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Physiological and clinical outcomes associated with use of one-way speaking valves on tracheostomised patients: A systematic review

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ABSTRACT

Background: The one way speaking valve was first engineered in 1985 to allow patients with tracheostomies to communicate. The research has indicated alternative physiological benefits of using a speaking valve, however this literature has not yet been evaluated. The purpose of this systematic review was to evaluate the evidence for one-way speaking valve in a range of physiological domains, including vital signs, aspiration, olfaction, ventilation and tracheostomy weaning, length of stay, and quality of life.
Methods: A literature search was conducted in September 2017. Studies were eligible if they compared the use of a one-way speaking valve against no speaking valve, across any physiological or clinical parameter.
Results: 16 eligible studies were included in this review. A meta-analysis random-effect model *($I^2 = 71.96$, $p = 0.006$)* found reduced instances of aspiration with a speaking valve in situ, compared to without a speaking valve in situ (OR 0.122; 95% confidence interval, 0.031–0.479; p = 0.003). Statically significant results were also found across the domains of olfaction, secretion management and ventilation.
Conclusion: There is emerging evidence of additional benefits for using speaking valves. Further studies should focus on clinical outcomes that have the potential to reduce healthcare costs as well as patient outcomes.

Introduction

A tracheostomy tube is an artificial airway inserted into the trachea to allow a more direct access for ventilation.[1] This is most commonly indicated for patients in the critical care setting who are anticipated to require prolonged mechanical ventilation.[2] Tracheostomy tubes have been shown to have a negative impact on physiological functions including swallowing, secretions clearance, and olfaction. Moreover, the presence of a tracheostomy tube can inhibit the production of speech and the patient's ability to communicate.[3]

In 1985, a tracheostomised and ventilator dependent patient, David Muir, invented the Passy-Muir Valve.[4] This one-way valve designed to enable speech in patients with tracheostomy tubes (now commonly referred to as a "speaking valve") is routinely used in intensive care units (ICUs) worldwide. Whilst the majority of literature relating to the use of speaking valves have focused on the benefits of speech, there have been a small number of studies that have reported additional physiological and clinical benefits. The use of a speaking valve in tracheostomised patients has been demonstrated to restore normal subglottic air pressures, a key component of swallowing, thereby potentially improving swallow function and reducing the risk of aspiration.[5] Additionally, speaking valve may expedite weaning from mechanical ventilation[6] by creating a "no leak" system that re-establishes physiological positive end-expiratory pressure (PEEP), thus allowing patients to become accustomed to normal expiratory airflow patterns.[4] It has been suggested that the restoration of physiological PEEP may facilitate weaning by improving arterial oxygenation.[7] In addition, secretion management may also be enhanced with the use of a speaking valve by enabling a stronger, more effective cough and oral expectoration of secretions.[4]

Abbreviations: SV, speaking valve; PMV, Passy Muir Valve; HR, heart rate; RR, respiratory rate; PaO_2, partial pressure of oxygen; $PaCO_2$, partial pressure of carbon dioxide; $EtCO_2$, end tidal carbon dioxide; SpO_2, peripheral oxygen saturations; FEES, fiberoptic endoscopic evaluation of swallowing; SaO_2, arterial oxygen saturations; FiO_2, fraction of inspired oxygen; HCO_3, bicarbonate; TT, tracheostomy tube; VFSS, videofluroscopic study of swallowing; MV, mechanical ventilation; ICU, intensive care unit; EIT, electrical impedance tomography; EELI, end expiratory lung impedance; VASES, visual analogue self-esteem scale; PEEP, physiological end expiratory pressure; VSA, ventilated surface area; RVD, regional ventilation delay.

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The purpose of this systematic review is to evaluate the evidence for the additional physiological and clinical benefits of using a one-way speaking valves in tracheostomised patients including swallowing and aspiration, physiological measures (including heart rate, blood pressure, and oxygen and carbon dioxide levels), olfaction, ventilator and tracheostomy weaning, ventilation, ICU and hospital length of stay, and quality of life. This review is registered with the International Prospective Register of Systematic Reviews (Registration Number: CRD42015028075).

Methods

Paper identification and selection

A systematic review was conducted of all published clinical studies that compared the use of a one-way speaking valve to no speaking valve for a range of physiological and clinical parameters in adult and paediatric patients (Table 1). Studies were excluded if patients had laryngectomies or similar head and neck surgeries where the vocal cords were no longer engaged. The outcomes measures in the literature were analysed, which included swallowing and aspiration, physiological measures (including heart rate, blood pressure, and oxygen and carbon dioxide levels), olfaction, ventilation, hospital length of stay, quality of life, and ventilator and tracheostomy weaning.

