I Miss the Sound of Your Voice: Earlier Speech in Tracheostomy Patients*

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The inability to verbally communicate is one of the most frustrating experiences reported by patients undergoing mechanical ventilation via tracheostomy and a major impediment to quality of life while in the ICU (1). Qualitative reports offer important insights from this uniquely vulnerable population including feelings of being trapped and caged, loss of personhood, and loss of control (2, 3). Thus, efforts to restore verbal communication represent an important area of patient-centered investigation with the potential to meaningfully improve patient, family, and clinician experiences. A variety of devices have been developed to facilitate phonation with the presence of a tracheostomy tube including speaking and swallowing valves that can be utilized in line with positive pressure mechanical ventilation (4). This technological advance provides the potential for earlier verbal communication among a subset of ventilator-dependent patients but has not received sufficient investigation to demonstrate improved outcomes.

In this issue of *Critical Care Medicine*, Freeman-Sanderson et al (5) report results from a randomized trial of an intervention to achieve earlier time to initiation of phonation in two groups of tracheostomy patients who were mechanically ventilated. The study showed statistical significance with respect to the primary outcome of time between tracheostomy insertion and return to phonation with subjects in the intervention group achieving phonation a median of 11 days earlier when compared with control subjects. Secondary outcomes including duration of tracheostomy, duration of mechanical ventilation, length of stay, time to oral intake, and quality of life were not different between groups. The intervention and control groups had similar, low numbers of clinical, adverse events.

Prior research on this important topic is limited to observational studies (6), case series (7), and before-after trials (8). Limitations to these designs have included unclear inclusion/exclusion criteria, ambiguity and variation in the "intervention," and bias all of which make it problematic to infer which patients might be appropriate for and benefit from an in-line speaking valve. A notable strength of the current investigation is the randomized design and systematic approach to subject recruitment, which help minimize bias. From the perspective of ICU clinicians, the study's inclusion and exclusion criteria could be readily adapted into clinical practice. In general, patients were required to have modest ventilatory support needs, be able to follow commands, and be considered tolerant of tracheostomy cuff deflation.

Another aspect of the study by Freeman-Sanderson et al (5) with potential clinical application is the structured approach used for the early intervention. Specifically, the intervention included 1) cuff deflation, 2) an in-line speech and swallowing valve, and 3) daily, progressively longer periods of time with the speech valve in place contingent on tolerating prespecified periods of time during the prior day's session. Physiologic criteria were used to proactively monitor clinical status and speech sessions were terminated if patients deviated outside a priori chosen parameters (Table 1 in [5]). Although this approach may mirror what has evolved in many ICUs, the systematic and stepwise protocol used by the investigators could inform a detailed and less ad hoc approach to utilization of in-line speaking valves among patients on mechanical ventilation.

Although these strengths are notable, the study has limitations. The sample size was small with a total of 30 patients (15 subjects per group) and thus definitive conclusions regarding efficacy or safety cannot be drawn. Furthermore, the primary study endpoint was reported as "return to phonation," which typically implies some sound generation produced by true vocal vibration. The operational definition of "return to phonation" in this study was defined as sustained counting from 1 to 10 that includes not only phonation produced by vocal fold vibration but also the process of speech production. Furthermore, there was no mention of the quality of phonation such as intensity, duration, or quality, which have notable implications for the return to functional oral communication. Given that this study was motivated by the isolation and quality of life issues related to the inability to communicate, and a study powered on a functional oral communication endpoint would have been more appropriate. As designed, the earlier time to some degree of voicing during counting is not surprising because phonation is expected in the absence of paralysis or injury and was facilitated early in the intervention group and not attempted until after mechanical ventilation was no longer needed in the control group.

Other investigators have utilized speech outcomes in ventilator-dependent patient populations such as voice intensity, speech intelligibility, and phonation duration that might have provided more nuanced insight into the benefits of the early intervention (9). Subsequent studies are necessary to characterize whether important patient-centered measures such as

*See also p. 1075.

Key Words: mechanical ventilation; speech language pathology; tracheostomy

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time to adequate verbal communication, quality of life, and psychological well being are affected. Also, staff time and staff perceptions of communication quality achieved through the use of in-line speaking valves represent important dimensions for future study because ICU staff exert considerable effort in communication attempts with tracheostomy patients. Clinical outcome measures are important to characterize from a patient safety and resource utilization perspective but should probably be viewed as secondary to patient-centered measures.

In summary, the findings from Freeman-Sanderson et al (5) can inform an ICU's efforts to help patients confined to mechanical ventilation achieve earlier phonation of unspecified quality and potentially mitigate the substantial patient distress by facilitating progression to speech production and effective verbal communication. ICUs are well served by adding speech-language pathologists to the ICU multidisciplinary team to facilitate oral communication.

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Blood, Sweat, and teARDS*

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Patients with hematologic diseases admitted to the ICU are one of the most challenging populations for the clinician because of the complexity of the underlying disease, the constant refinements in their treatment, and, more important, the high mortality rates. The management of these patients in the ICU has changed in the past 25 years, from the initial systematic rejection to avoid futile care (1) to an increased admission and improvements in their outcome (2), reflecting the changes in critical care medicine itself. Similarly, research in the field has evolved from case series to large observational studies (3) and, recently, randomized trials (4).

