



REVIEW

Above cuff vocalisation (ACV): A scoping review

Antonija Petosic^{1,2}  | Marit F. Viravong³ | Anna M. Martin⁴ | Cecilie B. Nilsen¹ | Kjell Olafsen⁵ | Helene Berntzen¹ 

¹Division of Emergencies and Critical care, Department of Postoperative and Intensive care, Oslo University Hospital, Oslo, Norway

²Faculty of Medicine, Institute of Health and Society, University of Oslo, Oslo, Norway

³Medical Division, Department of Clinical Services, Physiotherapy Service, Oslo University Hospital, Oslo, Norway

⁴Medical Division, Department for Clinical Services, Speech and Language Therapy Service, Oslo University Hospital, Oslo, Norway

⁵Division of Emergencies and Critical care, Department of Anesthesiology, Oslo University Hospital, Oslo, Norway

Correspondence

Antonija Petosic, Critical care nurse, MS, PhD student and Professional development nurse, General intensive care unit, Ullevål, Department of Postoperative and Intensive Care, Division of Emergencies and Critical Care, Oslo University Hospital, Kirkeveien 166, 0450 Oslo, Norway.
Email: antonija.petosic@studmed.uio.no

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Abstract

Introduction: Patients in intensive care frequently suffer from not being able to communicate verbally. The aim of this scoping review was to study the safety and effectiveness of the above cuff vocalisation (ACV) on speech and quality of life (QOL) in patients dependent on a cuffed tracheostomy.

Methods: A scoping review was conducted. The databases Ovid Medline, Cochrane Library, and Embase were systematically searched in May 2020. We included clinical studies with patients exposed to ACV where speech, QOL or safety issues were assessed.

Results: Overall, 17 studies were included, of which 15 were observational and 2 were randomised controlled trials. Totally, 231 patients were included. ACV enabled most of the included patients (115/131; 88%) to speak with an audible voice or whisper (moderate quality of evidence). Voice related QOL (V-RQOL) and QOL in mechanically ventilated patients (QOL-MV) improved from pre- to post- ACV compared to a control group not tolerating a one-way speaking valve ($P = .01$ and $P = .04$, respectively) (very low quality of evidence). Several minor complications or problems were reported in 20/75 (27%) cases in addition to two serious adverse events: subcutaneous emphysema in one patient where the tracheostomy was dislodged and a distended trachea in another due to the misconnection of continuous gas to the cuff (low/ very low quality of evidence).

Conclusion: ACV facilitated communication in patients dependent on a cuffed tracheostomy and attempting to communicate. Quality of evidence in improved V-RQOL and QOL-MV was very low. Several minor complications and two serious adverse events were reported.

1 | INTRODUCTION

Intensive Care Unit (ICU) patients on invasive mechanical ventilation are not able to speak due to the inflated tracheal tube cuff.¹⁻³

The inflated cuff prevents airflow through the larynx and vocal cords which inhibits vocalisation. Currently, with ICU patients being more alert and awake during their ICU stay, the inability to speak and communicate effectively with health care personnel (HCP) and family

may cause anxiety, stress, frustration, and depression.² Moreover, the challenge for HCP in understanding patients' thoughts and needs may influence safety and quality of critical care.^{4,5}

Above cuff vocalisation (ACV) is a method that may enable speech in patients dependent on a tracheostomy tube with an inflated cuff. To allow ACV, the tracheostomy tube must incorporate a subglottic suction aid (SGS). Applying a flow of 1-5 l/min of oxygen or air through the SGS-port may restore airflow through the vocal cords and thereby

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enable speech^{6,7} (Figure 1). The method was initially described in 1967 by Whitlock⁸ and in 1975 by Safar and Grenvik⁹ and was more recently further developed in Melbourne, Australia, and Manchester, United Kingdom, with sharing of protocols and experience via the Global Tracheostomy Collaborative.⁷ To our knowledge, the method has not yet been extensively implemented internationally.

The aim of this scoping review was, therefore, to study the safety and effectiveness of ACV on speech and quality of life in patients dependent on a cuffed tracheostomy.

2 | METHODS

This scoping review followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) statement,¹⁰ and the checklist is provided in Appendix 1. A multidisciplinary group consisting of three intensive care nurses, an intensive care physician, a speech and language therapist (SLT), and a specialist physiotherapist, conducted the scoping review with literature search assistance from a specialist librarian.

2.1 | Protocol and registration

This scoping review was performed as part of a hospital-based mini health technology assessment (HTA) at Oslo University Hospital and its initiation was registered in the publicly available Norwegian national database for mini-HTAs. The review was not registered in a database and the protocol was not published in advance.

