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Heated Humidifiers for Noninvasive Respiratory Support and the Risk of Burns in Neonates: A Bench Test Evaluation

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BACKGROUND: User errors in managing heated humidifiers (HHs) have been suggested to be a source of nasal burns in newborns treated with nasal CPAP. This study evaluated the risk of burns by reproducing 3 typical errors concerning the use of HHs. METHODS: Six HHs were tested on a bench in a traditional nasal CPAP setup: PMH5000, Aircon (Wilamed); MR730, MR850, MR950 (Fisher & Paykel); and H900 (Hamilton). Temperature was measured at the end of the inspiratory tubing limb. Errors tested were (1) misconnection of the HH thermal probes (NoProbe), (2) absence of gas flow while the HH is on (NoFlow), and (3) unsuitable repeated acknowledgment of the HH alarm (NoAlarm). These errors were combined in 3 standardized scenarios: (1) NoProbe + NoFlow + NoAlarm; (2) NoProbe + NoAlarm, and (3) NoFlow + NoAlarm. The NoProbe + NoFlow + NoAlarm and NoProbe + NoAlarm scenarios were not tested in the H900 and MR950 because the proprietary circuits of these HHs are equipped with embedded probes. RESULTS: For each HH, the highest inspiratory gas temperature (HIGT) and the rating on a self-designed risk-of-burn scale (ie, no risk, moderate risk, or severe risk) were reported. In the NoProbe + NoFlow + NoAlarm scenario, the risk was severe for the MR730, PMH5000, MR850, and Aircon, with HIGTs of > 65°C, 58°C, 56°C, and > 65°C, respectively. In the NoProbe + NoAlarm scenario, the risk was also severe for the same 4 HHs, with HIGTs of 56°C, 47°C, 56°C, and 48°C, respectively. In the NoFlow + NoAlarm scenario, the risk was severe for the PMH5000, Aircon, and H900, with HIGTs of 52°C, > 65°C, and 49°C, respectively, and moderate for the MR730, MR850, and MR950, with HIGTs of 45°C, 47°C, and 44°C, respectively). CONCLUSIONS: In case of misuse, 5 of the 6 tested devices presented a severe risk of inducing skin burns, whereas the MR950 presented a moderate risk. *Key words: newborn; premature; ventilator; nasal CPAP; NIV; heater-humidifier; burns; iatrogenic disease; adverse event.* [Respir Care 0;0(0):1–●. © 2021 Daedalus Enterprises]

Introduction

Active airway humidification with heated humidifiers (HHs) is fundamental for providing appropriately conditioned respiratory gases, especially in the care of neonates on invasive or noninvasive respiratory support (including nasal CPAP and high-flow nasal cannula therapy).[1-5] Although rarely reported in the literature, HHs can cause nasal skin burns of various degrees. Some authors have postulated that this complication may be due to accidentally inappropriate temperature regulation (ie, malfunction of the device).[6] Following a case of severe nose burn linked to nasal CPAP treatment, we performed a technical analysis of the HH used in this child, but we could not find any abnormal device function. We hypothesized that this accident was due to misuse of the equipment, which resulted in overheating of the delivered gas. We tested this hypothesis in a bench study.

From a technical point of view, most standalone HHs work according to the same principle. The cold and dry gas from a ventilator or flow driver passes through the first part of the non-heated inspiratory circuit and enters a water chamber heated by a hot plate. Contact with the hot water allows the gas to be heated to a set outlet temperature

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(typically 37°C) and to become saturated with moisture. After passing through the hot water chamber, the gas continues its path through the second part of the inspiratory circuit, which is equipped with a thermistor wire in its lumen or incorporated in the wall of the tubing. This thermistor begins a few centimeters after the water chamber and ends a few centimeters before the tip of the tubing. It is powered and regulated by the HH and allows the gas to heat up to the delivered target temperature (typically 39°C or 40°C, depending on the model or the user's choice). This ascending temperature is necessary to avoid water condensation in the tubing circuit. HHs reach these temperature targets using internal algorithms that regulate the heating power of the plate in the chamber and the thermistor in the tubing according to information provided by the 2 thermal probes. The first, called the proximal probe, is inserted at the outlet of the water chamber. The second, called the distal probe, is inserted at the very end of the tubing (after the thermistor end), reflecting the temperature of the delivered gas.

