**Early use of in-line speaking valve to accelerate weaning from mechanical ventilation in Intensive Care Unit patients with tracheostomies: a pilot randomised controlled trial**

**Background**

Patients who require tracheostomy in intensive care may require prolonged weaning from the ventilator, particularly when the indication for tracheostomy was respiratory failure. Minimising sedation, spontaneous breathing trials and early mobilisation are associated with reduced ventilator duration and length of stay.1–4

In line speaking valves are one-way valves that can be utilised during mechanical ventilation. The use of a one-way valve requires the tracheostomy cuff to be deflated, creating a leak in the ventilatory circuit. The valve directs air through the upper airway during expiration, allowing the patient to talk and communicate. Research suggests that the use of in-line speaking valves during mechanical ventilation is safe and may contribute to lung recruitment, with a potential to facilitate ventilatory weaning.5–8 A pilot randomised control trial by Martin et al of early vs late speaking valve use in tracheostomised patients demonstrated feasibility, safety and earlier decannulation in the intervention arm.9

Lack of speech and the impact of decreased communicative effectiveness have been described as one of the most frustrating components of an ICU stay.10–13 In patients with a tracheostomy, compromised ability to verbally communicate is associated with reduced participation in healthcare and bedside decisions.14 Earlier use of a speaking valve in patients with a tracheostomy has the opportunity to improve mood and engagement in care. Freeman-Sanderson et al. demonstrated significantly improved time to communication, mood and quality of life with the introduction of in-line speaking valves in mechanically ventilated patients with a tracheostomy.15

This study aims to investigate the effect of early use of one-way valves in mechanically ventilated patients with a tracheostomy. Our primary outcome will be feasibility and safety with the aim to provide data to guide a larger randomised control trial evaluating the effect on duration of mechanical ventilation post tracheostomy, with secondary measures including to, phonation and oral intake.

**Methods**

**Aims**

To investigate the feasibility of randomising patients to early or standard use of one way speaking valves in mechanically ventilated tracheostomised patients and to determine whether early use of inline speaking valve:

1. reduces the time for weaning from mechanical ventilation post tracheostomy
2. allows earlier speech and communication
3. reduces sputum load
4. improves patient satisfaction
5. is associated with any adverse effects

**Outcomes**

Co-Primary outcome

Feasibility of early use of in-line speaking valve use. This will be measured by meeting all of the following:

* >50% of patients suitable for the trial are enrolled
* >50% of patients successfully have speaking valve trial
* >70% of patients in intervention arm getting speaking valve within 72hrs of enrolment

Absence of adverse events during speaking valve trial. <25% of patients experience:

* Desaturation to <90%
* Visible aspiration

**Secondary outcomes**

* Mechanical ventilation duration post tracheostomy
* Days post tracheostomy to a) one-way valve application and b)phonation
* Patient satisfaction daily for the first 7 days of the trial– Likert scale
* Time to decannulation
* New hospital acquired pneumonia in the 7 days post tracheostomy
* Other adverse effects – pneumothorax, accidental decannulation
* Length of stay (ICU, hospital), mortality

**Inclusion Criteria**

Tracheostomy inserted in ICU – air filled cuffed tube

Mechanically ventilated but able to spontaneously breathe

Able to obey one stage commands within the previous 24 hrs

Tracheostomy leak demonstrated on cuff deflation to be >40% of tidal volumes

>18 years of age

Within 72 hrs of tracheostomy

Expected stay in ICU beyond next calendar day

**Exclusion criteria**

Deemed unsuitable for speaking valve by primary physician – reason to be recorded

Requiring heavy sedation for high intracranial pressures

PEEP required >10

FiO2 required >60%

Severe airway obstruction which may prevent sufficient exhalation

Severely reduced lung elasticity which may cause air trapping

**Intervention**

Intervention group: Use of in-line speaking valve within 24 hrs of randomisation post tracheostomy insertion

Speaking valve to be applied 30-60 minutes twice a day or longer if tolerated (if less than this reason to be recorded)

PEEP to be reduced to 5cmH20 as the one-way valve itself and the upper airway generate a degree of intrinsic PEEP. Above cuff suction beforehand and suction below upon deflation performed as is standard practice currently.

Control group: standard care.

**Randomisation**

Computer generated randomisation list – sequential envelopes used with patient’s study number and group allocation – block sizes of 6 – stratified by site

**Consent**

Prior to randomisation consent will be obtained from the patient or next of kin via the independent medical practitioner pathway

**Data collection**

Baseline demographics – age, APACHE, diagnostic category, Inotropes Y/N, Dialysis Y/N, Haemoglobin, Cardiac function LV and RV (mild-mod-severe dysfunction)

Mechanical ventilation – FiO2, PEEP, Peak pressures, Compliance (recorded twice a day)

Indication for tracheostomy (Resp, Neuro, Anatomical)

Negative inspiratory force – recorded daily

Secretions/sputum load (qualitative quantity recorded by nurse – minimal, small, moderate, significant)

Speaking valve

* Successful use that day
* Number of successful trials that day
* Duration of each SV trial

Duration of mechanical ventilation – pre and post tracheostomy

ICU Length of stay

Time to decannulation

Patient satisfaction

* Ease of communication scale

Family satisfaction

* FS-ICU

Mobilisation with physio (daily)

Sedation – intravenous infusion (propofol, midazolam, ketamine) Y/N, morphine equivalents

Adverse events – accidental decannulation, aspiration pneumonitis felt by primary intensivist secondary to SV trial

Speech path variables:

* Time to first phonation
* Speech possible/not possible each day
* Time to oral intake from tracheostomy

**Sample size calculation**

Sir Charles Gairdner Intensive Care performs 30 tracheostomies per year. If this grant application is successful, then other WA sites have indicated interest to participate to achieve the required sample size within the timeframe of the grant. With other sites involved and >50% recruitment rate it appears feasible that 40 patients may be enrolled.

