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Water content of delivered gases during Helmet Continuous Positive Airway Pressure in healthy subjects

Alberto Lucchini[1], Stefano Bambi[2], Stefano Elli[1], Martina Bruno[3], Dallari Roberto[4], Pamela Puccio[5], Silvia Villa[1], Roberto Rona[1], Roberto Fumagalli[6], Giacomo Bellani[1], Giuseppe Foti[1]

[1] General Intensive Care Unit, Emergency Department - ASST Monza - San Gerardo Hospital, Monza (MB), Italy - University of Milano-Bicocca; [2] Medical and Surgical Intensive Care Unit - Careggi University Hospital, Florence, Italy; [3] General Intensive care Unit - Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Milan, MI, Italy; [4] Anesthesia Service - Carate Hospital, ASST Vimercate, MB - Italy; [5] General Intensive care unit - Prato Hospital, USL Centro Toscana, Italy; [6] Department of Anesthesia and Intensive Care Medicine, Niguarda Ca' Granda, University Hospital of Milano-Bicocca, Milano, Italy

Abstract. *Introduction:* During Continuous Positive Pressure Ventilation delivered through helmet, the patient inhales high flows of gas without adequate conditioning. However, the need to humidify the inspired gas during Helmet-CPAP, has not been sufficiently explored. *Methods:* Experimental design study. Six healthy individuals underwent High Flow Helmet CPAP with different gas flows (60 and 80 L/min) and FiO_2 (0.35, 0.5, 0.7 and 1) generated by a Venturi system, with and without active humidification. The active humidifier setting was 26 ° at the humidification chamber and 28 ° at the helmet gas inlet. At each setting, measurements about temperature and relative humidity inside helmet were taken. Comfort level at each setting was evaluated using a visual analog scale rated from 0 to 10. *Results:* Without heated humidification, the mean value of absolute humidity in the eight combinations investigated was 5.9±2.1 mg H_2O/L, with a mean temperature of 25.8±0.9°. With heated humidification mean absolute humidity was 15.0±3.5 mg H_2O/L with mean temperature of 29.0±0.1°. The median comfort scale value was 6 (IQR: 5.25-6.75) during the phase without humidification vs 8 (7.25-8.0 - P<0.01) when active humidification was applied. *Conclusions:* In healthy subjects undergoing High Flow Helmet CPAP, heated humidifiers with heated wires tubes are necessary to avoid the under-humidification inside the helmet. To obtain patient's comfort and airways mucosal humidification during continuous Helmet CPAP, the most desirable conditions are reached by heated humidifiers with a humidifying chamber temperature settled between 26-28°C. (www.actabiomedica.it)

Key words: CPAP, Humidification, Comfort, NIV, Helmet, heated humidifier

Introduction

The application of free flow Helmet Continuous Positive Airway Pressure (Helmet-CPAP) may improve oxygenation in patients with acute respiratory failure (1, 2) and acute pulmonary oedema (3,4). Benefits of Helmet-CPAP are greater when the treatment time is prolonged until continuous application is reached (5). To obtain the highest patient's compliance to the treatment, nurses may optimize the type of helmet seal, noise levels, and humidification of the inspired gases (6-8). The American Association for Res-

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piratory Care (9), reported that active humidification is suggested for non-invasive mechanical ventilation, as it may improve adherence and comfort. However recommendations about the level of gas humidification and the strategy to employ during non-invasive ventilation (NIV) and high flow Helmet CPAP are missing, and few data are available.

One study suggested to use unheated humidifiers (10), because the optimum temperature setting may be between room temperature and 31°C, but with the humidifier used in this study the water temperature could not be set below 31°. Other authors discouraged the use of active humidifiers since these cause condensation inside the interface with increasing of patient's discomfort (11), while others sustain that it is not always necessary to humidify the gases inspired during Helmet-CPAP (12), under the assumption that the upper airways can actively condition the inspired gases. However, the lack of gas conditioning for long term NIV determines de-epithelialization, reduced comfort, and lesions to the tracheal mucosa (13). These aspects are key factors inducing reduced tolerance to NIV with the consequent decrease of its application times (13, 14).

