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Research Article

The Shikani HME: A New Tracheostomy Heat and Moisture Exchanger

Alan H. Shikani,[a,b] Elamin M. Elamin,[c] and Andrew C. Miller[d]

Purpose: Tracheostomy patients face many adversities including loss of phonation and essential airway functions including air filtering, warming, and humidification. Heat and moisture exchangers (HMEs) facilitate humidification and filtering of inspired air. The Shikani HME (S-HME) is a novel turbulent airflow HME that may be used in-line with the Shikani Speaking Valve (SSV), allowing for uniquely preserved phonation during humidification. The aims of this study were to (a) compare the airflow resistance ($R_{airflow}$) and humidification efficiency of the S-HME and the Mallinckrodt Tracheolife II tracheostomy HME (M-HME) when dry (time zero) and wet (after 24 hr) and (b) determine if in-line application of the S-HME with a tracheostomy speaking valve significantly increases $R_{airflow}$ over a tracheostomy speaking valve alone (whether SSV or Passy Muir Valve [PMV]).

Method: A prospective observational ex vivo study was conducted using a pneumotachometer lung simulation unit to measure airflow (Q) amplitude and $R_{airflow}$, as indicated by a pressure drop (P_{Drop}) across the device (S-HME, M-HME, SSV + S-HME, and PMV). Additionally, P_{Drop} was studied for the S-HME and M-HME when dry at time zero (T_0) and after 24 hr of moisture testing (T_{24}) at Q of 0.5, 1, and 1.5 L/s.

Results: $R_{airflow}$ was significantly less for the S-HME than M-HME (T_0 and T_{24}). $R_{airflow}$ of the SSV + S-HME in series did not significant increase $R_{airflow}$ over the SSV or PMV alone. Moisture loss efficiency trended toward greater efficiency for the S-HME; however, the difference was not statistically significant.

Conclusions: The turbulent flow S-HME provides heat and moisture exchange with similar or greater efficacy than the widely used laminar airflow M-HME, but with significantly lower resistance. The S-HME also allows the innovative advantage of in-line use with the SSV, hence allowing concurrent humidification and phonation during application, without having to manipulate either device.

Tracheostomy is a surgical procedure performed to relieve airflow obstruction through the larynx and upper trachea. Patients with tracheostomies face postprocedure adversities including loss of phonation and essential breathing functions including air filtering, warming, and humidification (Bard et al., 1992; de Kleijn et al., 2017; Manzano et al., 1993; Passy et al., 1993; Shikani et al., 2015). Phonation and communication are important for the patients' quality of life, medical care, and social interactions. In children, tracheostomy may be particularly disruptive by adversely affecting language skill development (DeMauro et al., 2014; Hull et al., 2005; Simon et al., 1983). To redirect the air through the vocal folds, the tracheostomy may be occluded using a finger or a device. Finger occlusion, however, has several limitations. It is unsanitary and requires a level of dexterity and respiratory timing that may be difficult for some patients. Tracheostomy speaking valves (TSVs) offer a more appealing alternative. Unidirectional TSVs have a displaceable element that allows air to flow through the cannula and into the lungs during inspiration. During expiration, air may not traverse the closed valve and is redirected through the upper airway to facilitate phonation and secretion expectoration (Fornataro-Clerici & Zajac, 1993; Leder, 1994; Lichtman et al., 1995; Passy, 1986; Passy et al., 1993; Shikani et al., 2000; Tippett & Siebens, 1995). Traditional TSVs, such as the Passy Muir Valve (PMV; Passy Muir, Inc.), are flapper-type valves. Such valves are based on a bias-closed membrane that is only open upon inspiration. Conversely, the Shikani Speaking Valve (SSV; The Airway Company), which is based on a

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ball-type design, may be used either in a "bias open" or in a "bias closed" configuration (Shikani & Dietrich-Burns, 2012; Shikani et al., 2000, 2015). In a "bias open" or "12 o'clock" position, the flow ball is directed posteriorly into the proximal portion of the chamber (i.e., away from the frontal opening) by a 2.5° ramp, thereby permitting exhaled air to escape through the frontal opening and carry with it warm pulmonary moisture to the Shikani Heat and Moisture Exchanger (S-HME) that may be worn in-line simultaneously (Shikani & Dietrich-Burns, 2012; Shikani et al., 2000, 2015). The patient may hence exhale through an open valve due to the SSV ball position and then inhale humidified air through the moisturized HME. This differs from older ball-valve designs that neither included a ramp nor the option of in-line TSV and HME application (French et al., 1991, 1984). Similarly, this feature is not possible with conventional flapper-type valves, which remain 100% closed upon exhalation. Furthermore, the new SSV ball-type design has been shown to have a lower airflow resistance ($R_{airflow}$) as compared to the Passy Muir and Shiley Phonate flapper-type speaking valves (Shikani et al., 2015).

