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Method of water nebulization used to prevent heat loss during laparoscopic surgery matters

James B. Presthus · Volker R. Jacobs · Jay A. Redan

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We read with interest the article by Schloterbeck et al. entitled "Cold nebulization used to prevent heat loss during laparoscopic surgery: an experimental study in pigs" [1]. To the best of our knowledge, the Pall (heated, humidified CO_2) system has never been evaluated clinically in humans or animals until this paper and is not sold in the United States. No Pall reference is listed in the bibliography. There are no Aeroneb studies in humans that demonstrate beneficial effect in preventing hypothermia and none in the bibliography. This paper shows that the Pall device is not effective in preventing laparoscopic-induced hypothermia. In contrast, there is a device that is efficacious and shows clinical utility in humans by preventing laparoscopic hypothermia: the Insu*flow*® device [2–7].

A study by Hazebroek that compared cold dry, cold wet (like the Aeroneb), warm dry, and warm wet (like the Insu*flow*®) showed hypothermia changes in cold dry, cold wet, and warm dry but not in the warm wet group [8]. This study was absent from this article. Because the actual temperature of the animals during the experiments was not reported, it is not possible to conclude whether the cold wet falling less than the cold dry group caused hypothermia. This information cannot be divined from Fig. 1 or Table 2 and is not defined in the paper.

From the results of this study, the only conclusion that is valid is that the Aeroneb and Pall device showed no difference in preventing laparoscopically induced temperature loss; the authors found that "the differences did not reach statistical significance." Or they could say that the Pall and Aeroneb devices are equally inefficient for preventing laparoscopic heat loss. Insinuating that the Pall device represents all humidifying warming devices for laparoscopy is false and incorrect. The Insu*flow*® device works and is validated, safe, and efficacious. The use of the Pall device as the comparative method for warming and humidifying gas when the only validated device (Insu*flow*®) was not used only indicts and highlights the shortcomings of the Pall device.

The authors use the term "hot" to indicate a change in gas temperature from 20°C to normal body temperature of 36°C. Although 36°C is hotter than 20°C, calling normal body temperature "hot" is misleading and incorrect.

These authors incorrectly site their reference 6. Ott found that the gas used was 21°C not an approximation and he did not estimate the decrease in core temperature of 0.3°C for each 50 l of cold dry CO_2—this is what was found; it was not an estimate [9].

The volume of CO_2 insufflated during each session was 719 l, and the specifications of use of the Pall device are to refill after 350 l of gas use. No refilling is stated in the experimental design. The Pall device states that it heats to 37.8°C, but the authors found a mean of 35.95—a difference of 2.15°C, which is unexplained and does not meet the manufacturer's claimed specifications [10]. The temperature standard deviation of the Pall device allowed a temperature swing of 5.2°C, whereas the Insu*flow*®

J. B. Presthus
Department of OB/GYN, University of Minnesota, Minneapolis, USA

V. R. Jacobs (✉)
Frauenklinik (OB/GYN), Technical University Munich, Munich, Germany
e-mail: volkerjacobs@hotmail.com

J. A. Redan
Department of Surgery, University of Central Florida, Orlando, USA

delivers gas at 35°C with virtually no fluctuation during use and 95% relative humidity.

In the *Materials and Methods* section, the authors state that "the animals were either wakened after removal of their instruments used for insufflation and placed back in their housing or killed," and in the *Results* section, "the animals all survived to the end of the study, and all were studied successively with the four protocols." They need to explain this contradiction.

The authors mislead readers by saying, "The results comparing the change in core temperature between the use of heated humidified gas (Pall group) and the use of standard gas agree with some previous studies [8, 9]." References 8 and 9 are Insu*flow*® studies. They correctly state that "Studies showing benefit from the use of heated humidified gas investigated more appropriate patient groups [8, 9]"—referring to the Insu*flow*® studies. Because the referenced studies that showed clinical benefits used the Insu*flow*® device why didn't these authors use this device in their study? The answer is that the Insu*flow*® device works differently than the Pall device; the Insu*flow*® device is clinically validated.

Despite that the focus of this study was temperature loss, the authors discuss postoperative pain and use two references, neither of which reached statistical significance, and then reference pain studies that used the Insu*flow*® device that did show significance but left out two others and one that was published after this paper [11–13].

The authors of reference 16 stated that the statistics used for their 4 groups of 11 was not of sufficient power to reach any conclusion and did not use the Aeroneb for the cold wet group. Furthermore, a letter to the editor regarding reference 16 did not have a response and is correct by default [14].

Because there is no disclosure "of any financial involvement in any organization with a direct financial interest in the subject matter or materials discussed in the manuscript" as required by the journal, it is unknown whether these authors received sponsorship for this study by Aeroneb or Pall. Reviewing the United States Food and Drug Administration device registrations website [15] and reading the "indications for use" for the Aeroneb, the use described in this article is off-label and is not stated in the article. The prevention of laparoscopic hypothermia really matters and should be seriously considered but with sufficient devices [16]. Conclusions in research should carefully be drawn while still insufficient gas heating devices are used [17] and animal models used might not always be the adequate biomodels [18].

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