

e-Table 1: Characteristics of the included studies

Lead author, year of publication	Setting	Study design and number of participants	Aims/Purpose	Outcome	Comments/Conclusion
Liberation of Ventilation					
Bach, 1996[1]	Ventilatory Unit, United States of America	Prospective observational (n=49)	To prospectively compare parameters that might predict successful extubation or tracheostomy tube removal.	49 decannulation attempts were made on 37 patients- 25 was successful on the first attempt and 7 on second attempt. Peak cough flow of >160L/min (assisted or unassisted) was predicting decannulation success (p=0.001).	Patients with the ability to sufficiently increase intrathoracic pressure and glottic control to generate higher peak-cough flows are more likely to be successfully decannulated, even in ventilatory insufficiency.
Carlucci, 2009[2]	Respiratory Intensive Care Unit (ICU), Italy	Physiological study (n=30)	To assess the determinants of weaning success in difficult-to-wean patients, once liberated from the ventilator.	16 (53%) patients were successfully weaned; average time to liberation was 11.4 days. Those patients had statistically significant differences in respiratory rate (26 v 32bpm, p=0.01), reduced tension-time index of diaphragm (0.21 v 0.4, p=0.008), and increase in	Weaning success is more likely in those with increase in the force-generating capacity of the diaphragm. Improving diaphragmatic strength may improve weaning success.

				maximal transdiaphragmatic pressure (34.9 v 43, p=0.02).	
Ceriana, 2003[3]	Respiratory ICU, Italy	Prospective interventional (n=72)	To assess the feasibility of following a decisional flowchart, based on clinical and physiological parameters, to decide whether to remove tracheostomy in long-term (>10 days) mechanically ventilated patients.	Used a decisional flow chart based on clinical and physiological parameters. 78% were decannulated, 3.5% required emergency intubation within the first three months. Tube downsizing, use of mini-tracheostomies and tube capping were used as steps towards decannulation.	Decisional flowcharts can be used for most patients to determine readiness for decannulation.
Corley, 2017[4]	ICU, Australia	Randomised crossover study (n=20)	To examine high flow tracheal oxygen effects on lung volumes, airway pressure, ventilation, respiratory rate, heart rate and	Cuff deflation resulted in improved SpO ₂ /FiO ₂ ratio and PaO ₂ /FiO ₂ ratio when comparing high flow therapy and T-piece ventilation (p<0.02). Mean airway pressure was higher using high flow therapy at 15 minutes but not 5 minutes (p=0.01). There was no	High flow therapy could be used in augmenting oxygenation in patients weaning from prolonged mechanical ventilation (MV).

			subjective dyspnoea.	difference in cardio-respiratory parameters of reported dyspnoea.	
Domingues, 2014[5] (Abstract)	semi-intensive care unit, Brazil	Prospective, pre and post - pre-intervention (n=15) - post-intervention (n=18)	To evaluate if a standard protocol can reduce the time spent on weaning in tracheostomised patients using Bi-level mechanical ventilation.	Used a weaning protocol, which included daily evaluation of readiness for weaning, and increasing time on T-piece each day. Pre-intervention group had a longer time to weaning compared to the post-intervention group (mean of 11 v 4 days, p=0.003).	Weaning guided by protocol can lower the time spent in weaning for those with prolonged ventilation. Limited by abstract only.
Fagoni, 2018[6]	general and neurological ICU, regional university-affiliated hospital, Italy	Parallel randomised controlled pilot trial - intervention (n=27) - control (n=38)	Assess the feasibility and safety of a nurse-led weaning protocol compared to weaning based on physician's clinical judgement in tracheostomised critically ill patients.	No difference in timing of weaning, start of weaning, success of weaning, or clinical stability/respiratory performance. Control group patients weaned by physician-led clinical decisions were more likely to be discharged from the ICU on a ventilator (relative risk 1.5; IC 95% 1.14-2.01). Significant difference in those discharge to ward weaned (45% control v 77% protocol, p=0.031).	Nurse-led weaning protocols is feasible and safe, with no change in outcomes or weaning success. Risk of being discharged from ICU while still ventilator was higher in control group (physician-led clinical-judgement led).
Gonzalez, 2017[7]	Spain	Prospective observational (n=10)	To determine the effectiveness of the Heat Moisture	All patients had increased inspired air humidity after one hour of use of HME-	HME-booster system is effective to maintain adequate humidification in

		- no comparator	Exchange (HME)- Booster system to humidify inspired air in patients on MV.	Booster system, with no failure, based on secretion quality.	tracheostomised ventilated patients.
Haberthur, 1999[8]	Medical ICU, university teaching hospital, Switzerland	Prospective clinical study (n=10)	To determine tracheostomy tube-related additional work of breathing in critically ill patients and to show its reduction by different ventilator modes.	In Continuous Positive Airway Pressure (CPAP) ventilation, tracheostomy additional work of breathing was higher than when using Automatic Tube Compensatory (ATC) or Inspiratory Pressure Support modes. It was also higher in high ventilation group.	Tracheostomy tubes can cause significant additional work of breathing at higher flow rates, and automatic tube compensation is a suitable mode to reduce work of breathing.
Hoffman, 2006[9]	Subacute medical ICU, university-affiliated hospital, United States of America	Prospective interventional study (n=192) - physician/nurse team (n=98) - physician only team (n=94)	To compare outcomes in a prolonged mechanical ventilation when medical management was provided by an attending physician and either 1) unit-	Compared weaning outcomes comparing management by attending physician and either (a) acute care nurse practitioner or critical care fellows providing rotation coverage. There were no differences between the cohorts. There was no difference in ICU length of stay (13 v 11 days, p>0.21), days of mechanical ventilation (11 v 10 days, p>0.47), weaning success at discharge or transfer	Acute care nurse practitioners (collaborating with attending physician) can provide safe and effective care to long-term ventilated tracheostomised patients. Outcomes were equivalent between care provided by acute care

			based acute care nurse practitioner, or 2) critical care/pulmonary fellows who rotated coverage.	(42% v 46%, $p>0.44$), or rates of re-admission. Uni- and multi-variant analysis was completed.	nurse practitioner and by fellows.
Joseph, 2013[10]	Surgical, burns, neurosurgical ICU, university-affiliated hospital, United States of America	Prospective observational (n=24) - comparator-data while intubated compared	Compare the effects of tracheostomy versus endotracheal tube on dead space, airway resistance and other lung parameters in critically ill ventilated patients.	Compared data from a single group of patients with a) endotracheal tubes, or b) tracheal tubes. When comparing endotracheal tubes to tracheostomy tubes, here was no significant change in airway resistance (12 v 10cmH ₂ O/litres/second, $p=0.07$), static or dynamic lung compliance ($p>0.42$), or average dead space volume (41 v 40%, $p=0.75$).	Tracheostomy tubes, compared to endotracheal tubes, does not affect dead space, affect compliance or other respiratory dynamics.
Lovas, 2013[11]	ICU, Hungary	Prospective observational (n=25)	To investigate the effects of breathing via T-piece on gas exchange as compared to continuous positive airway pressure	Measures of oxygenation and peripheral oxygen delivery were significant better with T-piece compared to either CPAP setting. Measures of gas exchange and haemodynamic stability did not change between the CPAP+PS and CPAP+ATC.	On the same FiO ₂ and PEEP settings, breathing via T-piece improved oxygenation and oxygen delivery compared to CPAP+PS. T-piece may be a useful tool in weaning

			with pressure support (CPAP+PS) and CPAP with automatic tube compensation (CPAP+ATC).	There was significant and gradual increase in PaCO ₂ and decrease in pH at all time points when using T-piece compared to other settings, however authors noted this can occur in any spontaneous breathing method.	from mechanical ventilation.
Mackay, 2019[12] (Abstract)	Critical care setting, United Kingdom	Pre - post intervention - pre-intervention (n=15) - post-intervention (n=19)	To assess the impact of protocolised weaning following introduction of a standardised weaning protocol.	Compared data from before and after implementation of a weaning protocol for tracheostomised patients. After implementation of the protocol, there were fewer mean days ventilated (15 v 16 days), more extubation attempts, reduced duration of tracheostomised (24 v 18 days), reduced critical care length of stay (44 v 38 days), and fewer days to first cuff deflation (20 v 11 days). There was a great proportion of days with two or more spontaneous breathing trials (19 v 44%) in the post intervention group.	Findings are suggestive that protocolised weaning can reduce time to weaning and time to first cuff deflations, however this is by abstract only publication, with insufficient data and no statistical analysis reported.
Michalopoulos, 2006[13]	Not specified, Greece	Prospective observational (n=11)	To compare the effect of different T-piece system arrangements on	Assessed different configurations of the T-piece, Venturi valve and mixing tube. Mean partial pressure of oxygen to fraction of inspired oxygen (PaO ₂ /FiO ₂)	Placing the mixing tube between the T-piece and Venturi valve improves

