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Comparative *ex vivo* study on humidifying function of three speaking valves with integrated heat and moisture exchanger for tracheotomised patients

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Objective: Assessment of humidifying function of tracheotomy speaking valves with integrated heat and moisture exchanger.
Design: *Ex vivo* measurement of water exchange and storage capacity of three tracheotomy speaking valves: Humidiphon Plus, Spiro and ProTrach DualCare (with two different heat and moisture exchangers: XtraMoist and Regular).
Setting: Comprehensive Cancer Centre.
Participant: Healthy volunteer.
Main outcome measures: Difference between end-inspiratory and end-expiratory weight as measure for water exchange capacity, weight after 10 min breathing as measure for water storage capacity, weighing at 1-min intervals to assess residual water exchange potential in speaking mode and absolute humidity in mg/L as measure for environmental and respiratory humidity.
Results: None of the tracheotomy speaking valves provides humidification while in speaking mode. Only the ProTrach DualCare allows blocking the speaking valve and breathing through the heat and moisture exchanger during inhalation and exhalation (heat and moisture exchanger mode). This leads to an increase in inspiratory humidity of 2.5 mg (XtraMoist) and 1.6 mg (Regular). There was no measurable water storage in speaking mode in any of the three tracheotomy speaking valves. In breathing mode, water storage in the DualCare heat and moisture exchangers was 47 and 37 mg, respectively. The remaining humidifying potential in speaking mode after 10 min breathing in heat and moisture exchanger mode for XtraMoist was 38%, 15% and 10% at 1, 2 and 3 min, respectively. For Regular, this was 47%, 24% and 13%, respectively.
Conclusions: Tracheostoma valves with integrated heat and moisture exchanger have no humidification function in speaking mode. Only ProTrach DualCare, allowing blocking the speaking mode, in heat and moisture exchanger mode enables a significant increase in humidification. Regular switching between speaking and heat and moisture exchanger mode with this latter device prolongs the humidification in speaking mode.

After tracheotomy, inspired air is no longer conditioned (moisturised and warmed) in the upper airways. Relatively cold and dry ambient air entering the trachea causes frequent coughing and excessive/thickened mucus production. This often requires forced expectoration to clear the airways and potentially causes crusting and obstruction of the tracheotomy tube. Therefore, immediately postoperatively, but also long-term, inspired air should be humidified.[1] Depending on the indication for the tracheotomy, many patients can tolerate a speaking valve, important to convalesce communication in general and to promote normal speech development in children.[1,2] Speaking valves for tracheotomised patients contain a hands-free, so-called bias-closed one-way valve, which redirects exhaled air through the vocal cords and vocal tract, enabling phonation and speech, and re-establishing physiological subglottic pressure. The valve opens upon inhalation, which allows inspired air to enter the trachea and lungs unconditioned. This functional loss is similar to that in laryngectomised patients, where continued use of heat and moisture exchangers therefore is well-established.[3] In laryngectomised patients, consistent 24/7 heat and moisture exchanger use has significantly decreased pulmonary problems and improved quality of life.[3] Consequently, also for tracheotomised patients, heat and moisture exchangers should be considered as an integral part of their

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respiratory rehabilitation.[1] This necessitates, however, switching between tracheotomy speaking valve and heat and moisture exchanger, when the tracheotomy speaking valve is not in use, for example when expiratory pressures become uncomfortably high, or during night-time.[2,4]

Until recently, there were no tracheotomy speaking valves with built-in heat and moisture exchanger function, similar to devices available for laryngectomised patients,[5] but now, three such devices claim to have this function integrated. However, so far, information about the actual heat and moisture exchanger capacity of these devices is lacking. To fill this void, we used the recently developed *ex vivo* method for establishing water exchange capacity of heat and moisture exchangers for laryngectomised patients. This test was developed because manufacturers are not always providing such information and because the *in vitro* ISO standard 9360 based on a mechanical lung model does not result in uniformly dependable data.[6] The *ex vivo* method overcomes this latter issue and recently allowed comparison of 23 different heat and moisture exchangers for laryngectomised patients of six different manufacturers.[7] This latter study showed that there is quite a wide variation in water exchange capacity, ranging from to 0.5 to 3.8 mg H_2O per breathing cycle. The results of the assessment of the three presently available tracheotomy speaking valves with built-in heat and moisture exchanger material, with the *ex vivo* method (with a slight modification to mimic expiration through the upper respiratory tract), will be reported here.

