## Evidence Table

### Use of a Passy-Muir Speaking Valve in Non-Ventilated Infants and Children

#### NHMRC hierarchies of study design and levels of evidence

<table>
<thead>
<tr>
<th>Study design</th>
<th>Level of evidence</th>
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<tbody>
<tr>
<td>Systematic review of all relevant randomised controlled trials (RCT)</td>
<td>I</td>
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<tr>
<td>Properly designed RCT</td>
<td>II</td>
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<tr>
<td>Well-designed pseudo-randomised controlled trial (e.g. Alternate allocation)</td>
<td>III-1</td>
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<tr>
<td>Comparative studies (or systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group</td>
<td>III-2</td>
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<tr>
<td>Comparative studies with a historical control, two or more single arm studies or interrupted time series without a parallel control group</td>
<td>III-3</td>
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<tr>
<td>Case series, post-test or pre-test/post-test, with no control group</td>
<td>IV</td>
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<tr>
<td>Expert opinion without critical appraisal, or based on physiology, bench research, or historically based clinical principles</td>
<td>V</td>
</tr>
<tr>
<td>Reference</td>
<td>Level of Evidence</td>
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- Only 1/3rd of tracheostomised children <18 months were referred to Speech Pathology. Overall rate of referral of tracheostomised children was <50%.  
- Culminated in development of a protocol to ensure routine Speech Pathology involvement with children with a tracheostomy at the Children’s hospital of Buffalo, NY. First tracheostomy change=routine referral to Speech Pathology.  
- Parent-child interaction is affected by presence of a tracheostomy and the limited vocalisation opportunity- can be facilitated by a Speech Pathologist. |
- Vocal efficiency is measured by simultaneous assessment of airflow, sound intensity and subglottic pressure. Usually invasive.  
- Study presents the airway interruption technique as a non-invasive measurement: NB: requires ++ subject compliance.  
- Findings of 35 trials produced by 5 participants supported high correlation between oral cavity pressure during airway interruption and percutaneous subglottic pressure during phonation. Measured by analysis of participants’ production of /pi/: /p/-closure phase-oral cavity pressure vs. subglottic pressure prior to occlusion in /i/, the open phase. |
- Children with tracheostomy: delayed vocalisation common. PMV should be placed as soon as possible to prevent language delay and improve quality of life. Not all children tolerate PMV.  
- PMV failure associated with high trans-tracheal pressures. Trans-tracheal pressure=intraluminal pressure of the trachea during expiration when the valve is closed. Excessive trans-tracheal pressure may cause carbon dioxide retention, discomfort, pulmonary injury. Trans tracheal pressure may be reduced by drilling a hole in the PMV.  
- Intolerance of PMV in a child commonly evident by respiratory distress with associated dyspnoea and cyanosis, discomfort and child may spontaneously blow off the valve. Manometry readings often >10cmH20 in these children.  
- Procedure described:  
  - Children referred for PMV assessment following thorough medical history.  
  - Describe procedure for assessment. Procedure fully explained to child and family, PMV placed under direct supervision with manometry and pulse oximetry.  
  - If pressure <10cmH20-parent educated as to use/monitoring. Child uses under parent supervision.  
  - If pressure >10cmH20-1/16th hole drilled to reduce pressure. Hole is drilled between the membrane and the hub. One hole will reduce pressure by 15-25cmH20.  
  - A second hole may be drilled if first hole does not sufficiently reduce pressure.  
  - >2 drilled holes not recommended. |
### Expert opinion and case studies presented

- **Use of PMV enables phonation by redirecting exhaled air via the glottis.**
- **Poor tolerance of PMV is common in children with upper airway obstruction, with excessive TTP.**
- **Drilling a small hole in the side of the PMV creates a pressure relief port.**
- **10 patients were included in drilling trial, due to previous inability to tolerate PMV.**
- **All 8 were able to phonate within 6 months of valve introduction.**

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### Expert opinion

- **Review Manzano’s article re: Improved verbal communication noted when wearing PMV**
- **Speech Pathologists working in this area need training and nursing staff support.**
- **AAC success is under-recognised—can create more independence for the patient.**
- **Need a team of experts to develop procedures and protocols.**
- **Improved quality of life reported in Manzano’s patients is sustained with time.**

Retrospective observational study (Chart review) re efficacy for PMV use in Children. No control.

- Retrospective evaluation of 55 consecutive cases between 1991-1995 at St Louis Children’s Hospital: Age of cannulation ranged from 3 days to 18 years. Age of patients at PMV evaluation ranged from 2 month – 18 years, median age of 3.35 years.
- Tolerance coded as:
  - Fail: Behavioural or Physiological Intolerance.
  - Conditional Pass: wear PMV for repeated times during the day for a set duration with direct supervision of parent, nurse or speech pathologist.
  - Pass: wear PMV as tolerated for waking hours
- Overall Findings:
  - 51% (28/55) passed
  - 44% (24/55) Conditionally passed
  - 5% (3/55) failed
- Of these 55 children:
  - ‘many’ required 2+ trials to demonstrate success
  - 38% (21/55) required tracheostomy down-sized before achieving a pass or conditional pass
- Analysed how long on average it took for a child to achieve a “pass” status:
  - ≤ 1 year: 7.8 months
  - 1-5 years: 3.4 months
  - > 5 years: 2.4 months
- Common reasons for a “conditional pass”- physiological and behavioural reasons
  - 30.9% (n=17) Increased viscosity of secretions
  - 29.1% (n=16) Coughing and gagging. Adjustment to secretions in the oropharynx
  - 30.9% (n=17) Irritability signalled by mood or activity
  - 29.1% (n=16) Behavioural issues
  - 14.5% (n=8) Child blew off valve.
  - Parents may have been anxious due to previous negative/stressful experiences.
- Once ‘Conditional Pass’ obtained, Management team determined whether barrier to ‘pass’ was physiological or behavioural.
  - If suspected to be behavioural, PMV trial would be performed during sleep (performed only for Ax purpose and only under nurse or SP supervision).
  - If physiological – ENT determined whether trach to be down sized.
- PMV use improves developmental outcomes and quality of life for the child and parent.