			arterial oxygenation in tracheostomised spontaneously breathing patients.	was significantly higher when the mixing tube was placed between the t-piece and Venturi valve (p=0.001).	PaO ₂ /FiO ₂ ratio compared to other configurations.
Mitaka, 2018[14]	ICU, Japan	Case Reports (n=2)	To discuss in two cases in which respiratory support with high flow oxygen via tracheostomy proved useful for weaning from prolonged mechanical ventilation.	Reports two case studies where high flow therapy was used in restrictive pulmonary function to aid in weaning from mechanical ventilation.	High flow therapy may increase alveolar ventilation, reduce work of breathing and aid in clearing upper airways of expired air and reduce dead space.
Natalini, 2014[15] (Abstract)	University-affiliated hospital, Italy	Randomised controlled cross-over trial (n=17)	To assess the effects of high flow oxygen therapy delivered through a tracheostomy on arterial blood gases and endotracheal	Applied high flow oxygen therapy at different flow rates for 20-minute periods. Flow rate from 10 to 30L/min was associated with increased PaO ₂ /FiO ₂ (p<0.001), PaO ₂ (p<0.001), and oxygen saturations (SaO ₂) (p<0.001), but not improved further at a flow rate of 50L/min. It also increased mean	High flow oxygen therapy can be used to improve oxygenation when used at high flow rates, however, does not affect carbon dioxide level or respiratory rate. Suggests that high flow therapy may provide

			pressure in critically ill adults.	endotracheal and mean expiratory pressures at all flow rates ($p < 0.001$). Change in oxygenation was not correlated with change in pressure. There was no effect on respiratory rate or partial pressure of carbon dioxide (PaCO_2).	significant clinical benefit. Limited by abstract only.
Pattani, 2014[16]	ICU, United Kingdom	Randomised, controlled trial (pilot) - spontaneous ventilation group (n=25) - reducing support group (n=25)	Compare two protocolised weaning techniques used on an intensive care unit in patients with a tracheostomy inserted primarily for weaning purposes.	Compared weaning using (a) increasing periods of spontaneous breathing trials, and (b) reducing pressure support. There was no statistically or clinically significant difference in length of time to weaning, or those who failed to wean. There was no difference in ICU or hospital length of stay, or in mortality.	Protocolised nurse-led weaning is safe and cost-effective. There was no difference between the methods of increasing period of spontaneous breathing, compared to reducing pressure support.
Thomachot, 1998[17]	ICU, France	Prospective (n=10)	Comparison of three different types of humidification system in spontaneously breathing,	Comparison between 1) heated humidified system, 2) cold humidifier system, 3) heat and moisture exchanger. Heated humidifiers and HMEs provided adequate humidification and thermic capacity. Cold humidifier was significantly lower performance ($p < 0.001$)	Heated humidified system and HMEs provide adequate humidification and thermic capacity, while the cold-humidifier system was performed

			tracheostomised ICU patients.	with absolute humidity below accepted parameters in 50% of patients.	inadequately in 50% of patients.
van der Lely, 2006[18]	Medical-Surgical ICU, Netherlands	Retrospective audit (n=129)	To determine time to wean from mechanical ventilation and time spent of the ventilator per day after tracheostomy in critically ill patients.	7% of admitted patients received a tracheostomy, at a median of 8 days after admission. Median time to weaning was 5 days, but was significantly shorter for neurosurgical, neurology, and cardiology patients (p<0.05). By day 7, 77% of neurosurgical and 66% of cardiology patients were weaned, compared to 34% of medical and 41% of surgical patients.	Time to wean differs significantly between patients' subgroups. Patients who are tracheostomised purely for airway protection wean more rapidly those whose tracheostomised for other indications.
Cuff Management					
Allam, 2019[19] (Abstract)	Surgical ICU, South Africa	Two-cycle clinical audit - pre-intervention (n=50)	To identify and improve on any deficiencies identified in endotracheal tube	Compared outcomes before and after implementation of an education intervention with poster, presentation, increased accessibility of manometers. Pre-intervention, 32% (n=16) of cuff	Improved education and availability of manometers improves adherence to safe cuff pressures and monitoring.

		- post-intervention (n=50)	and tracheostomy cuff pressure monitoring.	pressures were in range. In the post intervention group, 80% (n=40) were in range.	
Bach, 1990[20]	Pulmonary rehabilitation Unit, United States of America	Prospective interventional (n=104) - no comparator	To determine if non-invasive blood gas monitoring could be useful in evaluating the efficacy of intermittent positive-pressure ventilation with deflated cuffs or cuffless tracheostomy tubes during sleep.	Assessed the effectiveness of intermittent positive pressure ventilation on long-term tracheostomised patients. 91 of 104 patients (87%) were converted from positive pressure ventilation with inflated cuff, to deflated cuffs (n=28, 26%) or cuffless tubes (n=63, 60%). Based on oxygen saturations, this was well tolerated without any significant desaturations during sleep.	Most tracheostomised patients with severe respiratory insufficiency and can be safely and adequately ventilated up to 24h a day with cuffs deflated or removed.
Callon, 2019[21] (Abstract)	ICU, United Kingdom	Retrospective audit -post-intervention (n=17) - comparator-pre	To determine whether trials of cuff deflation as early as possible decrease tracheostomy days and lead to timelier decannulation.	Compared outcomes before and after implementation to promote early cuff deflation. There was a significant decrease in mean number of days between insertion and cuff deflation (p=0.043), mean number of tracheostomy days (38 v 16 days,	Limited as abstract only with inadequately described intervention.

		intervention (13)		p=0.015), mean length of ICU stay (45 v11 days, p=0.028).	
Ceriana, 2006[22]	Respiratory ICU, Greece	Prospective observational (n=13)	Examine whether a T-piece weaning trial with a deflated tracheal cuff is associated with different inspiratory effort and ventilatory pattern that the procedure with an inflated cuff.	Patients with cuff deflated had significantly higher tidal volumes and (342 v 401mL, p=0.04), mean inspiratory flows (0.32 v 0.42L/second, p=0.02), and diaphragmatic efficiency (p=0.01) compared to cuff inflated.	Cuff deflation, compared to inflation, during T-piece trial, is associated with reduced diaphragmatic effort and improved the diaphragm's efficiency. Cuff deflation may improve weaning success in difficult-to-wean patients.
Conway, 2004[23]	Critical care, United Kingdom	Pilot cross-over trial (n=16)	To investigate the advantages and disadvantages of cuff deflation, by measuring tracheal pressure and respiratory parameters, with	Measured tracheal pressures and respiratory parameters at different cuff-inflation pressures. Small drop in end-expiratory pressure during cuff deflation during CPAP (p<0.04), however no significant impacts on cardiopulmonary parameters with cuff inflated versus deflated. No increase in subjective work	Cuff deflation results in small reductions in pressure during continuous flow positive pressure, but is associated with respiratory stability, and may allow phonation and swallow.

