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Towards an improved understanding of the effect of a speaking valve on lung volumes and communication in the critically ill tracheostomised patient

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Abstract

Tracheostomised mechanically ventilated patients are often left unable to speak, which is frustrating for patients and the staff caring for them. Having no voice causes major distress and feelings of helplessness for patients. Voicelessness frequently leads to reduced information exchange between the patient and healthcare team, frequently to the detriment of patient care. An in-line speaking valve (**SV**) is a one-way valve that may be used in the mechanical ventilation circuit to enable verbal communication in tracheostomised patients. Limited data exist regarding the effect of SVs on respiratory mechanics. Deflation of the tracheostomy cuff is required for placement of the SV, effectively causing a “leak” in the ventilation circuit. Current bedside monitoring in intensive care unit (**ICU**) does not allow a clinician to observe what is happening in patients’ lungs during SV use. Concerns exist that this leak may cause lung derecruitment and atelectasis, delaying liberation from mechanical ventilation, thereby extending the patients’ length of stay in ICU.

Patients can use alternative means of communication in ICU, including: pen and paper, communication boards, gestures; and mouthing words silently. Numerous reports indicate that these methods are a poor substitute for verbal communication. Restoring verbal communication allows for dialogue between patient and ICU staff, ensuring more effective treatment. Restoring patients' ability to talk allows them to actively participate in their own care, potentially leading to increased cooperation and improvements to patients’ psychological welfare. However, data regarding the efficacy of SVs in improving communication for the ICU patient are scant.

As an experienced speech pathologist, I believe concerns over SV use to date have little evidence. The main objective, and first aim of this thesis was to investigate the effect of SV use on respiratory mechanics to determine whether SVs should be used in-line with mechanical ventilation of tracheostomised patients. The second aim was to assess the effect of introducing SVs into a cardio-thoracic ICU on patient tracheostomy specific outcomes. The third aim was to further clarify the effect of SVs on success with health-related communication for ICU patients. To achieve these aims, 5 studies were conducted, resulting in 5 manuscripts.

For the first aim, 20 tracheostomised ICU patients using a SV that met the inclusion criteria were recruited to the study from November 2013-December 2014. Electrical Impedance

Tomography (**EIT**) was used to assess the patients' end-expiratory lung impedance (**EELI**) and ventilation distribution continuously over 60 minutes (before, during and after SV use). Additional variables included oxygenation (**SpO_2**), respiratory rate (**RR**), heart rate (**HR**), end-tidal carbon dioxide (**$EtCO_2$**), ventilator data, ventilated surface area (**VSA**), and regional ventilation delay (**RVD**). Respiratory inductance plethysmography (**RIP**) was used to assess the respiratory muscle activity over the same time period. The results (**Chapter 3**) show significantly increased EELI both during and post SV use. The data also indicate significantly decreased RR and $EtCO_2$, with unchanged SpO_2 and HR during SV use. **Chapter 4** indicates a uniform increase of EELI across all lung sections, with no significant change in ventilation distribution. VSA and RVD findings are supportive of a potential recruitment effect of SVs. RIP data also presented in **Chapter 4** suggest increased diaphragm activity during SV use. A case study presented in **Chapter 5** highlights the need for clinicians to consider a patient's underlying disease prior to SV use, with special caution required in relation to chronic obstructive pulmonary disease (**COPD**).

To achieve the second aim, data were collected for all tracheostomised patients across four consecutive years, prior to (2011) and following the introduction of an in-line SV (2012-2014) into a cardio-thoracic ICU. Data included: demographics; disease specifics and severity – acute physiology and chronic health evaluation (**APACHE III**) and sequential organ failure assessment scores (**SOFA**); ICU survival; tracheostomy and ventilation duration and specifics; timeframes and specifics of verbal communication and oral intake. Chapter 6 reports that patients returned to verbal communication 3 times faster during 2011-2014. Seventy percent of tracheostomised patients used a SV on a ventilator in 2014 (compared to 0% in 2011). Other variables remained similar across the four years, with SVs having no impact on ventilator weaning and decannulation time.

For the third aim, 25 patients and 52 nursing staff were asked to fill out a custom-made questionnaire on success with health communication, firstly when the patients were voiceless, and, secondly, when they were using a SV. **Chapter 7** highlights individual differences and some disparity between patient and nursing ratings of communication success. Overall, however, following SV use both the patients and nursing staff reported a significant improvement in success with health communication.

In conclusion, the findings of this thesis addressed the research aims, and provide new knowledge through use of an innovative approach to assessing lung mechanics. Having already resulted in real clinical changes in our centre, the results indicate the potential for optimising communication, using SVs in tracheostomised cardiothoracic ICU patients undergoing weaning from mechanical ventilation.

Declaration By Author

This thesis is composed of my original work, and contains no material previously published or written by another person except where due reference has been made in the text. I have clearly stated the contribution by others to jointly-authored works that I have included in my thesis.

I have clearly stated the contribution of others to my thesis as a whole, including statistical assistance, survey design, data analysis, significant technical procedures, professional editorial advice, and any other original research work used or reported in my thesis. The content of my thesis is the result of work I have carried out since the commencement of my research higher degree candidature and does not include a substantial part of work that has been submitted to qualify for the award of any other degree or diploma in any university or other tertiary institution. I have clearly stated which parts of my thesis, if any, have been submitted to qualify for another award.

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Publications During Candidature

Peer reviewed Papers

1. Sutt A-L, Cornwell PL, 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 cardio-thoracic ICU patients.** Journal of Critical Care 2015;30:491-4

2. Sutt A-L, Fraser JF. **Speaking valves as part of standard care with tracheostomised mechanically ventilated patients in intensive care unit.** Journal of Critical Care 2015;30:1119-20

3. Sutt A-L, Caruana RL, Dunster KR, Cornwell PL, Anstey CM, Fraser JF. **Speaking valves in tracheostomised ICU patients weaning off mechanical ventilation – do they facilitate lung recruitment?** Critical Care 2016;20:91

4. Sutt A-L, Fraser JF. **Patients want to be heard – loud and clear!** Letter to Editor. Critical Care 2017;21:6

5. Sutt A-L, 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.** Journal of Critical Care 2017; 40:164-70

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1. Sutt A-L, Cornwell PL, Dunster KR, Spooner A, Fraser JF. **More than words… optimising communication in the critically ill.** Australian Critical Care 2014;27(1):60

2. Sutt A-L, Caruana LR, Dunster KR, Cornwell PL, Fraser JF. **Speaking valves in patients with obstructive lung disease – not for everyone.** Australian Critical Care 2015;28(1):50-1

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lung recruitment. American Journal of Respiratory Critical Care Medicine 191;2015:A3162.

5. Sutt A-L, Caruana LR, Cornwell PL, Dunster KR, Anstey CM, Fraser JF: **Verbal communication in tracheostomised mechanically ventilated patients leads to improved respiratory mechanics.** Intensive Care Medicine Experimental 2015, 3 (Suppl 1): A314

Oral Presentations

International Conferences, Lectures and Events

1. *Invited lecture.* Passy-Muir Inc, United States of America, Online Presentation September 2014. **'In-line speaking valves in an Australian Intensive Care setting'**
2. *Invited lecture.* International Tracheostomy Symposium 2014, Melbourne, Australia. **'Do speaking valves have an impact on weaning/decannulation times? A study using electrical impedance tomography to provide real time bedside imaging of the lungs'**
3. *Accepted abstract.* Australia and New Zealand Intensive Care Society Annual Scientific Meeting 2014, Melbourne, Australia. **'Improved lung recruitment and diaphragm mobility with an in-line speaking valve in tracheostomised mechanically ventilated patients – an observational study'**
4. *Invited lecture.* Passy-Muir International Webinar. March 2015. **'Speaking valves in mechanically ventilated ICU patients – improved communication and improved lung recruitment'**
5. *Invited lecture.* Passy-Muir clinical conference, Los Angeles, USA. May 2015. **'Speaking valves in our ICU – how did it all change?'**
6. *Invited lecture.* Industry dinner, Los Angeles, USA. May 2015. **'Speaking valves in mechanically ventilated ICU patients – how does it affect the lungs?'**
7. *Invited lecture.* Boston Children's Hospital, Boston, USA. May 2015. **'Speaking valves in our ICU – how did it all change?'**
8. *Invited lecture.* Johns Hopkins Medical Centre, Baltimore, USA. May 2015. **'Speech Pathology management of ventilated tracheostomised patients'**
9. *Invited lecture.* Johns Hopkins Medical Centre, Baltimore, USA. May 2015. **'Speaking valves in mechanically ventilated ICU patients – improved communication and improved lung recruitment'**

10. *Invited lecture.* 8th International meeting of physical medicine and rehabilitation in the critically ill. Denver, USA. May 2015. **'Speaking valves in mechanically ventilated ICU patients – what about lung recruitment'**

11. *Invited lecture.* Industry dinner. Denver, USA. May 2015. **'Speaking valves in our ICU – how did it all change?'**

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National Conferences, Lectures and Events

1. *Accepted abstract.* Speech Pathology Australia National Conference 2014, Melbourne, Australia **'Speaking valves in tracheostomised mechanically ventilated patients – gains and constraints in cardio-thoracic intensive care unit'**

2. *Invited lecture.* Austin Health, Melbourne. July 2014. **'An introduction of in-line speaking valves into cardio-thoracic ICU. Lung mechanics with and without an in-line speaking valve'**

3. *Invited lecture.* Victorian Critical Care Speech Pathology Special Interest Group, webinar presentation. June 2015. **'Speaking valves in mechanically ventilated patients'**

Local Conferences, Lectures and Events

1. *Invited lecture.* St. Andrew's War Memorial Hospital, Brisbane, 2013. **'In-line speaking valve in tracheostomised mechanically ventilated patients'**

2. *Accepted abstract.* The Prince Charles Hospital Research Forum 2014, Brisbane, Australia **'Improved lung recruitment and diaphragm mobility with an in-line speaking valve in tracheostomised mechanically ventilated patients – an observational study'**

3. *Invited lecture.* Uniting Healthcare, Brisbane. August 2015. **'Speaking valves in our ICU – how did it all change?'**

4. *Accepted abstract.* TPCH Annual Health Discoveries Forum. Nov 2015. **'Verbal communication in tracheostomised mechanically ventilated patients leads to improved respiratory mechanics'.** ***Won - Best Novice Clinical Presentation.***

5. *Invited lectures.* Nambour Hospital ICU, research group, and Speech Pathology Department. Feb 2016. **'Speech Pathology clinical care and research with tracheostomised patients in ICU'**

6. *Participant.* University of QLD, 3MT, Sept 2016. **'Dying to talk'**. ***People's Choice Award and Overall Winner of UQ 3MT 2016.***

7. *Invited lecture.* Local experts in the ICU environment. Feb 2017 **'Thrive, not just survive'**

Poster presentations

1. Australia and New Zealand Intensive Care Society Annual Scientific Meeting 2013, Hobart, Australia **'More than words…optimising communication in the critically ill'**
2. The Prince Charles Hospital Research Forum 2013, Brisbane, Australia **'A speaking valve increases functional residual capacity in tracheostomised ventilated patient: a case study using electrical impedance tomography'**
3. Australia and New Zealand Intensive Care Society Annual Scientific Meeting 2014, Melbourne, Australia **'Speaking valves in patients with obstructive lung disease – not for everyone'**
4. The Prince Charles Hospital Research Forum 2014, Brisbane, Australia **'Speaking valves in patients with obstructive lung disease – not for everyone'**
5. American Thoracic Society Conference 2015, Denver, Colorado, US **'Speaking valves in mechanically ventilated ICU patients – improved communication and improved lung recruitment'**
6. Speech Pathology Australia National Conference 2015, Canberra, Australia **'Speaking valves in patients with obstructive lung disease – not for everyone'**

Publications Included In This Thesis

Publications in this thesis have been included in the form of accepted manuscripts by the journal. Some repetition and retrospective referencing of research plans was unavoidable due to sequence of studies within the thesis. All tables, figures, graphs, sections and references in individual articles have been renumbered for consistency and continuous sequencing throughout the thesis document. Referencing style used throughout the thesis is Journal of Critical Care.

Sutt A-L, Caruana RL, Dunster KR, Cornwell PL, Anstey CM, Fraser JF. **Speaking valves in tracheostomised ICU patients weaning off mechanical ventilation – do they facilitate lung recruitment?** Critical Care 2016; 20:91 – incorporated as Chapter 3.

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Rachel Bushell	data collection for retrospective data audit
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List Of Abbreviations

AAC – *augmentative and alternative communication*
A:C ratio – *abdominal to chest ratio*
APACHE III – *acute physiology and chronic health evaluation*
ARDS – *acute respiratory distress syndrome*
AVR – *aortic valve repair*
BiVAD – *biventricular assist device*
CABG – *coronary artery bypass graft*
CAP – *community acquired pneumonia*
COPD – *chronic obstructive pulmonary disease*
CoV – *centre of ventilation*
CPR – *cardiopulmonary resuscitation*
CT – *computed tomography*
CVS – *cardiovascular system*
EELI – *end expiratory lung impedance*
EELV – *end expiratory lung volume*
EIT – *electrical impedance tomography*
$EtCO_2$ – *end tidal carbon dioxide*
ETT – *endotracheal tube*
FiO_2 – *fraction of inspired oxygen*
FRC – *functional residual capacity*
GI – *global inhomogeneity index*
HFTP – *high flow tracheostomy piece (as defined by >30L of continuous O_2 via tracheostomy tube)*
HR – *heart rate*
ICU – *intensive care unit*
iPEEP – *intrinsic positive end-expiratory pressure*
LFTP – *low flow tracheostomy piece (as defined by <30L of continuous O_2 via tracheostomy tube)*
LVAD – *left ventricular assist device*
NAVA – *neutrally adjusted ventilatory assist*
NIV – *non-invasive ventilation*
P_{aw} – *airway pressure*
$PaCO_2$ – *partial pressure of carbon dioxide in the arterial blood*
PE – *pulmonary embolism*
PEEP – *positive end expiratory pressure*
perc – *percutaneous*
PICS – *post-intensive care syndrome*
PIP – *peak inspiratory pressure*
PMSV – *Passy Muir speaking valve*
PPM – *permanent pace maker*
PSV – *pressure support ventilation*
RIP – *respiratory inductance plethysmography*
rNoVent – *region of no ventilation*
ROI – *region of interest*
RR – *respiratory rate*
RVD – *regional ventilation delay*
SBT – *spontaneous breathing trial*
SCC – *small cell carcinoma*
SD – *standard deviation*
SIMV – *synchronous intermittent mandatory ventilation*
SOFA – *sequential organ failure assessment*
SP – *speech pathology*

SpO_2 – *peripheral capillary oxygen saturation*

SV – *speaking valve*

$TcCO_2$ – *transcutaneous carbon dioxide*

TPCH – *The Prince Charles Hospital*

TT – *tracheostomy tube*

TV – *tidal volume*

TVar – *tidal variation*

VAP – *ventilator associated pneumonia*

VSA – *ventilated surface area*

WOB – *work of breathing*

Chapter 1

Introduction

Chapter 1 Introduction

1.0 Background and rationale

The liberation of long-term tracheostomised intensive care unit (**ICU**) patients from prolonged mechanical ventilation can be challenging and at a great cost to health care institutions [1-4]. Each year, more than 7000 patients receive tracheostomies in Australia and New Zealand. Many of these patients are initially ventilated in the ICU [5]. During the focus period of this thesis, 2010-2014, an average of 75 patients a year required a tracheostomy to facilitate liberation from prolonged ventilation at The Prince Charles Hospital (**TPCH**). Whilst being supported by mechanical ventilation, the tracheostomy cuff typically remains inflated to optimise ventilation. As a consequence, patients are left without the ability to use their voice, due to the loss of airflow via their upper airway (see *Figure 1-1* below).

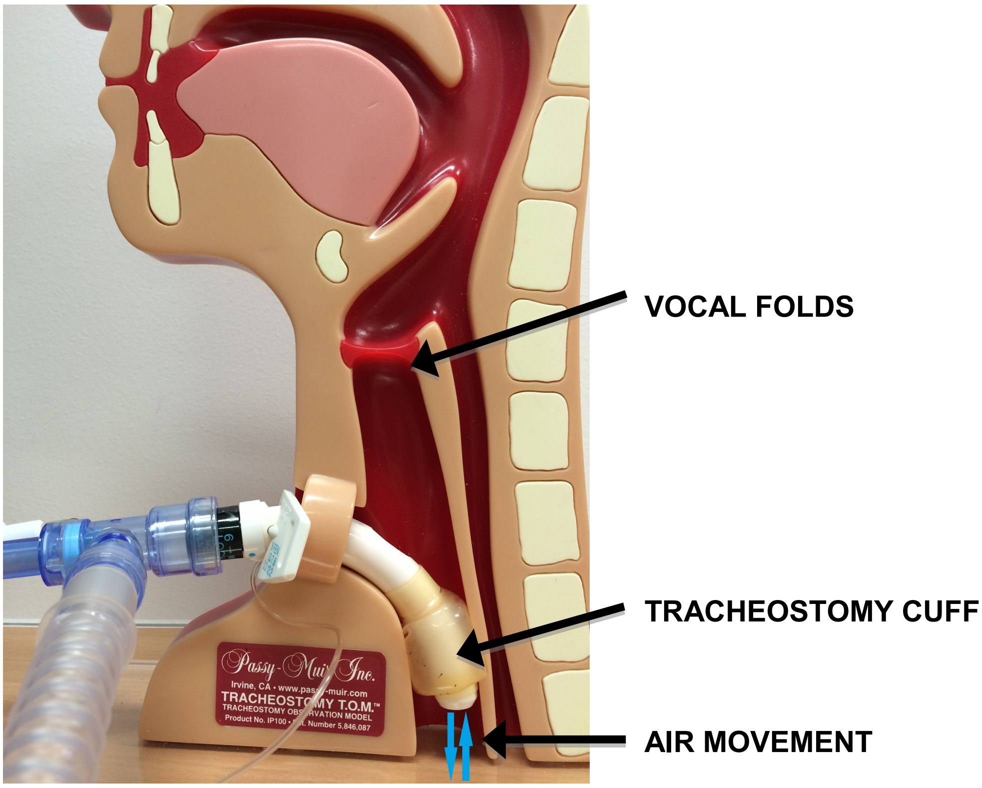

Figure 1-1: Tracheostomy in-situ. Cuff inflated, no air movement through the vocal folds

The traditional areas of focus in critical care medicine are physiology and physical well-being, with psychological health frequently receiving limited attention. In-line speaking valves have the potential to facilitate verbal communication in patients ventilated via tracheostomy, but their use is often limited in this population due the lack of research regarding their efficacy and concerns regarding their risk of impairing ventilation. As the cuff around the tracheostomy tube needs to be deflated for the placement of the speaking valve (**SV**), a ‘leak’ is created in the ventilation circuit, often thought to cause loss of lung volume, and potential collapse of the alveoli (derecruitment). Collapse of lung tissue can exacerbate respiratory compromise and impede or reverse the weaning process. However, there are no data examining the changes in lung volume or ventilation redistribution, which may occur in cuff deflation with or without a SV in-situ. Until recently, there has been no technology which could safely and simply assess these parameters.

Whilst there are other methods of communication that patients can use (e.g., mouthing; communication boards; pen and paper) to attempt to overcome the absence of their voice, current evidence indicates that patients rate verbal communication as the only means of communication that is highly successful [6]. Patients have associated the inability to verbally communicate with social withdrawal, leading to depression, lack of motivation to participate in care [7-10], poor sleep, and increased anxiety and stress levels [11]. Patients’ inability to communicate their needs to clinical staff leads to decreased exchange of vital diagnostic information, decreased adherence to recommendations, and poor patient satisfaction with the healthcare service [12]. To date there are no published data comparing the perceived success with health communication from the perspectives of both patient and nursing staff. Assumptions are often made that the message conveyed by a patient has been understood by staff. Communication occurs on a reciprocal basis (it is a "two way street"), however, there have been no studies to analyse the perception of communication from both equally important participants.

This thesis incorporates work completed on a cohort of tracheostomised mechanically ventilated cardio-thoracic ICU patients, in order to investigate SV use in a novel way, with a view to improving the patient journey and clinical outcomes.

1.1 Aims

The aims of this PhD are:

1. To investigate the effect of SV use on the respiratory mechanics of tracheostomised ICU patients weaning from mechanical ventilation;
2. To assess the effect of introduction of SVs into a cardio-thoracic ICU on patient tracheostomy specific outcomes;
3. To clarify the effect of SVs on success with health-related communication for tracheostomised ICU patients weaning from mechanical ventilation.

1.2 Hypotheses

For first aim:

1. Use of SVs in tracheostomised patients weaning from mechanical ventilation causes an increase in end-expiratory lung volumes (**EELV**).
2. SV use in tracheostomised patients weaning from mechanical ventilation causes a redistribution of ventilation into different parts of the lung.

For second aim:

3. Routine SV use in a cardio-thoracic ICU does not have a deleterious effect on tracheostomy specific outcomes for patients.
4. Routine SV use in a cardio-thoracic ICU results in tracheostomised patients regaining verbal communication earlier.

For third aim:

5. SV use results in increased success with patients' health-related communication reported by both the patients and nursing staff.

To test these hypotheses the following studies were performed:

For first aim

1. In order to determine the effect of SVs on EELVs, a prospective observational study was conducted with 20 patients. Electrical impedance tomography (**EIT**) was used to assess lung mechanics in real time before, during and after SV use in patients weaning from mechanical ventilation (Chapter 3).
2. To determine the region across which the increase of lung volume occurred, EIT data were analysed to assess ventilation distribution across four regions of interest (**ROI**) in the lung in the same group of 20 patients noted above (Chapter 4).
3. An opportunistic research case is reported in Chapter 5. This is a single case study of a patient with chronic obstructive pulmonary disease (**COPD**) in whom SV use created respiratory compromise.

For second aim (Chapter 6)

4. Tracheostomy and Speech Pathology (**SP**) specific outcomes for all tracheostomised patients across four consecutive years (pre- and post- introduction or SVs) were analysed to determine the potential effects of the introduction of SVs into routine clinical practice.

For third aim (Chapter 7)

5. Success with health-related communication was measured using a purpose-designed visual analogue scale before and during SV use on patients (n=20) and their nurses (n=52).

Chapter 2

Literature review

Chapter 2 Literature review

This chapter provides an overview of communication options in ventilated tracheostomised patients and provides information regarding respiratory physiology. The first part of the chapter gives a basic overview of tracheostomies (section 2.0); it then discusses the main options for restoring patients' voice and outlines potential concerns with using these options, and suitability of these for ICU patients (section 2.1). In the second part of the chapter a detailed overview of the respiratory system is given, which underpins verbal communication (section 2.2). The role of the upper airway in respiratory process, and imaging options for the respiratory system, are also discussed in this section. The chapter concludes with a more detailed overview of other communication options and their importance in the critically ill, tracheostomised patient population (section 2.3).

2.0 Tracheostomy

A tracheostomy is a common procedure in a complex intensive care environment. A tracheostomy tube (**TT**) is inserted into more than 7000 patients across Australia and New Zealand each year [13]. A tracheostomy is an artificial opening made into the trachea through the neck, either surgically in the operating theatre or, these days much more commonly, percutaneously in the ICU. A TT is inserted through the artificial opening and enables airflow to enter the trachea and lungs directly, bypassing the nose, pharynx and larynx (see *Figure 1-1* in *Chapter 1*). The opening is aimed to enter the trachea around the gap between the second and third tracheal rings [14]. An endotracheal tube (a tube into the airway through the patient’s mouth) usually precedes the TT in ICU. The endotracheal tube (**ETT**) is often replaced with a TT when the need for an alternative airway is seen to persist for longer, (i.e., in relation to patients needing prolonged mechanical ventilation). There is an ongoing debate in medical literature around the optimal time to perform a tracheostomy [15, 16], as any new procedure brings with it risks. When intubated with an ETT, patients are often sedated for tube tolerance [17, 18] since it usually causes considerable discomfort. Prolonged sedation, however, can result in other complications (e.g., increased critical illness polyneuromyopathy and delirium [19]). Once TT is performed, the patients are often more comfortable [20, 21], require less analgesics and sedative agents, and may be able to return to activities such as eating/drinking, sitting out of bed [22], walking and talking.

There are different types of TTs that are used for different purposes (e.g., different length or width of the tube; tubes with or without a cuff; tubes with a suction port, fenestrated tubes etc.). In the cardio-thoracic ICU where the studies for this thesis took place, most tracheostomised patients receive their tracheostomy due to a need for prolonged ventilation. In such cases, the preferred tube is a cuffed TT. The cuff is essentially a balloon around the tracheostomy tube inside the trachea that can be inflated or deflated. If inflated, it is most commonly filled with air. For patients on mechanical ventilation, the cuff is inflated to create a closed respiratory circuit, leaving no air leak towards the upper airway. This means that inhaled and exhaled air travels directly to the lower airways and back through the TT, thereby completely bypassing the upper airway. As a result, usual laryngeal/pharyngeal and nasal functions such as voice, cough, taste, smell, and swallow are limited. The patients, when asked, are often distressed about not being able to communicate during this critical time in their lives [8, 23, 24].

2.1 Communication with a tracheostomy tube

Communication is said to be a basic human right. It is a daily activity that develops at a young age and from this time forward we take the ability to communicate as a given, never thinking about the impact of losing this ability on our lives. It is only in situations where communication is lacking or not possible that we realise its importance. One situation where normal communication ability may be lost, or substantially changed, is in critically ill tracheostomised and mechanically ventilated ICU patients. Once an ICU patient is conscious it can be frustrating for the patient, staff and family when communication is difficult and limited. Moreover, communication difficulties during hospitalisation pose a significant risk factor for preventable adverse events [25]. The two more commonly discussed options for verbal communication in this population are "leak speech" and SV use.

2.1.1 Leak Speech

Leak speech is a term used to describe voice production during a period of cuff deflation. The cuff around the TT is deflated and, in most cases, some airflow through the upper airway is restored, with the potential for phonation to occur (see *Figure 2-1* below).

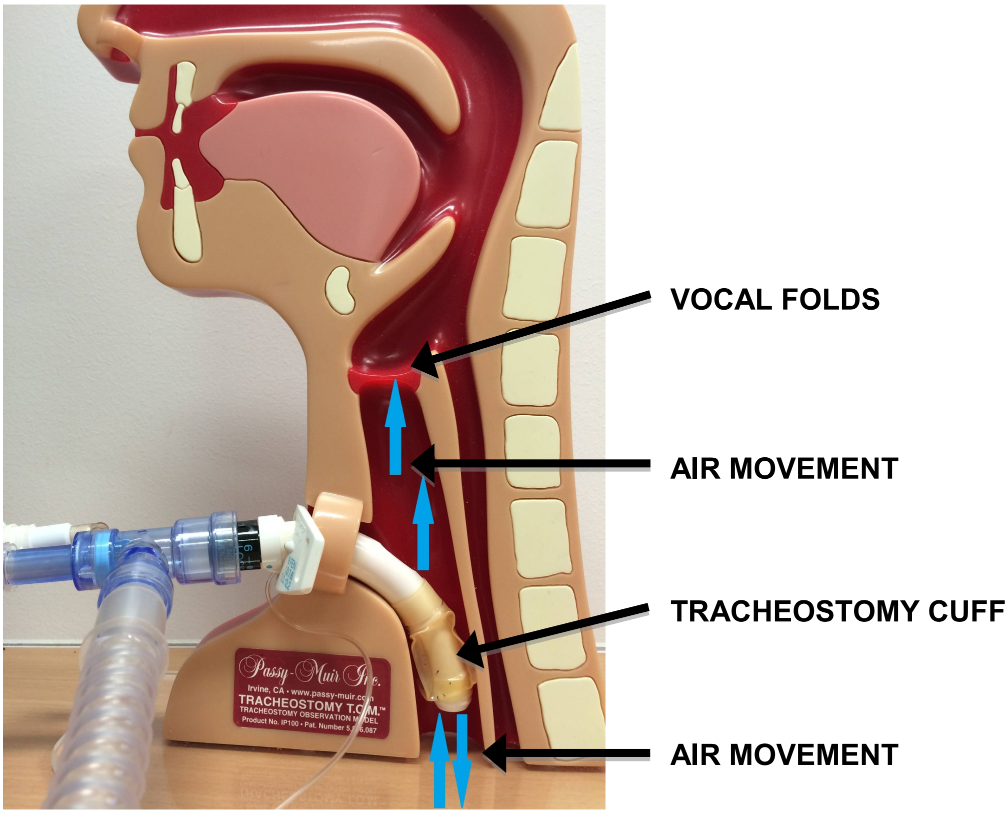

Figure 2-1: Tracheostomy in-situ. Cuff deflated, air movement through the vocal folds and back into tracheostomy tube (leak speech enabled)

Hoit et al [26] have described leak speech use in mechanically ventilated patients with spinal cord injury and neuromuscular disease. Their research has shown that lengthening the inspiratory phase and increasing positive end-expiratory pressure (**PEEP**) in the ventilatory settings resulted in improved speech production for their patients, with no subsequent respiratory compromise. MacBean [27] compared leak speech, addition of PEEP to leak speech, and use of SVs in a patient with spinal cord injury. They found that leak speech alone is not as successful as adding PEEP to leak speech or using a SV. Supplementing a patient's ventilation with PEEP during weaning can be dangerous, therefore this is not often a feasible option in the ICU. The cohort described in the two studies noted above is long-term ventilated patients with spinal cord injury, therefore differing to acute ICU patients with a ventilator weaning plan.

2.1.2 Speaking valves

SVs are one-way valves that can be used in tracheostomised patients to restore expiratory airflow through the upper airway, thereby facilitating functional use of the glottis/vocal folds (see *Figure 2-2* below).