The circuit tubing in a HH is a consumable that is changed for each new treatment, whereas the cables connected to the heating wire in the tubing and those of the 2 temperature probes are not. Thus, it is possible that the thermal probes may not be inserted correctly into the tubing, which may be a source of HH malfunction. Indeed, non-insertion or accidental mis-insertion of one or both temperature probes will lead to erroneous temperature measurements (eg, measurement of the ambient temperature instead of the gas temperature inside the circuit), resulting in faulty regulation. Thus, certain HH models, such as the H900 (Hamilton, Bonaduz, Switzerland) and the MR950 (Fisher & Paykel, Auckland, New Zealand) propose a single-use circuit with the 2 thermal probes embedded in the inspiratory circuit by the manufacturer. This makes it impossible to misconnect the temperature probe.[2] Furthermore, the 2 thermal probes do not precisely face the water chamber plate and thermistor but reside in the non-heated part of the heating tubing. Thus, gas movement becomes essential for the probe measurements to be relevant in regulating the heating sources. The corollary is that the HH must be compulsorily paused if the gas flow is interrupted, such as when the ventilator or flow driver is paused for various reasons (eg, CPAP pauses for weaning). Such withholding of the HH must be performed manually by the user or it can be recognized automatically by certain devices (eg, MR950) through the use of an internal gas-flow sensor. In addition to these control functions, the software of certain modern HHs has a safety algorithm that, in the event of a gas temperature that is out of range, generates an audible and visual alarm message and shuts down the heating. Some models offer a display with information and troubleshooting messages, such as the Aircon (Wilamed; Kammerstein, Germany). It is possible for the user to acknowledge the alarms and silence them, even repeatedly. However, certain HH models do not allow the user to acknowledge the same alarm too many times and block themselves (eg, > 3 times for the Wilamed PMH5000 or the Aircon).

QUICK LOOK

Current knowledge

Heated humidifiers are highly recommended in the care of neonates exposed to invasive or noninvasive respiratory support. User errors in managing heated humidifiers have been suggested to be a source of nasal burns in newborns treated with nasal CPAP, but no study has tested this hypothesis.

What this paper contributes to our knowledge

In a bench test study of 6 heated humidifiers on the market, our results indicate that classical user errors like thermal probe misconnection, absence of gas flow while heated humidifiers is on, or unsuitable repeated acknowledgment of alarm can lead to a severe risk of nasal burn in 5 devices and a moderate risk of nasal burn in the one.

We sought reported HH misuse errors in our local adverse event registry on the basis of the hypothesis of device misuse in our reported case. We retained 3 major types of observed errors that could theoretically lead to overheating of the delivered gases: (1) misconnection of the HH thermal probes to the ventilation tubing (ie, a NoProbe error), (2) leaving the HH switched on while the ventilator was switched off (ie, a NoFlow error), and (3) the inappropriate nonconsideration of the HH alarms (ie, a NoAlarm error). We developed a bench test that allowed us to reproduce these 3 error conditions under traditional nasal CPAP conditions and to measure the temperature of the inhaled gases. Our main objective was to evaluate the risk of burn with 6 different HHs when these errors occur in realistic clinical scenarios. The second objective was to measure water and gas temperatures attainable in a worst case scenario with these errors.

Methods

Six HH devices were tested: PMH5000 and Aircon (Wilamed); MR730, MR850, and MR950 (Fisher & Paykel); and H900 (Hamilton). This study was conducted at University Hospital of Geneva, Geneva, Switzerland.