Moreover, it is important for tracheostomy patients that inhaled air have substantially the same temperature (95 °F), moisture content (99% saturation), and dust concentrations as air that reaches the trachea by traversing the upper airway. However, air traversing an open tracheostomy reaches the lungs with substantially lower temperature, humidification, and without particulate filtering. When dryer, cooler, and unfiltered air reaches the lungs, detrimental health effects occur, including thickened mucus, impaired mucociliary transport, and mucosal damage (Clary-Meinesz et al., 1992; Freed et al., 1994; Omori et al., 1995; Van Oostdam et al., 1986). Aggregates of dried mucus may fall, occlude deeper airways, and promote atelectasis or infection. While TSV application may offset some adverse consequences of tracheostomy by allowing for phonation and improved olfaction and swallowing (de Kleijn et al., 2017; Leder, 1994; Manzano et al., 1993; Passy et al., 1993; Tippett & Siebens, 1995), humidification, warming, and filtering remain lost when air is diverted away from the nasal passages. HME use helps mitigate these effects.

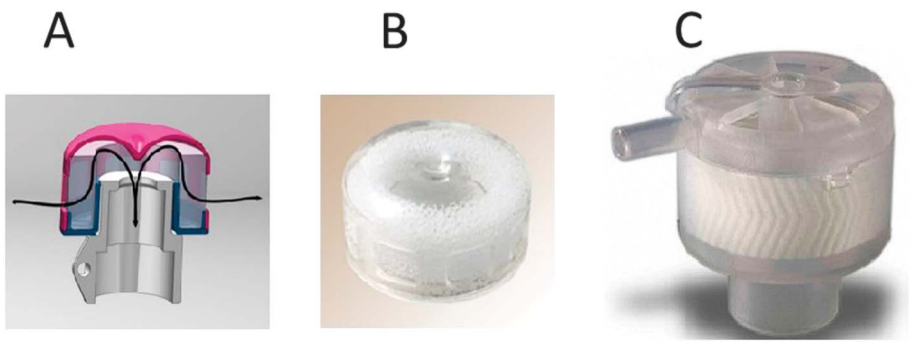
A typical HME device is placed externally, between the outside air and the tracheostomy tube. The ebb and flow of exhaled and inhaled air flowing across the HME's humidifying and moisturizing media allows a recurring transference of moisture and heat from the patient to the HME and back again. In this way, the HME restores some of the functions lost when inspired air no longer traverses the nose and nasopharynx. Although the HME cannot totally restore the physiological functions of the upper airway, it has considerable beneficial effects on tracheal and pulmonary mucosa; thus, they are routinely recommended to help maintain the pulmonary health of postlaryngectomy patients (Bień et al., 2010; Hilgers et al., 1991; Jones et al., 2003; Lorenz & Maier, 2009). Postlaryngectomy HME use has been shown to significantly reduce sputum production, forced expectoration, stoma crusting, stoma cleaning requirements, physiotherapy requirements, and pulmonary adverse events including infection (Ackerstaff et al., 1993; Foreman et al., 2016; Hilgers et al., 1991; Keck et al., 2005; Mérol et al., 2012; Scheenstra et al., 2010). Long-term HME use decreases pulmonary infections (Hilgers et al., 1991; Myer et al., 1988; Rosso et al., 2015; Rozsasi et al., 2006; Scheenstra et al., 2010; Thomachot et al., 1998). Moreover, symptoms of fatigue and malaise are significantly decreased, while social contact, speech, and sleep often improve (Ackerstaff et al., 1993; Bień et al., 2010). The impact of HME after a tracheostomy use remains understudied, with a small number of studies describing or assessing posttracheostomy HME use, despite obvious similarities in the physiology of breathing through a tracheostoma as compared to a laryngectomy stoma. Thus, HME acceptance and use by tracheotomized patients remain slow in the United States. There is research showing that HME use has a protective effect on dogs' tracheal mucosa following tracheostomy (Myer et al., 1988), and there are clinical studies indicating a beneficial effect on the mucosal lining of the human tracheobronchial tree when used over a prolonged time (Rozsasi et al., 2006; Thomachot et al., 1998).