Absolute Humidity (AH) is the amount of water vapour contained in a litre of air. Relative Humidity (RH) is the rate of water vapour contained in a litre of air at a given temperature, with respect to the maximum capacity of saturation, and it's expressed in percentage. The American National Standards Institute (15) suggested, although not specifically for NIV, that an absolute humidity of 10 mg H_2O/L is the lowest level needed to minimize mucosal damages in the upper airways. The temperature, AH and RH inside the helmet during CPAP, are affected by several factors such as the gas flow, room temperature and the medical gas delivery systems (11). Delivery of Helmet-CPAP with continuous flow (as opposed to mechanical ventilators) improves the CO_2 washout inside the interface (16, 17). The delivered gas flow should always be greater than 50 L/min to obtain an effective removal of the CO_2 expired by the patient (16). Moreover, a high flow would contribute to maintaining a constant pressure inside the helmet at the preset PEEP level, during the entire respiratory cycle (16-17). In this setting, as two separate ports for gas inlet and outlet are used, Heat Moisture Exchange cannot be used.

While the flow generation with Venturi systems will drag part some environmental air humidity in the helmet, when only medical gases are used, humidity and temperature inside the helmet will be strictly affected by the AH present in the delivered oxygen and in the compressed air (9).

The purpose of this study was to investigate the level of Absolute Humidity, Relative Humidity and temperature of inspired gas, inside the helmet during high flow CPAP, performed on healthy volunteers, with and without active humidification. We hypothesized that comfort of patients would have been highest with active humidification when inspiratory gas temperature was close to ambient temperature.

Materials and methods

We designed an experimental study on six healthy adult subjects (3 males, 3 females), in laboratory setting. The study was conducted in two phases. During the first phase, 6 healthy volunteers underwent High flow CPAP cycles with helmet (Castar CPAP™ STARMED Intersurgical Ltd U.K) without any gas humidification. Latex-free helmets that includes a transparent rigid polyvinyl chloride tube sealed at the top and connected at the bottom by a rigid ring to a soft polyvinyl chloride collar were used. The gas flow was generated with a Venturi system (Intersurgical™ LTD, UK) connected to an oxygen pressured line (4 bar). The expiratory gas outlet was connected to a mechanical PEEP valve (Deaflux™, DEAS) with a setting of 5 cmH_2O. In the first phase of the protocol (no humidification), each subject was evaluated while receiving eight different combinations of gas flow (60 and 80 L/min) and FiO_2 (0.35-0.50-0.75-1), via the helmet for 10 minutes of stabilization, after which measurements were taken (see below). At the end of the 10 minutes, for each combination of GF and FiO_2, the temperature of the gas inside the helmet and the relative humidity values were recorded.

During the second phase (active humidification), the volunteers underwent to helmet CPAP cycles with the same combinations of gas flow and FiO_2, described above, with the addition of heated humidification system with heated wires tubes (HC 2000™ - MALL-

INCKODT DAR, active humidifier - Medtronic LTD, USA). Heated humidifier was used with *"Non Invasive"* software version, with 26° of temperature setting (lowest setting temperature to bring the average room temperature level closer) to the humidification chamber and 28° to the end of the heated wire tube (Helmet inlet of gas flow). Even in this second phase of the protocol, each subject was assessed after receiving eight different combinations of gas flow (60 and 80 L/min) and FiO2 (0.35-0.50-0.75-1), via the helmet for 10 minutes of stabilization, for 10 minutes of stabilization, after which measurements were taken. The detection of RH and temperatures were performed, as described in the previous phase of the study. All subjects were informed that the phase one were without humidification system and phase two with use of heated humidifier.