			cuff inflated and deflated.	of breathing. All patients were able to speak, and four able to smell.	
Hernandez, 2013[24]	ICU, tertiary hospital, Spain	Randomised trial - intervention- cuff deflated (n=94) - control- cuff inflated (n=87)	To determine the effects of deflating the cuff during disconnections from mechanical ventilation of critically ill tracheostomised patients during weaning.	When comparing cuff deflated and inflated, there was improved swallowing on drink test (68 v 38%, p<0.01), reduced time to weaning (3 v 8 days, p<0.01), reduced respiratory infection (20 v 35%, p=0.02). Cuff deflated group had longer hospital length of stay (67 v 55 days, p=0.04). In multi-variate analysis, only cuff deflation and time to first mechanical ventilation disconnection was significant.	Cuff deflation can shorten time to weaning, reduce respiratory infections and improve swallow.
Pryor, 2016[25]	ICU, tertiary hospital, Australia	Retrospective chart audit (n=113)	To determine the proportion of success on initial continuous cuff deflation, describe common clinical	Successful continuous cuff deflation was achieved on first attempt in 95% of patients. Assessed nine patient factors to be considered prior to deflation- 77% who were first attempt successful met all 9 criteria. Three key indicators (medical	Readiness for successful cuff deflation can be predicted with good specificity and sensitivity, based on three key indicators: medical

			observations associated with continuous cuff deflation success, and to explore the...value of these clinical indicators.	stability, respiratory stability and <1mL/hr above cuff aspirates) when grouped demonstrated sensitivity of 95%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 55%.	stability, respiratory stability, and <1mL above cuff aspirates per hour.
Young, 2000[26]	ICU, district general hospital, United Kingdom	Prospective open randomised controlled study (n=12)	To compare a silicone cuff (with pressure limited inflation characteristics) and the Shiley cuffed tracheostomy tubes for aspiration of dye to the trachea.	Patients randomised to Shiley cuffed tracheostomy tube or silicone cuffed tube, with blue dye instilled into subglottic space to detect aspiration. 100% of Shiley cuff tubes leaked at day one and were converted to silicone cuffed. 0% of silicone cuffed leaked during trial period (until 10 days or ICU discharge).	Silicone cuff with pressure-limited inflation characteristics may prevent macro- and micro-aspiration, more effectively than standard cuffs. There is a high incidence of leak with conventional cuff tubes.
Tracheostomy change or revision					
Donnelly, 2006[27]	ICU, Australia	Phenomenological (n=4)	Investigate the lived experience of a tracheostomy tube change, using non-structured interviews.	Four key themes relating to tracheostomy change: physical sensation, psychological preparation, trust and confidence, and essentialness of communication.	

Fisher, 2013[28]	Respiratory Acute Care Unit, United States of America	Prospective observational - early change (n=38), - late change (n=92)	Evaluate ideal timing of initial tracheostomy tube change and impact of earlier use of speaking valve and oral intake.	Compared early and late tracheostomy changes. Patients with early change before 7 days has earlier use speaking valve (7 v 12 days, p<0.001), early oral intake (10 v 20 days, p=0.04), and shorted ICU stay (11 v 17 days, p=0.001). There was no difference in decannulation. There were no complications in either group.	Early tube change (before 7 days) is associated with early speaking valve use, oral intake and ICU discharge.
Optimisation of speech and communication					
Barros, 2017[29] (Abstract)	Not specified	Cross-sectional observational (n=15)	To identify the proportion of tracheostomised patients with indication of swallowing and speaking valve use.	Quality of speech- 66% 'good' intelligibility, prosody, articulation Cuff deflation was tolerated by 100% of patients. The Blue Dye test was negative in 60% of patients, and showed small quantity aspiration in 13%, and massive quantity in 26%.	A high proportion of tracheostomised patients had an indication for swallowing/speaking valve use. Cuff deflations were well tolerated. Limited by no statistical analysis and small sample size.
Bultsma, 2014[30] (Abstract)	Mixed ICU, Country not specified	Observation study (n=10) - Intervention -BiPAP (n=5) - control-	To compare weaning from MV between cuff-deflated ventilation with use of a Bilevel	Compared outcomes for patients managed with (a) BiPAP with cuff deflation and, (b) trial of spontaneous breathing with use of a speaking valve.	The use of cuff deflation with a speaking valve during mechanical ventilation results in shorter times to speaking.

		Passy-Muir valve (n=5)	Positive Airway Pressure (BiPAP) and a Passy Muir speaking valve (PMV), or by trial of spontaneous breathing with use of a speaking valve.	3 of 5 patients in BiPAP group able to speak, compared to 1 of 5 in PMV group. BiPAP group had higher PEEP levels and higher Sequential Organ Failure Assessment scores at first time speaking. No significant difference in other outcomes.	Limited detail in abstract only.
Fernández Carmona, 2015[31] (Abstract)	7 ICUs, Spain	Pilot randomised controlled clinical trial (n=19) - intervention (n=11) -control (n=8)	Determine the usefulness of speaking valve in preventing respiratory nosocomial infections in critical tracheostomised patients diagnosed with dysphasic secondary to artificial airway.	Compared rates of nosocomial respiratory infections during weaning between (a) use of speaking valve during mechanical ventilation, and (b) standard practice. Incidence of infection was lower in speaking valve group versus standard management (18% v 37.5%), as was time to decannulation (4.4 days versus 6 days).	Speaking valve may reduce respiratory nosocomial infections during weaning phase, but insufficient data or statistical analysis to be reliable. Limited by abstract only data, with no statistical analysis provided.
Flinterud, 2015[32]	ICU, Norway	Qualitative descriptive study (n=11)	To describe the experience of tracheostomised	Universal theme: experience of caring and understanding despite having uncomfortable feelings due to	

			patients in the ICU as they attempted communication and then provide an understanding of the results.	troublesome communication. Three categories/theme identified: emotionally challenging, experience changes with time, and successful communication.	
Freeman-Sanderson, 2015[33] (Abstract)	ICU, Australia	Prospective observational (n=25)	To measure the change in self-reports quality of life with the return of voice for tracheostomy patients within the ICU.	Assessed communication-related quality of life (QOL) using a daily five-point scale, and weekly general health status scale. Significant improvement in some parameters after return of voice (cheerfulness, being understood) (mean difference of 0.8 of 5 point scale). No improvement other parameters, or in general health status.	Return of voice may improve communication-related quality of life, particularly in mood and being understood by others. Limited by abstract only.
Freeman-Sanderson, 2016[34]	ICU, Australia	Prospective observational (n=22)	Describe the changes in communication related QOL and general health status that occur with the return of voice, as reported	Used VASES and EQ-5D scoring tools to assess voice-related QOL. Found significant improvement post return of voice for "being understood" (p=0.006), "cheerfulness" (p=0.04). Other factors favoured return of voice, but not reach statistical significance. EQ-5D tool (general health status) did not	Return of voice is associated with improved patient-reported self-esteem and improves some measures of quality of life.

			by patients who have been without their voice due to the presence of a tracheostomy.	demonstrate statistically significant improvement (p=0.059).	
Freeman-Sanderson, 2016[35]	ICU, tertiary Australia	Randomised clinical trial - intervention (n=15) - control (n=15)	To compare an early communication intervention with standard therapy in ventilated tracheostomy patients in a large tertiary ICU.	Compared outcomes between (a) early cuff deflation and insertion of an in-line speaking valve during mechanical ventilation, and (b) standard cuff deflation and speaking valve during self-ventilation. Found intervention group had reduced time to phonation (7 v 18 days, p=0.001). There was no significant difference in time to oral intake, decannulation, successful weaning or ICU discharge. Improvement in quality of life favoured the intervention group without reaching statistical significance.	Early intervention for communication during mechanical ventilation improved time to return of voice, compared to standard treatment.
Freeman-Sanderson, 2018[36]	ICU, Australia	Mixed method (n=17)	To investigate the patient-reported experience of tracheostomy tube	Uses VASES and EQ-5D tools Themes identified: 1) What is happening to me? 2) It's hard communicating without a voice, 3) A storm of dark	Return of voice improves patient reported mood, outlook and sense of recovery.

			placement over time regarding change in communication function, self-esteem and health-related QOL from ICU to six months after tracheostomy decannulation and discharge home.	emotions, 4) More than a response...its participating and recovering. VASES tool showed statistically significant positive change in 'misunderstood, cheerful, mixed-up, angry, trapped" between baseline and return of voice, but no change at 6 months. EQ-5D showed no statistically significant change from baseline but was significant at six months after return of voice.	
Frohlich, 2017[37]	ICU, Germany	Quality improvement project (n=9 patients)	To ensure safe swallowing and communication for ventilated patients with a tracheostomy, using a Passy-Muir Valve (PMV).	There were 51 applications of the PMV. There were three episodes of undesirable events (dyspnoea, desaturation). Clinicians felt confident with its use.	Passy-Muir speaking valve can be used safely and effectively, with a high degree of confidence after training.

