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The Use of Speaking Valves in Children With Tracheostomy Tubes: What is the Scope of the Literature?

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One-way speaking valves have been successfully used to restore audible meaningful speech in adult patients after tracheostomy tube placement. One-way speaking valves have also been used in pediatric patients after tracheostomy tube placement with promising results. We conducted a scoping review to synthesize and summarize the current evidence on the use of one-way tracheostomy tube speaking valves in the pediatric population to identify knowledge gaps that could inform future research programs and facilitate evidence-based clinical decision making. The Arksey and O'Malley 5-step methodological framework was used for this scoping review. We searched OVID MEDLINE, EMBASE, PubMed, Web of Science, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Google Scholar to locate articles published between January 1, 1946 and May 26, 2016. Our search resulted in a total of 524 articles. After removing 270 duplicates, we screened 254 abstracts, and 50 articles were identified for full text review. We excluded 38 references. A total of 12 articles met our inclusion criteria. Details of all studies were charted. Application of the Sackett levels of evidence to evaluate the qualitative strength of the evidence provided by the 12 articles selected for study found that 6 studies were level 5, 4 were level 4, and 2 studies were categorized as level 3 evidence. Eligibility criteria for trials of speaking valves were inconsistent across all studies and included a combination of clinical assessment coupled with published indications. Much of the literature has focused on tolerance/successful use of speaking valves in children with a tracheostomy with limited evidence on its impact on verbal communication. Current evidence on the use of speaking valves in children with a tracheostomy, its indication, and its impact on verbal communication is inadequate, mandating further research in this area. *Key words: speaking valve; Passy-Muir; tracheotomy speaking valve; tracheostomy speaking valve; swallowing and speaking valve; long-term ventilation speaking valve.* [Respir Care 0;0(0):1–•. © 0 Daedalus Enterprises]

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Introduction

A tracheotomy is performed to bypass an upper-airway obstruction, facilitate long-term mechanical ventilation and/or allow for pulmonary clearance.[1,2] Although principal indications for a pediatric tracheotomy have remained the same over the past decade, more children have tracheostomies for increasingly longer periods of time.[1]

Motor speech production and verbal communication are affected by the presence of a tracheostomy tube in the airway. Ensuring ongoing communication is an important aspect of care for children with tracheostomy tubes. It has previously been shown that the absence of an effective and consistent communication modality has a negative impact on a child's medical, psychological, and social well-being.[3]

The presence of a tracheostomy tube prevents the normal flow of air upward through the vocal folds; the vibration of the vocal folds produces the voice. One-way speaking valves have been successfully used to enable patients to vocalize after tracheostomy tube placement.[4] A speaking valve is placed on the hub of a tracheostomy tube to redirect air flow upward through the vocal folds during expiration. Criteria for selection of candidates for use of a speaking valve may include: tracheostomy tube size less than two thirds of the tracheal lumen, medical stability, ability to have the tracheostomy cuff deflated without aspiration, patency of airway above the tracheostomy, and absence of thick secretions.[5]

In addition to speech and language acquisition, literature from the adult population suggests additional benefits, including a reduction in aspirations as well as improved secretion management and ease of breathing.[6,7] One-way speaking valves have been used in children with promising results. However, a current understanding of the extent and scope of the current evidence on the use of speaking valves in children with tracheostomy tubes is lacking.

We conducted a scoping review to synthesize and summarize the current evidence on the use of one-way tracheostomy tube speaking valves in the pediatric population to identify knowledge gaps that could inform future research programs and facilitate evidence-based clinical decision making.

Review of the Literature

We used the Arksey and O'Malley 5-step methodological framework to conduct our scoping review.[8] The 5 steps included: (1) identification of the research question; (2) identification of studies relevant to the research question; (3) selection of studies to include in the review; (4) charting, collating, and summarizing the information and data within the included studies; and (5) reporting results of the review.