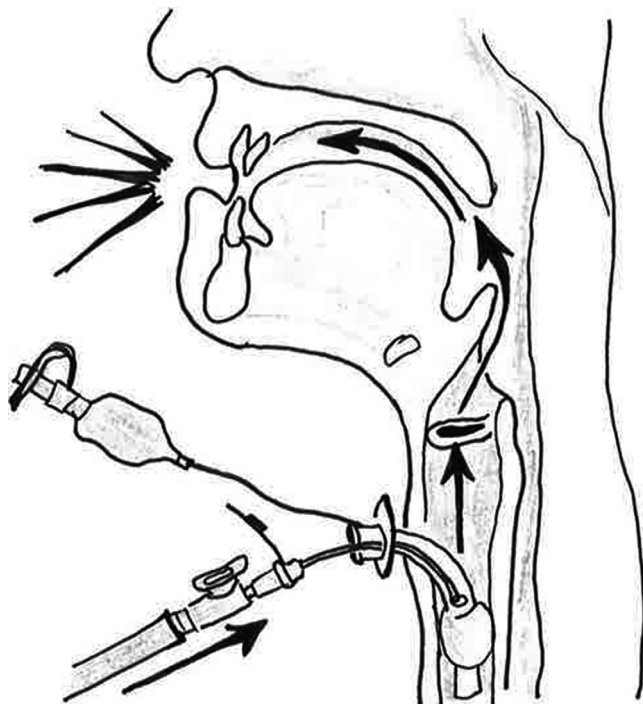


Illustration: Maret Toom

FIGURE 1 Illustration of above cuff vocalisation

Editorial Comment

In this scoping review, the desirable and undesirable effects of above cuff vocalisation on speech and quality of life in patients dependent on a cuffed tracheostomy were assessed. Overall quality of evidence ranged from moderate to very low. Above cuff vocalisation may provide audible voice or whisper. Due to several safety concerns, the patients should be under continuous observation in the ICU during the procedure.

2.2 | Search strategy and information sources

A population/problem, intervention, comparison, outcome (PICO) scheme was used as a basis for the search strategy and as eligibility criteria for inclusion of studies:

- Population/ Problem: Adult patients on mechanical ventilation or with a tracheostomy.
- Intervention: Above cuff vocalisation, speaking/ talking tracheostomy, external subglottic airflow.
- Comparison: Any comparison.
- Outcome: Communication, speech, phonation, voicing.

A broad systematic literature search was performed by a specialist librarian 03.05.2020 in the databases Ovid Medline, Cochrane Library, and Embase. Different combinations of Medical Subject Headings (MeSH) and textwords were used, including above cuff vocalisation, speaking/ talking tracheostomy, external subglottic airflow (ESAF). The literature search was limited to papers published in English or Scandinavian languages. The search result was exported into EndNote and duplicates were removed. See Appendix 2 for the PICO scheme and full search strategy.

2.3 | Selection of sources of evidence

Three members of the group individually screened the search results and selected eligible papers based on titles and abstracts before consensus was reached on which papers should be included in the full-text review. Any disagreements were resolved through discussion with the whole group.

2.4 | Eligibility criteria

Inclusion criteria were all primary clinical studies including adult and adolescent patients >14 years of age who were exposed to ACV, also called speaking/ talking tracheostomy. We excluded studies not including patients (e.g. reviews) as "not primary study" (Figure 2). To answer the aim of the scoping review, papers reporting data on the

effect of ACV on speech (audible voice or whisper), quality of life (QOL) as defined by original studies including voice-related QOL (V-RQOL) and QOL in mechanically ventilated patients (QOL-MV), or safety issues including any adverse events and complications related to the ACV-technique, were included in the review. Papers reporting only on other effects of ACV such as swallowing and secretion management were excluded as “not assessing speech” and studies reporting stomal complications caused by the tracheostomy tube itself as “not involving ACV” (Figure 2).

2.5 | Data items and synthesis of results

Study characteristics extracted were the year of publication, country of origin, aim of study, study design, type of population, type of tracheostomy, intervention with litres per minute (l/min) of air or oxygen used, and conclusion. Outcome measures of effect on speech were extracted with incidence or proportion of patients and ACV attempts with audible voice or whisper and reason for no voicing. Outcomes on V-RQOL and QOL-MV were extracted with significant change pre- and post-ACV. Outcome measures on safety included any adverse events and/or complications/problems reported. Three group-members, one independently and two as a pair, extracted data from each included study using a data extraction form. Any disagreement was resolved through discussion with the whole group. Findings are summarised and presented descriptively with absolute numbers and percentages of both patients and ACV episodes.

2.6 | Assessment of quality of evidence

We were interested in safety and the clinical effect of ACV on speech and QOL. We therefore assessed the overall

quality of evidence according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, thereby rating quality as high, moderate, low or very low.¹¹ In brief, we initially graded all observational studies as low and randomised trials as high. We adjusted quality downward based on the following five GRADE criteria: risk of bias, inconsistency, indirectness, imprecision and publication bias and adjusted upward based on the three criteria: large effects, dose-response, all plausible confounding. Two members of the group individually graded the quality of evidence and consensus were reached after thorough discussion.