There are several types of tracheostomy HMEs currently available on the market. Conventional HMEs typically consist of a tube that directs air in a "linear" fashion through a humidifying and moisturizing media. However, linear-type HMEs are relatively less efficient because (in part) air spends less time in contact with the media, thereby necessitating larger amounts of media material. This translates into bulkier designs with greater $R_{airflow}$, which may decrease patient comfort and detract from aesthetics. Moreover, most linear-flow HMEs contain pleated corrugated paper as a hydrophobic filter, which is inefficient and tends to degrade quickly, necessitating that the HME be changed several times per day.

Of further concern is that conventional TSVs and linear-flow HMEs are not compatible to be worn simultaneously in-line, which translates into the fact that patients would not be able to effectively achieve phonation and humidification concurrently. A small number of tracheotomized patients have been able to achieve some degree of phonation using HMEs alone; however, voice quality is suboptimal. Some have sought to overcome this obstacle by developing an integrated HME (de Kleijn et al., 2017), while we are introducing a TSV and HME that may be applied in-line simultaneously (Shikani & Dietrich-Burns, 2012; Shikani et al., 2000, 2015). The S-HME (The Airway Company; see Figures 1A and 1B) is a novel HME that utilizes turbulent airflow, which increases drag, friction, and heat exchange to increase HME efficiency. The S-HME is significantly lighter in weight and smaller in size than its linear-flow contemporaries. The hygroscopic media is composed of porous reticulated ester-type polyurethane foam impregnated with calcium chloride that efficiently traps moisture and heat while filtering particulates. Importantly, the S-HME is designed for in-line use with the SSV, allowing for effective phonation and humidification concurrently.

This study aims to (a) compare the $R_{airflow}$ and humidification efficiency of the S-HME and the Mallinckrodt

Figure 1. Image A is a schematic of the Shikani HME that highlights the path of airflow and how it generates turbulent airflow. Images B and C are photographic depictions of the Shikani HME and the Mallinckrodt Tracheolife II tracheostomy HME, respectively.



Tracheolife II tracheostomy HME (M-HME; also known as the Covidien DAR HME; see Figure 1C) when dry and wet and (b) determine if in-line application of the S-HME with a TSV significantly increases $R_{airflow}$ over a TSV alone (whether SSV or PMV). $R_{airflow}$ was measured by pressure drop (P_{Drop}) across the device (a surrogate of $R_{airflow}$), and humidification efficiency was measured as moisture loss (ML).

Method

The airflow characteristics studies were performed at the Technologie Institut Medizin in Göttingen, Germany, according to International Standardization Organization (ISO) 9360-1:2009 standards for anesthetic and respiratory equipment HMEs for humidifying respired gases in humans (https://www.iso.org/standard/23913.html). We evaluated the S-HME's $R_{airflow}$ and humidification efficiency and compared it to the M-HME both when the HMEs were dry (T_0) and when wet (after 24 hr of use). For additional context, the $R_{airflow}$ was measured for the S-HME used in-line with the SSV (SSV + S-HME) as compared to two TSVs alone: SSV (ball valve) and PMV (flapper valve).

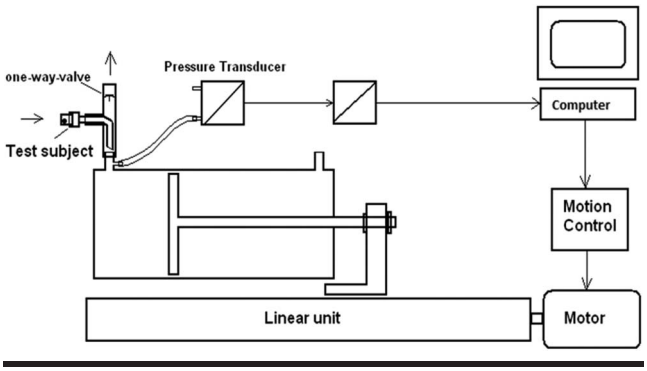
$R_{airflow}$ of the S-HME With and Without the SSV

$R_{airflow}$ correlates directly with the P_{Drop} across the device at a constant airflow rate (Q). A pneumotachometer was used to measure P_{Drop} across each device at varied constant flow rates. The validated ISO 9360-1:2009 method was used to deliver "inspiratory" and "expiratory" Q across the device via the piston drive of the lung simulation unit in the reservoir chamber. $R_{airflow}$ was measured for the S-HME used in-line with the SSV and compared to that of the SSV and PMV alone.