Research Question

The research question was formulated by an interprofessional team of clinicians from the Division of Respiratory Medicine, the Department of Otolaryngology–Head and Neck Surgery, and the Departments of Respiratory Therapy and Speech-Language Pathology at the Hospital for Sick Children (Toronto, Canada) based on current knowledge gaps in the use of speaking valves in children. The research question was as follows: What is the scope of existing literature to support the use of speaking valves in children with tracheostomy tubes?

Identification and Selection of Studies

We searched the following electronic databases from January 1, 1946 to May 26, 2016: OVID MEDLINE, EMBASE, PubMed, Web of Science, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Google Scholar. We also hand-searched key websites and existing organizations and networks, which included the Canadian, American, and European Respiratory Society websites as well as the Passy-Muir website.

Search terms were developed in consultation with an experienced information specialist. All studies that described a pediatric population (age 0–18 y) using a one-way tracheostomy speaking valve were included. Search terms such as "speaking valve," "Passy-Muir," "tracheotomy speaking valve," "tracheostomy speaking valve," "swallowing and speaking valve" and "long-term ventilation speaking valve" were used to locate studies relevant to our review.

We included all types of studies that described children with a tracheostomy using a speaking valve. Observational

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studies, randomized controlled trials, before-and-after (experimental) studies, retrospective studies, case series, and qualitative studies were included. We excluded single case reports, review articles, book excerpts, commentaries, editorials, opinion papers, and studies that were written in languages other than English because they did not fall within the 5 levels of evidence as per the Sackett levels of evidence scale (see below).[9,10] We used an EndNote X4 (Clarivate Analytics, Philadelphia, Pennsylvania) library for maintaining and managing our records.

Using a predesigned screening tool, 2 authors (RA and WZ) independently examined study titles and abstracts to identify eligible studies. For studies that were deemed potentially eligible, full text articles were obtained and reviewed by both authors for eligibility. Disagreements were resolved through discussion with a third author (TH).

Research Objectives

We had 2 main research objectives for this scoping review. Research objective 1 was to report the eligibility criteria in the literature for the use of speaking valves in children with tracheostomies. Research objective 2 was to summarize the reported benefits from the use of a speaking valve.

Charting the Data

The research team collectively developed a standardized charting form that included all of the variables relevant to the research question. The charting form was iteratively updated as needed. Using the charting form, each author (RA and WZ) independently abstracted the information from each article included. This information was then verified and checked for accuracy by a third author (TH). For each article included in this review, the charting form was utilized to collect the following data points: type of study, authors, year of publication, study setting, sample size, country where the study was conducted, age range of study participants, primary diagnosis and comorbidities of study participants, inclusion and exclusion criteria used for trials of the speaking valve, and the study outcomes.

Summarizing and Reporting Results

Summary tables were generated to report the counts and proportions of the study and cohort characteristics. We used the Sackett levels of evidence scale to evaluate the quality of each study.[9,10] This tool ranks articles from 1 (strongest evidence) to 5 (weakest evidence) based on the type of research and probability of bias. The levels of evidence according to Sackett are as follows: level 1, randomized control trials with clear-cut results; level 2, small randomized controlled trials with unclear results; level 3, cohort and case-control studies; level 4, historical cohort or case-control studies; level 5, case series studies with no controls. Information such as type of study, population, and research methods were scanned for each article to determine the level of evidence. A qualitative analytic method was used to identify, analyze, and report patterns in the data. For each article, characteristics of the study participants, selection of candidates for speaking valve trials, and study outcomes were reported.