3 | RESULTS

3.1 | Selection of sources of evidence

Overall, 17 studies with 231 patients were finally included in the scoping review (Figure 2). Only one study reported the number of ACV-episodes: 91 episodes with a median of 9 episodes in 10 patients.⁶

3.2 | Characteristics of sources of evidence

Most of the included studies were non randomised, observational studies, of which three were prospective observational studies involving 50 patients,^{6,12,13} six observational studies without further specification of design involving 90 patients,^{8,9,14-17} and six case studies involving 16 patients.^{7,18-22} Two randomised controlled clinical trials (RCT) with 75 patients assessing QOL related to the effect of ACV on speech were also included (Table 1).^{20,23} Age of patients, when reported, ranged from 14 to 83 years.^{6,7,12-19,21-24}

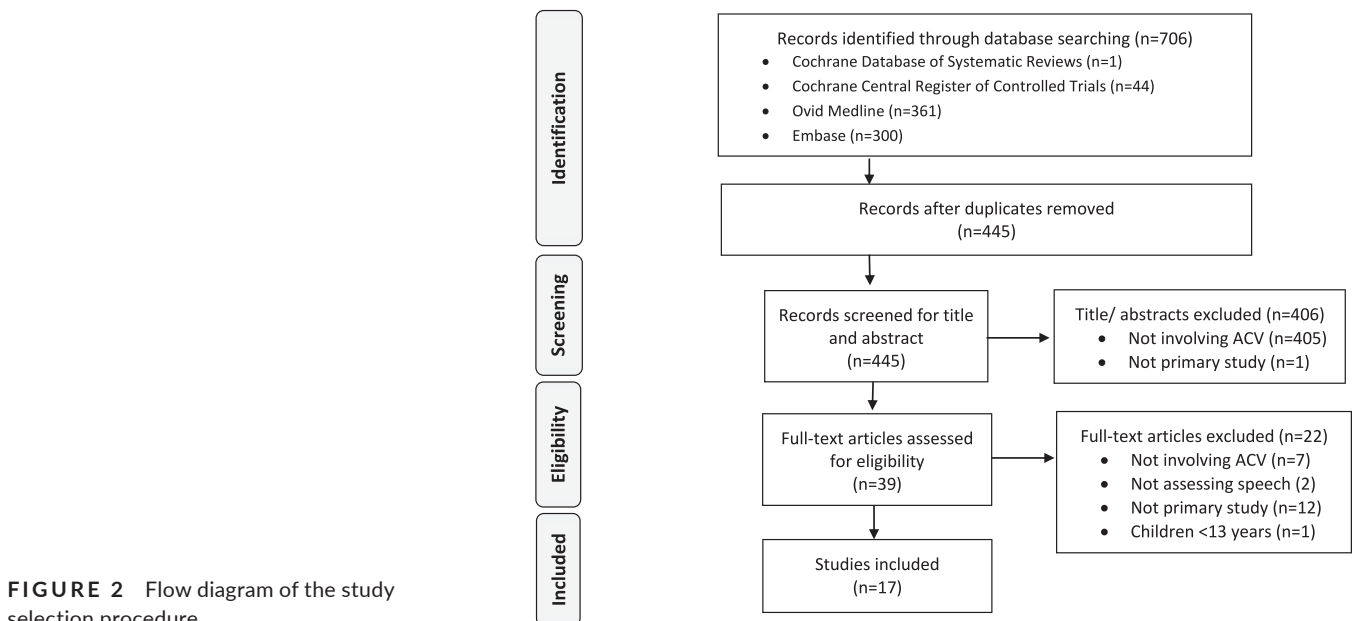


FIGURE 2 Flow diagram of the study selection procedure

TABLE 1 Literature Review Matrix of Above cuff vocalisation (ACV)