A literature search was conducted in September 2017 using the MEDLINE, CINAHL, PubMed and Cochrane Library databases and the key words "one way speaking valve" OR "Passy Muir Valve", and restricted to those studies published in English language. A supplementary search was conducted in May 2018, which revealed no new articles. Due to the limited number of studies, all articles were accepted if the date of publication was after the development of the Passy-Muir Valve in 1985. Articles were excluded based on the criteria outlined in the Table 1.

The online program 'Covidence' (www.covidence.org) was used throughout the screening process of this review. Two investigators (LO'C & JP) screened studies individually for eligibility based on the inclusion and exclusion criteria outlined in Table 1. A third investigator (NM) provided consensus if the initial two investigators were unable to reach an agreement regarding inclusion/exclusion of studies. Fig. 1 outlines the reasons for excluding studies from this review, which included incorrect study design, different comparators or ineligible patient groups.

Risk of bias (quality assessment)

The 20 question Institute of Health Economics (IHE) Quality Appraisal Checklist[8] was used to assess risk of bias across the domains of: study objective, design, population, intervention and cointervention, outcome measures, statistical analysis, results and conclusion, and competing interests and support. This checklist was validated[9] and documented as suitable in the quality assessment of case-series studies.[9]

Data extraction and analysis

Both investigators (LO'C & JP) collected information on the following data: study design, total length of study, sequence generation, allocation sequence concealment, blinding, participant number, setting, diagnosis, age, sex, country, co-morbidity, number of intervention groups, details of the intervention, outcomes measured and recorded, time points measured and recorded, definition of outcomes and unit of measurement, number of participants in intervention/control group, sample size for each outcome, loss to follow-up, summary data for each intervention, estimate of effect (confidence interval/p value), funding source, and key conclusions of authors. The extracted data were coded with the initials of the individual investigator and compared as part of the analysis. If there were any discrepancies in data extraction, the third investigator (NM) provided arbitration.

Results

The original search identified 180 articles; however, 134 were excluded on title and abstract review due to duplications, non-English language, and/or incorrect population groups. The 46 remaining studies were reviewed and excluded if they did not meet the inclusion and exclusion criteria for the study design, and/or the comparison outlined in Table 1. During eligibility screening, a further 32 articles were excluded, with 16 remaining studies included in this review, largely prospective case-controlled and observational studies ($n = 15$) and one retrospective audit (Fig. 1).

Demographics and setting

Specific details for comparative studies are shown in Table 2. Both adult and paediatric studies were included in the review, as well as research undertaken in a variety of clinical settings, from large teaching hospitals to community and outpatient settings. Paediatric studies were those with participants younger than 18 years of age. Participants ranged from 3 months to 89 years, with the mean age of 2.4 years for the paediatric studies, and 58.5 years for the adult studies. Both ventilator-dependent and spontaneously ventilating

Table 1
Inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Design	Clinical studies (including prospective randomized controlled studies, clinical case studies and cohort studies)	Single case studies Expert opinions/consensus Narrative/didactic reports Conference abstracts
Participants	Adults and paediatric populations with tracheostomies	Laryngectomies or similar head and neck surgeries where the vocal cords were no longer engaged
Comparison	Use of one way speaking valve compared with no speaking valve	
Outcome measures	Swallowing/aspiration Oxygenation Heart rate Olfaction Blood pressure Ventilator/tracheostomy weaning Length of stay	