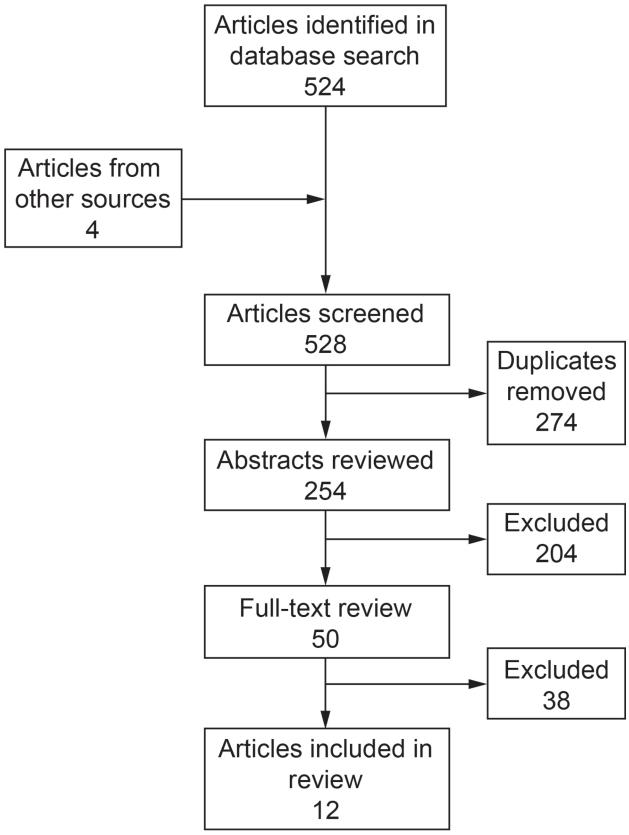

Fig. 1. Flow chart.

Results

Search Results

As delineated in Figure 1, our search resulted in a total of 524 articles; we excluded 270 duplicates. Our hand search of journals and relevant websites resulted in 4 additional articles. We screened 254 abstracts and identified 50 references for full text review. Of these 50 references, 38 were excluded for reasons of focus (ie, not about speaking valves) and population studied (ie, not pediatric). A total of 12 articles met our inclusion criteria.

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Characteristics and Level of Evidence of the Selected Studies

For the 12 studies included in this review, the sample size ranged from 2 to 64 children. Nine studies (75%) were conducted in the United States, one (8.3%) in the United Kingdom, one (8.3%) in Australia, and one (8.3%) in Thailand. Study designs included prospective cohort (16.6%, no. = 2), prospective case control (16.6%, no. = 2), retrospective cohorts (16.6%, *n* = 2), and case series (50%, no. = 6). Six studies (50%) were categorized as level 5 evidence. Four studies (33.3%) were level 4 evidence, and 2 studies (16.6%) were level 3 evidence. Two studies (16.6%) reported on the use of a speaking valve in an in-patient care setting, one (8.3%) in the ICU, and 2 (16.6%) in the NICU. The remaining studies (58%) reported the use of a speaking valve in an out-patient setting. See Table 1 and Table 2 for a summary of the study characteristics of the included studies that were graded using the Sackett levels of evidence.

Table 1 provides a summary of subject characteristics of the studies. Two studies (16.6%) reported on the use of a drilled speaking valve (a modified type of speaking valve with up to 2 holes, each 1.6 mm). The population of children included in each study for trials of a speaking valve was heterogeneous with regard to primary diagnosis, reasons for tracheotomy, and comorbidities. Most of the studies included children with more than one comorbidity and multiple diagnoses, including congenital and chromosomal abnormalities, mental, neurologic, musculoskeletal, and respiratory disorders. Key reported indications for tracheotomy included upper-airway obstruction, pulmonary clearance, and prolonged mechanical ventilation.

Two studies[4,16] included a total of 12 children who had tracheostomies for upper-airway obstruction. Five studies[4,12-14,20] included a total of 33 children with a tracheostomy for mechanical ventilation. The remaining 5 studies[11,17-19,21] included 162 children who had varied indications for tracheostomy. Specifically, 82 had a tracheostomy for upper-airway obstruction and laryngeal abnormalities, 54 required a tracheostomy for mechanical ventilation, and 26 children had a tracheostomy for pulmonary clearance (see Table 1).