In spite of the diversity of syndromes and treatments that may put one of these patients in a critical condition, there are three factors that are constantly repeated among the different published series. The first common factor is that the main cause of ICU admission is respiratory failure. In fact, the outcome of these patients is linked to the development of respiratory failure and its treatment: a respiratory event is one of the most relevant risk factors for death in this population (5). In addition, the ventilatory management has been a matter of debate because of the high mortality rates observed after intubation. This led to the widespread use of noninvasive ventilation that, as every treatment available, has its advantages and drawbacks (6). A second factor is the poor outcome of patients admitted to the ICU after hematopoietic stem cell transplantation (7). The high mortality rates in transplanted, critically ill patients can be explained by the severity of the underlying diseases, the toxicity of the conditioning regimes, and the deep disturbances in the immune response during the posttransplant period. The latter is especially relevant in allogeneic transplantation, where the presence of an acute or chronic graft versus host disease is uniformly related to a poor ICU outcome (8). The third factor

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Key Words: acute respiratory distress syndrome; epidemiology; hematopoietic stem cell transplantation; mortality; outcomes research

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Return of Voice for Ventilated Tracheostomy Patients in ICU: A Randomized Controlled Trial of Early-Targeted Intervention*

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Objectives: A cuffed tracheostomy tube facilitates prolonged mechanical ventilation and weaning but usually leads to prolonged voicelessness, which can be one of the most negative experiences of hospitalization. No randomized trials have examined the effects of targeted early communication intervention for the restoration of voice in ventilated tracheostomy patients in the ICU.

Design: A prospective randomized clinical trial.

Setting: The trial was conducted in the ICU of an urban tertiary level hospital.

Patients: Thirty adult participants enrolled, with 15 randomly allocated to the intervention and control groups.

Interventions: The early intervention group received early cuff deflation and insertion of an in-line speaking valve during mechanical ventilation. The control group received standard cuff deflation and a speaking valve during self-ventilation. A speech-language pathologist provided all treatments.

Measurements and Main Results: The primary outcome measure was time from tracheostomy insertion to phonation. Early intervention significantly hastened return to phonation (median difference = 11 d; hazard ratio = 3.66; 95% CI, 1.54–8.68) with no significant effect on duration of tracheostomy cannulation (hazard ratio = 1.40; 95% CI, 0.65–3.03), duration of mechanical ventilation in days from tracheostomy insertion (hazard ratio = 1.19; 95% CI, 0.58–2.51), length of stay in ICU (hazard ratio = 1.16; 95% CI, 0.54–2.52), or time to return to oral intake (hazard ratio = 2.35; 95% CI, 0.79–6.98). Adverse events were low and equal in both groups. There was no significant change in measures of quality of life.

Conclusions: Focused early intervention for communication during mechanical ventilation allows the restoration of phonation significantly sooner than standard treatment, with no increase in complications in a small patient cohort. Although these results are favorable, further research is needed to determine whether the effects on any of the secondary outcomes are statistically significant and clinically important. (*Crit Care Med* 2016; 44:1075–1081)

Key Words: communication; intensive care; phonation; speech-language pathology; tracheostomy

Tracheostomy facilitates the provision of prolonged mechanical ventilation and is commonly used for patients in the ICU. Over 160,000 patients are admitted and managed within an ICU in Australia and New Zealand annually, and up to 40% of these patient admissions require invasive mechanical ventilation (1). The prevalence of tracheostomy placement within ICU has been reported to range from 11% to 24% for patients requiring mechanical ventilation (2, 3).

Placement of a tracheostomy tube for mechanical ventilation often allows patients to be managed with reduced levels of sedation compared with an endotracheal tube. However, any potential for improved communication with the lighter sedation is offset by the patient's inability to speak due to the inflated tracheostomy cuff. The period of voicelessness is often prolonged and can be indefinite for some patients in ICU. In a cohort of 140 tracheostomy patients, the median time to return to voicing after tracheostomy insertion was 12 days for 59% of the cohort. The remaining 41% did not return to voicing (4).

The temporary lack of phonation and the consequential impact of reduced communication effectiveness have been documented as among the most negative hospital experiences for patients (5–8) and have been associated with long-term

*See also p. 1234.

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depression and post-traumatic stress disorder (9). An observational study of the change in quality of life and mood with the return of voice for tracheostomy patients has reported a significant increase in ability to be understood by others and cheerfulness on the day voice was restored (10).

In our hospital, speech-language pathologists (SLPs) manage communication disorders, including the lack of phonation in tracheostomy patients. The lack of high-quality evidence about early intervention to facilitate speech in tracheostomy patients may be why ICUs vary widely with respect to their services in this area. Reports range from no routine SLP input in ICU (11) to as many as 78% of tracheostomy patients receiving SLP input (4).

Several trials have examined the impact of a multidisciplinary tracheostomy management team, showing improved clinical outcomes including increased use of speaking valves, decreased length of tracheostomy cannulation, reduced ventilation time, reduced length of hospital stay, and reduced number of complications (12–16). Also, use of speaking valves in-line with mechanical ventilation has been reported as safe with no additional adverse events and no impact on duration of mechanical ventilation or tracheostomy cannulation (17). However, these studies were not randomized and used historical controls. Furthermore, interventions do not always have their intended effects (e.g., when assessed in a controlled trial where consecutive eligible participants are enrolled, speaking valves may not be tolerated early in the admission and therefore may not lead to earlier return of phonation). In response to these limitations in the existing research, we sought to determine the effect of targeted early communication intervention for the restoration of voice in tracheostomy patients in the ICU on time to phonation and verbal communication; the duration of tracheostomy cannulation and mechanical ventilation; the length of stay in ICU and hospital; the time to oral intake; and quality of life. We, therefore, conducted a randomized controlled trial to compare an early communication intervention with standard therapy in ventilated tracheostomy patients in a large tertiary ICU.