We have limited data currently. The average mechanical ventilation post tracheostomy is 90 hours with a standard deviation of 36. To see a reduction by 24 hours, 36 patients would be needed. Even 12 hrs reduction in mechanical ventilation would be clinically meaningful. On this basis the research team has elected to perform a pilot study which will then have the capacity to roll into a larger phase 2 RCT.

Descriptive statistics will be performed for baseline demographics. Independent t-tests will be used for the primary outcome.

For other outcomes - Non parametric tests where results are not normally distributed. And Chi square tests for categorical variables

A statistical plan will be finalised prior to enrolment of the first patient.

**Patients risks/mitigation**

By including only those with a leak around the tracheostomy of >40% (measured by comparing average expired tidal volume with cuff up versus cuff down), ensures patient comfort and that there is adequate flow through the vocal cords and upper airway to be safe.

Enrolled patients will be closely monitored by ICU physicians in conjunction with speech pathology for comfort – Respiratory rate, dyspnoea, general uncomfort and the speaking valve trial aborted if there are any concerns

**Data security**

Data collection will rely on a study-specific data dictionary and de-identified data will be recorded in specifically designed RedCAP data collection tool.

Once the study is completed, paper records will be shredded and the electronic database destroyed 15 years after the completion of the study. Only authorised study personnel will have access to the database.

**References**

1. Girard TD, Kress JP, Fuchs BD, et al. Efficacy and safety of a paired sedation and ventilator weaning protocol for mechanically ventilated patients in intensive care (Awakening and Breathing Controlled trial): a randomised controlled trial. *Lancet Lond Engl*. 2008;371(9607):126-134. doi:10.1016/S0140-6736(08)60105-1

2. Schaller SJ, Anstey M, Blobner M, et al. Early, goal-directed mobilisation in the surgical intensive care unit: a randomised controlled trial. *Lancet Lond Engl*. 2016;388(10052):1377-1388. doi:10.1016/S0140-6736(16)31637-3

3. Blackwood B, Alderdice F, Burns K, Cardwell C, Lavery G, O’Halloran P. Use of weaning protocols for reducing duration of mechanical ventilation in critically ill adult patients: Cochrane systematic review and meta-analysis. *BMJ*. 2011;342:c7237. doi:10.1136/bmj.c7237

4. Shah FA, Girard TD, Yende S. Limiting Sedation for Patients with ARDS – Time to Wake Up. *Curr Opin Crit Care*. 2017;23(1):45-51. doi:10.1097/MCC.0000000000000382

5. Sutt AL, Caruana LR, Dunster KR, Cornwell PL, Anstey CM, Fraser JF. Speaking valves in tracheostomised ICU patients weaning off mechanical ventilation - do they facilitate lung recruitment? *Crit Care*. 2016;20(1):91. doi:10.1186/s13054-016-1249-x

6. Sutt AL, Cornwell P, Mullany D, Kinneally T, Fraser JF. The use of tracheostomy speaking valves in mechanically ventilated patients results in improved communication and does not prolong ventilation time in cardiothoracic intensive care unit patients. *J Crit Care*. 2015;30(3):491-494. doi:10.1016/j.jcrc.2014.12.017

7. Sutt AL, Anstey CM, Caruana LR, Cornwell PL, Fraser JF. Ventilation distribution and lung recruitment with speaking valve use in tracheostomised patient weaning from mechanical ventilation in intensive care. *J Crit Care*. 2017;40:164-170. doi:10.1016/j.jcrc.2017.04.001

8. O’Connor LR, Morris NR, Paratz J. Physiological and clinical outcomes associated with use of one-way speaking valves on tracheostomised patients: A systematic review. *Heart Lung*. 2019;48(4):356-364. doi:10.1016/j.hrtlng.2018.11.006

9. Martin KA, Cole TDK, Percha CM, et al. Standard versus Accelerated Speaking Valve Placement after Percutaneous Tracheostomy: A Randomized Controlled Feasibility Study. *Ann Am Thorac Soc*. 2021;18(10):1693-1701. doi:10.1513/AnnalsATS.202010-1282OC

10. Rotondi AJ, Chelluri L, Sirio C, et al. Patients’ recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit\*. *Crit Care Med*. 2002;30(4):746-752.

11. Samuelson KAM. Unpleasant and pleasant memories of intensive care in adult mechanically ventilated patients—Findings from 250 interviews. *Intensive Crit Care Nurs*. 2011;27(2):76-84. doi:10.1016/j.iccn.2011.01.003

12. Tolotti A, Bagnasco A, Catania G, et al. The communication experience of tracheostomy patients with nurses in the intensive care unit: A phenomenological study. *Intensive Crit Care Nurs*. 2018;46:24-31. doi:10.1016/j.iccn.2018.01.001

13. Freeman-Sanderson AL, Togher L, Elkins M, Kenny B. Quality of life improves for tracheostomy patients with return of voice: A mixed methods evaluation of the patient experience across the care continuum. *Intensive Crit Care Nurs*. 2018;46:10-16. doi:10.1016/j.iccn.2018.02.004

14. Karlsen MMW, Happ MB, Finset A, Heggdal K, Heyn LG. Patient involvement in micro-decisions in intensive care. *Patient Educ Couns*. 2020;103(11):2252-2259. doi:10.1016/j.pec.2020.04.020

15. Freeman-Sanderson AL, Togher L, Elkins MR, Phipps PR. Return of Voice for Ventilated Tracheostomy Patients in ICU: A Randomized Controlled Trial of Early-Targeted Intervention\*. *Crit Care Med*. 2016;44(6):1075-1081. doi:10.1097/CCM.0000000000001610