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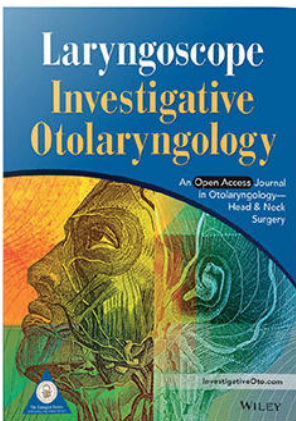


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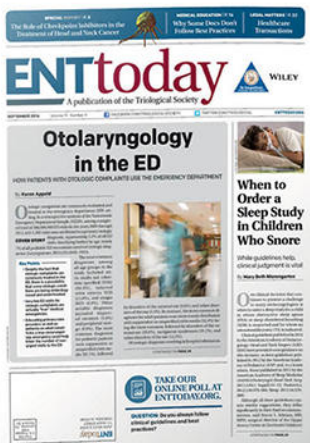
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# Evidence for Above Cuff Vocalization in Patients With a Tracheostomy: A Systematic Review

Claire S. Mills, MSc ; Emilia Michou, PhD ; Natalie King, MSc ; Mark C. Bellamy, PhD ;  
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**Objectives/Hypothesis:** To determine how above cuff vocalization (ACV) is implemented in clinical practice, to identify what evidence exists on the effectiveness and safety of ACV, and to evaluate the acceptability of ACV.

**Study Design:** Systematic review.

**Methods:** A literature search was conducted in eight databases (MEDLINE, Embase, AMED, CINAHL, Cochrane Library, PsycINFO, Scopus, and Web of Science) in May 2019 and updated in June 2020. Two reviewers independently screened, selected, and extracted data. Study quality was appraised using the Joanna Briggs Institute Critical Appraisal Tools and a narrative synthesis was conducted. Systematic review registration number: CRD42019133942.

**Results:** The searches identified 1327 records. The 13 eligible studies included four case studies, three case series, four observational studies without a control group, one quasi-experimental study, and one randomized controlled trial. Study quality was low, with most studies having high risk of bias. There was a high level of heterogeneity in study design and outcome measures used. Detailed information on ACV application and dose-delivered was lacking in 12 studies. Positive effects were reported for communication ( $n = 7$ ), swallowing ( $n = 4$ ), cough response ( $n = 2$ ), and quality-of-life ( $n = 2$ ), but with inconsistent use of objective outcome measures. There is limited quantitative or qualitative evidence for acceptability. Adverse events and complications were reported in nine studies, and four highlighted the importance of involving an experienced speech and language therapist.

**Conclusions:** There is limited evidence for the acceptability, effectiveness, safety, or optimal implementation of ACV. The evidence is insufficient to provide recommendations regarding optimal intervention delivery. Future research should ensure detailed recording of ACV delivery and utilize a core outcome set.

**Key Words:** Above cuff vocalization, talking tracheostomy, communication, deglutition, tracheostomy.

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## INTRODUCTION

Patients with a tracheostomy in intensive care often have their tracheostomy cuff inflated for extended periods of time. This impedes airflow through the larynx which results in desensitization of the upper airway<sup>1,2</sup> and prevents patients from speaking, which can lead to high levels of frustration.<sup>3,4</sup> Reduced oropharyngeal sensory input can lead to reduced swallowing frequency<sup>5</sup> and difficulties swallowing.<sup>6</sup> Additionally, patients are unable to protect their airway from aspiration.<sup>7</sup> This inability to eat, drink, or speak results in reduced quality of life (QoL) for patients with a tracheostomy.<sup>8,9</sup>

One solution to restore laryngopharyngeal airflow is above cuff vocalization (ACV). This technique was introduced in the mid-1960s<sup>10</sup> and is referred to as “talking tracheostomy,”<sup>11,12</sup> “speaking tracheostomy,”<sup>13,14</sup> and “external subglottic air flow.”<sup>15</sup> This review will use the term ACV to refer to the intervention.

ACV involves applying a continuous or intermittent flow of air via the subglottic port of a tracheostomy tube. This air passes through the larynx allowing vocalization, and can re-establish oropharyngeal and laryngeal sensation. It offers potential benefits for communication, swallowing, and QoL, but there are potential complications. A recent systematic review evaluated communication interventions in patients receiving mechanical ventilation,<sup>15</sup> including some ACV research, and a scoping

review studied the safety and effectiveness of ACV for speech.<sup>16</sup> There were various strengths and limitations of the scoping review including: focusing solely on speech, a wide inclusion criteria and inclusion of conference abstracts (resulting in double-counting of the randomized controlled trial [RCT] data), lack of registered protocol, limited searching (resulting in the omission of one key study<sup>17</sup>), and restricted risk of bias (RoB) assessment. The focus on speech allowed detailed reporting of speech outcomes and barriers. However, incorporating all relevant outcomes is essential to judge the clinical utility of ACV.

There has been no systematic evaluation of the quality of evidence for ACV use, effectiveness, and acceptability for both communication and swallowing, despite its increasing use worldwide. This systematic review aimed to identify methods of ACV implementation, current evidence on the efficacy, effectiveness and safety of ACV, and the acceptability of ACV to patients and healthcare professionals.

## METHODS

A protocol was developed and prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO) (registration number: CRD42019133942). This systematic review is reported in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) reporting guidelines.

### *Study Eligibility Criteria*

The eligibility criteria for this review were designed according to the Population Intervention Comparators Outcomes Study (PICOS) framework. The population included adult patients (≥18 years old) with a tracheostomy with an inflated cuff for any period of time during the day. The intervention was the application of an external airflow, via the tracheostomy subglottic port. Studies without comparators were included. A range of outcome measures were included: swallowing function, communication function, safety, acceptability (patients and healthcare professionals), incidence of pneumonia, time to decannulation, intensive care unit (ICU), and hospital length of stay (LoS), QoL, costs, and cost-benefits. Both qualitative and quantitative study types in any setting were included ranging from RCTs, nonrandomized, observational studies, and those evaluating the intervention or intervention acceptability. Peer-reviewed publications in English were included, with no restrictions to publication year.