Materials and methods

Three tracheotomy speaking valves of three manufacturers were tested [Humidiphon Plus Sprechventil (=speaking valve); Fahl, Cologne, Germany; Spiro Sprechventil mit Filtermedium (=speaking valve with filter media); Teleflex/Rüsch Medical, Westmeath, Ireland; and ProTrach DualCare; Atos Medical, Hörby, Sweden]. In the Humidiphon and Spiro devices, as well as the DualCare device in speaking mode, the heat and moisture exchanger media are only exposed to the breathing air during inspiration, and not during expiration, so that the exhaled air is not able to moisten the material. The DualCare speaking valve can be turned to switch off the speaking mode, allowing passage of both inspiratory and expiratory air through the tracheotomy tube, including the heat and moisture exchanger into the breathing circuit (further called heat and moisture exchanger mode).[8]

Water exchange capacity, absolute humidity and breathing volume were measured using the *ex vivo* method as described previously,[6] with one modification (inclusion of a one-way valve to mimic exhalation through the upper respiratory tract with the tracheotomy speaking valve in speaking mode, as schematically shown in Fig. 1 to the right). In the test configuration (also schematically shown in Fig. 1), the speaking valve was mounted on a T-tube containing a fast heated capacitive hygrometer (AH sensor, a response time of 0.1–0.2 s) and a spirometer (MLT300 Flowhead ADInstruments, Oxfordshire, UK). A healthy volunteer ‘supplied’ the breathing air: inspiratory air through the spirometer and expiratory air through a side opening containing the one-way valve. This side opening was blocked for breathing through the DualCare tracheotomy speaking valves in heat and moisture exchanger mode, allowing both inspiration and expiration through the spirometer and around the humidity sensor. Water exchange (the amount of water exchanged by the heat and moisture exchanger material in the tracheotomy speaking valve during the breathing cycle) is the difference of the weight of the heat and moisture exchanger at end-expiration and end-inspiration.[6]

Measurements were normalised to an environmental absolute humidity of 5 mg/L for comparison with heat and moisture exchange outcomes published previously.

Water storage is the amount of water a room-conditioned heat and moisture exchanger absorbs during equilibrium breathing. Measurements were performed once for each valve type. Earlier (validation) research showed that the calculated variation of the water exchange and absolute humidity measurements is between 0.1 and 0.3 mg.[7] Data were analysed in Microsoft Excel.[7] The study was approved by the medical ethical review board of the Netherlands Cancer Institute.

Results

For all tested tracheotomy speaking valves, there was no difference with end-inspiratory absolute humidity values during breathing through the open spirometer (see Fig. 2). Weighing the valves during the breathing cycle showed no changes in weight and thus no change in water content of the heat and moisture exchanger material for any of the tracheotomy speaking valves in speaking mode (shown in Table 1). For DualCare in heat and moisture exchanger mode, the absolute humidity in the inspired air increased with 2.5 mg for the XtraMoist and 1.6 mg/L for the Regular heat and moisture exchanger (at 0.5 L breathing volume). Water exchange for these two heat and moisture exchangers at various breathing volumes is shown in Fig. 3.

Water storage was negligible in speaking mode, but in heat and moisture exchanger mode, this was 47 and 37 mg for DualCare XtraMoist heat and moisture exchanger and Regular heat and moisture exchanger, respectively. For these heat and moisture exchangers, also the remaining humidifying potential in speaking mode after 10 min breathing in heat and moisture exchanger mode was assessed at 1-min intervals. For XtraMoist after 1 min 38%, after 2 min 15%