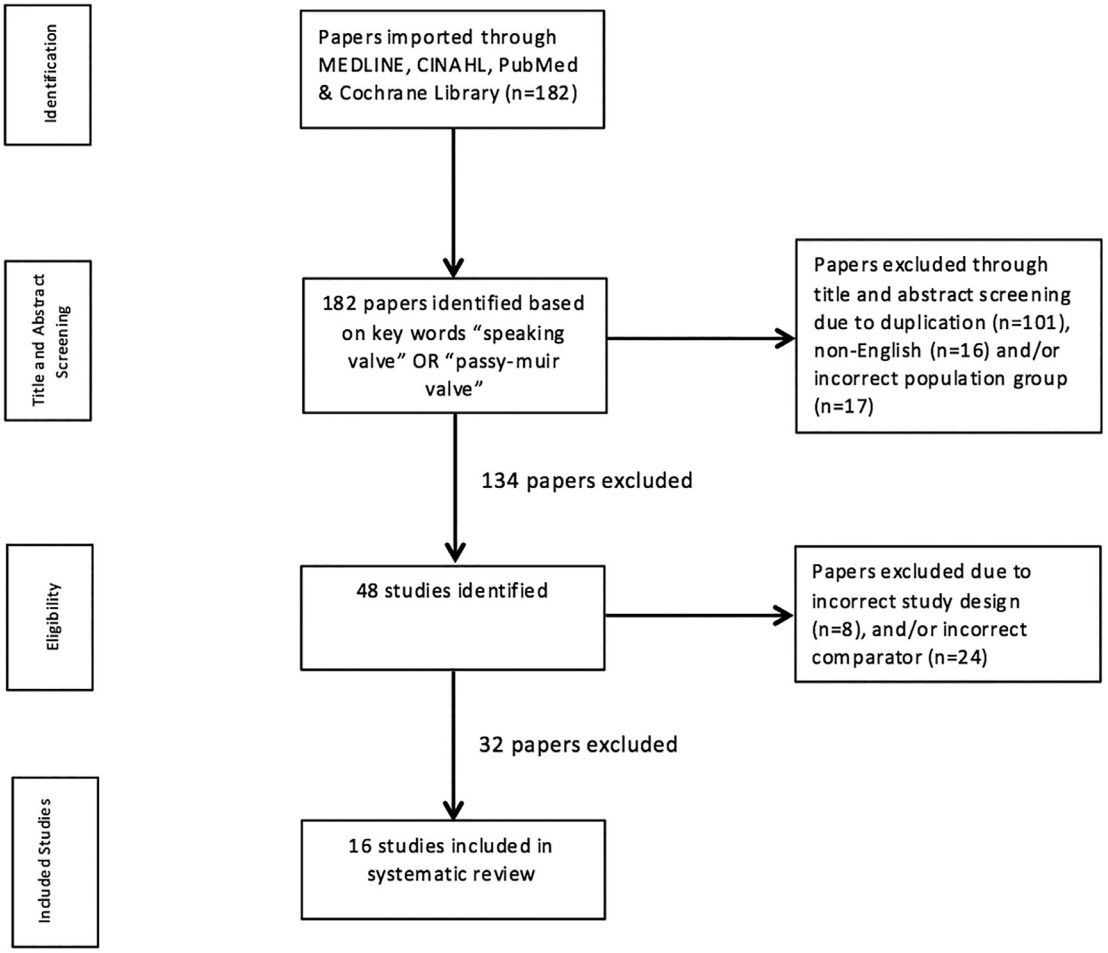

Fig. 1. Flow chart of study selection for the systematic review.

patients were included in the review, in addition to a range of diagnoses and length of time with tracheostomy.

Appraisal of evidence

Study quality and design

All included studies compared physiological and clinical parameters with and without a speaking valve. The majority of studies ($n = 15$) were prospective designs, with one study[10] being a retrospective audit.

Summary of findings

The demographics of the literature evaluated are outlined in Table 2, and the main findings and results outlined in Table 3. A forest plot (Fig. 2) is also included in the results below.

Due to the low number of studies ($n = 16$) and heterogeneity in outcomes measures, a meta-analysis was only possible to evaluate the instances of aspiration. Comprehensive meta-analysis software was used.[11] To compare the results between these trials, the dichotomous outcomes were expressed as odds ratio (OR) with 95% confidence intervals. The data were pooled using the fixed-effects model; however, when heterogeneity was statistically significant (Q statistic $p < 0.01$), the data were reanalysed using the random-effects model. Table 3 outlines the results from included studies in a descriptive fashion.

Aspiration

Eight studies[12–19] included aspiration as an outcome measure, with 5 of those studies able to be analysed in a meta-analysis.[12–15, 20] A random-effect model *($I^2 = 71.96$, $p = 0.006$)* found reduced instances of aspiration with a speaking valve in situ, compared to without a speaking valve in situ (OR 0.122; 95% confidence interval, 0.031–0.479; $p = 0.003$) (Fig. 2). Seven studies found that the use of a speaking valves reduced instances of aspiration, although this was only statistically significant in 5 of the studies. Caution should be applied to the results of the meta-analysis due to the inconsistencies of the study protocols including the use of thin, thick and pureed foods for the swallowing assessment. This is reflected in the results in Fig. 2.

Physiological measures

Physiological measurements related to using a speaking valve were reported by five studies.[3,21-24] Outcome measures included heart rate (HR), respiratory rate (RR), oxygen saturations (S_pO_2), partial pressure of oxygen (P_aO_2), end tidal carbon dioxide ($EtCO_2$), and partial pressure of carbon dioxide (P_aCO_2). For the majority of studies, there was no statistically significant difference reported with any physiological measures, except for a statistically significant decrease in $EtCO_2$ when using a speaking valve.[24] Two participants recorded a large decrease in their HR with use of speaking valves (100 vs 10 beats min^{-1}, and 89 vs 32 beats min^{-1}),[22] although this significant