Study	Aim	Methodology	Analysis & Results	Conclusions
Pandian et al (2020) Baltimore, United States of America	Determine the quality of life (QOL) using a talking tracheostomy tube. Voice Related Quality of life (V-RQOL) and Quality of life in Mechanically ventilated patients (QOL-MV) in ICU patients pre and post using a talking tracheostomy tube (BLUSA®), compared to standard communication tools such as communication boards, Ipads or writing.	Randomised clinical trial (n = 50) Adult ICU patients, mechanically ventilated, awake, alert, attempting to communicate. Tracheostomy > 48 h. Randomised 25 to the control and intervention group (BLUSA®)	Changes in V-RQOL (P = .01) and the QOL-MV (P = .04) from pre- to post-intervention were significantly higher in the intervention group compared to those who did not use BLUSA® or a one-way speaking valve in the control group. 73% could use the BLUSA® with some level of independence (n = 22). 41% reported some level of satisfaction, 36.4% were neutral, and 22.7 were dissatisfied with the use of BLUSA®. Mean V-RQOL in the intervention-group changed from 26.59 pre-treatment (n = 25) to 42.5 post-treatment (n = 22), and from 26.67 (n = 25) to 32.26 (n = 25) in the control group. Change in mean QOL-MV were from 44.65 to 50.24 in the intervention- and from 42.78 to 49.41 in the control group.	The study suggests that BLUSA® talking tracheostomy tube improves patient-reported QOL in mechanically ventilated patients with a tracheostomy who cannot tolerate cuff deflation.
McGrath et al (2019) Manchester, United Kingdom	Assess whether patients could achieve an audible voice using ACV and to assess the safety of the procedure using the Blue Line Ultra Suctionaid (BLUSA®) tracheostomy tube.	Prospective observational study (n = 10) Adult (>16 years), alert (awake and trying to communicate), ICU patients, dependent on an inflated cuff for ventilatory support. (BLUSA®)	Audible voice in 8/10 patients, during 66/91 ACV attempts. Complications were reported per ACV trial (25/91): Discomfort (10/91), Excessive oral secretions (9/91), Stomal air leak (2/91), Gagging (2/91), Nausea (1/91), Patient asked to remove (1/91). ACV was used for a median of 15 min, with additional gas flows of 1-5 l/min, during a median of nine episodes, over a median of three days.	ACV can achieve effective, safe, well-tolerated vocalisation in ventilator-dependent ICU patients. ACV has the potential to aid earlier, more effective communication, and may improve laryngeal function and rehabilitation.
Calamai et al (2018) Italy	Describe a sudden neck and face emphysema during ACV.	Case study (n = 1) A 74-year-old male mechanically ventilated for severe respiratory failure due to pneumonia. (Unspecified tracheostomy tube with suction-aid)	Barely audible voice (1/1) with 2 l/min. Adverse event (1/1): subcutaneous emphysema of the neck and face was noted on 3 l/min on day six after tracheotomy, due to the suction port being outside the tracheal lumen allowing gas flow to spread through the surrounding tissues.	Subcutaneous emphysema occurred within a few minutes of commencing ACV, due to malpositioning of the tracheostomy tube and thus the subglottic suction port.
McGrath et al (2016) Manchester, United Kingdom	Describe the use of the Blue Line Ultra Subglottic Suction (SGS) port of tracheostomy tubes to facilitate communication.	Case series (n = 5) Adult (30-76 years), general ICU patients. (BLUSA®)	Audible voice or whisper was achieved in 4/5 patients with 3-6 l/min. The patient unable to phonate had a permanently altered larynx due to inhalation/ burns trauma and intubation. Complications per patient (1/5): Burping occurred in 1/5 patients, possibly caused by air in the stomach. A laryngeal injury was discovered in 1/5 patient probably caused by intubation/ neurotrauma and not ACV.	The SGS port of tracheostomy tubes can be used to deliver a retrograde airflow above the cuff to facilitate speech.
Mitate et al (2015) Japan	Efficacy of a speaking tracheostomy tube and "modified" mouth stick stylus for a patient with ventilator-dependent tetraplegia.	Case report (n = 1) A 73-year-old male with ventilator-dependent tetraplegia due to cervical spinal cord injury. (BLUSA® and Vocalaid)	Audible voice 1/1 patient. The patient could talk for about 10 minutes using a speaking tracheostomy on 5 l/min, but with fatigue. Complications reported per patient (1/1): Discomfort with BLUSA (1/1), Fatigue with Vocalaid (1/1).	The patient could produce hoarse voice with a speaking tracheostomy tube, but use was limited to 10 min due to discomfort.

(Continues)

TABLE 1 (Continued)

Study	Aim	Methodology	Analysis & Results	Conclusions
Pandian et al (2015) Baltimore, Maryland, United States of America	Evaluate the feasibility of measuring outcomes of patients with talking tracheostomy tube using a pre-test-post-test research design.	Pilot prospective randomised controlled clinical trial (n = 25; 15 ACV, 10 control) Adult (>18 years), mechanically ventilated via tracheostomy (>48 hours), awake, alert, attempting to communicate.	Mean QOL-MV was 50.8, and VR-QOL was 32.9. No significant difference in the QOL-MV and VR-QOL scores between pre and post amongst the control group. Amongst the intervention group a trend was noted to improve in QOL-MV and VR-QOL.	Improvement in QOL and intelligibility of mechanically ventilated patients. Talking tracheostomy allows mechanically ventilated patients to communicate and in turn, helps optimize ICU care.
Pandian et al (2014) Baltimore, Maryland, United States of America	Present four cases of critically ill patients who benefited from talking tracheostomy tubes.	Case series (n = 4) Adult patients who benefited from talking tracheostomy tubes. (BLUSA®)	3/4 patients were able to speak with 2-4 l/min. The fourth was unable to compensate for severe flaccid dysarthria. One patient had meaningful communication using ACV; two patients communicated basic needs and short sentences. Complications reported per patient (1/4): 1/4 experienced sub-glottic air trapping due to laryngospasm, which was alleviated with vocal exercises.	Talking tracheostomy tubes allow patients with adequate motor speech control, who are unable to tolerate-cuff deflation, to achieve phonation.
Leder (1990) New Haven, United States of America	Investigate voice intensity at three different airflow levels, 5, 10, and 15 l/min with Portex "Talk" Tracheostomy Tube.	Observational study (n = 20) Cognitively intact, ventilator-dependent patients referred to placement of talking tracheostomy tube. (Age 24-80 years) (Portex "Talk" Tracheostomy Tube®)	All (20/20) were able to produce an audible voice with any airflow rate. Audible and intelligible speech was produced with significantly greater intensity over ambient room noise at 5, 10, and 15 l/min of airflow. Significantly greater voice intensity was noted as airflow increased. Complications: none reported.	Audible and intelligible speech can be consistently produced by cognitively intact, ventilator-dependent patients. Portex Talk® enables patients to speak sooner and more easily than Communi-Trach I®. Daily rehabilitation required for proper use and functioning.
Leder & Traquina (1989) New Haven, Connecticut United States of America	Investigate voice intensity levels at three different airflow levels, 5, 10, and 15 l/min with Communi-Trach I.	Observational study (n = 20) Cognitively intact, adult (21-81 years), ventilator-dependent patients (Shiley cuffed tracheostomy, Communi-Trach I®)	18/20 patients were able to produce audible voice at any airflow rate. 2 patients were unsuccessful due to laryngeal pathology. Significantly greater voice intensity at airflow rates of 5, 10, and 15 l/min versus ambient room noise. Significantly greater voice intensity was noted as airflow increased. Complications: none reported.	Consistent, audible, and intelligible speech can be produced by cognitively intact patients if proper functioning of the speaking tube is maintained.
Sparker et al (1987) Texas, United States of America	Examine the efficacy of speaking tracheostomy tubes, and report personal experience with 23 patients evaluated for its use, with 19 being appropriate candidates.	Observational study (n = 19) Adult (14-78 years), ICU or intermediate patients with intact cognitive and articulatory function. (Communi-Trach I® (9), Portex® (7), Both (3))	All (19/19) were able to speak, whereas 15/19 utilised the device effectively for communication. Complications per patient (12/19): Excessive secretion above cuff (5/19), inadequate air seal (7/19) of which 5 were due to cuff breakage).	Patients who receive speaking tracheostomy tubes, their families, and attending staff note improvement in communication. Careful screening to select appropriate candidates