Kochevar W, Germann J (personal communication, 2007). Cincinnati Children’s Hospital Medical Centre, Ohio, USA

Personal Communication. Expert Opinion without critical appraisal

Practice at CCHMC:
- Drilling [study in progress] Dr Rutter: drill a maximum of 2 holes (1/16th size) in to the side of the valve when EEP is too high (>10: 0-8 OK). Use manometry to assess the pressure of passive exhalations. Must defer assessment if the child is crying or distressed as this obfuscates the readings.
- Poor tolerance: trial a valve with membrane removed (3 Behavioural).
  - First trial usually scheduled as the child is coming out of sleep.
  - Trial at least 1 week after the stent comes out.
  - 1st speaking valve: aim for 10 minutes duration
  - Age for trials: youngest 3 months old. Usually started at 6 months when child has the truncal support and maturity to take solids.
  - Always use the PMV Ventilator valve (easiest to drill). Attach PMV directly on the hub of the tube
  - Valve replacement: parents given 3 at once-it is the parent’s responsibility to send back valve to CCHMC for drilling and to order replacements.
  - Use green dye in place of blue for the Evan’s Blue Dye test to avoid false alerts in nursing care
  - Decannulation process is flexible. Children usually inpatient for 48 hours then sent home capped during waking hours (not at night) for one month (or longer if awaiting surgery).
  - Children have decannulation parties.

| Prospective comparative study re aspiration +/- PMV | PMV placement eliminated aspiration or reduced aspiration in 11 adult patients (tracheostomised for > 1 week) with known aspiration.  
- Patients randomised (unblinded) as to order of swallows (i.e. PMV on/ff).  
- 100% Agreement obtained between videofluoroscopy raters.  
Result:  
- Aspiration was reduced or eliminated in 11/11 (100%) patients on liquid, semi-solid and puree consistencies when PMV on vs. PMV off. NB: For some patients, their first experience of PMV was during the VFSS procedure, others had previously worn it.  
Discussion  
- Aspiration in tracheostomised adults related to reduced laryngeal elevation and rotation, disruption of glottic closure and delayed pharyngeal emptying.  
- PMV restores upper airway pneumatic system and theoretically may restore or improve glottic closure-explaining improved swallow and reduced aspiration. Other reported benefits include increased end-expiratory pressure to the lungs, more forceful cough and increased airflow evaporation of secretions through the nasal and oral cavity. Authors suggest that diminished secretions with PMV use are due to improved swallow, not evaporation.  


| Tracheal expiratory pressure estimates for speech production:  
- Quiet talking- 4-6 cmH2O  
- Shout to achieve 40dB needs 20-30cmH2O.  


| Case study and Case series. No control. Pre/Post test. | III-3  
- Loss of subglottic and glottic air pressures may cause or exacerbate aspiration in patients with tracheostomy (loss of phasic glottic function). Subglottic and glottic pressures are restored with placement of PMV.  
- Study =Single case series under 2 conditions: PMV on vs. PMV off.  
- 11 adult tracheostomised patients known to aspirate on VFSS trialled on VFSS with/without PMV. 11/11 patients had significant reduction or elimination of aspiration when wearing their PMV. Measurements of subglottic air pressure and flow taken during swallow using a pneumotachometer with pressure and flow transducers connected via side port of an adapter attachment on the tracheostomy tube. Pressure and flow compared with PMV on/off.  
PMV in place:  
- Airflow ceased-corresponding with Peak pressure (average=10 cmH2O) at the time of swallow. Positive pressure occurred during swallow at 3.9 seconds;  
- Aspiration either reduced or eliminated.  
No PMV:  
- Minimal rise in pressure during swallow; Peak pressure did not occur.  
- Significant expiratory airflow occurred during swallow.  
- Aspiration occurred.
<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Type</th>
<th>Evidence Table</th>
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| Engleman SG, Turnage-Carrier C. Tolerance of the Passy-Muir speaking valve in infants and children less than 2 years of age. Pediatric Nursing 1997;23(6): 571-573. | Retrospective chart review to examine ‘tolerance’ of PMV in children ≤2. | 4. PMV placement found to facilitate vocalisation in children 13 days and older  
| Early PMV placement may minimise adverse impact of tracheostomy on speech & language and may enhance parental bonding.  
| Retrospective charts review-diverse sample, 29 children trialled PMV (age: 13 days-2 years). On first trial: 24 (83%) tolerated PMV.  
| Tolerance on 1st trial ranged from 5 seconds-30 minutes  
| 75% vocalised on initial trial  
| 21% vocalised on a subsequent trial  
| 13 day old infant tolerated well.  
| 5 “did not tolerate” PMV-intolerance signalled by change in colour/ increased work of breathing/ desats. Underlying diagnoses included subglottic stenosis, glottic oedema, congenital abnormalities, laryngeal atresia and extreme prematurity. Author reports retrospectively that these children should not have been trialled due to their upper airway obstruction.  
| Recommends that children should trialled in monitored setting with appropriate guidelines. | 5. |  
| Reported on pressure-flow characteristics of 4 one-way speaking valves: Kistner, Passy-Muir, Olympic and Montgomery. Each valve tested five times at 4 steady flow rates in isolation and when attached to a tracheostomy tube.  
| Describes the method that the valves work and design differences.  
| Resistance occurred at all flow rates; Kistner resistance greater than Passy-Muir, Olympic and Montgomery. Passy Muir significantly greater than Olympic and Montgomery  
| 2-3cmH2O/L/s= the resistance of the normal adult airway during resistance—normal resistance valves are different in infants and children. Only the Olympic and Montgomery valves had resistance ≤2-3 cmH2O/L/s.  
| Authors suggest that valve could be matched to patient’s medical profile according to suitable aerodynamic properties. | 2. |  
| Improved verbal communication noted when wearing PMV using the Vocal Profile Analysis (VPA).  
| 4 subjects used PMV—assessed 2 months after PMV placement using the VPA—continuing difficulties in ¼--difficulty adapting to ventilator speech cycle. Very diverse and small group of patients.  
| Need a multidisciplinary team to support PMV placement.  
| VPA is attached. |

Observational, descriptive case series/expert opinion. No control. No SAP.