Table 2
Study design and demographics

Authors	Study design	Study overview	Participant characteristics	Research setting	Inclusion/ exclusion criteria	Outcome measures
Barraza et al. (2014)[21]	Prospective case-control study	To evaluate the safety of SV overnight while sleeping	*n* = 9 2–11 years Mean age: 5.6 years	Paediatric inpatient setting	Inclusion: tracheostomy > 48 h, patent upper airway, alert and responsive, no acute respiratory tract infection	RR; HR; SpO_2; $EtCO_2$;
Dettelbach et al. (1995)[12]	Prospective descriptive study	To assess the benefits of SV in decreasing aspiration	*n* = 11 43–85 years Mean age: 65.9 years	Adult inpatient setting	Inclusion: partial laryngectomies, laryngeal innervation defects, central neurological disease Exclusion: no evidence of aspiration, not a candidate for modified barium swallow	Aspiration of thin, thick and pureed consistencies (VFSS)
Elpern et al. (2000)[14]	Prospective descriptive study	To assess the benefits of SV in decreasing aspiration	*n* = 15 32–84 years Mean age: 60.0 years	Multi-centre study, two acute care hospitals, one rehabilitation hospital	Inclusion: ≥ 18 years Exclusion: need for mechanical ventilation, inability to tolerate cuff deflation, compromised upper airway patency	Aspiration of thin liquid (VFSS)
Freeman-Sanderson et al. (2016)[26]	Prospective randomized clinical trial	To examine the effects of targeted early communication	*n* = 30 adults Mean age: 60 years	Adult ICU	Inclusion: tracheostomy > 48 h, mechanical ventilation, $FiO_2 < 0.4$, PEEP < 10 cm H_20, awake and obeying commands Exclusions: bulbar palsy, unable to tolerate cuff deflation, brainstem stroke, recent head and neck surgeries	Time to phonation, duration of tracheostomy cannulation (days), duration of mechanical ventilation, length of ICU and hospital stay, time to oral intake, quality of life (VASES and EQ-5D)
Leder et al. (1999)[16]	Prospective descriptive study	To assess the incidence of aspiration with and without SV	*n* = 20 44–86 years Mean age: 67.8 years	Large tertiary teaching hospital	Inclusion: tracheostomy tube; non ventilator-dependent, documentation of aspiration by FEES, no prior use of SV, ability to tolerate SV without oxygen desaturation, > 2 days use of SV with intelligent production, no motor speech disorders, no surgery of upper aero-digestive tract (except tracheostomy)	Aspiration of liquid and pureed consistencies (FEES)
Lichtman et al. (1995)[25]	Prospective observational study	To quantify if the use of SV will result in decreased secretions, increased arterial oxygenation and increased olfaction	*n* = 8 31–76 years Mean age: 56.6 years	Tertiary institution	Inclusion: ≥ 18 years, tolerate wearing SV > 3 h, able to follow oral directions, no unstable medical, neurological or cardiac conditions, no use of activase, streptokinase, coumadin, warfarin or other thrombolytic agents, able to tolerate cuff deflation and blue dye swallow evaluation	24 h secretion accumulation (mL); SpO_2; pH, $PaCO_2$, PaO_2, HCO_3, SaO_2; olfaction
Manzano et al. (1993)[22]	Prospective observational study	To assess whether communication capabilities of ventilator-dependent patients are improved by the use of a one way SV	*n* = 10 20–67 years Mean age: 56.3 years	University hospital, ICU	Inclusion: ability to eliminate secretions and maintain an unobstructed airway, adequate gas exchange while ventilated with an FiO_2 of ≤ 0.4, $PaCO_2$ of ≤ 55 torr, normal haemodynamics without the need for vasopressors, and normal mental state	Communication; RR; $PaCO_2$; PaO_2; HR; SBP; sense of well-being; tracheal secretion; olfaction
Ongkasuwan et al. (2014)[19]	Prospective case-control study	To determine if SV decreases laryngeal penetration and aspiration in tracheostomised children	*n* = 12 3 months – 9 years Mean age: 2.2 years	Not documented	Inclusion: able to tolerate SV	Aspiration of thin and pureed consistencies during a modified barium swallow, graded on an 8-point penetration-aspiration scale
Passy et al. (1993)[23]	Prospective study	To assess the effectiveness of speech with one way SV in ventilator-dependent patients	*n* = 15 6–65 years Mean age: 35.0 years	Not documented	Inclusion: ventilator-dependent patients, using SV for > 4 h per day Exclusion: severe acute patients	Speech/ communication (subjectively assessed); tracheal secretions; emotional status; olfaction; SpO_2

(*continued on next page*)

Table 2 (*Continued*)