Each test device was connected to both a differential transducer (Kal 84, Halstrup-Walcher) and to a pneumotachometer (TSI 4040E, TSI, Inc.) to allow for the measurement of air pressure and Q (see Figure 2). The devices were mounted on a cannula integrated with a T-piece. One end of the T-piece was connected to the outlet of the piston pump, while the other end was equipped with a one-way-valve. The calibrated pneumotachometer device was connected in sequence with the pressure source. In this configuration, the inspiratory Q may only pass through the TSV. Pressure was measured at the distal end of the cannula, which was coupled to a positive and negative pressure source. By varying the voltage to the device through a variable transformer, one may vary the speed at which the piston moves and, consequently, the Q and pressure (positive or negative) generated by the blower. The pneumotachometer was set to generate a tidal volume (V_T) of 0.5 L/cycle at a rate of 20 cycles/min, utilizing a square-wave flow curve. This V_T and cycle rate are representative of the usual rates experienced by tracheostomy patients during quiet breathing. The experiment was conducted at a Q range of 0.00–0.35 L/s, corresponding to those experienced by patients with TSVs during normal breathing and/or light activity.

A differential pressure transducer was used to measure the P_{Drop} across the device, with one port connected to the piston pump outlet and the other open to ambient air. Q was increased in stepwise increments of 0.05 L/s. The technique was repeated for a total of five measurements, each at different continuous Q amplitude. Values were averaged

Figure 2. Pneumotachometer apparatus to measure airflow versus change in pressure (a measure of airway resistance). Legend: (1) pressure transducer, (2) ISO 9360-1:2009 adapter for tracheostomy heat and moisture exchanger (HME; A/D), (3) motor-driven piston (simulates inhalation and exhalation, with piston moving to the right and/or left), (4) PC with screen, (5) test device (speaking valve or HME).



for each point on the resulting pressure curve to represent the resulting flow-dependent change in pressure (ΔP) at the respective flow step. To compensate for ΔP across the system, ΔP was measured at each flow rate without the test device connected, and these values were subtracted from the ΔP measured with the test device connected. The corrected pressures were used to generate the $\Delta P/Q$ curve. The measuring of P_{Drop} with this system was validated against the measuring of P_{Drop} according to ISO 9360-1:2009.

$R_{airflow}$ of the S-HME and the M-HME

The same pneumotachometer was used to measure $R_{airflow}$ for the S-HME and the M-HME over specified constant flows. A total of three S-HMEs and three M-HMEs were tested. The P_{Drop} across each device was tested at time zero (T_0; dry device before any moisture) and after 24 hr of moisture testing (T_{24}) at Q rates of 0.5, 1, and 1.5 L/s. Values were averaged for each device type at each point. The measuring of P_{Drop} with this system was validated according to ISO 9360-1:2009 (https://www.iso.org/standard/23913.html).

ML of the S-HME and the M-HME

The HME ML performance was determined according to the standard ISO 9360-1:2009-1:2009 (https://www.iso.org/standard/23913.html). The HME was connected to a lung simulator that simulates spontaneous respiration, including humidification within the physiological range. The lung simulator consisted of a bidirectional flow generator and a humidity generator. The bidirectional flow generator (piston pump) consisted of a linear motor drive controlled by a microcontroller and a computer program based on Visual Basic 6.0 (Microsoft Corp.). It generated the test conditions of ISO 9360-1:2009 (https://www.iso.org/standard/23913.html) and generated the constant Q for P_{Drop} measurements, with a V_T of 0.5 L at a rate of 15 cycles/min for 24 hr. The humidity generator consisted of a water vessel containing a heater and humidifying elements (see Figure 3). Both were placed in a tempered chamber (simulation chamber) to avoid condensation. Throughout the test procedure, the air temperature was maintained at 98.6 ± 1 °F, and the water bath temperature was maintained at 98.6 ± 1 °F. Additionally, the test rig contained a tempered HME chamber (73.4 ± 2 °F) in which the test device is placed. According to the standard, flow-controlled fresh gas passed through the HME chamber. The temperature of the fresh gas was aligned with the HME chamber temperature by directing it through a heat exchanger.