Measurements

A capacitive hygrometer (Tacklife HM01™ Classic Hygrometer Digital Humidity Meter) was used to measure temperature and relative humidity inside the helmet (range for relative humidity 1% to 100%). This system has a very low dead time (2.5 seconds for a quick reading) and good accuracy (±3% RH - manufacturer's data) and, with an error of 0.5°C and no variations with time. After each measurement, the tip of the capacitive hygrometer was dried to avoid any possible measurement error. The absolute humidity was computed using the following equation (11): absolute humidity = relative humidity × (0.0387 × T^2 - 0.6066 × T + 13.776), where T is the temperature (in °C). For all the measurements the probe sampling point was positioned near the nose-mouth intersection of the subjects, even if the temperature and relative humidity inside the helmet were previously found to be similar in the different positions within the helmet (11). The experimental set up is shown in figure 1. Subjective comfort was evaluated, after the ending of the second phase, using a visual analogue scale rated from zero (least comfortable) to 10 (most comfortable). Participants were asked to score their response to the question: *'How do you feel during the first and the second condition?'*. All the measurements related to phase 1 and 2 of the study and to the administration of the comfort scales were carried out by the same operator.

Data analysis

Data were collected with Excel Microsoft software (Microsoft Corporation, Redmond, Washington). Values are expressed as mean ± standard deviation for parametric, or median (interquartile range) for nonparametric distributions. Data were analyzed with repeated measures analysis of variance with the Apple version of IBM SPSS 21.0 statistical software. Statistically significance threshold was set to $P<0.05$.

Ethical considerations

This study was conducted according to the ethical standards laid down in the 1964 Declaration of Helsinki. The study was approved by the Ethical Committee of our institution (Università degli Studi di Milano-Bicocca). In accordance with national regulations, written informed consent was obtained from each enrolled subject.

Results

The six healthy volunteers had an average weight of 69.7±15.2 Kgs, height of 170.3±11.5 cm (BMI of 20.3±3.2). During CPAP delivered by helmet, the measured room temperature ranged between 22°C and 22.7°C and the AH ranged between 6.79 and 7 mg H_20/L (RH=35-36%). The temperature of pressurized oxygen ranged between 20 and 21°C with an AH equal to 0 mg H_20/L (RH=0%). In the first phase, without heated humidification of the inspired gases, with a Gas Flow equal to 60 L/min the mean temperature with the four different FiO_2 tested (0.35, 0.5, 0.7 and 1) was 25.8±0.9°, the mean AH was equal to 5.9±2.1 mg H_2O/L and the mean RH was equal to 22.9±8.8%. With a Gas Flow equal to 80 L/min the mean temperature with the four different FiO_2 tested (0.35, 0.5, 0.7 and 1) was 26.0±1.1°, the mean AH was equal to 5.2±1.8 mg H_2O/L and the mean RH was equal to 21.9±6.7%.

In the second phase with heated humidification of the inspired gases, with a Gas Flow equal to 60 L/min the mean temperature with the four different FiO_2 tested (0.35, 0.5, 0.7 and 1) was 29.0±0.1°,