Fukumoto, 2006[38]	ICU, Japan	Case Reports (n=2)	To discuss the use of fenestrated tracheostomy tubes for the purpose of difficult to wean patients.	Discussion of two case reports of difficult to wean patients. Reported improvement in chest wall expansion and oxygenation, reported due to role of vocal cords in determining airflow, pattern of breathing and airway resistance. Reports that vocal cords prevented collapse during expiration by providing greater resistance and functional residual capacity.	Fenestrated tubes with speaking valve can be used to aid weaning in difficult to wean patients by improving pulmonary mechanics.
Garry, 2016[39]	3 ICUs, Tertiary hospitals, United States of America	Pilot prospective study (n=12)	To implement eye-tracking devices in intensive care as a communication aide and to elucidate the resulting psychosocial impact.	Used Tobii C12 eye tracking computer in addition to education sessions. All patients able to communication essential needs; 50% able to use keyboard; 25% able to have discussions. Moderately positive statistically significant effect on psychosocial status (p=0.004), particularly in area of adaptability, self-esteem. 50% had increase in frustration, with three reporting moderate or strong increases.	Eye-tracking devices can be used to improve outcomes and communication in patients with communication difficulties. It can increase frustration and stress with use.
Happ, 2014[40]	2 ICUs, university-affiliated	Quasi-experimental, 3-phase	To test the impact of two levels of intervention using	Communication frequency and positive nurse communication behaviours increased significantly after invention in	Communication interventions, including augmentative devices,

	hospitals, United States of America	sequential cohort study - patients (n=89) - nurses (n=30)	augmentative and alternative (AAC) devices on communication frequency, quality, success, and ease of communication between nurses and intubated ICU patients.	one ICU only ($p < 0.01$). Percentage of successful communication exchanges about pain were greater for the two intervention groups than the usual care/control group across both ICUs ($p = 0.03$) with more successful sessions about pain and other symptoms in the AAC + speech-language pathologist (SLP) group ($p = .07$). Patients in the AAC+SLP intervention group used significantly more AAC methods ($p = 0.002$) and rated communication as “high difficulty” less often ($p < 0.01$).	clinician education, and speech-language pathologies consultations, can improve communication frequency and quality with greater ease.
Kuduk, 2010[41]	Academic and Research hospital, Turkey	Prospective observational (n=10)	To provide first-round observations of the efficacy and safety of the Blom Tracheostomy tube and speech cannula in ventilator-dependent tracheostomised patients.	Trials with Blom tracheostomy tube and Blom speech cannula. 9 of 10 patients were able to achieve phonation, able to say intelligible short phrases or conversation. Suction was required from 0 to 8 suction times during phonation. 2 patients experienced desaturations. 1 experienced anxiety and agitation. 1 was	Blom speech cannula (in line-speaking valve) can be used for effective phonation during mechanical ventilation with some adverse effects.

				unable to tolerate with poor ventilation and stress.	
Leder, 1989[42]	University-affiliated hospital, United States of America	Prospective observational (n=10)	Assess stomal complications and airflow line problems associated with a cuffed talking tracheostomy tube.	40% of patients with Communi-Trach I tube had stomal complications within three weeks, including pressure necrosis and wound extension (from position of airflow line), and bilateral granulomas. 80% complications due to airflow line kinking.	Stomal complications can occur with the Communi-Trach I cuffed talking tube, including relating to the airflow line.
Leder, 1989[43]	Not specified, United States of America	Prospective observational (n=20)	To investigate ambient room noise levels, voice intensity at different airflow rates, and whether audible, intelligible speech is produced by cognitively intact, ventilator-dependent patients.	Using Communi-Trach I cuffed speaking tube, patients were able to phonate with significantly greater voice intensity than ambient room noise at all flow rates between 5L/min and 15L/min ($p<0.01$). Voice intensity was significantly increased at higher flow rates ($p<0.001$).	Communi-Trach I cuff speaking tube can be used for effective phonation above volume of ambient room noise of an intensive care room with ventilators in use.
Leder, 1990[44]	University-affiliated hospital,	Prospective (n=20) - comparator:	To investigate voice intensity at different airflow rates using	Compared (a) Portex Talk Cuffed speaking tracheostomy tube and (b) previous data using Communi-Trach I	Portex Talk Tube has a shorter time to phonation when compared to

	United States of America	previously published study data	the Portex Talk tracheostomy tube to determine, 1) whether audible, intelligible speech was produced...and 2) when audible, intelligible speech first occurred.	tubes. Statistically shorter time to consistently intelligible voice intensity using Portex Talk tube, when compared to Communi-Trach (2.1 v 5.6 days, $p<0.001$). No differences in mean voice intensity at three different airflow rates. Intelligible voice was present at all flow rates (5, 10, 15L/min) but optimum between 10 to 15L/min.	previously published data on the Communi-Trach I tube. Voice intensity is best at airflow rate of 15L/min.
Maistry, 2017[45] (Abstract)	Cardio-respiratory ICU in United Kingdom, and Tertiary ICU, Australia	Retrospective audit (n=25)	To audit speech-language therapy intervention with patients with a tracheostomy in a cardio-respiratory ICU in London as compared to a clinical audit in an Australian ICU.	In the United Kingdom ICU, compared to the Australian ICU, there was reduced time to phonation (7 v 16 days) and reduced time to first oral intake (12 v 15 days).	An abstract of a comparative audit of two intensive care units in United Kingdom and Australia, found reduced time to phonation and oral intake in the United Kingdom ICU. Limited by abstract only.
Maistry, 2019[46] (Abstract)	Two cardiothoracic ICUs,	Retrospective comparative audit (n=44)	To assess whether fenestrated or non-fenestrated tracheostomy tubes	Non fenestrated tubes had less time to phonate (6 v 10 days, $p=0.003$) and lower median time to oral intake (14 v 18days, $p=0.029$). There was no	Limited by abstract only with limited data.

	United Kingdom		impact speech and language therapy outcomes, by comparing two cardiothoracic intensive care units.	significant change in time to decannulation.	
Manzano, 1993[47]	ICU, university hospital, Spain	Prospective (n=10)	To determine the Passy Muir speech valve usefulness, advantages, and disadvantages during mechanical ventilation.	PMV with cuff deflation during mechanical ventilation resulted in intelligible phonation in 8 of 10 patients within 24-48 hours, with associated decreased secretions and improved well-being. With cuff deflation, patients required a >50% increase in inspiratory volume to maintain peak inflation pressures. Arterial oxygenation and respiratory rate were maintained.	Unidirectional PMV can be used with cuff deflation during positive-pressure ventilation to facilitate speech. While ventilation volumes require adjustment to compensate for cuff-deflation leak, this appears to be well tolerated.
Maringelli, 2013[48]	General ICU, Italy	Prospective comparative - patients (n=15) - physicians (n=8)	To test if a gaze-controlled computer assisted communication device will improve of communication processes, the	Use of AAC devices significantly improved in ability to communicate with medical staff and families (p<0.001), reduced anxiety and depression (p<0.001). Use of devices in additional to educational interventions resulted in nurses and physicians reporting	AAC devices can be used effective to improve patient's ability to communicate, with improvements in mood and anxiety, as well as

		-nurses (n=15)	ability of medical staff to understand the clinical condition and reduce frustration due to lack of communication.	significant improvement communication ability in a self-reported survey.	improve clinicians' ability to communicate.
McGrath, 2016[49]	General ICU, United Kingdom	Case reports (n=5)	A series of case reports on the use of subglottic suction tracheostomy tubes to facilitate speech via above cuff vocalisation (ACV).	ACV can be used in ventilator dependent patients or those unable to tolerate cuff deflation. There are potential, but not yet confirmed, benefits of laryngeal sensitisation (thereby improving airway protection and swallow strength), and secretion clearance.	Above-cuff vocalisation may be a method for communication for critically ill patients. Speech-language therapists and multidisciplinary care is important.
McGrath, 2019[50]	ICU, tertiary centre, United Kingdom	Feasibility study-prospective interventional (n=10)	Feasibility study of ACV to determine whether patients achieve a functional voice, safety of ACV and any intolerance or adverse effects, and potential	When using ACV, audible voice achieved by 8/10 patients, during 72.5% attempts. There was significant improvement in 3 of the 5 measures used to assess swallow ($p<0.04$), and improvement in secretion management ($p<0.04$). There were no complications in 72.5% of episodes; the most common complication	Above-cuff vocalisation is a safe and feasible method for facilitating communication in patients unable to tolerate cuff-deflation. Complications are rare.

			benefits for communication, secretion management and swallow.	was discomfort 11% and excessive oral secretion 10%. There no were serious complications.	
Nomori, 2004[51]	Japan	Prospective (n=16) - no comparator group	Experimental data and clinical applications of voice tracheostomy tube (with dynamic cuff inflation/deflation based on ventilatory cycle).	Patient utilising a modified voice tracheostomy tube, were able to speak (15/16 patients) without a significant change in PaO ₂ or PaCO ₂ (p=0.6). 13 patients were able to vocalise without an adjunct, two were able to use a unidirectional valve to achieve speech. There were no complications, and no mucosal damage on bronchoscopy at two weeks.	Voice tracheostomy tubes can be used to achieve phonation without significant respiratory compromise and no complications.
Pandian, 2014[52]	Six ICU and two HDUs at a single academic tertiary centre, United	Prospective longitudinal pilot study (n=5)	To explore the feasibility of measuring quality of life in awake and alert mechanically ventilated ICU patients with tracheostomy.	Comparison between one-way speaking valves or simple alternative communication tools and use of 'talking tube' with education sessions. There was an overall improvement in QOL in both groups, however a greater improvement in those using talk tube. 'Pain' and 'speech' rated as more	Patients using talking tubes had higher quality of life scores compared to those using one-way speaking valves or simple communication tools like writing. Pain and speech

