU (Wardh, Hallberg, Berggren, Andersson, & Sorensen, 2000). Numerous commercially available oral care products, such as manual and electric toothbrushes, dentifrices, oral moisturizing agents, and a variety of oral swabs and solutions, are available. The effectiveness of most products or methods on oral health is not well known, especially in the context of intubated patients. For instance, foam swabs dipped in saline, mixtures of hydrogen peroxide and saline, or chlorhexidine are often used for oral care in ICU settings. In a survey of 59 ICUs in Europe, 88%

Intubation in critically ill patients often causes a deterioration of oral health, with the development of dental plaque, xerostomia, and bacterial growth.

of nursing respondents reported using primarily mouthwash for patients' oral care (Rello et al., 2007). ICU nurses use foam swabs for ease; swabs require less dexterity to manipulate than a toothbrush. Nonetheless, foam swabs appear to be inferior in removing plaque compared with a toothbrush (Pearson, 1996). Swabs, however, are useful in applying moisturizing gel or saline to dry tissues. The surface of the tongue has been identified as a major source of malodor (Bosy, Kulkarni, Rosenberg, & McCulloch, 1994), and tongue scrapers have been advocated as a means to reduce halitosis in outpatient settings.

Manual toothbrushes have been proposed as the ideal method of promoting the oral hygiene of orally intubated patients (Ford, 2008; Pearson & Hutton, 2002). In 2006, the American Association of Critical Care Nurses published a clinical practice alert recommending that ICU protocols include toothbrushing with a soft pediatric or adult-sized manual toothbrush to remove dental plaque. Five years later, 347 randomly selected members of the American Association of Critical Care Nurses were surveyed regarding their oral care protocols. The results indicated that oral care was performed in an average of every 2 (50%) or 4 (42%) hours, usually with foam swabs (97%; Feider, Mitchell, & Bridges, 2010). Despite various oral care protocols, little evidence supports protocol implementation, although oral hygiene appears to be safely tolerated by neuroscience ICU patients (Prendergast, Hagell, & Hallberg, 2011; Prendergast, Hallberg, Jahnke, Kleiman, & Hagell, 2009).

Using an electric toothbrush for 2 minutes twice daily has been deemed superior to a manual toothbrush for removing dental plaque and improving gingival health (Lazarescu, Boccaaneala, Illiescu, & De Boever, 2003; Robinson et al., 2005; Williams et al., 2004). Because the electric toothbrush improves oral hygiene in the general population, it also may have a beneficial effect among intubated patients in the ICU. The oscillating rotary head of electric toothbrushes may minimize the manual dexterity needed to clean the teeth and gingival

margins. The overall smaller surface area of the electric brush head, combined with its lower profile, may make it easier to navigate in the oral cavity than a manual toothbrush.

The type of toothpaste used may also influence oral health in ICU patients. Fluoridated toothpaste is often used in hospitals because the fluoride makes tooth enamel more resistant to decay (Jenkins, 1989). Sodium lauryl sulfate, a key ingredient in toothpastes, is a detergent that primarily acts as a surfactant and provides the foaming associated with toothbrushing. When the oral cavity is not thoroughly rinsed, the toothpaste adheres to and dries on the mucosal surface, worsening a xerostomic condition that can lead to mucosal desquamation (Herlofson & Barkvoll, 1996). Thus, during intubation, ordinary toothpastes may not be the product of choice. Toothpastes free of sodium lauryl sulfate are commercially available. These toothpastes and alcohol-free oral care products contain moisturizing polymers and are specifically formulated for patients with xerostomia.

Despite the importance of providing ICU patients an effective oral hygiene, randomized controlled trials (RCTs) to establish the efficacy of oral health protocols and the effect of specific oral care products are lacking (Berry et al., 2007). Providing oral care should be considered essential in the promotion of patient comfort and overall well-being (Ford, 2008). We therefore compared changes in oral health during intubation and through the first 48 hours after extubation among neuroscience ICU patients enrolled in a standard or a comprehensive oral care protocol.

Methods

This study was part of a larger RCT comparing the effects of two oral care protocols on ventilator-associated pneumonia among patients in a neuroscience ICU. The study was approved by the institutional review board at a tertiary medical center in the southwestern United States. It was conducted in accordance with the Helsinki Declaration of 2008 and registered at ClinicalTrials.gov (NCT 00518752). Written informed consent was obtained from each patient's legally identified decision maker.

Sample and Setting

All patients aged 18 years and older who were intubated within 24 hours of admission to the neuroscience ICU between August 2007 and August 2009 were eligible for study inclusion. For this report, patients with an OAG obtained on enrollment, the day of extubation (before extubation), and 48 hours after extubation were analyzed for measures of oral health. Exclusion criteria were pregnancy, an edentulous state,

facial fractures or trauma affecting the oral cavity, unstable cervical fractures, anticipated extubation within 24 hours, or a grim prognosis.

Patients were randomized into one of two methods of oral care using a computer-generated randomization list maintained separately from enrollment forms to prevent manipulation of eligibility judgments. The randomization list was available only to the principal investigator (V. P.) and four research assistants. Individuals who obtained informed consent and assigned patients to treatment groups were not directly involved in the patients' oral care. After informed consent was obtained, patients were assigned to the next available number for enrollment from the randomization list maintained in a secured area.