IV

- Speech development poor in children with tracheostomy. AAC discussed-disadvantages highlighted, speaking valve is ideal and PMV best suited to paediatric population. PMV enables babbling promoting earlier speech development than in other children with tracheostomies (expert opinion-no basis reported for this statement). PMV wear promotes decannulation.
- Child’s tolerance of PMV not clear by clinical assessment alone. Paed tracheostomy tube takes up more of trachea than in adult.
- First to present on measuring trans-tracheal pressure via manometry during PMV assessment-standard practice at Blythedale Children’s hospital, New York. Use Manometry assessment to obtain end-expiratory pressure reading.
  - NB: EEP in child with normal pulmonary function is ~4cm H2O
- Selection criteria used at Blythesdale, includes PMV company’s standard criteria (whenever possible) with additional criteria:
  - Adequate pulmonary function
  - Endoscopic confirmation of airway patency
  - End-expiratory Pressure (EEP) <10 cm H2O

EEP assesses:
- Pulmonary function
- Upper airway patency
- Ability to channel air through upper airway to produce speech

INTERPRETATION:
- EPP < 10 cm H2O: Management: PMV worn daily for speech and feeding
- EPP >10 cmH2O: May indicate that tracheostomy tube too large or subglottic/glottic narrowing. Could lead to ventilation/perfusion mismatch and damage the lungs. Management: Not for trials. Child monitored. Tracheostomy tube down-sized and remeasure EEP. Child reassessed following any medical change.

Procedure briefly reported on 12 children (aged 1-17 years) all with EEP < 10cmH20.

Indications to conduct Manometry:
- At initial assessment
- Following medical change
- Monthly reviews

#### Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tr>
<td>quasi-resonant nucleus</td>
<td>closed throat. Reduced breath. Nasality and/or creakiness. Immature form.</td>
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<tr>
<td>marginal syllable</td>
<td>immature CV: slow sequence between the C to V-slower movement of articulators (&gt;250 ms CV transition)</td>
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<tr>
<td>canonical syllable</td>
<td>mature CV. (&lt;250 ms C to V transition)</td>
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#### Participants

- **Participants:** 60 infants average age of 9.5 months (range-8 months 27 days – 10 months-14 days) and Mother dyads. Divided into 2 groups: treatments (n=30) and controls (n=30) and balanced for gender.
- **Treatment group 1. n = 15** --- contingent fully resonant vowels
- **Treatment group 2. n = 15** --- contingent CV words
- **Control group 1. n = 15** --- fully resonant vowels non-contingent: same type and frequency but unsynchronised with infant’s babbling
- **Control group 2. n = 15** --- CV words non-contingent: same type and frequency but unsynchronised with infant’s babbling

#### Method

- **ABA format:**
  - A baseline 1.
  - B either the treatment phase or the control phase
  - (Control phase—preserved arousal and vocalisation type (mimicked treatment recording) but unsynchronised with infant i.e. not contingent)
  - A baseline 2

#### Rating

- **Raters blinded to hypothesis (>90 % intra rater reliability) coded responses**
- **Infant responses coded as quasi-resonant nucleus, fully resonant nucleus, marginal syllable and canonical syllable—all typically present in 9.5 month old infants**
- **Matching between each mother-child utterance calculated as a proportion**
- **Overall results compared with random matching simulated results.**

#### Results

- **Stat significantly increased number of infant’s fully resonant nucleus vocalisations in during treatment phase in fully resonant nucleus contingent social feedback infant group—didn’t change proportion of CV vocalisations.**
- **Stat significant increased number of infant’s CV structured syllables during treatment phase in CV contingent social feedback infant group—didn’t change proportion of fully resonant nucleus vocalisations**
- **No significant increase in proportions of fully resonant vowels in non-contingent fully resonant vowel control group.**
- **No significant increase in proportions of CV structured syllables in CV control group.**

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#### Questionnaire

- **“Voice Outcome Survey” measuring quality-of-life (QOL) parent survey administer to 108 carers of children (2-18 years) who had a tracheostomy or a history of tracheostomy, treated at Cincinnati Children’s Hospital Medical Centre (CCHMC).**
- **Structural properties of Questionnaire examined:** Cronbach α-value of 0.86. Construct validity supported statistical significance.
- **Cross-sectional analysis:** Cannulated group had poorer voice QOL than decannulation group.
### Expert Opinion

| --- |
| • Variety of techniques described to facilitate phonation in tracheostomised patients (including PMV placement) to improve quality of life of patient.  
• Voice may be restored in patients without laryngeal or pharyngeal dysfunction.  
• Contraindications described for PMV use: unconscious, comatose, inflated cuff, foam-filled tracheostomy tube, thick and copious secretions, severe upper-airway obstruction, abnormal lung mechanics that prevent sufficient exhalation, patients with endotracheal tubes.  
• Discomfort experienced during SV placement may be due to the impact of prolonged reduction in airflow through the upper airway on laryngeal/pharyngeal tone and/or drying of the pharyngeal membranes. Reduced laryngeal/pharyngeal tone (weakness or atrophy) may be caused by prolonged mechanical ventilation.  
• Normal subglottic (tracheal) pressures during speech is between 5-10 cmH20.  
• Manometry assessment can measure tracheal pressure-the patient’s ability to exhale around the tracheal tube when PMV in place.  
• Manometry readings of passive exhalation >5cmH20 may indicate ‘excessive expiratory resistance’- consider assessment of upper airway for obstruction.  
• ? scan picture p.523 of manometer, tracheostomy tube, speaking valve?  

| --- |
| • 26 caregivers of child with tracheostomy completed questionnaire (Pediatric Tracheostomy Health Status Instrument) at ENT clinic regarding impact of the tracheostomy. Children of caregivers too young to complete the questionnaire independently.  
• Adverse effects for caregivers were reported in quality of life, sleep, relationships, social life, ability to work, reduction of annual household income.  
• Child’s QOL often rated by the caregivers as better than their own. |
### Procedure for Speaking Valve Assessment at Franciscan Hospital for Children, Boston