### *Search Strategy*

In May 2019 the following databases were searched: Ovid MEDLINE(R), Embase, AMED, CINAHL, Cochrane Central Register of Controlled Trials, PsycINFO, Scopus, and Web of Science Core Collection (Clarivate). We also searched the Prospero database, the trials registries ClinicalTrials.gov (U.S. NIH), and the International Clinical Trials Registry Platform (ICTRP-WHO) to identify any unpublished studies. In June 2020, the searches were re-run on all databases except the ICTRP-WHO which was closed to external users secondary to COVID-19. The search strategy was developed by project team members and peer-reviewed by an information specialist (Supporting Information, File S1). Further relevant studies were sought by citation searching of the included studies.

### *Study Screening and Selection*

Retrieved studies were independently screened by two reviewers to identify studies that met the a priori inclusion criteria. Any disagreement was resolved through discussion between the two reviewers and, when necessary, with the wider review team. The reason for exclusion was documented.

### *Data Extraction*

Data extraction forms were formulated a priori and piloted to refine the forms and ensure inter-rater consistency. Two reviewers independently extracted data for all eligible studies. Any discrepancies between the completed extraction forms were identified and discussed. Differences were resolved through discussion between the two reviewers and, where necessary, with the wider review team.

### *RoB Assessment*

The Joanna Briggs Institute (JBI) recommendations for levels of evidence<sup>18,19</sup> were used to rate each study. RoB was assessed for each study independently by the two reviewers using JBI Critical Appraisal checklists.<sup>20</sup> The following JBI Critical Appraisal checklists were used: case reports, case series, quasi-experimental studies, and RCTs (<https://jbi.global/critical-appraisal-tools>). This included assessment of (where applicable): reporting bias, internal validity, external validity, measurement bias, selection bias, power, attrition bias, confounding bias, performance bias, and detection bias. There is no scoring system for these checklists. No studies were excluded from analysis on the basis of the RoB outcomes. Any discrepancies in RoB analysis of were resolved through discussion and a consensus decision was made.

### *Data Analysis and Synthesis*

A narrative synthesis approach was used. This comprised four stages, as per the guidelines produced by the Economic and Social Research Council<sup>21</sup>: preliminary synthesis of findings, exploration of relationships in the data, development of theory of mechanism of intervention and who the intervention works for, and assessment of the robustness of the synthesis. A meta-analysis was not possible due to the variability of the study design and outcome measures.

## RESULTS

### *Search Results*

Database searches identified 3277 records. After duplicate removal there were 1128 records. One study was identified after the searches were completed. Citation searches did not identify any additional records. Following the search update in June 2020, a further 99 records were identified and reviewed. In total, 1228 records were reviewed. A PRISMA flow diagram<sup>22</sup> illustrates the selection process (Fig. 1). The final review was conducted on 13 studies from the USA,<sup>12,13,23–26</sup> the UK,<sup>17,27–29</sup> Japan,<sup>14</sup> Denmark,<sup>5</sup> and Italy<sup>30</sup> published between 1983 and 2019.

### *Study Characteristics*

The study characteristics are outlined in Supporting Information, File S2. The PICOS are summarized in Table 1.

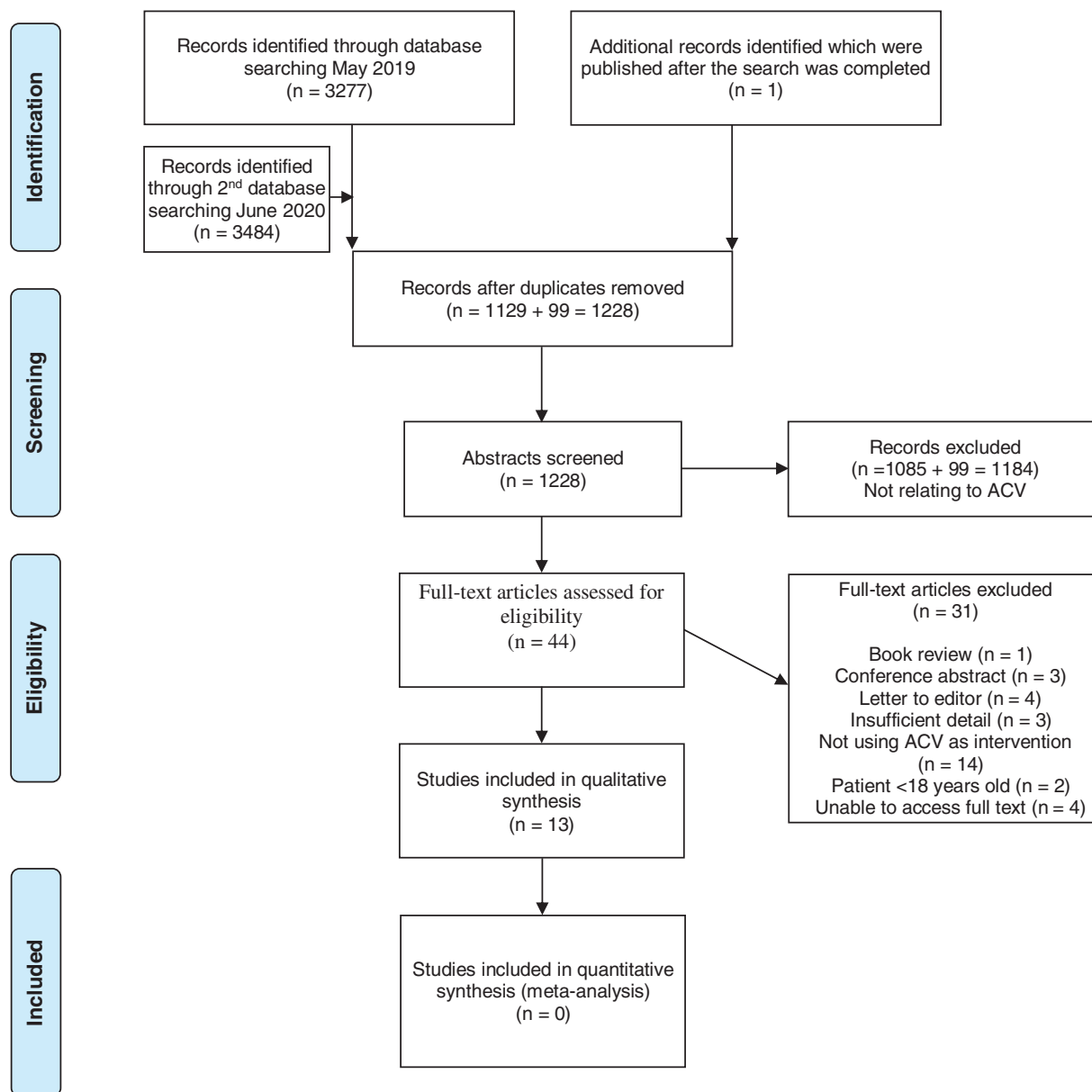


Fig. 1. PRISMA flow diagram. [Color figure can be viewed in the online issue, which is available at [www.laryngoscope.com](http://www.laryngoscope.com).]