Procedure

Before study initiation, all staff nurses and patient care technicians employed in the neuroscience ICU participated in an hour-long class that reviewed study objectives, oral care data sheets, oral care kit contents, and the role of the blinded oral hygiene evaluators. A registered dental hygienist provided

TABLE 1. Preparation for Oral Care for Both Groups

Procedure

1. Check that suction equipment is working.
2. Assemble oral care supplies from patient's oral care box. Draw NSS solution into Toomey syringe and set aside.
3. Assess cleanliness of suction equipment and attach clean suction catheter. Suction ballard and ETT secretions as needed before oral care.
4. Suction oropharyngeal secretions before oral care.
5. Position the patient with HOB elevated 30° or higher, in a semirecumbent position. Their chins should be flexed forward with the patient in the side-lying position to allow the mouth rinse to drain with gravity to reduce the risk of aspiration.
6. Obtain assistance from patient care technician or respiratory technician as needed.
7. Wash hands and don gloves and face shield.
8. Place kidney basin under chin.
9. Gently insert Yankauer suction inside mouth, toward back of teeth on dependent side.
10. Introduce syringe and rinse mouth with 30–40 cc of NSS.
11. Refer to and follow standard or intervention protocol.
12. Upon conclusion of oral care, document procedure.

Note. For both groups, this procedure will be followed when administering oral care. ETT = endotracheal tube; HOB = head of bed; NSS = normal sterile saline.

instruction on use of a manual pediatric toothbrush and an electric toothbrush. Protocols for each oral care group were explained and shown to volunteers. Nurses unfamiliar with electric toothbrushes used a sample unit to practice toothbrushing on a colleague. Oral care kits, consisting of white cardboard boxes with the study logo affixed on top, were placed in each patient's room at the time of enrollment. The contents included the assigned toothbrush and specified oral hygiene supplies. The inside flap of all kits contained a copy of the assigned oral care protocol for staff review as needed. The contents of the box were checked daily by research assistants for restocking.

Regardless of group assignment, all patients underwent identical preparation for oral care (Table 1). For both groups, the assigned oral care protocol was performed once during the day shift and once during the night shift (Table 2). In each group, bedside clocks were set to zero when brushing began. Nurses

recorded if toothbrushing was performed, the total time spent in performing oral care including patient preparation, and the cleaning of hygiene supplies. The products used in the control group consisted of a manual pediatric toothbrush; Freshmint fluoridated toothpaste (a product of India, distributed by NWI, Inc., Nashville, TN); sterile normal saline; and a biologically inert, water-based, water-soluble lubricant (K-Y Jelly, Johnson & Johnson, New Brunswick, NJ) as a moisturizing agent for oral mucosa and lips. Patients randomized to the comprehensive method underwent tongue scraping followed by toothbrushing with an electric toothbrush with a small, oscillating, rotary head (Oral B Vitality toothbrush, Newark, NJ) that had a built-in 2-minute timer. Teeth were brushed with Biotene toothpaste followed by Oral Balance (both from GlaxoSmithKline, Moon Township, PA) as the moisturizing agent for oral mucosa and lips.

Four registered nurses (RNs) were assigned to assess all enrolled patients with the OAG. Each

TABLE 2. Assigned Standard Versus Comprehensive Oral Care Protocol

Standard Protocol

1. Wet manual toothbrush and apply pea-sized amount of fluoridated toothpaste.
2. Before brushing, zero the bedside clock.
3. Place bristles along gumline at a 45° angle to allow bristles to touch tooth and gumline.
4. Begin brushing teeth in a gentle, back-and-forth circular motion for 2 minutes brushing two to three teeth at a time, include biting surface of teeth.
5. Insert brush to include inner tooth and gumline surface where possible.
6. Assess for significant gum bleeding and stop brushing if encountered.
7. Brush around ETT using caution not to damage or dislodge tube.
8. Brush tongue from back to front.
9. Use oral suction intermittently as needed for secretions.
10. Rinse mouth with 30–60 cc of NSS solution.
11. Apply lubricant to lips with gloved finger or cotton-tipped applicator.
12. Thoroughly rinse toothbrush in warm water and place on clean paper towel to air dry.
13. Discard gloves and document care and response.
14. Reassess patient every 2–4 hours for xerostomia. If noted, rinse with NSS and apply K-Y Jelly if indicated.

Intervention Protocol

1. **Gently scrape the surface of the tongue moving in a back-to-front direction, suction, and rinse as needed.**
2. **Wet electric toothbrush and apply pea-sized amount of Biotene toothpaste.**
3. Before brushing, zero the bedside clock.
4. **Place head of toothbrush along upper tooth surface and gumline and turn brush on.** Hold brush in contact with surface, and brush 2–3 teeth at a time, include the biting surface of the teeth.
5. Insert brush to include inner tooth and gumline surface where possible.
6. Assess for significant gum bleeding and stop brushing if encountered.
7. Brush around ETT using caution not to damage or dislodge tube.
8. Use oral suction intermittently as needed for secretions.
9. Rinse mouth with 30–60 cc of NSS solution.
10. **Fill a 30-cc medicine cup with Biotene rinse. Saturate foam swab and swab oral tissues. Repeat soaking in Biotene solution and repeat swabbing for 30 seconds.**
11. **Apply Oral Balance moisturizer to lips with gloved finger or sponge-tipped applicator.**
12. Thoroughly rinse tongue scraper and toothbrush in warm water and place on clean paper towel to air dry.
13. Discard gloves and document care and response.
14. Reassess patient every 2–4 hours for xerostomia and **apply Oral Balance moisturizer to inner cheek, tongue, and lips as needed.**