	States of America			important domains in both groups. When comparing endotracheally intubated patients and tracheostomised patients, there was a higher median QOL score in those with tracheostomies.	and important factors for determining quality of life.
Pandian, 2019[53]	7 ICUs in a single large academic tertiary care centre, United States of America	Randomised clinical trial - intervention - talking tube (n=25) - control- one way speaking valve (OWSV) (n=25)	To determine the quality of life using talking tracheostomy tube.	Compared (a) use of OWSV or alternative method like communication board, iPad or writing, and (b) Blue Line Ultra Suctionaid talking tracheostomy tube and education sessions. Both groups were assessed pre- and post-intervention. There was greater positive change in QOL measures from pre to post intervention, in the talk tube group than the one-way valve group (p=0.04). Speech intelligibility test scores decreased by 6.4 points for each 1-point increase in Sequential Organ Failure Assessment score (p=0.04).	Quality of life improves more with the use of talking tube, than with one-way speaking valves, in patients who initially would not tolerate one-way speaking valves. There is a correlation between reduced speech intelligibility and severity of illness.
Sparker, 1987[54]	ICU, United States of America	Prospective (n=19)	To examine the efficacy of speaking tracheostomy tube device and to report	100% of patients with either Portex Talk tube or Communi-Track I tube were able to speak; 15 of 19 (78%) were able to utilise the device effectively for	Tracheostomy talk tubes can be used effectively for communication, with

			our personal experience.	communication. The most common issue encountered with excessive suction and cough (n=5, 26%).	adverse effects occurring infrequently.
Sutt, 2015[55] (Abstract)	Cardio-thoracic ICU, Australia	Prospective Interventional (n=20)	To assess End-expiratory lung volume distribution and abdominal to chest ratio when using speaking valve in-line with mechanical ventilation circuit of tracheostomised ICU patients.	Patients undertaking spontaneous breathing trials with using in-line speaking valves were assessed in two different modes of ventilation support. In both ventilation modes, there was a significant increase in end-expiratory lung volumes in all regions of the lungs which continued to increase post-removal of the valve (p<0.001). There was a significant increase in abdomen:chest ratio (p=0.03) indicating increased abdominal mobility.	Use of in-line speaking valve during mechanical ventilation improved recruitment of the lungs, and improved diaphragmatic activity.
Sutt, 2015[56]	ICU, Australia	Letter to the editor (n=20)	To assess whether the clinical uptake of inline speaking valves continued after the initial 'honeymoon phase' associated with original research.	Review at 3.5 years after implementation of in-line speaking valves as a standard of practice. There was a significant reduction in time to first verbal communication since introducing in-line valves (p<0.01). 70% of ventilated patients using inline SVs compared to 34%, 37% and 0% in 2013, 2012, 2011	In-line speaking valves, as a standard of practice, resulted in a sustainable change with improved time to phonation in one unit. There was an impact on variability of weaning practices.

				respectively (p<0.001). 75% of tracheostomised patients able to communicate verbally. There was no change in time to oral intake.	
Sutt, 2015[57]	Medica-surgical ICU, university-affiliated teaching hospital, Australia	Retrospective pre-post-observational study -pre-intervention (n=56) -post-intervention (n=73)	To compare tracheostomy outcomes in mechanically ventilated patients in cardiothoracic ICU pre-introduction and post-introduction of in-line speaking valves (SV).	When comparing prior to implementation of in-line speaking valves and after implementation, there was a significant decrease in time to first verbal communication (18 v 9 days, p<0.05). While time from SV to decannulation was longer in the post-intervention group, the total average time to decannulation was not significantly different. There was no difference in time of mechanical ventilation, or time to first swallowing trials.	The use of in-line speaking valves results in earlier time to verbal communication, with no increase in average time to decannulation or time of mechanical ventilation.
Sutt, 2017[58]	Cardiothoracic ICU, Australia	Prospective observational (n=20)	To determine the ventilation re-distribution created by the increased end-expiratory lung impedance demonstrated	Used electrical impedance tomography to assess end-expiratory lung impedance, tidal volume, and other indicators of ventilation, during use of in-line speaking valves. There was an increase in end-expiratory lung impedance across all lung section	In-line speaking valves improve lung recruitment across the lung without causing hyperinflation. They allow communication, without negative impact of

			previously alveolar recruitment...when using in-line speaking valves.	($p < 0.001$). Other measures on tomography were non-significant. There was significant reduced respiratory rate and end-tidal carbon dioxide.	respiratory stability or ventilation.
Tolotti, 2018[59]	ICU, Italy	Phenomenological - patients (n=8) - nurses (n=7)	To explore the communication experience of tracheostomy patients with nurses and identify which and factors made patients increased comfort or distress.	Key themes were categories into three group: Lived experience of communication, sources of discomfort, and sources of comfort Themes of similarity between patients and nurses were found.	Communication is of key importance to tracheostomised intensive care patients and cannot be underestimated. There is a shared experience of frustration between patients and nurses.
Vallès Fructuoso, 2015[60] (Abstract)	Long-stay ICU, Spain	Experimental pilot (n=10)	To evaluate the quality of communication in tracheostomised ICU patient during weaning period and to assess the importance placed on the ICU patient security related to	A questionnaire of emotional distress (SPEACS-2 tool) showed an improvement in emotional distress in 100% of patients with use of the SV. 30% did not tolerate use of SVs due to desaturation and secretions.	Communication is important in reducing emotional distress and speaking valves can be used in most patients to facilitate communication.

			communication barriers.		
Optimisation of swallow and oral intake					
Amathieu, 2012[61]	ICU, France	Prospective observational (n=12)	To study the influence of the cuff pressure on the swallowing reflex elicited in tracheostomised patients.	Used instillation of distilled cold water into the pharynx with a catheter to stimulate the pharynx. Cuff pressure was strongly correlated with laryngeal acceleration and peak activity of the submental muscles ($r^2=0.91$, $p<0.01$). Latency time was linearly related to cuff pressure ($p<0.01$).	Cuff pressure significantly influences both sensory and motor components of the swallow reflex. Latency time of swallow is linearly related to cuff pressure.

Clarett, 2014[62]	ICU, Argentina	Randomised crossover study (n=14)	To determine whether there is difference between subglottic pressure during swallowing with and without air insufflation via a subglottic catheter in tracheostomised patients.	12/14 (85%) showed higher subglottic pressure valves during swallow with insufflation by the subglottic catheter (p=0.002).	Air insufflation via the subglottic catheter increases subglottic pressure during swallowing.
Garach, 2016[63] (Abstract)	Not specified, Spain	Cross-sectional (n=26)	Compare the extended Evan's blue dye test (EBDT) in predicting artificial airway dysphagia and fiberoptic endoscopic evaluation of swallowing fiberoptic evaluation of swallow as the gold standard.	EBDT compared to Fiberoptic evaluation of swallow (as gold standard): sensitivity 84.2%; specificity 100%, positive predictive value, 100%, negative predictive value 70%.	EBDT is a simple diagnostic screening tool for dysphagia. Where Blue Dye Test is negative and there is a high clinical suspicion, fiberoptic evaluation of swallow is recommended.