ML or water loss was assessed by two methods: (a) gravity method and (b) absolute humidity sensor. For the gravity method, the humidification system was weighed before and after the operation time according to ISO 9360-1:2009 (https://www.iso.org/standard/23913.html). Taking the applied gas volume (set V_T multiplied with set rate) into account, ML (mg/L) was calculated. Additionally, ML was measured with an integrated absolute humidity sensor located in the expiration limb. Expiratory air was separated from inspiratory air by a three-way valve connected to the machine port of the lung simulator. Humidification values were recorded over time. Each test was repeated 3 times, with a run time of 3 hr, V_T of 0.5 L at a rate of 15 cycles/min. To ensure the proper operation of the HME test rig, ML of the test equipment was validated with the calibrated HME according to ISO 9360-1:2009 (https://www.iso.org/standard/23913.html). A reference ML measurement under the same test conditions was performed with a calibrated

Figure 3. Lung simulator consisting of a bidirectional flow generator and a humidity generator to measure moisture loss (ML) including heat and moisture exchanger (HME) chamber and AQA-II HME Test rig. Legend: HME simulation chamber with moistening unit, lung simulation unit, heater and scale, reservoir chamber with supply water tank for humidification, pneumatic elements and bidirectional flow generator (piston pump) consisting of a linear motor drive controlled by a microcontroller and a computer program. The HME ML performance was determined according to the standard ISO 9360-1:2009.

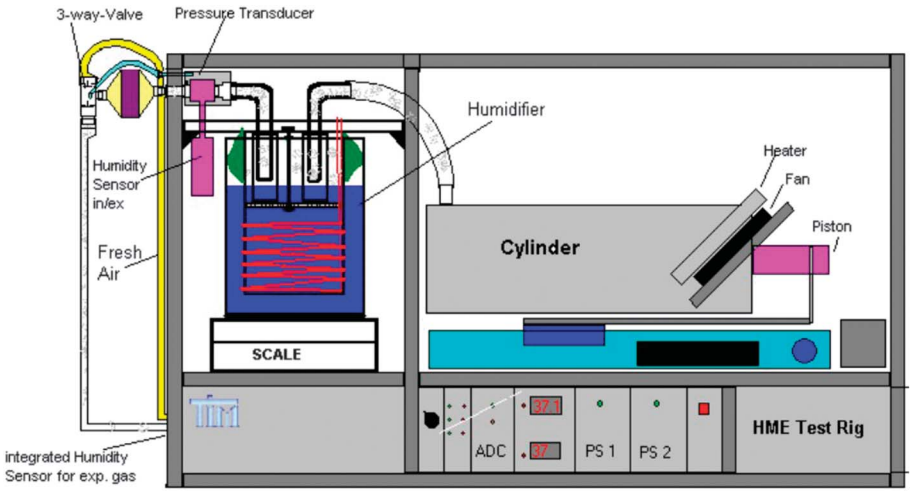
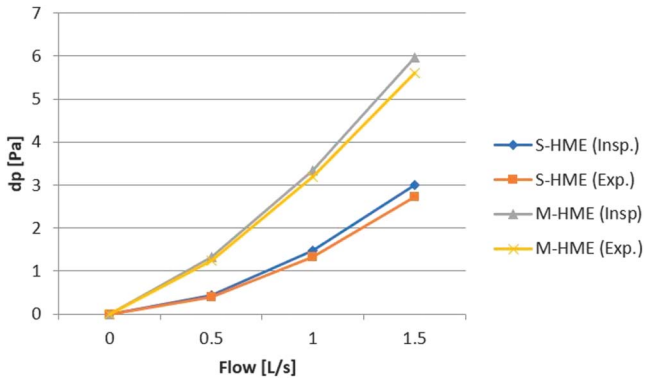


Figure 4. Airflow resistance (measured as pressure drop [hPa]) of the different dry heat and moisture exchanger (HME) devices at time zero (before moisture) during inspiration and expiration. S-HME = Shikani HME; M-HME = Mallinckrodt Tracheolife II tracheostomy HME; Insp. = inspiration; Exp. = expiration.