Note. ETT = endotracheal tube; NSS = normal sterile saline. Data in bold indicate key differences in comprehensive protocol.

nurse completed the required human subjects' protection education and training and fulfilled requirements and testing through the Collaborative Institutional Training Initiative. Before the study began, a registered dental hygienist met twice with all four nurses to teach components of an oral examination followed by a step-by-step explanation and demonstration of how to use the OAG. The original OAG included an item category of voice that was not applicable to intubated patients. To maintain the overall OAG rating category scale of 8–24, the category of voice was replaced with the category of odor. This item was scored on a scale of 1–3, similar with the other

seven items (Table 3). The four RNs, accompanied by the registered dental hygienist, examined five patients. The results of the OAG were reviewed, and the registered dental hygienist answered any questions. Each of the four evaluators then independently assessed the oral hygiene of 10 neuroscience ICU patients using the OAG to establish interrater reliability.

Data Collection

The demographic data collected from the patient's chart included age, gender, admission diagnosis,

TABLE 3. Modified Eilers' Oral Assessment Guide

Category	Tools for Assessment	Methods of Measurement	Numerical and Descriptive Ratings		
			1	2	3
Swallow	Observation	Ask patient to swallow; to test gag reflex, gently place blade on back of tongue and depress (<i>move ETT to test gag</i>)	Normal swallow	Some pain on swallow; impaired (<i>assume intubated patient has pain = minimum score of 2</i>)	Unable to swallow (<i>CN IX, X, XII; sedated or absent gag</i>)
Lips	Visual/palpatory	Observe and feel tissue (<i>lubricate finger and palpate</i>)	Smooth, pink, and moist	Dry or cracked	Ulcerated or bleeding (<i>HSV, candidiasis, and/or cheilitis</i>)
Tongue	Visual/palpatory	Feel and observe appearance of tissue	Pink, moist, and presence of papillae	Coated or loss of papillae with a shiny appearance with or without redness	Blistered or cracked (<i>bleeding, lacerations, or ulcers</i>)
Saliva	Mouth mirror	Insert blade into mouth, touching the center of tongue and floor of mouth (<i>slide a mouth mirror along the buccal mucosa</i>)	Watery (<i>no friction between mirror and mucosa</i>)	Thick or ropy (<i>slightly increased friction; no tendency for the mirror to adhere to mucosa</i>)	Absent (<i>significantly increased friction; the mirror adhering or tending to adhere to mucosa</i>)
Mucous membranes	Visual	Observe appearance of tissue	Pink and moist	Reddened or coated (increased whiteness) without ulcerations	Ulcerations with or without bleeding
Gingiva (<i>rate the worst area</i>)	Tongue blade and visual	Gently press tissue with tip of blade (<i>press triangle gum area between teeth</i>)	Pink, stippled, and firm	Edematous with or without redness	Spontaneous bleeding or bleeding with pressure
Teeth or dentures	Visual, vegetable dye	Observe appearance of teeth or denture-bearing areas (<i>wait at least 1 minute after applying disclosing solution with swab</i>)	Clean and no debris	Plaque or debris in localized areas (between teeth if present) (<i><50% surface areas; >50% surface area with thin biofilm coating</i>)	Plaque or debris generalized along gum line or denture-bearing areas (<i>>50% surface areas; heavy plaque and debris</i>)
Odor	Nose	Smell	Normal	Slightly to moderately foul	Strong, foul odor

Note. Used with permission from the University of Nebraska. Data in italics represent procedural techniques for all evaluations.

comorbidities, and smoking history. The Glasgow Coma Scale score was used at enrollment as a global indicator of neurological impairment. The presence of a Hi-Lo Evac endotracheal tube for subglottic secretion removal (Mallinckrodt Hi-Lo Evac, Nellcor, Boulder, CO), as documented by the respiratory therapist, was recorded. On each shift, the nursing staff completed oral care data sheets to document oral care, the number of times oral swabs were used, the overall length of time required to administer oral care, the time spent brushing teeth, and the number of staff required for oral hygiene. The registered dental hygienist made routine visits to the ICU to meet with staff to review toothbrushing techniques and to answer questions. The registered dental hygienist consulted on both patient groups.

The nurse OAG evaluators rounded on all study patients between 5:00 a.m. and 7:30 a.m. daily to allow 4–6 hours after the last toothbrushing. The oral evaluators were blinded to group assignment at all times. The bedside bright light source, disposable dental mirrors, tongue blades, cotton-tipped applicators, vegetable dye, and gloves were used during the evaluation. Odor was the first item assessed followed by swallow, lips, tongue, saliva, mucous membranes, and gingiva. At the conclusion of the visual examination, vegetable dye was used to coat the surfaces of the teeth. Approximately 60 seconds after the dye was applied, the teeth were assessed for plaque or debris. Each patient's OAG evaluation sheets were maintained in a locked drawer, separate from all other study documents.