- **Educating Family**: Valve purpose, eligibility criteria, evaluation protocol
- **Pneumologist First Assessed Child to Determine Candidacy**
  - **Inclusion Criteria for Candidacy**
    - Patent upper airway
    - Medically stable
    - Able to tolerate cuff deflation for trials
  - **Exclusionary Criteria for Candidacy**
    - Children with large tracheostomy tubes—inadequate leak
    - Minimally responsive
    - Considered “at risk” with valve on (e.g., copious secretions)
- **Valve Selection**
  - Passy-Muir Valve used for children with ventilator needs
  - Shiley Speaking valve used for children with no ventilator needs
- **Valve Assessment of Tolerance Conducted by Speech Pathologist and Respiratory Therapist**
- **Child Monitored with Pulse Oximeter**
- **Tracheal Suctioning Performed**
- **Cuff Deflated**
- **Clinical Observations Taken**
  - Respiratory rate
  - State (by facial expression)
  - Secretion management (NB: method of observation unspecified)
  - Swallowing (NB: method of observation unspecified)
- **Criteria for Clinical Tolerance**
  - Minimal anxiety (judged by facial expression + heart rate)
  - Oxygen saturation levels ≥ 95%
  - Stable heart rate and respiratory rate
- **(if 1st trial tolerated)** 3 subsequent trials completed over 1-2 weeks with 1:1 observation by a Speech Pathologist and Respiratory Therapist
- **Pneumologist, Speech Pathologist and Respiratory Therapist Determined Whether Child Should Continue Using the Valve**: if so, management plan generated for future trials (duration, level of monitoring)
- **Detailed Management Plan Distributed**: family, medical notes, bedside

**Report on 12 Retrospective Case Reviews** (age range 8 months-21 years) all unable to vocalise. 10/12 tolerated assessment. 10/10 achieved phonation: 50% achieved on 1st trial, 50% achieved during 3 subsequent trials.

**Benefits of Valve Placement Discussed**—the “intuitive” rational that tracheostomised, aphonic infants miss vocal exploration and babbling—critical steps in speech development.
| **Jackson D, Albamonte S.**  
Enhancing communication with the Passy-Muir Valve.  
Pediatric Nursing 1994; 20(2):149-153. | **Expert Opinion:** Procedure outlined for placing PMV at Children’s Specialized Hospital in Mountainside, New Jersey  
- Many children with tracheostomy tube unable to vocalise.  
- Majority of children < 8 years had cuff-less tracheostomy tube  
- Presence of tracheostomy tube leads to language delay in many children  
- Independent vocalisation, crying, cooing and babbling reduce interaction opportunities, may negatively impact on child-caregiver interactions (less responsive environment) and delay development of speech and language.  
- Children with tracheostomy may have delayed/disordered speech, breathy voice and limited length of vocalisations is common due to difficulty sustaining exhalation.  
- Tracheostomised children as a group are also vulnerable to other developmental interference e.g. prolonged hospitalisations, tube feeding, high incidence of otitis media.  
- Alternative communication systems should be provided and a PMV if possible.  
- “The PMV has proven to be a safe and effective way to enhance language development and improve quality of life for children with long-term tracheostomies and ventilator dependence” p. 153.  
- Parental education essential component of care for children with PMV.  
- Some children respond to initial PMV trials by pulling off/coughing, others adjust immediately.  
- Speech with a PMV: voice less breathy, decreased strain on vocal cords that may occur with leaked speech, restores exhalation-sustained vocalisation length.  
- Other PMV benefits: reduced tracheal infections as valve membrane filters air, reduced need for suctioning, increased humidification and warming of inspired air, improved swallow, increased smell and taste which may lead to weight gain and easier decannulation given adjustment to normal exhalation airflow pattern. Improved quality of life.  
- Do not wear PMV during aerosol treatment as medication may cause stickiness of the PMV membrane. Cleaning: do not use ethylene oxide, autoclave or radiation sterilizer. |
| **Jiang D, Morrison GAJ.**  
The influence of long-term tracheostomy on speech and language development in children.  
International Journal of Pediatric Otorhinolaryngology 2003; 67(S1): S217-220. | **Retrospective study:**  
- 39 children with history of tracheostomy (cannulation < 5 years old) divided into 2 groups: presence vs. absence of a “primary disorder”*  
  *neurological disorder, mental retardation or severe cranial facial anomalies  
  NB: heterogeneous groups re: still cannulated vs. post decannulation  
- Children assessed with formal, standardised Speech Pathology assessment:  
  - Group 1: with primary disorder n=16: 94% delayed  
  - Group 2: without primary disorder n=23 (73.9% had laryngeal abnormality): 26.1% delayed  
In Group 2: Children cannulated prior to 1 year of age (subgroups: delayed vs. normal), decannulation <15 months associated with ‘good’ speech and language outcome. No mention of access to PMV or AAC:  
- Group 2: Delayed sub-group(n=6): median age at decannulation =18 months [mean= 25.4 months, SD=10.1]. Mean length of cannulation was 21 months.  
- Group 2: Normal sub-group(n=8): median age at decannulation =14.5 months [mean = 14.4, SD=6.8]. Mean length of cannulation duration was 9.8 months.  
Authors concluded that earliest decannulation improves chance of normal speech and language development.  
In Group 2: children cannulated after critical language period and for short periods found to have normal speech and language (n=3):  
Mena age: 36 months. Median decannulation age: 2 months.  
Authors suggested that tracheostomy after critical language period may enable normal speech and language development. |

Pilot
- Prospective study: Sept 97-June 98-determine difference in manometry pressures due to speaking valve and/or breathing pattern—after 3 minutes of quiet breathing used manometry ax* (1. mean passive exhalation pressure, 2 mean exp peak pressure on cough)and dyspnoea ax using the 10-point BORG scale on 21 patients, each assessed under 4 conditions (randomly assigned with ≥2 mins break between condition trials): 1. open airway, 2. Montgomery, 3. Passy Muir 007, 4. Shiley.

*Manometry procedure: pt instructed to breathe quietly/normally. Captured 2 measurements:
1. MEAN EXPIRATORY PRESSURE (PExp): measured peak inspiratory (neg) pressure and peak expiratory (positive) pressure from 5 passive breaths and used the mean pressure.
2. MEAN PEAK EXPIRATORY PRESSURE: recorded from assessment of 3 coughs.

Compared results using student-t-tests: results as follows:
- Pressures greater during deep breathing with all speaking valves (p<0.002).
- Inspiratory pressure more negative with PMV than other valves on both quiet and deep breathing (p<0.001) (inspiratory pressure associated with valve's specific pressure gradient). Since then-PMV introduced the PMV 2000—with lower inspiratory resistance—PMV 007 only for ventilator inline use.

