

Study Number: NCT02018562

Official Title: *Evaluation of a Tracheostomy Tube That Enables Communication*

Principal Investigator: Vinciya Pandian

Date: 12/19/2013

JHM IRB - eForm A – Protocol

Use the section headings to write the JHM IRB eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.

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1. Abstract

- a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

Verbal communication greatly affects people’s autonomy and is directly related to how they perceive their quality of life (Hess, 2005). The need for effective communication is heightened during critical illness. Critically ill patients requiring mechanical ventilation often need an endotracheal tube or a tracheostomy tube. When a patient is intubated, communication is often accomplished through facial expressions, gestures, and/or writing, depending on the person’s neurological status and sedation level (Batty, 2009). However, these simple modes of communication are not always effective and can often result in frustration for the patient (Patak et al., 2006).

A benefit of tracheostomy over an endotracheal tube is that it may facilitate the ability to communicate by mouthing words. Additionally, when a person receives a tracheostomy tube, several methods used to elicit phonation can be utilized, including the use of a one-way speaking valve, leak speech, and digital occlusion. All of these methods require toleration of cuff deflation (Batty, 2009; Astrachan, Kirchner, & Goodwin, Jr., 1988; Hess, 2005; Nomori, 2004). Unfortunately, some critically ill mechanically ventilated patients cannot tolerate cuff deflation despite their ability to maintain arousal and to initiate meaningful communication. Uniquely designed tracheostomy tubes are available that enable speech and do not require cuff deflation. These “talking tracheostomy tubes” are rarely used because of a general lack of awareness among care providers. However, recently, at the Johns Hopkins Hospital, there has been an increase in the use of these tubes to facilitate speech. One of the tubes that has proven to be effective is the Blueline Ultra Suctionaid (BLUSA).

In 2010, we conducted a retrospective review of 4 cases and found that BLUSA tracheostomy helped facilitate communication in this unique population (IRB #: NA_00041547). Now, we would like to formally conduct a prospective study to evaluate the outcomes of patients using a BLUSA using a pretest-posttest research design.

Identifying the predictors of intelligibility and the impact of BLUSA on Quality of Life (QOL) and communication will promote communication between patients and healthcare providers. This empowers patients and allows healthcare staff to obtain a more accurate assessment of patients’ condition and tailor care accordingly.

2. Objectives (include all primary and secondary objectives)

Specific Aim 1: Determine the impact of a BLUSA on QOL in patients requiring prolonged mechanical ventilation in the hospital

Hypothesis 1a: The mean health-related QOL scores of patients who use BLUSA will be significantly higher compared to patients who do not use BLUSA.

Hypothesis 1b: The mean voice-related QOL scores of patients who use BLUSA will be significantly higher compared to patients who do not use BLUSA.

Specific Aim 2: Determine the outcomes of communication following the use of BLUSA in patients requiring prolonged mechanical ventilation in the hospital.

Hypothesis 2: Effectiveness of communication in patients who use BLUSA will be significantly improved compared to patients who do not use BLUSA.

Research Question 2a: What is the time to speech among patients who are unable to speak using a speaking valve?

Research Question 2b: What is the frequency and duration of speech with use of BLUSA?

Specific Aim 3: Identify the predictors of intelligibility in patients requiring prolonged mechanical ventilation in the hospital.

Hypothesis 3: Several factors such as age, sex, educational level, primary diagnosis, indications for mechanical ventilation, indication for tracheostomy, co-morbidities, and severity of illness will significantly contribute to speech intelligibility in patients requiring prolonged mechanical ventilation in the hospital.

Specific Aim 4: Validate the speech item in the health-related QOL instrument to evaluate speech as a domain of QOL in patients requiring prolonged mechanical ventilation in the hospital

Hypothesis 4: The mean health-related QOL scores will moderately correlate negatively with mean voice-related QOL (VR-QOL) questionnaire (criterion validity).

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

1. Abstract from the prior study (IRB #: NA_00041547) that got accepted for publication in Journal of Medical Speech-Language Pathology:

Purpose: To describe the types of talking tracheostomy tubes available, present four case studies of critically ill patients who used a specialized tracheostomy tube to improve speech, discuss their advantages and disadvantages, propose patient selection criteria, and provide practical recommendations for medical care providers.

Method: Retrospective chart review of patients who underwent tracheostomy in 2010.