Table 1. Characteristics of Studies Included

Characteristics	no. (%)
Study characteristics	
Country	
United States	9 (75.0)
United Kingdom	1 (8.3)
Australia	1 (8.3)
Thailand	1 (8.3)
Study design	
Prospective cohort	2 (16.6)
Prospective case control	2 (16.6)
Retrospective cohorts	2 (16.6)
Case series	6 (50.0)
Study setting	
In-patient	2 (16.6)
ICU	1 (8.3)
NICU	2 (16.6)
Out-patient	7 (58.0)
Sample size	
1–10	5 (41.6)
11–30	5 (41.6)
31–65	2 (16.6)
Sackett level of evidence	
Level 5	6 (50.0)
Level 4	4 (33.3)
Level 3	2 (16.6)
Levels 1 and 2	0 (0.0)
Cohort characteristics	
Type of speaking valve used	
Passy-Muir	9 (75.0)
Shiley + Passy-Muir	1 (8.3)
Drilled Passy-Muir	2 (16.6)
Total number of children included in 12 studies	230 (100)
Upper-airway obstruction	111 (48.2)
Long-term ventilation	84 (36.5)
Pulmonary clearance	35 (15.2)
Eligibility criteria for speaking valve trial	
Team assessment and added criteria	7 (58.3)
Passy-Muir valve manufacturer guidelines and added inclusion/exclusion criteria	5 (33.3)
Reported benefits	
Success/tolerance of use (awake hours)	10 (83.0)
Safety of use during sleep	1 (8.3)
Improved communication	8 (66.6)
Secretion management/aspiration	3 (25.0)
Improved swallowing	2 (16.6)
Improved cough	1 (8.3)
Ease of breathing	1 (8.3)

Eligibility Criteria for Trials of a Speaking Valve

The majority of studies reported on the use of one of 2 main strategies to determine eligibility for a speaking valve trial: (1) clinical assessment by a team of experts or (2) indications listed from a speaking valve manufacturer as a general guide and population-specific criteria. The clinical team of experts included pediatric otolaryngology head and neck surgery, speech and language pathology, pediatric pulmonology/general pediatrics, and pediatric respiratory therapy (see Table 1, bottom). Seven studies (58.3%) reported a team approach to assessing children before a speaking valve trial. Cho Lieu et al[11] included children assessed by the tracheal airway communication team. No specific inclusion criteria were reported. Four studies[12,15,20,21] reported the involvement of a team and a team-based protocol. In addition, these studies reported inclu-

Table 2. Characteristics of the Studies That Were Graded According to the Sachett Evidence Scale and Included

Author, Year, Study	Location	Study Design	Type of One-Way Speaking Valve	Sample Size	Age of Subjects	Levels of Evidence (Sackett)
Cho Lieu et al (1999)[11]: Passy-Muir valve in children with tracheostomy	United States	Retrospective cohort	Passy-Muir valve	55	3 d to 18 y (50% ≤12 mo)	4
Hull et al (2005)[12]: Tracheostomy speaking valves for children: tolerance and clinical benefits	United States	Retrospective case series	Passy-Muir valve and Shiley	12	8 mo to 21 y	5
Fraser et al (1998)[13]: Long-term ventilator-dependent children: a vocal profile analysis	United Kingdom	Prospective case series	Passy-Muir valve	4	7 mo to 5 y, 10 mo	5
Gereau et al (1996)[14]: Selection of pediatric patients for use of the Passy-Muir valve for speech production	United States	Prospective case series	Passy-Muir valve	12	1–17 y	5
Torres et al (2004)[15]: Clinical benefits of Passy-Muir tracheotomy and ventilator speaking valves in the NICU	United States	Prospective case series	Passy-Muir valve	2	9 d to 10 mo	5
Buckland et al (2012)[16]: Drilling speaking valves to promote phonation in tracheotomy-dependent children	Australia	Retrospective case series	Drilled Passy-Muir valve	10	2 mo to 15 y	5
Engleman and Turnage-Carrier (1997)[17]: Tolerance of the Passy-Muir speaking valve in infants and children less than 2 years of age	United States	Retrospective cohort	Passy-Muir valve	64	<2 y	4
Utrarachkij et al (2005)[18]: Measurement of end-expiratory pressure as an indicator of airway patency above tracheotomy in children	Thailand	Prospective cohort	Passy-Muir valve	22	3.2 mo to 17 y	4
Brigger and Harnick (2009)[4]: Drilling speaking valves: a modification to improve vocalization in tracheostomy-dependent children	United States	Prospective case series	Drilled Passy-Muir valve	2	12–21 mo	5
Ongkasuwan et al (2013)[19]: The effects of a speaking valve on laryngeal aspiration and penetration in children with tracheotomies	United States	Prospective case control	Passy-Muir valve	12	3 mo to 9 y	3
Barraza et al (2013)[20]: Safety of Passy-Muir tracheotomy speaking valve in pediatric patients during sleep: a pilot study	United States	Prospective case control	Passy-Muir valve	9	1–18 y	3
Stevens et al (2011)[21]: Passy-Muir valve use in NICU	United States	Prospective cohort	Passy-Muir valve	27	<1 y	4