MATERIALS AND METHODS

Ethics approval was given by the local Area Health Service Protocol X09-0380 and HREC/09/RPAH/643. The trial was prospectively registered on www.ANZCTR.org.au, protocol number ACTRN12610000075088.

Design

A prospective randomized controlled trial was conducted with concealed allocation, blinded assessment of some outcome measures, and intention-to-treat analysis. All tracheostomy patients were consecutively screened during the scheduled recruitment periods and enrolled if eligibility criteria were met. Written consent was gained from each participant or person responsible. Participants were randomly allocated to an intervention or control group using computer-generated, permuted-block randomization, with concealed allocation via sealed opaque envelopes.

Participants and Setting

The study was conducted at the Royal Prince Alfred Hospital, a tertiary referral hospital in Australia. Participants were recruited from the intensive care department, which has 52 beds including general, cardiothoracic, and neurosurgical beds. Eligibility criteria were greater than 18 years old, formation and placement of the tracheostomy greater than 48 hours, air-filled cuffed tracheostomy tube in situ, actively mechanically ventilated with positive end-expiratory pressure less than or equal to 10 cm H_2O pressure, F_{IO_2} less than or equal to 40%, spontaneously breathing, triggering ventilatory support, voiceless greater than or equal to 48 hours, awake, and able to obey verbal commands. Patients were excluded if there was any contraindication to deflation of the tracheostomy cuff as decided by the treating intensive care specialist. Patients with bulbar palsy, brainstem stroke, or recent head and neck surgery were also excluded.

Interventions

A senior SLP implemented the study protocol on weekdays if the participant's clinical observations were within the range as defined for this trial (listed in **Table 1**). In addition to these criteria, a clinical examination of oromotor cranial nerve function was conducted prior to each treatment session to document any change in swallow or communication function from a new focal weakness. In the event of major bulbar weakness, treatment was to be withheld, but this did not occur with any participants. Fiberoptic endoscopic evaluation of swallowing was provided for any subject in either group when indicated. One of our acceptability criteria was that the number of adverse events was low and similar between groups. We defined adverse events during treatment as death; prolongation of hospitalization; life-threatening or permanently disabling event; or medically important event including new-onset chest infection as decided by treating intensive care specialist (characterized by fever, purulent sputum, and new pulmonary infiltrates). This definition was based on the definition of adverse events with the use of medical devices published by the Australian Therapeutic Goods Administration (18).

TABLE 1. Clinical Criteria Limits Applied During Each Application of the Study Interventions

Clinical Criteria	Prerequisite Values
Respiratory rate, breaths/min	8–24[a]
Oxygen saturation, %	> 88
Heart rate, beats/min	40–120
Systolic blood pressure, mm Hg	90–160
Glasgow Coma Scale	No fall ≥ 2 points
Patient distress	Not reported by patient, medical, nursing, or allied health staff

[a]Or at the discretion of the treating intensive care specialist.

Early Intervention. Early intervention was defined as cuff deflation and use of an in-line Passy Muir "Ventilator Speech and Swallowing Valve 007" (PMV) during pressure support ventilation via the tracheostomy tube. The PMV is a one-way, positive-pressure valve with a unique design; the flange closes at the end of inspiration, which allows it to be used during mechanical ventilation, in contrast to all other speaking valves, in which the flange closes on expiration (19). Initially, the PMV was used for a period of up to 60 minutes as tolerated. On subsequent days, the PMV was used for increasing periods while the patient was on mechanical ventilation: up to 2 hours on day 2, up to 4 hours on day 3, and up to 8 hours on day 4 and beyond. However, the duration of PMV use was only increased if the participant tolerated the full preceding period. At the end of each early intervention session, the PMV was removed and the tracheostomy cuff was reinflated. During the application of the PMV, the participant was continuously monitored, and the early intervention session was ceased if the patient's clinical observations were outside the ranges defined in Table 1 or if an adverse event occurred. Once participants were taken off mechanical ventilation, they continued with cuff deflation and PMV as tolerated.

Standard Intervention (Control Group). Standard intervention was defined as cuff deflation and provision of a Portex orator speaking valve (Smiths-Medical, Sydney, Australia) after the participant was off mechanical ventilation. Standard intervention commenced after the participant was established on Swedish nose (Themovent-T) (heat and moisture exchange filter; Smiths-Medical) breathing trials and the medical team, nursing staff, or physiotherapist made a referral.

Other Care. All other usual care in the ICU was provided to participants in both groups including ventilator weaning, sedation protocols, management of pain, staff-to-patient ratios, and clinical monitoring.

Outcome Measures

Primary Outcome. Time to phonation was the primary outcome. It was measured from tracheostomy insertion to the ability to count from 1 to 10 using voice and reported in days. The presence of phonation was assessed daily by an SLP or nurse who was not otherwise involved in the trial.

Secondary Outcomes. The secondary outcomes were duration of tracheostomy cannulation, duration of mechanical ventilation, length of stay in ICU, length of stay in hospital, time to oral intake, safety, and quality of life.

The duration of tracheostomy tube cannulation was measured from tracheostomy insertion to decannulation and reported in days. The duration of mechanical ventilation was measured from tracheostomy insertion to 24 hours off pressure support ventilation and reported in days. The length of stay in ICU and the length of hospital stay were reported in days. The time to commencement of oral intake was measured from tracheostomy insertion to the commencement of oral intake of fluid or food and was reported in days. For each outcome, participants who died were treated as censored cases.

A measure of the safety of the two interventions in this study was made by documenting any clinical observation from a participant that was outside the range defined by Table 1 and by the number of adverse events recorded during the study period.