(Continues)

TABLE 1 (Continued)

Study	Aim	Methodology	Analysis & Results	Conclusions
Levine et al (1987) Michigan, United States of America	Describe four cases with different design constraints and system configurations, to allow independent voice control with talking tracheostomy systems for quadriplegic patients. (Non-ICU)	Case series (n = 4) Cases (17-71 years) with neuromuscular impairment, requiring prolonged mechanical ventilation via a cuffed tracheostomy (non-ICU) (Unspecified tracheostomy tube)	4/4 obtained whispering intelligible speech. When an air compressor was used, additional background noise did not noticeably affect speech intelligibility. Complications none reported.	Independent voice control greatly enhances communication for these individuals.
Kluin et al (1984) Michigan, United States of America	Report experiences with the single-cuffed tracheostomy "talk" tube.	Observational study (n = 19) Adult (17-71 years), ventilator-dependent patients, 6 quadriplegic, 9 neuromuscular disease, 4 respiratory failure. (Portex "Talk" Tracheostomy Tube®)	14/19 patients acquired intelligible speech. Audible whisper in most with 5l/min, normal talk with 8-10 l/min. 2/19 were judged unsuccessful; one due to vocal cord paralysis and one due to secretion that could not be controlled. 3/19 patients had fluctuating function due to problems with secretions. Complications per patient (4/19): 1/19 had uncontrolled secretions. 3/19 problems with secretions or change in mental status. Gagging/ tickling sensation possible with increased airflow (no patient numbers).	Satisfactory phonation can be acquired by most ventilator-dependent patients with normal laryngeal anatomy. An increase in airflow rate can cause upper airway irritation.
Gordan (1984) Columbia, United States of America	Examined the effectiveness of the Pitt speaking-cuffed tracheostomy tube.	Observational study (n = 10) Adult (32-65 years) divided into two groups: 5 patients with neuromuscular disease and 5 patients without. (Pitt speaking-cuffed tracheostomy®)	5/10 patients achieved intelligible whisper or speech; none of the 5 patients with and all 5 without evidence of neuromuscular disease with an airflow of 4-6 l/min. Complications (0/10): No complications occurred, like leakage through stoma or to paratracheal tissue. Airflow higher than 8 l/min caused discomfort (no patient numbers).	The Pitt tracheostomy tube failed to induce speech in tracheostomised patients with neuromuscular disease due to articulatory difficulties.
Szachowicz et al (1983) Minneapolis, United States of America	Evaluate intelligible speech with modified tracheostomy tube.	Observational study (n = 10) Patients (14-80 years) in acute and extended care facilities. 9/10 were ventilator dependent. (Communi-Trach I®)	8/10 had intelligible speech with 6-8 l/min. 2/10 unsuccessful; one had granulation tissue between the vocal cords, and one had Myasthenia Gravis and could not voluntarily move vocal cords. Complications (0/10): No complications were observed related to tracheostomy and its speaking air supply system.	Patients with normally functioning larynx and no upper airway obstruction were able to speak intelligibly.
Feneck & Scott (1983) London, United Kingdom	Describe tracheal dilatation following inadvertent connection of continuous oxygen flow to the cuff.	Case study (n = 1) A 58-year-old conscious female on mechanical ventilation in the ICU (Portex 'vocal aid' tracheostomy)	1/1 satisfactory voice with 2-4 l/min. Used the "vocal aid" tracheostomy device to communicate easily with staff and visitors and was happy with it. Adverse event (1/1): After 3 days the cuff burst due to the disconnection of continuous gas to the pilot tube to the cuff, resulting in tracheal distention.	Misconnection of continuous oxygen flow caused the cuff to burst and dilate the trachea.