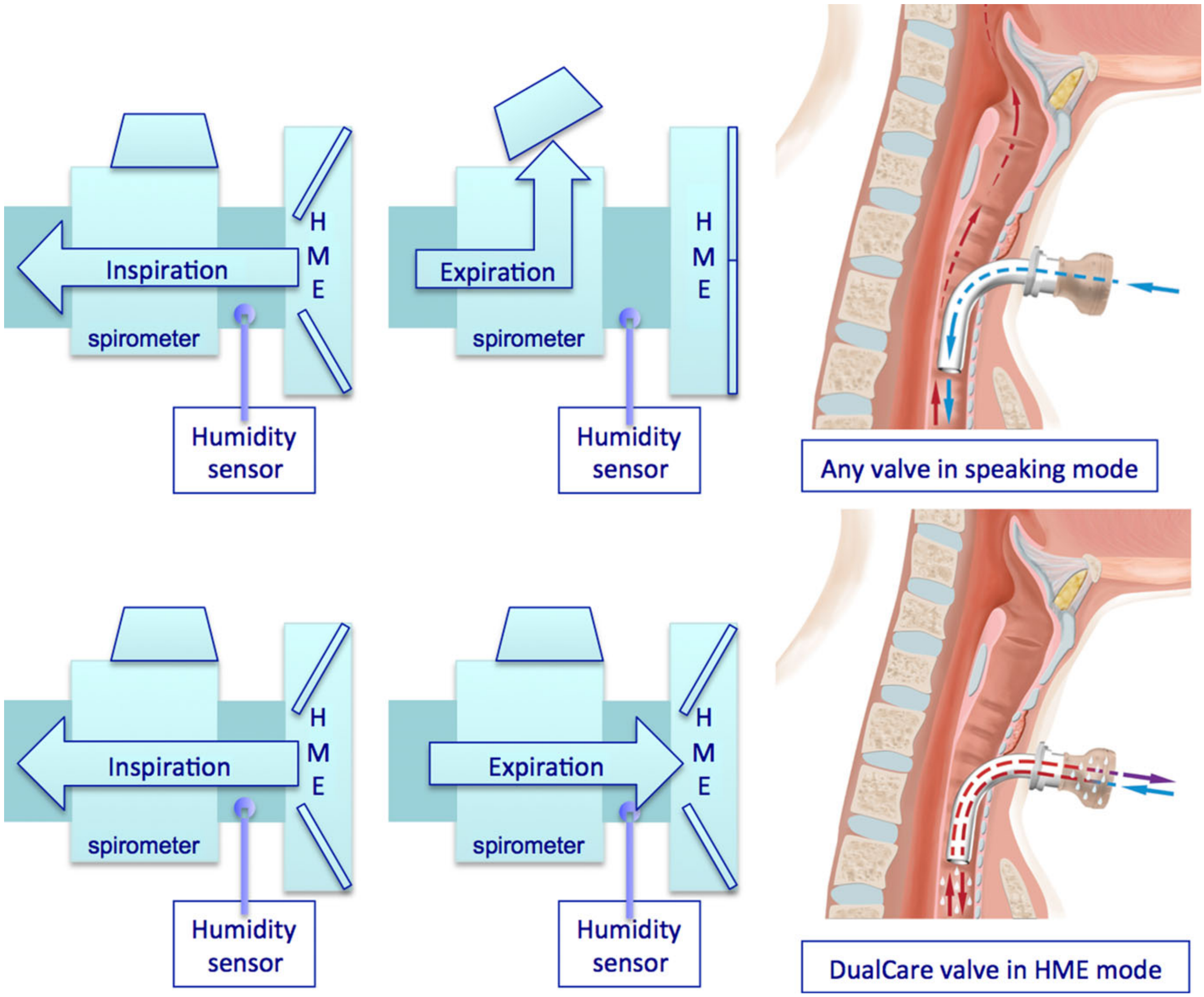

Fig. 1. Schematic *ex vivo* test set-up for hands-free/bias-closed speaking valves for tracheotomised patients (to mimic the *in vivo* situation as schematically depicted on the right): in speaking mode, the volunteer is breathing in through the open speaking valve and out through a side opening mimicking the exhalation through the upper respiratory tract in tracheotomised patients. In the HME mode (with the speaking valve locked), the volunteer is breathing in and out through the tube and thus the HME, similar to what the patient does in HME-mode.

and after 3 min 10% of the water uptake was left in the heat and moisture exchanger. For Regular, this was 47%, 24% and 13%, respectively. At 4 min, both heat and moisture exchangers were back to their baseline 'room-conditioned' weight (start measurement 22.2°C and 30% and end measurement 22.3°C and 33% relative humidity).