Quality of life was measured with two tools: the visual analog self-esteem scale (VASES) (20) for communication-related quality of life and the EuroQol-5D questionnaire (EQ-5D) (21) for general health status. The VASES consists of 10 items represented pictorially with a bipolar scale. The 10 items include the following: cheerful, trapped, optimistic, confident, frustrated, confused, misunderstood, outgoing, intelligent, and angry. An evaluation of the scales has shown strong internal validity in populations both with and without neurologic injury impacting language function, with a Cronbach alpha of 0.86 (20). The EQ-5D contains a descriptive profile of five dimensions of health status (mobility, self-care, usual activities, pain/discomfort, and pain/anxiety) and a 20-cm visual analog scale of general health status. The validated Australian version of the tool has a range of scores from 0 = worst imaginable health state to 100 = best imaginable health state. Although we administered the full tool to preserve their psychometric validity, we elected a priori to analyze only the 8 items of the VASES and the visual analog scale data of the EQ-5D due to the limited potential of these items to be affected by the return of voice. The EQ-5D has been used to measure quality of life in tracheostomy patients in ICU (10) and the visual analog scale has high reliability and validity in patient-reported quality of life in mechanically ventilated patients (22).

Data Analysis

Descriptive statistics were used to summarize the baseline characteristics of the participants. Continuous data were summarized using means and SDs. Dichotomous data were summarized using counts and percentages. The characteristics of each group were tabulated for comparison. The reporting of other aspects of the study was also consistent with the 2010 Consolidated Standards of Reporting Trials statement (23). The effect of the intervention was estimated using between-group comparisons. Continuous data were again summarized using means and SDs and then compared using an independent *t* test, with the estimate of the treatment effect summarized as a mean difference with a 95% CI. Dichotomous data were again summarized using by counts and percentages and compared between groups using relative risk (RR) with a 95% CI. Time-to-event data were analyzed using Kaplan-Meier survival curves in MedCalc statistical software version 14.10.2 (MedCalc, Oostende, Belgium). All quality-of-life measures were analyzed between groups using a time-weighted average for the first 7 days of enrollment. Time-weighted average is calculated as the area under the curve for each case (taking 0 as the baseline) divided by its total time interval (time of last observation minus time of first observation available in the first 7 d). Scores are reported as mean differences with a 95% CI, calculated as experimental minus control so that positive values favor the experimental group. For all outcomes, an intention-to-treat analysis was performed.

A sample size calculation was conducted for the primary outcome. The SD used in the sample size calculation was

converted using the methods proposed by Hozo et al (24) from medians and ranges published in audit data on tracheostomy practice (4). The estimated effect size was alpha set at 0.05, and 12 participants per group were required to yield a power of 80%. Thirty participants were recruited, and this was based on a morbidity rate of 25% as previously reported (4).

RESULTS

Thirty participants were recruited from August 2010 to September 2011 and October 2012 to August 2014. All participants were randomly assigned to their treatment blocks, resulting in two equal groups. Four participants died before reaching the primary outcome of return to phonation, but none withdrew or was otherwise lost to follow-up. All available data from all participants for the duration of their participation were included in the intention-to-treat analysis. Flow of participants through the study is illustrated in **Figure 1**. Baseline characteristics of the participants are summarized in **Table 2**.

Compliance With Trial Protocol

In the early intervention group, all 15 participants received the treatment protocol. They received a mean of six treatments (SD: 4; range, 1–16). In the control group, all 15 participants received the standard protocol, in which SLP treatment occurred after referral. Ten participants were referred and received the Portex valve and cuff deflation. They received a mean of four treatments (SD: 3; range, 1 to 11). Among the remaining five participants in the control group, three died prior to referral to SLP and two were successfully decannulated by the medical team without prior referral to SLP.