Authors	Study design	Study overview	Participant characteristics	Research setting	Inclusion/ exclusion criteria	Outcome measures
					requiring 24 h assisted control ventilation with cuffed tracheostomy tubes	
Prigent et al. (2012)[28]	Prospective observational study	To assess upper airways and tracheostomy tube flows during swallowing and the breathing-swallowing interactions with and without a SV	*n* = 8 29–62 years Mean age: 44.3 years	Outpatients from home ventilation service	Inclusion: tracheostomy with cuffless tube for > 6 months, used a SV, ate without ventilation assistance, clinically stable	Tracheal and nasal airflow (pneumotachograph); and tracheal pressure (pressure transducer); swallowing function including: duration of swallow (s); number of swallows per bolus; number of ventilator cycles per bolus; percentage of swallows followed by expiration
Srinet et al. (2015)[15]	Prospective consecutive cohort study	To investigate the biomechanical effect SV on movement of the hyoid bone and larynx during swallowing	*n* = 10 61–89 years Mean age: 71.2 years	Not documented	Inclusion: ≥ 18 years, English speaking, ability to tolerate changing to a Blom tracheostomy tube and tolerating a SV with a fully deflated cuff	Larynx to hyoid bone excursion during swallowing (VFSS)
Stachler et al. (1996)[17]	Prospective study	To assess the presence and amount of aspirate with and without a SV in place	*n* = 11 Mean age: *unable to be calculated*	Not documented	Inclusion: tracheostomised patients suspected for aspiration, tolerate a plugged tracheostomy tube for short periods	Aspiration (VFSS)
Suiter et al. (2003)[13]	Prospective study	To assess the effects of SV on aspiration and swallow physiology	*n* = 18 19–80 years Mean age: *unable to be calculated*	Acute care hospital	Inclusion: non-ventilator dependence, ability to tolerate cuff deflation during VFSS, no surgery to upper aerodigestive tract except for tracheostomy, no history of oropharyngeal cancer or stroke, at least occasion of aspiration on thin liquid or puree	Aspiration (8-point penetration-aspiration scale); swallow duration (s); hyolaryngeal excursion (mm); residue
Sutt et al. (2015)[10]	Retrospective audit	To assess the effect of the introduction of in-line tracheostomy SV on the duration of mechanical ventilation	*n* = 56 pre-implementation, Mean age: 58.5 years *n* = 73 post implementation Mean age: 59.0 years	Cardiothoracic ICU	Inclusion: all tracheostomised patients in a 2-year period	Duration of MV (days); ETT duration (days); TT duration (days); TT insertion to SV (days); SV to decannulation (days); TT to first oral intake (days)
Sutt et al. (2016)[24]	Prospective observational study	To assess end expiratory lung impedance with use of SV	*n* = 20 Mean age: 60 years	Cardiothoracic ICU	Inclusion: tolerated SV for > 30 min, mechanically ventilated or spontaneously ventilating Exclusion: significant language or cognitive deficits, not suitable to wear an EIT belt	End expiratory lung impedance (EIT – lectrical impedance tomography), HR, RR, $EtCO_2$, SpO_2
Sutt et al. (2017)[27]	Prospective observational study	To determine changes in ventilation distribution with use of SV	*n* = 20 Mean age: 60 years	Cardiothoracic ICU	Inclusion: tolerated SV for > 30 min, mechanically ventilated or spontaneously ventilating Exclusion: significant language or cognitive deficits, not suitable to wear an EIT belt	EELI distribution and tidal variation (TV), alveolar recruitment (VSA – ventilated surface area and RVD – regional ventilation delay)

Abbreviations: SV – speaking valve; HR – heart rate; RR – respiratory rate; PaO_2 – partial pressure of oxygen; $PaCO_2$ – partial pressure of carbon dioxide; $EtCO_2$ – end tidal carbon dioxide; SpO_2 – peripheral oxygen saturations; FEES – fiberoptic endoscopic evaluation of swallowing; SaO_2 – arterial oxygen saturations; FiO_2 – fraction of inspired oxygen; HCO_3 – bicarbonate; TT – tracheostomy tube; VFSS – videofluroscopic study of swallowing; MV – mechanical ventilation; ICU – intensive care unit.

