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Analysis of Trans-Tracheal Measurements in Children Wearing Speaking Valves during Sleep

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ABSTRACT:

Purpose: There is some evidence supporting the safety of speaking valve use for tracheostomy patients during sleep. The purpose of this study is to further validate the safety of speaking valve use while asleep with the use of trans-tracheal manometry by comparing expiratory pressure measurements while the patient is awake and asleep.

Materials & Methods: Children, ages 1-18 years, who routinely wear a speaking valve during wake periods, were included in this single center, non-randomized study. Subjects' vital signs, end tidal CO_2, and trans-tracheal pressures were monitored, while awake and sleeping during a 24-hr period. Data was collected for each patient, including sleep status and whether or not they were wearing the speaking valve, at the times data were collected. Data was analyzed via means & 95% confidence intervals.

Results: 8 patients were included in the study. Trans-tracheal manometry measurements taken while patients were awake versus asleep, wearing the speaking valve, showed no statistically significant difference (awake: 12.25 cm H_2O *vs.* asleep: 8.98 cm H_2O; p=0.38). No significant differences in patient's vital signs or end-tidal carbon dioxide values were noted between times when patients were awake or asleep while wearing the speaking valve. No major adverse events were recorded during the 24 hour study period.

Conclusions: This study further supports that a speaking valve can be safely used during sleep in children with tracheostomy tubes. Objective parameters using vital signs and trans-tracheal pressure manometry can safely evaluate children who use the speaking valve during sleep periods. The management of children that are tracheostomy dependent can be improved by obtaining the full benefits of wearing a speaking valve.

Keywords: Speaking valve; Tracheostomy; Upper airway obstruction; Speech; Chronic respiratory failure Introduction:

Many children who are born medically fragile due to prematurity, multiple congenital abnormalities or as a result of an acquired insult (i.e. cardiac, neurologic, etc.) may require tracheostomy tube placement due to need of chronic respiratory support. Children who are tracheostomy dependent are often unable to vocalize, causing speech delay and poor speech[1].

Passy evaluated the efficacy of a one-way speaking valve in 15 adult ventilator-dependent patients. They concluded that the speaking valve is a safe and effective adjunct to ventilator-dependent patients in improving communication skills, speech flow and volume[2]. Speaking valve restores normal phonation and promotes language development in young pediatric patients[3]. Speech is not the only benefit seen with speaking valves. Speaking valve improves swallowing, and reduces secretions which therefore, decreases the risk of aspiration[3]. The

reduction in secretion improves hygiene around the tracheostomy tube. It enhances both smell and taste sensation[4,5]. The speaking valve improves ventilator weaning and leads to more rapid tracheal decannulation.

Barraza previously has shown at our institution that the speaking valve is safe to use during sleep in children[6]. However, it continues to be contraindicated for use while patients are asleep. Evaluation of speaking valve tolerance and safety is done by monitoring vital signs (i.e. respiratory rate, heart rate, and oxygen saturation) and end-tidal CO_2 levels.

Trans-tracheal pressure measurement allows one to safely and easily assess patency of the upper airway and the ability to force air through the vocal cords[7]. Trans-tracheal pressure measurement is reflective of the intraluminal pressure of the trachea during exhalation when the valve is closed[8]. Trans-tracheal pressure is obtained by measuring the pressure during quiet passive breathing on exhalation. If the trans-tracheal pressures are elevated, greater than 10 cm H_2O on exhalation phase, it would indicate a need to downsize the tracheostomy tube or possibly an extrathoracic obstruction (i.e. subglottic stenosis) may be present[9]. If the trans-tracheal pressures are greater than 35 cm H_2O on inhalation consistently and does not reduce to less than 5 cm H_2O, there is a concern for over-distension and breath stacking[9].

Measurements of trans-tracheal pressure is an invaluable tool in evaluating subjects for speaking valve placement and is predictive of good tolerance of the valve[7]. The purpose of this study is to continue to validate the safety of the speaking valve during sleep with the use of trans-tracheal manometry by comparing expiratory pressure measurements while the patient is awake and asleep.