Discussion

New findings

The presently available hands-free/bias-closed speaking valves for tracheotomised patients with integrated heat and moisture exchanger media have no heat and moisture exchanger function when in speaking mode. Due to one-way breathing, it is not possible to exchange moisture in the heat and moisture exchanger media. Any claim to that extent is thus invalid. At best, the heat and moisture exchanger material acts as a kind of 'filter'. However, DualCare in heat and moisture exchanger mode does have a substantial water exchange capacity and therefore increases the absolute humidity of the inspired air, dependent of the heat and moisture exchanger used (XtraMoist higher than Regular). Moreover, when turned into in speaking mode, it takes several minutes to evaporate the remaining water in the heat and moisture exchanger into the inhalation air. This means that switching to speaking mode (here assessed after 10 min breathing in heat and moisture exchanger mode, which is

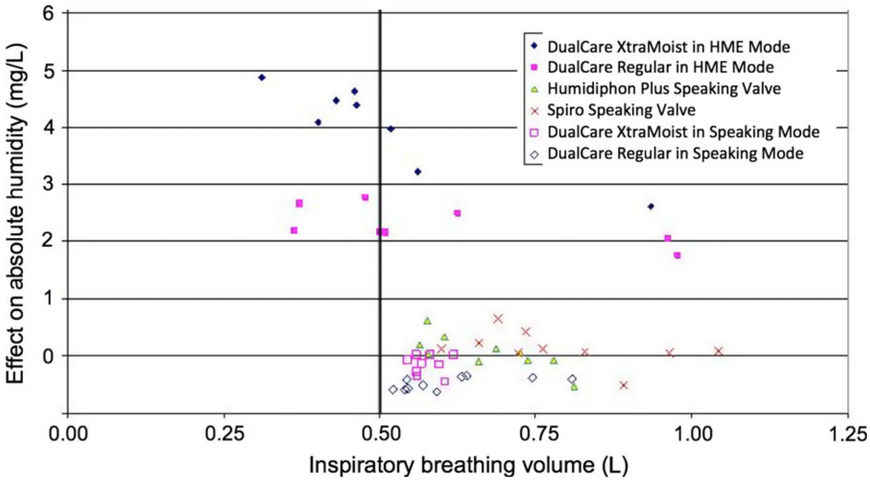

Fig. 2. End-inspiratory absolute humidity values for the tested TSVs in speaking mode and HME mode (the latter only available for the DualCare devices) for the various breathing volumes: the level of AH without any valve (5 mg H_2O/L) on the spirometer is already subtracted from the level measured for the various devices at the individual data points.

Table 1. Water exchange in milligram at a breathing volume of 0.5 L, which is the approximate tidal volume at normal rest breathing

Speaking valve	Water exchange in mg
Humidiphon Plus Speaking Valve	0
Spiro Speaking Valve	0
DualCare Regular in speaking mode	0
DualCare XtraMoist in speaking mode	0
DualCare Regular in heat and moisture exchanger mode	1.6
DualCare XtraMoist in heat and moisture exchanger mode	2.5

enough to reach saturation of the heat and moisture exchanger material with water[6]), at least the first minute of breathing still 'profits' from the moistened heat and moisture exchanger.

The reason that there are two versions of the DualCare heat and moisture exchanger with a different water storage/exchange capacity is that both also have a different airflow resistance: the better capacity of the XtraMoist heat and moisture exchanger results in a higher airflow resistance and the lower capacity of the Regular heat and moisture exchanger in a lower airflow resistance. A higher airflow resistance is physiologically beneficial, as over 50% of the airflow resistance of the normal respiratory tract is contributed by the upper airways, which are short-circuited in tracheotomised patients, as they are in laryngectomised patients.[9] However, for some patients, the higher airflow resistance of the XtraMoist heat and moisture exchanger version might be uncomfortable, hence the availability of a lower resistance version, the Regular heat and moisture exchanger. This probably will lead to better overall compliance, as it does in laryngectomised patients using a heat and moisture exchanger.[10,11] But this issue is beyond the scope of this *ex vivo* study and is something that has to be assessed in clinical studies.

Strengths/limitations of the study

The use of the validated *ex vivo* water exchange measurement method allows reliable absolute humidity and water exchange assessment of tracheotomy speaking valves.[6] Although carrying out these measurements with only one healthy volunteer seems to be a limitation, earlier research has shown that the measurements with more healthy volunteers ($N = 6$) showed that the interindividual variation is small and that the impact of an heat and moisture exchanger on absolute humidity and weight changes can be measured as reliable with one volunteer only.[6,12] Another advantage of this *ex vivo* method is that there is no need to bother patients with this type of research as in both cases the expired air is almost fully saturated with water.[6] Moreover, the use of a tracheotomised patient would not have influenced the results that there is no heat and moisture exchanger function in valves in speaking mode.