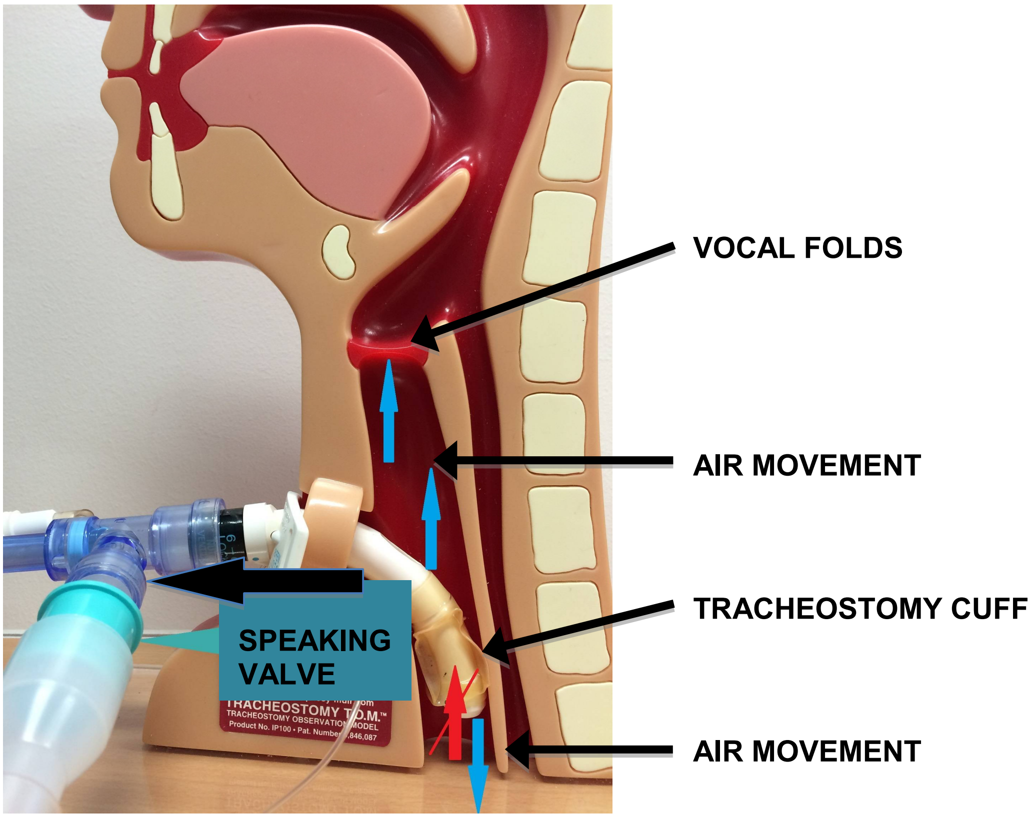

Figure 2-2: Tracheostomy in-situ. Cuff deflated, SV in-line with ventilator tubing. Exhalation through the vocal folds only.

There are a number of different SVs available. All SVs allow inhalation via the tracheostomy cannula, but exhalation is redirected around the tracheostomy cannula out through the upper airway. Most SVs cannot be used in-line with a mechanical ventilation circuit. There are closed and open position SVs. SVs that are used in-line with mechanical ventilation circuit are generally closed position SVs, such as the SV shown on Figure 2-2. A closed position SV means that inspiratory flow is needed to open the diaphragm of the valve for inspiration. The diaphragm then closes at the end of inspiration once inspiratory flow is minimal. That keeps a column of air inside the TT. All of the exhalation is then redirected around the deflated cuff towards the vocal folds, with no air able to flow back to the TT [28]. An open position SV has a diaphragm in an open position, meaning that expiratory flow is needed to close the diaphragm. As a consequence the first part of expiratory air has to travel through the TT and close the diaphragm of the SV, leaving the rest of expiratory air to flow through the upper airway. This often results in patients coughing secretions into the TT and partially blocking the open-position SV.

The use of SVs with a cuffed TT first requires the cuff to be fully deflated to create a path for expiration via the upper airway. SVs, like TTs, can have an impact on respiration depending on their design and characteristics. Studies investigating different SVs [28-30] found that SVs varied significantly in terms of their aerodynamic characteristics, including in relation to their impact on airway resistance, work of breathing (**WOB**), and timing of closure of the SV diaphragm for expiration. In conclusion, the authors recommended that these characteristics should be considered when choosing a SV, with reference made to the underlying condition of the patient.

A valve reported to have mid-range airway resistance and WOB implications, with no leak volume or closure delay between the beginning of expiration and closure of the valve [28-30], was deemed most appropriate for the cardio-thoracic ICU population investigated in this thesis. Independently, this SV (PMV007, Passy Muir Inc, California, USA) has been found to produce the best speech quality, as reported by listeners and participants [31].

2.1.3 Concerns about SVs and leak speech

Leak speech and SVs are the most sustainable options for verbal communication in tracheostomised patients that are mechanically ventilated. Both of the options require deflation of the tracheostomy cuff. The role of the cuff around the TT in mechanically ventilated patients is to create a closed circuit of ventilation. Deflation of this cuff creates a leak in the ventilator system, meaning some of the gas meant to enter the lungs exits via the upper airway. In these circumstances less gas enters the lungs and it has been suggested this could cause derecruitment in the patients' lungs.

No studies reporting on lung physiology of critically ill patients with acute respiratory disease using leak speech or SVs have been published. However, our research group assumed that fully restoring the patient's glottic function with a SV, thereby potentially restoring the patients' physiological PEEP, is better than just partially enabling it with leak speech. Anecdotally, concerns have also been raised about the recommendation to increase PEEP for leak speech in critically ill patients weaning from mechanical ventilation. It is not known whether adequate ventilation and perfusion during leak speech is guaranteed when following the above-mentioned modifications that improved leak speech in chronically ventilated patients [26].

Some suggestions about changes in the ventilator settings to better accommodate a SV have been offered. For instance, Passy-Muir™ suggests increasing tidal volume (**TV**) in volume controlled ventilation modes until the peak inspiratory pressures (**PIP**) match those prior to cuff deflation, and turning off ventilator delivered PEEP, as physiologic PEEP is restored with the SV [32]. However, it is only possible to increase the TVs of mandatory breaths. The majority of patients in Australian ICUs, when using a SV in-line with a ventilator, are breathing spontaneously and frequently in pressure support ventilation (**PSV**) mode. Therefore, such ventilator modifications are often not feasible to compensate for the leak in the circuit. More research is needed to inform best practice of mechanical ventilation for successful SV use. In order to understand how deflation of the cuff and SVs may cause changes in respiratory mechanics, however, it is first necessary to understand the physiology of breathing.

2.2 Respiration

Adequate respiration is essential for successful verbal communication in a healthy person. Good airflow is needed to produce voice, regardless of the presence of a TT. In a tracheostomised mechanically ventilated patient, the ventilator can usually compensate for what is lacking in a compromised respiratory system and successful voice production can still be achieved with a SV. The following sections give an overview of anatomy of the respiratory system and the basic physiology of breathing, to better understand the potential effect of cuff deflation and SV use on lung mechanics.

2.2.1 Anatomy of the respiratory system

Respiratory structures can be divided into the upper and lower airways. The upper airway consists of the nose, mouth, pharynx and larynx. When a person has a tracheostomy for ventilation purposes, the upper airway does not take part in respiration, having been ‘cut off’ by the inflated tracheostomy cuff (see *Figure 1-1* on *page 2*). The lower airways still actively take part in respiration when a cuffed tracheostomy is in-situ. The lower airways include: trachea; bronchi; bronchioles; terminal bronchioles (known as the conducting zone) and respiratory bronchioles; alveolar ducts and alveolar sacs where gas exchange occurs (known as the respiratory zone) [33] (see *Figure 2-3* below). At the distal end of trachea, the airway divides 23 times, terminating in an estimated 30000 pulmonary acini. Each pulmonary acini contains more than 10000 alveoli. An individual may have between 270 million to 790 million alveoli, the number depending on the height of that individual and total lung volume. At the end of expiration (functional residual capacity) their diameter is 0.2mm. From here onwards gas exchange occurs through the alveolar septa [34]. Oxygen is delivered to, and carbon dioxide adsorbed from, pulmonary circulation.

Ventilation (gas movement) occurs throughout the respiratory structures. As mentioned above, perfusion and gas exchange take place in the lower airway. Alveoli need to be kept open and perfusion guaranteed around the alveoli for adequate gas exchange to occur. The area where ventilation occurs but no perfusion takes place is known as anatomic dead space (with this area including all of the upper airways and conducting zone). The anatomic dead space in a patient with a tracheostomy is significantly shortened, due to exclusion of the supraglottic area.

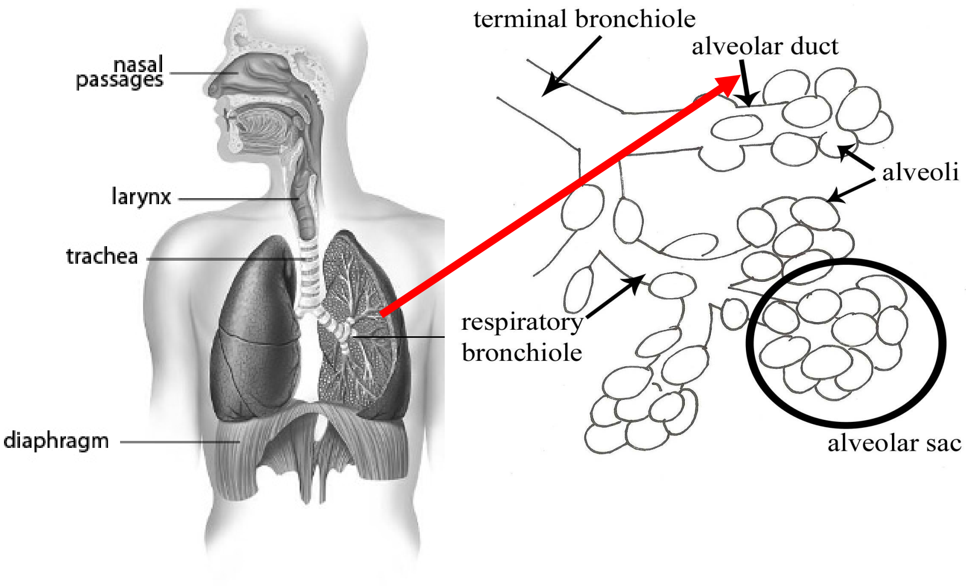

Figure 2-3 [35]: Anatomy of upper and lower airways (image on left custom-made by Cognuse; image on right used with permission from Dr.Rode)

2.2.2 Importance of the upper airway in respiration process

There is limited knowledge regarding the specific role and function of upper airways in the ventilation/perfusion process. In normal breathing patterns it is established that nasal breathing is typical. This has several major advantages over mouth breathing – e.g., filtration by the vibrissae hairs, humidification and warming of the inspired gas [34]. None of these can occur when breathing via a cuffed TT. Ventilation via a TT limits or removes any role/function the upper airways have in the ventilation and/or perfusion process. In this context, however, cuff deflation and SV use has the potential to partially restore the function of upper airways.

There is limited research investigating the role of glottis as intra-abdominal pressure and intra-thoracic pressure regulator [36, 37], or in the quality of postural control/balance [38].

Pressures in the abdomen and thorax are affected by the glottis, and glottal function varies between tasks such as talking, breathing and coughing. Massery [38] found that partial opening of the glottis, such as when counting out loud, resulted in best postural control. Research has also linked breath-holding (glottal closure) as a natural response to heavy loads [39]. England [40] found that vocal fold movements influence the pattern of breathing. The larynx is capable of withstanding pharyngeal pressures as high as 80kPa (600mmHg) which may be generated during swallowing [34]. In patients that are tracheostomised and mechanically ventilated, all pressures are regulated by the positive pressure coming from the ventilator rather than the usual negative pressure ventilation in a healthy person. Accordingly, the upper airway has little to no role in coordinating intra-abdominal and intra-thoracic pressure in these patients.

Conceptualisation of the respiratory system as a whole from glottis at the top down to the pelvic floor has been described as a "soda pop can model" [41]. Whenever the system has a ‘leak’ due to stress, incontinence or an open TT, the whole system’s pressure regulation is altered. With a cuffed TT in-situ, and ventilation occurring mechanically via the ventilator, the function of the upper airway is not utilised, as mentioned above. Once again, however, by deflating the cuff and using a SV this could potentially be restored, at least partially.

Clinicians are primarily interested in assessing the resistance of the intrathoracic (lower) airways [42] rather than the upper airway and its role in respiration. The ventilator can be set to deliver PEEP which assists in splinting the alveoli open in a patient with a TT. There are a number of factors that keep the alveoli open in a healthy person. Key amongst these would be unadsorbable nitrogen (N_2), surfactant, and upper airway resistance. The upper airway is responsible for physiological PEEP [40]. The ventilator is unable to mimic the variability of physiological PEEP caused by the opening and closing of the glottis throughout the respiratory cycle and tasks such as talking and coughing. Hyatt [42] found that there is large variability in upper airway resistance between participants. The upper airway was found to normally account for approximately 45% of the combined airway resistance (expiratory + inspiratory). By contrast, it accounted for 20% resistance in emphysematous participants, with the difference in resistance attributable to resistance in the lower airways only. Resistance in the lower airways is far greater in cases of obstructive airway disease. Given these considerations, caution needs to be taken when additional resistance from the larynx is added by deflating the cuff and using a SV in patients with obstructive lung disease. Hyatt [42] also found that upper airway resistance decreased with increasing lung volumes. Ferris et al [43] reported that nasal breathing increased upper airway resistance significantly. Hyatt [42] found that most of the upper airway flow resistance (i.e., PEEP) during mouth breathing occurs in the larynx. If the vocal folds move into complete adduction, airway resistance becomes infinite. This also explains the variable physiologic PEEP.

The use of the upper airways in tracheostomised patients during expiration may be facilitated by the use of a SV in the ventilator circuit, which requires deflation of the TT cuff (see *Figure 2-1* on *page 9*). This, however, may cause an air leak towards the upper airways during inspiration, unless the patient is strong enough to close their glottis for inspiration. Hence, inadequate inspiratory gas delivery to the alveolus for adequate gas exchange could induce hypoxemia and hypercarbia. At the same time, the restored physiological PEEP provided by the upper airways with the deflated tracheostomy cuff may facilitate persistent alveolar opening, more than compensating for the ‘leaking air’ in the anatomic dead space. Also, the restoration of some negative pressure ventilation by deflating the cuff and using the SV may have an impact on cardiac output and perfusion. There have been no published studies looking at the impact of cuff deflation and SV on lung mechanics or perfusion, which has significantly limited the use of SVs with patients in ICU.

2.2.3 Measurement of ventilation

Usual bedside monitoring equipment is limited to monitoring the patients’ oxygen saturation (**SpO_2**), respiratory rate (**RR**), and WOB to ensure their ventilation is adequate when a SV is in-situ. Even TVs and pressure data are not accurately displayed on the ventilator once the SV is in-line with the ventilator circuit as there is no expiration back towards the ventilator. Once the SV is removed, these data, including end-tidal carbon dioxide (**$EtCO_2$**), can once again be assessed. Usual bedside monitoring equipment does not enable monitoring of EELV or regional ventilation and ventilation distribution in the lungs. As a consequence, it is impossible to know whether derecruitment or hyperinflation of some parts of the lungs occur when making any changes to the ventilator set-up (including the SV) without further imaging.

The conventional means to monitor ventilation is with computed tomography (CT). This is expensive, exposes the patient to radiation and often requires the ICU patient to be sedated and transferred to the medical imaging department. The transfer of patients adds risks to patient care, including the possibility of equipment failure due to less monitored environment during transportation, as well as potential exposure of patients to infection risk [44, 45]. The need for sedation makes CT less suitable if its purpose is to see potential changes in a fully conscious patient (such as someone using a SV). To be able to assess any changes before, during and after an intervention would require serial imaging, which in the case of CT would entail exposing patients to more radiation.

Chest x-rays that are commonly used in ICU are not precise enough to visualise any changes: this technique only captures one brief moment in breathing cycle. A tool gaining popularity – lung ultrasound [46, 47] - has not been proven to be precise enough to detect the changes anticipated with SV use. In addition, it can only cover a small part of the lung at a time. Another relatively novel technique for imaging the respiratory system is Electrical Impedance Tomography (**EIT**), the subject of detailed discussion below.

2.2.3.1 Electrical Impedance Tomography

EIT is a non-invasive, radiation free, real-time bedside imaging equipment that allows for continuous monitoring of ventilation distribution and end-expiratory lung impedance (**EELI**). EELI has been shown to be highly correlated with EELV or functional residual capacity (**FRC**) [48-50].

EIT involves placing a belt equipped with 16 electrodes around the circumference of the patient's chest at intercostal space 5-6. Small electrical currents are sent through each of the 16 electrodes and the voltage is then read by all electrodes, creating 208 potentials per image (see *Figure 2-4* below). Impedance is measured and translated to gas in the lungs, generating a real time moving image of air in different parts of the lung on a computer screen. Impedance means resistance, and resistance to electrical currents moving through the patient's chest varies depending on the amount of gas present in their lungs. As lung volumes change throughout inspiration and expiration, this translates to varying impedance throughout the respiratory cycle.

EIT data is highly dependent on the belt position, and only captures data from the segment of lung where the EIT belt is situated [51, 52]. Therefore the images do not necessarily detect ventilation changes in the whole lung.

EIT can be used to identify and assess changes in EELI and ventilation distribution over time (i.e. before, during and after SV use). EIT can measure changes in EELI only as long as the electrode belt is kept around the patient's chest. Upon removal and replacement of the belt, a new baseline is calculated, therefore EELI results are not comparable to those previously measured [48, 53-55], meaning that prolonged monitoring is difficult in a clinical setting.

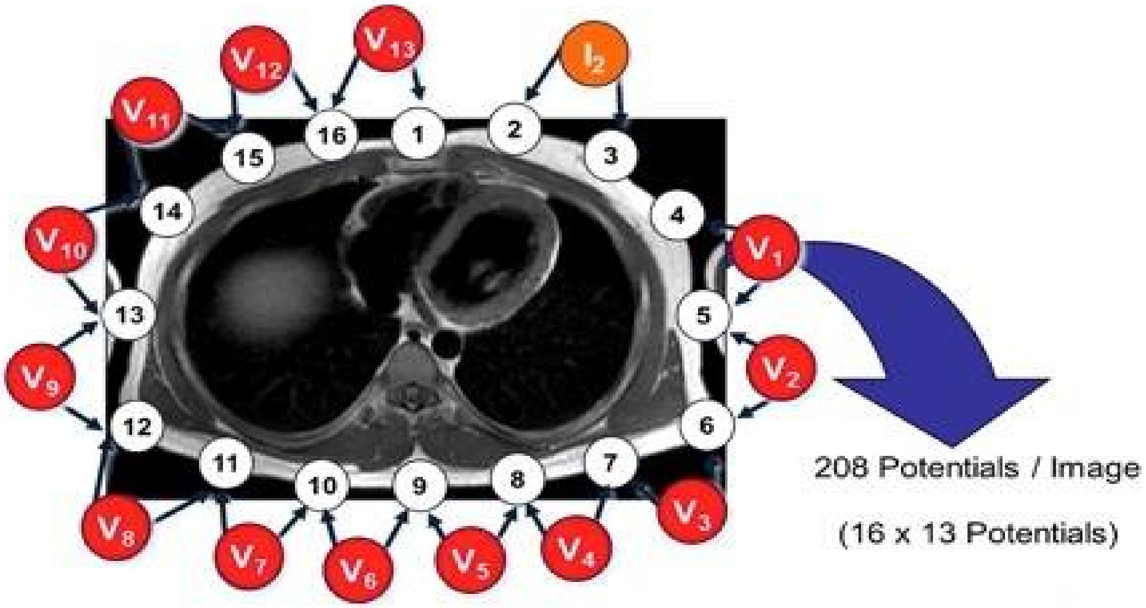

Figure 2-4: Electrode placement and current injections with EIT (used with permission from Professor John Fraser)

It is known that patients receiving positive pressure ventilation shift their ventilation distribution towards ventral parts of the lungs [56, 57]. Being supine in bed may also be a contributor to this ventral shift in ventilation. Such shifts can be seen with using EIT. It is not known whether cuff deflation and SV would cause any shift in ventilation distribution.

2.2.4 Muscles of respiration

Positive pressure ventilation delivered from the ventilator differs from the natural negative pressure ventilation that we all experience when breathing spontaneously. This is where the muscles of respiration play a vital role.

There are other structures outside the airways that have a vital role in respiration, most of which take part in inspiration (the active phase of breathing). Several muscle groups are involved in breathing. Muscles of the pharynx and larynx control upper airway resistance. The diaphragm, ribcage, spine and neck muscles bring about inspiration. Muscles of the abdominal wall, ribcage and spine are used when active expiration is required. While respiratory muscles are discrete, it must be remembered that they act almost harmoniously rather than as separate muscles in isolation. This extraordinarily complex interaction is influenced by factors including posture, minute volume, respiratory load, disease and anaesthesia [58].

The most important muscle of inspiration is the diaphragm, a membranous muscle separating the abdominal cavity and chest. In adults it has a total surface area of about 900 cm^2 [58]. During normal breathing the diaphragm moves about 1cm, but on forced inspiration and expiration a total excursion of up to 10cm may occur. A healthy diaphragm moves down during inspiration to force the abdominal contents downward and forward, thus increasing the vertical dimension of the chest cavity. When the diaphragm is paralysed, it moves up rather than down during inspiration because the intrathoracic pressure falls [33]. It is recognised that diaphragm weakness develops rapidly with mechanical ventilation, which can lead to prolonged liberation from ventilatory support. Studies have shown that disuse atrophy in the diaphragm develops as quickly as 18hrs on controlled mechanical ventilation [59]. This is due to positive pressure ventilation use, during which the diaphragm has no active role, as opposed to normal respiration, when negative intrapleural pressures exist.

The external intercostal muscles contract during inspiration and pull the ribs upward and forward, increasing the diameter of the thorax in lateral and anteroposterior aspects. The accessory muscles of inspiration include the scalene muscles. There is minimal activity in these muscles during quiet breathing but during exercise they may contract vigorously. Other muscles that play a role include the *alae nasi*, which cause flaring of the nostrils, and small muscles in the head and neck [33], including the vocal folds which control upper airway resistance by abducting to minimise resistance on inspiration and adduct slightly to increase resistance during expiration. This may help prevent collapse of the lower airways [58]. The alae nasi and vocal folds do not take part in respiration when a patient is breathing through a cuffed TT.

In healthy lungs expiration is usually passive. It is only during voluntary hyperventilation and exercise that expiration becomes active in a healthy person. The most important muscles of expiration are those of the abdominal wall, including the rectus abdominis, internal and external oblique muscles, and transversus abdominis. When these muscles contract, intra-abdominal pressure is raised and the diaphragm is pushed upward [33].

These muscles, and the vocal folds, also contract forcefully during coughing, vomiting, and defecation.

There have been a number of studies investigating the relative contribution of the ribcage and abdomen to lung volume displacement during quiet breathing and different speech tasks. Mandros et al [60] found that the pattern of chest wall configuration during quiet breathing largely predicts the pattern of ribcage and abdomen displacement during speech. Hixon [61] stated that the relative contribution of the ribcage and abdomen may vary among healthy individuals, and further found with Hoit [62] that in individuals with different body structure the pattern of ribcage and abdominal displacement for resting breathing was not predictive of the pattern of chest wall motion for speech production. To date, no such data have been reported on mechanically ventilated ICU patients with potential diaphragm weakness.

2.2.5 Measurement of respiratory muscle activity:

There are several relatively accurate ways to measure diaphragm activity. One of these is using neutrally adjusted ventilatory assist (**NAVA**) probes to measure the electrical activity of the diaphragm [63-66]. This method was not considered an appropriate technique for use in this PhD due to it being costly and invasive in nature.

Measuring esophageal pressure and gastric pressure is another way of assessing diaphragm strength. Most commonly this method involves using a nasogastric feeding tube with balloon(s) attached to the far end of the tube. The feeding tube needs to be connected to a pressure transducer to calculate transdiaphragmatic pressure (esophageal pressure minus gastric pressure), which is a specific measure of diaphragm activity [67]. This method was not considered for use in this PhD due to lack of such equipment, funds and specialist knowledge around issues with catheter positioning and validation.

Another method of measuring respiratory muscle activity, diaphragm ultrasound, is quickly gaining popularity [68-70]. This technique was not considered appropriate for use in this PhD since there is little to no immediate effect on muscle fiber thickness anticipated with SV use that diaphragm ultrasound could identify and visualise.

Though not the most accurate way to measure diaphragm activity, respiratory inductance plethysmography (**RIP**) was chosen as the most suitable tool to use in conjunction with EIT to assess ribcage and abdominal mobility and thereby gain a better understanding of the effect of a SV on diaphragm activity for the purpose of this PhD.

2.2.5.1 Respiratory Inductance Plethysmography

RIP is a validated technique to assess abdominal activity and, in this case, the potential effect of SV on chest and / or abdominal displacement during respiration. It is a non-invasive respiratory monitoring technique that quantifies changes in the cross-sectional area of the chest wall and the abdominal compartment. The technique uses two elastic bands that contain wires attached to the bands in a zigzag form. One is placed around the patient's chest, 3cm above the xiphoid process, and the second is placed around the abdomen (see *Figure 2-5* below). Each of these bands produces an independent signal and the sum of these two signals is calibrated against a known gas volume [71]. TVs and abdominal-to-chest ratio (**A:C ratio**) can be calculated based on extent to which the belts stretch during breathing. For the purposes of this thesis, only A:C ratios were calculated, and not the TV, due to difficulties measuring TVs in spontaneously breathing tracheostomised patients with an expiratory leak.

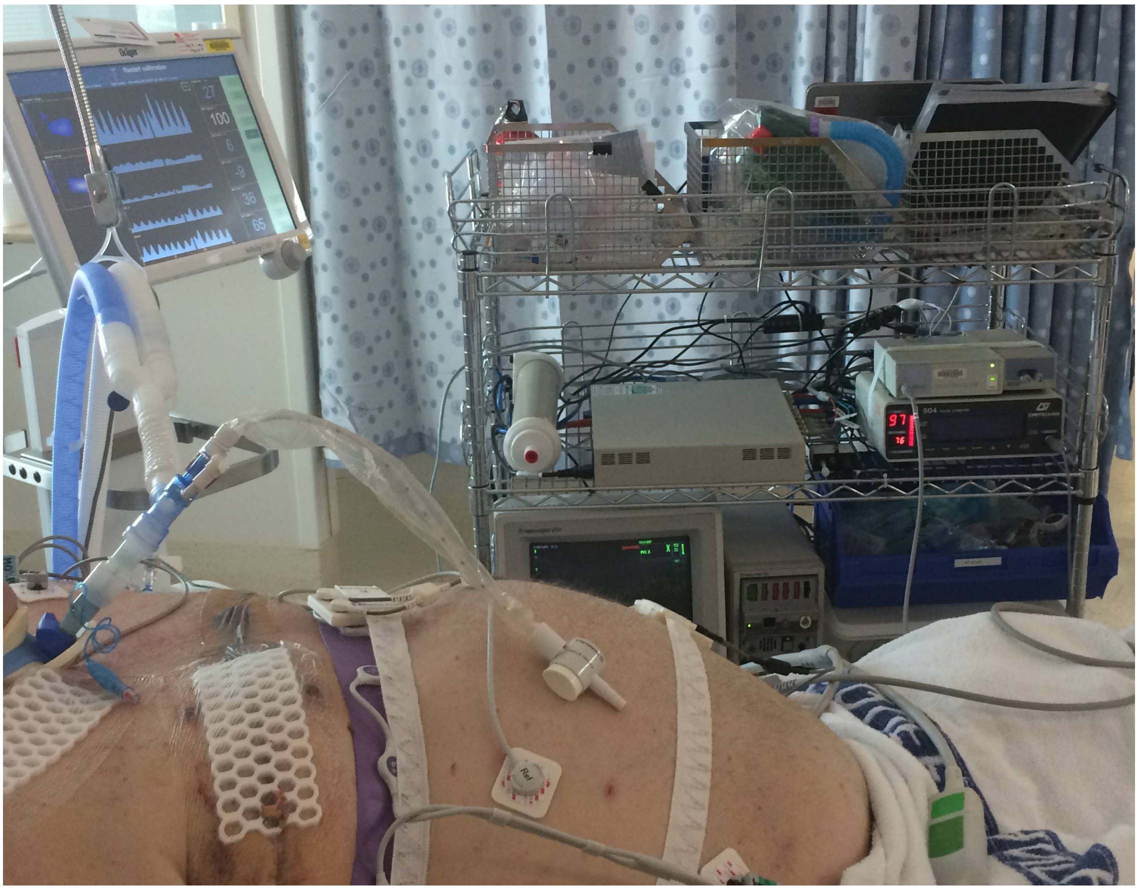

Figure 2-5: EIT and RIP set-up on a tracheostomised mechanically ventilated ICU patient (with patient permission)

In terms of measuring A:C ratios, it is assumed that increased abdominal mobility would suggest increased diaphragm activity. However, due to the complexity of the muscular system involved in breathing, the changes in the A:C ratio cannot be attributed to changes in the force of contraction in any particular muscle [58]. Therefore the change in the abdominal mobility is an estimated change in diaphragm activity. RIP can be used to monitor changes over time, for example before, during and after the SV use.

This chapter has considered and described the two most common ways of restoring verbal communication in critically ill tracheostomised patients still requiring support from a ventilator. An overview of respiratory mechanics and ways to measure it has also been presented. It is demonstrably the case that patient communication is important, especially in the critical care environment. Restoring the patients' own voice is not always possible due to various reasons. The next section in this chapter gives an overview of all other communication options for these patients, most of which are commonly used due to concerns over cuff deflation and SV use.