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sion criteria for trials of a speaking valve. Gereau et al[14] reported selection of children based on speaking valve manufacturer recommendations and additional inclusion criteria introduced by a team of experts. Buckland et al[16] included children for trials of a drilled speaking valve based on a protocol and team assessment. In addition, authors also reported a decision making algorithm that specified each team member's role in the assessment process.

Four studies[4,13,17,18] (33.3%) used speaking valve manufacturer indications as a general guide and reported additional inclusion/exclusion criteria. One study[19] (8.3%) did not report any inclusion/exclusion criteria. Supplementary Table 1 provides details on the inclusion criteria for speaking valve candidacy (see the supplementary table at http://www.rcjournal.com).

Benefits of Speaking Valve Use

The reported benefits of a speaking valve are summarized in Table 1. The most commonly reported study outcome (primary and secondary study outcome) was tolerance/successful use of a speaking valve, reported in 10 studies.[4,11,12,14-18,20,21] Of these 10 studies, only 4[12,15-17] studied tolerance/successful use of a speaking valve as a primary outcome. These 4 studies[11,12,17,20] defined tolerance/successful use of a speaking valve during awake hours as stable vital signs, stable oxygen saturation, and absence of symptoms of intolerance (eg, agitation, anxiety, skin color change, coughing/gagging) from a baseline before trials of a speaking valve were introduced. Ninety-three of 103 subjects from these studies tolerated the speaking valve if trialed. Five[14,15,18,19,21] (of a total of 10) studies reported tolerance and successful use of a speaking valve during awake hours as a secondary outcome but did not define tolerance or success. One study[20] (of a total of 10) reported safety of a speaking valve during sleep as a primary outcome, defined as stable vital signs and gas exchange (oxygen saturation and end-tidal CO_2) 1 night before trials of a speaking valve. A speaking valve while asleep was safely used in all 7 children it was trialed on.[20]

Verbal communication was reported in 8 studies.[4,11,15-17,12-14] Only one study[13] reported communication (vocal function with speaking valve) as a primary outcome in a case series. In this study, 12 parameters of communication were selected for assessment by 3 trained speech therapists and rated as normal and abnormal. Parameters included: modal voice, phonation type, pitch, loudness, breath support, and voice continuity. The study recorded spontaneous speech in older children and babbling in infants and those in the prelinguistic developmental stage. Two subjects scored 9 and 10 out of 12, and the other 2 had a poor score (3 and 4 out of 12).[13] In all other studies,[4,11,12,14-17] communication was assessed clinically using different nonspecific terms and studied as secondary outcomes. Audible crying, nonspecific vocalization, word approximation, single words, short phrases, making noises, and production of voice were terms used to report communication with a speaking valve. For studies that included different age groups, no age-specific milestone was used to evaluate communication and speech. Two studies[4,16] reported communication with a drilled speaking valve in children with upper-airway obstruction. Communication was defined as "production of sustained voice for $\geq$ 2 seconds" by Buckland et al[16] and reported as production of voice based on clinical assessment by Brigger et al.[4] Overall, audible phonation was feasible in 107 of 144 pediatric subjects between 3 d and 12 months of age across 7 studies of speaking valve use in children with a tracheostomy.[4,11-16]