HME before and after each series of tests. ML was compared between the S-HME (turbulent airflow) and M-HME (linear airflow).

Statistical Analysis

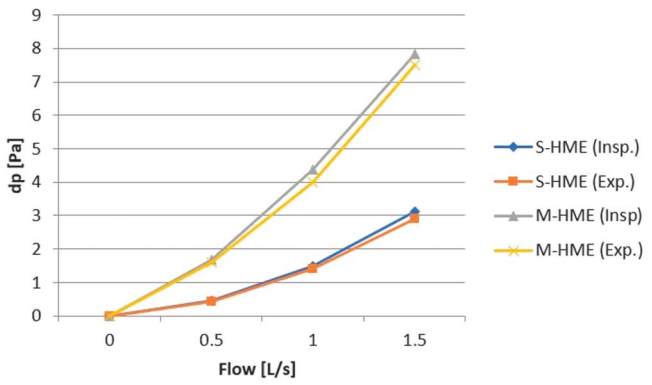
Statistical analysis was performed using Microsoft Excel 2016 (Microsoft Corp.) and the IBM SPSS Software Version 22.0 (IBM Corp.). Parametric data were expressed as mean ± standard deviation.

When comparing $R_{airflow}$ of the S-HME and M-HME devices, analysis of variance (ANOVA) for repeated measurements was performed for P_{Drop} across different Q rates. Significance was set at a p value of < .05. Tukey's honestly significant difference was performed, and significance was set at a p value of < .05.

The $R_{airflow}$ was compared for each of the S-HME, SSV, and SSV + S-HME devices at eight different flow rate measurements, and ANOVA was performed for the repeated measurements. When the ANOVA reached a p value of < .05 (F test), pairwise comparisons were performed using the least squares means for resistance with 95.0% confidence intervals. Significance was set at a p value of < .05.

When comparing ML between the S-HME and the M-HME, statistical analysis was done using ANOVA for repeated measurements. Significance was set at a p value of < .05.

Figure 5. Airflow resistance (measured as pressure drop [hPa]) of the different wet heat and moisture exchanger (HME) devices at time 24 hr (after 24 hr of before moisture) during inspiration and expiration. S-HME = Shikani HME; M-HME = Mallinckrodt Tracheolife II tracheostomy HME; Insp. = inspiration; Exp. = expiration.



Results

$R_{airflow}$ of the S-HME Versus M-HME

The results of $R_{airflow}$ (measured as P_{Drop}) at different constant flow rates is shown at T_0 (before moisture) for the dry S-HME and M-HME (see Figure 4). The $R_{airflow}$ results for the wet (T_{24}, after moisture) S-HME and M-HME devices are shown in Figure 5. The statistical analysis results are shown in Table 1. A significant difference in $R_{airflow}$ in favor of the S-HME was observed between devices at T_0 (p = .001) and T_{24} (p < .001).

$R_{airflow}$ of the S-HME With and Without the SSV

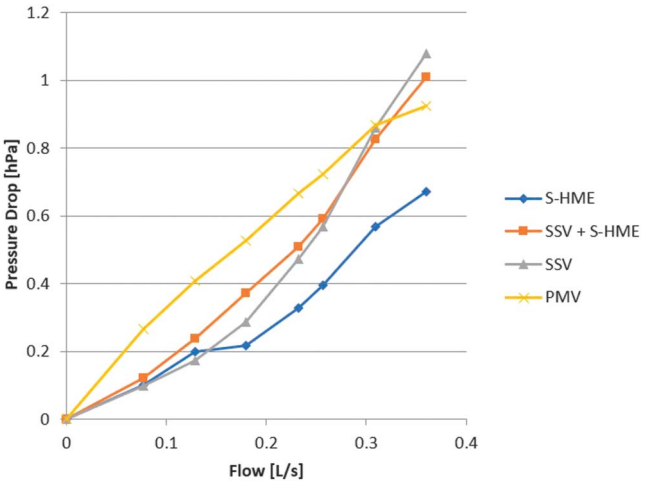
The results of $R_{airflow}$ (measured as P_{Drop}) at different constant Q rates are shown for the S-HME, the SSV + S-HME, the SSV alone, and the PMV alone in Figure 6. The measurements are plotted to reflect P_{Drop} (hPa) versus

Table 1. Analysis of variance results comparing the airflow resistance (measured as pressure drop across all flow rates) of the dry heat and moisture exchanger (HME) devices at time zero (before moisture) and the wet HME devices after 24 hr of moisture exposure.