Bench Test Setup

The bench test setup, shown in Figure 1, was based on an Eve turbine ventilator (Stephan, Gackenbach, Germany) delivering a constant flow of 10 L/min. The RT265 double-

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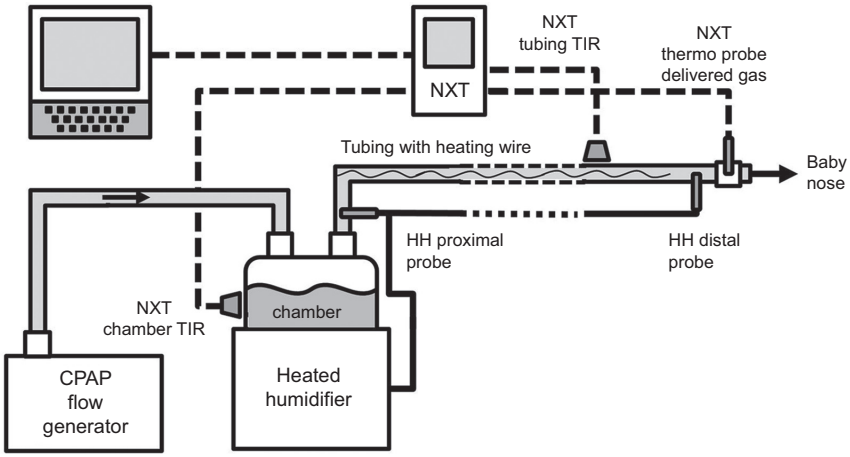

Fig. 1. Bench setup reproducing a classical nasal CPAP circuit, including a ventilator, a tubing set, and a heated humidifier (HH). The temperatures were monitored with an NXT data-logging device equipped with a chamber TIR (thermal infrared sensor) to optically measure the temperature of the water inside the chamber, a tubing TIR to measure the gas temperature in the middle of the heating tubing, and a traditional thermocouple probe to measure the temperature of the delivered gas.

limb circuit (Fisher & Paykel) was used for the ventilation circuit on 4 HH devices; this double-limb circuit was not used with the H900 and MR950 because they have their own proprietary circuits. For each HH, the proximal and distal probe temperature targets were set according to manufacturer recommendations (Table 1). Temperatures in the circuit were measured with an NXT datalogging module (Lego Mindstorms, Billund Denmark) equipped with 2 thermal infrared sensors (TIR; Dexter Industries, Washington, DC), one measuring the temperature of the water in the chamber (chamber TIR), the other measuring the gas temperature in the middle of the heating tubing (tubing TIR). The difference in temperature between these 2 TIRs made it possible to know whether

Table 1. Device Characteristics and Temperatures Measured in Various Error Scenarios

	MR730	PMH5000	MR850	Aircon	H900	MR950
Device specifications						
Embedded thermal probe	No	No	No	No	Yes	Yes
Embedded heating wire	No	No	No	No	Yes	Yes
Embedded gas flow meter	No	No	No	No	No	Yes
Circuit model	F&P RT265	F&P RT265	F&P RT265	F&P RT265	Proprietary	Proprietary
Device settings						
Setting chamber outlet	37°C	37°C	37°C	37°C	37°C	37°C
Setting tubing outlet	39°C	39°C	40°C	39°C	40°C	40°C
Standardized scenarios*						
NoProbe + NoFlow + NoAlarm						
Maximum gas temp (≥ 15 s)	> 65°C	58°C	56°C	> 65°C	NA	NA
Burn risk scale	Severe	Severe	Severe	Severe		
NoProbe + NoAlarm						
Maximum gas temp (≥ 15 s)	56°C	47°C	56°C	48°C	NA	NA
Burn risk scale	Severe	Severe	Severe	Severe		
NoFlow + NoAlarm						
Maximum gas temp (≥ 15 s)	45°C	52°C	47°C	> 65°C	49°C	44°C
Burn risk scale	Moderate	Severe	Moderate	Severe	Severe	Moderate
Worst case scenario						
Water temp	> 95°C	> 95°C	> 95°C	> 95°C	56°C	64°C
Heating wire on/off	On	On	On	On	On	Off
Gas temp	> 65°C	> 65°C	> 65°C	> 65°C	49°C	44°C

* Maximum gas temperature for ≥ 15 s and worst "risk of burn" attained for any of the 3 iterations for each standardized scenario.
NA = not applicable (ie, not feasible in this device due to embedded temperature probes).

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the thermistor was powered. Finally, the NXT datalogger used a classic thermocouple probe (Open Thermal Probe, Dexter Industries) to measure the temperature of the gases delivered at the end of the inspiratory circuit, directly defining the risk of burns. The average temperature and humidity in the laboratory were 25°C and 45%, respectively. A set of temperatures was recorded every 5 s, and the data were processed using Excel (Microsoft, Redmond, Washington).