(Continues)

TABLE 1 (Continued)

Study	Aim	Methodology	Analysis & Results	Conclusions
Safar & Grenvik (1975) Pittsburg, United States of America	Describe observations using the Pitt Speaking Tracheostomy Tube to speak in ICU patients.	Observational study (n = 25) Adult ICU patients (Pitt speaking-cuffed tracheostomy®)	Most patients (unspecified number) were able to talk with a whispering voice with an airflow of about 5 l/min. A flow of 8-10 l/min may be necessary to allow patients to talk understandably. Satisfaction and safety increase in patients able to communicate with method. Complications: no numbers reported. Higher airflow (8-10 l/min) may cause discomfort. Possible subcutaneous emphysema in new or shallow tracheostomy.	Conscious patients with cuffed tracheostomy tubes can and should be given the opportunity to communicate by talking, and the Pitt Speaking Tracheostomy Tube enables talking.
Whitlock (1967) Auckland, New Zealand	Describe a newly developed simple tracheostomy-tube attachment for communication.	Observational study/ clinical trial (n = 7) Patients with cuffed tracheostomy (Customised Portex tube)	6/7 patient communicated successfully with 5 l/min. Failure in 1/7 patients with a tracheostomy larger than usual, allowing air to flow out around the tracheostomy more readily than through the vocal cords. Complication reported per patient (1/7): 1/7 found the airflow too uncomfortable after a successful trial. A delay of three days is recommended to allow the tracheostomy to be sealed by granulation tissue, thus preventing the escape of air around the tracheostomy or worse into the tissue of the neck and mediastinum.	The speaking aid makes communication easier and relieves patients from frustration and fear of not being able to make his requirements known.

3.3 | Critical appraisal

The overall quality of evidence across the body of evidence according to GRADE is presented in Table 2 and in sections related to respective outcome measures.

3.4 | Effect on speech

Overall, 115/131 (88%) patients in the 14 studies reporting patient numbers were able to communicate with an audible voice or whisper using ACV, ranging from 50% to 100% in the individual studies.^{6-8,12-19,21,22,24} McGrath et al (2019) reported speech or whisper in 66/91 (72,5%) ACV-episodes.⁶ Safar and Grenvik (1975) reported that “most” out of “about 25 patients” included could voice successfully.⁹ Sparker et al (1987) reported that all 19 subjects with talking tracheostomy tube could speak, whereas 15 communicated successfully with the system.¹⁴ Airflow ranged from 1 to 15 l/min, and both compressed oxygen and air were used.^{6-9,12,13,15-20,22,24}

Overall, 16 patients were unable to speak with ACV and the reasons were reported in nine out of these 16 patients. Reported reasons included permanent laryngeal injury due to inhalation/burns and trauma (one),⁷ severe flaccid dysarthria (one),²⁴ tracheal air leak (one),⁸ vocal cord paralysis (two),^{15,17} excessive secretions (one),¹⁵ granulation tissue between the vocal cords (one)¹⁷ and unspecified laryngeal pathology (two).¹³

The overall quality of evidence for the effect on speech according to GRADE was moderate (Table 2).

3.5 | Quality of life

Two RCTs including 75 patients reported V-RQOL and QOL-MV.^{20,23} In the first pilot RCT there were no significant differences between the intervention (n = 15) and control groups (n = 10).²⁰ A statistically significant improvement in V-RQOL and QOL-MV from pre to post ACV (n = 22) compared to a control group that did not tolerate a one-way speaking valve (n = 15) (P = .01 and 0.04, respectively) was found in the second RCT.²³ This comparison is, however, not quantified in the paper. Mean V-RQOL in the intervention-group changed from 26.59 pre-treatment (n = 25) to 42.5 post-treatment (n = 22), and from 26.67 (n = 25) to 32.26 (n = 25) in the control group. Change in mean QOL-MV was 44.65 to 50.24 in the intervention- and from 42.78 to 49.41 in the control group.²³ P-values for these changes were not reported in the paper.

The overall quality of evidence for the effect on QOL according to GRADE was very low (Table 2).

3.6 | Safety

Two adverse events were reported in two patients.^{18,22} Subcutaneous emphysema occurred in a patient with a malpositioned tracheostomy