***T* = 0**				
	M	***SD***	***SE***	***n***
S-HME	1.56	1.04	0.24	18
M-HME	3.44	2.08	0.49	18
	df	**Sum of squares**	**Mean square**	
Between groups	1	31.92	31.92	
Within groups	34	92.88	2.73	
	***F* stat**	***p***		
	11.68	.001		
***T* = 24 hr**				
	M	***SD***	***SE***	***n***
S-HME	1.63	1.10	0.26	18
M-HME	4.52	2.58	0.60	18
	df	**Sum of squares**	**Mean square**	
Between groups	1	75.11	75.11	
Within groups	34	134.26	3.94	
	***F* stat**	***p***		
	19.02	< .001		

Note. S-HME = Shikani HME; M-HME = Mallinckrodt Tracheolife II tracheostomy HME.

Figure 6. Airflow resistance (measured as pressure drop [hPa]) for tracheostomy speaking valves and the Shikani HME at eight different constant flow rates. S-HME = Shikani HME; SSV = Shikani Speaking Valve; PMV = Passy Muir Valve.



airflow (L/s). The results indicate that there was no statistically significant difference between the devices and that in-line use of the SSV + S-HME does not add significant $R_{airflow}$ beyond that of the SSV alone or the PMV alone. The PMV alone showed a trend toward a higher $R_{airflow}$; however, the difference did not achieve statistical significance. The ANOVA results are shown in Table 2.

ML of the S-HME and the M-HME

ML was compared between the S-HME (turbulent airflow) and the M-HME (linear airflow). The S-HME had a mean ML of 17.25 mg/L, as compared to 19.85 mg/L for the M-HME, translating to a 10.85% increased ML efficiency for the S-HME; however, the difference did not achieve statistical significance.

Discussion

Posttracheostomy airway colonization and infection is a serious complication that increases patient morbidity and mortality. Complications associated with insufficient airway humidity include tracheitis, pneumonia, and tracheostomy obstruction. Colonization with one or more potential pathogens at the stoma and trachea may be as high as 95% and 83%, respectively, with more than half of patients colonized within 1 week (Acharya et al., 2014; Harlid et al., 1996). The incidence of pneumonia in tracheostomy patients may exceed 12%, with the most common bacterial pathogens being *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Acinetobacter* species (Acharya et al., 2014). Additionally, the prevalence of pneumonia in tracheostomy patients on mechanical ventilation may be even higher, about 14% and 21% in early and late tracheostomy, respectively (Terragni et al., 2010), with such infections carrying a poor prognosis and high mortality rates (Ahmed & Niederman, 2001; Yang et al., 1989).

HME use has been shown to significantly reduce sputum production, forced expectoration, stoma crusting and cleaning requirements, physiotherapy requirements, and pulmonary adverse events, including infections (Ackerstaff et al., 1993; Foreman et al., 2016; Hilgers et al., 1991; Mérol et al., 2012; Myer et al., 1988; Rosso et al., 2015; Rozsasi et al., 2006; Scheenstra et al., 2010; Thomachot et al., 1998). The S-HME differs from other conventional HME devices in that air traverses the device in a turbulent rather than linear fashion. This turbulence improves efficiency by increasing friction, pressure drag, and heat/energy transfer as compared to linear airflow devices. The dome-shaped outer shell provides additional dead space above the media to augment condensation. The dimple in the dome center allows air to recirculate with turbulent eddy currents before being redirected to the openings on the side of the device. The resultant air turbulence increases with breathing effort and airflow speed. Conversely, with laminar airflow HMEs, airflow is smooth, regular, and follows Bernoulli's principle, which states that a fluid (such as air) traveling over

Table 2. Analysis of variance (ANOVA) results comparing the airflow resistance (measured as pressure drop) of the Shikani Speaking Valve (SSV), the Shikani HME (S-HME) in combination with the SSV, the S-HME alone, and the Passy Muir Valve (PMV) alone at eight different constant flow rates.