Data Analysis

All data were analyzed with SPSS Version 17.0 (SPSS Inc., Chicago, IL). For hypothesis testing, the alpha level was set at 0.05 (two-tailed). For demographic and clinical characteristics of patients, nominal and ordinal data were expressed as percentages. Continuous variables were expressed as means and standard deviations and analyzed. Differences between groups were assessed using the Chi-square test or Fisher's exact test for nominal data and the Mann-Whitney *U* test for ordinal data. Kendall's coefficient of concordance was used as the reliability statistic for OAG measurement among raters. Friedman's test was used to analyze repeated measures of the OAG scores obtained at enrollment, before extubation, and 48 hours after extubation. The Wilcoxon signed-rank test was used for post hoc analyses followed by a Bonferroni correction with a revised alpha level of 0.017. Difference and effect size of changes between enrollment and before extubation, before extubation and 48 hours after extubation, and enrollment and

48 hours after extubation were analyzed with the Wilcoxon's signed-rank test.

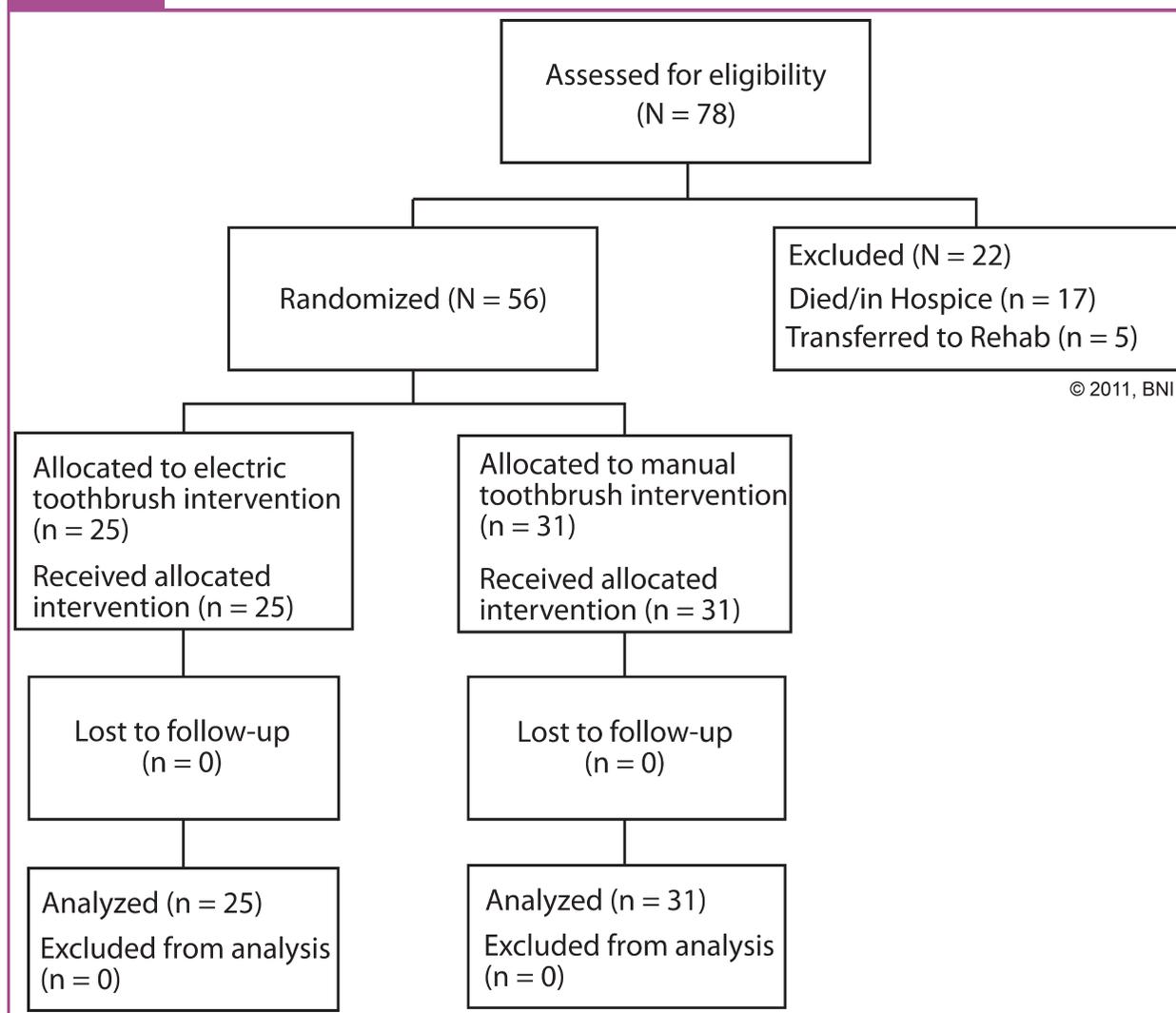
Effect sizes within each group were calculated to measure deterioration and compared between groups for the distinct periods: from enrollment to before extubation, from before extubation to 48 hours after extubation, and from enrollment to 48 hours after extubation. The effect size of the total OAG score and each item score was calculated as the mean change at each time point divided by the standard deviation at the first time point for the corresponding variable (Kazis, Anderson, & Meenan, 1989). The effect size was calculated to examine the difference between the two groups with results converted from positive to negative and vice versa to illustrate the deterioration in overall oral health and item indicators of oral health. Interpretation of effect sizes was based on small (0.2), medium (0.5), and large (0.8) nomenclatures (Cohen, 1977).