**Patient cohort.** The studies were conducted predominantly in the ICU, although a few recruited patients from other wards. ACV was used with a wide variety of patients with diagnoses including: burns, respiratory, spinal cord injury, haematology, neurological (including neurosurgery), general/thoracic/cardiac/cardi thoracic surgery, progressive immune disorders, oncology, renal, hematology, genetic conditions, and out-of-hospital cardiac arrest. A total of 143 patients were included in this review, with a median sample size of 10 and an age range of 19–83.

**Intervention delivery.** Most studies did not report the time ACV commenced post-tracheostomy insertion. Of those that did, timing varied from 30 hours to 107 days post-tracheostomy insertion. Of those that stated an earliest time post-tracheostomy that the

intervention would commence, this ranged from 48 hours<sup>12</sup> to 72 hours.<sup>28,29</sup>

**Outcome measures.** The outcome measures varied greatly between studies and included: presence or absence of aspiration on fiberoptic endoscopic evaluation of swallowing,<sup>14</sup> aspirated material from the subglottic port,<sup>14</sup> abnormality to tracheal or laryngeal mucosa,<sup>14</sup> stomal complications or airflow line kinking,<sup>25</sup> the Functional Oral Intake Scale,<sup>5</sup> subglottic volume of secretions,<sup>5</sup> the Secretion Severity Rating Scale,<sup>29</sup> the Penetration Aspiration Scale,<sup>29</sup> number of swallows,<sup>29</sup> number of coughs,<sup>29</sup> the Airway Protection Scale,<sup>29</sup> time to audible voice production,<sup>13,24</sup> voice intensity in decibels sound pressure level (dB SPL),<sup>13,24</sup> voice therapy outcome measure,<sup>28,29</sup> GRBAS (Grade, Roughness, Breathiness, Asthenia, Strain) scale,<sup>29</sup> subjective assessment of speech

TABLE 1.  
Population, Intervention, Comparator, and Outcomes Characteristics.

Study	Gender	Age	Primary Diagnoses	Time From Tracheostomy Insertion to ACV	Type of Airflow Delivery	Rate of Airflow	Duration of ACV	Frequency of ACV	Brand and Size of Tracheostomy	Adverse Events and Complications	Outcome Measure and Follow-Up Time Points
Observational descriptive											
Akhtar & Bell (1993)	M	76	Postlaparotomy, ARDS	30 hr (1st attempt); 50 hr (2nd attempt)	Oxygen; unclear whether continuous or intermittent	6 L/min	30 sec (1st attempt); not recorded for 2nd attempt	Not reported	Portex Vocalaid #8.0	Neck and facial emphysema. Resolved within 6 hr	No outcome measures. Followed up 4 d post-successful attempt
Calamai et al. (2018)	M	74	CAP	6 d	Air, continuous	3 L/min (starting at 2 L/min)	A few minutes	Not reported	Not reported	Subcutaneous emphysema of neck and face	No outcome measures. No follow-up
Feneck et al. (1983)	F	58	Hypothermia, HoTN, acidosis	Vocalaid inserted 8 d after initial tracheostomy. Unclear whether ACV started same day.	Oxygen; continuous	Not reported	Not reported	Not reported	30 FG Portex Vocalaid	Misconnection of the airflow line leading to the cuff bursting and tracheal dilation	No outcome measures. No follow-up. Patient died 4 d later from complications of original condition
Leder & Astrachan (1989)	5F, 5M	Mean: 52.2; Range: 21-74	ARDS; C2 spinal injury; RT/chemotherapy induced cardiomyopathy +restrictive lung disease; CHF; Left cerebellar infarct; COPD x 2; HIV+ pneumonia; recurrent uterine leiomyosarcoma +respiratory distress; SLE + quadriplegia	Not reported	Not reported	Not reported	Not reported	Not reported	Communi-Trach <sup>®</sup> , size not reported	Stomal complications in 40% of patients within 3 wk of insertion; airflow line kinking in 80% of patients resulting in reduced voice intensity and pressure necrosis and wound extension	Outcome measures not reported. Followed up over 3 wk.
McGrath et al. (2016)	1F, 4M	Mean: 52.8; range: 30-76 (calculated from raw data)	Infective exacerbation of asthma + T2RF + PD + influenza A; COPD + double lung transplant; COPD + left upper lobectomy for lung carcinoma; CAP & ARDS; burns	Not outlined specifically but described for 4 patients (5 d; ~3 wk; 5 d; a week).	Not reported whether oxygen or air; implied use of intermittent airflow as discussed thumb port	Not outlined specifically but described for 3 patients (5 L/min; 3 + 5 L/min; 6 L/min)	Not outlined specifically but described for 2 patients (5 min spells; 5 min spells)	Not outlined specifically but described for two patients (spells; every day for spells)	Portex BLUSA SGS	Burping; risk of air trapping with vocal folds fixed in paramedian position	Outcome measures are not outlined specifically but described for some patients (Case 1: appears to be pre-ACV and during first trial of ACV; Case 2: no pre-ACV rating, voice TOMS appears to be completed during first trial of ACV; Case 3: not reported; Case 4: no pre-ACV rating, rating appears to have been completed during first ACV trial; Case 5: no pre-ACV rating, rating appears to have been completed during first ACV trial). Follow-up not reported.