TABLE 2 GRADE evidence profile: Outcomes of above cuff vocalisation

Study design (No of studies)	Effect	Result	Downward rating					Upward rating			Quality of evidence
			Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Large effect	Dose response	All plausible confounding	
Prospective observational (1)	Audible voice or whisper	66/91 (72,5%) [#]	Serious ^{a,b}	Not applicable	Not serious	Not serious	Undetected	Large	Evidence of gradient	— ^c	Moderate
Observational (14) ¹		50%-100% [*]	Serious ^{a,b,d}	Serious ^e	Not serious	Not serious	Undetected	Large	Evidence of gradient	Reduced effect ^f	Moderate
RCT (1) ²	Quality of Life (QOL) Change in V-RQOL and QOL-MV		Serious ^{a,b,d}	Not applicable	Not serious	Very serious ^{g,h}	Undetected	—	—	—	Very low
Complications/ Problems	Safety										
Prospective observational (1)	Complications/ Problems	25/91 (28%) [#]	Not serious	Not applicable	Not serious	Not serious	Undetected	—	Evidence of gradient	—	Moderate
Observational (9) ¹		0%-100% [*]	Serious ^{a,b,d}	Serious ^e	Not serious	Not serious	Undetected	—	Evidence of gradient	—	Low
Adverse events											
Case studies (2)		— ⁱ	Serious ^a	Not applicable	Not serious	Not applicable	Undetected	—	—	—	Very low

Abbreviations: GRADE; Grading of Recommendations Assessment, Development, and Evaluation, RCT; QOL-MV, Quality of life in Mechanically ventilated patients Randomised controlled trial, V-RQOL; Voice related quality of life.

^aSelection bias and small studies.

^bBias in measurement.

^cConfounders largely accounted for due to the application of fibre optic endoscopic evaluation of swallow (FEES).

^dBias in reporting outcomes.

^eFindings vary in individual studies.

^fLack of voice could be due to lack of laryngeal function, not by fault of the ACV-technique.

^gLack of blinding, loss to follow up, few patients included.

^hConfidence intervals are not provided.

ⁱOnly two cases reported.

¹Excluding Saifar and Grenvik (1975) due to unspecified numbers.

²Excluding Pandian et al 2015 due to lack of information (congress-abstract only).

[#]Outcome reported in ACV trials.

^{*}Outcome reported in % of patients.

tube where the suction port was located outside the tracheal lumen, allowing gas flow to spread subcutaneously.¹⁸ Tracheal distention was reported in a case where continuous airflow was incorrectly connected to the cuff line, resulting in cuff rupture and tracheal distention.²²

Complications or problems occurred in 20/75 (27%) patients during correct use of the method in the eight studies reporting patient numbers,^{7,8,14-17,19,24} and in 25/91 (27,5%) ACV trials in one study.⁶ Complications included discomfort, which was reported in 10/91 ACV-episodes⁶ and in two patients.^{8,19} Discomfort was also reported in an unspecified number of patients with the use of airflow higher than 8 l/min.^{9,16} Excessive secretions in the oropharynx was reported in 9/91 episodes⁶ and in nine patients.^{14,15} Cuff breakage was reported in five patients after one to eight weeks.¹⁴ Air leak around the stoma was reported in 2/91 episodes,⁶ and in seven patients, of which five were due to cuff breakage.¹⁴ Swallowing of air which resulted in burping was reported in one patient⁷; subglottic air-trapping in one patient with laryngospasm²⁴; and retching and nausea, which was described as a risk in a few unspecified cases^{7,15,24} and specified by McGrath et al (2019) in 3/91 episodes.⁶ Fatigue was experienced by one patient who also reported discomfort¹⁹ and by an unspecified number of other patients.²⁴ However, these patients were able to communicate basic needs in short sentences.^{19,24}

The overall quality of evidence according to GRADE was moderate and low for complications and very low for adverse events (Table 2).

4 | DISCUSSION

The main finding was that most patients were able to communicate verbally with ACV.^{6-8,12-19,21,22,24} Furthermore, ACV could improve V-RQOL and QOL-MV.²³ Several minor complications (eg, discomfort, excessive secretion, cuff breakage) were described.^{7,8,14-17,19,24} Moreover, two serious adverse events (ie, tracheal distention and subcutaneous emphysema) resulted from the incorrect application of the method and incorrectly placed tracheostomy.^{18,22} Overall quality of evidence according to GRADE ranged from moderate to very low.

In a selected patient population, ACV was effective in enabling audible voice or whisper in 115 of 131 (88%) of patients dependent on a cuffed tracheostomy after not being able to voice before the introduction of ACV.^{6-8,12-19,21,22,24} Although no randomised controlled trials assessing the effect on speech were found, the patients in the observational studies served as their own controls by being able to communicate verbally with ACV after not being able to speak before the introduction of the method. Nevertheless, the included studies were small observational studies and the overall quality of evidence was moderate. Moreover, the reported voice quality achieved by patients was insufficiently specified in the studies to compare the results. Voice quality, from audible whisper to normal voice, is dependent upon vocal cord health and mobility, oromotor function, laryngeal muscle strength²⁵ and adequate subglottic air

pressure⁷ and thus airflow used. Most studies did not quantify these aspects or attempt to measure voice output, and those that did used different tools.^{6,7,12,13,23} The high proportion (88%) of patients able to communicate verbally may reflect the selected population being alert and trying to communicate, in addition to adequate vocal tract function. Gordan (1984) reported the lowest proportion (50%) of patients with intelligible speech, with none of the patients with neuromuscular disease being able to communicate with ACV.¹⁶ This result may reflect the severity or duration of disease and underlines the need for careful patient selection.