Clinical Pathway Trialled
- Clinical pathway established reliant on manometry Ax (on quiet breathing and on deep breathing) and then examined on 100 patients.
  - NB- rec that Pexp>10cmH2O-down size tube prior to speaking valve trial.
  - 0-5 cm H2O expiratory pressures and inspiratory pressure ≥ -3: Ax for capping.
  - 0-5cm H2O expiratory pressures and inspiratory pressures < -3: Speaking valve as tolerated.
  - 5-10cm H2O expiratory pressures: speaking valve-but only for short times as this is a higher level of resistance.
  - >10cmH2O expiratory pressures: often correlated with increased Borg scale result-overt signs of respiratory difficulty. Action=downsize tracheostomy tube and reassess.
- Retrospective study, no control. Dec 03 – June 05: Single SP conducted manometry ax before and after tracheostomy tube changes on 100 patients.

Findings:
- Downsizing the trach tube resulted in reduced expiratory pressure and less negative inspiratory pressure on capping but similar results with inspiratory pressure on speaking valve, pre/post downsized.
- Higher expiratory pressures associated with female gender (smaller trachea), larger outer diameter tubes and larger deflated cuffs.

Recommendations
- Manometry assessment clinical pathway successfully guided process of capping and PMV placement.
- Based on findings, capping not recommended if inspiratory pressure more negative than -3 cm H2O.
- Reassess patients with changes in tolerance: as may reflect change in upper airway resistance or fault with speaking valve; e.g. very negative pressure may indicate speaking valve stuck shut with build up of secretions.
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<tr>
<td>• Cannulation &lt; 1 year with aphaonia can alter the vocal tract anatomy and physiology and limit tongue movement with a tendency for retraction. Descent of the larynx at 6 months is limited by the presence of the tracheal cannula-promoting a more primitive supralaryngeal vocal tract shape and limits tongue movement (? reduced movement of genioglossus posterior). Higher position of the larynx, shortened oropharyngeal cavity and limited tongue movement affects resonance characteristics within the vocal tract.</td>
<td>• Children with history of tracheostomy had reduced acoustic space for vowel production. Author hypothesised that this may be related to anatomic implications of tracheostomy tube placement on tongue mobility.</td>
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</tr>
<tr>
<td>• 16 children: 8 Tracheostomy Group (Age 39-60 months) and 8 controls matched age, gender, socioeconomic, developmental and language ability. Exclusions: neurological problems, craniofacial abnormalities, chromosomal abnormalities, stuttering, vocal fold pathology, neuromotor deficits.</td>
<td>• Compared to matched-controls, the decannulated children had:</td>
<td>• Compared to matched-controls, the decannulated children had:</td>
</tr>
<tr>
<td>• Tracheostomy Group: all had history of cannulation &lt;1 year old. Length of cannulation-mean=30 months, range=15-42. Average time since decannulation was 14 months, range=10-24 months.</td>
<td>- Limited ability to produce extreme vowel configurations /a/ /i/ /u/.</td>
<td>- Limited ability to produce extreme vowel configurations /a/ /i/ /u/.</td>
</tr>
<tr>
<td>• Children with history of tracheostomy at risk of speech/language delay.</td>
<td>- Immature oral-motor patterns</td>
<td>- Immature oral-motor patterns</td>
</tr>
<tr>
<td>Kaslon K, Stein RE. Chronic pediatric tracheotomy: assessment and implications for habilitation of voice, speech and language in young children. International Journal of Pediatric Otalaryngology 1985; 9:165-171.</td>
<td>10 pre-Ax findings discusse d. 3/10 post-Ax after treatment 1. No case control and methodological flaws, but serves to facilitate discussion.</td>
<td>IV</td>
</tr>
<tr>
<td>• Children with tracheostomy at risk of speech/language delay.</td>
<td>• Delayed expressive and receptive language skills in children with long term tracheostomy</td>
<td>• Children with tracheostomy at risk of speech/language delay.</td>
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<tr>
<td>Assessed 10 tracheostomised patients (age: 16 months – 41 months) all had tracheostomies inserted &lt;12 months of age (7/10 cannulated ≤4 months):</td>
<td>• Average deviation of 4.8 month receptive delay and 9 month expressive delay.</td>
<td>• Average deviation of 4.8 month receptive delay and 9 month expressive delay.</td>
</tr>
<tr>
<td>• Only 6/10 could vocalise.</td>
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<td>Consideration of factors that contribute to delays in this population:</td>
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<td>• A lack of oral-sensory and auditory that usually accompanies speech acquisition.</td>
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<td>• Lack of opportunity to socialise with other children-e.g. due to frequent illness, cautious and overprotective parenting.</td>
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<td>Children given therapy programme—in depth parent training re facilitating interaction, parent log book to document child’s interactions, individual Speech therapy and enrolment in preschool or play group to encourage social interaction.</td>
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<td>• Systematic progress noted in all cases.</td>
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CAHS CLINICAL PRACTICE GUIDELINE
Use of a Passy-Muir Speaking Valve in a Non-Ventilated Patient: Evidence Table Speech Pathology June 2011
<table>
<thead>
<tr>
<th>Reference</th>
<th>Table</th>
<th>Notes</th>
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</table>
| Kaut K, Turcott JC, Lavery M. Passy Muir speaking valve. Dimensions of Critical Care Nursing 1996;15(6): 298-306. | • Discusses the importance of communication (beyond conveying medical needs) in terms of patient well being, mental health and motivation.  
• Discussion of AAC, fenestrated tracheostomy tubes and passy muir speaking valves (PMV).  
PMV Discussion:  
• PMV use improves speech, smell, cough, swallow and promotes decannulation.  
• Only valve can use on a ventilator.  
• PMV opens with <2 cmH20 (7-12 cmH20 required to open other valves)  
• Positive closure by biased-closed position restores normal pressures PEEP (Physiologic end-expiratory pressure).  
• Ensure that the tracheostomy tube occupies ≤ 2/3rd size of the trachea.  
• Procedure outlined: Upon referral, Nurse liaises with Physician to order the PMV. SP joins Nurse to assess pt readiness for valve and to evaluate pt response during trial.  
• Procedure is fully explained to the patient. Not uncommon for patient to be anxious. Distract patient and try voicing exercises.  
• Not expected that patient will achieve voice on first trial—may take repeated trials and adjustment period to achieve voice.  