One-way ANOVA			
Source of variation	**Sum of squares**	***df***	**Mean square**
Between groups (influence factor)	0.2302	3	0.07674
Within groups (other fluctuations)	2.8990	28	0.1035
Total	3.1293	31	
F ratio	0.741		
Significance level	$p = .536$		
Factor	***n***	***M***	***SD***
(1) PMV	8	0.5474	0.3133
(2) S-HME	8	0.3100	0.2288
(3) SSV	8	0.4424	0.3793
(4) SSV + S-HME	8	0.4585	0.3461
D'Agostino–Pearson Test for normal distribution		accept normality ($p = .5304$)	

the surface of an object exerts less pressure than if the fluid were still (Smith, 1972). Turbulent flow, however, is chaotic and unpredictable. Particles exhibit additional transverse motion, which consists of irregular circular eddy currents that push on the surface in unexpected ways (Stoll, 1974). This increases drag, mass exchange rates, momentum, and heat (Stoll, 1974). The kinetic energy cascades from these large-scale structures to smaller scale structures, eventually creating structures that are small enough that higher molecular diffusion and energy dissipation occurs (Kambe, 2007). The scale at which this happens is the Kolmogorov length scale (Anbarlooei et al., 2018). Therefore, under turbulent flow conditions, particles exhibit substantially higher transverse motion and drag (air resistance) and enhanced heat and water transfer (Anbarlooei et al., 2018).

P_{Drop} correlates directly with $R_{airflow}$ and patient energy expenditure and inversely with patient comfort, thus making it one of the most important features in determining HME quality (Verkerke et al., 2001). This study observed significantly lower P_{Drop} with the turbulent flow S-HME as compared to the laminar flow M-HME. However, further study is needed to verify if this finding translates into decreased patient exergy expenditure and improved patient comfort in vivo.

Another unique feature of the S-HME is its hygroscopic media, which remains intact throughout the usable 24-hr life of the device. This differs from the linear-flow HMEs whose corrugated paper material degrades quickly, necessitating device change several times daily. Further study is needed to verify if S-HME device longevity in vivo.

Lastly, the most obvious advantage of the S-HME is that it may be used in unison (in-line) with the SSV, thereby allowing for retained phonation and humidification concurrently (see Figure 7). Only one other valve on the market combines a speaking valve with an HME (the ProTrach DualCare, AtosMedical). However, although the ProTrach DualCare contains both TSV and HME features, the patient may only use one at a time. One must choose between either the TSV or HME modes by physically twisting the lid of the speaking valve (de Kleijn et al., 2017). The SSV and the S-HME are the only available devices that, when used in-line, allow tracheotomized patients to speak and humidify without having to handle or touch either device. The patient will benefit from the HME component during inhalation and exhalation, while benefiting from the speech production during the exhalation. Moreover, this benefit comes without significant increase in $R_{airflow}$ as compared to the TSV alone. The clinical implications of this are important as it means that tracheostomy patients are able to phonate, filter, warm, and humidify air without added work of breathing or discomfort.

Figure 7. Shikani HME used in unison with the Shikani Speaking Valve.

Limitations

Our study compared airflow characteristics and resistance patterns of the S-HME with those of the M-HME because it is one of the most widely used HMEs. Further studies comparing the S-HME to additional HMEs may be needed. However, it is worth noting that the M-HME has similar aerodynamics to many other HMEs on the market (Lucato et al., 2015; McNamara et al., 2014; Passy, 1986; Vargas et al., 2017). Multicenter clinical trials should be undertaken to assess phonation quality during in-line SSV + S-HME application and to evaluate the impacts of long-term HME application on the comfort, pulmonary health, and quality of life of tracheostomy patients.

Conclusion

The S-HME is a compact HME that provides heat and moisture exchange with similar or greater efficacy than conventional HMEs, but with significantly lower resistance and the advantage of in-line simultaneous use with the SSV. The latter allows for concurrent phonation and HME application without increasing $R_{airflow}$. Further clinical investigation is needed to assess impacts on patient work of breathing, comfort, pulmonary health, and quality of life.

Disclaimer

The opinions expressed are the view of the authors. They do not represent any position or policy of the Veterans Administration or the U.S. Government.

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