Materials and Methods:

Study design:

We conducted a single center, prospective, non-randomized study of pediatric patients in St. Mary's Healthcare System to objectively determine the safety of the speaking valve during sleep. The study was approved by the Institutional Review Board. Informed consent and assent (if applicable) were obtained. This clinical trial is registered at www.clinicaltrials.gov (NCT02935140).

Primary outcome:

Analysis of trans-tracheal manometry measurements recorded while patients are awake and asleep wearing the speaking valve.

Secondary outcomes:

a) Analysis of vital signs (i.e. heart rate, respiratory rate, oxygen saturation) and end-tidal CO_2 levels while the patients are awake and asleep wearing the speaking valve.

b) Analysis of vital signs (i.e. heart rate, respiratory rate, oxygen saturation) and end-tidal CO_2 levels while the patients are asleep with or without wearing the speaking valve.

Demographics:

The study group included child residents, 0 to 18 years old, of St Mary's Healthcare System for Children who have a tracheostomy tube and were approved for use of the speaking valve. This study took place in 2015-2016. From the patient's chart, demographic information (i.e. age, gender, patient's information regarding primary disorder, indications for tracheostomy, duration after tracheostomy, type and size of tracheostomy tubes) was collected.

Inclusion criteria:

a) Any subject between the ages of 0-18 years of age who is a resident of St Mary's Healthcare System for Children with a chronic tracheostomy may be enrolled.

b) Patients approved for a speaking valve as per St Mary's Healthcare System for Children written policy.

Exclusion criteria:

a) Patients who do not meet the criteria for the use of speaking valve (i.e. unconscious and or comatose patients, inflated tracheostomy tube cuff, foam-filled tracheostomy tube, severe airway obstruction, unmanageable thick secretions, severe risk for aspiration, severely reduced lung elasticity, and not intended for use with endotracheal tubes).

b) Patients with an acute illness and not at baseline status.

c) Patients with respiratory distress.

Procedure:

St. Mary's Hospital for Children written policy, effective December 2006 (lastly revised in August 2013), evaluates children who are candidates for a speaking valve trial. A multidisciplinary team consisting of a pediatrician, otolaryngologist or pulmonary specialist, nurse, speech language pathologist (SLP), and a respiratory therapist (RT) evaluates the patient's eligibility for the device. In order to be eligible to use a speaking valve during

the day, the patient's tracheostomy should have been placed at least 48 hours earlier, and upper airway patency should have been evaluated by direct observation. The candidate has to be alert and responsive, and should not have any acute respiratory tract infection.

Subjects enrolled in the study were connected to the cardiac-respiratory monitor; heart rate, oxygen saturation, and respiratory rate were recorded. Tracheal suctioning was performed as needed. For patients with a cuffed tracheostomy tube, the cuff was deflated. Prior to placement of the speaking valve, an end-tidal CO_2 measurement was also recorded. The speaking valve was attached to the tracheostomy tube along with the trans-tracheal pressure manometer. Heart rate, oxygen saturation, and respiratory rate were recorded every minute for five minutes. After five minutes, the speaking valve and trans-tracheal pressure manometer was removed. An end-tidal CO_2 measurement was recorded after removal of the speaking valve and trans-tracheal pressure manometer.

Any symptoms, such as choking, gagging, increased respiratory rate, abnormal breathing pattern, coughing, chest tightness and aversion were recorded during these five minutes. The trans-tracheal pressures were recorded every minute for five minutes. The patients resumed usual activity after all measurements were completed. The above assessments were measured in a twenty-four hour period while awake and asleep. The evaluation was stopped if any child exhibited breathing difficulty, chest tightness and air trapping with or without coughing.