Results

Of the 78 patients with OAG scores recorded on admission, 56 had OAG scores documented on enrollment, before extubation, and 48 hours after extubation (Figure 1). There were no significant differences in age, gender, tobacco use, admission diagnosis, or Glasgow Coma Scale classification (Table 4). Compliance with performing the assigned oral care protocol exceeded 91% in both groups. No differences were detected in the frequency of the oral care procedure with the exception of the length of time spent in administering hygiene. Patients in the comprehensive oral care group required a mean of 1 minute more per occasion for total oral care compared with those in the standard oral care group ($p = .015$, CI [0.30, 2.65], Mann-Whitney *U* test; Table 4). For the four nurse evaluators, overall OAG interobserver agreement was 0.85%; Kendall's coefficient of concordance was 0.76.

The results of the Friedman test reflected a significant deterioration in the total OAG score and all eight categories ($p < .001$) within the standard oral care group over time (Table 5). Within the comprehensive oral care group, the total OAG score significantly worsened over time ($p = .004$). However, there was no significant worsening in four of the item categories: tongue, mucous membranes, gingiva, and teeth (Table 5). The scores for these four categories and the total OAG score are presented in Figure 2A and B.

The total OAG score between groups from time of enrollment to before extubation and to after extubation worsened more in the standard oral care group than in the comprehensive oral care group

FIGURE 1 CONSORT Flowchart of Study Patients

Note. Used with permission from Barrow Neurological Institute.

(Table 6). At these same time intervals, a large effect size for mucous, gingiva, and teeth was detected in the standard oral care group, whereas a small effect size was present in the comprehensive group for the same categories at the same time points. The scored category of teeth significantly improved between enrollment and after extubation for the comprehensive oral care group. Odor significantly improved in the comprehensive oral care group compared with the standard oral care from the time of enrollment to 48 hours after extubation ($p = .013$). There were no significant differences in effect sizes for swallow, lips, and saliva between the two groups.

Discussion

Intubated patients are at risk for worsening oral health because of the myriad of factors that negatively affect oral status, such as xerostomia and dental plaque. Yet despite the use of the widely

recommended standard protocol as implemented in this study, the oral health of patients receiving that care significantly deteriorated in all categories of the OAG, from enrollment to before extubation and from enrollment to after extubation. The increase of 3.5 and 2.5 points in total OAG score, respectively, indicates a worsening of overall oral health. Although oral health may be expected to decline during intubation because of the limited oral access, significant deterioration continued after extubation with no single category returning to the baseline assessment. The greater negative values of effect size indicated significant worsening of oral health among patients receiving standard care, underscoring the importance of a revised oral care protocol. Overall, these results can be interpreted as poor recovery of oral health despite patients receiving the recommended oral care. In fact, the findings suggest that the current standard of oral care is substandard.

TABLE 4. Patient Characteristics at Enrollment, *n* = 56

Variable	Standard Protocol (<i>n</i> = 31)	Comprehensive Protocol (<i>n</i> = 25)	<i>p</i>
Age in years, mean (<i>SD</i> ; min–max)	52 (19; 18–85)	51 (19; 19–87)	.93 ^a
Gender			.26 ^b
Male, <i>n</i> (%)	14 (45)	15 (60)	
Female, <i>n</i> (%)	17 (55)	10 (40)	
Smoking			.27 ^b
No, <i>n</i> (%)	25 (81)	17 (68)	
Yes, <i>n</i> (%)	6 (19)	8 (32)	
Admission diagnosis			.10 ^c
Hemorrhagic stroke, <i>n</i> (%)	21 (68)	12 (48)	
Closed head injury, <i>n</i> (%)	7 (23)	7 (28)	
Other ^d , <i>n</i> (%)	3 (9)	6 (24)	
Admission GCS ^e			.71 ^c
Severe, <i>n</i> (%)	18 (58)	15 (60)	
Moderate, <i>n</i> (%)	11 (35)	10 (40)	
Mild, <i>n</i> (%)	2 (6)	0	
ETT With HiLo ^f			.87 ^b
No, <i>n</i> (%)	18 (58)	14 (56)	
Yes, <i>n</i> (%)	13 (42)	11 (44)	
Total number of days intubated, mean (<i>SD</i> ; min–max)	8 (4; 2–19)	8 (4; 3–18)	.99 ^c
Number of days of stay in the ICU, mean (<i>SD</i> ; min–max)	16 (8.3; 4–39)	18 (9.4; 3–39)	.34 ^c
Number of times of toothbrushing in 12 hours (<i>SD</i>)	1 (0.04)	1 (0.04)	.89 ^c
Minutes spent in brushing per episode, mean (<i>SD</i>)	2 (0.18)	2 (0.31)	.53 ^c
Minutes spent in administering hygiene per episode, mean (<i>SD</i>)	6 (1.5)	7.0 (2.5)	.015 ^c
Number of RNs used for oral care (<i>SD</i>)	1 (.17)	1 (.05)	.07 ^c
Number of swabs used per 12 hours (<i>SD</i>)	3 (2)	3 (1.6)	.91 ^c

^aStudent's *t* test.^bChi-square test.^cMann–Whitney *U* test.^d“Other” indicates traumatic brain injury, brain tumor.^eGlasgow Coma Scale (GCS): possible score range is 3–15 (15 = no impairment of consciousness; sum score of 3–8 = severe; sum score of 9–12 = moderate; sum score of 13–15 = mild).^fThe Hi-Lo Evac endotracheal tube has a separate dorsal lumen for continuous aspiration of subglottic secretions.