(Continues)

TABLE 1.  
Continued

Study	Gender	Age	Primary Diagnoses	Time From Tracheostomy Insertion to ACV	Type of Airflow Delivery	Rate of Airflow	Duration of ACV	Frequency of ACV	Brand and Size of Tracheostomy	Adverse Events and Complications	Outcome Measure and Follow-Up Time Points
Naito et al. (1996)	M	65	SCI	Unclear. Argyle Aspiraid was 2nd tube inserted	Oxygen; continuous	1 L/min	Not reported	Not reported	Argyle Aspiraid, Nilton Sherwood. Size not reported	Not reported	Unclear when first FEES took place. 2nd FEES conducted 5 d after the 1st. State 71 d post-injury free from mechanical ventilation. No repeat FEES/ outcome measures at this point
Pandian et al. (2014)	1F, 3M	Mean: 41; range: 25–54	Bilateral orthoptic lung transplant for progressive interstitial lung disease + respiratory failure; progressive lymphoproliferative disorder status post chemotherapy and bone marrow transplant + severe GVHD + ARDS; type II neurofibromatosis and multiple schwannoma resections with residual left facial weakness, right facial nerve damage, right vocal fold paralysis, severe oropharyngeal dysphagia and severe GORD; ALS	Not reported	Air; state used intermittent airflow for two of the patients, not reported for other two patients	Not outlined specifically but described for 2 patients (5 L/min; 3 L/min and then 2–3 L/min when tracheostomy tube upsized)	Not reported	Not reported	Portex Blue Line Ultra SGS; size of tube not outlined specifically for all patients; one patient had a #8.0 changed to a #9.0; one patient had a change to a #8.0 but no information regarding size of 1st tube)	Strained voice quality from tensing vocal folds to control airflow; inability to achieve adequate phonation due to stomal leakage; air trapping due to vocal cord spasms	No prescribed times for descriptive outcome measures to be recorded. Follow-up not reported.
Observational analytic Kothari et al. (2017)	2F, 8M	Mean: 49.4 ± 5.12; range: 19–78	Severe brain injury with low arousal levels	Median: 20; range 10–107	Air; intermittent	3 L/min (starting at 1 L/min)	5 min (total of 100 sec of air application)	3 applications of 5 min during 150 min testing	Portex Blue Line Ultra SGS; size not reported	Not reported	Over the course of 150 min. Swallow frequency included 3 pre-treatment, 3 during treatment and 3 post-treatment. Subglottic aspirates included 3 pre-treatment, 3 just before the 3 treatment sessions. Last follow-up was 25 minutes after the final treatment session

(Continues)

TABLE 1.  
Continued

Study	Gender	Age	Primary Diagnoses	Time From Tracheostomy Insertion to ACV	Type of Airflow Delivery	Rate of Airflow	Duration of ACV	Frequency of ACV	Brand and Size of Tracheostomy	Adverse Events and Complications	Outcome Measure and Follow-Up Time Points
Leder (1990)	7F, 13M	Mean: 61.2; range: 24-80	COPD; ARDS; aortic stenosis; CHF; HIV +; Tetralogy of fallot/pulmonary HTN; primary biliary cirrhosis + ARDS + liver transplant; CNS hypoventilation; C5-6 fracture; Duchenne's; Polycystic kidney disease + renal transplant; idiopathic pulmonary fibrosis; GBS, primary hypoventilation syndrome	Not reported	Unclear whether oxygen or air; intermittent	5 L/min, 10 L/min, 15 L/min	5 sec x 3 at each airflow (unclear if having further trials between sessions)	Unclear but stating daily rehab needed to stimulate vocal fold adduction and synchronize with airflow and use thumb port	Portex "Talk" tracheostomy tube, 8 mm and 9 mm outer diameter with inner cannula removed	Not reported.	Patients were tested every day but outcome measures only taken once able to produce audible voice. One patient followed up at 1 yr; others unclear follow-up
Leder & Traquina (1989)	6F, 14M	Mean: 59.1; range: 21-78	C3-C4 fracture; C5-C6 fracture; left frontotemp-roparietal subdural hematoma; muscular dystrophy; ARDS; metastatic colon cancer; COPD; lung cancer; GI bleeding; failed angioplasty; C2 fracture; RT/chemotherapy-induced cardiomyopathy + restrictive lung disease; CHF; left CVA; HIV+; pneumonia; respiratory distress	No information provided about time from Communi-Trach I <sup>®</sup> being inserted to using ACV. Report the time from previous trachea insertion to Communi-Trach I <sup>®</sup> being inserted—mean: 11.9 d; SD 11.4; range: 0-43	No information about oxygen versus air; intermittent delivery	5, 10, 15 L/min	5 sec at each airflow for measurement purposes. Unclear if also had additional trials between assessment sessions.	Unclear but states daily rehab needed to support ACV use	Communi-Trach I <sup>®</sup> ; no information about size	None reported. State "optimum speech... without significant patient discomfort" implying there is some discomfort	Outcome measures taken daily until voice intensity recorded. Followed up until voice produced. Range from 2 to 70 d.
McGrath et al. (2019)	3F, 7M	Median: 60; IQR: 26; Range: 28-83	Cardiothoracic; general; pneumonia+left ventricular assist device; elective right lower lobe lobectomy; emergency laparotomy for ischemic gut; elective lobectomy complicated; respiratory syncytial viral pneumonitis requiring ECMO; double lung transplant for cystic fibrosis; biventricular heart failure due to	Median: 8; IQR: 9; Range: 3-46	Not reported whether oxygen or medical air; intermittent; implied nonhumidified	1-5 L/min	Median: 15 min; IQR: 10; Range: 1-20	No report of daily frequency. Reports number of episodes for all patients averaged over course of their treatment. Median: 9; IQR: 7; Range: 4-19	Portex BLUSA SGS (9) percutaneous and 1 surgical); #7.0 (1), #8.0 (4), #9.0 (5)	Discomfort in 10/91 episodes; excessive oral secretions in 9/91 episodes; stomal air leak in 2/91 episodes; gagging in 2/91 episodes; nausea in 1/91 episodes; patient asked to stop in 1/91	Initial ACV assessment and follow-up 3-7 d later