2.3 Communication

Communication can be categorised in multiple different ways. For successful verbal communication one needs both speech and language. Language is the content and meaning of what we are saying. Speech is the execution of those thoughts into sounds and words. Essential components of speech are respiration, phonation, resonance and articulation [72].

There are language centres in the brain that are responsible for comprehension and expression of thoughts. These language centres translate thoughts into words and sentences that are produced verbally as a result of signals sent to the muscles that are responsible for speech production. In ICU a patient's ability to communicate may be limited due to either a neurological disruption that prevents or impedes the formulation of words and sentences, or else a physical or structural problem (e.g., a breathing tube) that deprives the patient of the use of their voice. Where an ICU admission is due to a neurological event, the patient's speech and/or language centres may be affected, causing communication impairment. In cardio-thoracic ICU patients, a primary neurological basis to communication disability is less likely. Basic speech and language abilities are generally intact, with the patients' level of alertness often sufficient for communication.

Communication is often challenging when ICU patients are tracheostomised and mechanically ventilated. Respiration for these patients takes place through the TT below their vocal folds, rendering patients voiceless due to the temporary change in the anatomy of their upper airway (as discussed above; see also *Figure 1-1* on *page 2*). As verbal communication is often not possible for these patients, other modes of communication need to be used. All modes of communication other than natural speech are often referred to as augmentative and alternative communication (**AAC**), which can include both verbal and non-verbal modes of communication.

2.3.1 Non-verbal communication

Non-verbal communication is utilised by people on a daily basis to accompany and augment verbal communication (such as gesture, facial expression, drawing). Reliance solely on non-verbal modes of communication can present challenges to both the "communicator" and communication partners, limiting the success/effectiveness of conveying the intended message.

With any type of non-verbal communication difficulties start with gaining the attention of a prospective communication partner to initiate 'conversation'. In a usual communicative situation we can gain attention verbally, although the same result can be achieved using other sources of noise (e.g., clapping hands, tapping foot etc.). Initiating conversation is especially difficult for patients in a noisy ICU environment, where they often have restricted limb movement and no voice when tracheostomised and mechanically ventilated. There is limited research assessing communication initiation of ICU patients. Lasiter [73] reported on "The Button" (i.e., the nurse call light), which participants found somewhat helpful in getting the help they needed.

One of the most common modes of communication attempted by non-verbal patients in ICU is mouthing and gesture. It is attempted by most tracheostomised mechanically ventilated patients in ICU at some stage and success is highly dependent on the patient's oromusculature ability, level of alertness and also the communication partner's ability to lip-read. It is often frustrating for both parties and makes it difficult for the patients' thoughts to be understood. Freeman-Sanderson reports an increase in patients' ability to be understood by others as soon as patients have the ability to verbally communicate [74] instead of mouthing their message.

AAC devices are a common option used for communication in the ICU. These can be divided into low-tech and hi-tech devices, with the latter being able to convey longer and more complex messages and offer a voice output option also (with this option considered a method of verbal communication). Some AAC systems are picture based while some are word-based, with the preferred system dependent on individual patient needs. Most devices come with pre-set messages; to know what they are able to "talk about", a patient will first need to be familiarised with what is on the board/booklet. There are specific communication boards that have been developed for ICU patients [75]. Patients that had experienced ICU stay and mechanical ventilation were consulted during the creation of the Vidatak communication boards to ensure that all the needs of a typical ventilated patient could be met.

Non-verbal communication in an ICU environment often has both content and physical limitations. Most AAC devices require intact vision and some require the ability to learn new things, as successful use requires training of communication partners as well as the patient. AAC devices are often limited to word or phrase levels, potentially making the message less specific or accurate. Additionally, introducing fomites in the form of communication devices and boards into ICU can generate issues around infection control.

In terms of content limitations, non-verbal communication is often focused on conveying basic needs rather than conversation since the methods employed are usually time consuming and lack accuracy. Pen and paper would allow for more precise messages to be communicated, however physical limitations such as level of alertness, upper limb strength and mobility restrictions make this option difficult for ICU patients. There are different access options that can be used with AAC devices depending on limb dexterity – from complex keyboards to a joystick. Eye gaze access is an option for patients with very limited or no limb mobility, with patients able to use their eyes instead of limbs to point to messages. Eye gaze access has been reported to be somewhat successful in patients with spinal cord injuries that have no limb movement but who are able to purposefully track with eyes [76]. Eye gaze access is slow and requires extensive training and is therefore often not suitable for all ICU patients.

Notwithstanding the potential availability of alternate modes of communication, patients strongly prefer verbal communication and it guarantees better success in conveying a message to the healthcare team and family [6].

2.3.2 Verbal communication

When patients were asked to reflect on and rate different modes of communication, they reported verbal communication as the most successful mode of communication. Pen and paper were rated as moderately successful, and mouthing and gesture were rated with a low success rate [6]. Commonly we associate verbal communication with an individual using their own voice, however devices such as voice output applications and electrolarynx can be included as forms of verbal communication.

2.3.2.1 Electronic voice options for communication

An increasing number of voice output devices are available, ranging from those that use preset recordings of a spoken word or a whole message at the press of a button through to “type to speak” applications on smart phones and tablets. Their biggest advantage over non-verbal communication is being heard. Most of the high-tech AACs again require the user to have good fine-motor skills, learn the steps of the application and work to individualise the content, which makes use of these devices in the ICU environment challenging.

The electrolarynx has been successfully used as a verbal communication option for some tracheostomised patients [77], although it is primarily designed for laryngectomised patients that have no other means of producing voice. It requires the speaker to have the vibrating head (sound source) of the electrolarynx placed against their neck or cheek and use clear articulation to mouth their message. The downsides of the electrolarynx are numerous: patients have to learn a new skill; patients need to have excellent oromusculature movement for intelligible articulation; good fine-motor skills are required to be able to hold the electrolarynx in a suitable spot on the neck or cheek; the voice is ‘mechanical’, not produced using the vocal folds, and therefore it is not the patient’s own actual voice. An electrolarynx could be a feasible communication option for some long term or permanently tracheostomised patients but is not considered a viable option for most ICU patients.

2.3.2.2 Natural voice options for verbal communication

Verbal communication options that use the tracheostomised patient’s own voice all involve some form of modification to the TT or to the way in which it is used with or without a ventilator. Modifications or alterations to the tracheostomy set-up include: SVs; leak speech with or without ventilator adjustments; above cuff vocalisation; TTs with a special inner cannula with a SV; cuffless TTs; capping/corking, and finger occlusion. McGrath [78], whilst concentrating on above cuff vocalisation, describes some of the other communication options available for TT patients in ICU. Not all of these options can be used with tracheostomised patients that are mechanically ventilated.

2.3.2.2.1 Verbal communication options for non-ventilated tracheostomised patients only

Table 2-1 – Verbal communication options for tracheostomised patients

	Applicable to mechanically ventilated tracheostomy patient	**Applicable to ventilated and non-ventilated tracheostomy patients**
Above cuff vocalisation	Yes	Yes
Special TTs (i.e. Blom TT)	Yes	Yes
Leak speech	Yes	Yes
Speaking valve	Yes	Yes
Finger occlusion	No	Yes
Capping / corking	No	Yes
Cuffless TTs	Sometimes	Yes

Finger occlusion can be used to test for patients' ability to breathe around the deflated tracheostomy cuff or for momentary voicing. Whilst longer periods of voice production could be trialed with finger occlusion, this method is not feasible for prolonged communication in ICU as someone needs to hold their finger in front of the tracheostomy cannula at all times during phonation. This is difficult for the patients to coordinate with potentially poor upper limb function and could therefore also create an infection risk. In the ICU environment finger occlusion is often used as a diagnostic intervention to assess whether a patient is a suitable candidate for a SV. This method can only be used with patients that can tolerate a period of time off mechanical ventilation [79].

Instead of finger occlusion, capping/corking is sometimes used to occlude the tracheostomy cannula. Although its efficacy is not evidenced in literature, it is still used as a step towards decannulation in some countries. It involves deflating the tracheostomy cuff and covering the TT with a cap, so that all inhalation and exhalation occurs via the upper airway. Hussey at al [80] reported that the pressures required for the patient to breathe around a deflated cuff far exceed the pressures in a normal native human airway (i.e., size

8 TT required more than 20 cmH_2O at all flows higher than 20 L/min). Unless the TT is size 4 in an adult trachea, this method should not be used.

Verbal communication is sometimes successful with a cuffless TT. Cuffless TTs are often used in the paediatric population; they are generally used in adults only if there is no need for mechanical ventilation and airway protection. Though there are reports in the literature [81] that the vast majority of tracheostomised patients with severe respiratory insufficiency and reasonably competent oropharyngeal muscles can be safely and adequately ventilated up to 24h a day with their cuffs deflated or removed, this is not done in the Australian ICU environment. As ventilators used in ICUs do not usually cope with leaks in the ventilatory circuit, it is not a feasible option for ICU patients. In addition, no studies have reported on the impact of using cuffless tubes in liberating critically ill patients from mechanical ventilation.

2.3.2.2.2 Verbal communication options suitable for non-ventilated and mechanically ventilated tracheostomised patients

The use of a patient's own voice for communication in the mechanically ventilated tracheostomised population can be achieved by modifying or altering the ventilator and tracheostomy set-up. This includes above cuff vocalisation, special TTs, leak speech, and SV.

Some TTs are designed with above the cuff suction lines that enable 'above cuff vocalisation' when gas-flow is connected to the suction-line port. The suction line has an opening above the cuff to help remove secretions from this area, which has shown to decrease risk of ventilator associated pneumonia (**VAP**) [82]. Besides being able to keep the area clean from secretions and potential colonising bacteria, gas-flow can be connected to the above the cuff suction-aid tubing to enable airflow through the upper airway and vocal folds despite the inflated cuff. This method has shown some success in tracheostomised patients. Leder [10] suggests that 10-15L/min of airflow produces intelligible speech with minimal patient discomfort. McGrath [78] has also reported on a few recent ICU cases where above the cuff vocalisation was successfully employed. However limited data exist on the effectiveness of functional use of the vocal folds with this technique. The drying effect, including the potential for laryngeal injury of continuous non-humidified air running through the glottis, is also a potential problem area with above cuff vocalisation [83].

Another option is a special fenestrated TT that comes with a speech cannula and two valves that can be used for patients to phonate with an inflated cuff. Inspiratory pressure opens the flap valve and closes the bubble valve, sealing the fenestration so that all of the inspired air goes to the lungs. As inspiration ends, the flap closes. Expiratory air collapses the bubble valve, which unblocks the fenestration and directs all of the exhaled air to the upper airway for phonation [84]. Kunduk et al [85] reported that this speech cannula was safe, effective and well tolerated while maintaining cuff inflation. The use of this method requires a TT change, as these special tubes are not usually the first choice of tubes upon tracheostomy insertion. There is limited literature exploring the use of these tubes in the ICU population, indicating these tubes are not suitable for patients weaning from mechanical ventilation [86].

There is also a special TT that has a cuff which only deflates on expiration, allowing for partial expiratory flow to bypass the tracheostomy cannula and exit via the upper airway. This type of tube, if successful, allows TT patients to talk without any modifications needed to the TT [87]. The use of leak speech and SV also fit in this category (see *sections 2.1.1 and 2.1.2* for specifications).

2.3.2 Communication in ICU

With so many different communication options available for a tracheostomised ICU patient, it takes specialist knowledge to choose the most suitable option for each patient. A recent systematic review attempted to present a flowchart to guide the clinician with decision making around the best communication option for such patients [88], however this flowchart fails to emphasise the importance of verbal communication. Speech pathologists are widely acknowledged to be key members of the multidisciplinary team helping tracheostomised patients with communication in ICU [89]. Early SP intervention for these patients has been shown to result in less time taken for tracheostomised patients to return to verbal communication [90].

A significant proportion of patients have limited communication abilities during most of their ICU stay; their inability to communicate effectively can have both short- and long-term impact. Communication has been identified as one of the key areas of frustration for patients in ICU [8, 23, 24]. A recent study [74] reports increased satisfaction and quality of life for tracheostomised ICU patients once able to verbally communicate using a SV.

Anecdotal observations and informal reports from clinical staff suggest that the presence of confusion/delirium is easier to establish when patients are talking. It is also easier to re-orientate and reassure the patient when they are able to verbally respond. There is no published literature determining the role of early verbal communication in ICU, nor its impact on the development and duration of delirium. Anecdotal evidence also suggests that enabling early verbal communication in tracheostomised patients can lead to patients being able to better report on their previous and current health condition, which has the potential to result in better use of healthcare expenditure.

A significant volume of published literature exists around the importance of communication in the ICU environment. There are studies that examine how patients and ICU physicians, nursing staff, and families perceive communicative interactions. There are also many studies looking at staff communication during clinical handover practices and delivery of care [91-95]. All of these studies report the importance of communication from all parties to warrant best patient care.

Despite this emphasis on communication, less has been reported around patients' success with communication in ICU. Very few published studies provide a comparison between patient and staff perceptions of communication success in the ICU when the patient is tracheostomised. There is one study [96] exploring the perceived difficulty of communication in ICU with ventilated patients in which both multidisciplinary staff and previously ventilated patients were asked to rate the level of difficulty with communication. Not surprisingly, the study found that patients reported a higher level of difficulty in communicating as compared to staff. As tracheostomised and mechanically ventilated patients have a 1:1 nurse to patient ratio in Australian ICUs, this is a critical relationship to study. Nurses spend the most time with patients, therefore their ability to understand the patient is critical. A study by Leathart [97] found that nurses' interactions with a ventilated ICU patient on average lasted less than 30 seconds. This is clearly not enough time for a patient to successfully convey their message. Nursing staff have found that verbal communication makes it easier for them to look after patients [8, 97, 98].

2.4 Conclusions of literature review

This chapter has highlighted the importance of verbal communication in the critically ill tracheostomised ICU patient population. SV use was identified as being the best method for restoring verbal communication for these patients, as it "normalises" physiology during exhalation and enables use of patients' own natural voice. The unfounded concerns over

the SV’s potential negative effect on respiratory mechanics, and best ways to measure these mechanics were introduced in this chapter. These concerns have stopped SVs from being routinely used in ICU population, and therefore needed exploring.
This PhD thesis, through innovative research studies presented in the next 5 chapters, provides answers to the following questions: does a SV increase EELV? (Chapter 3); does it cause a shift in ventilation distribution? (Chapters 4 and 5); is it safe to use SVs on patients that are still mechanically ventilated? (Chapters 3 and 4); how does SV impact diaphragm activity? (Chapter 4); does routine SV use effect tracheostomy and ventilation specific ICU outcomes for patients? (Chapter 6); does a SV improve the patient’s success with health related communication? (Chapter 7).

A summary of the thesis findings, limitations and areas for future research are included in Chapter 8.

Chapter 3

Chapter 3 Speaking valves in tracheostomised ICU patients - weaning off mechanical ventilation – do they facilitate lung recruitment?

3.0 Rationale and significance

It was established in Chapter 2 that patients prefer to be able to communicate verbally: one way to achieve this outcome is through the use of a SV. This chapter focuses on the effect of SVs on the patients' EELVs and bedside respiratory parameters. The specific SV used in this study is a Passy Muir SV (PMV007, Passy Muir Inc., California, USA).

To recap, concerns have been raised in the past regarding patient lung physiology and recovery if SVs are used; related primarily to the risk of lung derecruitment. There are no published data to support these concerns, with no detailed information available as to what happens to the lungs when a TT cuff is deflated with or without a SV. The insertion of a SV, which allows leakage of expiratory gas, dramatically diminishes the data available to the clinician from the ventilator. There is no way to monitor the patients' lung volumes or obtain other data on expiration with routinely available clinical bedside techniques due to the absence of expiratory flow back into the ventilator. It is therefore essential to rigorously examine the effect of the SV on regional ventilation within the patients' lungs to determine whether or not SV use entails the risks outlined above. As transporting patients to radiology for CT is expensive and comes with increased risk [44, 45], this was not an option. EIT, being a relatively new real-time radiation free bedside imaging tool [99-102], was found to be ideal in answering this key clinical question of whether patients' lungs are compromised when using SVs.

To address the main aim of this thesis, this study was designed to monitor patients' lung mechanics before, during and after SV use through examining the following key variables: (1) EELI; (2) RR; (3) heart rate; (4) SpO_2; (5) $EtCO_2$, and ventilator data, including: (1) PEEP; (2) PS; (3) PIP, and (4) TV. Prior to this study, this analysis had never been attempted.

The results of this study have been presented in over 25 international, national and local invited conferences and lectures, as highlighted in *Presentations during candidature* on page vii. Best Novice Clinical Presentation Award was gained at the TPCH Research Forum in November 2016 following presentation of this study. This chapter was published in Critical Care in 2016. Sections, tables and figures have been renumbered, abbreviations continued and formatting changed according to the style of Journal of Critical Care to align with the rest of the thesis document. References to ‘open lung strategy’ and ‘work of breathing’ have been removed from the Introduction and Discussion sections in the manuscript below.

Speaking valves in tracheostomised ICU patients weaning off mechanical ventilation – do they facilitate lung recruitment?

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3.1 Abstract

Introduction

Patients who require positive pressure ventilation through a tracheostomy are unable to phonate due to the inflated tracheostomy cuff. Whilst a SV can be used on a TT, its use in ventilated ICU patients has been inhibited by concerns regarding potential deleterious effects to recovering lungs. The objective of this study was to assess EELI and standard bedside respiratory parameters before, during and after SV use of tracheostomised patients weaning from mechanical ventilation.

Methods

A prospective observational study was conducted in a cardio-thoracic adult ICU. 20 consecutive tracheostomised patients weaning from mechanical ventilation and using a SV were recruited. EIT was used to monitor patients' EELI. Changes in lung impedance and standard bedside respiratory data were analysed pre, during and post SV use.

Results

Use of in-line SVs resulted in significant increase of EELI. This effect grew and was maintained for at least 15 minutes after removal of the SV *($p<0.001$)*. $EtCO_2$ showed a significant drop during SV use *($p=0.01$)* whilst SpO_2 remained unchanged. RR decreased whilst the SV was in-situ *($p<0.001$)*, and HR was unchanged. All results were similar regardless of the patients' respiratory requirements at time of recruitment.

Conclusions

In this cohort of critically ill ventilated patients, SVs did not cause derecruitment of the lungs when used in the ventilator weaning period. Deflating the tracheostomy cuff and restoring the airflow via the upper airway with a one-way valve may facilitate lung recruitment during and after SV use, as indicated by increased EELI.

3.2 Introduction

Invasively ventilated patients are unable to phonate due to either the ETT positioning through the vocal folds, or when ventilating through tracheostomy, the air bypassing the vocal folds. SVs can be used in-line with mechanical ventilation, but use of these requires deflation of the tracheostomy cuff [103]. Cuff deflation causes a leak in the ventilator circuit, which has been considered detrimental to patients' ventilation, and potentially deleterious to weaning.

The key concern raised by physicians is that by deflating the cuff, and thus losing PEEP this could lead to loss of lung volume through alveolar collapse. It has been demonstrated that loss of PEEP in other events, such as suctioning [71, 104] and ventilator disconnection [105], causes loss of lung volume. Hence, practices that may cause loss of lung volume must be used with some degree of caution.

One small case series has described the apparently safe use of SVs during weaning from mechanical ventilation [106]. Another study found no significant difference in ventilator weaning and decannulation times post the introduction of in-line SVs into an adult ICU [107, 108]. Whilst these studies provide preliminary clinical support for use of in-line SVs with tracheostomised mechanically ventilated patients, there are no physiological data to prove or allay fears.

Currently there are no data regarding the effect of SVs on EELV, a critical point when the lungs are at most risk of collapsing. A SV is a one-way valve that allows for inspiration via the TT whilst expiration is redirected to the upper airway via the vocal folds enabling phonation [103] and restored upper airway resistance. Hence it can be considered functionally as a PEEP valve on the tracheostomy. As there is no airflow back into the ventilator tubing with the one-way valve, current in-situ monitoring of ventilation with standard bedside equipment provides the clinician with limited information regarding ventilation. While computerised tomography may be able to provide this information, the repeated use of these imaging procedures could be seen as ethically unjustifiable, expensive, may require a level of sedation and put patients at risk with the transfer outside of the ICU environment [44, 45].

EIT is a radiation-free real time bedside imaging tool capable of measuring the air movement in and out of the thorax [99-102]. It has been observed as being a safe, reliable and reproducible technique to assess regional ventilation in the lung, specifically during recruitment manoeuvres [71]. In the future it may be possible for absolute EIT to directly measure EELV but current time-differencing systems rely on measuring the difference between end-inspiratory lung impedance and EELI to measure tidal variation of impedance and changes in EELI [100]. A linear correlation exists between changes in the EELI and changes in EELV [48, 50, 109], although this relationship tends to over-estimate changes in EELV [109]. A limitation of time differencing EIT is that it is unable to detect the pre-existing EELI [53, 54] which means it can only detect changes in EELI if the device remains in-situ and running between readings [48, 53-55]. Researchers, however, have successfully used EIT to detect changes in EELI due to various clinical interventions such as suctioning, position change, and changes in PEEP [55, 101, 109-112].

This study aimed to assess the effect of SVs on EELI. Based on the findings of prior case studies it was hypothesised that there is an increase in global EELI with the SV in-situ when patients are performing trials off the ventilator (i.e. on 50L of 40% oxygen via tracheostomy). This may potentially be similar when patients are constantly supported by mechanical ventilation, given restored physiological PEEP. Secondary aims included determining the effects of SV on patients' RR, HR, SpO_2 and $EtCO_2$. The potential effect of talking versus quietly breathing with SV in-situ on respiratory mechanics and the effects of SV and its dependence on the patients' ventilatory requirements at the time were also investigated.

3.3 Methods

Following human ethics approval by the Institutional Review Board (HREC/13/QPCH/95) a prospective observational study (ACTRN12615000589583) using a repeated measures design was conducted. The study took place in a primarily cardio-thoracic ICU at a metropolitan tertiary teaching hospital. Consecutive patients tracheostomised and undertaking weaning from mechanical ventilation from November 2013 to December 2014 were considered for inclusion in the study if they were tolerating a SV for a minimum of 30 minutes, as jointly assessed by a speech pathologist and a physician. Patients were excluded if they had significant language or cognitive deficits, or were not suitable to wear an EIT belt (i.e. patients with ventricular assist devices, open chest, extensive sternal dressings/drains or dependent on cardiac pacing). Twenty patients were recruited in 2 groups: 1) 10 on PSV, and 2) 10 patients having trial periods off mechanical ventilation (and transferred onto high flow or low flow oxygen via tracheostomy). All patients provided written informed consent, or, for those unable to sign consent was provided by a legally authorised person (e.g. family member) or by the patient's nurse witnessing verbal consent. The study was conducted in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

3.3.1 Measures

Following informed consent, patients were enrolled in the study. EIT (Pulmovista, Draeger Medical, Lubeck, Germany) measurements were taken continuously for 60 minutes with the frame rate set to 10Hz to give EELI per breath. Transitions to and from SV were followed by 15-minute periods, to allow for stabilisation [113].

Set ventilator delivered PEEP and FiO_2 data were collected from the ventilator (Puritan Bennett 840, Covidien, Dublin, Ireland). HR and SpO_2 were measured with pulse oximeter (504, Criticare systems, Wisconsin, USA). Airway pressure (**P_{aw}**) was measured directly via a neonatal feeding catheter (6F). This was introduced through the Luer port of an adaptor (Ikaria, New Jersey, USA) advanced to lie just distal to the tracheostomy cannula in the trachea, and measured with a pressure transducer (PPT, Honeywell, New Jersey, USA). Oximeter and pressure data were collected at 200Hz (PowerLab, ADInstruments, Sydney). $EtCO_2$ was sampled from the feeding tube and measured (Marquette Solar 8000, GE Healthcare, Little Chalfont, UK). $EtCO_2$ was measured continuously throughout the 60 minutes apart from 2 minutes before, during and after SV use when continuous P_{aw} measurements were taken through the same catheter. There was no flow through the catheter during pressure measurements to ensure highest possible fidelity. All data were collected on a breath-to-breath basis using custom written software.

3.3.2 Procedure

The patients were positioned either in bed at 45 degrees or in a straight backed chair with the EIT electrode belt around their chest at the level of the 5^{th} to 6^{th} anterior intercostal space. As patient position has been shown to have an impact on ventilation distribution [101], we ensured that there were no significant changes in patient positioning throughout the data collection. A neonatal feeding catheter was inserted as described above and the pulse oximeter was positioned on the finger.

Fifteen minutes of data were recorded continuously during four discrete periods: (1) baseline – prior to placement of the SV in-line with mechanical ventilation; (2) quiet breathing with SV in-line; (3) talking with SV in-line, and (4) post removal of the in-line SV. After the baseline period the tracheostomy cuff was deflated with simultaneous tracheal suctioning to clear secretions pooling above the cuff and minimise aspiration. The SV (PMV007, Passy Muir Inc., California, USA) was then inserted in-line with the ventilation circuit following the adapter that accommodated the $EtCO_2$/ P_{aw} catheter. Ventilator settings were changed while the SV was in-situ in the patients supported by PSV. This included switching the system to non-invasive (NIV) mode for PSV (to more easily control expiratory alarms) and reducing the set ventilator delivered PEEP by 5cmH_2O [32]. This change in settings was based, in the absence of any scientific data to define optimal settings, on recommendations by the SV manufacturer. During the second data collection period patients were instructed to continue to breathe normally and avoid talking. Once data collection period 3 commenced the patients were instructed to converse as they wished with the researcher, family member, or healthcare team. In the case where verbal communication was limited, the researcher used picture cards and open-ended questions to facilitate verbal output. As there is a suggested difference in breathing patterns between different speech tasks (planned vs. non-planned) [114], no set tasks were given to participants, instead, spontaneous speech was encouraged. At the completion of period 3, the ventilator settings were returned to baseline, SV was removed, and the tracheostomy cuff re-inflated. Data collection continued in period 4 as per baseline conditions. Routine tracheal suctioning was performed during data collection as per individual patient needs.

3.3.3 Data analysis

Data were analysed offline following data collection using commercially available Draeger software (Draeger EIT Data Analysis Tool 6.1). EELI was averaged across the readings and displayed as mean EELI for each of the 4 data collection periods. To investigate the changes in EELI compared to baseline a mixed effects regression model was used. Planned comparisons between baseline and each subsequent data collection period were conducted using paired t-tests for RR, $EtCO_2$, HR and SpO_2.

The level of significance was set at $p < 0.05$ throughout with 95% confidence intervals quoted where appropriate. All statistical analyses were conducted using $STATA_{TM}$ (version 12.0).

3.4 Results

During the study period 55 tracheostomised patients used a SV and were assessed for inclusion in the study. Of these patients, 20 met the inclusion criteria and were enrolled in the study. *Figure 3-1* below details the reasons for exclusion or non-participation in the study.

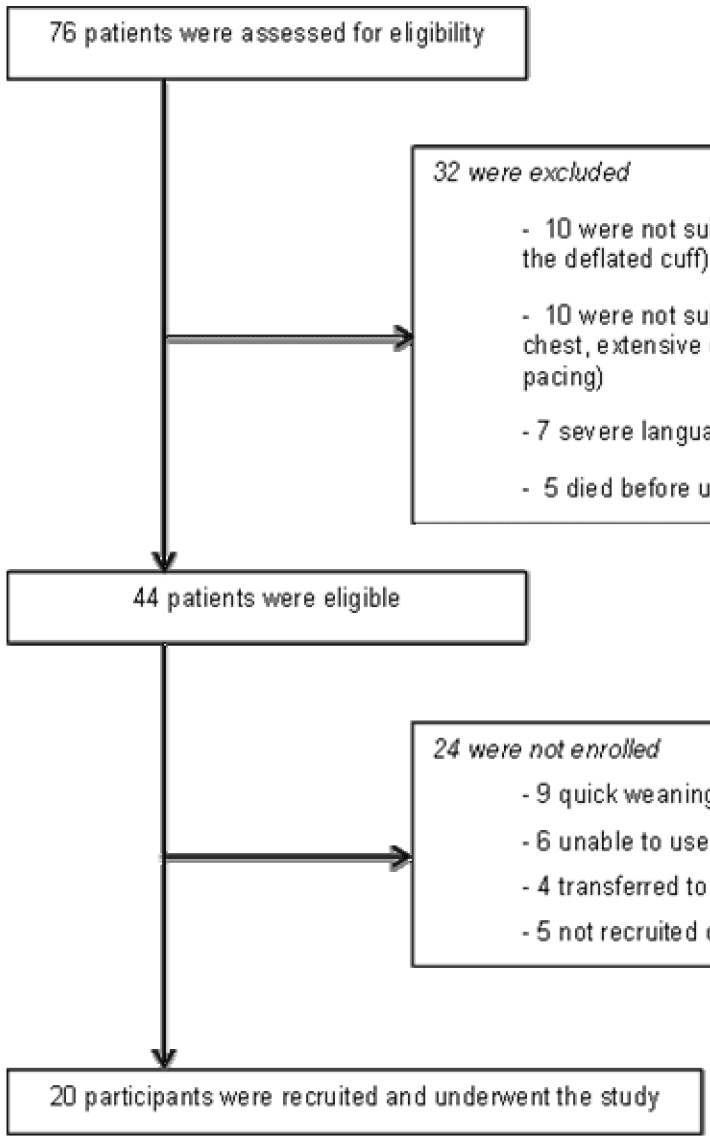

Figure 3-1: Participant selection chart

BiVAD – biventricular assist device; EIT – electrical impedance tomography; LVAD – left ventricular assist device; PMSV – Passy-Muir Speaking Valve; PPM – permanent pace maker

The mean age of the patients in the study was 60.4±14.9 years (50% male). The mean age for all tracheostomised patients in the ICU throughout the recruitment period was 57.1±17.4 years (64.6% male). On average patients used a SV for 2.5 days prior to recruitment to the study. Ten patients were assessed whilst being ventilated with PSV, and 10 were assessed during periods off the ventilator (9 on high flow, one on low flow oxygen) for the duration of data collection. All but one patient assessed off ventilator were still requiring >12 hrs/day of mechanical ventilation. See *Table 3-1* below for the specifics of respiratory requirements.