Other benefits of a speaking valve, including improved secretion management; better cough management; and/or improved swallowing; ease of breathing; and reduced aspiration were reported in 6 studies[11,12,15,19,21] (50%). Only one article[19] studied reduced aspiration with a speaking valve as a primary outcome. This study used a scoring system and fluoroscopy to define and report reduced laryngeal aspiration and improved swallowing. A speaking valve was shown to have no effect on aspiration in any of the 12 pediatric subjects between the ages of 3 months and 9 y.[19] Other secondary benefits, such as improved secretion management, better cough management, ease of swallowing, and ease of breathing, were reported by caregivers or assessed by clinicians[11,12,15,21] but were not defined a priori. Additional details of reported benefits and key findings for each study are given in Table 3.

Discussion

The main aim of our review was to summarize and synthesize the current body of evidence related to speaking valve use in children with tracheostomy tubes. Overall, there is a dearth of strong evidence (level 1 and 2 studies) to support the use of one-way speaking valves in the pediatric population. A Passy-Muir valve is the only one-way speaking valve that has been studied in children. The current level of evidence is inadequate to optimally guide clinical decision making for speaking valve use in children who have a tracheostomy, and there is a need for well-designed randomized controlled trials and cohort studies in this field. Furthermore, there is a need to develop clinical practice guidelines using multidisciplinary panels of experts to provide pragmatic guidance for clinicians, given the current paucity of data in this field.

Most of the current literature has focused on tolerance of speaking valves. The literature does not provide sufficient evidence regarding the impact of a speaking valve on verbal communication in children. Communication is an important aspect of early childhood development, and this area needs to be further studied and explored. Critical

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Table 3. Study Outcomes and Key Findings of the Studies Graded According to the Sackett Evidence Scale

Study	Defined and Reported Outcomes	Key Findings Reported
Cho Lieu et al[11] (1999): Passy-Muir valve in children with tracheostomy	Successful use of Passy-Muir valve defined as pass/conditional pass (stable heart rate, breathing frequency, oxygen saturation, skin color, and activity level, ability to adapt to an oral exhalation pattern, lack of coughing/gagging, stable behavior and mood)	52 children tolerated use of speaking valve
	Decannulation status (time with tracheostomy in months)	
Hull et al[12] (2005): Tracheostomy speaking valves for children: tolerance and clinical benefits	Tolerance of tracheotomy speaking valve (minimal anxiety, O_2 saturation $\geq$ 95%, stable heart rate and breathing frequency for duration of trial)	10 children tolerated speaking valve and achieved phonation
	Phonation with speaking (audible crying, nonspecific vocalizations, word approximations, single words, and short phrases)	Minimal to no improvement in coughing, secretion, and swallowing
	Secondary benefits of valve reported (coughing management, secretion management, swallowing/feeding and oxygenation (clinically observed)	
Fraser et al[13] (1998): Long-term ventilator-dependent children: a vocal profile analysis	Vocal function with Passy-Muir valve (phonation, pitch, loudness, breath support, and continuity measured using an auditory perceptual rating scheme)	1 of 4 children on mechanical ventilation had normal speech
Gereau et al[14] (1996): Selection of pediatric patients for use of the Passy-Muir valve for speech production	Vocalization/speech production and successful use of Passy-Muir valve	12 children could successfully use a speaking valve and vocalize
Torres et al[15] (2004): Clinical benefits of Passy-Muir tracheotomy and ventilator speaking valves in the NICU	Communication (crying, making noise)	2 children on mechanical ventilation could tolerate the valve and produced voice
	Secretion management (reduced secretion and aspiration, ease of breathing)	
	Ease of swallowing	
Buckland et al[16] (2012): Drilling speaking valves to promote phonation in tracheotomy-dependent children	Tolerance of drilled Passy-Muir valve (wearing the speaking valve for $\geq$2-h periods within 2 weeks of valve introduction, transpulmonary pressure $\leq$10 cm H_2O on passive manometry, no significant changes in arterial oxygenation, heart rate, or breathing during trials)	8 children tolerated drilled speaking valve
	Phonation with drilled Passy-Muir valve (production of sustained voice for $\geq$2 s)	5 children could phonate using the drilled valve
Engleman and Turnage-Carrier[17] (1997): Tolerance of the Passy-Muir speaking valve in infants and children less than 2 years of age	Tolerance of Passy-Muir Valve (O_2 saturation of $\geq$88%, stable breathing frequency, heart rate, no agitation and no change in color, no increase in respiratory effort from baseline)	24 tolerated a speaking valve use
	Vocalization with Passy-Muir valve (clinically assessed as production of voice)	23 produced vocalization
Utrarachkij et al[18] (2005): Measurement of end-expiratory pressure as an indicator of airway patency above tracheotomy in children	Tolerance of Passy-Muir valve (stable heart rate, breathing frequency, and O_2 saturation for 5 min after speaking valve introduction)	13 children tolerated use of a speaking valve
Brigger and Harnick[4] (2009): Drilling speaking valves: a modification to improve vocalization in tracheostomy dependent children	Tolerance of Passy-Muir valve and drilled Passy-Muir valve (trans-tracheal pressure of $<$10, lack of respiratory distress assessed clinically)	2 children tolerated a drilled speaking valve and could communicate
	Vocalization with drilled Passy-Muir valve (production of voice assessed clinically)	
Ongkasuwan et al[19] (2013): The effects of a speaking valve on laryngeal aspiration and penetration in children with tracheotomies	Laryngeal aspiration with Passy-Muir valve (decrease in laryngeal aspiration and penetration measured with Rosenbek 8-point scale and barium swallow)	12 children showed no improvement in aspiration, but improvement in swallowing was reported
	Improved swallowing with Passy-Muir valve (decreased piriform sinus residue)	
Barraza et al[20] (2013): Safety of Passy-Muir tracheotomy speaking valve in pediatric patients during sleep: a pilot study	Safety of Passy-Muir valve during sleep (stable heart rate, breathing frequency, oxygen saturation, and end-tidal carbon dioxide compared with baseline one night before placing the Passy-Muir valve)	7 children safely used a speaking valve during sleep
Stevens et al[21] (2011): Passy-Muir valve use in NICU	Safety of Passy-Muir valve use (lack of complications assessed clinically)	19 children safely used a speaking valve