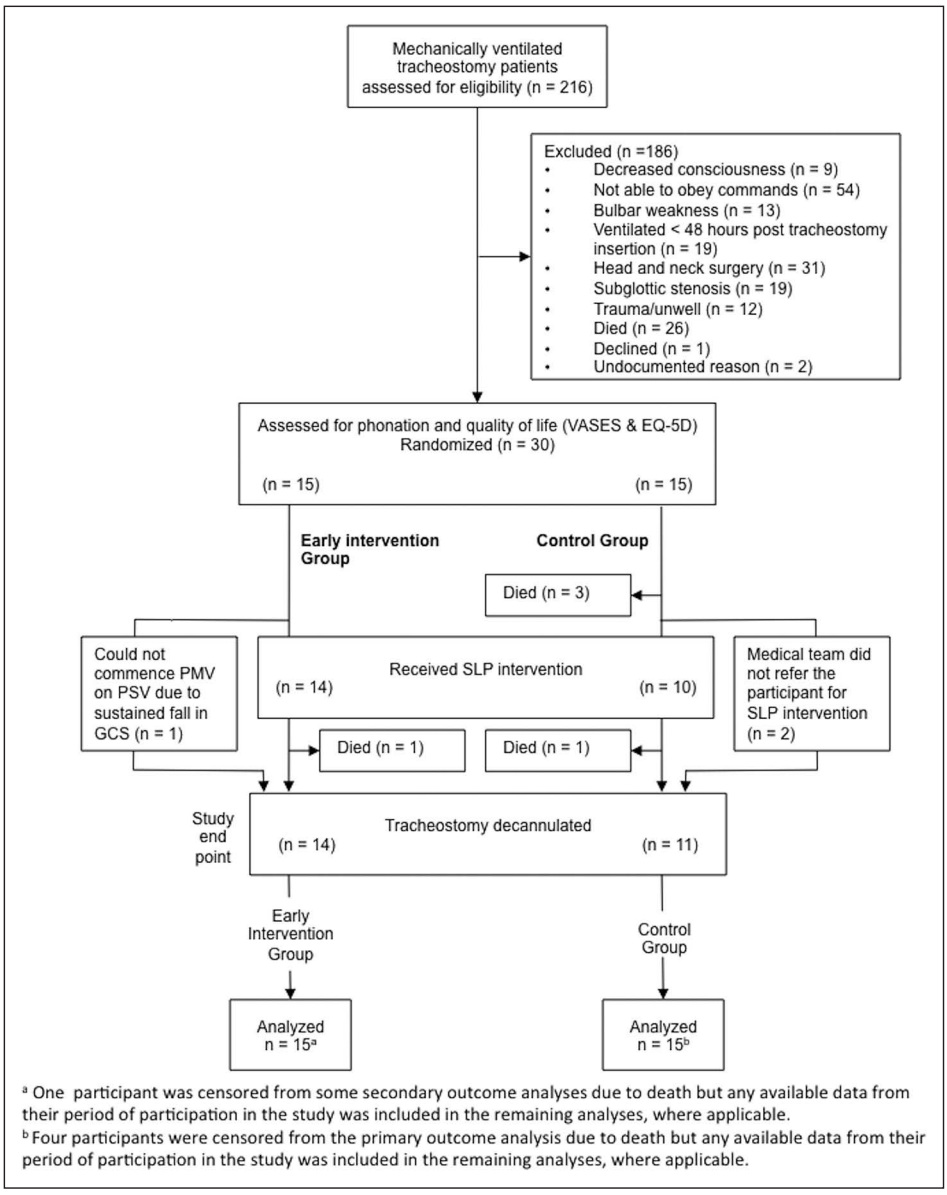

Figure 1. Flow of participants through the study. EQ-5D = EuroQol questionnaire, PMV = Passy Muir Ventilator Speech and Swallowing Valve, PSV = pressure support ventilation, SLP = speech-language pathologist, VASES = visual analog self-esteem scale.

Effect of Interventions

Time to Phonation. In answer to our primary research question, the early intervention group had a significantly hastened return to phonation, with a median difference of 11 days ($p = 0.001$; hazard ratio = 3.66; 95% CI, 1.54–8.68). The Kaplan-Meier survival analysis curve is presented in **Figure 2**. The median time to return to phonation from tracheostomy insertion was 7 days for the early intervention group compared with 18 days for participants in the control group. Therefore, the restoration of phonation occurred at more than triple the rate in the intervention group compared with the control group.

Tracheostomy Cannulation Time. The early intervention group achieved tracheostomy decannulation a median of 1 day later than the control group, but this was not statistically significant ($p = 0.38$; hazard ratio = 1.40; 95% CI, 0.65–3.03).

Mechanical Ventilation Time. The early intervention group had a shorter duration of mechanical ventilation than the control group by a median of 1 day, but this was not statistically significant ($p = 0.62$, hazard ratio = 1.19; 95% CI, 0.58–2.51).

Length of Stay. There was no statistically significant difference between the groups for length of stay in ICU with a median difference of 0 days ($p = 0.69$; hazard ratio = 1.16; 95% CI, 0.54–2.52) or hospital length of stay with a median difference of 14 days

TABLE 2. Baseline Characteristics, Diagnostic Categories, and Tracheostomy Details of Participants

Characteristics	Randomized ($n = 30$)	
	Early Intervention ($n = 15$)	Control ($n = 15$)
Age (yr), mean (SD)	53 (21)	67 (11)
Gender, males, *n* (%)	11 (73)	6 (40)
Acute Physiology and Chronic Health Evaluation-II score (0–71), mean (SD)	19 (4)	18 (5)
Diagnostic category, *n* (%)[a]		
Neurology	3 (20)	4 (27)
Cardiothoracics	4 (27)	5 (33)
Respiratory	4 (27)	2 (13)
General medical	4 (27)	4 (27)
Tracheostomy insertion method, *n* (%)		
Percutaneous	13 (87)	14 (93)
Surgical	2 (13)	1 (7)
Tracheostomy size, *n* (%)		
7.0	1 (7)	2 (13)
7.5	1 (7)	1 (7)
8.0	8 (53)	11 (73)
9.0	5 (33)	1 (7)
Tracheostomy type, *n* (%)		
Portex cuffed nonfenestrated	14 (93)	13 (87)
Portex adjustable phlange	0 (0)	1 (7)
Cook cuffed nonfenestrated	1 (7)	1 (7)
Time from intubation for mechanical ventilation to tracheostomy (d), mean (SD)	13 (7)	13 (5)

[a]Specific diagnoses included the following: neurology–traumatic brain injury and acute disseminated encephalomyelitis; cardiothoracic–coronary bypass graft, mitral valve replacement, and aortic valve replacement; respiratory–pneumonia, respiratory arrest, exacerbation of chronic obstructive pulmonary disorder, and influenza (A & H1N1); and general–liver transplant, necrotizing pancreatitis, myocardial infarction, ileus, gun shot wound, and perforated bowel.

shorter in the early intervention group ($p = 0.42$; hazard ratio = 1.37; 95% CI, 0.62–3.07).

Time to Oral Intake. There was no statistically significant difference between the groups for time to return to oral intake ($p = 0.14$; hazard ratio = 2.35; 95% CI, 0.79–6.98). Although nine participants (60%) in the early intervention group returned to oral intake, no median difference can be reported because only four (27%) of the control group had returned to oral intake by the time of decannulation.