Study Design

Three user error scenarios were tested. The first scenario was the "NoProbe" error, which consisted of faulty installation of the 2 HH thermal probes (ie, the probes were connected to the HH but not inserted into the ventilation circuit). Thus, the HH received "false" gas temperatures (typically the ambient temperature of the room or a value between the room temperature and the gas temperature in the tubing), thus highly disturbing its regulation. This error was not applicable to the H900 or the MR950 due to the presence of embedded thermal probes. The second scenario was the "NoFlow" error, which consisted of the absence of gas flow while the HH was on, obtained by turning off the ventilator but not the HH. The third scenario was the "NoAlarm" error, which consisted of the repeated acknowledgment of the alarm in an unsuitable way, regardless of the cause (eg, misunderstanding of the message, being distracted, etc). The acknowledgment was performed 10 s after the onset of the audible alarm. In the case of automatic blockage of the HH after repeated acknowledgments, a hard reset was carried out by turning the HH off and then on again.

Standardized Scenarios. An initial pilot study, not reported here, in which each of the 3 errors was individually applied, did not indicate significant hyperthermia of the gas. We therefore chose to combine the errors in the form of 3 standardized scenarios that reproduced sequences reported in our adverse events register or were, in our opinion, realistic possibilities in clinical practice: NoProbe + NoFlow + NoAlarm, NoProbe + NoAlarm, NoFlow + NoAlarm. As already mentioned, the NoProbe error was not possible with the H900 and MR950 models. Thus, only the NoFlow + NoAlarm scenario was possible with these 2 HHs.

Worst-Case Scenario. In addition to these realistic clinical scenarios, we also tried to explore the hardware and software security limits by finding a worst-case scenario for each HH, thus producing the highest obtainable gas and water temperatures. To generate these scenarios, we voluntarily exploited the possible flaws of each device by combining and repeating the 3 different types of error at will. Due to this design, the sequences applied in these worst-case scenarios are very unlikely to occur in clinical practice.

Levels of Risk Assessment

The first outcome of the study was the highest inspiratory gas temperature obtained over 15 consecutive seconds in each standardized scenario. The second outcome was the risk of burn in the standardized scenarios according to a self-designed risk-of-burn scale. Because the maximum temperature for 15 s does not necessarily fully describe the risk of burns in situations of less intense but more prolonged gas hyperthermia, we created a 3-level scale for the risk of burns, based on a combination of the intensity and duration of the delivered hyperthermic humidified gases: no risk, moderate risk, and severe risk. The construction of this scale was based on the limited literature data describing the risk of skin burns as a function of temperature and exposure time to hot gases in newborns.[7-11] The risk was considered to be severe in the following situations: 48°C for $>$ 10 s, 47°C for $>$ 20 s, 46°C for $>$ 60 s, 45°C for $>$ 120 s, or 44°C for $>$ 300 s. The risk was considered to be moderate in the following situations: 48°C for 1 to 10 s, 47°C for 1 to 20 s, 46°C for 1 to 60 s, 45°C for 10 to 120 s, 44°C for 30 to 300 s, 43°C for $>$ 80 s, and 42°C for $>$ 300 s. The risk was considered to be negligible ("no risk") in the following situations: 45°C for $<$ 10 s, 44°C for $<$ 30 s, 43°C for $<$ 80, 42°C for $<$ 300 s and $\leq$ 41°C for any duration (Fig. 2). Finally, our third outcome was the maximum gas and water temperatures in the worst-case scenario.

Statistical Analysis

Each scenario was tested in triplicate for each HH. The pragmatic aim of this study was not to measure the average risk of burns, but to measure the maximum risk within each scenario. Thus, the highest inspiratory temperature measured for each triplicate was reported.