periods of speech and language acquisition and age-specific communication milestones early in life for children with tracheostomy tubes should be taken into consideration when designing future studies.

In addition, there is minimal anecdotal evidence from case series and small studies regarding the secondary benefits of a speaking valve, including better secretion and cough management, improved swallowing, increased ease of breathing, and reduced aspiration. Considering the medical vulnerability of children living with a tracheostomy in the home milieu who are prone to respiration-related complications, addressing this gap in the literature may be an opportunity to reduce morbidity and potentially contribute to a reduction in mortality of these children.

The population of children included in the majority of the studies was heterogeneous with regard to primary diagnosis, comorbidities, and indications for tracheotomy with collective results reported. Three main reasons for tracheotomy were upper-airway obstruction, the need for long-term ventilation, and pulmonary toilet. Because these

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characteristics are likely to impact the use of speaking valves and the outcomes, future studies are needed that are sufficiently powered to cogently study these subgroups of children. Evidence from such studies will result in a scientifically based general consensus on indications for use of a speaking valve that could be used consistently by health professionals and researchers in the future.

Conclusions

This review documents the lack of adequate qualitative and quantitative evidence on the use of a speaking valve in the pediatric population (< 18 y old) with tracheostomy tubes. Verbal communication, although a crucial aspect of care of children with a tracheostomy, has not been adequately explored in the current scientific literature. There is a need for pragmatic and interventional studies that can better inform clinical practice in the future.