Safety. The number of adverse events was low and equal between groups. There were four deaths prior to decannulation in the control group, and one death in the early intervention group prior to decannulation. One participant in the early intervention group died from respiratory failure following aspiration of vomit and chemical pneumonitis on day 41 after randomization. At this time, she had received five treatments, with the last treatment being 5 days prior to vomit, which was 24 days before death. In the control group, three participants died prior to referral to SLP, and the remaining participant in the control group died from gastrointestinal bleeding, on day 64 after randomization. At this time, she had received three treatments, with the last treatment being 45 days before death. There were no other reported serious adverse events recorded for either participant group during the trial. The complications associated with tracheostomy cuff deflation and tracheostomy weaning include changes to baseline saturation of peripheral oxyhemoglobin, RR, reported upper respiratory tract secretions, and coughing, which occurred equally in both groups as reported in **Table 3**.

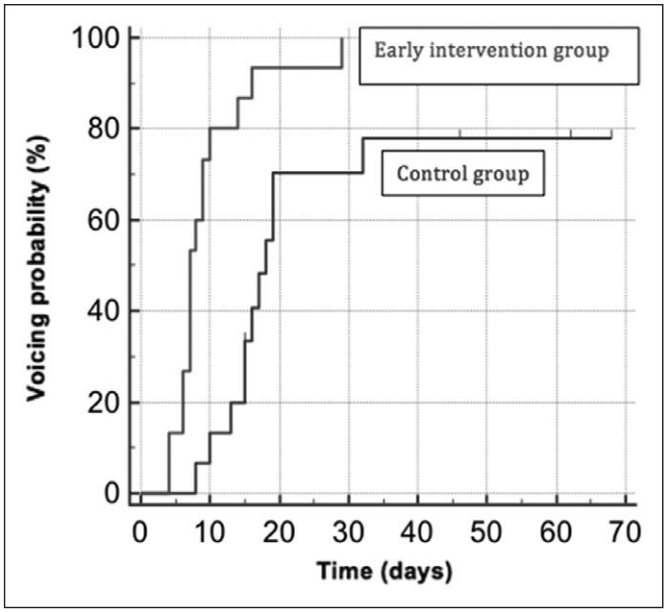

Figure 2. Time to phonation.

TABLE 3. Number of Clinical Events Associated With Tracheostomy Cuff Deflation

Clinical Event	Early Intervention	Standard Care
Oxygen desaturation < 88%	1	1
Respiratory rate > 35 breaths/min	2	2
Increased upper respiratory tract secretions	0	2
Excessive coughing	1	0
Systolic blood pressure > 160 mm Hg	1	0
Total events	5	5

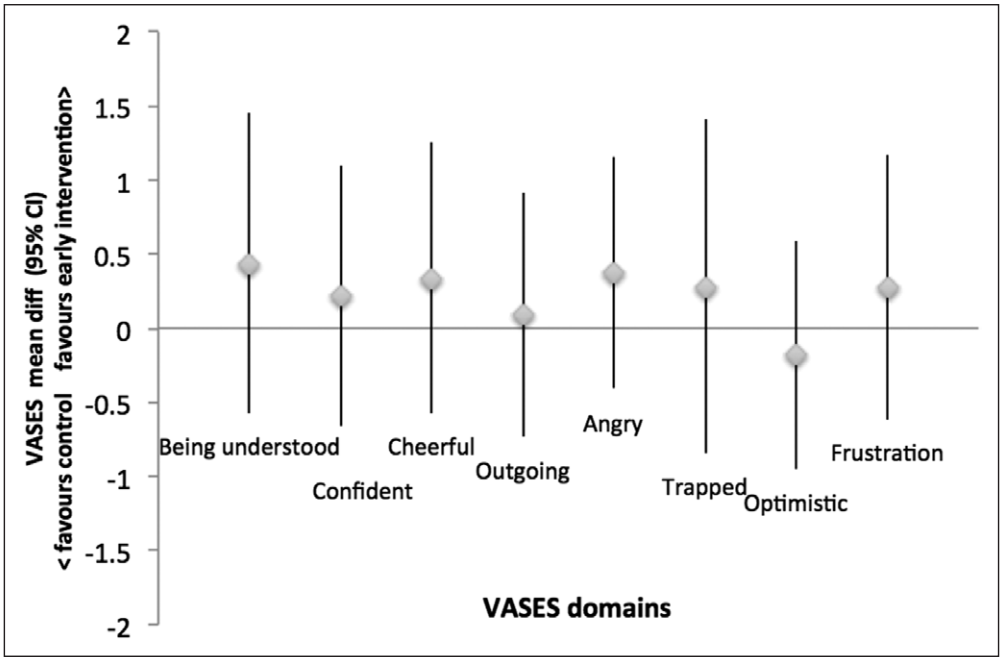

Figure 3. Time-weighted average scores for communication quality of life.

Quality of Life. None of the eight domains of the VASES that we measured showed a statistically significant benefit from the early intervention. However, seven of the eight domains had mean between-group differences that favored the early intervention group, as presented in **Figure 3**. Similarly, the EQ-5D did not show a statistically significant difference between the groups, but the mean difference favored the early intervention group by 2 points (95% CI, –22 to 26 points).