Higgins, 1997[64]	ICU, Australia	Case reports (n=6)	Six cases regarding the use of Evans blue dye test for establishing the presence of aspiration.	Highlights risk of aspiration is high in tracheostomised patients. EBDT can be useful in establishing aspiration. Speech assessments often only occurred after transfer to ward, or after change to a cuffless tube (rather than before), or recommendations regarding safety for oral intake not adhered to be medical or nursing staff.	Dysphagia in tracheostomised patients is common and can result in dangerous complications. A multidisciplinary approach to decision making regarding tracheostomy management and decannulation should be used.
Pryor, 2016[65]	Tertiary hospital, Australia	Retrospective audit (n=126)	To document patterns of clinical management around the commencement of oral intake throughout hospital admission and along the decannulation pathway in patients with a new	Noted significant variation in markers of progression (cuff deflation, oral intake, decannulation and cessation of enteral nutrition) between clinical populations. 43% of patients started oral intake in ICU, with 86% managing oral intake by time of hospital discharge. 82% commenced oral intake while tracheostomy was in situ. 86% of patients were decannulation prior to hospital discharge. Of those decannulated, 33% were decannulated	Clinical sub-populations and indication of tracheostomy influences course of recovery from tracheostomy, including oral intake, cuff deflation and decannulation.

			tracheostomy, and to examine the nature of variability across multiple clinical populations.	in ICU; 61% of those were decannulation after only a cuff deflation period, without a trial of smaller or uncuffed tube.	
Rodrigues, 2015[66]	ICU, university hospital, Brazil	Prospective feasibility study (n=14) - no comparison group	To assess the feasibility of implementing an early swallowing rehabilitation program in tracheostomised patients under mechanical ventilation with dysphagia.	Implementation of a swallowing rehabilitation program including oral intake with one-way valve and oro-motor exercises. At inclusion, 4 patients had grade 1 dysphagia, and 10 with grade 2. 10/14 patients were able to receive oral intake. After the intervention (average 12 days), two grade one patients had full improvement. In grade 2 group, 40% had full improvement, while 2 had partial improvement.	Early swallowing rehabilitation programs are feasible in tracheostomised patients undergoing mechanical ventilation.
Romero, 2010[67]	ICU, university-affiliated tertiary and teaching hospital, Chile	Prospective observational (n=40)	To establish the incidence of swallowing dysfunction in non-neurological critically ill patients undergoing	38% patients had swallowing dysfunction; of these 73% were silent aspirating. There was no difference in number of days of, or duration of MV. When comparing those with swallowing difficulties and those without, there was a statistically significant difference in total	Nearly 40% of non-neurologic critically ill tracheostomised patients with prolonged mechanical ventilation have swallowing dysfunction.

			tracheostomy and to evaluate its impact in the tracheostomy decannulation process.	duration of tracheostomy tube (50 v 30 days, $p < 0.01$), and time from fiberoptic evaluation of swallow to decannulation (19 v 2 days, $p < 0.001$).	This can delay the decannulation process.
Tolep, 1996[68]	Respiratory care unit, tertiary centre, United States of America	Prospective observational (n=35) - no comparator	To evaluate swallowing function in patients who receive prolonged ventilation by defining the specific swallowing abnormalities, comparing different assessment methods, evaluating the relationship between swallowing dysfunction and neuromuscular disorders, and studying the temporal resolution.	Assessment of swallow on bedside examination, videofluoroscopy, endoscopic examination, and laryngoscopy. 34% of all patients had at least one swallowing abnormality on bedside examination. Of those, 83% had an abnormal videofluoroscopy study. 50% patients who had a laryngoscopy had laryngeal abnormalities that contributed to swallow dysfunction. At one month, most patient demonstrated significant improvement on repeat studies.	There are several methods for assessment of swallow, which can provide useful information on dysfunction. Most patients with swallowing dysfunction will have some degree of resolution at one month.

Vitacca, 2005[69]	Weaning centre, Italy	Prospective crossover randomised and physiological study (n=16)	To evaluate both physiological effects and subjective sensations induced by meals either in spontaneous breathing or in pressure support in tracheostomised difficult-to-wean chronic obstructive pulmonary disease patients.	In spontaneously breathing patients compared to PSV, there was significant increase in respiratory rate (RR) (p<0.001), end-tidal carbon dioxide (p<0.03), and subjective dyspnoea (p<0.01) during meals. In patients on pressure support ventilation (PS), there was significantly higher tidal volumes (p<0.001), lower RR (p<0.032), and lower heart rate p<0.047) when compared to spontaneously breathing patients. 18% had transient desaturations without haemodynamic instability.	In tracheostomised COPD patients, meals while spontaneously breathing may increase RR, eTCO2 and dyspnoea, while pressure support can reduce dyspnoea. There is little evidence of instability associated with meals and physiological changes are likely compensatory.
Other					
Ahmadinejad, 2014[70]	ICU, trauma centre, Iran	Double-blinded randomised clinical trial - intervention (n=40) - control (n=40)	Compare the efficacy of absorbent form with gauze dressing for prevention of tracheostomy site infection.	Assessed incidence of tracheostomy site infection comparing absorbent foam dressing and gauze. Non-significant reduction in incidence of infection- 17.5% in gauze group v 10% in foam group (p=0.051).	Use of absorbent foam does not reduce risk of stomal infection

Al Sindi, 2016[71]	ICU and Medical wards, Bahrain	Retrospective cohort study - ICU and ward-based patients (n=640)	To assess the impact of a specialised multidisciplinary tracheostomy team on tracheostomy care.	Types of tracheostomy: 41% Shiley, 57% Portex, 1% metal. 20% were decannulated, ranging from 1 months to 36 months. 12.9% had no complications, 83% had no complications documented. Most common complications were 1.7% failed decannulation, 0.9% granulation tissue formation, 0.8% tube dislodgement.	Suggests use of MDT reduces time to decannulation and complications rates.
Bahadur, 2008[72]	ICU, Urban teaching hospital, London, United Kingdom	Descriptive observational (n=30)	To define the number of occasions of sitting out of bed (SOOB) following tracheostomy formation, and to determine who was providing this type of rehabilitation.	63% SOOB, 37% did not SOOB with no statistical difference in demographic or severity scores. When comparing those who SOOB and those who did not, there was lower mortality (5% v 73%, p<0.01), and higher rates of ICU discharged (95% v 27%, p<0.05).	Sitting out of bed is associated with improved mortality and discharge from ICU. Severity of illness is not associated with likelihood of SOOB.

Blondonnet , 2014[73]	General and Neuro ICUs, France	Observational descriptive survey study (n=148 intensivists)	To survey units on their management on tracheostomised patients in and out of ICU.	Intensivists report an average duration of tracheostomy 10-21 days. 48% report high rates of successful weaning prior to discharge. 38% of units will discharge patients from ICU with tracheostomy in place. There is significant variation in protocol use between departments. Multi- disciplinary teams (MDT) and post- discharge services are rarely used in only two of 148 units.	Significant variability of practice within one country, particularly regarding indication, tracheostomy care, and care at discharge. MDTs are rarely utilised.
Bocci, 2009[74] (Abstract)	Not specified	Retrospective observational - post- intervention (n=181) - pre- intervention historical controls	Assess impact of team approach to mechanical ventilation including comprehensive tracheostomy care program to reduce mortality and length of stay (LOS).	Compared outcome before and after introduction of multidisciplinary approach including weaning protocol, daily assessment for tracheostomy, care education program for patients/families, and long-term acute care placement strategies. Decreased hospital LOS by 6.4 days and ICU LOS by 4.1 days. Reports reduced mortality by 10%.	Abstract only with limited data provided

Burns, 1998[75]	Medical/Surgical ICU, university-affiliated tertiary centre, United States of America	Quasi-experimental prospective study. - intervention (n=27) - comparator (n=33)	To determine the incidence of obstruction and colonisation...who received inner cannula changes daily versus those who did not.	Compared incidence of obstruction and colonisation of (a) inner cannula changes every 24hs, compared to (b) no inner cannula changes. There was no statistically significant difference in colonisation (p=0.13). The study identified range of bacterial species. There were no occurrences of obstruction.	Frequent inner cannula changes do not reduce colonisation or risk of obstruction.
Conley, 2013[76]	Progressive care unit, quaternary care hospital, United States of America	Prospective case control (n=75) - comparator National Health and Safety Network benchmark data	To determine the effectiveness of an oral care protocol in reducing the ventilator associated pneumonia (VAP) rate in mechanically ventilated patients with tracheostomy in progressive care unit.	Assessed incidence rate of VAP, when using twice daily application of an oral care protocol or teeth brushing and chlorhexidine solution application compared to national benchmarks. When using the oral care protocol, VAP rate was 1.1 per 1000 ventilator days (two cases), compared to benchmark rate of 1.5 per 1000 ventilator days.	Oral care protocol of toothbrushing and applying chlorhexidine solution can reduce VAP rate in tracheostomised patients. Limited by comparison to benchmark data, which includes both intubated and tracheostomised patients.