REFERENCES

1. Lawrason A, Kavanagh K. Pediatric tracheotomy: are the indications changing? Int J Pediatr Otorhinolaryngol 2013;77(6):922-925.
2. Kremer B, Botos-Kremer AI, Eckel HE, Schlöndorff G. Indications, complications, and surgical techniques for pediatric tracheostomies–an update. J Pediatr Surg 2002;37(11):1556-1562.
3. Baker BM, Blackwell PB. Adult and infant vocalization: speaking valves used in individuals with tracheostomy and ventilator dependency. J Ky Med Assoc 2001;99(5):193-203.
4. Brigger MT, Hartnick CJ. Drilling speaking valves: a modification to improve vocalization in tracheostomy dependent children. Laryngoscope 2009;119(1):176-179.
5. Sherman JM, Davis S, Albamonte-Petrick S, Chatburn RL, Fitton C, Green C, et al. Care of the child with a chronic tracheostomy: this official statement of the American Thoracic Society was adopted by the ATS Board of Directors, July 1999. Am J Respir Crit Care Med 2000;161(1):297-308.
6. Adam SI, Srinet P, Aronberg RM, Rosenberg G, Leder SB. Verbal communication with the Blom low profile and Passy-Muir one-way tracheotomy tube speaking valves. J Commun Disord 2015;56:40-46.
7. Bultsma R, Koopmans M, Kuiper M, Egbers P. Ability to speak in ventilator-dependent tracheostomized ICU patients. Crit Care 2014; 18(Suppl 1):P323.
8. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol 2005;8(1):19-32.
9. Sackett D SS, Richardson W. Evidence-based medicine: how to practice and teach EBM. Edinburgh: Churchill Livingstone; 2001.
10. Sackett D, Rosendberg W, Haynes R. Evidence-based medicine: how to practice and teach EBM, 2nd edition. Edinburgh, Scotland: Churchill Livingston; 2003.
11. Cho Lieu JE, Muntz HR, Prater D, Blount Stahl M. Passy-Muir valve in children with tracheotomy. Int J Pediatr Otorhinolaryngol 1999; 50(3):197-203.
12. Hull EM, Dumas HM, Crowley RA, Kharasch VS. Tracheostomy speaking valves for children: tolerance and clinical benefits. Pediatr Rehabil 2005;8(3):214-219.
13. Fraser J, Pengilly A, Mok Q. Long-term ventilator-dependent children: a vocal profile analysis. Pediatr Rehabil 1998;2(2):71-75.
14. Gereau SA, Navarro GC, Cluterio B, Mullan E, Bassila M, Ruben RJ. Selection of pediatric patients for use of the Passy-Muir valve for speech production. Int J Pediatr Otorhinolaryngol 1996;35(1):11-17.
15. Torres LY, Sirbegovic DJ. Clinical benefits of the Passy-Muir tracheostomy and ventilator speaking valves in the NICU. Neonatal Intensive Care. 2004;17(4):20-23.
16. Buckland A, Jackson L, Ilich T, Lipscombe J, Jones G, Vijayasekaran S. Drilling speaking valves to promote phonation in tracheostomy-dependent children. Laryngoscope 2012;122(10):2316-2322.
17. Engleman SG, Turnage-Carrier C. Tolerance of the Passy-Muir speaking valve in infants and children less than 2 years of age. Pediatr Nurs 1997;23(6):571-573.
18. Utrarachkij J, Pongsasnongkul J, Preutthipan A, Chantarojanasri T. Measurement of end-expiratory pressure as an indicator of airway patentcy above tracheostomy in children. J Med Assoc Thai 2005; 88(7):928-933.
19. Ongkasuwan J, Turk CL, Rappazzo CA, Lavergne KA, Smith EO, Friedman EM. The effect of a speaking valve on laryngeal aspiration and penetration in children with tracheotomies. Laryngoscope 2014; 124(6):1469-1474.
20. Barraza G, Halaby C, Islam S, Gutekunst W, Simpser E, Pirzada M. Safety of Passy-Muir tracheostomy speaking valve in pediatric patients during sleep: a pilot study. Chest Conference meeting abstract; 2013. doi: 10.1378/chest.1692327.
21. Stevens M, Finch J, Justice L, Geiger E. Use of the Passy-Muir valve in the neonatal intensive care unit. Neonatal Intensive Care 2011; 24(7):22-23.