(Continues)

TABLE 1.  
Continued

Study	Gender	Age	Primary Diagnoses	Time From Tracheostomy Insertion to ACV	Type of Airflow Delivery	Rate of Airflow	Duration of ACV	Frequency of ACV	Brand and Size of Tracheostomy	Adverse Events and Complications	Outcome Measure and Follow-Up Time Points
Quasi-experimental			hypertrophic cardiomyopathy +heart transplant; OHCA, severe interstitial lung disease+single lung transplant		Warm humidified compressed air; no information on intermittent versus continuous	4, 6, 7, 10, 12 L/min	Not reported	4-5 times per day or 'whenever indicated'	Pitt speaking-cuffed tracheostomy; no information about size	No complication reported including stomal leak or leak into paratracheal tissue. Reported airflows >8 L/min causing patient discomfort	Assessed at every trial of ACV which was repeated 4-5 times per day. However, only one outcome measure reported per patient. Followed-up over 5 d.
Gordan (1984)	2F 8M	Mean: 48.2; Range: 32-65 (calculated from raw data)	GBS; ALS; COPD +acute respiratory failure; bowel perforation+sepsis +acute respiratory failure; multiple trauma+acute respiratory failure; bronchopneumonia +acute respiratory failure	Not reported							
Experimental											
Pandian et al. (2020)	25F, 25M	Mean: 54.3 ± 16.5	Medical pulmonary, medical neurological, surgical thoracic, surgical, nonthoracic	48 hr consideration of insertion of Portex BLUSA. Unclear exactly when tube inserted or treatment commenced.	Intermittent, no information on type of air	Mean optimal flow 4.7 ± 1.3	Not reported	Not reported	Portex Blue Line Ultra SGS; no information on size	None reported	Outcome measures taken at day 1 and day 5. No further follow-up.

ACV = above cuff vocalization; ALS = amyotrophic lateral sclerosis; ARDS = acute respiratory distress syndrome; BLUSA = blue line ultrasuction aid; C = cervical vertebrae; CAP = community acquired pneumonia; CHF = chronic heart failure; CNS = central nervous system; COPD = chronic obstructive pulmonary disease; CVA = cerebrovascular accident; CXR = chest x-ray; ECMO = extracorporeal membrane oxygenation; F = female; FEES = fiberoptic endoscopic evaluation of swallowing; FG = French gauge; GBS = Guillain Barré syndrome; GI = gastrointestinal; GORD = gastro-esophageal reflux disease; GVHD = graft versus host disease; HIV = human immunodeficiency virus; HoTN = hypotension; IQR = interquartile range; L/min = liters per minute; M = male; OHCA = out of hospital cardiac arrest; OWV = one way valve; PD = Parkinson's disease; RT = radiotherapy; SCI = spinal cord injury; SGS = subglottic suction; SLE = systemic lupus erythematosus; SOFA = Sequential Organ Failure Assessment; T2RF = type 2 respiratory failure; TOM = therapy outcome measures.



TABLE 2.  
Risk of Bias.

Joanna Briggs Institute Appraisal Tool		Bias	No Bias	Unclear	N/A	Reporting Bias	Internal Validity	External Validity	Measurement Bias	Selection Bias	Power	Attrition Bias	Confounding Bias	Performance Bias	Detection Bias	
Study	Level of Evidence and Study Design															
Level 4: Observational-descriptive																
Akhtar & Bell (1993)	Level 4.d, Case study	2	6	0	0	+	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Calamai et al. (2018)	Level 4.d, Case study	6	2	0	0	-	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Feneck et al. (1983)	Level 4.d, Case study	3	5	0	0	+	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Leder & Astrachan (1989)	Level 4.c, Case series	1	9	0	0	-	+	+	-	+	-	+	-	+	?	?
McGrath et al. (2016)	Level 4.c, Case series	9	0	0	1	-	N/A	N/A	-	-	N/A	N/A	?	?	-	-
Naito et al. (1996)	Level 4.d, Case study	2	6	0	0	+	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pandian et al. (2014)	Level 4.c, Case series	1	8	0	1	-	N/A	N/A	-	+	N/A	N/A	?	?	?	?
Level 3: Observational-analytic <sup>†</sup>																
Kothari et al. (2017)	Level 3.e, Observational study without a control group	0	6	4	0	+	-	-	-	-	-	+	?	?	?	?
Leder (1990)	Level 3.e, Observational study without a control group	1	9	0	0	+	-	-	+	?	-	+	?	+	+	+
Leder & Traquina (1989)	Level 3.e, Observational study without a control group	2	8	0	0	+	-	-	+	?	-	+	?	+	+	+
McGrath et al. (2019)	Level 3.e, Observational study without a control group	2	7	1	0	+	-	-	-	+	-	-	?	?	-	-
Level 2: Quasi-experimental																
Gordan (1984)	Level 2.d, Quasi-experimental	7	2	0	0	-	-	-	-	-	-	+	?	-	-	-
Level 1: Experimental																
Pandian et al. (2020)	Level 1.c, RCT	5	7	1	0	+	-	+	+	-	+	-	-	?	-	-

+ = low risk of bias; - = high risk of bias; ? = unclear risk of bias. The numbers in the Joanna Briggs Institute columns are the number of questions in the tool that were positive for bias, negative for bias, or unclear or not applicable.

<sup>†</sup>The case series critical appraisal checklist was used for these studies as one does not exist for observational studies without control groups.

intelligibility/voice,<sup>13,23,24,26,28,29</sup> the speech intelligibility test,<sup>12</sup> the ICU Functional Communication Scale,<sup>29</sup> QoL in mechanically ventilated patients,<sup>12</sup> voice-related QoL,<sup>12</sup> satisfaction rating,<sup>12</sup> independence rating,<sup>12</sup> ICU LoS,<sup>12</sup> and hospital LoS.<sup>12</sup> The only outcome measure utilized by more than two studies was the subjective assessment of speech intelligibility or voice quality.