Table 3-1 – Participant ventilation need

Pt No.	Vent. needs[a]	Weaned Y/N	PS	PEEP	FiO_2	Flow
1	HFTP	N	N/A	N/A	40%	40L
2	HFTP	Y	N/A	N/A	40%	40L
3	LFTP	N	N/A	N/A	30%	5L
4	HFTP	N	N/A	N/A	40%	50L
5	PSV	N	10	5	40%	N/A
6	HFTP	N	N/A	N/A	40%	50L
7	HFTP	N	N/A	N/A	40%	40L
8	PSV	N	15	10	35%	N/A
9	HFTP	N	N/A	N/A	50%	50L
10	PSV	N	13	10	40%	N/A
11	HFTP	N	N/A	N/A	40%	40L
12	PSV	N	10	7.5	40%	N/A
13	PSV	N	15	5	35%	N/A
14	HFTP	N	N/A	N/A	30%	30L
15	HFTP	N	N/A	N/A	40%	40L
16	PSV	N	10	8	40%	N/A
17	PSV	N	10	5	35%	N/A
18	PSV	N	12	5	40%	N/A
19	PSV	N	12	8	45%	N/A
20	PSV	N	12	7.5	40%	N/A

[a] respiratory needs at point of recruitment. Considered not weaned if needed mechanical ventilation in the preceding 24hours

FiO_2 – fraction of inspired oxygen; Flow – O_2 flow requirements at point of recruitment; HFTP – high flow tracheostomy piece (>30L/min of O_2); LFTP – low flow tracheostomy piece (<30L/min of O_2); PEEP – positive end expiratory pressure; PS – pressure support; PSV – pressure support ventilation

The majority of patients *(17)* had their TTs inserted percutaneously in the ICU. Primary reasons for ICU admission included cardiac surgery *(n=13, 65%)* or respiratory disease *(n=5)*. Nineteen of the patients *(95%)* had received a tracheostomy due to prolonged need for mechanical ventilation. Patient number 3 had the tracheostomy initially inserted for surgery in the upper airway, but required prolonged respiratory support following cardiac surgery. See *Table 3-2* below for more detailed description of all patients in the study.

Table 3-2 – Demographics and tracheostomy data

Pt No.	Age	Gender	Primary reason for ICU	# days TT to SV	# days to decannulation	Insertion method	TT type and size	# days of SV use when recruited
1	63	M	acute myocardial infarct; CABG	11	18	perc	long flange Portex 8	2
2	48	F	acute myocardial infarct; tamponade	5	12	perc	cuffed Portex 8	6
3	72	F	Buccal SCC + CABG	5	7	surg	cuffed Portex 7	0
4	71	M	tissue AVR for infective endocarditis	2	4	perc	cuffed Portex 8	1
5	29	M	endarterectomy	2	5	perc	cuffed Portex 8	1
6	77	M	CABG x3 and mechanical AVR	6	23	perc	cuffed Portex 8	1
7	44	F	aortic dissection	6	7	perc	cuffed Portex 8	1
8	33	F	endarterectomy	4	12	perc	cuffed Portex 7	4
9	61	M	H1N1, ARDS	12	23	perc	cuffed Portex 8	8
10	70	M	CABGx2	3	5	perc	cuffed Portex 8	1
11	70	F	cardiac tamponade	4	6	perc	cuffed Portex 7	1
12	43	F	PE	2	5	perc	cuffed Portex 7	2
13	47	F	Influenza A ARDS	4	6	perc	cuffed Portex 8	1

Pt No.	Age	Gender	Primary reason for ICU	# days TT to SV	# days to decannulation	Insertion method	TT type and size	# days of SV use when recruited
14	70	F	CAP	2	7	perc	cuffed Portex 8	5
15	58	M	CAP	3	N/A	surg	cuffed Portex 8	1
16	62	F	CAP	2	6	perc	cuffed Portex 8	1
17	74	F	extensive gastrointestinal surgery	10	31	perc	cuffed Portex 7	7
18	78	M	CABG x4	3	5	perc	cuffed Portex 8	2
19	60	M	chest trauma	7	12	surg	long flange Portex 8	2
20	77	M	re-do sternotomy for tissue AVR, CABGx1	4	13	perc	cuffed Portex 8	2

ARDS – acute respiratory distress syndrome; AVR – aortic valve repair; CABG – coronary artery bypass graft; CAP – community acquired pneumonia; PE – pulmonary embolism; perc – percutaneous; SCC – small cell carcinoma; surg – surgical; TT – tracheostomy tube; # - 'number of…'

A statistically significant increase in EELI was observed between baseline and all subsequent data collection periods. A mean increase by 19.7% (213 units) occurred from baseline to period 2 (SV + quiet breathing, *p=0.034*). Further increase from baseline by 83.6% (905 units) (*p<0.001*) and 120% (1299 units) (*p<0.001*) were seen in data collection period 3 and 4 respectively (see *Figure 3-2* and *Table 3-3* below).

It is notable that patients' ventilatory requirements at time of recruitment did not have a significant impact on change of EELI or change in any of the respiratory parameters or HR. The patients that were supported on PSV during data collection showed an initial non-significant drop in EELI. However, a similar increase in EELI with patients off the ventilator was noted for the 3rd and 4th period of data collection (see *Figure 3-2*).

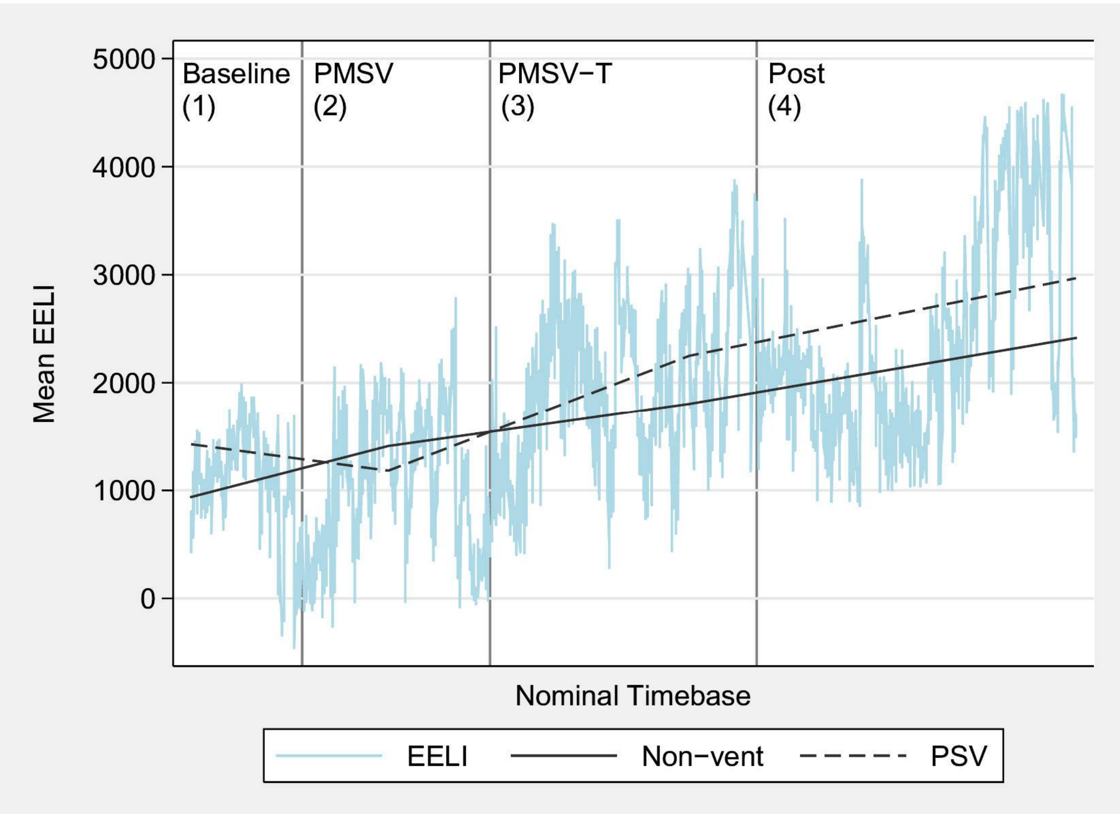

Figure 3-2: Mean EELI vs time with average EELI trend for non-vent and PSV

Mean EELI is plotted on the y-axis against a nominal timebase. A lowess smoothing line has been added to clarify the overall trend.
EELI – end expiratory lung impedance; non-vent – patient off mechanical ventilation during recruitment; PSV – pressure support ventilation; SV – speaking valve

$EtCO_2$ showed a significant decrease during SV use (*p=0.02* for period 2 and *p=0.01* for period 3) and returned to baseline for period 4. RR showed a significant decrease from baseline while SV was used in-line with the ventilation circuit (*p=0.001, p<0.001* for periods 2 and 3 respectively), and returned to baseline once the SV was removed. HR and SpO_2 showed no significant change throughout data collection.

Table 3-3 – Outcome measures across 4 time periods

	Baseline (1)	SV (2)	SV-talk (3)	Post SV (4)
SpO_2	96.5 (0.5)	95.5 (0.7)	94.7 (0.7)	96.0 (0.8)
RR	25 (1.6)	22 (1.5)*	20 (1.7)*	25 (1.4)
HR	95 (2.8)	95 (2.4)	96 (2.9)	96 (3.0)
$EtCO_2$	29 (1.1)	27 (1.1)*	26 (1.2)*	28 (1.0)
Mean EELI	1082 (57)	1295 (61)*	1987 (60)*	2381 (75)*

All data are presented as mean (SEM)
** Statistically significant change, $p<0.05$*
$EtCO_2$ – end tidal carbon dioxide; HR – heart rate; mean EELI – mean end-expiratory lung impedance; RR – respiratory rate; SpO_2 – peripheral capillary oxygen saturation; SV – speaking valve

Only limited data on P_{aw} were captured (3 participants with full data, 7 with partial data). These data all indicated similar drops in P_{aw}, coinciding with the reduction of ventilator-delivered PEEP for the duration of the SV use. Ventilator data showed minimal expired tidal volume when SV was in-line (see *Table 3-4*).

Table 3-4 – Airway pressures (P_{aw}), expired tidal volumes (TV) and peak inspiratory pressures (PIP)

	Baseline (1)	SV (2)	Post SV (4)
P_{aw} (n=7)[a]	10.5cmH_2O	5.6 cmH_2O	10.7 cmH_2O
TV (n=10)[b]	0.550L	0.024L[c]	0.534L
PIP (n=10)[b]	19.8	15.1	20

[a] full data for all 3 periods from 3 patients only
[b] data from all 10 mechanically ventilated patients in the study
[c] two patients had higher TVs of 0.106L and 0.088L on average, and two patients had TVs of 0.0L

3.5 Discussion

The findings indicated that use of SVs in this cohort did not result in any significant derecruitment of the lungs, contrary to the concerns initially voiced by physicians. Standard bedside monitoring demonstrated reduced respiratory rate with adequate gas exchange. The increase in EELI may indicate increased EELV. Further analysis is necessary to more fully determine ventilation distribution as an increase in EELV could be due to further recruitment or over-inflation of already aerated parts of the lung.

The increase in EELI with the SV in the ventilator circuit is likely to occur through the restoration of the patient's ability to breathe through the larynx and upper airway, as opposed to the continuously patent TT. Upper airway resistance is increased due to the resistance created by exhalation against and around the effectively closed TT (through the actions of the SV) and its deflated cuff, ensuring more residual air in the lungs at the end of expiration. Further analysis is required to confirm that lung hyperinflation did not occur as it could be argued that an increase in EELI may correlate to tidal hyperinflation. We used SpO_2 and $EtCO_2$ as simple measures, to exclude pathological degrees of hyperinflation, but this cannot exclude it fully. Of note, all patients had been using a SV before the study with no gross signs of hyperinflation on routine chest x-ray.

The subsequent increase in EELI seen when patients talked is explicable through the additional, but variable, upper airway resistance caused by the glottis [115], with vocal folds closing and opening during attempts at phonation. The SV appeared to act as a recruitment manoeuvre. An increase in EELI was observed during SV use and its effect remained after removal of the SV from the patients' ventilation circuit. EELI remained stable for 8-9 minutes once the SV was removed from the ventilator circuit and the tracheostomy cuff re-inflated before further increase occurred.

There are several potential explanations for the drop in $EtCO_2$ during the SV use. One reason may be a drop in $EtCO_2$ due to using one's voice, as observed in a study done on healthy subjects [116]. Another potential reason is dead-space washout in the upper airway that has been found to coincide with an increase in tidal volumes in other studies [117, 118]. With our current data, we cannot categorically state, however, that tidal volumes increased for patients in this study. A third potential aetiology may be that the exhaled air just past the tracheostomy cannula where $EtCO_2$ was measured from was being diluted with fresh inspiratory flow in all patients on high flow oxygen, and some on PSV while the cuff was deflated. Transcutaneous carbon dioxide (**$TcCO_2$**) and partial pressure of carbon dioxide in the arterial blood (**$PaCO_2$**) may need to be measured in similar studies in the future.

Only limited data on P_{aw} were captured. This was due to rapid and repeated obstruction of the fine bore catheter with secretions caused by the presence of no flow through the catheter during the several 2-minute measurements. A similar reduction in P_{aw} coinciding with the turning down of the set ventilator-delivered PEEP for the duration of the SV use was noted. However, due to lack of data, it is difficult to draw any conclusions. Further studies are needed to further look at P_{aw} and ventilator delivered PEEP with and without a SV in circuit.

It was surprising to observe that the ventilator demonstrated substantial exhaled tidal volume whilst the SV was in-situ. This may indicate the presence of a leak in the SV or some form of back-pressure. This means that the ventilator may actually still be delivering PEEP when a one-way valve is in place, and will be the subject of further studies.

Communication is a key issue for ventilated patients, who find the inability to speak distressing [8, 24, 119]. Difficulties with communication in the tracheostomised patient population have been associated with social withdrawal, leading to depression, lack of motivation to participate in care [7-10], poor sleep, and increased anxiety and stress levels [11] which has both short and long term impacts on patient outcomes in and post ICU. By demonstrating the potential physiological benefits on top of the already known and more obvious psychological benefits, SVs present an excellent way to improve patient care in the ICU.

Increased use of SV raises various important questions. For instance, how long should the SVs be used for at any one time? Does this lead to fatigue? Should the SVs be used with patients during mobilisation? Future studies are needed to look at the efficacy of SVs in the weaning and rehabilitation process of mechanically ventilated tracheostomised ICU patients.

3.5.1 Limitations of the study

This study was conducted on a specific cohort of ICU patients, mostly cardiothoracic, and extrapolation of these data to patients with different pathologies may not be wise. This is even more relevant in patients with spinal and brain injuries where central control of breathing might be affected.

No patients in this study were ventilated using volume-controlled modes, hence there is a need to determine whether restored physiological PEEP through SV helps compensate for the leak in the ventilatory circuit similarly in volume-controlled ventilation.

Airway pressures were only measured for the second half of the study patients (n=10) with limited data obtained as described above. Hence the reported P_{aw} data may be a poor representation of the actual P_{aw} across the time points in the study and was therefore not reported in detail. Different methods to obtain this important data are recommended for future similar studies. Minor difficulties also occurred with $EtCO_2$ measurements (measured in all patients in the study) through the same catheter. However, the presence of airflow in the catheter during $EtCO_2$ measurement reduced the likelihood of the catheter blocking with secretions, resulting in close to full data across 60 minutes obtained from all patients.

Routine suctioning was performed as per patient needs throughout data collection. It is known that tracheal suctioning causes a degree of derecruitment [111]. The quantitative effect of suctioning was not specifically analysed as part of this study, nor were these periods excised from data analysis. Derecruitment caused by tracheal suctioning could therefore be a confounding factor and negatively skew our data on the effect of SVs.
The duration of the study was only a total of one hour, with SV in-situ for 30 minutes. Clinically the same patients would be using the SV for several hours at a time. Due to the inability to compare the change in EELI between sessions, and the patients needing to remain in the same position, the EIT belt stayed in-situ for the duration of the study with the patients sitting up. Therefore it was not feasible to monitor the patients for longer.

3.6 Conclusions

When SVs were used in this cohort of cardio-respiratory patients, we observed no evidence of lung derecruitment whilst weaning from mechanical ventilation. Deflation of the tracheostomy cuff with restoration of the airflow via the upper airway with a one-way valve facilitated an increase in EELI both during and after a period of SV use in our cohort of patients, which may indicate recruitment of the lungs. Use of the SV resulted in reduced RR and a reduced $EtCO_2$.

Chapter 4

Chapter 4 The effect of SV on ventilation distribution, lung recruitment and diaphragm activity

4.0 Rationale and Significance

The results in Chapter 3 demonstrate that SV use causes a significant increase in EELI. However, this study did not assess the specific regionality in the changes of EELI. An increased EELI can mean either recruitment of lung tissue (potentially beneficial) or hyperinflation (definitely deleterious) in some areas of the lung. Therefore it could not be safely concluded that SVs are harmless to the patients' lungs. To further expand on the main aim of this thesis, this next study analyses additional parameters using EIT technology to identify ventilation distribution. Updated software for use with our existing EIT device became available following our first publication (Chapter 3). It allowed analysis of (1) ventilated surface area (**VSA**) and (2) regional ventilation delay (**RVD**) investigating lung recruitment, alongside (3) distribution of EELI, and (4) tidal variation (**TVar**). These new techniques were therefore utilised to analyse data from before, during and after SV use to further determine the safety of SV use in cardiothoracic tracheostomised ICU patients weaning from mechanical ventilation.

Currently, there are few published studies that have examined such new modalities of EIT analysis on spontaneously breathing patients. Hence, being novel and innovative, as well as being able to assess for potential harm, it was felt an essential and logical addendum to the original question. There are no published guidelines on how to measure hyperinflation with EIT, especially with no access to pressure measurements. A potential method to interpret these new parameters to predict hyperinflation and/or recruitment, has been included in the discussion section of this chapter to compliment the findings.

Additionally, this chapter presents findings of a second study addressing the primary aim of this thesis. The importance of the diaphragm in breathing was established in Chapter 2. The significance of this muscle in breathing cannot be over-emphasised, therefore determining if a SV causes any adverse effect to the diaphragm is paramount. Data on A:C ratio using RIP techniques to predict diaphragm activity with and without SV are presented in section 4.2 of this chapter.

The results of these two studies have been presented in over 10 international, national and local invited conferences and lectures as highlighted in *Presentations during candidature* on page vii. Presentation of the studies in chapter 3 and 4 led me to win the University of

QLD 3-minute-thesis (3MT) competition in September 2016. The first part (4.1) of this chapter was accepted for publication in Journal of Critical Care in April 2017. The results of the second part (4.2) of this chapter have been partially published in an abstract format following ANZICS and ATS conferences. Sections, tables, figures and graphs across this chapter have been renumbered, and abbreviations continued to align with the rest of the thesis document.

Changes from the manuscript in press with Journal of Critical Care:

In the original manuscript tidal variation was abbreviated as TV to align with previously published EIT literature. In the thesis document, the abbreviation for tidal variation has been changed to TVar to differentiate this from tidal volume (TV). Additional details have been added in the data analysis section.

4.1 Ventilation distribution and lung recruitment with speaking valve use in tracheostomised patient weaning from mechanical ventilation in intensive care

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4.1.1 Abstract

Purpose

SVs are used infrequently in tracheostomised ICU patients due to concerns regarding their putative effect on lung recruitment. A recent study in cardio-thoracic population demonstrated increased end-expiratory lung volumes during and post SV use without examining if the increase in EELI resulted in alveolar recruitment or potential hyperinflation in discrete loci.

Materials and Methods

A secondary analysis of EIT data from a previous study was conducted. EELI distribution and TVar were assessed with a previously validated tool. A new tool was used to investigate VSA and RVD as indicators of alveolar recruitment.

Results

The increase in EELI was found to be uniform with significant increase across all lung sections ($p<0.001$). TVar showed an initial non-significant decrease ($p=0.94$) with subsequent increase significantly above baseline ($p<0.001$). VSA and RVD showed non-significant changes during and post SV use.

Conclusions

In this study, hyperinflation did not occur with SV use, which is consistent with previous data. These data, along with obvious psychological benefits to patients are encouraging towards safe use of SVs in this critically ill cardio-thoracic patient population.

4.1.2 Introduction

SVs are not routinely used with tracheostomised patients while they still require mechanical ventilation in the ICU. These patients are generally left without a voice for prolonged periods due to concerns that the required cuff deflation could lead to alveolar collapse and derecruitment of the lungs. A recent study reported improved EELI when using a SV in-line with mechanical ventilation [120]. Whilst increases in EELI may indicate alveolar recruitment, the analyses conducted to-date cannot exclude hyperinflation of some parts of the lung or in fact no clinically significant changes in lung volumes [54, 121]. Without analysing the distribution of EELI we do not know where this increase occurred, whether it was uniformly increased or only increased in dependent / non-dependent areas of the lung. The effect of increased EELI is important to determine as hyperinflation of the lungs could have a detrimental effect on patients' lung recovery and weaning from mechanical ventilation.

Currently several options exist to examine ventilation distribution using EIT data, thereby assessing lung recruitment in greater detail. Using TVar as one of EIT measures of ventilation distribution has been demonstrated by a number of studies [56, 122, 123] to provide valid information about the percentage of tidal volume in different parts of the lung. It is well known that mechanical ventilation (positive pressure) causes a shift in ventilation towards the ventral parts of the lungs [56, 124], which is more pronounced in the supine position. TVar can indicate whether similar shifts occur in a temporal manner. Changes such as a significant increase in EELI may have an impact on ventilation distribution.

Novel methods of estimating lung recruitment using EIT have recently been described in the literature [125, 126]. Two of these emerging EIT analyses to estimate changes in ventilation distribution and lung recruitment are VSA and RVD. In this study, VSA represents the number of pixels in which the local impedance change is greater than a pre-determined percentage of the maximum of the local impedance change, calculating the VSA. It uses the ventilation distribution map to calculate the number of pixels within an EIT signal [126]. A higher value indicates a greater area of lung surface that is ventilated. RVD is a calculation of the delay between the global start of inspiration and the point in time where the regional impedance curve reaches a pre-determined impedance change (in this study 40%, as per Muders [127]). It gives data on delayed opening of lung areas that have been previously unopened or collapsed. Thus, alveolar recruitment can be detected by EIT and expressed as a simple index [123, 125]: the smaller the index, the smaller the delay. VSA and RVD calculations in this study slightly differ from these of Blankman [126] as results are presented in pixel values, rather than percentage.

Global inhomogeneity index (**GI**), a measure describing the homogeneity of lung ventilation, is also gaining more attention in EIT literature [128, 129]. However, this index was not used for this study due to its difficulties in detecting hyperinflation and collapse of lung tissue.

These emerging methods for the analysis of EIT data are new and little has been reported on their significance and their correlation with lung disease and function. Together with previous methods of analysis such as EELI, EELI distribution and TVar there is the potential to obtain greater insights into how the previously observed increase in EELI during and post SV use [120] may impact lung recruitment and ventilation distribution.

The aim of this paper is to determine the ventilation re-distribution, if any, created by the increased EELI reported previously [120]. The secondary aim was to determine the efficacy of the novel EIT data analysis tool (EITdiag^{TM}, Dräger Medical, Lűbeck, Germany) to further delineate the changes in alveolar recruitment. Due to the EITdiag^{TM} software averaging raw data, this can result in loss of data fidelity and sensitivity prior to analysis. This may lead to difficulties in achieving statistical significance.

4.1.3 Material and methods

As none of the above-mentioned methods alone can give an absolute picture on the causes of increased EELI with SV use, a combination of these was decided to be the best method. Variables designed for detection of hyperinflation and collapse of alveoli were chosen from published literature and combined with previously reported EELI analysis on the same data. VSA and RVD were analysed together with EELI distribution and TV to better understand the mechanism of the reported increase in EELI.

Data obtained from a previous study [120] underwent secondary analysis using EIT Data Analysis tool 6.1 (PulmoVista 500, Dräger Medical, Lűbeck, Germany) to assess EELI distribution and TVar into 4 ROIs. EITdiag™ was used to assess VSA and RVD globally and in 4 ROIs. Ethics approval was obtained from the local ethics committee (HREC/13/QPCH/95). Informed consent was granted by the patient or their legal representative.

4.1.3.1 Participants and Procedures

Data sets were obtained from twenty consecutive patients admitted to a cardiothoracic ICU in whom a SV (PMV007, Passy-Muir Inc, Irvine, California, US) was used in-line with mechanical ventilation and met the study inclusion criteria [120]. Two subgroups existed within the data set: (1) 10 patients receiving PSV using a PB840 (Puritan

Bennett/Covidien, Carlsbad, California) ventilator, and (2) 10 patients receiving high or low flow oxygen (Optiflow, Fisher&Paykel Healthcare, Auckland, New Zealand) via the tracheostomy while undergoing spontaneous breathing trials (**SBT**) at the time of recruitment. As per the data collection processes outlined in the previous study, there were four 15 minute time periods for data collection: baseline ventilation (*Baseline*, no SV); silent breathing with SV in the ventilation circuit (PM*SV*); talking with SV in the ventilation circuit (PM*SV-T*), and return to baseline ventilation (*Post-PMSV*, no SV) making it a total of one hour of continuous measurements. As per study protocol [120] the set PEEP from the ventilator was lowered by 5cmH2O for the duration of SV use (time periods SV and SV-T) to accommodate for restored physiological PEEP. No changes were made to settings for patients on SBT.

4.1.3.2 Data analysis

The EIT data analysis tool 6.1 was used to assess distribution of EELI and TVar in 4 ROIs. This tool enabled use of breath-by-breath raw data to calculate the results and significance. EITdiag^{TM} was utilised to generate values for VSA and RVD (maximum regional impedance change set at 40%). A threshold of impedance change >15% per pixel was set for both to suppress minor impedance changes caused by noise or cardiac oscillations in non-ventilated regions. No Medibus data were available due to the PB840 ventilator not being able to be connected to EIT equipment, therefore compliance data could not be calculated. EITdiag^{TM} produces average values for each time period for the user with no access to breath-by-breath raw data, substantially reducing the number of data points available for statistical analysis. All of the above mentioned variables were analysed firstly as a global measure of the lungs and then separately in 4 ROIs - dorsal, ventral, right and left. An example of VSA and RVD across the 4 time-points is given below in *Figure 4-1*.

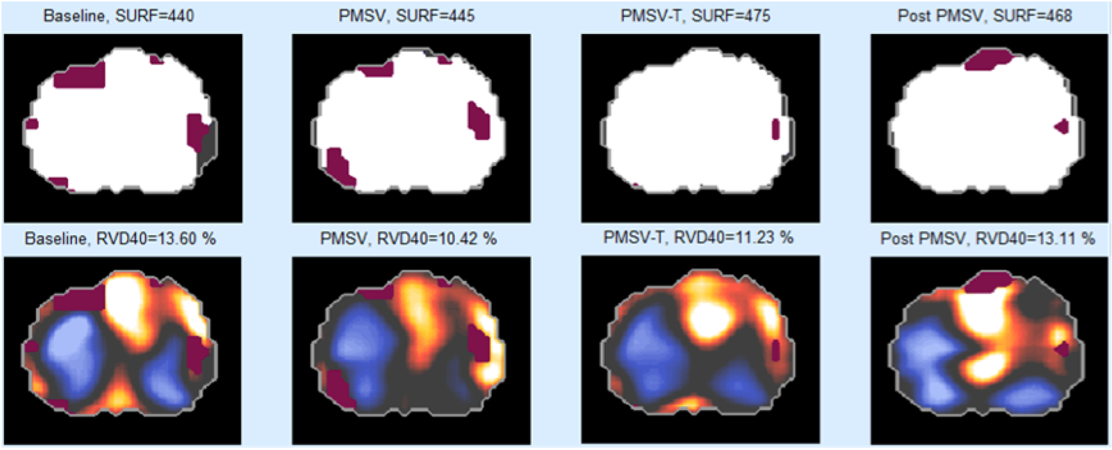


Figure 4-1: Example VSA and RVD as displayed on EITdiag™

RVD (RVD40 on graph) – regional ventilation delay; VSA (SURF on graph) – ventilated surface area
The VSA image describes the size and the location of ventilated regions of the corresponding section. A pixel whose regional impedance change exceeds a certain threshold (>15% in our study) is interpreted as ventilated and displayed in white colour. A light grey line is used to illustrate the contour of ventilated area surrounding all pixels that have been ventilated at least temporarily in any of the defined sections.
RVD image expresses the delay between the global start of inspiration and the point in time, where the regional impedance curve reaches a certain impedance change.
A value greater than 0 is interpreted as a delay of the inspiration (red colour) and a value less than 0 is interpreted as early inspiration (blue colour) [125].

STATA™ (version 12.0) was used to calculate and present the mean/median values, standard error of the mean/interquartile range, and p values for each of the variables for 4 different time points. An a priori power analysis was conducted for the original study [120] with breath-by-breath data available in the original EIT data analysis tool. The same participant numbers may therefore not be powered for the new EITdiag™ tool making this part of the study a feasibility study.

For all data that was not normally distributed at baseline (VSA, RVD), summary statistics are reported as median (IQR). Mann Whitney U-test was used for the analysis and baseline comparisons between ventilated and non-ventilated patient groups. Shapiro-Wilk test was used to test normality with a $p<0.05$ considered as statistically significant. Kernel density plots are displayed for VSA and RVD to demonstrate the overall shape of the data distribution, as well as range, measure of central tendency (mean, median or mode(s)), the degree of spread (variance), skew (left or right tailed) and kurtosis (pointedness). P-values are included for each curve and indicate the probability that the data distribution is normally distributed. Thus a P-value < 0.05 indicates a data distribution that is non-normal.