Conversely, among those enrolled in the comprehensive protocol, the total OAG score increased by 1.7 and 0.5 points, respectively, from enrollment to before extubation and from enrollment to after extubation. Interestingly, the enrollment OAG scores were worse in the comprehensive group (mean = 15) compared with the standard group (mean = 14). Yet the degree of deterioration was not as severe during intubation. Nor was there a significant difference between enrollment and after extubation, reflecting an overall maintenance of oral health in patients receiving the comprehensive protocol. Furthermore, oral health scores during intubation were stable in key areas (i.e., teeth, gingiva, mucous membrane, and odor) for those receiving the comprehensive oral care protocol.

It is not possible to attribute specific changes in OAG scores or the effect size to a single component of the comprehensive oral care protocol. Nonetheless, the disparity between the scores of the two groups for teeth and gingiva may partially reflect the use of the electric toothbrush. In the outpatient setting, the efficacy of the electric toothbrush for dental plaque removal and promotion of gingival health has been shown (Outhouse, Al-Alawi, Fedorowicz, & Keenan, 2006). The electric toothbrush appears to have the same effect among the critically ill, as reflected by the improved score for teeth after extubation compared with that noted at enrollment. The cost of an electric toothbrush may raise an economic warning flag. However, its superior efficacy for oral

TABLE 5. Deterioration in Oral Assessment Guide (OAG) Scores Over Time According to Protocol

Variable	Enrollment, mean (SD; min–max)	Before Extubation, mean (SD; min–max)	48 Hours After Extubation, mean (SD; min–max)	<i>p</i> ^a	Post hoc ^b
Total OAG score ^c					
Standard	14.45 (2.51; 10–21)	17.97 (2.51; 13–22)	16.97 (2.53; 12–22)	<.001	A, B, C
Comprehensive	15.36 (2.70; 10–19)	17.08 (1.91; 13–20)	15.88 (2.33; 11–20)	.004	A, B
Swallow ^d					
Standard	2.84 (3.74; 2–3)	2.58 (.37; 2–3)	2.03 (.60; 1–3)	<.001	A, B, C
Comprehensive	2.80 (0.41, 2–3)	2.72 (.46; 2–3)	2.08 (.76; 1–3)	<.001	B, C
Lips ^d					
Standard	1.77 (.67; 1–3)	2.35 (.69; 1–3)	2.26 (.68; 1–3)	<.001	A, C
Comprehensive	1.96 (7.4; 1–3)	2.6 (.50; 2–3)	2.52 (.51; 2–3)	<.001	A, C
Tongue ^d					
Standard	1.87 (.56; 1–3)	2.32 (.48; 2–3)	2.32 (.46; 2–3)	<.001	A, C
Comprehensive	1.8 (.66; 1–3)	2.08 (.40; 1–3)	2.04 (.46; 1–3)	.273	
Saliva ^d					
Standard	1.52 (.57; 1–3)	1.94 (.44; 1–3)	1.97 (.48; 1–3)	<.001	A, C
Comprehensive	1.52 (.51; 1–2)	1.72 (.54; 1–3)	1.92 (.57; 1–3)	.017	C
Mucous membrane ^d					
Standard	1.32 (.65; 1–3)	2.10 (.87; 1–3)	2.00 (.82; 1–3)	<.001	A, C
Comprehensive	1.64 (.70; 1–3)	1.80 (.71; 1–3)	1.84 (.80; 1–3)	.202	
Gingiva ^d					
Standard	1.35 (.55; 1–3)	1.87 (.43; 1–3)	1.77 (.43; 1–2)	<.001	A, C
Comprehensive	1.48 (.58; 1–3)	1.60 (.50; 1–2)	1.56 (.51; 1–2)	.368	
Teeth ^d					
Standard	1.94 (.57; 1–3)	2.42 (.56; 1–3)	2.29 (.53; 1–3)	<.001	A, C
Comprehensive	2.12 (.72; 1–3)	2.20 (.50; 1–3)	1.96 (.61; 1–3)	.239	
Odor ^d					
Standard	1.84 (.64; 1–3)	2.39 (.56; 1–3)	2.13 (.43; 1–3)	<.001	A, B, C
Comprehensive	1.96 (.68; 1–3)	2.36 (.64; 1–3)	1.96 (.54; 1–3)	.013	B

Note. Standard, *n* = 31; comprehensive, *n* = 25.

^aFriedman's test.

^bWilcoxon's signed-rank test followed by Bonferroni adjustment (revised alpha = 0.017): A = significant difference between enrollment to before extubation; B = significant difference between before extubation to after extubation; C = significant difference between enrollment and after extubation.

^cOAG total possible score range: 8–24 (8 = normal).

^dItem scores range: 1–3 (1 = normal).