Table 3
Results from included studies

Authors	Results	Conclusion	Favours
Barraza et al. (2014)[21]	No significant differences occurred in RR, HR, SpO_2 or $EtCO_2$ with speaking valve in situ while asleep No adverse events occurred while sleeping with speaking valve in situ	Speaking valves can be safely used during sleep in children with tracheostomy tubes.	Not statistically significant
Dettelbach et al. (1995)[12]	Aspiration of all consistencies was reduced when participants had speaking valve in situ	Speaking valves reduces, or eliminates aspiration in patients with tracheostomies	Intervention group
Elpern et al. (2000)[14]	Aspiration was significantly reduced with speaking valve in situ (6.9 % vs 29.5%) $p = 0.016$	The speaking valve is a simple inexpensive option to reduce aspiration in patients with tracheostomies.	Intervention group
Freeman-Sanderson et al. (2016)[26]	Speaking valves significantly hastened return to phonation (median difference 11 days, $p = 0.001$), no difference in decannulation time, mechanical ventilation time, length of stay, or time to oral intake, adverse events, or quality of life	Speaking valves hastens return to phonation in mechanically ventilated patients	Intervention group
Leder (1999)[16]	Aspiration was eliminated in seven out of 20 patients with use of speaking valve ranging from 2 to 7 days	Speaking valves reduced aspiration in some patients, but no difference in the length of time with speaking valve use	Intervention group
Lichtman et al. (1995)[25]	While wearing the speaking valve, patients accumulated fewer secretions (74.3 +/− 63.6 mL vs 122.8 +/− 44.6 mL) and improved olfaction accuracy (28.4 +/− 5.2 vs 8.1 +/− 2.9%). There was no significant difference in oxygen saturation and arterial blood gases with and without the speaking valve	Speaking valves demonstrate significant secondary benefits, including a decrease in total secretions accumulated and improved olfaction.	Intervention group
Manzano et al. (1993)[22]	The speaking valve was effective in improving communication in 8 out of 10 participants. Cardiorespiratory changes were insignificant; but there was subjective improvement in well-being, and reduction in secretions.	The speaking valve allows ventilator-dependent patients to talk and communicate without assistance. Participants had improved well-being and were motivated to participate in their own cares.	Intervention group
Ongkasuwan et al. (2014)[19]	Laryngeal aspiration and penetration was reduced in pureed consistencies compared with thin liquid, but there was no difference with or without the speaking valve. There was a decrease in piriform sinus residue with the presence of the speaking valve.	Speaking valves did not decrease laryngeal aspiration or penetration in children with tracheostomies, but did improve piriform sinus residue.	Not statistically significant
Passy et al. (1993)[23]	All patients had a subjective improvement in speech, including improvements in intelligibility, volume, and quality. Nursing staff also reported that patient had a decreased need for suctioning, and 9 out of 15 reported improvements in energy levels. 14 out of 15 also had improvements in olfaction with the speaking valve in place. There was no significant difference in oxygen saturations with or without the speaking valve.	The speaking valve is a safe adjunct to improving communication in ventilator-dependent patients. Improvements in the patients energy levels and emotional state, in additional to a decrease in oral and nasal secretions, has given patients a feeling of independence resulting in improved physical and mental health, improved dietary intake, and a better outlook on life.	Intervention group
Prigent et al. (2012)[28]	Without the speaking valve a significant part of the expiratory flow leaked through the tracheostomy tube. The speaking valve increased the expired volume through the upper airways after swallowing, which was negligible without the speaking valve. The duration of swallowing, number of swallows and number of ventilator cycles did not differ with or without the speaking valve.	The use of a speaking valve should be offered routinely during periods off mechanical ventilation to facilitate expiration through the upper airways after swallowing and to decreased the risk of aspiration or laryngeal penetration.	Intervention group
Srinet et al. (2015)[15]	No difference was found for laryngeal excursion or hyoid bone displacement during swallowing with or without a speaking valve. Aspiration status was also unchanged by use of speaking valve.	These results do not support the placement of a one-way speaking valve to reduce prandial aspiration.	Not statistically significant
Stachler et al. (1996)[17]	Patients aspirated significantly less with the speaking valve on, than with the tracheostomy open.	Speaking valve may help keep patients in the best physical, nutritional and respiratory status possible. The use of a speaking valve could facilitate earlier enteral feeding with a smaller risk of aspiration.	Intervention group
Suiter et al. (2003)[13]	Cuff inflated vs deflated had no effect on penetration or aspiration. Speaking valves significantly reduced scores on the penetration-aspiration scale for liquid bolus.	Patients who are able to tolerate cuff deflation and speaking valves, may benefit from eating with a speaking valve in place. Tracheostomised patients who are unable to tolerate thin liquids may be able to safely take thin liquids when a speaking valve in place.	Intervention group
Sutt et al. (2015)[10]	In-line speaking valves did not negatively impact on duration of mechanical ventilation and led to a significant increase in time where verbal communication was possible. There was no significant difference in time to first oral intake, however modification of fluids was less frequent following the introduction of in-line speaking valves.	The use of in-line speaking valves allow verbal communication sooner and improved oral intake, with no adverse effect on ventilation times.	Intervention group
Sutt et al. (2016)[24]	Speaking valves result in significant increase of EELI (mean increase by 83.6% from baseline, $p < 0.001$). $EtCO_2$ and RR significantly decreased with speaking valve in situ. No change to SpO_2.	Speaking valves do not cause derecruitment of the lungs. Speaking valves may facilitate lung recruitment during and after use	Intervention group
Sutt et al. (2017)[27]	Use of speaking valves result in increases in EELI uniform across all lung sections ($p < 0.001$), TV significantly improved above baseline ($p < 0.001$). No significant changes to VSA and RVD.	The use of a speaking valve does not lead to hyperinflation	Intervention group