DISCUSSION

This is the first randomized controlled trial of a treatment for initiation of speech in ventilated patients. Early, targeted intervention by speech pathology services for tracheostomy patients during mechanical ventilation resulted in return of speech by a mean of 11 days compared with standard care. This was a statistically significant finding for the study's primary outcome. Overall patient safety was maintained throughout the treatment, with no differences in length of time on the ventilator, tracheostomy cannulation time, or length of stay.

The routine use of in-line speaking valves during mechanical ventilation for acute adult patients in ICU has only recently been documented to occur within a cardiothoracic cohort (17) with the authors reporting similar findings of no adverse effects on mechanical ventilation time, tracheostomy cannulation, or safety. The return of phonation with the use of speaking valves has been associated with significantly improved patient-reported quality of life within the ICU (10). Therefore, a treatment that promotes the earliest possible return of speech may represent an important patient-centered care goal and impact patient health-related quality of life. Patient-focused care and participation in personal goal setting is highly valued and a current focus on healthcare engagement. The study has clearly shown that early speech-language pathologist intervention during mechanical ventilation leads to the effective restoration of speech significantly earlier in the ICU admission. However, a larger trial would be necessary to adequately assess whether this earlier restoration of voice also influences objective measures of clinically relevant outcomes such as length of stay and aspects of quality of life (QOL) such as prevalence and severity of depression and post-traumatic stress disorder. Nevertheless, given the adverse experience attributed to voicelessness by ICU patients (as previously highlighted), we consider that even if no other outcomes improved, the ability to communicate verbally an average of 11 days earlier during an ICU admission is a worthwhile outcome of the intervention.

The significant benefit in hastening the return of speech was achieved without any significant worsening of tracheostomy cannulation time, duration of mechanical ventilation time, time to oral intake, or length of stay. The safety data were also reassuring; apart from five deaths, which were not believed to be related to the early intervention, there were no serious adverse events. The participant death in the treatment group was considered to be unrelated to the early intervention as the aspiration was acute and occurred off mechanical ventilation, with the death occurring 29 days after the last treatment. An additional safety aspect of the PMV that has not specifically been addressed by this trial is the impact of reducing aspiration during oral intake, which has been previously highlighted as a benefit of the PMV (25).

The overall mortality in all patients was 17%, with 27% in the control group and 7% in the early intervention group. This difference was not statistically significant due to the small number of subjects and was lower than the reported rate of death for tracheostomy patients of 30% (26). Illness severity (Acute Physiology and Chronic Health Evaluation-II) scores show that the control group did not have greater clinical severity although that group had a greater average age with wide variability in both groups.

There are limitations to the study. In asking participants to count to 10, the measure used for the primary outcome failed to capture the complexity of their communication; patients were able to produce words, phrases, and sentences in conversations with their relatives and ICU staff. However, it was an objective measure of their ability to phonate. The use of outcomes that directly measure successful communication may be more informative. Newly developed validated outcome tools for measuring QOL in mechanically ventilated patients should be considered in future studies (22). There was no blinding of participants, the therapists who administered therapy, or the

assessor of the primary outcome. However, blinding of most secondary outcomes was achieved. Also, the assessors collecting the unblinded outcome measures did not conduct any part of the treatment and were not involved in any other aspects of the data collection or analysis. The study sample was small but was appropriately powered for the primary outcome. Future clinical trials should involve other facilities and enroll greater numbers of patients to ensure adequate power to improve our understanding of treatment effects, increase precision of treatment effects, and confirm clinically significant differences in all of the secondary outcomes including quality of life. However, the study did achieve its a priori sample size with sufficient power for the primary outcome. Although the proportion of excluded participants was large, this is largely due to the inability to undertake measurement procedures in the trial. Many of these patients would be eligible to receive the intervention in clinical practice. Further research into the benefits of phonation on the management of delirium, confusion, and pain would add to the overall clinical management of this population.

CONCLUSIONS

In conclusion, targeted early treatment during mechanical ventilation hastened return to phonation for patients with a tracheostomy tube. Earlier return of voice facilitates effective communication that is beneficial for improved patient care in the ICU that may include improved reporting of medical symptoms and assessment and management of pain, delirium, and emotional distress experienced in ICU. In the study cohort, there were no adverse impacts on other facets of care including time to tracheostomy weaning milestones; however, additional studies with larger participant numbers need to be conducted to replicate these findings, monitor safety, and confirm secondary clinical benefits with this particular treatment. Early treatment by an SLP to promote the return of phonation may therefore be considered for selected ventilated tracheostomy patients in the ICU.

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editorial by Dr. Orlowski (2) "My kingdom for an intravenous line" in the *American Journal of Diseases of Children* called for increased awareness of IO-based resuscitation. In 1986, intraosseous cannulation was integrated into pediatric advanced life support training. The next two decades would usher innovations in user-friendly intraosseous cannulation devices such as the EZ-IO system (Vidacare, Shavano Park, TX). As a result, in 2010, the Adult American Heart Association guidelines for cardiopulmonary resuscitation (CPR) advocated for intraosseous needle placement if IV catheters are not readily available (3).