Results

Maximum Airway Temperature in Standardized Scenarios

For each HH and each scenario, the iteration showing the highest temperature over a 15-s period is reported in Table 1; the raw data is presented in Figure 2. The scenario involving all 3 errors (NoProbe + NoFlow + NoAlarm), which was possible only with the MR730, PMH5000, MR850, and Aircon, systematically resulted in very high temperatures of $>$ 65°C, 58°C, 56°C, and $>$ 65°C, respectively. The NoProbe + NoAlarm scenario, which was possible for the same 4 models, still generated high temperatures of 56°C, 47°C, 56°C, and 48°C, respectively. The reaction

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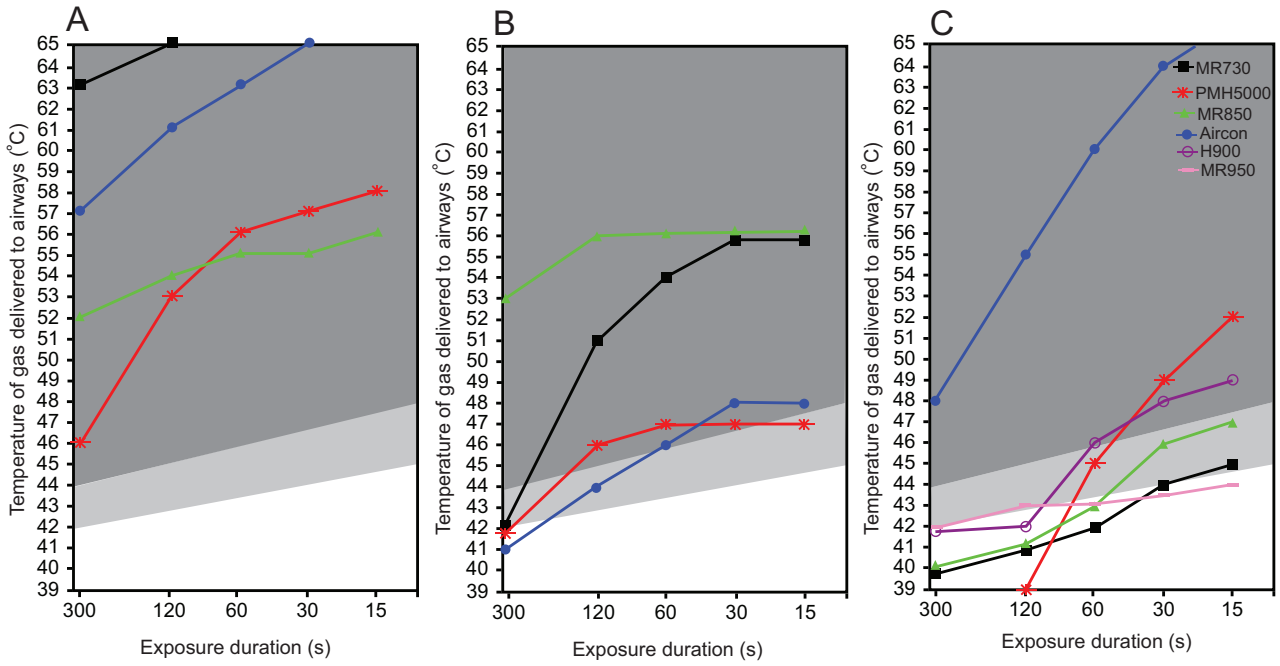

Fig. 2. Graphical representation of the measured temperature of gases delivered to the airways according to error scenario for each device studied. A: NoProbe + NoFlow + NoAlarm scenario; B: NoProbe + NoAlarm scenario; C: NoFlow + NoAlarm scenario. The worst iteration of each triplicate for the standardized scenario is depicted. The risk of burn is classified into 3 categories: no risk (white), moderate risk (light gray), and severe risk (dark gray), depending on the temperature and duration of exposure.

to the NoFlow + NoAlarm scenario, possible for all 6 models, gave a wider range of results, the worst being a delivered gas temperature of > 65°C for the Aircon and the best being 45°C for the MR730 and 44°C for the MR950.

Risk-of-Burn Scale for the Standardized Scenarios

In most cases, the maximum gas temperature for 15 s fit our self-designed risk-of-burn scale (Fig. 2). However, for 2 conditions, the maximum temperature underestimated the risk of burn due to the length of hyperthermia. In the first case, the PMH5000 was classified as severe risk in the NoProbe + NoAlarm scenario because of a moderate peak temperature of 47°C that lasted, however, for > 60 s. In the second case, the MR950 was classified as moderate risk in the NoFlow + NoAlarm scenario because the gas temperature remained > 43°C for > 120 s and > 42°C for > 300 s.