In our study, patients used the Passy-Muir tracheostomy speaking valve (Irvine, CA). Humidification was delivered via a tracheostomy collar mask. The subject's baseline continuous heart rate and oxygen saturation were monitored using the Masimo Radical-7 (Irvine, CA). End tidal carbon dioxide was measured using a BCI 8401 Capnocheck II hand-held capnograph (Smiths Medical, St. Paul, Minnesota). The capnograph is a handheld device, which is attached to the tracheostomy tube and provided readings within 15 seconds without interfering with the oxygen supply. Trans-tracheal pressure manometry was measured using an 8199 Posey Cufflator™ Endotracheal Tube Inflator and Manometer. The manometer was attached to a connecting device with the speaking valve which is attached to the tracheostomy tube.

Statistical methods:

Data was collected for each patient according to each situation (i.e. awake or asleep wearing speaking valve; awake or asleep not wearing speaking valve) via descriptive statistics such as means and 95% confidence intervals.

Data collected from patients were in a 5-minute range while wearing the speaking valve. The data were averaged for trans-tracheal pressure, heart rate, respiratory rate, oxygen saturation, and end-tidal CO_2. The mean values were used as the unit of analysis. For end-tidal CO_2 measurements, the 5-minute change was summarized and compared to when the patient was asleep *vs.* awake wearing the speaking valve. To compare end-tidal CO_2 levels (patients wearing the speaking valve *vs.* not wearing the speaking valve); the 5^{th}-measurement when the valve was used was compared to the single end-tidal CO_2 measurement taken without the valve.

Formal statistical testing to compare paired outcome measurements from the same person (valve *vs.* no valve; asleep *vs.* awake) was performed initially via paired t-test, and then Wilcoxon signed rank testing to assess the robustness of the reported result, using SAS 9.4® (SAS Institute; Cary, NC), with two-sided p-values ≤ 0.05 considered to be significant

Results:

A total of eight patients were recruited in the study. Four patients were males and four were females. The mean age of the subjects was 6.4 years (77 months). The subjects had different medical indications for the tracheostomy tube placement Table 1.

Baseline parameters were measured in patients asleep versus awake when not wearing the speaking valve Table 2. All baseline measurements had no statistically significant differences in patients awake *vs.* asleep when not wearing the speaking valve, except for heart rate (average HR=107 when awake *vs.* 86 when asleep; p=0.01). Non-parametric analysis using Wilcoxon signed rank test for paired data (data not shown) had no statistically significant difference, except for heart rate (average HR=105 when awake *vs.* 89 when asleep; p=0.01). The reduction in heart rate is to be expected due to physiologic differences in wake versus sleep state.

During the intervention, no patients had any clinical respiratory adverse events while wearing the speaking valve. Two subjects who require oxygen supplementation at baseline, continued with the same oxygen requirement while wearing the speaking valve. One subject (subject #5) required

Subjects	Age (months)	Gender	Medical Diagnosis	Primary indication for a tracheostomy tube*
1	8	Male	Nemaline Myopathy	Prolonged need for ventilation due to apneas
2	120	Male	Quadriplegic Cerebral Palsy	Prolonged need for ventilation due to respiratory failure
3	120	Female	Spastic Quadriplegic Cerebral Palsy	Prolonged need for ventilation due to respiratory failure
4	83	Female	Lissencephaly	Prolonged need for ventilation due to respiratory failure
5	132	Male	Tracheomalacia, Lissencephaly	Prolonged need for ventilation due to respiratory failure
6	61	Male	Congenital Myasthenia Gravis	Prolonged need for ventilation due to respiratory failure
7	69	Female	Hypoxic Ischemic Encephathlopathy	Prolonged need for ventilation due to respiratory failure
8	22	Female	Congenital Arthrogryposis	Prolonged need for ventilation due to respiratory failure
*No subjects were chronically ventilated at the enrollment of the study.				

Table 1: Patient characteristics.