• Stop trial when patient is obviously fatigued. Establish ongoing plan.  
• Recommend not to wear PMV during chest physio, eating, nebulizer treatment: schedule when patient is at rest.  
• Algorithm of PMV application described “Passy Muir decision tree.” | B-3  
6 children (age range 2;8 – 6;8) with a history of cannulation < 8 months of age underwent spectral phonology analysis at 2 time points.  
Heterogeneous group in terms of medical diagnoses and ability to vocalise during cannulation. All had cognitive skills and language skills WNL.  
• Time 1: Within three months of being able to achieve consistent vocalisation  
• Time 2: Three months after Time 1.  
Findings:  
• 5/6 children exhibited phonological delay (ranged from mild to profound)  
• 4/6 had difficulty with voiced/voiceless discrimination.  
• All children exhibited ≥1 phonological process compared to normative data  
• Specific difficulties noted with vowel production e.g. lower formant frequencies for /i/ as in sea. Authors hypothesised that this may be due to reduced extension/retraction action of tongue to create /i/ whilst cannulated. |
Leder SB. Importance of verbal communication for the ventilator dependent patient. Chest 1990;98 (4): 792-793. | • Speaking Tracheostomy Tube described:  
  o Single cuffed tube with external airflow line  
  o Gas travel through airflow line and exits via opening superior to cuff up via vocal cords to enable phonation.  
  o Airflow between 10-15L/min produces intelligible speech with minimal discomfort  
• Candidacy:  
  o Inclusion: Spinal Cord trauma, neuromuscular diseases, acute respiratory distress syndrome  
  o Exclusion: significant organic laryngeal pathology  
• Criteria for success/failure: intensity of voice for intelligible speech  
• Daily sessions of rehabilitation required to practice use, practice breath support, reduce anxiety and train self-use of the airline.  
• Preferred Product: Portex “talk” tube | V |
<table>
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<tr>
<th>Reference</th>
<th>Summary</th>
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<tr>
<td>Liberman, P, Knudson, R &amp; Mead, J. Determination of the rate of change of fundamental frequency with respect to subglottal air pressure during sustained phonation. 1969. Journal of the Acoustical Society of America, 45(6), 1537-1543.</td>
<td>Aim: To determine the range over which fundamental frequency and transglottal pressure varies while singing sustained notes. Outcome: variations in F0 that occurred during normal speech are due to both variations in transglottal pressure and laryngeal tension, not just laryngeal manoeuvres.</td>
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</table>
| **Lichtman SW, Birnbaum IL, Sanfilippo MR, Pellicone JT, Damon WJ, King ML. Effect of a tracheostomy speaking valve on secretions, arterial oxygenation and olfaction: a quantitative evaluation.** *Journal of Speech and Hearing Research* 1995;38: 549-555. | **Ordered Prospective Repeated measure Design.** Stages of testing counterbalanced. Single blinded. | **III-3** | **-** | 8 patients assessed using 24 hour secretion accumulation and arterial oxygenation assessment over 2 separate 24 hr periods under 2 conditions; PMV on/PMV off. 6/8 patients completed olfactory identification testing under the 2 conditions.  
- Inclusion: ≥ 18 years, medically stable, able to wear PMV for 3 hrs, able to follow oral directions.  
- Method: Order of testing balanced to counteract possible order effects; 4 patients had PMV on for Day 1, 4 had PMV off for Day 1, then switched for Day 2.  
- Arterial oxygenation measured by blood gas samples taken 1 hour prior to PMV removal and 24 hour pulse oximetry.  
- During PMV on assessment, PMV remained in situ for full 24 hour period.  
- Results: Statistically Significant decrease in accumulation of oral-nasal secretions when patient wore SV. n=7. 1/8 had no change. Overall decrease was 40%.  
- Significantly improved olfaction when wearing SV n=6  
- No significant improvement to arterial oxygenation (measured by pulse oximetry and arterial blood gas) when wearing SV. |
- Authors suggest that ‘audibility of babbling contributes to its onset’  
- Draws comparison between case study of normally developing child, tracheostomised between 5 months – 20 months and the congenitally deaf population.  
- Aphonia prevented her “discovering the referential value of vocal expression and discouraged the formation of a phonetic repertoire that could be appropriate for normal lexical service” (quote) |
| **Los Angeles Children’s Hospital November, 2007 Katy Peck-Frost, MA., CCC-SLP Department of Hearing and Speech** | **Expert Opinion without critical appraisal** | **V** | **1.** Candidacy Assessment: first child has a sleep study-must assess if CO2 output is sufficient  
2. Written Approval (prescription) from Respiratory Physician and Tracheostomy Specialist Nurse to trial  
3. Education of parents/child-several sessions with competencies ticked  
4. Suction and deflate cuff  
5. Trial: Observations and Pulse Oximetry  
6. Tolerance: If > 15 minutes: considered ready for home trials under parental supervision  
7. If trial length <5 minutes: not considered ready for home trials: continue hospital based sessions (NB: families unable to take pulse oximeter home for trials as not available for loan)  
8. Photos collected pre-trials, initial trial and during subsequent trials and the family is given a personalised book on ‘graduation’ (when child can tolerate PMV for all waking hours).** | **-** | **Retrospective review of 122 tracheostomy cases between 1987-2003 at Starship Children’s Hospital, Auckland, New Zealand.**  
- Mean age of Cannulation: 7.8 months  
- Median age of Cannulation: 4.5 months in patients with upper airway obstruction 16 months in patients requiring prolonged ventilation  
- 6/92 (6.5%) of decannulated patients ongoing voice issues (hoarse or weak).  
- Upper airway obstruction most common reason for tracheostomy (70% patients) |
<table>
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<tr>
<th>Source</th>
<th>Study Design</th>
<th>Evidence Table</th>
<th>Evidence type</th>
<th>Findings</th>
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</table>
| Manzano, JL, Lubillo, S, Henriquez, D, Martin, JC, Perez, MC & Wilson, DJ. Verbal communication of ventilator-dependent patients. 1993. Critical Care Medicine, 21(4), 512-517. | Prospective descriptive case series. IV | • 10 adult ventilator dependent tracheostomised patients with normal mental state treated in ICU at University Hospital, Las Palmas, Spain trialled with a PMV.  
Method/Procedure of PMV assessment described. NB: Ax included monitoring of inspiratory thoracic movement, expired gas flow through the mouth and nose, heart rate and blood pressure (every 30 minutes). Gas exchange monitored by pulse oximetry and arterial blood gases monitored every 2 hours.  