Worst-Case Scenario

The search for the worst-case scenario by repeating the NoProbe + NoFlow + NoAlarm error as many times as necessary resulted in our finding the maximum attainable temperature of the delivered gases and, in that moment, the maximum attainable temperature of water in the chamber. For the MR730, PMH5000, MR850, and Aircon, we obtained a maximum delivered gas temperature of > 65°C and a concomitant water temperature of > 95°C (ie, boiling water). The MR950 allowed the water temperature to rise to 64°C, which is high, but the tubing TIR measurement indicated that the heating wire had been automatically switched off and the delivered gas had time to cool down to 44°C during the transit from the chamber to the tip through the circuit. In contrast, a maximum water temperature of 56°C was achieved for the H900, but the tubing TIR showed that the heating wire remained active, leading to a gas temperature of 49°C delivered to the airways.

Discussion

In this study, motivated by a case of severe nasal burn of a newborn treated with nasal CPAP in our unit, we tested the risk of gas hyperthermia and skin burns in situations of misuse for 6 HHs. We observed that combinations of 2 or 3 classic HH errors (ie, No Probe, No Flow, and No Alarm) can lead to a high risk of nasal burns in 5 of the 6 HHs that we tested (ie, PMH5000, MR730, Aircon, MR850, and H900). Only the MR950 presented a moderate risk. In the worst-case scenarios, exploring the security limits of the hardware and software, water could be heated to the boiling point, systematically generating outlet gases > 65°C for 4

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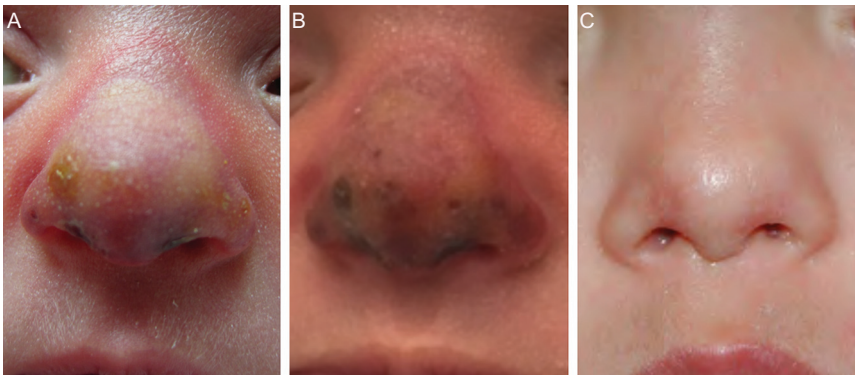

Fig. 3. Case report of nasal burn after nasal CPAP treatment. Evolution at day 1 (A), day 4 (B), and 12 months after (C) a nasal burn induced at day 0 following a brief nasal CPAP treatment delivered via nasal mask to a newborn delivered at 34 weeks gestation. Evolution of the burn was marked by cutaneous and subcutaneous necrosis, followed by slow healing over several weeks. At 1-y follow-up, the child showed no skin sequelae.

of the 6 HHs (ie, PMH5000, MR730, Aircon, and MR850). In contrast, the worst-case scenarios led to a much lower achievable maximum gas temperatures of 49°C and 44°C for the H900 and the MR950, respectively.

The case that inspired this quality improvement study involved a preterm infant born at 34 weeks gestation with a birthweight of 2,030 g who was supported by nasal CPAP for a transient tachypnea of newborn for only a short period of time (between 4 and 12 h of life). Nasal CPAP was provided with the CNO (Medin Medical Innovations, Olching, Germany), with the PMH5000 for humidification. When nasal CPAP was discontinued, the nurse noted a paler aspect of the skin facing the mask. After a few hours, the appearance of a second-degree burn was confirmed. The lesion progressed to cutaneous and subcutaneous necrotic patches, gradually evolving into scabs after day 4. Management was based on local hydrocolloid-type dressings enriched with hyaluronic acid (Ialugen, Ibsa, Switzerland). Consistent with a case reported by Choi et al,[6] healing was of good quality after 12 months, with no visible skin sequelae, such as hyper/hypopigmentation, contracture, or hypertrophy (Fig. 3).