	AWAKE			ASLEEP			
Measurement	**Mean**	**LCL***	**UCL****	**Mean**	**LCL**	**UCL**	**P-VALUE[1]**
Heart Rate (bpm)	107.50	75.15	139.85	86.00	65.30	106.70	0.01
Respiratory Rate (bpm)	29.38	21.79	36.96	26.13	19.22	33.03	0.34
O_2 Saturation (%)	97.88	96.83	98.92	97.50	96.16	98.84	0.61
ET-CO_2 (mmHg)	38.38	32.52	44.23	40.13	34.16	46.09	0.27
[1]Corresponding to a paired t- test (awake *vs.* asleep) * Lower confidence interval, LCL ** Upper Confidence interval, UCL							

Table 2: Baseline Measurements on patients without the valve (n=8).

suctioning due to increased secretions. This subject was known to have increased secretions at baseline. No sleep disturbance, reduction in oxygen saturation, or apneas were noted while patients wore the speaking valve.

Primary outcome:

Trans-tracheal pressure was observed for all patients (n=8) while wearing the valve (awake *vs.* asleep) the mean measurements and differences are presented in Tables 3 and 4, respectively. Analysis of trans-tracheal manometry measurements while patients were awake versus asleep, wearing the speaking valve, showed no statistically significant difference (mean trans-tracheal pressure 12.25 cm H_2O when awake *vs.* 8.98 cm H_2O when asleep; p=0.38). The mean trans-tracheal pressure difference when awake *vs.* asleep was 3.28 cm H_2O; 95% CI: (-4.98, 11.53). Non-parametric analysis using Wilcoxon signed rank test for paired data (data not shown) confirmed no statistically significant difference.

Secondary outcome:

Mean measurements and their differences for other parameters (i.e. heart rate, respiratory rate, oxygen saturation, and end-tidal CO_2) were observed for all patients (n=8) while wearing the valve (awake *vs.* asleep) are presented in Tables 3 and 4, respectively. There were no statistically significant differences while asleep *vs.* awake in any of the measurements while wearing the valve except for heart rate, which decreased by about 25 beats per minute (bpm) on average during sleep (mean HR=111 when awake *vs.* 85.8 when asleep; p=0.01). The mean heart rate difference when awake *vs.* when asleep =25.6; 95% CI: (9.75, 41.45).

The mean initial end-tidal CO_2 measurements were similar when awake and asleep (mean was 38.4 mmHg *vs.* 40.13 mmHg; p=0.27). The mean initial end-tidal CO_2 measurements difference when awake and asleep = -1.75; 95% CI: (-5.75, 1.68). The mean end-tidal CO_2 after 5 minutes were also similar when awake or asleep (39.75 *vs.* 40.38; p=0.67). The mean

	AWAKE			ASLEEP			
Measurement	**Mean**	**LCL***	**UCL****	**Mean**	**LCL**	**UCL**	**P-VALUE[2]**
Trans-tracheal Pressure, (cm H2O)	12.25	7.56	16.94	8.98	2.04	15.91	0.38
Heart Rate, (bpm)	111.40	80.39	142.41	85.80	65.46	106.14	0.01
Respiratory Rate, (bpm)	30.88	21.08	40.67	27.75	21.28	34.22	0.24
O_2 Saturation, (%)	96.58	95.13	98.02	97.35	95.66	99.04	0.42
ET-CO_2 at 1st minute, (mmHg)	38.38	32.52	44.23	40.13	34.16	46.09	0.27
ET-CO_2 at 5th minute, (mmHg)	39.75	32.67	46.83	40.38	35.07	45.68	0.67
Δ ET-CO_2 (5min-1min), (mmHg)	1.38	-2.08	4.83	0.25	-1.52	2.02	0.42

[1] The average of 5 measurements taken over 5 minutes for trans-tracheal pressure, heart rate, respiratory rate, and O_2 saturation
[2] Corresponding to a paired t- test (awake *vs.* asleep)
* Lower confidence interval, LCL
** Upper Confidence interval, UCL

Table 3: Measurements[1] on patients wearing the valve (n=8).