All studies were unclear about data capturing time points, including repetition or reassessment, except for two studies which specified timings and captured outcome measures consistently. The follow-up periods for both were short: 150 minutes<sup>5</sup> and 5 days.<sup>12</sup>

### Study Quality

The JBI levels of evidence were generally very low, 4.d to 2.d, with one Level 1.e RCT.<sup>18,19</sup> All studies had a moderate to high level of bias, with RoB in multiple domains for most studies (Table 2). Bias was observed in the following domains: reporting bias (5/13 studies), internal validity (7/7 studies), external validity (5/7), measurement bias (6/9), selection bias (4/9), power (6/7), attrition bias (2/7), confounding bias (2/9), performance bias (1/9), and detection bias (4/9).

### Study Results

The results of the individual studies along with recommendations made for the use of ACV are outlined in Supporting Information, File S3.

**Acceptability.** Six of the 13 studies described ACV acceptability for patients or staff. Signs of acceptability for patients included: ability to use the intervention with ease and independence, satisfaction with the intervention, lack of frustration with the intervention, ability to communicate with staff, family and visitors, effective and meaningful communication, intelligibility of speech, sustained ability to communicate, reduced anxiety, ability to express basic needs and emotions, comfort, adequate voice intensity, and minimal adverse events or symptoms. Pandian et al. reported patient satisfaction levels, 41% stated they were somewhat or very satisfied with ACV, and 23% reported they were somewhat or very dissatisfied.<sup>12</sup> Additionally, they reported 74% of participants were able to use ACV with some level of independence.<sup>12</sup> Signs of acceptability for staff included: cooperation of the patient.<sup>28</sup>

**Adverse events and complications.** Nine studies reported adverse events or complications. Various adverse events were reported in the literature including subcutaneous emphysema of the neck and face in two patients,<sup>17,30</sup> and dilation of the trachea in one patient.<sup>27</sup> Complications and side-effects reported included: granulation and pressure necrosis at the stomal site with Communi-Trach I<sup>®</sup> in 40% of patients,<sup>25</sup> air trapping in two patients,<sup>26,28</sup> discomfort<sup>13,23</sup> in 11% of patients in one study,<sup>29</sup> aerophagia resulting in burping/abdominal distension in one patient,<sup>28</sup> excessive oral secretions in 10% of patients,<sup>29</sup> stomal air leak in three patients,<sup>26,29</sup> gagging in 2% of patients,<sup>29</sup> nausea in 1% of patients,<sup>29</sup> and hoarse and strained voice quality in two patients.<sup>26</sup>

**Communication.** Seven studies reported positive effects on communication including: voice intensity being

greater than ambient room noise in 45%–100% of patients at flows from 5 L/min to 15 L/min,<sup>13,24</sup> ability to produce an intelligible whisper or speech in 50%–80% of patients,<sup>23,28,29</sup> more effective communication,<sup>28</sup> more meaningful communication,<sup>26</sup> improved ability to communicate basic needs and discomfort,<sup>26</sup> ability to participate in short conversation,<sup>26</sup> reduction in the need to repeat to be understood,<sup>12</sup> improvements to the voice therapy outcome measure in 60%–80% of patients,<sup>28,29</sup> and improvements to the ICU Functional Communication Scale in 60% of patients.<sup>29</sup> Some studies also reported difficulties with ACV including: difficulty producing intelligible speech at lower flows,<sup>13</sup> inability to produce voice with laryngeal pathology in 10% of patients,<sup>13</sup> inability of 100% of patients with neuromuscular disease to produce intelligible speech,<sup>23</sup> delay to intelligible speech from 2.1 to 5.6 days on average and need for training from a speech and language therapist (SLT).<sup>13,24</sup> Optimal voice intensity and speech intelligibility were found to be between 10 and 15 L/min for the Communi-Trach I<sup>®24</sup> and the Portex “Talk”<sup>®</sup> tracheostomy tube.<sup>13</sup> The mean flow rate for optimal voicing with the Portex Blue Line Ultra SuctionAid (BLUSA) was reported by one study as 4.7 (±1.3) L/min.<sup>12</sup>

**Swallowing.** Positive benefits for swallowing were reported by four studies including subjective reports, such as elimination of aspirated food or drink particles in the subglottic port,<sup>14</sup> swallowing improving more quickly than expected,<sup>28</sup> stimulation of swallowing,<sup>28</sup> and improved laryngeal sensation.<sup>28</sup> Quantitative measures included: increase in spontaneous swallowing frequency with an average increase of 1.5–2 swallows per minute,<sup>5,29</sup> reduction in subglottic secretion volume from a mean of 3.10 ± 0.31 mL to 0.50 ± 0.30 mL,<sup>5</sup> and improvements in the Secretion Severity Rating Scale in 50% of patients by 0.5 (scale of 0 to 3).<sup>29</sup> ACV had no effect on the Penetration-Aspiration Scale.<sup>29</sup>

**Airway protection.** Two studies reported positive effects on cough,<sup>28,29</sup> with subjective statements of cough being stimulated,<sup>28</sup> and an increase in the number of spontaneous coughs per minute of 0.5 in 50% of patients.<sup>29</sup> ACV had no effect on the Airway Protection Scale.<sup>29</sup>

**Quality of life.** Pandian et al. subjectively stated that QoL was improved.<sup>26</sup> The RCT reported greater improvements in the Voice-Related QoL Score with ACV (26.59 ± 16.81 to 42.50 ± 17.69 versus 26.67 ± 16.72 to 32.26 ± 24.90;  $P = .001$ ) and greater improvements in the QoL in mechanically ventilated patients (data not provided)  $P = .04$ , when excluding 10 patients in the control group who received Passy Muir Valve for speech.<sup>12</sup>

**Length of stay.** One study examined the impact of ACV on LoS and found that both ICU and hospital LoS were greater in the ACV group (49 days ICU; 60 days hospital) than the control group (29 days ICU; 35 days hospital).<sup>12</sup> They suggested this was due to severity of illness; however, there was no significant difference between the sequential organ failure assessment scores presented.

