

# **Early Speech with One-Way Speaking Valve in Tracheostomy Patients**

**NCT03008174**

**February 6, 2018**

## JHM IRB - eForm A – Protocol

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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.

Over the past several decades, age-adjusted, population-based rates of tracheostomy has doubled (Mehta, Syeda, Bajpayee, Cooke, Walkey & Wiener, 2015). Acutely ill patients with tracheostomy have reported that the ability to speak is fundamental to social communication and to their personal identities, and conversely, the lack of voice often leads to frustration and feelings of confinement (Carroll, 2007; Foster, 2010). The use of one-way speaking valves (OWSV) is supported in the literature as a way to restore speech in patients with tracheostomy who are on or off of mechanical ventilation (Hess, 2005). The benefits of speech restoration and the consequences of its delay suggest that the early use of OWSV in patients with tracheostomy may be beneficial. However, the literature lacks clear evidence for the optimal timing to initiate the use of OWSV or its clinical outcomes.

The timing for initiating OWSV use varies internationally, and the timing most appropriate for specific patient populations is unknown. In the United States, evaluation for speech using an OWSV has traditionally been at least 48 hours following tracheostomy procedure. On the other hand, speech language pathologists (SLPs) in Europe and Australia indicated (personal communication) that they initiate OWSV evaluation as early as 4 hours after the tracheostomy procedure. Furthermore, the safety of early use of OWSV may be related to the type of tracheostomy procedure itself. A representative from Passy-Muir, the manufacturer of OWSV, stated in an interview that the 48 hour waiting period in the United States is based on traditional open surgical tracheostomy, rather than the percutaneous procedure. Notably, percutaneous tracheotomy has been shown to be associated with a lower overall postoperative complication rate when compared with open operative tracheotomy, and the use of percutaneous technique is on the rise (Freeman, Isabella, Lin, & Buchman, 2000).

Therefore, we propose a prospective randomized clinical trial - pilot study to investigate the safety of early use of OWSV in patients undergoing a percutaneous tracheostomy.

### 2. Objectives (include all primary and secondary objectives)

#### Specific Aim 1: Identify patients who would benefit from early use of the OWSV.

Hypothesis 1a: Several factors such as age, sex, educational level, primary diagnosis, indication for tracheostomy, co-morbidities, and severity of illness will significantly contribute to early tolerance of the OWSV.

#### Specific Aim 2: Determine the effect of the early use of the OWSV on the quality of speech.

Hypothesis 2a: The increase in the speech intelligibility scores from pre- to post- assessment will be significantly higher in the patients who receive early OWSV compared to those who receive it the traditional way 48 hours after undergoing a tracheostomy.

Research Question 2b: Is the duration of speech longer for patients who start using OWSV earlier compared to those who start late?

#### Specific Aim 3: Determine the effect of early use of the OWSV on clinical outcomes.

Hypothesis 3a: The increase in the health-related quality of life scores from pre- to post- assessment will be significantly higher in the patients who receive early OWSV compared to those who receive it the traditional way 48 hours after undergoing a tracheostomy.

Hypothesis 3b: There will be no significant changes in the rate of complications between patients receiving early versus standard use of the OWSV.

Hypothesis 3c: Patients who begin to use the OWSV early will have a significantly shorter lengths of stay in the ICU than patients who start using OWSV after 48 hours.

**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)

Current standard of care to wait 48 hours following tracheostomy procedure to initiate OWSV assessment and treatment, however, there is scant evidence in the literature justifying this amount of time. 201 patients out 272 patients who received a tracheostomy received SLP consult for in 2014. Based on prior data from the tracheostomy database 30% of mechanically ventilated and / or tracheotomized patients tend to be awake and interactive, and attempt to communicate.