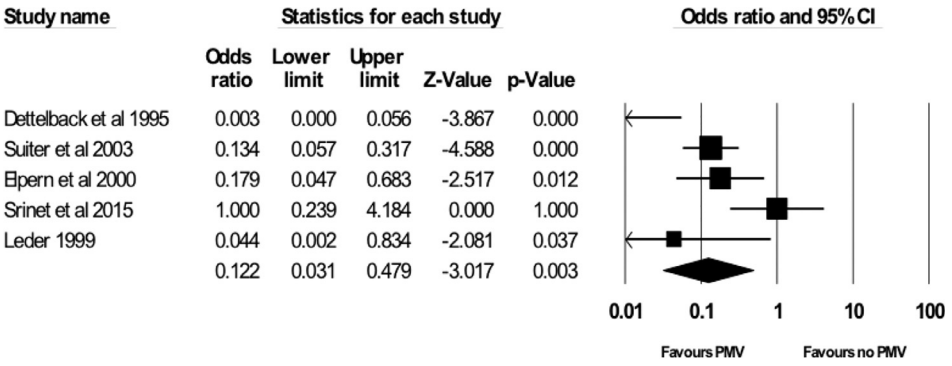

Fig. 2. Instances of aspiration with and without one-way speaking valve.

change was not reported in their study and not documented as an adverse event. No studies reported adverse events with use of speaking valves, and only one participant reported intolerance of the speaking valve, necessitating its removal.[22]

Olfaction

Changes in olfaction with use of speaking valves was investigated in three studies.[2,22,23] The first study[22] looked at whether participants had a regained a sense of smell whilst using the speaking valve, and found that at 1 week after using the speaking valve, 80% of participants regained a sense of smell. Subjective improvements in olfaction,[23] and statistically significant improvements in olfaction accuracy[25] were also reported.

Secretion management

Secretion management, including 24-h secretion accumulation[3] and number of tracheal suctions required[22,23] with and without a speaking valve, were investigated in three studies. The first study[25] demonstrated a statistically significant reduction in secretion accumulation with speaking valve in situ. Similarly, it was subjectively reported that there was a decreased need for suctioning when the speaking valve was in situ.[22,23]

Weaning

Weaning from mechanical ventilation was investigated in two studies.[10,26] The first study[10] conducted a retrospective audit following the implementation of a speaking valve, and found that the use of a speaking valve did not negatively impact the duration of mechanical ventilation time. The use of speaking valves was also found to shorten the length of mechanical ventilation by a median of 1 day,[26] though this was not statistically significant. In addition to weaning from mechanical ventilation, weaning of the tracheostomy tube was also improved with use of speaking valves by a median time of 1 day, but again was not statistically significant.[26]

Ventilation

Resting ventilation was investigated in two studies[24,27]using measurements of end-expiratory lung impedance (EELI) to indicate changes in ventilation. EELI was measured by means of electrical impedance tomography (EIT), with an increase in EELI indicating an increase, or recruitment of alveolar units. In the first study,[24] the results demonstrated significant increases in EELI, of up to 120% from baseline, during 30 min of quiet breathing, while using a speaking valve. The second study,[27] used a data analysis tool (EIT Data Analysis 6.1) to investigate ventilation distribution. This study demonstrated a uniform increase in ventilation across all lung segments, indicating that hyperinflation was not occurring.

ICU and hospital length of stay

Length of ICU and hospital stay following the implementation of speaking valves was only investigated in one study. This study showed no statistical difference in either hospital or ICU length of stay with the use of a speaking valve.[26]

Quality of life

The *Visual Analog Self Esteem Scale* (VASES) for communication quality of life, and the *EuroQol-5D* questionnaire (EQ-5D) for general health status was used to examine quality of life.[26] Whilst seven out of eight domains of the VASES and the mean difference in EQ-5D scores favoured the use of a speaking valve, these results were again not statistically significant.[26]

Discussion

Whilst the one-way speaking valve was initially developed in 1985 to enable speech and enhance communication, further studies have since assessed its benefits across various physiological and clinical domains. As such, this systematic review is the first to formally assess these additional benefits of using a speaking valve in terms of outcome measures such as swallowing and aspiration, secretion management, physiological measures, olfaction, weaning, ventilation, ICU and hospital length of stay, and quality of life. Although there were disparities in reported benefits in the literature, the most notable outcomes were in the domains of swallowing and aspiration where the use of a speaking valve reduced aspiration in tracheostomised patients (Fig. 2).