4.1.4 Results

Twenty patients with an average age 60 +/- 15 years (50% male) were recruited to the study. Ten patients were receiving continuous PSV and the remaining 10 were undergoing

SBTs, 9 of whom had required support from the ventilator in the preceding 24 hours (see *Table 4-1*).

Table 4-1 – Demographics and ventilation data upon recruitment

Pt No	Age[a]	Gender[a]	Primary reason for ICU admission	vent duration (# days)	Resp support mode[a]	PEEP[a,b]	PS[a,b]	Flow[a]	FiO_2[a]
1	63	M	Cardiac Sx	19	HFTP	-	-	40L	40%
2	48	F	Cardiac Sx	15	HFTP	-	-	40L	40%
3	72	F	ENT Sx -> Cardiac Sx	5[c]	LFTP	-	-	5L	30%
4	71	M	Cardiac Sx	5	HFTP	-	-	50L	40%
6	77	M	Cardiac Sx	9	HFTP	-	-	50L	40%
7	44	F	Cardiac Sx	13	HFTP	-	-	40L	40%
9	61	M	Respiratory	13	HFTP	-	-	50L	50%
11	70	F	Cardiac Sx	13	HFTP	-	-	40L	40%
14	70	F	Respiratory	30	HFTP	-	-	30L	30%
15	58	M	Respiratory	5	HFTP	-	-	40L	40%
5	29	M	Cardiac Sx	15	PSV	5	10	-	40%
8	33	F	Cardiac Sx	12	PSV	10	15	-	35%
10	70	M	Cardiac Sx	13	PSV	10	13	-	40%
12	43	F	Cardiac Sx	6	PSV	7.5	10	-	40%
13	47	F	Respiratory	8	PSV	5	15	-	35%
16	62	F	Respiratory	9	PSV	8	10	-	40%
17	74	F	General Sx	28	PSV	5	10	-	35%
18	78	M	Cardiac Sx	10	PSV	5	12	-	40%
19	60	M	Thoracic Sx	13	PSV	8	12	-	45%
20	77	M	Cardiac Sx	10	PSV	7.5	12	-	40%

[a] *data from Sutt et al [120]*

[b] *measured in cmH_2O*

[c] *had not needed mechanical ventilation in the preceding 24hrs to being recruited in the study*

 # - 'number of…'; ENT – ear-nose and throat; FiO_2 – fraction of inspired oxygen; flow – flow of gas; HFTP – high flow tracheostomy piece; LFTP – low flow tracheostomy piece; PEEP – positive end-expiratory pressure; PS – pressure support; PSV – pressure support ventilation; vent duration – ETT+TT period in days; Sx – surgery

At baseline the two groups of patients did not statistically differ on any variables (see *Table 4-2* below). Descriptively, however, the ventilated group tended to have values indicative of increased lung recruitment across all three variables (TVar, VSA, RVD). Due to a similar trend in EELI between groups across time-points in the original study [120] and non-significant differences between the two groups on the global analyses at baseline for the new variables, all subsequent data analysis was conducted as single group (n=20).

Table 4-2 – Global measures of TVar, VSA and RVD (no units)

	Ventilated	Non-ventilated	p-value
TVar at baseline[a]	2018.5 1158.2-3160.8	1870.8 1354.2-2552.3	0.36
VSA at baseline[b]	432.5 262.0-440.0	356.0 251.0-414.0	0.33
RVD at baseline[b]	6.69 5.45-9.29	9.45 7.14-10.50	0.13

[a] *analyses performed on dataset with 7981 observations (3995 ventilated, 3986 non-ventilated)*

[b] *analyses performed on dataset with 20 observations (10 ventilated, 10 non-ventilated)*

Mean EELI was observed on average to significantly increase in most lung sections across the time periods. The exceptions were a significant drop in EELI in the dorsal lungs during the first 15 minutes with SV (PMSV) and a non-significant drop on the left side during the same time period (see *Table 4-3*). EELI increased significantly throughout the next 15 minutes in both of these areas with patients talking (PMSV-T), with a further significant increase in all areas once the SV was removed.

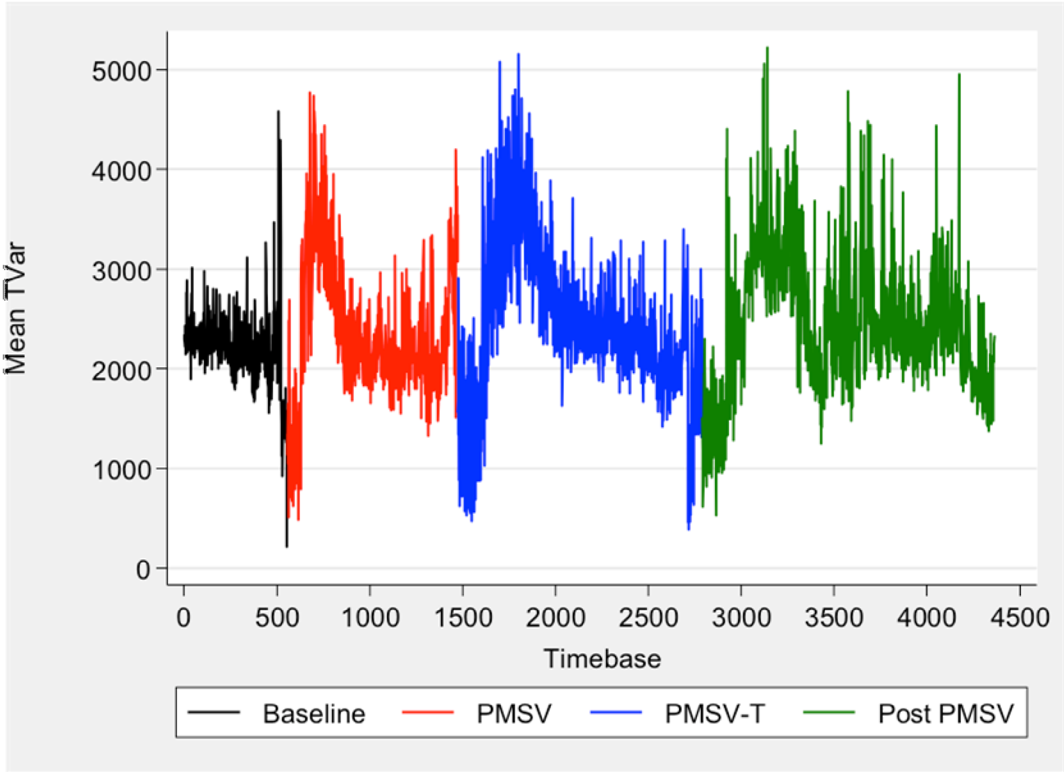
Table 4-3 – EELI and TVar (no units)

	Baseline	PMSV	PMSV-T	Post PMSV
EELI				
left				
mean (SE)	586 (13)	565 (15), p=0.28 (#)	766 (14), p<0.001	1093 (20), p<0.001
right				
mean (SE)	585 (15)	702 (20), p<0.001	1226 (21), p<0.001	1526 (24), p<0.001
ventral				
mean (SE)	532 (18)	705 (23), p<0.001	1054 (23), p<0.001	1427(31), p<0.001
dorsal				
mean (SE)	639 (12)	561 (15), p=0.01 (#)	938 (17), p<0.001	1192 (12), p<0.001

	Baseline	PMSV	PMSV-T	Post PMSV
TVar global				
median	1947	1885	2180	2217
IQR	(1315, 2799)	(1237, 2909)	(1458, 3208)	(1502, 3184)
		p=0.94	p<0.001	p<0.001
left				
median (%)	39	36	38	38
IQR (%)	30-46	24-46	23-45	29-46
		p<0.001	p<0.001	p=0.03
right				
median (%)	61	64	62	62
IQR (%)	54-70	54-76	55-77	55-71
		p<0.001	p<0.001	p=0.02
ventral				
median (%)	42	39	41	42
IQR (%)	32-50	27-49	28-50	33-49
		p<0.001	p<0.001	p=0.005
dorsal				
median (%)	58	61	60	58
IQR (%)	50-68	51-72	51-72	51-67
		p<0.001	p<0.001	p=0.002

 # denotes a decrease from baseline

A significant increase was detected in Global TVar during the second half of SV use (PMSV-T), followed by a further increase once the SV was removed (see *Table 4-3*). Additional observations were that an increase in TVar occurred at the beginning of each time period (see *Graph 4-1*), returning to baseline midway during each time-point.



Graph 4-1 – Tvar across time-points

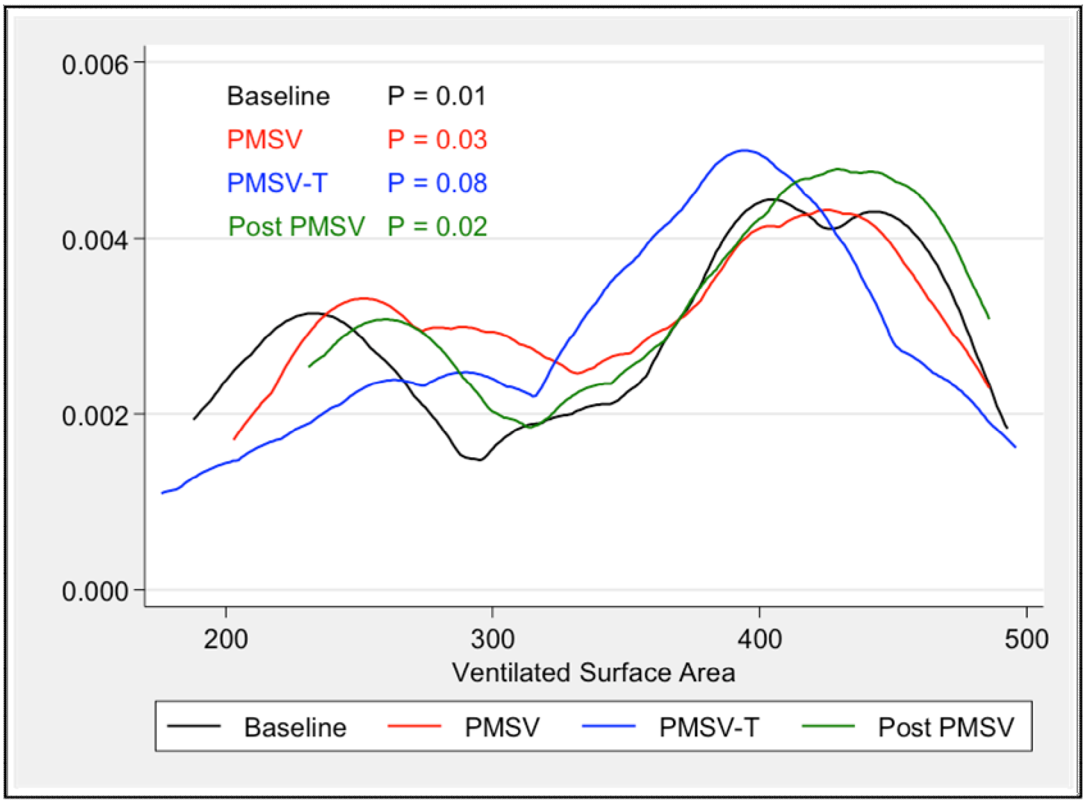
There were no statistically significant changes detected in global or regional VSA (see *Table 4-4*). Descriptively, there was an increase in VSA noted with introduction of a SV, which continued to increase post SV use. When looking at ROIs separately an increase in VSA was more visible in the right and dorsal sections of the lung.

Table 4-4 – Distribution of VSA and RVD (no units)

	Baseline	PMSV	PMSV-T	Post PMSV
VSA global				
median	363	376	383	384
IQR	257-433	275-442	288-438	277-451
		p=0.76	p=0.74	p=0.46
left				
median	180	173	178	188
IQR	112-203	120-215	127-219	140-210
		p=0.97	p=0.94	p=0.63
right				
median	204	203	207	211
IQR	165-226	167-227	171-225	177-229
		p=0.99	p=0.98	p=0.52

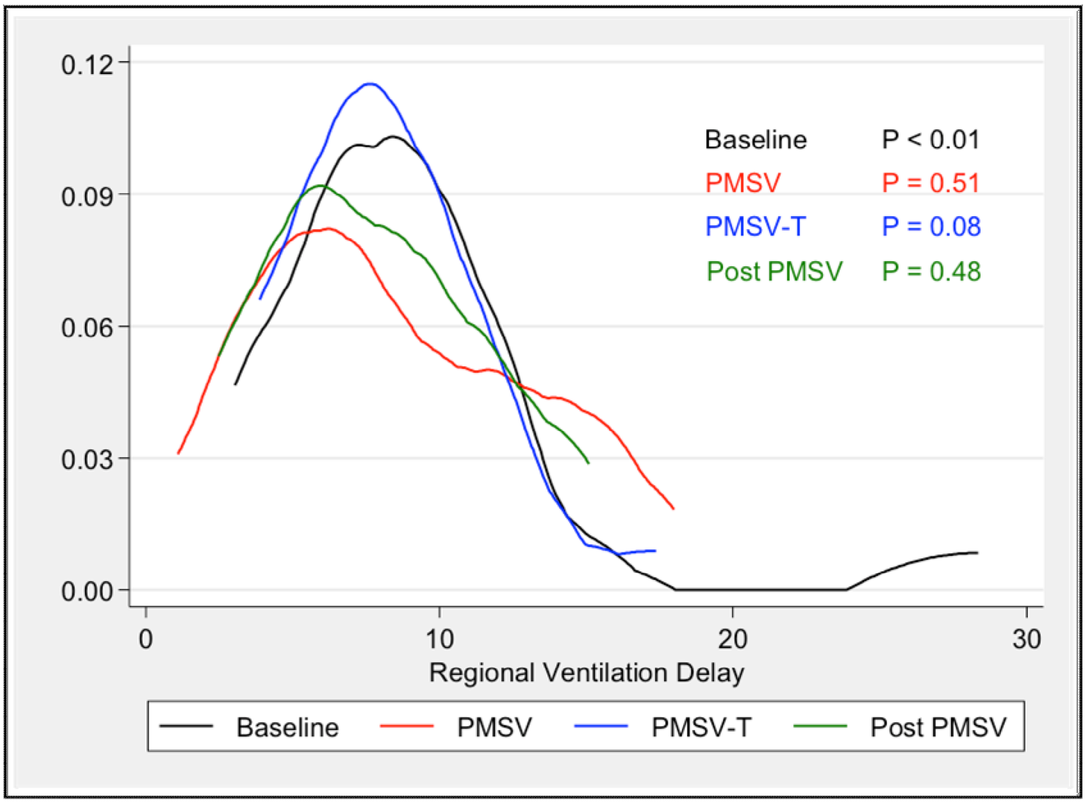
	Baseline	PMSV	PMSV-T	Post PMSV
ventral				
median	176	161	175	191
IQR	109-207	108-214	118-206	125-214
		p=0.91	p=0.91	p=0.55
dorsal				
median	203	216	209	221
IQR	134-228	175-234	161-232	167-231
		p=0.36	p=0.44	p=0.53
RVD global				
median	8.7	7.4	7.7	7.6
IQR	6-9.9	4.8-12.5	6-10.3	4.6-11
		p=0.81	p=0.80	p=0.50
left				
median	8	6.5	7	7.8
IQR	5.4-10.6	4.2-10.8	5.9-9.1	5.2-10.2
		p=0.57	p=0.78	p=0.74
right				
median	8.7	8.5	8.8	7.7
IQR	5.8-10.1	4.1-11.8	5.5-11.7	3.9-9.7
		p=0.96	p=0.96	p=0.40
ventral				
median	7.1	7.4	7.3	7.4
IQR	5.9-12	5.1-13.1	5.5-10.3	4.4-12.7
		p=0.83	p=0.57	p=0.63
dorsal				
median	7.8	7.5	7.7	6.5
IQR	5-10	4.5-11.3	5.6-10.5	4.4-10.8
		p=0.96	p=0.72	p=0.56

The Kernel density plot displays the VSA data across the 4 time-points (see *Graph 4-2)*, highlighting the flattening of data clustering around the 230 mark and indicating a general shift in the data to the right (towards higher VSA) during and post SV use. With the exception of the PMSV-T data, all curves are not normally distributed and generally bimodal with peaks around 230 and 400.



Graph 4-2 - Kernel Density plot for VSA

No significant differences in RVD, either globally or for each ROI were found (see *Table 4-4)*. Descriptively, global RVD was found to be lower during and post SV use with a general pattern of decreased RVD in the left, right and dorsal lung sections. The Kernel density plot further describes the RVD data across the 4 time-points and indicates reduced data spread and lower RVD values during and post SV use (see *Graph 4-3*). With the exception of the right-skewed Baseline data, all other plots were normally distributed with means around 8. Exclusion of outliers above 20 resulted in normally distributed Baseline data.



Graph 4-3 - Kernel Density plot for RVD

4.1.5 Discussion

Describing research in the area of EIT is a difficult task due to lack of consistent terminology and variability in methods used by different authors. Recent publication by the TREND group [130] is an excellent attempt to streamline EIT image analysis and interpretation. In this current manuscript all efforts were made to ensure clarity of methods and consistency with terminology comparable to previously published studies.

This study analysed ventilation distribution in tracheostomised patients weaning from mechanical ventilation patients using a number of EIT parameters in order to better understand the effect of previously reported increases in EELI attributable to SV use. If the increased EELI caused hyperinflation in some areas, this would be associated with increased risk of lung disease. However, we have demonstrated on this current small data set that the increase in EELI [120] was uniformly distributed throughout the lung, with significant increase in all ROIs. Accompanied with improvements in bedside respiratory markers, such as significantly decreased RR and reduced $EtCO_2$ from our previous study of the same cohort [120], the increased EELI is therefore less likely to indicate over-distension of the lungs.

EITdiag™ appears to be a useful clinical tool as it quickly displays trends in ventilation distribution and alveolar recruitment between time points. One limitation of the current technique is that it provides only data averages rather than raw data. Hence it may be less effective in determining significance for research purposes, as it results in a restricted raw data set per variable. In our study therefore, analyses for VSA and RVD were performed on 20 observations per variable, whereas analyses for EELI distribution and TVar there were 7981 observations at baseline alone – a 300-fold increase in data points. This made reaching statistical significance for VSA and RVD difficult to achieve with current participant numbers. Despite their lack of significance statistically, these valuable data provide further tools to clarify ventilation distribution with SV use. Despite the VSA and RVD data showing non-significant changes between time periods, these values were noted to accurately display differences between the ventilated and non-ventilated group of patients (see *Table 4-2*), making the analysis tool more reliable.

Over-distension of the lung as a consequence of increased EELI would be supported by reduced VSA with increased RVD, potentially alongside increased TVar and significantly altered EELI distribution (increase in EELI in some areas, and decrease in others). These patterns were not consistently detected in our data despite the statistically non-significant findings. Conversely, some indicators for potential recruitment were detected such as a relatively evenly spread EELI increase, together with a trend towards increased VSA coinciding with a decrease in RVD, both globally and in separate ROIs. Surprisingly, this was the case regardless of the patients' respiratory requirements.

Upon analysing the 4 time points in more detail, an increase in EELI was noted to be well aligned with other variations in right to left sections of the lung (TVar and VSA also increased and RVD reduced indicating potential recruitment), but opposite in dorsal to ventral direction (an initial decrease in EELI coincided with an increase in TVar and VSA and a decrease in RVD, all suggesting potential recruitment despite reduced EELI). It has to be noted that these are trends only, and due to no significant correlations, it is not possible to make further assumptions of these data relating to anything clinically significant. Larger studies are needed to look at the potential effect of SVs on ventilation distribution, and its potential for lung recruitment.

In addition to heterogeneous breathing patterns observed in spontaneously breathing patients, it is likely that ventilation changes are impacted upon by the patients' ability to close their glottis against high pressures (generating variable upper airway resistance for closure during inspiration from the ventilator) and the ventilator's ability to trigger PEEP and compensate for the leak with a one-way valve in-situ. Patient and ventilator synchrony (in other words respiration-phonation coordination during SV use) is something that speech pathologists can work on with spontaneously breathing patients using a SV. The PB840 ventilator used in this study performs well with most patients when the SV is used in NIV mode. This is not the case with many other ventilators that do not cope with such a leak in the ventilatory circuit [131-133]. The specific make of ventilator could therefore have a significant effect on being able to successfully use a SV in-line with mechanical ventilation circuit.

Another important variable is the space between the deflated cuff and patient's trachea causing resistance to exhalation when SV is used. Sufficient space is needed around the deflated cuff to avoid air trapping and potential hyperinflation of the lungs. In the ventilated population, we look for a significant drop in expired TVs (usually 40-60%) once the cuff has been deflated to determine the patient's suitability for SV use. In spontaneously breathing patients this is less precise with a reliance on patient comfort and respiratory parameters during digital occlusion of the TT for expiration during cuff deflation.

Patients have identified communication difficulties as one of the main sources of frustration for them whilst ventilated in ICU. This has reportedly led to social withdrawal, reduced motivation to participate in care, depression, poor sleep with increased anxiety and stress levels [7-11]. The results of the current study have led to wide use of SVs in the ICU where the study took place. Using SVs is now routine practice [108] and has become increasingly common with very sick tracheostomised patients [134]. Patients have reported feeling their autonomy returning when able to speak again, and feeling as part of the human race again. Having these patients talking makes it easier to look after them for the whole ICU team. Although these data may not be able to be extrapolated to other clinical populations, these should be encouraging towards wider use of SVs with the cardio-thoracic cohort.

4.1.5.1 Limitations of the study

The biggest limitation in such detailed analysis of ventilation distribution was low patient numbers and the inability to access raw data with the new data analysis tool. In such an inhomogeneous group of spontaneously breathing patients, several outliers added to the difficulty of seeing any significant changes.

EITdiag^{TM} adds valuable options to further analyse ventilation distribution, however the current set-up of the tool makes analysing data from spontaneously breathing patients rather difficult, with suitability for use in research being questionable. The tool averages data for the user, therefore limiting the amount of data available for analysis, thereby making it less meaningful. To achieve significance in findings, one would need to investigate a lot more patients, or have access to all of the raw data.

RVD has been shown to give accurate data during 12-mL/kg slow insufflation manoeuver by Wrigge [123], later confirmed by Muders [125]. In our case, the data were from spontaneously breathing patients, therefore we cannot know with certainty that the RVD index relates to cyclic opening and closing of the alveoli. However, the algorithm, which is used in the EITdiag^{TM} software does not consider that a slow inflation manoeuver is required for calculating the RVD and regardless calculates RVD for each section. Hence the algorithm is not exactly correlated to protocol by Wrigge [123], as stated in the EITdiag^{TM} user manual .

Additional and more precise data may be gained in future studies by obtaining simultaneous airway pressure data directly alongside with EIT data collection. Due to the use of ventilators other than Dräger in the ICU where the study took place, it was not possible to obtain such data alongside our EIT data. Due to the same reason, Medibus data for additional EIT data analyses (such as compliance data) could not be captured.

EIT data is highly dependent on the belt position, and only captures data from the segment of lung where the EIT belt is situated [51, 52]. Therefore these images do not necessarily detect ventilation changes in the whole lung.

Clinically, similar patients are using SVs for much longer duration at a time. Due to difficulties of maintaining patient position and keeping the EIT belt in-situ for more than one hour, it is unclear whether similar patterns of ventilation distribution occur with longer duration of SV use.

4.1.6 Conclusions

Analysing lung recruitment using EIT is still novel, and is certainly more difficult in spontaneously breathing patients with limited options for airway pressure measurements alongside EIT. Given the previously published data on increased EELI it was necessary to clarify regionality of ventilation distribution in these patients. This change in EELI caused non-significant changes in EIT parameters used to detect recruitment or over-distension with the data trend favoring recruitment. Therefore the concern that cuff deflation together with SV use in patients undergoing weaning from mechanical ventilation may cause lung derecruitment seems unfounded. This, along with obvious psychological benefits to patients and previously published gas exchange data [120], serve to support the wide use of SVs in cardio-thoracic patients weaning from mechanical ventilation.

For similar in-depth analysis of ventilation distribution in the future a bigger sample size is needed. The manufacturers should allow analysis of raw data as well as the averaged data, as this too will allow a more definite answer to similar questions that clinicians may have in the future.

4.2 Diaphragm activity

The importance of respiratory muscles, including the diaphragm, in respiration has been discussed previously in Chapter 2. The preceding manuscript (4.1) gave an overview of ventilation distribution with SV use. Another aspect of respiration that is interlinked with changes in EELI and its distribution is respiratory muscle activity.

4.2.1 Background

It is known that ventilator-induced diaphragm weakness develops rapidly, with signs of deterioration demonstrable within 18 hours of mechanical ventilation initiation [59]. Generally, days or weeks of mechanical ventilation via an ETT precede a tracheostomy. Therefore tracheostomised mechanically ventilated patients are likely to have developed diaphragmatic weakness. The partial restoration of negative pressure ventilation with SV use, and patients taking larger breaths during talking, may lead to changes in patients' intra-thoracic and abdominal pressures. Hence, SV use may result in different levels of diaphragmatic involvement in breathing, with diaphragm involvement likely to be highly dependent on the level of pre-existing diaphragm weakness. RIP belts can measure abdominal and chest volume changes during breathing. Increased abdominal volume change compared to chest volume may predict increased diaphragmatic involvement. There has been limited research on A:C ratio when breathing at rest and comparing this to period of verbal communication [60]. There have also been differences reported due to age [135] and disease process [136]. This study's primary hypothesis was that there would be a shift towards increased abdominal activity when SVs were used compared to closed circuit ventilation with an inflated cuff. RIP was chosen as the most pragmatic tool to measure A:C ratio and predict diaphragm activity in a cardio-thoracic ICU population weaning from ventilation whilst using a SV.

4.2.2 Methods

The same 20 participants described in chapter 3 and section 4.1 of this chapter were included in the study. A respiratory inductance plethysmograph system with self-calibration functionality, 'Respitrace QDC' (CareFusion Corporation, San Diego, USA), was used to measure abdominal and chest mobility (volume change) simultaneously with EIT measurements reported in Chapters 3 and 4. Two RIP belts were used; one around the patient's chest at the level of C5-6 directly over the EIT belt, and the second RIP belt around the patient's abdomen at the umbilical level (as shown on *Figure 2-5* in *Chapter 2*). Data recording was continuous over 60 minutes, with periods of interest including *Baseline* (first 15 minutes + last 15 minutes), *PMSV* with SV in-situ, quiet breathing and no talking (second 15 minutes), and *PMSV-T,* SV in-situ with active talking (third 15 minutes).

4.2.2.1 Data analysis

The continuous RIP data was recorded at 1kHz (PowerLab 8/30, ADInstruments and LabChart 7.0, ADInstruments) from the chest and abdominal belts separately. Data were analysed (LabCHart 7.0, ADInstruments) to calculate A:C ratio for each of the three time-periods (baseline, PMSV, PMSV-T). The program combined the first and the last 15 minutes of observations together automatically, generating data for baseline period. A:C ratio data were normally distributed. Paired t-tests were used to compare A:C ratio for combined baseline and SV periods, after first determining there was no significant difference (p=0.21) in A:C ratio between the PMSV and PMSV-T periods (GraphPad 6 and SPSS). Comparison of A:C ratio in both conditions (baseline and SV) was also completed for the two patient groups (PSV vs HFTP).

4.2.3 Results

Twenty patients with an average age 60 +/- 15 years participated in the study. Ten patients were receiving PSV and 10 were on HFTP during recruitment into the study. Measurements were unable to be analysed for one patient out of 20 due to equipment failure during data collection.

Initial group comparison (n=19) revealed a significant increase in A:C ratio from 1.3 to 1.5 (p=0.047), indicating increased abdominal mobility suggestive of increased diaphragm activity when the SV was put in-line (Baseline compared PMSV). While no significant difference was found between PMSV and PMSV-T periods, it was noted descriptively the

A:C ratio was smaller for 12 of the participant once they started talking (p=0.98). Descriptively 80% of ventilated patients showed an increase in A:C ratio (p=0.039) during the PMSV period as opposed to 67% of patients that were receiving high flow oxygen (p=0.552) through their TT during recruitment to the study (see *Table 4-5* below). For six patients, the A:C ratio dropped below baseline once the patients started talking. These data indicate that for these patients there was more movement of the chest once they started talking. One patient showed an opposite response – increased abdominal mobility once they started talking. No gender differences in the results could be identified. All patients that had been mechanically ventilated for <9 days showed increased A:C ratio with SV use (n=5). At the same time, one patient that had been ventilated for 28 days also showed increased A:C ratio with SV use. Individual A:C ratios across the three time-periods are presented in *Table 4-5* below.

Table 4-5 – Gender, ventilation status, ventilation duration and A:C ratio

Participant number	Gender	Vent status	Vent duration (# of days)	A:C ratio Baseline [a]	A:C ratio PMSV [a]	A:C ratio PMSV-T [a]
1	M	HF	19	2.07	2.84	1.24
2	F	HF	15	1.82	1.46	1.63
3	F	HF	5	0.57	0.84	0.36
4	M	HF	5	1.04	1.07	1.59
6	M	HF	13	N/A	N/A	N/A
7	F	HF	13	3.12	3.24	1.36
9	M	HF	30	1.18	1.24	1.77
11	F	HF	15	1.28	1.70	0.70
14	F	HF	6	0.76	0.93	0.87
15	M	HF	8	1.96	1.27	2.14
5	M	PSV	9	1.02	1.01	0.99
8	F	PSV	13	3.76	4.99	4.46
10	M	PSV	5	0.64	1.24	1.37
12	F	PSV	12	0.59	0.39	0.44
13	F	PSV	13	0.54	0.92	1.12
16	F	PSV	9	1.64	1.84	1.92
17	F	PSV	28	0.92	1.44	1.08
18	M	PSV	10	0.65	0.93	0.89
19	M	PSV	13	0.98	1.09	0.57
20	M	PSV	10	0.39	0.40	0.38

[a] *higher value in A:C ratio means more abdominal activity relative to chest*

4.2.4 Discussion and conclusions

Upon the initial introduction of the SV, an increase in A:C ratio was observed across the cohort. However, the tendency for the A:C ratio to be smaller once the patients started talking, was surprising. As preparation for an utterance usually includes taking a larger breathe, it was hypothesised that the patients would use their diaphragm more during the talking phase, and therefore show increased abdominal mobility during SV use. This increase was not observed, which may be attributable to the variable degree of diaphragmatic atrophy between patients. It may also indicate that patients were trying to compensate for lack of diaphragm involvement by utilising the muscles around their thoracic cage when needing to take a larger breath.