However, despite endorsements by professional societies, awareness and utilization of intraosseous devices in the adult inpatient setting is still lacking (3, 4). This is highlighted by the recent letter to the editor by Iskrzycki et al (5). The authors polled 60 hospital physicians and found that only 30% were aware of intraosseous device use during CPR. Even less (20%) had exposure to intraosseous devices. Following a brief 10-minute didactic session followed by hands-on training with two different devices (EZ-IO and NIO [Houston, TX]) in simulated CPR settings, the participants were able to establish intraosseous access in under 30 seconds. The favorable learning curve and procedure speed support the findings in our previous study (4). Other studies assessing awareness and attitudes toward intraosseous access show significant knowledge gaps in terms of indications, guidelines, and potential complications (3, 4). A systematic review by Voigt et al (3) suggest that there are very few hospital protocols specifically addressing intraosseous device use during inpatient emergencies. In summary, 70 years since the first human intraosseous cannulation, we have achieved significant advances in intraosseous device form factor and acceptance by professional societies. However, much work remains in advocating and educating individual providers at the level of the hospital system. Given the highly favorable learning curve and success rates, more inpatient providers should be exposed to and trained in intraosseous device use. Furthermore, contrary to current Advanced Cardiac Life Support guidelines, we believe that intraosseous access should be considered first line in cardiac arrest in the absence of indwelling, large-bore, central venous catheters.

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Return of Voice for Tracheostomized Patients in ICU, Not Only Psychologic Advantages

To the Editor:

Regarding the article in a recent issue of *Critical Care Medicine* by Freeman-Sanderson et al (1), we want to congratulate this initiative and this team for the launch of their study and their concern reflected in several publications disseminating the importance of giving oral communication back to our patients.

Currently, there are more and more initiatives with intent to humanize ICUs in relation to environmental factors care, enable patients to hear music or watch television, and be accompanied by their family. However, there are few units that take into account that inability to speak is one of the more distressing sensations perceived by our patients, in addition to pain (2, 3).

Thus, although the sample is small and significative comparisons probably cannot be done, it is noteworthy that data provided in this study about a similar perception of quality of life-mood among groups, when the group of nonintervention took 11 days on average to recovery phonation against the group in which the speech valve was used. These results contradict the experience previously described by Sutt et al (4).

The use of speaking valves is growing in units that have started working with them in tracheostomized critically ill patients as well as the feeling that patients change emotionally and the prevalence of delirium decreases. In addition, the need for treatment (sedatives, neuroleptics, etc) is reduced; although this must be studied, it is in line with other nonpharmacologic measure results (2, 3).

Furthermore, the beneficial effects of phonation are not only mental but also physiologic. The restoration of the air passage through the natural airway rehabilitates musculature and laryngeal receptors and allows the reset of subglottic pressure and coordination of breathing and swallowing. This is crucial in our tracheostomized patients, mostly undergoing prolonged mechanical ventilation in which the presence of laryngeal dysfunction and dysphagia is almost assured (5).

At present, our team is coordinating a multicenter randomized trial (Estudio, DIsfagia, VALvula fonadora study, dysphagia, speaking valve [EDISVAL] study), with the aim to determine the usefulness of speaking valve in preventing respiratory nosocomial infections in patients diagnosed of dysphagia secondary to artificial airway (tracheostomized adults patients without upper airway disease or neurologic disease) during weaning and tracheostomy decannulation process.

In conclusion, studies like published by Freeman-Sanderson et al (1) or Sutt et al (4) are vitally important to emphasize

that simple and safe interventions can improve the quality of life of our patients in a significative way and even to decline depressive pathology or traumatic stress of our patients. But also it cannot be ignored the likely beneficial physiologic effects of early restoration of phonation in terms of improvement of dysphagia present in most of these patients, which is critical during weaning and decannulation process. All these issues should be subject of further research studies.

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Problem Shared Is a Problem Acknowledged

To the Editor:

We would like to thank Weiss et al (1) for their article published in a recent issue of *Critical Care Medicine*, demonstrating the difficulty of translating low tidal volume ventilation for acute respiratory distress syndrome (ARDS) patients into practice despite international consensus (2). University Hospital Birmingham is Europe's largest colocated ICU, and for the past 3 years we have been working to attempt to improve our practice in this area. Initial audits demonstrated that only 15% of our ARDS patients were receiving lung protective ventilation (LPV) to standards as described by Weiss et al (1).

Following introduction of LPV guidelines, an extensive promotional and educational campaign, incorporation of LPV into hospital guidelines, and ongoing discussion with colleagues we have increased this to 29% (3).

Weiss et al (1) highlight important reasons for this lack of uptake. We have surveyed our own medical and nursing staff and identified further barriers to changing practice: role uncertainty among nursing and medical staff as to ventilator settings, reluctance to modifying ventilator settings without senior approval even with a guideline to support decision making, fear of loss of professional autonomy and a resistance to standardization, differences in practice between different subspecialty areas of critical care, barriers to disseminating new practice and information across a large workforce, and a lack of resource for staff continuing professional development and the regular rotation of trainee doctors inhibiting practice becoming embedded in the junior medical workforce.

Weiss et al (1) comment that their findings may not be translated internationally, yet our experience mirrors theirs. Many of these are universal obstacles to achieving change in practice for LPV and beyond.

Our solutions have been to attach our local guidelines to every ventilator, ensure nursing staff are empowered to modify ventilator settings and are aware they will be supported in following LPV guidelines, repeated local audits to raise awareness of practice among consultant colleagues, and incorporation of LPV into our induction process for new medical staff.

In the future, we hope to use social media platforms to help dissemination of new developments rapidly through the workforce. We hope that these strategies can continue to improve our performance and hope that by sharing our experience we can help develop solutions to increase adoption of LPV bringing proven outcome benefits to our patients.

The authors have disclosed that they do not have any potential conflicts of interest.

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ABCDEF: Not So Simple

To the Editor:

The unequivocal endorsement of the ABCDEF bundle, as suggested by Drs. Teegarden and Prough (1), should be cautiously considered, given the available evidence and the bundle's limitations.

The ABC Randomized Controlled Trial (RCT) (2) enrolled patients between 2003 and 2006 and led to the bundle's "ABC"