**Mechanism of action.** It is hypothesized that ACV enables vocal fold vibration to facilitate voicing,<sup>28</sup> and that to successfully produce speech, functioning vocal folds and articulators are required.<sup>23</sup> Pandian et al.

stated that the restoration of vocalization facilitated improved QoL.<sup>12</sup> It was hypothesized that delay in voice production or inability to produce voice is caused by poor vocal fold adduction due to laryngeal pathology,<sup>13,24</sup> prolonged vocal fold abduction and disuse,<sup>13,24</sup> prolonged endotracheal intubation,<sup>13</sup> or poor ventilator-phonatory timing with phonation attempts occurring during the inspiratory cycle.<sup>13</sup> Leder and Traquina hypothesized that tracheostomy tubes with multiple openings for subglottic airflow will increase patient comfort and reduce the airflow needed.<sup>13</sup> Various mechanisms of action for improving swallow function were suggested, including increasing subglottic airway pressure which facilitates glottal closure during swallowing,<sup>5,14</sup> stimulation of subglottic mucosa and the superior laryngeal nerve facilitating vocal fold closure,<sup>5</sup> stimulation of laryngeal mechanoreceptors regulating swallowing function,<sup>5</sup> increase in afferent neural activity,<sup>29</sup> re-sensitization of the larynx,<sup>28,29</sup> improving swallowing strength,<sup>28</sup> improving airway protection,<sup>28</sup> and providing airflow to eject secretions from the trachea and larynx.<sup>29</sup>

**Recommendations for ACV delivery.** Several studies made suggestions regarding the earliest that ACV should commence post-tracheostomy insertion, with one stating 48 hours<sup>17</sup> and two stating 72 hours,<sup>28,29</sup> with the caveat that it could be started earlier if the stomal site is adequately healed.<sup>29</sup> Recommendations for airflow delivery included using intermittent airflow wherever possible,<sup>27</sup> avoiding prolonged use of nonhumidified air,<sup>14,26,28</sup> using minimal airflows to prevent laryngeal drying or hyperadduction of the vocal folds,<sup>26,28</sup> switching off airflow and/or unblocking the thumb when not speaking to reduce aerophagia,<sup>26</sup> and labeling the pilot balloon and subglottic port to prevent misconnection of the airflow.<sup>26</sup> The only contraindication suggested was upper airway obstruction.<sup>26,28</sup> Criteria for suitable patients for ACV included: not suitable for cuff deflation,<sup>26</sup> awake and attempting to communicate,<sup>26,28</sup> adequate speech and language function,<sup>26</sup> intact laryngeal function,<sup>28</sup> and established tracheostomy stoma.<sup>26</sup> Kothari et al. suggested that there is benefit in using ACV in patients with severe subglottic aspiration.<sup>5</sup> Gordan stated that ACV should be avoided in patients with neuromuscular disease, as there are no speech benefits.<sup>23</sup>

Two studies asserted that daily rehabilitation with an SLT is required for patients to synchronize vocalization with the airflow and the ventilator cycle, and to avoid or resolve negative side-effects, such as hoarse or strained vocal quality.<sup>13,24</sup> Pandian et al. stated that some patients need vocal fold exercises to reduce vocal fold spasms or laryngeal spasticity and to prevent air trapping.<sup>26</sup> They also advocated for education and training for communication partners.<sup>26</sup> McGrath et al. emphasized that an experienced multi-disciplinary team and trained SLTs should supervise ACV to minimize complications.<sup>28</sup> Two studies suggested the use of nasendoscopy to exclude laryngeal pathology in patients unable to vocalize with ACV.<sup>13,26</sup>

## DISCUSSION

We conducted a comprehensive systematic literature search and a narrative synthesis to evaluate the evidence

for the use of ACV in tracheostomized patients. We have determined that there is large variation in ACV implementation and a lack of evidence for how it should be implemented in clinical practice. There was limited, low-quality, and potentially biased evidence to show the efficacy or effectiveness of ACV for the various outcome measures in question, including communication, swallowing, airway protection, QoL, LoS, and acceptability. For other outcomes, such as incidence of pneumonia, time to decannulation, intervention costs, and costs-benefits, there was no published evidence. This review demonstrated that there are reported safety issues with ACV, with both adverse events and minor complications described. The extent of these safety issues is unclear.

The 13 studies included were a mixture of case reports, case series, observational, quasi-experimental, and one RCT. Levels of evidence were low and there was a high RoB in more than two domains for every study. Additionally, sample sizes were low with one study having 50 participants and all others having  $\leq 20$ . Different effects of ACV were examined in different studies including: adverse effects ( $n = 4$ ), communication ( $n = 4$ ), swallowing ( $n = 2$ ), communication and swallowing ( $n = 2$ ), QoL and communication ( $n = 1$ ). The studies can be split into two cohorts. The first, published pre-1996, used tracheostomy tubes specially designed for the application of an airflow to facilitate speech: the Portex Vocalaid, the Portex "Talk" Tracheostomy, the Communi-Trach I<sup>®</sup>, and the Pitt-speaking cuffed tracheostomy. Notably, the subglottic port of tracheostomy tubes was originally created for the purpose of speech and was first reported in 1967.<sup>10</sup> It was not until 1977 that these subglottic tubes were modified to enable the removal of aspirated secretions.<sup>31</sup> The second cohort, published from 1996 onwards, used tubes with the subglottic port designed for the removal of secretions: the Portex BLUSA and the Argyle Aspiraidd.

## Summary of Evidence

Both cohorts of studies evaluated ACV in a wide range of diagnoses. Some studies advised against use in certain populations, such as people with neurological conditions<sup>23</sup> or people unable to communicate or cooperate.<sup>28</sup> However, these recommendations appear to be attributable to a lack of observed benefits for communication, whereas other studies have demonstrated swallowing benefits even in patients with reduced consciousness.<sup>5</sup>

In contrast to the findings of the scoping review, which reported "...detailed descriptions of the ACV technique which was regarded as very similar..." that "...adds to the replicability of ACV both in research and clinical settings...",<sup>16</sup> this systematic review found considerable variability in ACV delivery. The first cohort of studies tended to use higher flows of  $\leq 15$  L/min, whereas the second cohort of studies used  $\leq 6$  L/min. There was variability in whether humidified oxygen, nonhumidified oxygen, or medical air was used. Airflow was mostly applied intermittently using a thumb-port, but some studies used a continuous airflow. Several studies mentioned concerns regarding potential for laryngo-tracheal mucosal drying.