Measurement	Mean difference	95% CI	
		LCL	**UCL**
Trans-tracheal Pressure, (cm H2O)	3.2750	-4.9813	11.5313
Heart Rate, (bpm)	25.6000	9.7512	41.4488
Respiratory Rate, (bpm)	3.1250	-2.6698	8.9198
O_2 Saturation, (%)	-0.7750	-2.9096	1.3596
ET-CO_2 at 1st minute, (mmHg)	-1.7500	-5.1752	1.6752
ET-CO_2 at 5th minute, (mmHg)	-0.6250	-3.9069	2.6569
Δ ET-CO_2 (5min-1min), (mmHg)	1.1250	-1.9851	4.2351

[1] The difference between awake and asleep with the valve.
[2] Corresponding to a paired t- test (awake *vs.* asleep)
* Lower confidence interval, LCL
** Upper Confidence interval, UCL

Table 4: Measurement differences[1] on patients wearing the valve (n=8).

end-tidal CO_2 measurements difference at 5 minutes when awake and asleep = -0.63; 95% CI: (-3.91, 2.66).

Mean measurements for other parameters (i.e. heart rate, respiratory rate, oxygen saturation, and end-tidal CO_2) were observed for all patients (n=8) asleep wearing the speaking valve and compared when asleep not wearing the speaking valve are presented in Table 5. There were no statistically significant differences in any of the measurements while asleep (wearing the speaking valve *vs.* not wearing the speaking valve).

Discussion:

This single center, small prospective, non-randomized study provides additional evidence that tracheostomy tubed patients may wear the speaking valve during sleep periods without having any adverse cardiopulmonary events. Trans-tracheal pressure measurements were not significantly different between awake and asleep patients wearing the valve during the study period. Additionally, our study continues to show that there were no significant difference in vital signs (i.e. respiratory rate and oxygen saturation) and end-tidal CO_2 measurements between patients awake and asleep wearing the valve.

Trans-tracheal pressure measurements for patients wearing the speaking valve during sleep was observed to be reduced on average by 3.3 cm H_2O compared to when awake. The 95% confidence interval, which represents a plausible range for this difference was computed to be -5 cm to +11.5 cm H_2O, which indicates based on our study, that future studies, an average increase above 5 cm H_2O in trans-tracheal pressure while asleep is not expected.

Six of the eight patients wearing the speaking valve while awake had average trans-tracheal pressure measurements below 12 cm H_2O (3 were ≤ 10 H_2O). Of the two patients with average trans-tracheal pressure measurements above 12 cm H_2O while awake (14.4 and 24.4c m H_2O) one patient had an

ASLEEP WITH VALVE				ASLEEP W/O VALVE			
Measurement	**Mean**	**LCL***	**UCL****	**Mean**	**LCL**	**UCL**	**P-VALUE[1]**
Heart Rate (bpm)	85.80	65.46	106.14	86.00	65.30	106.70	0.92
Respiratory Rate (bpm)	27.75	21.28	34.22	26.13	19.22	33.03	0.24
O_2 Saturation (%)	97.35	95.66	99.04	97.50	96.16	98.84	0.76
ET-CO_2 (mmHg)	40.38	35.07	45.68	40.13	34.16	46.09	0.75

[1]Corresponding to a paired t- test (awake *vs*. asleep)
* Lower confidence interval, LCL
** Upper Confidence interval, UCL

Table 5: Measurements on patients asleep (n=8).

average trans-tracheal pressure below 10 cm H_2O while asleep while the other was observed to have a trans-tracheal pressure of greater than 25 cm H_2O while asleep. Of the six patients with average trans-tracheal pressure measurements below 12 cm H_2O while awake, 67% (4/6) were observed to have trans-tracheal pressure measurements while asleep below 10 cm H_2O.

One patient's trans-tracheal pressure increased to 27 cm H_2O during sleeping while wearing the speaking valve, previously had a flexible bronchoscopy which did not demonstrate any subglottic stenosis. Our speculation for the increased trans-tracheal pressure during sleep in this patient may possibly be secondary to obstructive sleep apnea (OSA) when wearing the speaking valve. However, a polysomnography would be needed to diagnose OSA.