8/10 PMV placement with insignificant cardiorespiratory changes and increased secretion management. For 8/8 patients, improvements were noted in:  
- Communication  
- Well-being and motivation (improved dignity and independence)  
- Secretion management (nursing staff suctioning less)  
- Cough  
- Sense of smell (after 1 week of use).  
2/10 PMV placement not tolerated-couldn’t be used.  
Discussion:  
- With PMV use, air escapes through the mouth and nose and contributes to its evaporation, this can reduce secretions.  
- Improved glottic function may improve cough effectiveness. |   |   |
- Improved quality, pitch, intensity and intonation of vocalisations.  
- Reduced frustration  
- Facilitate babbling; facilitate overall development. |   |   |
Rate of decannulation shorter in PMV but not statistically significant difference.  
Patients using one-valve valve vs. capping appeared more comfortable.  
Manometry of tracheal pressures > 5cm H2O on expiration associated with problems in decannulation.  
Arterial blood gases post 30 min occlusion of tracheostomy found to be helpful indicator/predictor of successful decannulation. For 10/12 successful decannulations: PaCO2 increase was ≤ 5 torr. Pa O2 fall was ≤ 60 torr.  
One-way valve use should improve patient’s secretion management and phonation. |   |   |
| Observation/Descriptive statistics on retrospective chart review. | V | Retrospective chart review of 80 cases at Red Cross War Memorial Children's hospital in Cape Town, South Africa. 64/80 (80%) presented with dysphagic symptoms: assessed with video fluoroscopy and scintigraphy.  
- Oral phase dysphagia: 52/64 (81.25%)  
- Oral sensory problems: 61.5%  
- Pharyngeal phase dysphagia: 39/64 (60.9%)  
- Esophageal phase dysphagia (79.9%)  
- ~70% cannulated in first year of life  
- Upper airway obstruction was primary indication for tracheostomy (71.25% cases)  
- Impact of dysphagia discussed-including risk to attachment. |
|---|---|---|
| V | Claims about the primary impact of the PMV  
- Development of ‘back pressure’ sub-glottic—increases oxygen content in bloodstream and ventilation.  
- Partially filters/cleans the air  
- Enables speech  
- Increased evaporation reducing the amount of nasal and oral secretions  
- Smell improved  
- Ability to cough up pulmonary secretions  
- Claims about the secondary impact of the PMV  
- No need for finger occlusion—not possible for quadriplegic—for others, frees the hands to ‘talk’  
- Patients feel better due to improved oxygenation  
- Beneficial for sleep apnoea patients  
- Helpful in promoting decannulation-especially in children  
- Quality of life improved  
- Exclusion: Selection criteria for candidacy described:  
  - Severe laryngeal or tracheal stenosis  
  - Unconscious  
  - Tracheostomy tube with an inflated cuff  
  - Seriously ill patient  
- From the manual of the valve  
- Passy Muir recommendations:  
  - Inclusion: Selection criteria for candidacy described:  
    - Medically stable  
    - Cognitively intact  
    - Oxygen saturation >90  
    - Intact laryngeal mechanism  
    - No upper airway obstructions |
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<tr>
<th>Source</th>
<th>Type</th>
<th>Study Design</th>
<th>Findings/Recommendations</th>
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<tbody>
<tr>
<td>Passy-Muir Tracheostomy and Ventilator Speaking Valves instruction booklet, 2005. 2nd edition. Passy Muir Inc.</td>
<td>Expert Opinion with some research references</td>
<td>NA</td>
<td>From the manual of the valve Passy Muir recommendations: Inclusion: Selection criteria for candidacy described: • Medically stable • Cognitively intact • Oxygen saturation &gt;90 • Intact laryngeal mechanism • No upper airway obstructions • Exclusion: Selection criteria for candidacy described: • Severe laryngeal or tracheal stenosis • Unconscious • Tracheostomy tube with an inflated cuff • Seriously ill patient • Single use only</td>
</tr>
<tr>
<td>Rosingh HJ, Peek SHG. Swallowing and speech in infants following tracheostomy. Acta Oto-Laryngologica Belg. 1999; 53: 59-63.</td>
<td>Retrospective chart review</td>
<td>IV</td>
<td>36 children recruited (NB: 13/36 were premature) Hx of cannulation in the period between 1991-1998 Inclusion criteria: Infants with a history of tracheostomy. Cannulated before 12 months of age Post operative review (NB ranged from 4 months – 5 years post cannulation) • Speech delay noted in 38% of children • Delay evident in speech, swallowing skills and oro-motor skills. • Frequent oral aversion/hypersensitivity. • 14/32 (41%) exclusively PEG fed-unable to have anything orally. • 17/32 (50%) required NG/PEG (not exclusive) Authors concluded that intensive rehabilitation warranted to stimulate speech and swallowing development and reduce potential complications.</td>
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<tr>
<td>Reference</td>
<td>Study Design</td>
<td>Study Details</td>
<td>Evidence Level</td>
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<td>Simon B, Silverman J.</td>
<td>Expert Opinion</td>
<td>Implications for development may be related to time and duration of cannulation. Children cannulated during the pre-linguistic stage of development may be significantly at risk of delayed speech/language development. Speech Pathology (SP) intervention during pre-linguistic period can improve communication function, decrease frustration and improve overall quality of life. Children with long term tracheostomies are likely to need continual intervention. Feeding difficulties common-organic and sensory/behavioural. Presence of tracheostomy tube causes structural changes to laryngeal airway. Oral stimulation during non-oral period may promote development. Force feeding may exacerbate behavioural feeding problems. Parent-child interaction negatively affected if child cannot participate in verbal turn taking. The SP can facilitate parents to interact non-verbally with their child. Long term speech/language delay post-decannulation may occur if child has been deprived of early vocalisations in their linguistic stage of development. Long hospitalisations may contribute to developmental delay. Child needs to wean to use PMV (some children find it difficult or uncomfortable to use) but its placement increases frequency of verbal productions. Provide AAC for aphonic children e.g. key word signs, electrolarynx.</td>
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<td>Singer LT, Kercsmar C, Legris G, Orlowski JP, Hill B, Doershuk C.</td>
<td>Retrospective, cross-sectional developmental follow-up, No control.</td>
<td>Developmental assessment of 32 children who had a tracheostomy for &gt;3 months during the decade between 1972-1982 (mean cannulation period 30.4, SD 21.3 months) were assessed. Inclusion Criteria: Age of cannulation &lt; 13 months. Excluded Criteria: Cognitive impairment or severe physical disability. Findings: compared to published normative data: Excessive speech articulation difficulties. Higher than normal incidence of behavioural difficulty. Low-average language skills-WNL. Higher than normal levels of social isolation.</td>