Results: Of the 220 patients who received a tracheostomy in 2010, 164 (74.55%) received a percutaneous tracheostomy and 56 (25.45%) received an open tracheostomy. Among the percutaneous tracheostomy patients, speech-language pathologists were consulted on 113 patients, 74 of whom were on a ventilator. Four of these 74 patients received a talking tracheostomy tube, and all four were able to speak successfully while on the mechanical ventilator even though they were unable to tolerate cuff deflation.

Conclusions: Talking tracheostomy tubes allow patients who are unable to tolerate cuff deflation to achieve phonation. Our experience with talking tracheostomy tubes suggests that clinicians should consider their use for patients who cannot tolerate cuff deflation.

2. Additionally, over the last couple of years, the use of BLUSA has increased dramatically at the Johns Hopkins Hospital.

4. Study Procedures

- a. Study design, including the sequence and timing of study procedures (Distinguish research procedures from those that are part of routine care).
Design: Prospective Pretest-Posttest design Clinical Trial – Pilot Study

Sequence and timing:

A. Pre – Assessment

1. Electronic Patient Records (POE, EPR, or EPIC)
 - a. Demographic Data
 - b. Patient Characteristics
 - c. Patient Outcomes
2. Patient Survey
 - a. Quality of life
 - b. Voice-Related quality of life

B. Intervention vs. Control Group

Intervention Group:

- a) The BLUSA trial involves placement of a BLUSA tracheostomy tube by respiratory therapist after obtaining an order from an authorized prescriber (MD, PA, or NP). The SLP sets up the tracheostomy tube for speech and then determines the optimal air flow required for voicing. This amount of air flow is communicated to the ICU staff for further use.
- b) We will ensure that the SLP meets with the patient for a minimum of 3 sessions within a week to optimize the use of a BLUSA.
 - i. SLP will also assess the duration of successful speech during each session
 - ii. Sentence intelligibility will also be assessed during the 3rd session. This session will be audio-taped and reviewed by a second rater for sentence intelligibility.
 - iii. SLP will determine the level of independence with BLUSA during the 3rd session.

Control Group:

- a) This group will also receive BLUSA trial as standard of care but a week later after the pre and post assessments have been completed