Cumpstey, 2013[77] (Abstract)	Survey of medical students, United Kingdom	Cross-sectional questionnaire survey (n=81)	Quantify the training medical students receive about tracheostomy management; increase the training on preventing and managing complications; assess the effectiveness of this training at six months.	Surveyed knowledge and confidence before and after an education intervention. Knowledge and confidence were poor prior to education intervention (70% rating 'not at all confident') but improved after education intervention. Knowledge fade was demonstrated at a six months review of knowledge.	Teaching on managing tracheostomy complication is rare and variable. Most junior doctors report poor confidence and knowledge, despite most having care for patients with tracheostomies. Limited data provided; abstract only.
Davies, 2013[78] (Abstract)	Specialised weaning centre, United Kingdom	Retrospective audit (n=458)	Audit of long-term outcomes in a specialised weaning centre including impact of referral source, non-invasive ventilation and diagnosis.	458 patients received ventilation, and 92% tracheostomised. 91% survived to discharge, while 72% weaned from ventilation. Patients with chronic obstructive pulmonary disease has the lowest rate of death and failed decannulation (13%). Non-invasive ventilation was associated with survival (p=0.01).	Specialised weaning centres are associated with high survival rates and discharge from hospital. Limited by abstract data only.

Eid, 2011[79]	2 step-down units, Private hospitals, Brazil	Quasi-experimental, interrupted time series study Phase 1: n=247 Phase 2: n=250	Evaluate the implementation of preventative measures on device-associated pneumonia; evaluate the effect of various interventions implemented to reduce the incidence of VAP.	Mean incidence density of tracheostomy associated pneumonia was 6 per 1000 tracheostomy days in phase 1 (usual care phase), and 0.7 in 1000 tracheostomy days in phase 2 (usual care plus compliance intervention and audits (p=.002)). In phase 2, there was a reduction in the rate of tracheostomy associated pneumonia from 2.9 to 0.29, per 1000 tracheostomy days (p=0.001), and reduction in ventilator associated pneumonia rate from 7 to 0.79 per 1000 ventilator days (p<.001).	Tracheostomy- and ventilator-associated pneumonia can be used using prevention bundle interventions, and can be improved with audits, education, and correctional interventions.
Elise, 2018[80] (Abstract)	Post-ICU rehabilitative weaning centre France	Retrospective audit (n=96)	Description of the characteristics and main outcomes of the patients admitted over the first year of activity to a post-ICU rehabilitation centre.	86% were ventilated, and 85% tracheostomised. 70% were successfully weaned, and over half discharged to the ward. 64% developed ICU-acquired weakness, and 60% had complications during their stay. The mean LOS was 19.5 days.	Limited by abstract findings only.

Elpern, 1994[81]	Ventilator Support Centre, suburban hospital, United States of America	Prospective descriptive observational (n=83)	Describe feeding aspiration events in long-term mechanically ventilated adult patients with tracheostomies.	42 (50%) aspirated at least once; of these 77% were silent, when assess with videofluoroscopy. Age was statistically significant for risk of aspiration (72.5 v 64.8 years p=.007). There was no significant difference in sex, size of tracheostomy, duration of tracheostomisation, duration of ventilation, or type or presence of feeding tube.	Aspiration is frequency in long-term tracheostomised patients with prolonged ventilation. Silent aspiration without clinical features of distress is common. Age is a significant risk factor.
Foster, 2010[82]	Critical care setting, United Kingdom	Phenomenological (n=3)	Describe the experience of tracheostomy tube as lived by a group of people who had this tube inserted as part of their critical illness or a procedure related to an acute event.	Key themes: necessity of communication, retaining normality, psychosocial discomfort, painful procedures, fear of the unknown, relationships with staff.	The lived experience of patients with tracheostomy tubes in ICU is an important area of research. A patient's confidence and trust in the nurse's skill and proficiency in tasks relating to tracheostomy care is key.

Freeman-Sanderson, 2011[83]	ICU, Australia	Retrospective audit (n=140)	Audit of patient demographics, timing and purpose of tracheostomy insertion, involvement of SLPs and time to recovery of functions.	Speech pathology was involved in care of 78% of patients, with an average time to first assessment of 14 days post tracheostomy insertion. The median time from insertion to phonation was 12 days, and to oral intake was 15 days. 20% had return to verbal communication within one week.	Speech-language pathologists have an important role in caring for tracheostomised patients.
Haniez, 2017 [84] (Abstract)	Specialised weaning centre, France	Observational cohort study (n=106)	Audit of patients admitted to mechanical ventilation centre in first year of practice.	66% were tracheostomised prior to admission. Mean duration of ICU stay preceding admission was 236 days. Mean length of stay was 29 days, with mortality of 4.7%. 16 (15%) required readmission to ICU, 85 (80%) to rehab centre, 10 to acute step-down unit, and 29 were discharged home.	Specialised weaning centres should be considered for patients with prolonged weaning failure, with favourable short-term outcomes. Abstract only with limited data.

Hwang, 2011[85] (Poster)	Academic, tertiary care hospital, United States of America	Retrospective cohort study (n=168)	To analyse potential risk factors associated with tracheostomy-related pressure sores.	Assessed 23 potential risk factors for tracheostomy-related pressure injuries. Percutaneous tracheostomy was the only factor of statistical significance (p=0.004). Others trending towards significance (age, obesity, duration of ICU stay, duration of faceplate sutures, low albumin) were not found to have statistical significance after multi-variate analysis.	Percutaneous tracheostomy is a risk factor for tracheostomy related pressure injuries.
Ibrahim, 2006[86]	ICU, tertiary hospital, Australia	Double blinded randomised placebo-controlled pilot study - intervention (n=14) - control (n=18)	To test improvement in nightly sleep comparing melatonin to placebo in tracheostomised patients weaning from mechanical ventilation and not receiving continuous sedation.	In patients given nocturnal melatonin compared to placebo, there was no improvement in minutes of sleep (240 v 243 minutes, p=0.98), diurnal sleep (128 v 104 min, p=0.4). There was no significant increase in agitation (p=0.11) or need for sedation or haloperidol (p=0.56).	Melatonin, while well absorbed, did not increase observed nocturnal sleep or affect agitation or need for sedation.

Kumar, 2018[87]	Neurotrauma ICU, tertiary care teaching hospital, India	Prospective observational study (n=69)	To find the late-onset speech and swallowing complication of tracheostomy in neurotrauma cases.	69 cases were reviewed, with 21 available at follow up. The most common long-term complications were inability to phonate (n=9), feeble voice, pain on speaking, and reduced loudness (each n=6). 6 patients report stomal related complications.	Speech and swallow problems are common in tracheostomised neuro-trauma patients.
Ledgerwood, 2013[88]	Medical-surgical ICU, university-affiliated hospital, United States of America	Non-blinded randomised clinical trial (n=18) - intervention (n=9) - control (n=9)	To evaluate the ability of suction-above-the-cuff tracheostomy tubes to reduce the incidence of ventilator-associated pneumonia.	Compared incidence of VAP between (a) use of Portex Blue Line Ultra Suctionaid tracheostomy tube and (b) standard Portex tube without suction port. Incidence of VAP was significantly lower in the intervention group (suction above the cuff), compared to control (tube without suction above the cuff) (11% v 56%, p=0.02). There was a non-significant trend for reduced length of stay and length of mechanical ventilation in the intervention group.	Suction above the cuff tracheostomy tubes, result in lower rates of VAP and may reduce length of mechanical ventilation and length of stay.

Marchese, 2010[89]	22 respiratory intensive care units, Italy	Retrospective cross-sectional survey (n=22 ICU departments)	A survey evaluating clinical characteristics, types of tracheostomies and complications, and clinical criteria and systems for performing decannulation, and outcomes.	22 centres responded, including 846 patients with mean age of 64 years. Most common cause for admission was respiratory failure secondary to comorbidities. 2% of patients had major complications after tracheostomisation. At discharge, 22% were decannulated, 27% were discharge with a tracheostomy, and 41% were discharged on home ventilation. 10% died or were lost.	Complications relating to tracheostomises are rare. A substantial proportion of patients managed in respiratory ICUs will be discharged with tracheostomy in situ.
Mitchell, 2013[90]	United States of America	Clinical Consensus statement	To improve care for paediatric and adult patients with tracheostomy tube...to reduce variations in practice...to minimise complications.	A clinical consensus statement using a Delphi process to form 77 agreed statements regarding tracheostomy care in both adults and children.	