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<tr>
<td>Speech Pathology Australia.</td>
<td>Summary of evidence and guidelines re scope of practice.</td>
<td>Tracheostomy management is a post-graduate skill for Australian Speech Pathologists. Speech Pathologists practicing within this specialty area should seek ongoing training, credentialing, legal advice, support and formal approval from their employer.</td>
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<tr>
<td>Stacher RJ, Hamlet SL, Choi J, Fleming S.</td>
<td>Prospective Case series, non-randomised, comparison of Aspiration +/- PMV.</td>
<td>PMV placement reduced the amount of aspiration in pts at risk of aspirating. 11 adult patients—either known or suspected to aspirate were assessed drinking thin fluids using videofluoroscopy and scintigraphy. All patients aspirated with/without the PMV on. Amount of aspiration was significantly less when PMV on. Patients reported improved sense of smell with PMV on (level 5 evidence) Benefits discussed regarding PMV’s bias closed position. On exhalation, the column of air maintained in the tube prevents entry of secretions. PMV placement may promote the necessary build up of sub-glottic pressure for swallow, promoting secretion clearance at the end of the swallow. Inspiration post-swallow is through the tracheostomy tube-minimising risk of inhaling pharyngeal residue.</td>
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<tr>
<th>Comparator study</th>
<th>Case series</th>
<th>Inter-rater reliability</th>
<th>Random assignment of treatment conditions</th>
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<tr>
<td>18 adult non-ventilator dependent patients with tracheostomy assessed on videofluoroscopy.</td>
<td>1. Time since cannulation ranged from 5 days-29 days. Time off ventilator prior to VFSS ranged from 2 days to 19 days. Varying underlying medical diagnoses.</td>
<td>All patients had worn a PMV at least once before VFSS for ≥15 minutes.</td>
<td>Patients with a cuffed tracheostomy (n=14) completed 12 swallows under 3 different conditions: 1. Cuff inflated 2. Cuff deflated 3. Cuff deflated and Passy Muir speaking valve (PMV) in place.</td>
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<td>Random presentation of conditions to minimise order effects.</td>
<td>US one-cent coin at angle of left mandible used as a marker to assess hyolaryngeal movement.</td>
<td>Swallows analysed with the 8-point penetration-aspiration scale.</td>
<td>Good Inter-rater reliability-2 SP raters-validated using Pearson’s product correlations.</td>
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<td>Authors conclude that clinicians should conduct videofluoroscopy with PMV in place. PMV may improve laryngeal sensation and improve cough.</td>
<td>PMV will not always improve swallow—may increase potential for oral and pharyngeal residue.</td>
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<tr>
<th>Expert Opinion</th>
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<tr>
<td>• Explanation of practice at Great Ormond Street Hospital for Children&gt;</td>
<td>1. Rüsch speaking valves (bias open) are used for initial assessment as cheap and easily available—useful for children with suprastomal obstruction. These children may struggle with a Passy Muir valve but may tolerate the Rüsch speaking valve. 2. If Rüsch valve is tolerated during assessment, Child uses it for 2 week period at home, supervised by parents. 3. If there have not been any problems, the child the progresses to a Passy Muir valve (PMV) (bias closed). Passy Muir valve is the preferred valve for long term use. PMV use aids cough, swallow and improves voice production.</td>
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<tr>
<td>Author(s)</td>
<td>Prospective design</td>
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<tr>
<td>Utrarachkij J, Pongsasnonkul J, Preutthipan A, Chantarajana Sri T.</td>
<td>Measurement of end-expiratory pressure as an indicator of airway patency above tracheostomy in children. Journal Med Assoc of Thailand 2005; 88(7):928-932.</td>
</tr>
<tr>
<td>Ward E, Agius E, Solley M, Cornwall P, Jones C.</td>
<td>Preparation, clinical support, and confidence of speech-language pathologists managing clients with a tracheostomy in Australia. American Journal of Speech-language Pathology 2008;17: 265-276.</td>
</tr>
<tr>
<td>专家意见和描述性观察性案例研究无SAP</td>
<td>经验者评估和管理医学上脆弱的儿童，气管切开术和通气支持。语言，言语和听觉服务在学</td>
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</table>
| Woodnorth GH. Assessing and managing medically fragile children, Tracheostomy and ventilatory support. Language, Speech & Hearing Services in Schools 2004;35:363-372. | Expert Opinion and descriptive, observational case studies without SAP | • Leaked air with trach in place reduces subglottic air pressure available for speech. Leaked speech generally week and choppy. The child may compensate by using ventricular phonation or hyperfunction. Communication options for the child may include:  
  • Gloved finger to block stoma of young child trach.  
  • Chin tuck (child may do this spontaneously) — but may contribute to suprastomal collapse (neck flexion). — American Thoracic Society reference.  
  • Speaking valves: types discussed use at Children’s Hospital Boston. PMV discussed for benefits to phonation etc. –  
  • Mouthing words.  
  • AAC.  
  • Work in team. Educate, counsel, guide child’s team to help child achieve potential with swallow and communication. Thorough assessment of voice. Set clear goals and ways to achieve. 4 case studies presented. |
1st Assessment: Resistance to steady state flow tests: airflow at 0.45/l/s, 0.50/l/s and 0.55/l/s (Inspiratory rates associated with mechanical ventilation) Findings:  
  • Similar resistance of all valves: between 2-3cmH2O (typical of nasal resistance)  
  • Olympic resistance significantly lower than Passy-Muir-aqua and Montgomery valves  
  • Passy Muir (biased closed) did not have significantly higher resistance than other valves (No change in design since testing in 1993—reduced thickness of the diaphragm—company did not respond to author’s request for confirmation).  
2nd Assessment: Assessment of air loss during 5 repetitions of /pa/ on single exhalation. Tracheostomy-speech production was simulated. One speaker completed exercise for all valves. Findings:  
  • There was consistent air loss for all valves tested.  
  • Significantly greater air loss in Olympic valve compared to other valves (Implications for respiratory effort).  
  • Air loss with PMV was lower than other valves (not significant).  
  • No recommendation for particular valve made based on this data. Authors acknowledged limitations of stimulating speech rather than assessing tracheostomised patients. |