**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 Randomized Clinical Trial – Pilot Study

**Sequence and timing:**

- A. Screening by Tracheostomy Nurse Practitioner following percutaneous tracheotomy
  - 1. Glasgow Coma Scale (GCS)
  - 2. Richmond Agitation Sedation Scale (RASS)
- B. Speech-Language Pathologist consult is placed for patients meeting study inclusion criteria
- C. Patient consent is obtained by Tracheostomy Nurse Practitioner or Speech-Language Pathologist
- D. Randomization into Intervention and Control groups
- E. Session 1 within 12-24 hours following percutaneous tracheotomy:
  - 1. Both groups complete pre-assessment consisting of the following:
    - i. Electronic Patient Records (POE, EPR, or EPIC)
      - 1. Demographic Data
      - 2. Patient Characteristics
      - 3. Sequential Organ Failure Assessment (SOFA)
    - ii. Confusion Assessment Method for the ICU (CAM-ICU)
    - iii. Health-related quality of life survey, Quality of Life – Mechanical Ventilation (QOL-MV)
    - iv. Tracheostomy-related assessment
      - 1. Trach size
      - 2. Mechanical ventilation status
      - 3. Secretions & tolerance of cuff deflation
      - 4. Presence of complications
        - i. Bleeding at stoma
        - ii. Subcutaneous air
        - iii. Infection at stomal site
        - iv. Pneumothorax
        - v. Accidental decannulation
  - 2. Intervention Group completes standard SLP evaluation and OWSV trial:
    - i. SLP evaluation includes the following to assess candidacy for OWSV trial:
      - 1. Level of alertness
      - 2. Cranial nerve exam
      - 3. Ability to cough
      - 4. Ability to tolerate cuff deflation
      - 5. Ability to tolerate finger occlusion
      - 6. Vocal quality
    - ii. If appropriate, OWSV will be trialed and assessed for the following:
      - 1. Duration of tolerance
      - 2. Change in vital signs
      - 3. Vocal quality
      - 4. Presence of air trapping
      - 5. Sentence Intelligibility Test
    - iii. Recommendations are made for OWSV use outside of SLP supervision
      - 1. Supervision requirement (RN, Respiratory therapist, trained family, independent)
      - 2. Duration of OWSV use
  - 3. Control Group receives no further evaluation or treatment during Session 1, which constitutes current standard of care.
- F. Session 2 within 48-60 hours following percutaneous tracheotomy:
  - 1. Both groups complete post-assessment:

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Principal Investigator: Vinciya Pandian  
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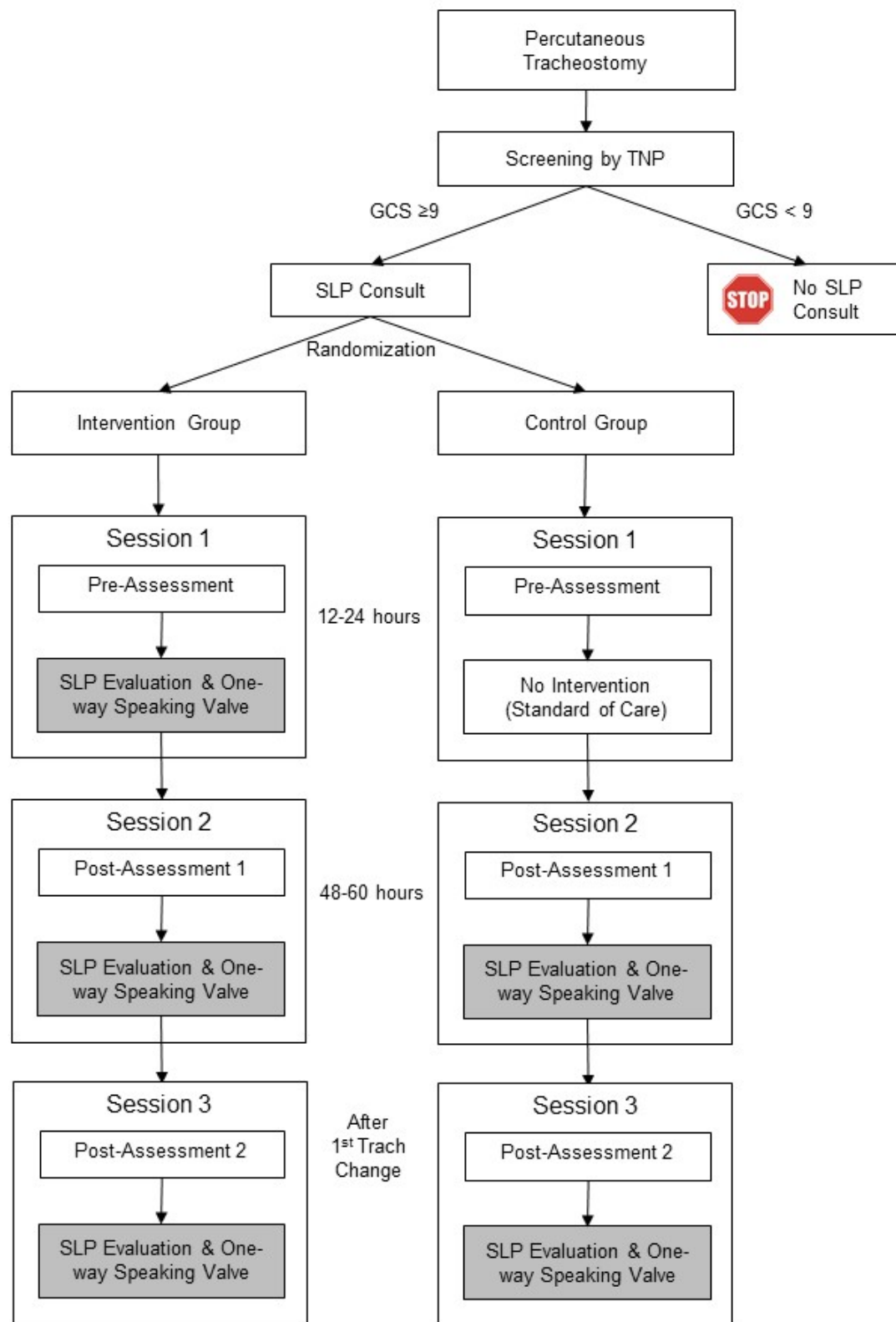
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  2. Intervention Group completes second SLP evaluation and OWSV trial.
  3. Control Group completes initial SLP evaluation and OWSV trial.
- G. Session 3 following first trach change
1. Both groups receive follow-up SLP re-evaluation and OWSV trials as appropriate per standard of care.