Barraza has previously shown that the speaking valve is safe to use during sleep in children[6]. This study showed children with speaking valves during sleep was not associated with adverse cardiopulmonary events by evaluating heart rate, respiratory rate, oxygen saturation, and end-tidal CO_2 levels[6]. Our study continues to confirm the safety of the speaking valve during sleep in children with the use of trans-tracheal pressure manometry. The review of literature is scant for evaluating the safety of wearing the speaking valve during sleep in both the pediatric and adult population. One adult study evaluated ten seriously ill tracheostomy patients and observed no respiratory distress or cardiac arrhythmias during nocturnal speaking valve use[10]. Another adult study showed 14 of 32 patients with tracheostomy were able to tolerate a speaking valve for 24 hours (both when awake and during sleep periods)[11].

During the initial placement of the speaking valve, the respiratory therapist and the speech-language pathologist assess the patient for tolerance. Prior to trans-tracheal manometry availability, speaking valve use assessment methods to determine tolerance of the speaking valve were informal[12]. The informal assessment consisted of observing patients for breathing comfortably with the valve[13]. The addition of trans-tracheal pressure manometry with the vital signs improves the evaluation for tolerance and safety of the speaking valve. The successful use of the speaking valve is more challenging with infants and younger pediatric patients compared to adults[14]. The challenge is due to the small airways in pediatric patients requiring smaller and tighter fitting tracheostomy tubes which reduce air leak. The air leak around the tracheostomy tube is necessary for the speaking valve to function.

The use of speaking valve has many potential benefits, especially with the use during the night. Restoration of phonation is crucial not only for promoting development of early communication (speech and language development), but also allows for vocalization/noise in case of an emergency at night[3]. There is a high incidence of aspiration (50% to 80%) in patients with tracheostomy tubes and this may be worse at night[15]. Management of secretions and the ability to expectorate them appropriately is an issue with patients with tracheostomy[15]. Evidence suggests that the mechanism responsible for aspiration in patients with tracheostomy is due to the decreased subglottic air pressure, which can be restored with the use of the speaking valve[16].

Secondary benefits with the speaking valve are assisted ventilator weaning, and more rapid tracheal decannulation[4]. In infants who require invasive mechanical ventilation, the use of continuous positive airway pressure (CPAP) is typically used to maintain functional residual capacity (FRC) in a spontaneously breathing patient due to the fact their chest wall is more compliant than the lungs[17]. Infants actively maintain FRC above the lung's end expiration volume by constricting laryngeal adductors and initiating inspiratory muscle contraction. Placing a tracheostomy tube in a newborn can impair some infant's ability to maintain FRC. However, this may be restored with a speaking valve[17].

There are several limitations in our study. Our study was conducted at a single institution with an enrollment of a small number of patients. With a small sample size (n=8), all results (statistically significant or insignificant) should be interpreted with caution. The paired nature of the design allowed us to more efficiently estimate changes in clinically important outcomes and the corresponding 95% confidence intervals may provide additional insight into the plausible range of changes in these parameters during sleep. Our results need to be confirmed by larger prospective studies. On the other hand, the number of children that are tracheostomy dependent is small in the pediatric population. Another limitation is the short period of observation and intervention of only one night. Observing subjects over multiple nights can give us a better perception of its safety profile during the night. Although not the purpose of this study, we did not assess the safety and tolerance of the speaking valve during an acute illness. Lastly, we did not evaluate subjects with an overnight polysomnography at baseline and while wearing the speaking valve to evaluate for sleep disordered breathing or disturbances.

Conclusion:

We continue to show the speaking valve in children can be safely used during sleep. Objective parameters using vital signs and trans-tracheal pressure manometry can safely evaluate children who use the speaking valve during sleep periods. Improvement in the future management of children that are tracheostomy dependent can be provided so they may be able to obtain the benefits of wearing the speaking valve.

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