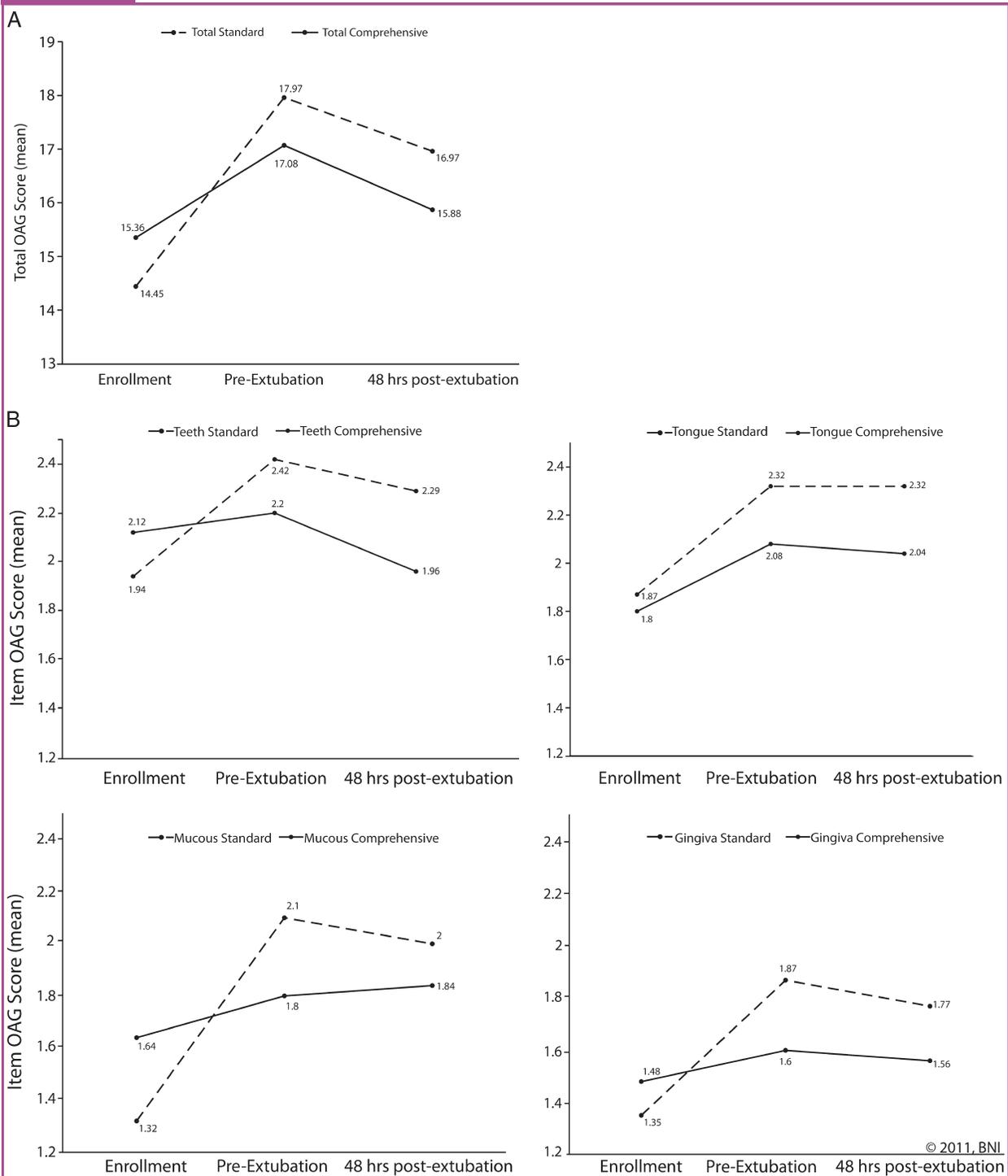
hygiene coupled with its ability to be reused represents a significant savings compared with prepackaged 24-hour oral care kits requiring daily replenishment.

The use of tongue scrapers as part of the comprehensive protocol may have helped preserve tongue hygiene throughout intubation and thereafter. Alternatively, poor tongue hygiene was noted at all three time points for patients in the standard care group. The effect size was moderate during intubation. Cleaning the tongue is difficult in the presence of an oral endotracheal tube, occasional bite block, and impaired visualization. The tongue has been suggested

to harbor pathogenic microorganisms. Consequently, the benefits of cleaning the dorsum of the tongue warrant investigation. Tongue scraping has been moderately successful in reducing halitosis among outpatients and may account for the difference in odor noted between the two study groups. Use of a tongue scraper among intubated patients has not been previously described in published oral care protocols for ICU patients but should be considered as part of the oral care armamentarium.