Comparison with other studies

Heat and moisture exchanger function of the DualCare in heat and moisture exchanger mode is comparable to that of heat and moisture exchangers used in pulmonary rehabilitation in laryngectomised patients.[7] The present study is also adding to the comparative information about 'tracheotomy-heat and moisture exchangers' already avail-

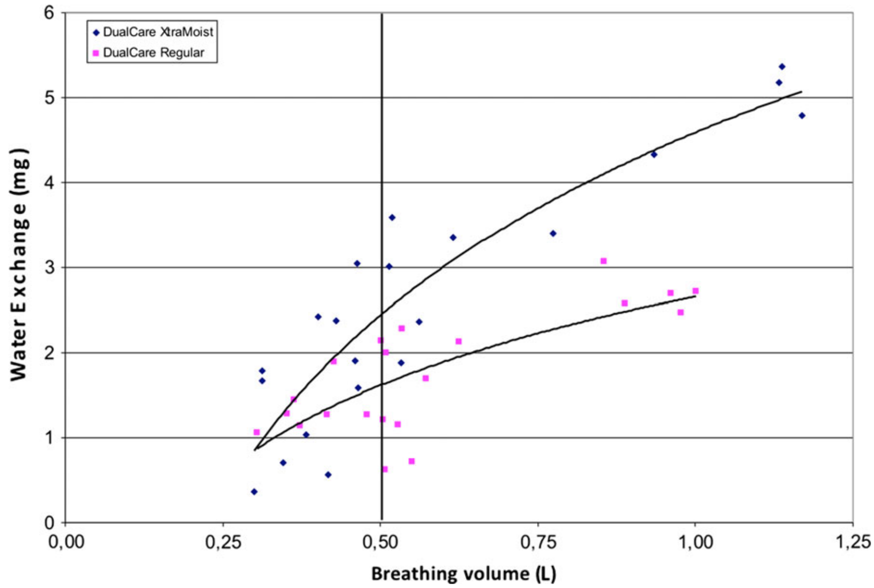

Fig. 3. Water exchange (weight change between inhalation and exhalation) as a function of the breathing volume for the XtraMoist and the Regular DualCare HME: the line indicates the breathing volume of 0.5 L, which is the approximate tidal volume at normal rest breathing.

able in literature.[13] It is known that long-term use of heat and moisture exchangers results in fewer clinical complaints such as mucus production and coughing and therefore increases the quality of life.[14]

Clinical applicability

This device is mainly intended for chronic/long-term tracheotomised patients. However, also in short-term situations in the hospital, such automatic speaking devices can already be advantageous as patients can speak more easily and still use the heat and moisture exchanger mode when not speaking. Heat and moisture exchangers in general can replace external humidifiers in patients and this makes the patient more mobile and is cost effective as has been shown in a clinical study in laryngectomised patients.[15]

It is important to realise that tracheotomised patients inhale colder and dryer air that is not moistened and warmed by the upper airways even when using a speaking valve. Patients are at increased risk for pulmonary complaints and infections. Next to speech rehabilitation, the need for pulmonary rehabilitation should receive at least as much attention. In daily practice, tracheotomised patients do not always replace the speaking valve by an heat and moisture exchanger during periods when the speaking valve is not used or tolerated. With a device like DualCare, this is no longer a problem. Moreover, clinicians now also can advise patients to switch to heat and moisture exchanger mode during periods when speaking is not required, thereby increasing overall airway humidification.

Keypoints

- Tracheotomy speaking valves (TSVs) with integrated Heat and Moisture Exchanger (HME) media do not provide humidification while in speaking-mode.
- The HME in TSVs only can function as intended when 'active' during the entire breathing cycle (inhalation and exhalation), which is only possible in one of the devices (the ProTrach DualCare (PTDC) in HME-mode).
- The water exchange capacity of the PDTC in HME-mode depends on the HME applied (XtraMoist higher than Regular).
- Regular switching between the speaking- and HME-mode of the PTDC prolongs the humidification in speaking-mode.
- Integration of speaking- and airway-conditioning functions in the ProTrach DualCare renders switching between devices (a TSV and a HME) superfluous.

Conflict of interest

The department of Head and Neck Oncology and Surgery of the Netherlands Cancer Institute receives an unrestricted research grant of Atos Medical, the manufacturer of rehabilitation devices for patients with head and neck cancer.

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