Other notable outcomes were the significant improvements in EELI, an indication of ventilation.[24,27] This suggests an improvement in ventilation by up to 120% from baseline following 30 min of using a speaking valve, and furthermore the presence of speaking valve did not cause de-recruitment or over-distention,[24,27] a previous concern in the literature.

A number of limitations were identified in this review, including the small number of studies, low subject numbers, and heterogeneous populations. Heterogeneity is often observed in systematic reviews, and this was evident for this investigated topic. In this report, heterogeneity was related to baseline characteristics of the subjects, including age, primary diagnosis, and length of time with tracheostomy prior to use of a speaking valve, and each of these factors can greatly affect the outcomes under investigation due to physiological changes that occur with aging, underlying swallow pathology, and the altered anatomy, disuse and desensitization that

occurs with the presence of a tracheostomy.[28] Although speaking valves are widely used in ICUs worldwide, these are only suitable for small percentage of ICU patients. Hence, it is difficult to gain strong evidence to support its full utility unless large multicentre randomized trials are conducted.

From a clinical perspective, many patients utilise a speaking valve primarily to enhance speech and communication, but may in fact be improving other physiological and clinical parameters. Whilst the evidence to date is not strong to support these, all the studies favoured the intervention group or reported improvements that were not statistically significant. None of the studies reported negative clinical outcomes when subjects were using a speaking valve, suggesting that along with the potential psychological benefits of using a speaking valve, they may provide improvements in other clinical areas. Additionally, if the evaluation of the benefits for speaking valves were focused on the additional utilities rather than just communication, this may help build a stronger evidence base.

It should also be noted that although very few adverse outcomes were reported, the definition of an adverse event was not well defined in any of the studies. An example of this is the study in which two subjects experienced large decreases in their HR while using a speaking valve.[22] This was not reported as an adverse event despite their recorded HR being well below the normal range. Another study[23] reported that 9 out of 15 participants required an increase in their tidal volume, and 7 out of 15 participants required an increase in their inspiratory pressure on the ventilator settings to maintain adequate oxygenation when using the speaking valve, and that all participants required a $>$ 50% increase in inspiratory volume to maintain peak inflation pressure.[22] These changes were considered within normal practice for use of a speaking valve; however, some may consider these adverse events necessitating major ventilator changes to maintain optimal clinical status.

Another limitation of this review is the limited ability to generalise the study results to a range of clinical patients. An example of this is the assessment of safety with speaking valves during sleep. It has previously been recommended that speaking valves should only been used while patients are awake as they may cause increased work of breathing trying to exhale around the tracheostomy tube. Only one study[21] assessed safety with speaking valves during sleep, and although there were no adverse events, the study only assessed children less than 9 years of age, with a stable clinical status, and during one 8-h period of sleep. This study also did not collect data on the quality of sleep, and although the results from this study reported that speaking valves appeared to be safe during sleep in this specific clinical group, it cannot be recommended that speaking valves are safe for use while sleeping across all populations.

Future studies should therefore address the limitations of the current literature. In addition, the overall well-being of patients with speaking valves has not been adequately assessed. It is hypothesised that with improved communication, the patients' overall well-being would also improve. Although there were reported improvements in the participants well-being,[22,23] this was only subjectively commented on by either nursing staff or the patient, and not quantified in any quality of life outcome measures. The only study to comment on objective improvements in quality of life[26] favoured the intervention group across the domains on the VASES and the EQ-5D. Studies relating to overall physiological improvements which result in reduced ICU and hospital length of stay and/or a reduction in overall healthcare costs would be of interest to stakeholders. However, this has not yet been widely examined in the literature. Length of stay was only investigated in one study,[26] and whilst it did address both quality of life and length of stay outcomes, the study was underpowered with a small sample of only 15 participants and not statistically significant.

Conclusion

The results were not statistically significant for the majority of outcome measures including physiological measures, weaning, quality of life, and length of stay. However, statistically significant results were found for improvements in ventilation and ventilation distribution, olfaction and secretion management. A meta-analysis was only possible for comparing aspiration across five studies, and this remains the only outcome with a statistically significant result. Further studies evaluating physiological and clinical outcomes with the use of a speaking valve could provide a strong evidence base for implementation in a variety of clinical settings, particularly across the domains of ventilator and tracheostomy weaning, ventilation, and ICU and hospital length of stay which have to potential to reduce healthcare costs.

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