The difference in the health of the mucous membrane may also be attributed to the difference in

FIGURE 2 (A) Changes in Mean of Total Oral Assessment Guide (OAG) Scores Over Time. (B) Changes in Mean of Item OAG Scores Over Time



Note. Used with permission from Barrow Neurological Institute.

brushes and mouth moisturizer. Saline evaporates when exposed to air, whereas the moisturizing agents in the oral rinse and Oral Balance provide a barrier to moisture loss. For intubated patients who are already at risk for xerostomia, interventions to avoid or

minimize such complications are crucial. Various oral rinses have been proposed for the oral care of ICU patients. Oral bactericidal rinses of 0.12% chlorhexidine have been recommended for oral decontamination (Grap, 2009). Although the efficacy of this

TABLE 6. Effect Size in Oral Assessment Guide (OAG) Scores Over Time Between Groups (Standard, $n = 31$; Comprehensive, $n = 25$)

	Effect Size Between Enrollment and Before Extubation (Comprehensive/Standard)	Effect Size Between Before Extubation and 48 Hours After Extubation (Comprehensive/Standard)	Effect Size Between Enrollment and 48 Hours After Extubation (Comprehensive/Standard)
Total OAG score ^a	-1.72/-3.52	1.20/1.20	-0.52/-2.32
Swallow ^b	0.08/0.26	0.64/0.55	0.72/0.81
Lips ^b	-0.64/-0.58	0.08/0.09	-0.56/-0.49
Tongue ^b	-0.20/-0.45	0.04/0.00	-0.16/-0.45
Saliva ^b	-0.20/-0.42	-0.20/-0.03	-0.40/-0.45
Mucous membrane ^b	-0.16/-0.78	-0.04/0.10	-0.20/-0.68
Gingiva ^b	-0.12/-0.52	0.04/0.10	-0.08/-0.42
Teeth ^b	-0.08/-0.48	0.24/0.13	0.16/-0.35
Odor ^b	-0.40/-0.55	0.40/0.26	0.00/-0.29

Note. “-” value indicates deterioration in OAG score. Higher score reflects greater deterioration over time. Effect size: 0.2 = *small*, 0.5 = *medium*, 0.8 = *large*.

^aTotal possible OAG score range: 8–24 (8 = *normal*).

^bOAG item score range: 1–3 (1 = *normal*).

strategy is unclear, these rinses contain 12% alcohol, which worsens mucosal dryness, an issue not examined in studies that promote their uses.

The lack of stable scores for lips and saliva in both groups is an area of concern. Patients in both groups had moisturizer applied to their lips. Yet scores on these two factors deteriorated over time. Further investigation of product, frequency of application, or both may be required. Nurses may have been reluctant to apply too much lubricant for fear of impeding the adhesive strength of the tape used to secure the endotracheal tube. The lack of stable scores within the category of saliva may reflect the overall xerostomia that occurs while the mouth is open throughout intubation and despite best efforts to avoid it. All patients were on medications that resulted in xerostomia, and a reduction in salivary volume is not surprising. Finally, given the mean of three swabs used to provide additional moisturizer to the mouth, this finding may underscore the need to use mouth-wetting agents more often than a minimum of every 4 hours. Chlorhexidine gluconate has been used as an antiseptic rinse as part of oral care protocols (DeRiso, Ladowski, Dillon, Justice, & Peterson, 1996; Tantipong, Morkchareonpong, Jaiyindee, & Thamlikitkul, 2008). However, its alcohol content would already likely adversely affect xerostomic tissues, and its efficacy remains unclear (Fourrier et al., 2005; Pineda, Saliba, & El Solh, 2006). Because of the lack of oral health assessment scales used in conjunction with oral care protocols, this issue has not been fully explored. That the

category of swallow did not change significantly is predictable because all patients were intubated. Although the swallow score tended to improve slowly 48 hours after extubation, the change was not significant.

One of the main limitations of this study is the inability to establish which part(s) of the comprehensive intervention contributed to the effect. Although research supports the use of electric toothbrushes among the general public for superiority in cleansing teeth and the promotion of gingival health, RCTs among ICU patients are lacking. The development of a complex intervention, drawn on best practices combined with a theoretical basis and implemented via a comprehensive intervention, provides the basis for evidence-based care (Medical Research Council, 2000). This RCT is an example of such an intervention.

Additional limitations to this study include the use of the OAG, which was originally developed to measure health in nonintubated ICU patients. However, the OAG has been used in a wide variety of inpatient populations and has been found to reliably indicate changes in oral health (Andersson et al., 1999, 2002; Andersson, Hallberg, & Renvert, 2003). Further investigations regarding the reliability and validity properties of the OAG among intubated patients should be performed to improve understanding of the changes in scores. Modifications, such as incorporation of chlorhexidine swabs to oral care protocols based on OAG scores over the course of intubation, should also be explored. Although the comprehensive protocol took an average of 1 minute longer to perform than the

standard protocol, the stable oral health scores in this group suggest that the slight additional effort was worthwhile.

In the comprehensive oral care group, there was a significant difference in the magnitude of preventing deterioration between enrollment and before extubation and between enrollment and after extubation. The total OAG after extubation was almost equal to that at enrollment. The finding may reflect that oral health was maintained throughout intubation in this group. Stable assessments in key areas in the comprehensive protocol group, from the time of enrollment throughout intubation to the time of extubation, reflect the effectiveness of providing oral care with an electric toothbrush, tongue scraper, and oral moisturizing agents in intubated ICU patients.

By learning to recognize clues of oral health deterioration and what it portends, nurses are better positioned to deliver effective oral care. Barriers to oral hygiene should not preclude oral care. As described in this protocol, comprehensive oral care promotes and maintains the oral health of intubated neuroscience ICU patients. Clinical care needs to be directed at preventing, as much as possible, the deterioration of oral health during intubation by adopting such a method.

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