C. Post-Assessment

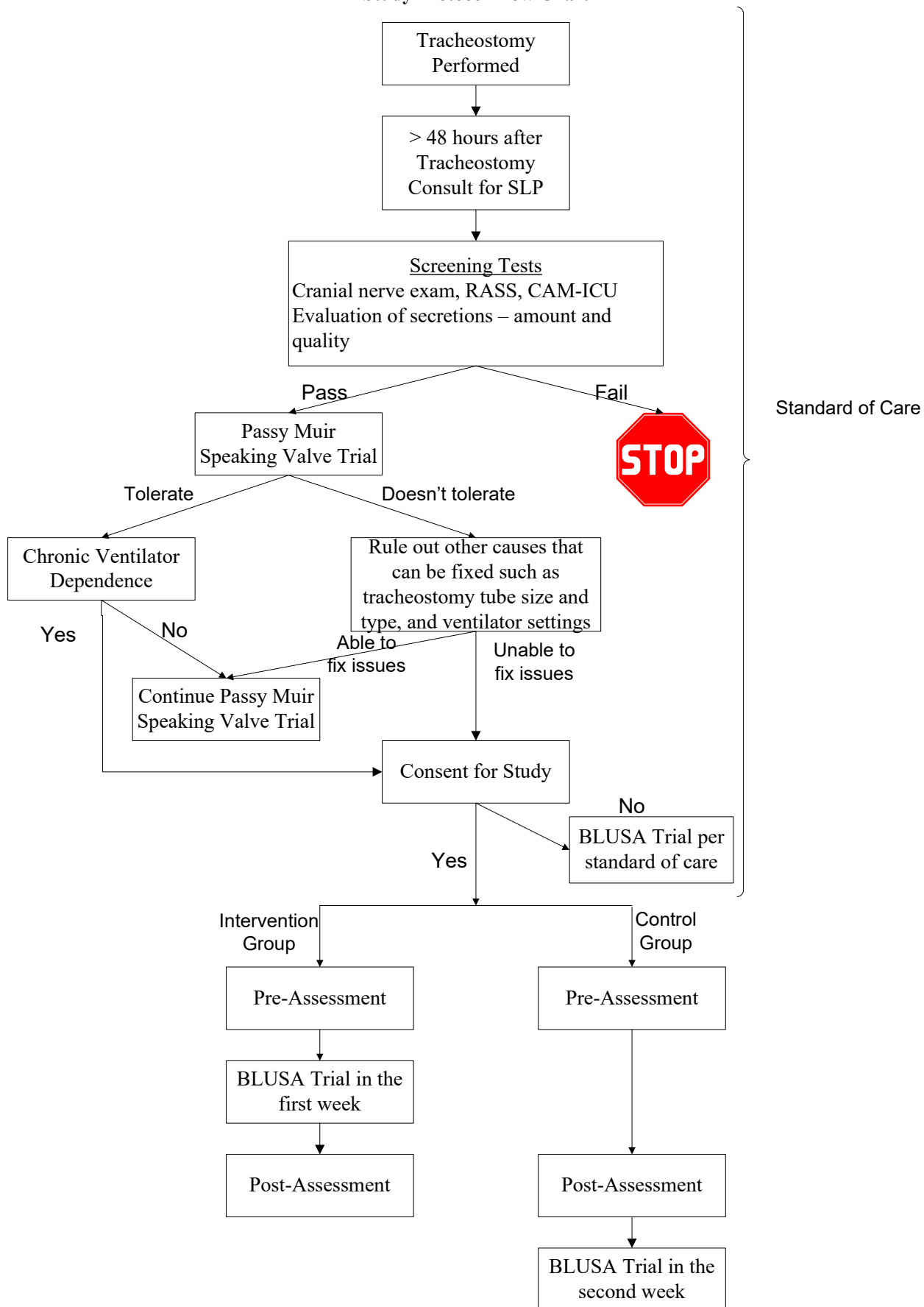
1. Electronic Patient Records (POE, EPR, or EPIC)
 - a. Patient Characteristics
 - i. Severity of Illness
 - b. Patient Outcomes
 - i. Time to BLUSA in days
 - ii. Time between speaking valve trial and BLUSA
2. Patient Survey
 - a. Quality of life
 - b. Voice-Related Quality of life
 - c. Level of independence to use of BLUSA
 - d. Patient satisfaction to use of BLUSA

Setting: All vented units at the Johns Hopkins Hospital (MICU, SICU, CICU, CCU, NCCU, WICU, Wbg 5D, Wbg 5C & MPCU)

Instruments:

Name	Concept measured	Number of items
QOL-MV	Quality of life in mechanically ventilated patients questionnaire	12
VR-QOL	Voice-related quality of life questionnaire	10
SIT	Sentence intelligibility test	11
SOFA	Sequential Organ Failure Assessment Tool	6
RASS	Richmond Agitation Sedation Scale	1
CAM-ICU	Confusion Assessment Method	4
Additional questions	Demographic Data Patient's independence and satisfaction with BLUSA	2

Study Protocol Flow Chart



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- b. Study duration and number of study visits required of research participants.
The study duration is estimated to be approximately 2 weeks per patient with a total of 5 visits by study team.
- c. Blinding, including justification for blinding or not blinding the trial, if applicable. Patients will not be blinded to intervention or control group.
- d. Justification of why participants will not receive routine care or will have current therapy stopped.
If patient is not willing to participate in the study, their routine care will not be altered. They will still have the opportunity to use BLUSA per current standard of care. Patients who are in the control group will also receive BLUSA but a week late.
- e. Justification for inclusion of a placebo or non-treatment group. N/A
- f. Definition of treatment failure or participant removal criteria.
If there is a change in clinical condition that prevents study team from continuing with the BLUSA trial or if the patient is discharged from the hospital, the patient will be dropped from the study.
- g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.
If participants receiving BLUSA complete the study (after the post-assessment), they will continue to use BLUSA per our current standard of care. If the participant's participation using BLUSA ends prematurely due to change in clinical condition, then they will be dropped from the study. But if their condition improves and warrants reuse of BLUSA, they will be offered BLUSA per our standards of care but will not be re-enrolled in the study.