**Setting:** All ICUs at the Johns Hopkins Hospital

**Instruments:**

Name	Concept measured	Number of items
QOL-MV	Quality of life in mechanically ventilated patients questionnaire	12
SIT	Sentence intelligibility test	11
SOFA	Sequential Organ Failure Assessment Tool	6
Additional questions	Demographic Data	

**Study Protocol**



- b. Study duration and number of study visits required of research participants.  
The study duration is estimated to be 4 weeks per patient with a total of 3 visits by the 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. Participants in the control group will receive routine care, and participants in the intervention group will initiate the same intervention as routine care with timing to be 24-60 hours earlier than the current routine care.
- 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 OWSV trial or if the patient is discharged from the hospital, the patient will be removed 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 the OWSV complete the study (after Session 3), they will continue to use the OWSV per our current standard of care. If the participant's participation using the OWSV 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 the OWSV, they will be offered the OWSV per our standards of care but will not be re-enrolled in the study.

## 5. Inclusion/Exclusion Criteria

### Inclusion Criteria:

- Patient who received a percutaneous tracheostomy
- Glasgow Coma Scale score  $\geq 9$
- Confusion Assessment Method –ICU (CAM-ICU): negative
- Richmond Agitation Sedation Scale (RASS): -1 to +1
- Able to understand English

### Exclusion Criteria:

- Open tracheostomy
- Laryngectomy
- Presently using OWSV or capped trach
- Foam-filled cuffed tracheostomy tube
- Presence of known severe airway obstruction
- Presence of post-operative bleeding requiring transfusion or packing
- Presence of air-leak around the cuff resulting in respiratory decompensation

## 6. Drugs/ Substances/ Devices

- a. The rationale for choosing the drug and dose or for choosing the device to be used.  
We are not studying the efficacy of the one-way speaking valves. We know that they work. We are studying the timing of when to start using OWSV.
- 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 variable.

Speech intelligibility

- b. Secondary outcome variables.

- Patient characteristics
- Quality of Life
- Complications
- Time to events
- Length of stay
- Mortality

\*See codebook for list of additional variables

- c. Statistical plan including sample size justification and interim data analysis.

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. Sample size is estimated based on 30% of tracheostomy patients who might be awake and interactive at the Johns Hopkins Hospital in 2016, as per the tracheostomy database. According to the 2014 data, we found that about 55 patients were awake and interactive while having a percutaneous tracheostomy tube at the hospital. Considering a 10% of the patients who may not be interested in the study, we will plan for a sample size of 50 with 25 in the intervention group and 25 in the control group.

- d. Early stopping rules.

If patients have changes in clinical condition that prevents cuff deflation, they will be dropped from the study. The study will be halted if any major complications occur from early trial of OWSV.

## 8. Risks

- a. Medical risks, listing all procedures, their major and minor risks and expected frequency.  
Risks of OWSV use include development of subcutaneous air and air trapping that could lead to respiratory distress.

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.

Patients will be screened by the tracheostomy nurse practitioner for inclusion in the study, and all patients enrolled in the study will undergo thorough evaluation with an SLP per standard protocol, prior to the trial with the OWSV. Trial of the OWSV will be deferred if the SLP determines that the patient is not an appropriate candidate to trial the OWSV at the time. The SLP will follow standard protocol during OWSV trials of appropriate candidates. OWSV trials will be discontinued and SLP will refer to the medical team if the patient experiences any complications.

During administration of questionnaires, the interviewer will stop the interview and refer to the medical team providing care in the ICU if at any time the participant appears upset or distressed. 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.

- 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 medical 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 from the study by having the opportunity to receive see the SLP earlier than the current standard of care and potentially may attain speech sooner than under the current standard of care. The patient also has the opportunity to spend additional time with the SLP during the pre- and post-assessments. Identifying the effects and patient candidacy for early OWSV use may help with developing individualized communication treatments for patients with tracheostomy.

**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