Verbal communication in tracheotomised patients has traditionally required deflation of the cuff, which may not be tolerated by all ICU patients. Alternative communication methods such as body language, lip-reading, charts, tablets, and writing have limitations and when not leading to successful communication, can increase patient frustration and distress.^{2,3,26} The restoration of voice may empower the vulnerable population of conscious patients unable to communicate.²³ In addition, lack of precise verbal communication may represent a barrier for HCP in performing symptom assessment²⁷ which could be counteracted by ACV. According to Pandian (2020) V-RQOL and QOL-MV improved amongst patients from pre to posttest use of ACV.²³ This study, however, suffers from a very high risk of bias, and further QOL-research is warranted.

The reported minor complications such as discomfort, excessive secretions, stomal air leak, burping, subglottic air trapping, retching, and nausea^{6-8,15,19,24} will seldom override the benefits of the ability to speak in this population. Patient discomfort may be inevitable in intensive care²⁸ and should not necessarily be categorised as a complication or problem in relation to safety, but rather identified as an area in which comfort may be enhanced. The inability to communicate may in itself contribute to patient discomfort.²⁸ Facilitating speech may enhance safety, comfort, and quality of care, by enabling both self-expression and communication of symptoms to HCP.^{27,29}

The most serious adverse events described were subcutaneous emphysema,¹⁸ and cuff rupture following an incorrect procedure.²² These adverse events were not caused by the ACV method itself, but by procedure deviation and incorrectly placed tracheostomy.^{18,22} A delay of 48 hours after tracheotomy is recommended to reduce the risk of subcutaneous emphysema.^{8,9} In actual fact, this complication occurred several days after tracheotomy in one case report, but as a result of a malpositioned tracheostomy tube.¹⁸ This emphasises the need for careful monitoring of the patient and the tracheostomy both prior and during ACV. Optimal timing for introducing ACV is not established, and McGrath et al (2019) suggest ACV could be attempted earlier assuming the stoma site is healing well, thereby enabling earlier vocalisation and laryngeal function benefits without significantly increasing the risk of complications.⁶

Neither optimal airflow nor duration of each ACV-episode to achieve benefits and avoid complications have been established. ACV has in studies been limited to 10-15 minutes to mitigate concerns about airflow drying the laryngeal mucosa.⁶ However, McGrath et al (2019) did not observe any short-term evidence of laryngeal drying or laryngeal complications related to ACV with

airflow up to 5 l/min and duration up to 15 minutes, demonstrated on follow-up fibre optic endoscopic evaluation of swallowing (FEES).⁶ Safar and Grenvik (1975) stated that up to 10 l/min may be necessary to achieve vocalisation,⁹ and Leder (1990) and Leder and Traquina (1989) showed increased voice intensity with increased airflow from 5 l/min to 10 and 15 l/min.^{12,13} A gradual increase from 2 up to 5 l/min to reduce complications and patient discomfort seems reasonable and safe, but may not be sufficient to generate voice. According to the UK guidelines, an SLT should always be involved in the initial assessment of ACV to determine laryngeal function and safety.²⁵ Limited availability of SLT may however delay the initiation of ACV. The presence of continuous monitoring by appropriately educated HCP ensures that potential complications would be promptly detected and acted upon. Education could be provided in already existing educational sessions, and by social media for sharing educative YouTube videos.³⁰ An educational video of the ACV procedure made by the SLTs from the UK National Tracheostomy Safety Project is available on YouTube.³¹

4.1 | Limitations and strengths

This scoping review was restricted to the effect of ACV on speech, quality of life, and safety issues and has several limitations. First, it was performed as part of a planned mini or hospital-based HTA which was registered in the Norwegian national database for HTA. However, no protocol was registered or published prior to initiation. Second, most of the included studies were small non-randomised studies with high risk of bias and thus with moderate to a very low quality of evidence. Several of the included studies were old with unclear or unreported data, making the extraction of data challenging.

Last, we may have missed relevant studies due to the restriction to English and Scandinavian languages only in our literature search.

A strength of this scoping review is the multidisciplinary make-up of the review group ensuring a variety of relevant HCP perspectives on the literature. The scoping review's results contribute to the somewhat limited existing knowledge and recent literature about ACV as a method for facilitating speech in patients with a cuffed tracheostomy. Despite the low evidence of the summarised studies, they did provide detailed descriptions of the ACV technique which was regarded as very similar even in the older studies^{8,9} and similar to the technique used today. This adds to the replicability of ACV both in research and clinical settings.

5 | CONCLUSION

In this scoping review including 17 studies and 231 patients, it was found that most patients were able to communicate verbally with ACV. The overall quality of evidence was moderate. The quality of evidence of an improvement in V-RQOL and QOL-MV with ACV was very low. Several minor complications and two serious adverse events were reported. Quality of evidence regarding these

outcomes was low and very low, respectively. Further research into the effectiveness of ACV on verbal communication and early laryngeal rehabilitation is warranted, with standardised measurement of voice, QOL, and reporting of complications.

CONFLICT OF INTEREST

The authors have no conflicts of interest.

ORCID

Antonija Petosic  <https://orcid.org/0000-0003-0801-9892>

Helene Berntzen  <https://orcid.org/0000-0001-5262-7911>

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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