5. Inclusion/Exclusion Criteria

Inclusion Criteria:

Mechanically ventilated via tracheostomy
Awake, alert, and attempting to communicate
Able to understand English

Exclusion Criteria:

Delirium
Fresh tracheostomy within 48 hours
Laryngectomy

6. Drugs/ Substances/ Devices

- a. The rationale for choosing the device to be used.
 - 1. Enables speech in patients who are mechanically ventilated and unable to tolerate cuff deflation.
 - 2. Over the last couple of years, the use of BLUSA has increased dramatically at the Johns Hopkins Hospital.
 - 3. Its impact on quality of life is unknown.
 - 4. This device has the speech attachment that the routine tracheostomy tubes do not have.
 - 5. This device' speech attachment has a wider lumen and is detachable for cleaning.
- b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed. N/A
- c. Justification and safety information if non-FDA approved drugs without an IND will be administered. N/A

7. Study Statistics

- a) Primary outcome variables
 1. Quality of life
- b) Secondary outcome variables
 1. Sentence intelligibility
 2. Level of independence with BLUSA
 3. Patient satisfaction with BLUSA
- c) Variables of Interest
 1. Age, Sex, Race
 2. Indication for ICU admission
 3. Indication for Tracheostomy
 4. Severity of Illness (measured by SOFA scores)
 5. Delirium (CAM-ICU)
 6. Sedation (RASS)
 7. Motor Speech (Cranial nerve assessment V, VII, IX, X, and XII)
 8. Information about secretions (suction frequency, secretion quality and quantity)
 9. Time to SLP consult in days
 10. Time to initial in-line speaking valve trial
 11. Severity of Illness
 12. Time to BLUSA in days
 13. Time between speaking valve trial and BLUSA

d) Statistical plan including sample size justification and interim data analysis.

In order to compare changes in health-related quality of life from pre-assessment to post-assessment, we need 73 participants in each group. This allows for a 20% drop out rate and is based on a sample size of 61 individuals in each group to achieve 80% power and a clinically meaningful 20% increase in health-related QOL mean score from 61.16 (SD \pm 21.74) to 73.38 (SD \pm 26.09) based on another "Quality of Life in Mechanically Ventilated Patients" study by PI. We assume a two-tailed test with a significance level of $\alpha = 0.05$.

Interim data analysis will be conducted after 12 months of data collection. Mean, standard deviation, median and inter-quartile range will be calculated for continuous variables. Paired t-tests will be used to compare pre and post assessment scores for continuous variables. Frequencies and percentages will be calculated for categorical variables. Chi square and Fisher Exact tests will be used to compare pre and post assessment scores of categorical variables. Validation of the QOL instrument will include calculation of Cronbach's alpha, Pearson correlation, Kappa.

e) Early stopping rules.

Reasons for stopping data collection for a participant will include

1. change in clinical condition
2. discharge from the hospital

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

Administration of questionnaires repeatedly can be burdensome. In addition, questions about their quality of life while mechanically ventilated may be emotionally distressing.

b. Steps taken to minimize the risks.

If at any time the participant appears upset or distressed, the interviewer will stop the interview and refer to the medical team providing care in the ICU. The interviewer will remain with the participant until she or he has regained emotional equilibrium. If the participant states that he/she is tired and would like to rest, the interviewer will stop the interview and come back at a later time to continue with the interview. The participant may wish to withdraw from the study anytime they choose to.

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- c. Plan for reporting unanticipated problems or study deviations.
The PI will discuss any unanticipated problems of study deviations that pertain to the participants' health with the ICU team caring for the patient.
- d. Legal risks such as the risks that would be associated with breach of confidentiality.
Data will be stored in RedCap database that is password protected on the ICTR server. The database can only be accessed by the study team and the PI. Upon, completion of data collection, names and medical record numbers will be removed. A new research ID number will be assigned for analysis. Any document that may re-identify the patient will be destroyed. Once the data are de-identified, then analysis will begin.
- e. Financial risks to the participants. N/A

9. Benefits

- a. Description of the probable benefits for the participant and for society.
The participant may benefit personally from the proposed study because they will have the opportunity of spending additional time with SLP during the 3 sessions. Identifying the predictors of intelligibility and the impact of BLUSA on QOL and communication will promote communication between patients and healthcare providers. This empowers patients and allows healthcare staff to obtain a more accurate of patients' condition and tailor care accordingly.

10. Payment and Remuneration

- a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol. N/A

11. Costs

- a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them. N/A