Mol, 2004[91]	11 ICUs, South Africa	Survey of Practice - 112 nurses working in 11 different ICUs	To establish whether ICU staff were adequately informed about the use and care of endotracheal and tracheostomy tube cuffs.	Survey identified that 38% respondents incorrectly thought that cuff was to secure position to prevent self-extubation and 90% were unaware of cuff types available. Accurate regulation of cuff pressures not routine practice. 76% of privately employed nurses and 7.5% of public nurses were aware of an accurate way to measure cuff pressure. Noted variation between location of practice.	There are knowledge deficits and lack of training regarding the management tracheal cuffs in the surveyed population of nurses.
Nieszkowska, 2005[92]	ICU, tertiary hospital, France	Retrospective observational (n=72)	To evaluate sedative administration, sedation levels and patient's autonomy during the seven days before and after tracheostomy.	After tracheostomisation, there was a significant reduction in fentanyl and midazolam administration per day compared to pre-tracheostomisation (p<0.001). There was reduction in time "heavily sedated" reduced from 7h to 1 hr/day (p<0.001). Patients were able to commence oral intake (48%) and sit out of bed (22%).	Tracheostomisation in mechanical ventilated ICU patients results in administration of less sedation, less time spent heavily sedated. It promotes oral intake and autonomy.

Ojukwu, 2013[93] (Abstract)	Neurocritical ICU, and General ICU, tertiary neuroscience centre, United Kingdom	Retrospective cohort analysis (n=48) - neurocritical cohort (n=29) - general cohort (n=19)	To compare the differences in the weaning process between neurocritical and general intensive care unit patients who underwent tracheostomy.	There was a non-significant trend towards longer time of mechanical ventilation for neurocritical patients (p=0.6). There was a high proportion of neuro patients were unable to be cannulated, compared to general patients (52% v 37%). Speaking valves were used earlier in neuro patients (9 v 12 days).	Indication of tracheostomy, neurocritical or general, can affect the weaning process, particularly use of speaking valve, time of ventilation and success of decannulation. Limited by abstract only.
Orchard, 2018[94] (Abstract)	ICU, United Kingdom	Prospective observational pre-post study (n=38)	To survey intensive care staff on their confidence managing tracheostomy emergencies (after posters and regular simulation training were introduced).	Survey of intensive care nurses and doctors before and after implementation of the National Tracheostomy Safety Project (including posters and simulation training). Post- intervention, staff reported more confidence in managing emergencies, and higher rates of formal training.	Quality and training interventions to improve tracheostomy safety and management of emergencies can improve staff confidence.

Rabach, 2015[95]	Medical ICU, United States of America	Prospective proof-of-concept (n=20)	To determine if the Blom tracheostomy tube with suction-above-the-cuff inner cannula reduce the quantity of microorganisms in suction samples from the supra-versus subglottic spaces.	Demonstrated proof-of-concept for Blom tracheostomy tube with suction-above-the-cuff inner cannula. Significant reduction in suction samples/normal flora when comparing supraglottic versus subglottic suction (p=0.04). There was no reduction in pathogens in suction samples (p=0.8).	Blom tracheostomy tubes with suction-above-the-cuff inner cannula can reduce microorganisms from the subglottic space. Associated with ventilator associated pneumonia was not investigated.
Rees, 2014[96] (Abstract)	Multiple general ICUs, United Kingdom	Survey of practice (n= 117 ICUs)	Assess the use of subglottic suction ports in intensive care units.	98% of units used percutaneous tracheostomies. 43% utilised tracheostomies with a subglottic suction port, of which 38% used this port. This study highlights the variation in practice, and that presence of port does not necessarily dictate use.	Subglottic suction ports are available in some intensive care units, however, are not always used, and is an area of variable practice. Limited by abstract only.
Riera, 2014[97] (Abstract)	ICU, Spain	Prospective cohort (n=75)	To determine the stressful perceptions that are related to the ICU environment and	93.3% report at least one stressor, both in general and related to communication. 89% report trouble falling asleep and headaches while 88% report being affected by thirst, noise, feeling blue or	Patients experience a wide range of stressors in the intensive care unit, most related to difficulty with communication,

			the tracheal cannula in tracheostomised patients.	depressed, and missing relatives/friends. Highest levels of stress were related to not being able to speak (61%), thirst (59%), missing family (57%) and waking up in middle of night (53%).	sleep, thirst, and loneliness.
Roche-Campo, 2013[98]	Medical ICU, France	Randomised crossover clinical trial (n=16)	To evaluate the direct impact of mechanical ventilation on sleep quantity and quality in patients who were able to tolerate separation from mechanical ventilation over prolonged periods.	Overall, sleep time was short with sleep efficiency of 50% and high fragmentation index. Total sleep time significantly higher in mechanical ventilation versus spontaneous ventilation (183 v 132min p=0.04). There was no significant difference in Rapid Eye Movement sleep, slow wave sleep or fragmentation index. There was no difference in respiratory of hemodynamic instability between the groups.	Sleep quality in ICU is generally poor. While patients have more total minutes of sleep when mechanically ventilation than when spontaneously ventilated, indicators of quality of sleep do not increase. A well-adjusted ventilatory setting may be more important than the specific mode use.

Santos, 2018[99] (Abstract)	University-affiliated community hospital, United States of America	Prospective interventional Pre- and Post- - pre-intervention (n=70) -post-intervention (n=32)	Evaluate the overall impact of multidisciplinary tracheostomy team on the overall care of post-tracheostomy patients.	Assessed outcomes after implementation of a multidisciplinary team for tracheostomised patients in and after ICU. There was a reduction in ICU length of stay (29 v 14 days), total hospital length of stay (30 v 22 days), time to oral intake (18 v 6 days), and time to decannulation (26 v 20 days). There was a non-significant reduction in days of mechanical ventilation (6 v 4 days). There was a decreased incidence of pneumonia, aspiration, tube blockage and rapid response calls due to respiratory distress.	Use of a multi-disciplinary team for assessment, management and follow-up of tracheostomised patients may improve a range of outcomes. Limited by abstract only.
Terragni, 2017[100] (Abstract)	3 ICUs, Italy	Matched cohort study - intervention (n=125) - control (232)	To measure ventilator associated pneumonia incidence in tracheostomised patients with suction above the cuff.	When comparing tubes with subglottic suction and those without suction, there was a reduction in the incidence of ventilator associated pneumonia (8% v 19%, p<0.004). When propensity score was used to balance matching between groups, incidence was 8.3% compared to 21.7% (p=0.04).	The use of subglottic secretions results in reduced incidence of ventilator-associated pneumonia in tracheostomised ventilated patients.

Veelo, 2008[101]	44 ICUs, Netherlands	Survey of practice (n=44 intensive care units)	To determine tracheostomy-management practices in Dutch intensive care units and post-ICU step-down facilities.	64% only use cuff deflation only spontaneously breathing and completed weaned from ventilation. 59% do not routinely change the tube; the most common reason for change is for smaller size (36%), or switch to another cannula type. Almost half use an inner cannula; 80% who use an inner cannula would remove and clean the inner cannula several times a day. 64% had no guideline for managing discharge tracheostomy patients.	There is significant variation in practice in the management of tracheostomies across the Netherlands. There are few to no guidelines to support practice.
Welton, 2016[102]	ICU, Canada	Retrospective, pre- post-intervention study - pre (n=20) - post (n=24)	To evaluate the interprofessional tracheostomy team and its impact on time from weaning off mechanical ventilation to decannulation, and time from weaning to speech-language pathology referral.	After implementation of a MDT, there was a significant reduction in time from tracheostomy insertion to first tube change, (36 v 22.9 days, p=0.01), and time to speech-pathologist referral (p=0.01) There was a significant reduction in time from insertion to weaning and shorter mechanical ventilation time in the post-intervention group (p=0.03). There was no change in time to decannulation.	Multidisciplinary tracheostomy teams may reduce time to first tracheostomy changes and shorten time of mechanical ventilation. It may improve clinician-reported subjective quality of care.

Abbreviation List

ICU- intensive care Unit

MV- mechanical ventilation

HME- heat moisture-exchanger

CPAP- continuous positive airway pressure

ATC- automatic tube compensation

PS – pressure support

PaO₂- partial pressure of oxygen

FiO₂- fraction of inspired oxygen

SaO₂- saturation of oxygen

PaCO₂ – partial pressure of carbon dioxide

BiPAP- Bilevel Positive Airway Pressure

PMV- Passy-Muir speaking valve

QOL- quality of life

AAC- augmentative and alternative communication

SLP- speech-language pathologist

ACV – above cuff vocalisation

SV- speaking valves

EBDT- Evan's Blue Dye Test

RR- respiratory rate

SOOB- sit out of bed

MDT- multi-disciplinary team

LOS- length of stay

VAP- ventilator-associated pneumonia

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