It was hypothesised that duration of mechanical ventilation prior to recruitment to the study may impact the probability of increased A:C ratio with SV use. This relationship was not observed in this the small cohort of patients.

The inconsistent data from this study highlight the known limitations when choosing a measurement device for such detailed analysis of A:C ratio on a small critically ill patient cohort with variable durations of mechanical ventilation prior to the study. These patients were likely to have variable levels of diaphragmatic dysfunction prior to being enrolled in the study, relating to a range of potential variables that include pre-existing pathologies, cause for mechanical ventilation, levels of participation in physiotherapy, nutritional status etc. Data on diaphragmatic recovery has not been adequately described in literature to determine whether a short intervention, such as 30 minutes of SV use, could impact diaphragm mobility or recovery. This could also depend on the fibre types and the level of remaining muscle thickness of the diaphragm.

The increased abdominal mobility observed in this study is suggestive of increased diaphragm activity. To confirm this, further data are required using additional techniques more suited to direct diaphragmatic measurements, such as using NAVA probes [63-65], diaphragm ultrasound [68-70] or transdiaphragmatic pressure [67] as described in Chapter 2. Lack of data into such an important muscle of respiration necessitates further research into the impact of mechanical ventilation on the diaphragm, and the most efficient ways to rehabilitate it.

Chapter 5

Chapter 5 Tracheostomised patients with obstructive airways disease – can speaking valves be used?

5.0 Rationale and significance

Chapters 3 and 4 gave an overview of EELI and ventilation distribution of tracheostomised ICU patients using a SV whilst undergoing weaning from mechanical ventilation. All of these patients presented with acute lung injury (without chronic respiratory condition), which was improving at the point of inclusion into this study. There was substantial uniformity in the response of all patients' respiratory systems to SV use – showing significantly increased EELI and signs of recruitment in several ROIs in the lung. However, not all patients and all diseases are equal. Patients with obstructive lung disease could potentially have a significantly different respiratory response to SV use since their EELVs are already high at baseline. This chapter presents a case report describing the effects of SV use in an undiagnosed COPD patient. The specific SV used in this study is a Passy Muir SV (PMV007, Passy Muir Inc., California, USA).

This study contributes to the main aim of the thesis. It was designed to monitor the patient's lung mechanics before, during and after SV use and analyse the following key variables: (1) SpO_2; (2) EELI and its distribution; (3) TVar and its distribution; (4) VSA; (5) RVD; (6) centre of ventilation (**CoV**), and (7) region of no ventilation (**rNoVent**).

This is the first attempt to describe lung mechanics of a patient with chronic obstructive lung disease when using a SV. Whilst a single case report, it highlights the importance of understanding the patients' pre-existing lung condition and the physiology that determine this. The pathophysiological pulmonary process may be exacerbated by the physiological effects of SV, and the two combined may lead to harm.

The results of this study were presented in abbreviated form as a poster presentation at ANZICS conference, and have been published in an abstract format as listed in *Published abstracts on page vi*. Formatting of the manuscript is according to the style of Journal of Critical Care. Sections, tables and figures have been numbered to align with the rest of the thesis document.

Tracheostomised patients with obstructive airways disease – can speaking valves be used?

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Submitted to *Critical Care and Resuscitation* in April 2017

5.1 Introduction

The use of SVs in tracheostomised ventilated patients is increasing substantially due to recent positive data regarding their efficacy and safety [90, 107, 108]. However, research data to guide optimal patient selection for SV use is lacking. One of the key mechanisms by which a SV appears to improve respiratory function is through its action as a "PEEP valve". This action results in an increase in EELVs that continues post SV removal [120]. Extra PEEP, however, could adversely affect patients with COPD – a hallmark of which is persistent hyperinflation of lungs at baseline.

5.2 Rationale

Whilst recruiting patients to a previously reported study by our group [120, 137], one patient in whom no past medical history of respiratory disease had been reported suffered a significant drop in oxygenation when a SV was attached to his TT in-line with high-flow oxygen therapy. This could not be rectified even when correcting the airflow (L/min) and FiO_2. This occurred in the context of no obvious change in comfort or WOB for the patient. The aim of this case report is to explore the cause for this desaturation and thereby inform best clinical practice for SV use in patients with obstructive lung disease.

5.3 Case report

5.3.1 Patient background

A 51 year-old gentleman was admitted to ICU following a 16-minute downtime till return of spontaneous circulation following an out of hospital cardiac arrest. The medical history available on admission included paranoid schizophrenia and substance abuse. Bystander cardiopulmonary resuscitation (**CPR**) resulted in left-sided anterolateral fractures of the 2^{nd}, 3^{rd} and 4^{th} rib, as reported by a radiologist based on a series of chest X-rays. No obvious signs of hypoxic brain injury were reported. The patient required stenting of his right coronary artery.

Nothing in the medical history and blood gas analysis excluded the patient from assessment and use of SV. SP had been unsuccessfully trialing a SV for short periods with the patient for several days, initially in-line with mechanical ventilation. The patient was desaturating with SV in-situ, despite showing no change in his WOB. CO_2 retention was not observed during weaning from mechanical ventilation. Admission and first 24-hour blood gases can be seen in *Table 5-1.*

Table 5-1 - Blood gases on admission

	Day 0 11am	Day 0 2pm	Day 0 8pm	Day 1 3am
$PaCO_2$ (mmHg)	52	38	34	36
PaO_2 (mmHg)	149	81	84	62
Bicarbonate (mmol/L)	26	26	24	27
Base excess (mmol/L)	-0.4	2.0	1.0	3.6
pH (mol/L)	7.32	7.44	7.47	7.48

At time of determining the patient's suitability for recruitment to the study (day 16 in ICU, day 11 with tracheostomy) the patient was being liberated from mechanical ventilation, spending most awake hours on HFTP.

5.4 Methods

Due to the limited bedside data available to detect the cause for desaturation during SV use, EIT was used to assess regional ventilation and indicate potential aetiologies for the abnormal gas transfer issues. EIT has been used in numerous studies to investigate the volume and distribution of gas in the lungs, including in the COPD population [138, 139]. It is a non-invasive, radiation free bedside imaging tool that allows for monitoring of patients' breathing in real time by using an electrode belt around their chest [130]. Previously EELI and EELI distribution were the primary measures used with EIT. EELI has been shown to be highly correlated with EELVs [48, 50]. In recent times, a broader range of data has been able to be extracted and analysed using EIT. Variables such as RVD, VSA, CoV, and rNoVent are enabling an improved understanding of lung recruitment [56, 122, 125]. Ethics approval (HREC/13/QPCH/95) from local ethics committee was gained, an altered methodology similar to the research protocol described in Chapters 3 and 4 was utilised. Following patient consent, the patient's breathing was monitored with EIT before, during and after short term SV use, to clarify regional ventilation and investigate potential aetiologies that could explain the desaturation.

EIT (Drager, Lubeck, Germany) was used for continuous measurements over 33 minutes. Data were captured at 20Hz with the patient sitting up in a regency chair. EIT data were captured for 5 minutes at baseline with the patient receiving 40L/min of 40% oxygen through his tracheostomy. The tracheostomy cuff was then deflated and a SV (PMV007, Passy-Muir, Irvine, California, United States) was inserted in-line with the HFTP tubing. The SV was removed and cuff re-inflated 21 minutes later. EIT measurements continued for another 7 minutes. A total of 33 minutes continuous measurements were taken. SpO_2 was monitored throughout data collection. EIT data analysis 6.1 (Drager, Lubeck, Germany) was used to calculate EELI and TVar, both global and regional across all 3 time-periods. EITdiag™ (Drager, Lubeck, Germany) was used to calculate RVD, VSA, CoV and rNoVent across the same time-periods.

5.5 Results

A significant increase in global EELI (by 33%, $p<0.001$) was observed during SV use, coinciding with a significant drop in SpO_2 (96% -> 86%) over 21 minutes. The increase in EELI was evenly distributed (see *Figures 5-1a* and *5-1b*) with a significant increase in all lung sections during SV use. A drop to below baseline (globally by 40.7%, $p<0.001$) was observed in all sections after the SV was removed. SpO_2 rapidly increased back to baseline post removal of the SV.

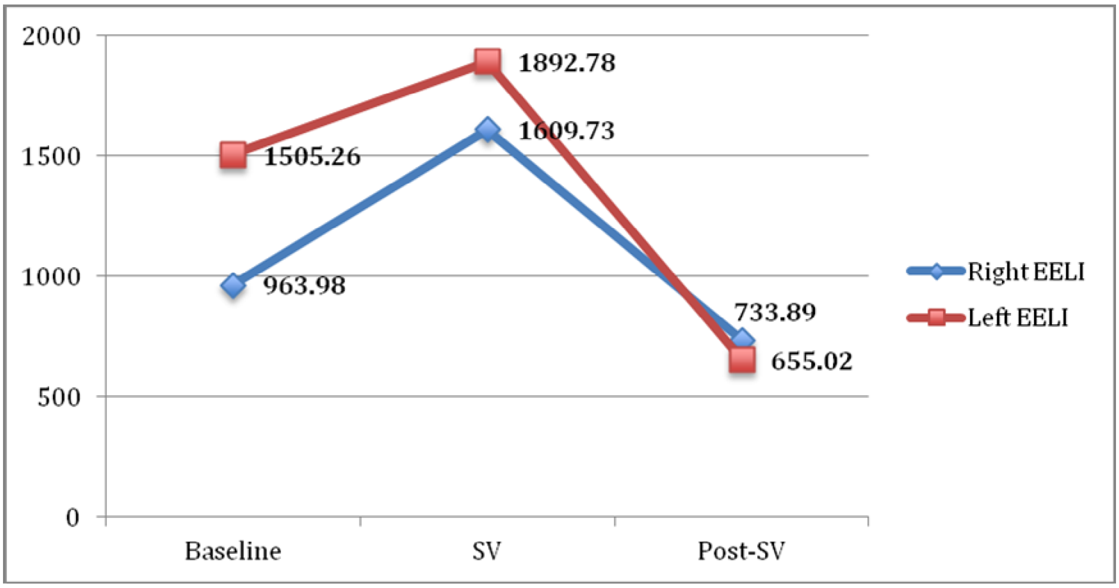

Figure 5-1a: EELI distribution in right-left direction across time-periods

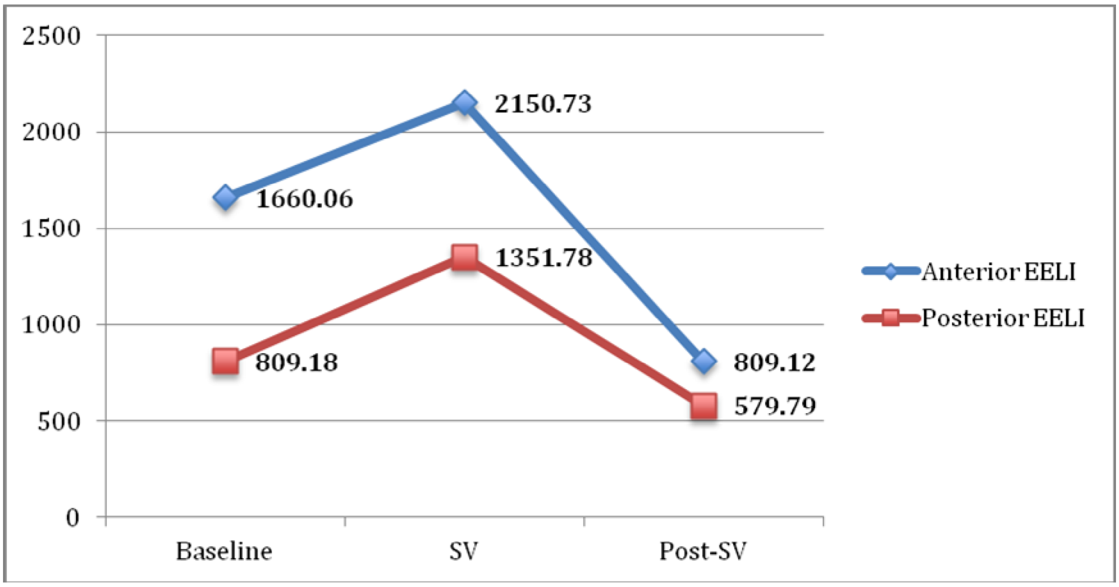

Figure 5-1b: EELI distribution in anterior-posterior direction across time-periods

Global TVar increased by 23% during SV use (p<0.001), dropping back to below baseline once the SV was removed (globally by 20.1%, p<0.001). There were no significant changes in TVar between different lung sections (see *Figures 5-2a* and *5-2b*).

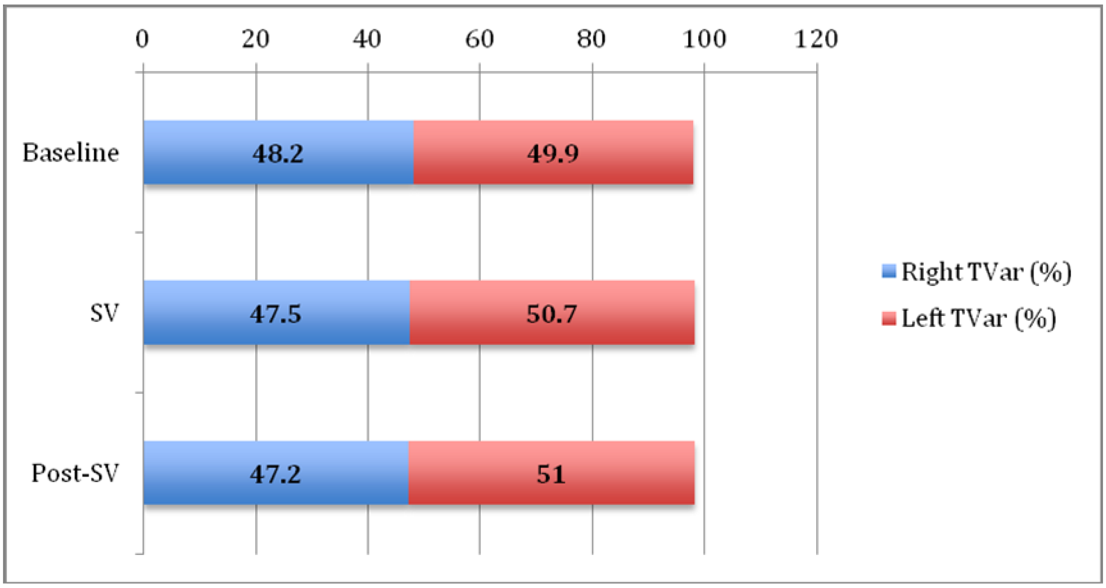

Figure 5-2a: Distribution of TVar in right-left direction across time-periods

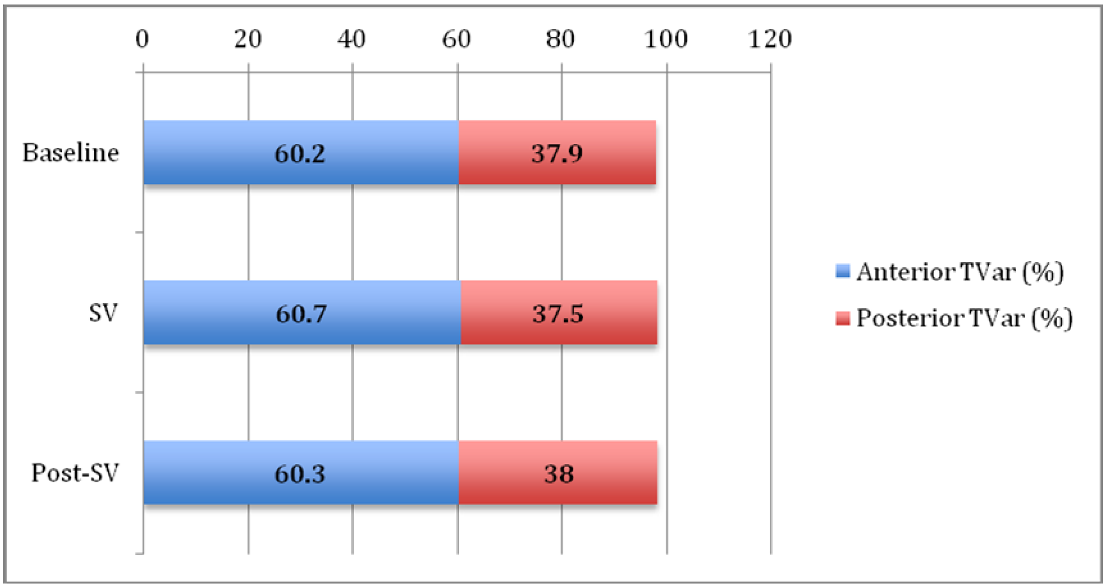

Figure 5-2b: Distribution of TVar in anterior-posterior direction across time-periods

An increase in RVD was noted during SV use (3.65->12.48, no units), which dropped once the SV was removed (11.29). VSA showed a decrease (508->451->489, no units) during SV use, and remained below baseline once the SV was removed, see *Figure 5-3*. rNoVent increased from 0.37 at baseline to 12.55 during the SV period and dropping to 2.06 post SV use. This correlates with RVD and VSA, indicating a bigger area that was not ventilated during SV use, despite the increase in EELI. CoV shifted during SV use as can be seen in *Figure 5-3*. During SV placement the CoV reduced to 50 on the right and 49 on the left compared to baseline of 54 and 50 equivalently. This indicates a shift in ventilation towards the dorsal aspects of the lungs on the right side during SV use.

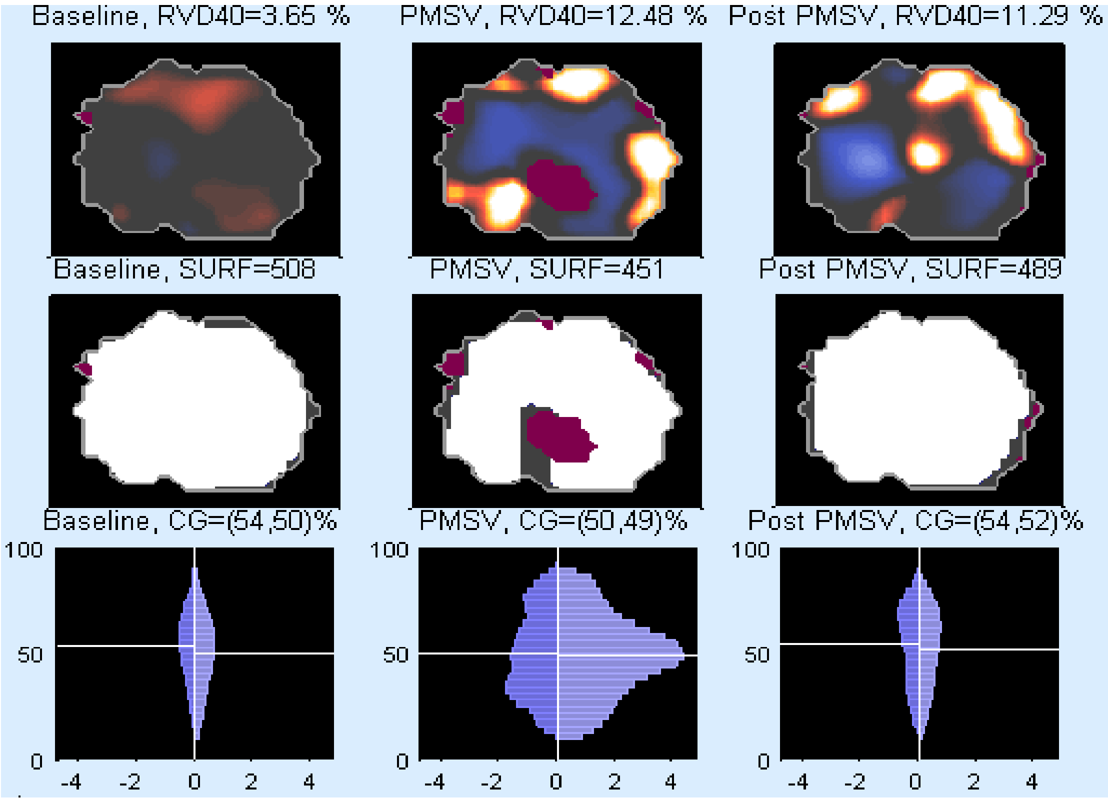

Figure 5-3: RVD (RVD40 on graph), VSA (SURF on graph) and CoV (CG on graph) across time-periods. Screenshot from EITdiag™

RVD40 – indicates a delay in opening of alveoli in certain lung regions. The bigger the number, the greater the delay; VSA – indicates ventilated surface area on the lung. The bigger the number the greater the ventilated surface area; CoV –indicates the centre of ventilation taking into account right-left and anterior-posterior shifts in ventilation.

Further examination of the patient's chest x-rays revealed substantial hyperinflation, which was considered to be consistent with probable COPD (see *Figure 5-4* below). Patient questioning (only able to be done with SV in-situ) regarding his exercise tolerance and chronic cough confirmed that this had gone undiagnosed prior to this admission.

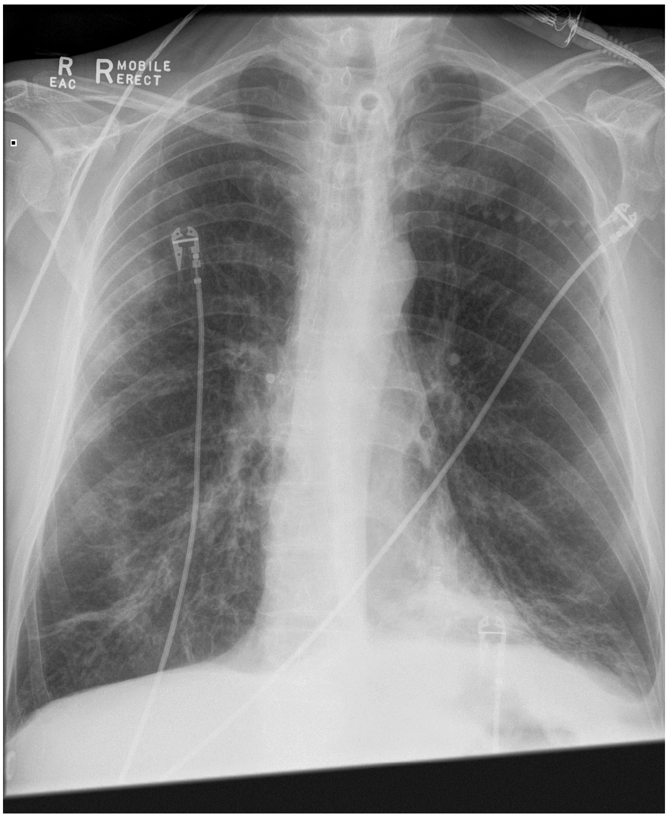

Figure 5-4: Chest XR on the day of recruitment to the study
Chest XR consistent with bilateral hyperinflated lung fields and flattened diaphragms

5.6 Discussion

Previously published data [137] on ventilation distribution during and post SV use revealed increased EELI and TVar similar to this case study, further confirming the effect of SVs on respiratory mechanics. However, these findings so far have all been observed on patients recovering from acute lung injury and represent a combination of decreased RVD and increased VSA with stable or improved oxygenation. In contrast, this case study revealed signs of hyperinflation in the lungs during SV use with some recovery observed post SV removal. Increased RVD and rNoVent, together with decreased VSA in the setting of significantly increased EELI, all indicate potential hyperinflation of the lung. Regional analysis indicates potential hyperinflation more in the anterior aspects of the lungs. In a previous study [120] on a non-COPD cohort EELI had increased and remained significantly above baseline even once the SV was removed. In this case study, however, EELI dropped to below baseline as soon as the SV was removed. This may also indicate stretching of lung tissue, suggesting hyperinflation during SV.

Combining EIT data and the patient's chest x-ray, it is possible that the patient developed ventilation-perfusion inequality [33] during SV use. High ventilation / increased gas flow, as indicated by significantly increased EELI and other EIT parameters suggesting hyperinflation of the lungs during SV use, may have caused excess pressure on the alveoli resulting in reduced blood flow in the surrounding pulmonary arterioles. In these areas, airway pressure may have exceeded arterial pressure, resulting in a shunt which may have manifested in a drop in arterial oxygen saturation.

It is highly likely that SV use resulted in increased PEEP for this patient. High flow oxygen therapy via a TT provides very little PEEP, if any [140]. SV use restores physiological PEEP, with expiration happening via the upper airway. Since the patient has to breathe around a deflated cuff and a TT, expiratory resistance is increased with SV use. Previous attempts to measure physiological PEEP with SV in tracheostomised patients have had little success [120]. Reports of more invasive methods [42] could help target the 'sweet spot' just below the vocal folds. The trachea to TT size ratio plays a significant role in amount of resistance experienced. The size of the TT may be one of the easiest and only variables to modify when determining the suitability for SV use in tracheostomised patients with obstructive lung disease.

COPD patients have dynamic airways compression and flow limitation. As a consequence, dynamic hyperinflation and intrinsic positive end-expiratory pressure (**iPEEP**) occur [141, 142], creating ventilation-perfusion mismatch [143], affecting WOB and gas exchange. In mechanically ventilated patients, the ventilator is set to deliver minimal PEEP and allow for prolonged expiration time to overcome these consequences. Spontaneously breathing COPD patients often use pursed lips breathing in order to achieve the same effect. Pursed lip breathing has shown to decrease airway compression [144, 145], and lead to decreased RR and increased tidal volumes [145-147]. There have been studies showing that applying external resistance to mechanically ventilated COPD patients reduces iPEEP and compression of the airways [141, 148]. Other studies with mechanically ventilated patients found these PEEP effects damaging [149, 150]. SVs could theoretically have the same effect: the added resistance in the upper part of the trachea should act similarly to pursed lip breathing. The only exception is the lack of variability during SV use that the patient could exercise with pursed lip breathing. The resistance to breathing around the deflated cuff is constant when a SV is used. The added extrinsic PEEP could be too high for some patients using a SV, and thus exceed the critical level of external PEEP as described by Tobin [151]. The above mentioned TT to tracheal size ratio could be essential in determining the success of SV use in having similar effects to pursed lip breathing.

SVs have been used as part of routine clinical practice for the past 5 years in the cardiorespiratory ICU at TPCH. During this time only a small number of patients have been noted to de-saturate significantly with a SV in-situ. While the features of the current case are thought to relate to his COPD diagnosis, it should be noted that the ICU frequently manages patients with poorly defined obstructive lung disease yet only a few have displayed similar features.

5.6.1 Limitations of the study

Whilst merely a single case, the study highlights the fact that SVs may have risks as well as benefits. Their use should be considered on a case-by-case basis. One particular population where caution may need to be exercised is in patients with severe or covert COPD.

The study was unable to capture carbon dioxide measurements or measure pulmonary shunt during the investigation, which would have provided further evidence of potentially inadequate gas transfer related to SV use in this patient with parenchymal disease.

5.7 Conclusion

This is the first report describing the physiology, and more specifically the lung mechanics, of a tracheostomised ventilated COPD patient when using a SV. Confirmation of potential lung hyperinflation should help clinicians seek solutions (such as downsizing a TT) to help safely facilitate verbal communication with the use of SV in this population.

Chapter 6

Chapter 6 <u>Impact of speaking valve use on patient outcomes in ICU</u>

6.0 Rationale and significance

Making any changes to the weaning regime (such as using SVs) for patients still needing support from the ventilator may result in changes to ICU outcomes, such as time spent on the ventilator, number of days from TT insertion to decannulation etc. As the results of the studies in Chapters 3, 4 and 5 show, SV use causes an increase in EELI and alters bedside respiratory markers, therefore potentially also affecting tracheostomy specific outcomes.

Restored upper airway function provides the opportunity for patients to commence activities such as talking, eating and drinking; all roles of the upper airway. There are no published data on the impact of SV use on such outcomes. To address the second aim of this thesis, this chapter presents two published manuscripts on tracheostomy and SP specific outcomes pre and post the implementation of SV use into ICU. The chapter is divided into two parts. The study presented in the first part aims to compare if and how the introduction of an in-line SV into ICU impacted the tracheostomy and SP specific outcomes for patients. All tracheostomised patients in the ICU the year before the introduction of the in-line SV (2011) are compared to all of the patients with a TT during the first year that the in-line SV was introduced into the ICU (2012). Although swallowing and dysphagia are not a focus area of this PhD, the outcomes for patients commencing oral feeding were included as part of this study to inform future research in the area.

The second part of this chapter contains a study analysing similar outcomes for all tracheostomised patients from the following two years (2013-2014), when use of the SV had become routine clinical practice. It was hypothesised that an in-line SV would improve communication and swallowing specific outcomes with no increase in average time to decannulation or the number of adverse events.

The findings of the first study were first presented at the International Tracheostomy Symposium in Melbourne, October 2014. Since then results from both studies have been presented in numerous invited international, national and local lectures as listed in *Presentations during candidature* on page vii. This chapter includes 2 manuscripts, both published in Journal of Critical Care in 2015. All sections and tables have been renumbered, and abbreviations continued to align with the rest of the thesis document. Table 6-2 has an added column with p values.