However, no studies reported any symptoms or signs of this post-ACV.

Intervention delivery information was incomplete for all studies. Only one study provided information about planned frequency and dosage of the intervention (up to 15 minutes every 2 hours) and dose delivered.<sup>29</sup> There was limited information on the interval between tracheostomy insertion and intervention commencement. There was marked variation in outcome measures used, supporting the findings of a recent systematic review which explored use of outcome measures for communication in mechanically ventilated individuals.<sup>15</sup> Subjective judgment of speech intelligibility was the only consistent measure used, but how this was performed was unclear for most studies.

All studies that outlined who performed the initial assessment of the intervention used either an SLT<sup>12,13,24–26,28,29</sup> or an occupational therapist, as per local guidelines.<sup>5</sup> Four studies specified that SLT input for ACV introduction is essential to maximize effectiveness and minimize complications.<sup>13,24,26,28</sup>

Only one study explored patient satisfaction with ACV. Fewer than half reported satisfaction. A single study examined patient-reported complications, finding that <30% had complications. Patient or staff acceptability was reported descriptively and focused predominantly on communication, ability to use ACV and comfort. No studies explored acceptability or satisfaction from a dysphagia perspective. Various studies reported adverse events and complications from the serious, such as subcutaneous emphysema and tracheal dilation, to the mild, for example, stomal air leak and discomfort.

All studies exploring effects on communication (n = 7) or swallowing (n = 4) reported either qualitative or quantitative benefits for patients. Although two studies reported positive effects on cough sensitivity with increased spontaneous initiation of cough, there was no evidence of improved cough effectiveness or airway protection. Patients' QoL was reported to improve in one study using two QoL measures; only one of these measures demonstrated improvements with the entire sample. The other measure found improvements in the intervention group only when almost half the control group was excluded, leading to a RoB and reduced study power. The finding of increased ICU and hospital LoS with ACV is difficult to interpret in light of different protocols applied to the intervention and control arms (40% of the control group, but not of the intervention group, underwent cuff deflation trials).

Hypotheses for the mechanism of action were advanced by several studies, but none were mechanistic studies. The studies proposed that airflow elicits vocal fold vibration to facilitate vocalization, and that swallowing benefits are a result of increased subglottic pressures or increased laryngopharyngeal stimulation.

### ***Facilitators and Barriers to Implementation of ACV***

The studies reviewed suggested various factors facilitating effective use of ACV, including involvement of

SLT in ACV assessment and introduction with patients, appropriate patient identification, waiting 48–72 hours post-tracheostomy insertion before commencing ACV to minimize risk of subcutaneous emphysema, and optimizing airflow delivery. Potential barriers to implementation may include: lack of access to SLT, inadequate training of staff in the appropriate use of ACV, lack of clear evidence for optimal timing and delivery of ACV, and lack of access to nasendoscopy to identify laryngeal pathology and verify safety.

### ***Strengths and Limitations***

This review synthesized the key evidence for ACV and included a variety of qualitative and quantitative data. The strengths of this review include the use of a systematic approach and registered protocol reducing RoB. Data extraction and RoB analysis were carried out independently by two reviewers, improving reliability and accuracy of our findings. Sample sizes, the levels of evidence, and the quality of evidence was all low. A meta-analysis was not possible due to the heterogeneity of the studies. All studies lacked detail of the prescribed and delivered intervention, contributing to a lack of clarity regarding optimal timings, airflow type, airflow limits, frequency, and duration of ACV.

### ***Implications for Clinicians and Researchers***

This review reveals serious potential complications if ACV is delivered too early,<sup>17</sup> the tube is in the incorrect position,<sup>30</sup> or is carried out incorrectly or with inadequate training.<sup>27</sup> Misapplication of the intervention or inadequate support for the patient can lead to adverse events or the development of complications, such as strained vocal quality. The findings suggest cautious implementation of ACV in patients with a tracheostomy, taking into account the limited and low quality evidence available. The research findings suggest that SLTs, or other voice specialists, should be involved in the assessment and introduction of ACV to minimize laryngeal complications. We suggest that the development of guidelines, competencies, and education packages is essential to ensure staff have the appropriate skills to assess or deliver ACV. Given the limited and low quality of evidence available, it is not possible to make specific recommendations regarding the intervention delivery.

The evidence suggests that there are potential benefits from ACV for swallowing, communication, cough, and QoL; however, there are still many unanswered questions. It is important that future studies ensure a detailed description of ACV prescription and delivery to enable replicability and evaluation of optimal intervention delivery. The development of a core outcome set to include QoL, communication, swallowing, and airway protection would help to ensure that research is comparable.

When comparing this systematic review with the recent scoping review which studied the safety and effectiveness of ACV for speech,<sup>16</sup> various similarities and differences are noted. While this systematic review had a broader scope, it had a narrower inclusion criteria which excluded conference abstracts, studies with patients

<18 years old, studies using other interventions in addition to ACV or not providing clear data. This resulted in the inclusion of fewer studies than the scoping review. As a result of conducting RoB assessment on each study, this systematic review reported low quality of evidence overall for ACV. In contrast, the scoping review which conducted RoB assessment on three outcome measures, reported moderate quality of evidence for communication, low quality of evidence for QoL and complications, and very low quality for adverse events.<sup>16</sup>

## CONCLUSION

This is the first systematic review of ACV evaluating the evidence for acceptability and effectiveness for all identified potential benefits. The data require cautious interpretation because of the small sample sizes and methodological issues. Current evidence is insufficient for the provision of recommendations for optimal intervention delivery. There is a need for more, higher quality, and larger studies. Future research could benefit from a core outcome set and the accurate recording of prescribed and delivered intervention.

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## Author Contributions

C.S.M., E.M., C.A.B., C.B., M.C.B., and H.J.S. designed the study. C.S.M. and N.K. designed the search strategy. N.K. completed the searches. C.S.M. and E.M. performed the study screening and data extraction. C.S.M. drafted the manuscript. C.S.M., E.M., C.A.B., C.B., M.C.B., H.J.S., and N.K. revised the manuscript for important intellectual content.

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