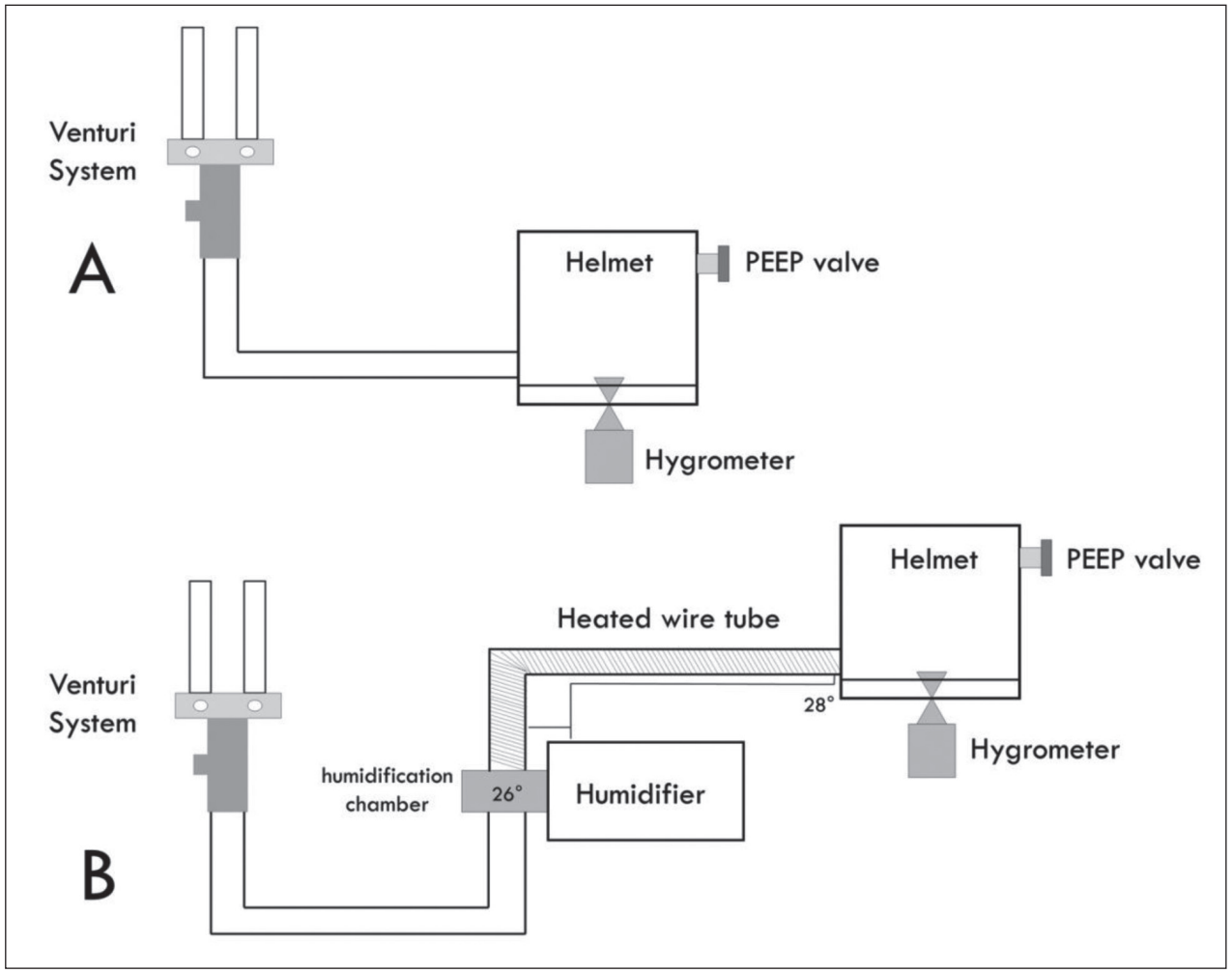

Figure 1. Experimental setup
Legend: Set-up without (A) and with (B) heated wire humidification system

the mean AH was equal to 15.0±3.5 mg H_2O/L and the mean RH was equal to 52.1±3.5%. With a Gas Flow equal to 80 L/min the mean temperature with the four different FiO_2 tested (0.35, 0.5, 0.7 and 1) was 29.0±0.2°, the mean AH was equal to 14.3±1.0 mg H_2O/L and the mean RH was equal to 49.1±3.4%. In none of the investigated phases condensation occurred inside the element. Table 1 shows the data related to the two phases of the study, split for each condition of Gas Flow and FiO_2 investigated. As shown in table 1, without heated humidification, the set FiO_2 determines statistically significant differences on the AH and the RH ($P < 0.001$) inside the helmet. The set flow (60 L/min vs. 80 L/min) does not determine statistically significant changes in temperature, AH and RH.