Note:

Although the studies in Chapters 3, 4 and 6 occurred at the same time, the timing of the publication of these manuscripts in peer reviewed journals means that the conclusions and references to gaps in literature in the manuscripts included in the present chapter are not inclusive of information in Chapters 3 and 4.

6.1 The use of tracheostomy speaking valves in mechanically ventilated patients results in improved communication and does not prolong ventilation time in cardio-thoracic ICU patients.

Sutt A-L, Cornwell P, Mullany D, Kinneally T, Fraser J

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6.1.1 Abstract

Purpose

The aim of this study was to assess the effect of the introduction of an in-line tracheostomy SV on duration of mechanical ventilation and time to verbal communication in patients requiring tracheostomy for prolonged mechanical ventilation in a predominantly cardiothoracic ICU.

Materials and Methods

We performed a retrospective pre-post observational study using data from the ICU clinical information system and medical record. Extracted data included demographics, diagnoses and disease severity, mechanical ventilation requirements, and details on verbal communication and oral intake.

Results

Data were collected on 129 patients. Mean age was 59+/-16 years, with 75% male. Demographics, casemix and median time from intubation to tracheotomy (6 days pre-post) were unchanged between timepoints. A significant decrease in time from tracheotomy to establishing verbal communication was observed (18 days pre and 9 days post, $p<0.05$). There was no difference in length of mechanical ventilation (20 days pre-post) or time to decannulation (14 days pre-post). No adverse events were documented in relation to the introduction of an in-line SV.

Conclusions

In-line SV was successfully implemented in mechanically ventilated tracheostomised patient population. This resulted in earlier verbal communication, no detrimental effect on ventilator weaning times, and no change in decannulation times.

6.1.2 Introduction

An in-line SV is a one-way valve that blocks airflow from returning to the ventilatory circuit, and redirects it through to the upper airway enabling functional use of the glottis [152] in a tracheostomised patient. The valve is designed to be inserted in-line with the ventilator tubing and requires the tracheostomy cuff to be deflated allowing air to bypass the tracheostomy cannula and be exhaled through the larynx. In-line SVs have the potential to improve the quality of life of tracheostomised mechanically ventilated patients by enabling verbal communication and improved swallowing. However, the impact of the valve on respiratory mechanics remains unclear. Cuff deflation alongside placement of the SV in-line creates a leak in the ventilatory system. This has led to concerns that lung derecruitment could occur reducing EELV, leading to alveolar collapse and atelectasis. This may be deleterious to liberating patients from the ventilator and prolong their length of stay in ICU. There is currently no published research documenting the effect of talking with a deflated cuff (leak speech) or SV on EELV, and limited research documenting the effect of leak speech or SVs on weaning from mechanical ventilation.

6.1.2.1 Communication

Communication in mechanically ventilated patients is extremely restricted and in many cases is reliant on non-verbal modes (e.g. mouthing, gesture and communication boards). The inability to use verbal communication results in decreased exchange of diagnostic information between staff and patient, leading to decreased adherence to recommendations, therefore poor patient satisfaction with the healthcare service [12]. Patients report a preference for verbal communication [6] and have associated the inability to verbally communicate with depression, social withdrawal, and reduced motivation to participate in care [7-10]. In addition poor sleep, and increased anxiety and stress levels have been associated with the mechanically ventilated patients' inability to effectively communicate [11].

6.1.2.2 Swallowing

There are inconsistencies reported as to the effect a TT has on swallowing physiology [153-163]. By restoring the airflow through the upper airway, return of subglottic pressure during swallowing is facilitated [164]. Improved taste and smell have also been reported [152, 165]. However, it is unclear if this is necessary for a successful swallow. Practice in some ICUs is for tracheostomised patients to be nil-by-mouth until they are able to tolerate cuff deflation with or without a SV. This might unnecessarily delay return to activities of daily living, and could also lead to increased costs with enteral feeds. Also, tracheostomised patients often report extreme dryness of mouth, thirst and discomfort when left nil by mouth [166-168].

In-line SVs have the potential to improve the quality of life of tracheostomised mechanically ventilated patients through restoration of communication and eating / drinking capacity. However it is important to ensure this benefit is not lost through worsening of respiratory function. A team decision was made to trial implementation of an in-line SV for one year with a view to assess patient outcomes with tracheostomies and adverse events with the introduction of the in-line SV. The aim of this study was to compare tracheostomy outcomes pre and post implementation of the in-line SV over two consecutive 1-year periods.

6.1.3 Materials and Methods

6.1.3.1 Sample

Tracheostomised patients in a cardio-thoracic ICU.

6.1.3.2 Setting

The study was conducted in a university affiliated teaching hospital with 630 acute care beds. The ICU is a 27 bed mixed medical surgical adult ICU with a predominantly cardiothoracic case-mix, including thoracic organ transplantation and extracorporeal life support. Neurosurgical and trauma patients are not managed at the facility. The ICU is staffed by a multidisciplinary team (medical, nursing, and allied health) with SP services provided as a part-time week day service with an open referral system for tracheostomised patients. SP services for tracheostomised patients prior to January 2012 did not include the provision of the in-line SV. The SVs available in the ICU (Portex Orator) were not designed to be used in-line with mechanical ventilation circuits and therefore could only be introduced with spontaneously breathing patients that did not need more than a couple of litres of oxygen via their TT for respiratory support. This was able to be administered via the side port of the SV. In January 2012, in-line SVs (PMV007) were introduced to the ICU. These were seen as an option for enabling earlier verbal communication due to their design allowing these SVs to be used in the ventilator circuit.

6.1.3.3 Data collection

Following human research and ethics committee approval (number HREC/13/QPCH/95) a retrospective audit was conducted of all tracheostomised mechanically ventilated patients managed within the ICU from January 2011 to December 2012. During the period January to December 2011 the ICU used a SV (Portex Orator) that was not designed to be used in-line with mechanical ventilation. Patients managed in the ICU between January to December 2011 formed Group 1 in the study. January 2012 saw the introduction of an in-line SV, designed to allow for use in-line with mechanical ventilation tubing to the ICU. Patients in the ICU between January 2012 to December 2012 formed Group 2. Data were obtained from the SP tracheostomy and ICU clinical information system and databases and supplemented by data from the medical record. Patients transferred from other ICU's with a tracheotomy *in situ* were excluded. One outlier with complications of severe pancreatitis leading to tracheostomy duration in excess of 217 days who was nil by mouth due to surgical reasons was excluded. In patients where the tracheostomy was reinserted, total duration of time was recorded.

6.1.3.4 Outcomes

Data collected on all patients included demographics, tracheostomy / ventilation, communication, and swallowing information. Demographic information included age, gender, admission diagnoses, surgical interventions, APACHE III and SOFA scores, and survival rates in ICU. Tracheostomy and ventilation information included length of endotracheal intubation, time to decannulation, and respiratory status/ventilation requirements at time of return to verbal communication. Communication and swallowing data collected included time to first verbal communication, time to return to oral intake, type of initial oral intake (i.e. fluid and / or food consistencies), cuff status at commencement of oral intake. All outcome measures that are documented as 'time to…' or 'length of…' were recorded in days.

6.1.3.5 Statistical analysis

Data were collated with subsequent data cleaning undertaken to check for data entry errors, with correction of any such errors identified before data analysis. Data were checked for skewedness. Descriptive analysis of the data collected for each year was undertaken to inspect for and report trends using cross-tabs in SPSS. Comparison of key outcomes such as ETT duration, TT duration, days from ETT to TT, days from TT to SV, days from SV to decannulation, days from TT to first oral intake, APACHE III and SOFA scores were completed using independent t-tests for the Groups 1 and 2 using SPSS ver.21. An α-level of $<.05$ was used to indicate statistical significance.

6.1.3.6 Data specifics

Due to the nature of the research questions different patient numbers were included for data analysis. For ETT and TT duration, all tracheostomised patients were included for

Group 1 and 2. For TT insertion to SV, and SV to decannulation, only patients that were using a SV were included. For TT to first oral intake only patients that were having oral intake whilst tracheostomised, were included. The patients that died with TT in-situ were included in statistical analysis and their data were not censored.

6.1.4 Results

6.1.4.1 Demographics and clinical characteristics

One hundred and twenty nine patients were included; 56 pre and 73 post the implementation of the in-line SV. The demographic and clinical characteristics of both groups are summarised in *Table 6-1* below. There were no statistically significant differences between the group in terms of age, gender, diagnoses on admission or surgical intervention during ICU admission (p>.05). APACHE III and SOFA (days 2, 3, and 4) scores were significantly higher (p<.05) in Group 2 when compared to the Group 1. The % of sepsis was significantly higher in Group 2. ICU survival rates across both groups were similar at 83.9% in Group 1 and 80.8% in Group 2.

Table 6-1 – Demographic and clinical characteristics

	2011 (n=26)	**2012 (n=73)**
Age (mean, SD)	58.5- (15.5)	59 (17)
Male	40 (81.4%)	50 (68.5%)
Diagnoses on admission		
CVS	34 (60.7%)	40 (54.8%)
Respiratory	15 (26.8%)	14 (19.2%)
Sepsis	6 (10.7%)	16 (21.9%)
Other [a]	1 (1.8%)	3 (4.1%)
Surgery during ICU stay (% within group) [b]		
CVS	33 (97.1%)	35 (87.5%)
Thoracic	8 (53.3%)	7 (50%)
Sepsis	5 (83.3%)	13 (81.3%)
Other	1 (100%)	2 (66.7%)
APACHE III [mean (SD)]	71 (19.9)	83[c] (30.2)
SOFA score (mean, SD)		
Day 1	8 (2.7)	9 (3.3)
Day 2	8 (2.2)	9 [c] (3.6)
Day 3	7 (2.6)	9 [c] (3.9)
Day 4	7 (2.6)	8 [c] (3.8)

[a] *includes patients with gastrointestinal and neurological diagnoses*

[b] *most common interventions across all Dx groups included cath lab, valve surgery, reopen, thoracotomy and laparotomy*

[c] *p<.05 vs 2011 group*

CVS – cardiovascular system; ICU – intensive care unit; APACHE III – acute physiology and chronic health evaluation; SOFA – sequential organ failure assessment

6.1.4.2 ETT and tracheostomy outcomes

There was no significant difference between groups with respect to ETT duration and days from TT insertion to decannulation (p>.05), with durations of 6 and 14 days respectively (see *Table 6-2*). There were significant differences between groups in terms of time from insertion of TT to first use of SV (p<.05) and time from SV to decannulation (p<.05). On average the introduction of SVs occurred 9 days earlier in Group 2 as compared to those in Group 1.

Table 6-2 - ETT and tracheostomy outcomes

	2011		**2012**		
	mean (SD)	**n (%[a])**	**mean SD**	**n (%[a])**	***p value***
ETT duration(days)	6 (4.5)	56 (100%)	6 (4)	73 (100%)	*0.96*
TT duration(days)	14 (13.2)	56 (100%)	14 (10.9)	73 (100%)	*0.47*
TT insertion to SV(days)	18 (21.3)	9 (16%)	9 (7.3)	42 (57.5%)	*0.02*
SV to decannulation(days)	1 (0.9)	9 (16%)	8 (8.3)	42 (57.5%)	*0.001*
TT to first oral intake(days)	6 (5.3)	39 (69.6%)	7 (6.8)	59 (80.8%)	*0.40*

[a] *% of tracheostomised patients*

ETT=endotracheal tube; TT=tracheostomy tube; SV=speaking valve

6.1.4.3 Communication

The number of patients with a tracheostomy using a SV of any type was significantly higher after the introduction of the in-line SVs, 42 in 2012 compared to 9 in 2011 (*p*<.05). Patients in Group 2 had access to verbal communication (SV to decannulation time) for a significantly longer period (8 days) than Group 1 (1 day).

The use of SVs (not in-line SVs) for all nine Group 1 patients commenced when they were on low flow oxygen or room air via tracheostomy. The introduction of in-line SVs to the ICU resulted in a more variable practice in terms of ventilator status at the time an SV was introduced. Descriptive analysis revealed that 4 patients commenced using a SV on synchronous intermittent mandatory ventilation (**SIMV**); 11 patients on PSV; 20 on high-flow tracheostomy piece (HFTP – as defined by >30L/min of humidified airflow through tracheostomy in our ICU) and 7 on low-flow oxygen.

Of the tracheostomised patients that did not survive ICU in 2011, none were able to verbally communicate during their ICU stay. In 2012, five tracheostomised patients out of 14 that died had a chance to verbally communicate before dying.

6.1.4.4 Swallowing

Group comparisons of time to first oral intake revealed no significant differences between the two groups (*Table 6-2*). The need for modification of fluids was less frequent post the introduction of in-line SV. In Group 2, 74% of patients were drinking fluids of any consistency as compared to 68% in Group 1. The majority of patients in both groups commenced oral intake of fluids on thin fluids. Interestingly, Group 1 patients were more likely to be on extremely thick fluids as compared to Group 2 patients (12.5%;4%). All tracheostomised patients in 2011 commenced oral intake with their tracheostomy cuffs inflated. In 2012, 42% of patients commenced oral intake with the tracheostomy cuffs deflated.

6.1.5 Discussion

There has been an increase in the number of tracheostomised patients [169] in ICUs due to the improved safety and training for percutaneous tracheotomies and some evidence for benefits of early tracheostomy [170]. This means that there is an increasing number of patients potentially able to verbally communicate whilst mechanically ventilated and awake. Despite clinical concerns that SVs may affect patient outcomes such as ventilation duration and time to decannulation the current study found that in-line SVs did not negatively impact on duration of mechanical ventilation and led to a significant increase in time where verbal communication was possible. No adverse events were reported. Despite the patients in Group 2 having higher APACHE III and SOFA scores, the average time to decannulation did not change with the introduction of the in-line SV. Because of such a disparate group of critically ill patients, more data are needed to investigate if early use of SVs could in fact facilitate weaning from mechanical ventilation. Our data indicate that SVs are not deleterious to weaning from mechanical ventilation.

Little is known about the effects of SV on patients' respiratory mechanics. Physiological studies are needed to better understand respiratory mechanics and determine the optimal methods for successful and beneficial use of in-line SVs in the mechanically ventilated ICU population. Our group and others have reported on EIT [104]. It provides real time assessment with no risk of ionising radiation [171], and could be utilised to look at respiratory mechanics in patients with SVs also.

There have been numerous studies looking at communication interactions between the patient and nursing staff, and studies where patients have been asked to retrospectively rate their success with different modes of communication whilst mechanically ventilated in the ICU [6-9, 119, 172]. However, little has been reported on success of communication in ICU patients comparing patients' and nursing staff perspectives. The effect that reduced level of alertness, delirium and not being able to verbally communicate has on the quality and success of health communication for patients and in nursing staff looking after their patients is also relatively unknown. The ability to verbally communicate whilst still mechanically ventilated could also have a positive effect on the much spoken about 'post-intensive care syndrome' (**PICS**), which in turn would require further investigation [173].

The introduction of in-line SVs into our ICU has changed practice significantly. SVs are now being used as a communication option / weaning tool for tracheostomised patients. It seemed to be a mere step before decannulation with the previously used SVs that were unable to be fit in-line with the ventilator tubing. These SVs were therefore only used with limited number of patients that were nearing decannulation, and did not need more than a few litres of oxygen via their TTs for respiratory support. Use of in-line SVs in our ICU has led to the practice where the patients are assessed for suitability to use a SV as soon as their haemodynamics are stable: they are awake and attempting to communicate, regardless of their ventilation needs.

The fact that there were no adverse events reported with the significant increase in the use of SVs has a lot to contribute to ongoing and frequent in-servicing of staff to ensure patient safety. Based on our experience, SP presence in the ICU and an open referral system for tracheostomised patients have had a positive effect on improved communication options and earlier oral intake for patients. SP was directly involved with the majority of the tracheostomised patients in the ICU across the two years with the exception of a few that never fully regained consciousness, and died in ICU.

6.1.5.1 Limitations of the study

It is an observational 'before and after' study at a single centre. The results in cardiothoracic patients in this sample may not be generalisable to other settings such as those with neurological diagnoses. Due to the small sample size we were unable to compare the outcomes of similar patients across the two groups, which would have allowed us to obtain more accurate data on the potential impact of in-line SVs on time to decannulation.

6.1.6 Conclusion

The use of in-line SVs in tracheostomised patients enables a return to verbal communication sooner, accompanied by improved oral intake. However, more research is needed to determine the efficacy of SVs in the weaning process of tracheostomised mechanically ventilated ICU patients. These results demonstrate that the ability of the patient to communicate can be improved substantially, with no adverse effect on ventilation times. If our data on SVs is replicated in other centers it would suggest that SVs can be used more widely to improve the quality and comfort of care of the critically ill patient.

6.2 Speaking valves as part of standard care with tracheostomised mechanically ventilated patients in intensive care unit.

Sutt A-L, Fraser JF

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6.2.1 Rationale and significance

No change occurs overnight, especially in the critical care environment. Whilst in-line SV use at TPCH ICU commenced in 2012, widespread use and routine practice took time to develop. It was decided to investigate similar data from the subsequent two years once SV use had become a part of routine practice at TPCH ICU. Although no incidences had occurred, the aim was to investigate whether patient outcomes in ICU had changed over time, with safety being of utmost importance.

6.2.2 Background

We recently reported (see *section 6.1*) on tracheostomy related outcomes comparing two consecutive years before (2011) and after (2012) the introduction of an in-line tracheostomy SV into practice in a primarily cardio-thoracic ICU [107]. Our results indicated a significantly earlier return to verbal communication for tracheostomised patients after the introduction of an in-line SV without effecting ventilator weaning or decannulation time.

The practice of using SVs in our ICU has continued to increase and is now part of standard care with tracheostomised mechanically ventilated patients. Following ethics approval we collated and analysed similar outcomes of all tracheostomised patients in ICU for the following two years (2013 and 2014). Our aim was to assess whether clinical uptake had continued after the initial “honeymoon” phase associated with the original research. Equally, as our process matured, we looked to assess how tracheostomy outcomes had changed.

6.2.3 Results

There were 274 tracheostomised patients in our ICU across the relevant four years (2011-2014). The vast majority of tracheostomies (98.5% in 2013, 96.1% in 2014) were performed percutaneously in ICU. Patient demographics, disease severity, ICU survival, intubation and tracheostomy specific outcomes are collated in *Table 6-3*. There were no significant changes in diagnoses groups compared to the previous two years, majority of patients admitted with cardiovascular or respiratory disease. There has been a significant reduction in the average number of days from TT insertion to return to verbal communication since the previous study – time to return of verbal communication has reduced three-fold since introducing the in-line SVs into the ICU, on average now being 6 days post tracheostomy insertion *($p<0.001$)*. Analyses of the patients' ventilation needs revealed a notable increase of patients with whom SV use was initiated whilst still mechanically ventilated (70% of SV users in 2014, 34%, 37% and 0% in 2013, 2012 and 2011 respectively, $p<0.001$). Overall, ~75% of all our tracheostomised patients are now communicating verbally. There was no change in time to return of oral intake between the two studies. This improvement in ability to speak has not been associated with any deterioration of any measurable ventilatory or respiratory outcomes.

Table 6-3 – Results

Demographic and clinical characteristics	2011 (n=56)		2012 (n=73)		2013 (n=68)		2014 (n=77)		*p* [b]
Age (mean, SD)	58.5 (15.5)		59 (17)		59 (16)		57 (17)		
Male	40 (81.4%)		50 (68.5%)		43 (63.2%)		49 (63.6%)		
APACHE III [mean (SD)]	71 (19.9)		83[c] (30.2)		71 (21.3)		81 (28.4)		*=0.029*
SOFA score (mean, SD)									
Day 1	8 (2.7)		9 (3.3)		8 (2.6)		9 (3)		
Day 2	8 (2.2)		9[c] (3.6)		8 (2.6)		9 (3.2)		*=0.035*
Day 3	7 (2.6)		9[c] (3.9)		8 (2.9)		9 (2.9)		*=0.022*
Day 4	7 (2.6)		8[c] (3.8)		8 (3.3)		8 (2.8)		*=0.012*
Survived ICU[a]	83.9%		80.8%		88.2%		77.9%		
ETT and tracheostomy outcomes	mean (SD)	%[a]	mean (SD)	%[a]	mean (SD)	%[a]	mean (SD)	%	
ETT duration (days)	6 (4.5)	100%	6 (4)	100%	5 (4.2)	100%	6.5 (5)	100%	
TT duration (days)	14 (13.2)	100%	14 (10.9)	100%	13 (9.1)	100%	13.5 (16.8)	100%	
TT insertion to SV (days)	18 (21.3)	16%	9 (7.3)	57.5%	8 (7)	77.9%	6 (5.6)	74%	*<0.001*
SV to decannulation (days)	1 (0.9)	16%	8 (8.3)	57.5%	6 (4.9)	77.9%	9 (16.9)	74%	*=0.048*
TT to first oral intake (days)	6 (5.3)	69.6%	7 (6.8)	80.8%	9 (7.9)	73.5%	6 (7)	72.7%	

[a] *% of tracheostomised patients*

[b] *p-value comparing 2011 and 2014*

APACHE III – acute physiology and chronic health evaluation; SOFA – sequential organ failure assessment; ETT=endotracheal tube; TT=tracheostomy tube; SV=speaking valve

6.2.4 Discussion and Conclusions

There is an ongoing debate in literature regarding outcomes, safety and efficacy of early versus late tracheostomy in patients requiring prolonged mechanical ventilation [16]. Whilst there are still proponents and opponents of early tracheostomy one absolute advantage is the ability for patients who still require mechanical ventilation to be able to speak. Our data presented here show that clinical uptake of this technique and safety associated with it continues to increase. Without a TT, mechanically ventilated patients would not be eating and drinking and they would be unable to speak. Voicelessness may have other disadvantages such as agitation and confusion due to their inability to communicate their pain, distress and wishes. There are accumulating data concerning the benefits of early rehabilitation in ICU [174, 175]. Having a TT as opposed to an ETT is the only way to restore verbal communication and safe oral intake in our mechanically ventilated patient population. Certainly, there remains the need for physiological studies using SVs and further similar studies with different patient populations to be able to confirm the safety and benefits of SVs.

Use of SVs as part of standard care with our tracheostomised mechanically ventilated patients in ICU for the last 3.5 years has resulted in a situation where having a non-verbal tracheostomised patient is an exception. It has somewhat confused our weaning practice, with patients often using a SV all day whether still on ventilator or doing trials off the ventilator. Data indicating increased EELVs and improved diaphragm mobility during SV use [176] further confirms potential benefits of the valve. This, however, raises some questions about rehabilitation practices – what is the physiological ‘sweet spot’ for diaphragm recovery? Are we exercising some of our patients too much by having them use a SV all day whilst still mechanically ventilated? More research is needed to clarify the role of SVs in weaning.

Chapter 7

Chapter 7 Speaking Valves and Communication Success in the ICU

7.0 Rationale and significance

As summarised in Chapter 2, use of SVs is one of the best ways to ensure successful communication for tracheostomised ICU patients. In Chapter 6 it was explained that the uptake of SVs at TPCH ICU has been excellent, leading to a significantly earlier return to verbal communication for tracheostomised patients. Data in Chapters 3 and 4 support the respiratory safety of SV use, whilst Chapter 5 explains the extra caution that needs to be taken when introducing SVs to specific patient groups. These findings, however, do not capture the benefits of using a SV to improve communication.

It is easy to assume that communication success must improve significantly following the restoration of the patient's ability to talk. ICU patients, however, are often very weak, which makes talking a challenge despite the restoration of airflow via their glottis. At the same time, some patients' ability to "mouth" their message is excellent, making non-verbal communication also effective. It is therefore important to measure the difference, if any, in communication success with and without SV use. Communication is a two-way process. Successful communication needs both the communicator and the communication partner to succeed in delivering and capturing the message. For these reasons the present study measured the patients' success with health communication, asking both the patients and nursing staff to rate the patients' success before SV use, and again during SV use on a visual analog scale, addressing the third aim of this thesis. The specific SV used in this study is a Passy Muir SV (PMV007, Passy Muir Inc., California, USA).

The results of this study were partially presented at the 2015 ATS conference in Denver, Colorado and have been published in an abstract format. The results have also been presented at numerous other local, national and international presentations listed in *Presentations during candidature* on page vii. Sections, tables and graphs have been numbered, and abbreviations continued to align with the rest of the thesis document.

7.1 Introduction

Communication in ICU can be challenging for both the patients and the ICU team. It is especially difficult for mechanically ventilated patients that often cannot use their voice due to air bypassing their larynx. Non-verbal communication is often not specific enough, and its success is frequently impacted by ICU acquired weakness [88].

Studies to date have examined how patients and ICU physicians, nursing staff and families perceive communicative interactions, including communication during clinical handover practices and delivery of care [91-95]. Magnus [96] studied the perceived difficulty of communication from the perspectives of recent ICU patients and multidisciplinary staff. The study included 8 patients and 9 staff across 5 ICUs and involved a semi-structured interview. Magnus found that patients perceived the communication difficulties to be greater compared to staff ratings. Some of the study participants had experienced a period of voicelessness throughout their ICU stay.

To date, there are no published data comparing communication success as between the period of voicelessness and the period with restored communication in a similar situation (i.e., being voiceless and then using a SV in ICU). Assumptions are often made that staff have understood the message conveyed by a patient, however the success of the communication interaction in terms of accuracy of information conveyed and communication partner satisfaction have not been reported.

There are tools that are designed to measure communicative effectiveness in patients with language difficulties, such as the Communicative Effectiveness Index. Lomas et al [177] designed and validated this tool for people with aphasia. As it is very specific to day-to-day life and situations experienced by people with aphasia, it was found not to be suitable for implementation in an ICU setting. On the other hand, there are tools that have been effectively used to measure quality of life in ICU [178] which also address communication, among other parameters. Without having communication at the forefront, however, this tool is less susceptible to changes that SV use may bring and it would be difficult to measure communication success specifically. With no suitable existing tools, new 5 and 6 item questionnaires were developed as part of this study. These enabled the assessment of patient communication success with and without a SV from the perspectives of both patients and nursing staff.

7.2 Methods

7.2.1 Setting

A prospective study in a cardio-thoracic ICU at a metropolitan teaching hospital was conducted to assess the success of health communication for patients that are tracheostomised and weaning off mechanical ventilation.

7.2.2 Sample

Following approval from the local ethics committee, participants were screened for eligibility. Twenty-five consecutive ICU patients that were using a SV and managing well with basic communication were recruited to the study. Informed consent was gained from the patients or their next of kin. Fifty-two nurses that were caring for these patients were also recruited following informed consent.

7.2.3 Communication questionnaire

Due to the absence of any suitable existing tools, communication success questionnaires were designed for this study (see *Appendices 2 and 3*). These asked both participant groups to rate the patients' success with ICU specific communication on a 10cm visual analogue scale. A score of 0 meant profound communication difficulties; a score of 10 indicated no communication difficulties. The types of questions asked were decided upon following numerous discussions with ICU staff and tracheostomised patients throughout the months preceding, ensuring the most important topics for these type of patients were covered.

The patient questionnaire was designed to address different underlying mechanisms for communication in the ICU, such as saying something quickly, or giving detailed information. For example, in order to be able to let the nursing staff know about pain a patient needs to be able to give detailed information, and in some instances must be able to say it quickly. The difference in communication success with the healthcare team and the patients' family was also queried. The nursing staff questionnaire was designed to assess the patients' success in communicating information and needs that are often acute whilst in ICU (such as pain, allergies, past medical history). The nurses were also asked to rate how big of an obstacle communication was for them in looking after the patient.

7.2.3.1 Patients

The patients were asked to fill out their 6-item questionnaire twice. Initial administration of the questionnaire took place when they were voiceless. Patients subsequently completed the questionnaire when using a SV. Initial and second administration occasionally took place on the same day, and in some cases up to two days apart. The nursing staff was blinded to the patients' ratings, and vice versa. In cases where the patient's fine motor skills did not enable independent administration of the questionnaire, the patient pointed out the appropriate spot on the visual analogue scale and this was marked on the scale by the primary author, with further confirmation provided by the patient regarding accuracy.

7.2.3.2 Nursing staff

Nursing staff were asked to fill out a similar 5-item questionnaire twice, first when the patient they were caring for was voiceless, then subsequently when the patient was still tracheostomised but able to use their voice with a SV in-situ. In cases where a nurse had only been looking after the patient in one condition only (i.e., with a SV), a different nurse was approached to fill out the questionnaire about the opposite condition. At least two nurses were recruited per every patient. Some nurses filled out the questionnaire about several patients.

7.2.4 Data analysis

All data were collated in an Excel spreadsheet, and mean values calculated. To calculate the average success score with communication, all but the last question in the questionnaire were included for both patients and the nursing staff. Paired t-tests were used to calculate *p* values and SD, using SPSS. Data were not tested for normality.