As mentioned, following this nasal burn accident, a technical analysis of the HH used did not reveal any hardware or software dysfunction. An inquiry with the nurses in charge of this baby, carried out a few days after the event, did not succeed in identifying a precise cause. Nevertheless, we found that the work load on that day was very high and the device assembly had been carried out directly by the nurse in charge, whereas this task is usually performed by a dedicated care assistant in our unit. This could have led to a NoProbe error (ie, incorrect assembly of the TIR probes). Similarly, caregivers could not exclude a few minutes delay between turning on the HH and turning on the CPAP monitor, which could have induced a NoFlow error (ie, heated humidification without gas flow). In a context of extreme work load during this time period, the presence of alarms, which are extremely frequent with HHs, might have been neglected by the nursing team (ie, a NoAlarm error). Finally, as our investigation yielded little additional information to better understand this undesired event, we decided to develop 3 standardized test scenarios as we thought each of them may be causal in our case.

While skin burns are not expected to be extremely rare in the neonatal population with the use of heated and humidified gases, we found only one comparable case report in the literature.[12] In addition, sharing our experience with other neonatologists, many of them had observed episodes of HH dysregulation, and a few of them had experienced skin burn events. Actually, superficial burns may be easily underdiagnosed as preterm neonates could have many causes for erythema formation, and such lesions seem to heal fast. When considering invasive ventilation, burns due to HH might be located within the trachea and could also be underrecognized while contributing to neonatal necrotizing tracheobronchitis.[13] This rare complication, reported in intubated premature babies mainly in the 1980s and 1990s, was diagnosed via bronchoscopy showing necrosis of the tracheal epithelium with casts, and some authors had raised the possibility of a burn mechanism related to HHs.[12,13]

We did not find any other reports on the safety of HHs with regard to the risk of skin burn in either in vivo or in vitro studies. However, safety issues of HHs have been known for decades, since old publications reported tracheal burns or promoted the use of a safety device that cuts off the HH power supply in case of excessive delivered gas temperatures. Nevertheless, the perceived risk in using HHs appears to be lower than the perceived risk in using a ventilation device, the latter being extensively studied.[14-16] Similarly, we did not find any study that specifically evaluated the accuracy of HH alarm strategies and the risk of inducing alarm fatigue, whereas these topics are recognized for the use of mechanical ventilators.[17]

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In this study, we developed various error scenarios on the basis of events that have been repeatedly observed and are thought to be responsible for respiratory gas hyperthermia, according to our initial analysis of internal incident reporting. The NoProbe error, due to incorrect installation or accidental disconnection of the thermal probes in the circuit, was not reported frequently in our department. It occurred more often in the context of an emergency assembly or heavy unit work load as in the situation of our reported case. The MR730 and MR850 models appear to be particularly sensitive to this type of error. Conversely, the H900 and MR950 models do not allow this error, given their design with the thermal probes already embedded in the proprietary circuit.

The NoFlow error (ie, HH turned on while the ventilator is paused) is more frequently encountered in our unit than the NoProbe error, either at the start of nasal CPAP treatment or during treatment pauses. This error appears to be most often due to inattention rather than a lack of knowledge. We observed that the hyperthermia at gas restart is sudden and can reach the maximum temperature in < 10 s. The thermal probes quickly identify this phenomenon (within 10–15 s), and the software emits an alarm and immediately shuts down the heating wire and heating plate. However, because of the thermic inertia of the heating wire and the time required for the water in the chamber to cool, normalization of the gas temperature to target values takes a minimum of 45 s. The Aircon, PMH5000, and H900 models are particularly sensitive to this error. The MR950 model, on the other hand, resists this error because it has an internal flow sensor that limits the heating power during the ventilator pause. Nevertheless, the risk is not reduced to zero because a temperature of 43°C can persist for > 120 s when the gas flow is resumed, classifying this HH as a moderate-risk device.

A useful mistake-proofing concept to prevent the NoFlow error could consist of an electronic link between the ventilator and HH that would allow the HH software to automatically switch itself into standby mode in situations of a ventilator pause or disconnection. However, this may not be easy to do for older or less sophisticated CPAP flow drivers. We also suggest the introduction of a thermal probe upstream of the HH water chamber that could allow the software to identify measurement patterns evocative of the absence of gas flow, as well as probe misconnection, thus addressing both NoProbe and NoFlow errors.