After the ending of the second phase, subjective comfort was evaluated. The median comfort scale value was 6 (IQR: 5.25-6.75) for the phase 1 (no humidification) vs 8 (IQR : 7.25-8.0 - $p<0.01$) for the phase 2 (with heated humidification).

Discussion

The main results of this paper are that: during the Helmet-CPAP with high flow, while the use of medi-

Table 1. Absolute humidity, with and without active humidification, in the investigated steps

		Without heated humidification		With heated humidication	
FiO_2		Gas Flow 60 L/min	Gas Flow 80 L/min	Gas Flow 60 L/min	Gas Flow 80 L/min
0.35	Temp°	26.3±0.6	26.5±0.8	29.0±0.0	28.9±0.2
	RH (%)	30.8±8.5§	28.5±5.7§	54.3±4.4	52.0±3.2
	AH (mgH_2O/L)	7.7±2.3*	7.1±1.5	15.7±1.4	14.9±0.9
0.5	Temp°	26.0±1.2	26.0±1.3	29.0±0.1	29.0±0.2
	RH (%)	26.2±4.9§	25.0±1.0§	52.0±3.6	54.5±1.1
	AH (mgH_2O/L)	6.6±1.6*	5.9±0.2	14.9±1.0	14.1±0.9
0.7	Temp°	25.5±0.9	25.8±1.3	28.9±0.2	29.0±0.0
	RH (%)	20.1±2.4§	21.0±2.8§	51.0±3.1	51.3±1.5
	AH (mgH_2O/L)	4.9±0.8*	5.0±0.9	14.6±0.1	14.7±0.4
1	Temp°	25.4±0.7	25.5±1.0	26.0±0.1	29.0±0.0
	RH (%)	14.8±2.3§	13.0±2.2§	54.2±3.0	49.0±5.2
	AH (mgH_2O/L)	3.6±0.6*	3.1±0.5	13.4±1.0	14.1±1.5

Legend :
Temp°: temperature, RH : relative Humidity, AH : Absolute Humidity
*repeated measures analysis of variance (rm ANOVA) = p<0.001
§ repeated measures analysis of variance (rm ANOVA) = p<0.001

cal gases only (FiO2 1, in our experiment), or venture system, the gas humidification is far below the recommended 10 mg H_2O/l value, the use of an heated humidifier set allows adequate humidification without any condensation (9,15). The lack of humidification using only medical gases is not surprising. However, also with a Venturi system in a room with a temperature between 22.0°C and 22.7°C and a RH of 40%, the AH inside the Helmet ranged between 6.79 and 7.0 mg H_20/L (RH=35-36%). This indicates that the rate of humidity dragged with air from the external environment does not allow to reach the value of 10 mg H_2O/L inside the helmet.

Chiumello and colleagues (11) underlined the possibility of using humidifiers with invasive ventilation set-ups upon applying a high-flow Helmet-CPAP. The only contraindication registered was the formation of condensation inside the interface (*the so called "fog effect")*. While this situation can resolve the problem of the amount of humidity inspired by the patient, on the other hand it might reduce patient's comfort and consequently his/her tolerance to the treatment (10), simulating condition of a day with a temperature of 37° and an RH greater than 80%. To prevent the condensation, the temperature of the humidifying chamber must be set at a value below the mean tempera-

ture recorded inside the helmet (25.8±0.9°, as showed in our study). The heated humidifier systems work in optimal conditions when the temperature of the gases increases from the humidification chamber to patient (generally with a gradient of 2°). Therefore, we may assume that the ideal set-up temperature should range between 24°-26°C for the humidification chamber and 26-28° for the Helmet inlet point. However, many of the humidifiers currently used in intensive care units, have fixed temperature settings in NIV configuration. In many cases (for example Fisher & Paykel MR 850® and Hamilton H900®) the temperature set for the humidification chamber is equal to 31° and cannot be modified. This temperature is higher than the one detected inside the helmet in our study. Such a set-up would cause condensation to form inside the helmet. For this reason, it would be important that heated humidifiers had a NIV set-up with temperatures that can be chosen and set by the nurses (manual modes). Unlike what was detected in phase one of the study, the use of an heated humidifier (26° at the humidification chamber), allows an average delivery of about 15 mg H_2O/L, regardless of: the FiO_2 settled, the gas supply (Venturi or compressed gas only - FiO_2 = 1) and imposed gas flow (60 L/min vs. 80 L/min).