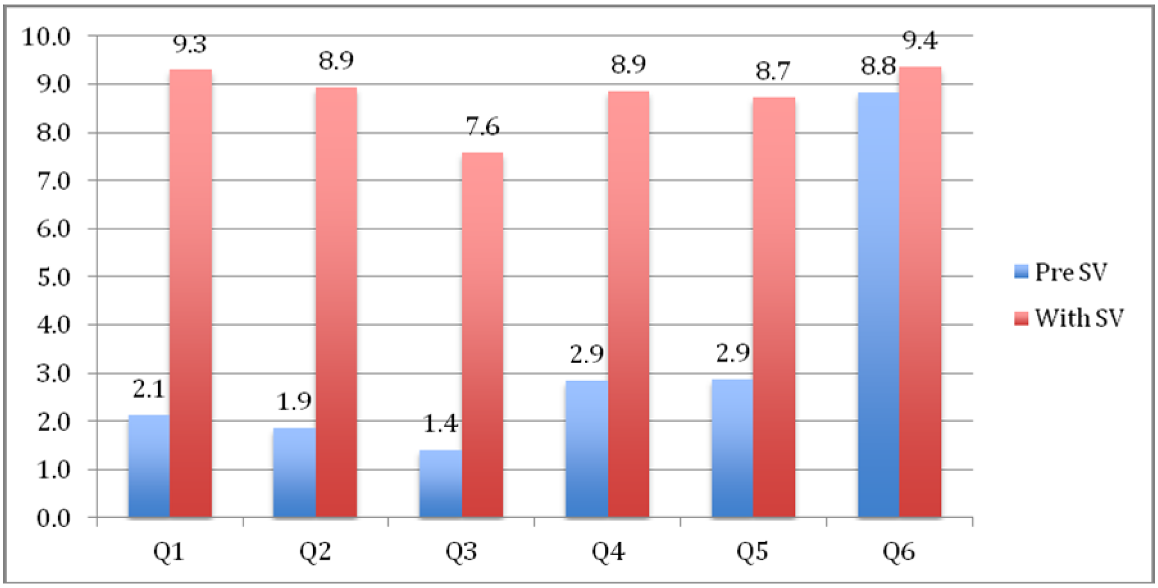
7.3 Results

Twenty-five tracheostomised patients (52% male, average age 60.1) and 52 nurses (81% female, average 10.5 years of experience in ICU) were approached to fill out the questionnaire. Twenty pre-SV and 19 with SV questionnaires were successfully filled out by 20 patients in total, 45 pre-SV and 51 with SV questionnaires were filled out by 52 nursing staff in total (135 questionnaires in total). Each patient had 2-4 nurses filling out the questionnaires about their communication success.

Patients rated the importance of being able to communicate with others (Q6) as very high (see *Graph 7-1* below). The scores did not change significantly (p=0.102) once the patients were using a SV, with the importance of communication remaining very high (8.8/10 to 9.4/10). Prior to SV use, patients rated the effectiveness of communicative interactions poorly (average of 2.2/10) while nursing staff rated the patients' communication success as average (average of 4.95/10). A significant improvement in communication success after SV implementation was observed ($p<0.001$), with improved ratings from both patients and nurses looking after them. See *Graphs 7-1 and 7-2 below*.

7.3.1 Patients

Similar scores were attributed to patients' perception of how well their families (Q5) and healthcare team (Q4) could understand them when they were voiceless (2.9/10), and once they were using a SV (8.9/10 for healthcare team and 8.7/10 for family). The most difficult communication tasks for the patient while limited to non-verbal communication were: asking questions (Q1); giving detailed information (Q2), and saying something quickly (Q3). All of these tasks improved significantly ($p<0.001$ for all) with the use of SV. See *Graph 7-1* below.

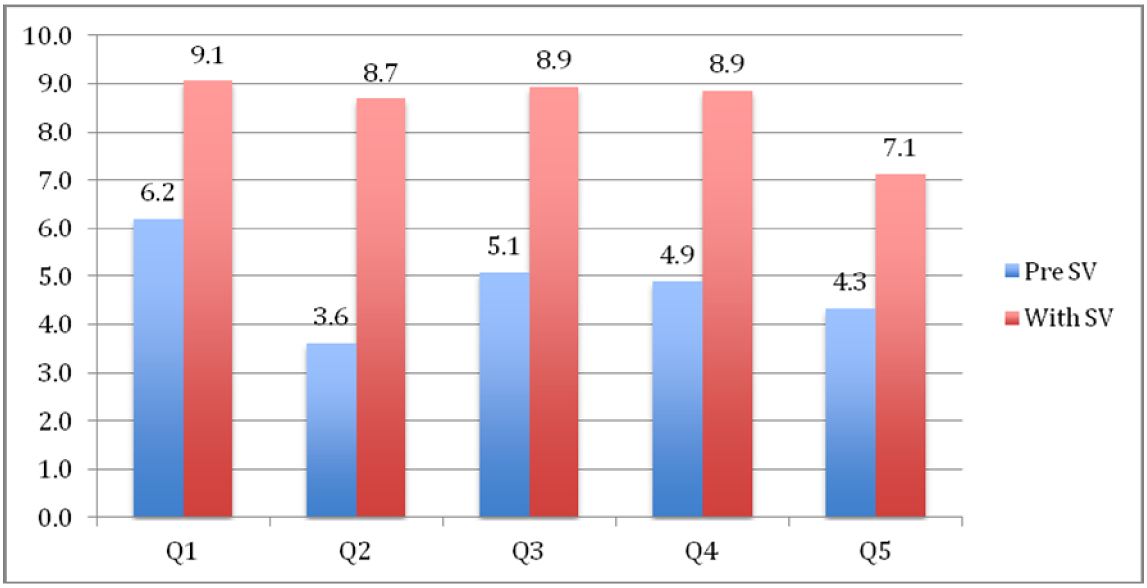


Graph 7-1 – Patients' ratings of success with communication before and after the implementation of SV

Q1=How successful are you in asking something quickly?; Q2= How successful are you in giving detailed information?; Q3= How successful are you in saying something quickly?; Q4=Overall, how successful are you in getting your message across to the healthcare team?; Q5= Overall, how successful are you in getting your message across to family and friends?; Q6=Overall how important is being able to communicate to others for you?

7.3.2 Nurses

Overall, the nursing staff reported that communication was a barrier in looking after their patients (Q5). Understanding patients' needs, wants and wishes (Q4) was scored low (4.9/10) for the voiceless patients. Once the patients were using a SV, this increased to 8.9/10. The nurses indicated that they were able to understand if their patient had pain or discomfort relatively well even when the patients were voiceless (6.2/10), the rating significantly increasing with SV use (9.1/10, p <0.001). Nursing staff felt that it was more challenging to get detailed information from patients when they were not able to use their voice (with relevant information including details on past medical history and allergies, and the presence of confusion or communication difficulties - Q2 and Q3, respectively). This improved once the SV was in use (p <0.001). See *Graph 7-2 below*.



Graph 7-2 – Nurses' ratings of patient's success with communication before and after the implementation of SV

Q1=How well are you able to understand if your patient has any pain/discomfort?; Q2=How well are you able to get information from your patient about their previous medical history/allergies?; Q3=How well are you able to assess presence of confusion and/or communication difficulties in your patient?; Q4=How well do you feel you understand the patient and their needs/wants/wishes?; Q5=How big of an obstacle is the patient's communicative ability for you in looking after them?

7.3.3 Case examples

There were 3 patients who rated their communication success above 5/10 (average 5.9) prior to SV use, and close to maximum once they were using a SV. For these patients the average communication success as rated by nursing staff was also high (7.2/10), reaching close to maximum once the patients were verbally communicating. These patients were noted to have good oro-motor and upper limb movement and they were able to communicate with moderate success by mouthing or writing their message when voiceless.

There were also 3 patients that rated their communication very poorly (0; 3.4 and 0.4) when they were voiceless with an improvement to maximum of 10 by all three once they were talking. Nursing staff scores for these patients also indicated a similar jump (pre SV – 3.4; 1; 4.3), with scores reaching 9.3 on average once the patients were talking.

There were 4 patients that rated their communication success below 7.5 (5.6; 6.3; 7.1 and 7.3) even once they had a SV in-situ. Nursing ratings for most of these patients' communication success were high (8.9; 8.9; 8.4 and 6.9 respectively). Numerous patients rated their communication success very poorly, with nursing staff scores remaining moderate. The last two examples create a discrepancy in the overall success rate scores when the patients were voiceless.

7.4 Discussion

SVs increased success with health communication in general. The magnitude of change in communication success with the introduction of the SV was noticeably greater in the patients' responses (6.2-7.2 point improvement with SV) than it was for nursing staff (2.9-5.1 point improvement with SV). The ratings of success with communication between nurse and patient prior to SV use were clearly disparate, with nurses perceiving communicative interactions to be more successful than patients. This could perhaps be partially explained by the nurses being used to similar situations with voiceless patients, influencing their ratings, whereas being voiceless in the ICU is usually the first such experience for the patient, potentially increasing their dissatisfaction and frustration. At the same time, the patient is more likely to have a better idea of the communicative success as the holder of original needs, wants and questions that are unable to be passed on to the nurse looking after them. Whatever the cause of this asymmetry, the situation may lead to increased frustration for the patient with the nurse thinking they have understood the patient prematurely. The conversation may therefore finish with the intended thoughts/requests from patient yet to be conveyed. This may further explain the reported patient frustration, anxiety and stress levels associated with voicelessness [11, 24].

The case examples indicate that patients fell into 2 different groups when they were voiceless: (1) patients that were able to successfully communicate by alternative means, whether 'mouthing' or using AAC devices, and (2) patients that experienced no communicative success whilst voiceless. The success of non-verbal communication is often dependent not only on the patients' level of alertness, their upper limb dexterity and oro-motor abilities, but also their willingness to accept and use an AAC device. For many of these patients, communication success was restored to a near maximum level with the use of SV. Equally, these cases highlight the reality that communication does not always become fully successful with the return of the ability to use one's voice. Many patients continue to experience notable difficulty when saying something quickly (Q3), even once they are able to talk. Some patients' overall success scores remain low despite having their voice back. Clinically, this is often due to critical illness weakness contributing to reduced intelligibility of speech. This emphasises the need for healthcare staff to be extra vigilant and give the patients more time during interactions.

Another important factor in determining the success of communicating a message is the duration of communication interaction. Leathart [97] monitored nursing staff and patient interactions during usual care of a ventilated patient and found that the average interaction only lasted <30 seconds and the overall time spent communicating with a ventilated patient was generally very low. Although, not directly measured as part of this study, informal observations in ICU suggest that duration of time spent on communicating with a patient increases significantly once the patient is able to actively engage in conversation. This would also lead to more information being exchanged, and communicative success hopefully being greater. Further research into this area is warranted.

Overall, the introduction of the SV significantly increased the success with communication for tracheostomised mechanically ventilated patients from both the patient and nurse perspectives. Having a voice made it significantly easier for the patients to express themselves in a more comprehensive way.

7.4.1 Limitations of the study

Due to specific questionnaires/scales not being available in the literature, original non-validated questionnaires needed to be used for this study. Best efforts were made to ensure the questionnaires included the most relevant topics for the tracheostomised patients and the nurses caring for them. The two questionnaires differed slightly for the patients and nursing staff. This makes the results somewhat less comparative.

The participants at times appeared to misinterpret the last question in the nursing staff questionnaire, with clarifying questions asked from the main author. Rewording of this would need to be considered if the questionnaires were to be used again for similar studies.

7.5 Conclusion

Healthcare staff may not be as successful at understanding their non-verbal patients as they believe, and may underestimate the communication difficulties experienced by patients. SV use with tracheostomised patients has the potential to improve patient involvement in their healthcare and reduce misinterpretations of meaning and patient frustration.

Chapter 8

Summary, Discussion and Conclusions

Chapter 8 Summary, Discussion and Conclusions

8.1 Summary

This thesis consists of 8 chapters. Four of these chapters include published [107, 108, 120], accepted or submitted manuscripts [137, 179] in peer-reviewed journals. Manuscripts have been included in pre-publication format and numbering of tables, graphs and figures modified to align with the rest of the thesis.

To address the three aims of the thesis, 5 hypotheses were generated and five studies conducted. The main aim of the thesis was to investigate the effect of SV use on respiratory mechanics to determine whether these should be used in-line with mechanical ventilation of tracheostomised patients. The first hypothesis ‘Use of SVs in tracheostomised patients weaning from mechanical ventilation causes an increase in EELV’ is addressed in Chapter 3. That chapter contains an overview of a prospective observational study with 20 consecutive tracheostomised ICU patients weaning from mechanical ventilation and using a SV. The findings suggest that there is a significant increase in EELI / EELVs during and post SV use, as measured by EIT. Alongside the increase in EELI, the patients showed reduced RR and $EtCO_2$, and unchanged SpO_2 [120]. These findings provided evidence that concerns over the detrimental effect of SV use on lung recruitment may be unfounded, contributing to a wider rollout of SV use in TPCH ICU that is presented in Chapter 6.

The second hypothesis addressing the first aim was ‘SV use in tracheostomised patients weaning from mechanical ventilation causes a redistribution of ventilation into different parts of the lung’. To investigate the physiology behind the significant increase in EELI as described in Chapter 3, EIT data were further analysed to exclude any potential deleterious effects to weaning patients off mechanical ventilation. The first part of Chapter 4 presents data on ventilation distribution and concludes that SV use does not cause any significant shifts in ventilation, with the increase in EELI being uniform across anterior-posterior and left-right sections of the lung. Additionally, newer EIT variables such as TVar, VSA and RVD are reported suggesting potential for recruitment and excluding hyperinflation as a result of increased EELI. The second part of Chapter 4 presents data on A:C ratio with SV use. The results show increased abdominal activity during SV use suggesting increased diaphragm activity. The findings in Chapter 4 further ensure safety of SV use in the cardio-thoracic ICU population [137].

Additionally, a case study is presented in Chapter 5. This chapter summarises a COPD patient case in whom a SV caused an increase in EELI, similarly to studies described in Chapters 3 and 4. However, in this instance the SV use caused lung hyperinflation, impacting on gas exchange and resulting in significant desaturation [179]. Whilst SVs are generally safe, this case highlights the need to individually assess patients for suitability of SV use, taking into consideration their underlying respiratory condition. Equally, it highlights the importance of close observation during initiation of SV use, and the SVs' potential in actually assisting in covert diagnoses, as occurred in this case.

The second aim of this thesis was to assess the effect of introduction of SVs into a cardiothoracic ICU on tracheostomy specific outcomes in patients. Two hypotheses were generated to address this aim: (1) routine SV use in a cardio-thoracic ICU does not have a deleterious effect on ICU and SP outcomes for tracheostomised patients, and (2) routine SV use in a cardio-thoracic ICU facilitates an earlier return of vocal function for tracheostomised patients. Two publications presented in Chapter 6 summarise tracheostomy and SP specific patient outcomes for all tracheostomised patients (n=274) admitted to TPCH ICU from 2011-2014. The results highlight a 3-fold decrease in the time taken from TT insertion to first use of SV across these 4 years (6 days on average in 2014, and 18 days in 2011). The majority of tracheostomised patients (75%) were reported to use a SV in 2014 (70% starting SV use in-line with mechanical ventilation) as compared to 16% in 2011 (0% using SV in-line with mechanical ventilation). Such a significant surge in SV use had no negative impact on the average ventilation time or time to decannulation [107, 108].

The third aim of this thesis was to further clarify the effect of SVs on success with health-related communication for ICU patients. It was hypothesised that SV use would result in increased success with health-related communication reported by both the patients and nursing staff. Chapter 7 focuses on 20 consecutive ICU patients using a SV and the 52 nurses looking after them. As part of the study both the patients and the nurses were asked to fill out a simple 5 and a 6-item visual analogue scale questionnaire before and during SV use. The results indicate significantly improved success with health related communication when the patients were using a SV as reported by both groups. Interestingly, when the patients were voiceless, the nurses rated the patients' success with communication significantly higher than the patients' own rating. As there is a mismatch, this may explain some of the frustration experienced by patients that are left voiceless that has been previously reported in the literature [11, 24].

8.2 Clinical implications

Whilst these studies occurred in one hospital, the ramifications of this work have been widespread, with changes occurring across Australia, the USA and Europe, as reported to me by my international colleagues. This thesis provides clinicians with fundamental data on the impact of SV use on respiratory mechanics, patient outcomes associated with ICU and tracheostomy, and patients' success with health related communication whilst tracheostomised and in ICU. All of the data presented are encouraging towards widespread SV use in the mechanically ventilated, tracheostomised cardio-thoracic ICU population.

Locally, the findings of this research project have significantly changed practice. From 0% of ventilated TT patients talking in 2011, 75% of ventilated patients were using a SV in 2014 [108]. SV use is now routine practice, and questions are raised by the ICU team whenever there is an occasional patient that is not talking. The implementation of SVs has improved communication in the ICU. This has facilitated patients becoming active participants rather than passive recipients of care. 'SV gives me back my autonomy and makes me feel like part of the human race again', was a comment from one long-stay patient in ICU. The ICU has progressed to using SVs with patients that are critically unwell, including patients on extracorporeal circuits, cardiac transplants and with open chests [134]. These patients would have previously been deeply sedated, and therefore passive recipients of care. With SV use, patients report feeling empowered, able to maintain focus and often negotiate therapy goals with the multidisciplinary team. This allows for earlier and more active rehabilitation. Reports from the patients and the whole multidisciplinary team reveal the significantly improved quality of life in the ICU for these patients that were previously left voiceless.

This thesis is an example of how research into important clinical vacuums of data can translate into change and improved outcomes.

8.2.1 Barriers to implementation

(Within Australia)

Speech Pathologists are the main facilitators of patient communication. Use of SVs with patients has therefore always been a SP role. Assessing someone's ability to manage their oral secretions and upper airway patency for successful cuff deflation and suitability for SV trials is part of routine SP practice. The majority of SPs currently have inadequate knowledge of respiratory physiology and ventilatory management to independently control the safe implementation of SV with tracheostomised mechanically ventilated patients.

There are ICUs where physiotherapists have advanced skills and are more involved with altering ventilatory settings, however, in general, Allied Health do not have active input in ventilatory weaning in Australia. The role for nursing staff in weaning also varies significantly across ICUs. In the difficult to wean patients, generally only the intensivists determine weaning strategies. A multitude of clinical and non-clinical commitments mean that intensivists do not have the ability to be available at all times for the speech pathologists when using the SV. Upskilling of senior speech pathologists in areas of physiology and understanding of mechanical ventilation will greatly enhance their ability to lead SV use with the mechanically ventilated ICU population. Augmenting the knowledge base within the SP craft group further advances the importance of SP and potential contributions to the ICU in relation to ventilated patients. When speech pathologists can comprehensively and fully understand and explain the use of SVs in mechanical ventilation and their effect on lung mechanics, their key role in the multidisciplinary ICU team will be further cemented. There is an acute need to up-skill Allied Health staff in Australia to be able to actively implement SV use. The specific knowledge that respiratory therapists possess in the US is desperately needed for Allied Health staff working in the ICUs in Australia.

8.3 Limitations

One limitation of this thesis is the specific patient cohort of ICU patients with primarily cardio-respiratory disease. Despite this being the most suitable cohort to answer the key clinical and research questions around respiratory physiology with and without SV use, extrapolation of the data to other clinical populations should be undertaken with due caution.

Some results including diaphragmatic function and airway pressure data presented are weak due to limitations with available measuring techniques, as discussed in Chapters 3 and 4. Although $EtCO_2$ monitoring was successful in the study described in Chapter 3, $TcCO_2$ could be considered, as an attractive non-invasive option for future studies. Cost and some limitations with operating time may limit its use in clinical practice. $TcCO_2$ monitoring was not used as part of this study due to lack of availability of the necessary equipment at the time.

A separate group of patients receiving volume-controlled ventilation would have added significant value to Chapters 3 and 4 as ventilation mode may have a significant impact on EELV and ventilation distribution. Inclusion of such a group was not feasible due to the very limited patient numbers in whom volume-controlled ventilation was still being used whilst awake and attempting to communicate. This would have been more easily achieved in countries such as USA where volume-controlled ventilation is often preferred to pressure-controlled ventilation.

The study was conducted with patients supported on Puritan-Bennett 840 ventilators. Whilst the majority of ventilators work on similar principles, there are many subtle differences between models and brands. One of the important aspects may be the location and timing of set PEEP delivery. As SV use does not allow for exhalation back towards the ventilator, it may lead to the ventilator not delivering any PEEP during SV use, depending on the exact location of PEEP triggering. Another aspect that impacts PEEP delivery is the patient's ability to close their glottis during inhalation. Neither of these variables could be controlled for or precisely measured as part of this study.

Another aspect to potentially have a significant impact on respiratory physiology with SV use is the TT to trachea ratio. This will always be variable between patients, and aside from ensuring there was sufficient space for the patient to comfortably breathe around the deflated cuff it could not be measured as part of this study. A different TT to trachea ratio would mean variable resistance to air moving around the TT in all patients (in addition to an already variable physiological PEEP), which may potentially also affect EELI and ventilation distribution.

8.4 Future directions

There are numerous observations that were made throughout the implementation of widespread SV use that will lead to future studies. Being able to speak is just one aspect of optimising care for these patients, but being an active participant in their care is equally if not more important. This subjective concept is difficult to quantify, and reports thus far are purely based on patients' comments.

Also, personal observation indicates that once long-stay patients are able to speak again, staff tend to re-orientate them much more actively. This may lead to reduced rate and duration of delirium, a condition known to be associated with significantly increased mortality and morbidity, and increased cost of care [180-182]. These observations have led to a separate study on improving the diagnosis and management of delirium in our ICU patients.

Another common observation is that patients tend to receive less sedative drugs once they are talking. It may be due to the patients being able to ask questions and clarify the situation that often causes extreme frustration and distress [8, 23, 24] leading to agitation and delirium often necessitating re-sedation. This observation is now being more formally assessed through investigating the effect of SVs on sedative drug use.

Dr. Mary Massery theories [38, 41] on the role of glottis in postural stability and control were touched upon in Chapter 2. Stemming from these theories we have initiated a project in conjunction with the ICU physiotherapists looking at the effect of SVs on mobility and limb strength.

Now that SVs are used with patients sometimes for the whole day, more research is necessary to look at some of the following:

- What is the physiological 'sweet-spot' for diaphragm recovery – how much SV use is enough and when is it too much to cause muscle fatigue?
- Are there long-term benefits of early SV use in the ICU – perhaps reduced incidence of PICS and improved quality of life?
- How do patients manage their oral secretions with a deflated cuff on a ventilator that is often set to deliver high pressures and flows?

TT size and type is commonly determined at the patient's bedside immediately prior to tracheostomy, through assessment of the patient's neck anatomy and the size of the ETT. As witnessed in clinical practice, occasionally the size and/or type of the chosen TT is incorrect, causing issues with ventilation due to cuff leak or potentially resulting in tracheal pressure injuries. More research is needed to investigate better ways to ensure the most accurate TT type and size for best TT fit and positioning. This is essential for suitable candidacy for SV, but more importantly for adequate ventilation and reducing the rate of tracheal complications during and post TT. Some work in this area has commenced elsewhere [183-185], but no clinically feasible options have been reported on. Preliminary discussions have been held locally, and the need for a potentially new design ETT and TT has been identified amongst other research ideas.

Moving forward, my greatest interest remains around physiology. Several additional areas of future research have arisen based on clinical observations during SV use. Essential research into further investigating the role of larynx in breathing and other bodily functions is needed. The impact of SVs on cardiac physiology remains unclear – the way negative pressure ventilation potentially changes pressures and preload is of great interest to me.

In addition to more specific research, the dissemination of this new knowledge is needed worldwide to increase SV use in ICU. A recent systematic review [88] published in a high impact critical care journal on communication options for ventilated ICU patients failed to even mention SV as an option. They opined that SVs could not be used when patients are still fully ventilated. There is certainly a lack of data on suitable ventilator parameters for SV use, however leaving SVs out of the systematic review shows how much more work and education is needed in the area. To contribute to this body of work, I co-authored a letter to the editor in response to this article [134] *(also see Appendix 4)* to draw readers' attention to SVs as an excellent communication option for some of these patients.

To investigate the barriers and gaps in knowledge for wider roll-out of SVs in the ventilated ICU population our multidisciplinary team (intensivist, physiotherapist, speech pathologist, nurse) is in the process of finalising a questionnaire to be distributed amongst the multidisciplinary staff working in Australian ICUs.

To address the need for further knowledge on respiratory mechanics and mechanical ventilation for Allied Health staff, multiple multidisciplinary workshops in Australian capital cities have been organised for later this year, involving respiratory therapists from the US amongst local experts.

8.5 Conclusions

In conclusion, my PhD thesis has explained some of the respiratory physiology behind SV use in tracheostomised ICU patients weaning off mechanical ventilation. The promising data are accompanied by the reports of significantly improved success with health communication for the patient.

Recommendations from this study are not to start using EIT on every patient before/during/after SV use, but to rely on patient's underlying diagnosis, bedside cardio-respiratory monitoring and patient reports to guide clinical decision-making.

This research has resulted in significant change in routine clinical practice locally where all tracheostomised patients are now assessed for early SV use. Uptake of similar practice elsewhere is rapidly gaining ground, benefitting critically ill patients around the world.

My PhD has taught me to ask clinically relevant questions, find gaps in literature, and answer these via research. My limited research to date has helped me showcase the relevance and benefits of SP input with tracheostomised mechanically ventilated ICU patients to the multidisciplinary ICU team. This has resulted in SP being a fulltime member of the ICU team and automatically involved in the care of all tracheostomised patients from day one. I am excited about the opportunities ahead and the continuing potential to contribute first-hand original knowledge to the world. I am equally excited to be able to continue help others commence their research journeys to further increase our knowledge and improve healthcare.

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Appendices

Appendix 1
Ethics Approvals

The Prince Charles Hospital Human Ethics and Research Committee

29/4/2013 – Full NEAF application accepted (HREC/13/QPCH/95)

17/9/2013 – amendments accepted

12/12/2013 – amendments accepted

22/5/2013 – Site Specific Assessment and governance accepted

19/11/2013 – QCAT accepted (QCAT reference CRL025-13)

The University of Queensland Human Ethics and Research Committee

15/1/2014 – accepted (approval number 2014000005)

Study retrospectively registered for inclusion in the Australian New Zealand Clinical Trials Registry (ANZCTR) on 4/6/2015, study registration number: ACTRN12615000589583

Appendix 2
Quality of Health Communication in ICU Questionnaire – Nursing Staff

To answer the following questions please think about the success of ____________________________'s [insert patient name] communication attempts over _____________________________ [researcher to indicate time] when they were/ were not [researcher to indicate one] using a speaking valve.

Using the scale provided indicate through a mark on the line for each question the level of success you have had in communicating with your patient. A mark at the far left of the line would indicate no success at all, while a mark at the far right of the line would indicate very successful (i.e. no problems).

1. How well are you able to understand if your patient has any pain/discomfort?

No success	Very successful

2. How well are you able to get information from your patient about their previous medical history/allergies?

No success	Very successful

3. How well are you able to assess presence of confusion and/or communication difficulties in your patient?

No success Very successful

4. How well do you feel you understand the patient and their needs/wants/wishes?

No success Very successful

For this question please think about the patient's communication and indicate on the line how much is the patient's communicative ability an obstacle for you in looking after them. A mark at the far left of the line would indicate that the patient's communication is a big obstacle in cares, while a mark at the far right of the line would indicate that the patient's communication is not an obstacle at all.

5. How big of an obstacle is the patient's communicative ability for you in looking after them?

A big obstacle Not at all

6. Any other comments?

<u>Please also fill out the following details:</u>

Age:

Gender:

Classification: RN CN other………………….

Years of experience:

Participant code (for the principal researcher to fill out)**:**

Appendix 3
Quality of Health Communication in ICU Questionnaire - Patient

Participant No: Date:

Data Point: pre-PMSV ☐ PMSV insitu ☐
Length of PMSV use to-date:____________ (days)

Quality of Health Communication in ICU Questionnaire - Patient

To answer the following questions please think about the success of your communication attempts over ___________________________ [researcher to indicate time].

Using the scale provided indicate through a mark on the line the level of success you have had with communication for each question. A mark at the far left of the line would indicate no success at all, while a mark at the far right of the line would indicate very successful (i.e. no problems).

No success ______________________________________ Very successful

1. How successful are you in:

(a) asking questions?

No success Very successful


(b) giving detailed information?

No success Very successful


(c) saying something quickly?

No success Very successful


2. Overall, how successful are you in getting your message across to the health care team?

No success | Very successful

3. Overall, how successful are you in getting your message across to family and friends?

No success | Very successful

To answer the following question you will also need to mark / indicate on the line your response, but in this case the far left end means not important at all and the far right means very important.

4. Overall how important is being able to communicate to others for you?

Not important | Very important

Appendix 4
Letter to the Editor

Patients want to be heard – loud and clear!

Anna-Liisa Sutt, John F Fraser

Letter to the Editor; Critical Care 2017; 21:6

Accepted on 25th of Nov 2016

We congratulate Ten Hoorn et al on the systematic review of communication with ICU patients (1). Their work in defining an algorithm to assist improving communication options for these patients addresses a clear gap in patient-centred care in ICU. Despite the article giving a good overview of possible communication options for the ventilated ICU patient, we respectfully suggest that the most important communication option is the restoration of the patient's own voice by enabling airflow through their larynx. This is particularly in the conscious patient cohort - the focus of the review article. We are supported by patient data, who have indicated that verbal communication is the most successful form of communication (2). Once tracheostomised, a speaking valve (SV) should be considered as the first option for communication – as it restores our natural way of communication. Beliefs that cuff deflation required for the restoration of laryngeal function with SV causes atelectasis or would be deleterious in the weaning process have been proven to be unfounded (3). There are currently lack of published data on safe ventilatory parameters for SV use. However, patients in our studies using a SV whilst mechanically ventilated, had substantial levels of PS and PEEP requirements, and were able to communicate using a SV in-line with their mechanical ventilation circuit successfully without any discernible harm to their respiratory function or weaning from the ventilator (3).

Using SVs is common in our cardio-thoracic ICU (4), may commence on day of tracheostomy insertion with patients spending hours, sometimes all awake hours being able to talk with the treating teams and loved ones.

Following the success of this work, we now use SVs successfully with patients on VA ECMO, VADs and open chest. The difference it makes for the patients to have their own voice, and therefore be active participants in their care, is immeasurable with current tools. Studies elsewhere have also demonstrated benefits of early SV use in the ventilated tracheostomised ICU patient (5). Alternative communication options should be used only if natural communication is not able to be achieved or as complementary devices when verbal communication is not fully successful. In the most critically ill, weakness frequently limits the use of AAC boards, and teaching complex new skills (i.e. electrolarynx) is fraught with difficulty. We concur with the importance of communication but suggest that before moving to more complex interventions, the larynx must always be considered.

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