The NoAlarm error, linked to the non-consideration and muting of alarm messages, is extremely frequent in our unit. This error (ie, alarm fatigue and ignoring alarms) is encountered with all biomedical devices but appears to be particularly frequent with HHs. Following our pilot study, we chose to introduce the NoAlarm error in each scenario, as this error appears to be necessary to induce inadvertent gas hyperthermia. We confirmed this hypothesis in all but 2 conditions in which the hyperthermia occurred before triggering of the alarm. The first concerned the Aircon device during an iteration of the NoProbe + NoAlarm scenario; the alarm did not sound until 30 s after the delivered gas had already reached a peak temperature of 48°C. The second case occurred with the MR850 device, also for the NoProbe + NoAlarm scenario; the audible alarm was triggered as much as 30 s after the temperature reached 48°C, and once the alarm was acknowledged, it did not sound again until 500 s later even as the hyperthermia rose to 56°C. Failure of caregivers to comply with the alarm messages emitted by biomedical devices is a major problem in terms of accident prevention. This phenomenon is often linked to insufficient reliability and accuracy of the alarm messages. Indeed, in situations of misuse, HHs often detect abnormal operation but incorrectly identify and state the problem. For example, in situations of the NoProbe error, many HHs may give a false "low gas temperature" message instead of a "probe misconnection" message. Aware of such inappropriate alarm acknowledgment, the makers of certain HHs, such as the PMH5000 and the Aircon, block the ability to silence the alarm after 5 successive acknowledgments. However, if caregivers consider these alarms to be inaccurate, they can reset this last security measure by performing an OFF/ON maneuver, which is, unfortunately, a common approach to unblock most electronic devices that malfunction. A software improvement of the alarm system is imperative to improve HH safety. It is essential to address erroneous messages by enriching the algorithms through an exhaustive analysis of the various patterns encountered in situations of inappropriate operator use. This also requires clear and detailed communication of the identified problem, ideally accompanied by a troubleshooting guide.

Finally, the worst-case scenario highlighted the last axis of HH safety by limiting the temperature that can be reached in the water chamber. Indeed, our study showed that, in the four HHs tested, the water temperature was not limited by either the software or the hardware. It may be necessary to introduce an embedded thermal probe in the heating plate to limit the water temperature to $\sim$ 55–60°C, which should be sufficient to safely reach effective gas temperature and humidity targets.

The main limitation of our bench test study is that we had to design a risk-of-burn scale without robust data from human or animal studies to support a precise correlation between risk of burn and both high-flow steam and exposure time, respectively. Reports of skin burn in babies mainly related to brief exposure to hot liquids, and little is known about prolonged exposure to hot dry gas; however, these burn sources are hardly comparable to exposure to hot humid gas, as the latter is a much more powerful source of heat and thus much more dangerous for causing burns. Indeed, if one compares the enthalpy of air at 65°C with 10% humidity blown from a hairdryer to that of gas at 65°C

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with 100% humidity coming from an HH, the heating power (ie, the energy released) quadruples from 109 J/L to 477 J/L. Finally, in addition to the exposure to a given amount of heat, the appearance and severity of nose burn in a premature baby on nasal CPAP also depends on the baby's low ability to dissipate this heat and the high intrinsic fragility of the skin. Although our scale may over- or underestimate the true risk of burns, it might be helpful in determining how far beyond the stated safety range a specific HH might stray.

Conclusions

Our results indicate that HHs may cause severe burns in situations of application errors because safety algorithms and concepts incorporated into current HHs are insufficiently developed. Adequate training of the users is obviously required but is likely insufficient to achieve the risk-free use of HHs, especially during nasal CPAP therapy in neonates. Manufacturers must work to equip their devices with error-proofing hardware features, such as integrated thermal sensors and an automatic standby function in case of interrupted gas flow; manufacturers should also limit the maximum temperature the water can reach in the heating chamber. They also need to improve software and user interfaces (eg, intuitive displays) with more reliable alarm analysis and better operator–device interaction.

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