On the contrary, without heated humidifier, with a relatively low FiO_2 (0.35) and Venturi system the combination of AH drawn from the ambient air and the AH exhaled by the patient, reached the suggested 10 mg H_2O/L. This consideration is important in case of short application cycles of Helmet-CPAP (e.g.: acute pulmonary oedema or postoperative treatment for major surgery) (18). With FiO_2 <0.5, the costs and complexity imposed by heated humidifier might not be worth in respect to the added benefit. Instead, in the case of high FiO_2 (especially if FIO_2 is 1), when only medical gases are used to flush the helmet, the moisture exhaled by the patient is not enough to recondition the inspired gases. A survey performed by Crimi and colleagues (14) has shown that in Italy and Spain (countries that most use the helmet for the continuous high flow CPAP), only in 50% of cases (especially in intensive care units), the gas source are usually flowmeters powered by oxygen and medical compressed air (2). In critically respiratory patients (requiring high FiO_2 and prolonged application time) the use of heated humidification could improve the patient's comfort, the mobilization of the airways secretions, and reduce the sensation of dryness and thirst (19). Ueta and colleagues (10) provide evidence that, during clinical delivery of inspiratory gas through helmet NIV, humidification at ambient temperature is desirable for patient comfort, as well as for preventing mucosal damage.

Conclusions

In the absence of active humidification during high flow Helmet-CPAP, under-humidification will occur (11). The problem is more relevant with Venturi system at an FiO_2 greater than 50% and when only medical gases are employed. The modern active heated humidifiers, through NIV software, are able to deliver an absolute humidity above 10 mgH_2O/L. While these finds need to be confirmed on a large group of patients, in our exploratory study, the use of an active humidifier set at 26°C, with a temperature gradient increasing towards the patient (+ 2°/28° at the helmet gas inlet port) improves absolute and relative humidity inside the helmet, while avoiding under-humidification in healthy subjects.

Limitations of the study

First this is a study conducted on a small number of healthy volunteers, we cannot exclude that in patients, presenting with hyperthermia and/or increased minute ventilation the results would have been different. Chiumello and colleagues (11) suggest that the humidity of the expired gases mixed with the fresh gases was similar in patients with acute respiratory failure and healthy individuals during Helmet CPAP. Primiano and colleagues (20) found no difference in the temperature and humidity of the expired gases between patients with cystic fibrosis during Mask CPAP and healthy individuals breathing ambient air. Second, global patient comfort was also evaluated only over a short period. Third, only one type of helmet was used. However, similar to the issue carbon dioxide rebreathing, the volume of the helmet should not directly in-

fluence the final level of humidity of the medical gases but only the rate at which the level is reached.

Finally, expectations related to the experimental protocol could have influenced subjects' comfort level during the study.

The present study was performed at the General Intensive Care Unit, Emergency Department and Intensive Care, San Gerardo Hospital - ASST Monza, Via Pergolesi 33 - Monza (MB), Milan-Bicocca University - Italy.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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Correspondence:
Alberto Lucchini
Head Nurse, General Intensive Care Unit -
San Gerardo Hospital - ASST Monza,
Milan-Bicocca University - Italy
Via Pergolesi 33 - Monza (MB), Italy
Tel. +39 039 233 9824
Fax +39 039 233 3288
E-mail: alberto.lucchini@unimib.it; a.lucchini@asst-monza.it