PAPER

Double-blind, Prospective, Randomized Study of Warmed, Humidified Carbon Dioxide Insufflation vs Standard Carbon Dioxide for Patients Undergoing Laparoscopic Cholecystectomy

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Hypothesis: Patients undergoing warmed, humidified carbon dioxide (CO_2) insufflation for laparoscopic cholecystectomy will (1) maintain a warmer intraoperative core temperature, (2) have their surgeon experience less fogging of the camera lens, and (3) have less postoperative pain than patients undergoing laparoscopic cholecystectomy with standard CO_2 insufflation.

Design: A double-blind, prospective, randomized study comparing patients undergoing laparoscopic cholecystectomy with standard CO_2 insufflation vs those receiving warmed, humidified CO_2 (Insuflow Filter Heater Hydrator; Lexion Medical, St Paul, Minn) was performed. Main variables included patient core temperature, postoperative pain, analgesic requirements, and camera lens fogging.

Results: One hundred one blinded patients (69 women, 32 men) undergoing laparoscopic cholecystectomy were randomized into 2 groups—52 receiving standard CO_2 insufflation (group A) and 49 receiving warmed, humidified CO_2 (group B). Mean patient intraoperative core temperature change (group A decreased by 0.03°C, group B increased by 0.29°C, $P=.01$) and mean abdominal pain (Likert scale, 0-10) at 14 days postoperatively (group A, 1.0; group B, 0.3; $P=.02$) were different. Other variables (camera lens fogging, early postoperative pain, narcotic requirements, recovery room stay, and return to normal activities) between groups were similar.

Conclusion: While patients undergoing laparoscopic cholecystectomy with warmed, humidified CO_2 had several advantages that were statistically significant, no major clinically relevant differences between groups A and B were evident.

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ACHIEVING EARLY HOSPITAL dismissal, prompt return to full recovery, and minimization of patient discomfort remain laudable goals following any surgical intervention. Rapid acceptance of newer minimally invasive techniques, perioperative instrumentation, and pharmaceutical options has become commonplace even though objective data supporting such usage is often lacking. Surgeons should use beneficial technology in a cost-effective manner, but they should discard pharmaceutical hype and resist industry and patient pressure if "new and improved" is not truly better. While patients undergoing laparoscopic cholecystectomy (LC) are dismissed routinely within hours of having the procedure and many return to work in short order, any medication, technique, or technology that potentially benefits some 700 000 Americans per year deserves careful investigation.

The current approach in the United States for most laparoscopic procedures uses carbon dioxide (CO_2) gas at a temperature of 21°C and 0% relative humidity to insufflate the peritoneal cavity for visualization. Recent studies suggest warming (to 35°C) and humidifying (95%) the CO_2 is beneficial in that it may cause (1) less patient hypothermia, (2) less fogging of the camera lens, (3) less pain for the patient, and (4) lesser doses of narcotics.[1-3] Earlier dismissal and potentially lower overall cost has been implied.[4,5]

Lexion Medical (St Paul, Minn) has produced a novel adaptation to allow warmed, humidified CO_2 to be used in place of standard (room temperature, nonhumidified) CO_2. The device is called the Insuflow Filter Heater Hydrator, which was Food and Drug Administration approved in January 1998. We elected to study the product in a double-blinded, prospective, randomized trial.

Table 1. Mean Equivalent Daily Dose (MEDD) Conversion Table

Medication (Type of Administration)	MEDD Factor*
Codeine (orally)	0.05
Meperidine (IV)	0.10
Meperidine (orally)	0.05
Fentanyl (IV)	0.10
Morphine (IV)	1.00
Oxycodone (orally)	0.83
Propoxyphene (orally)	0.08

Abbreviation: IV, intravenously.
*Morphine equivalents = dose (expressed in milligrams or micrograms) × MEDD factor (adapted from Charrois et al[6] and Pereira et al[7]).

Table 2. Patient Demographics

Demographic Variable	Group A (n = 52)	Group B (n = 49)	*P* Value
Age, mean (range), y	50 (19-79)	55 (24-86)	.20
No. of patients aged <65 y	37	33	.68
Sex, M/F	20/32	12/37	.13
BMI, mean (range)	29.7 (21-46)	29.5 (17-50)	.44
Patients with CAD, COPD, HTN, or MI	27	26	>.99

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; HTN, hypertension; MI, history of myocardial infarction.

METHODS

A double-blind, prospective, randomized study comparing patients undergoing LC with and without warmed, humidified CO_2 was proposed to and approved by our institutional review board. All general surgeons at the Mayo Clinic, Rochester, Minn, agreed to participate. The study was open to all patients aged 18 through 100 years who gave written consent. Such patients were randomized to group A (standard CO_2) or group B (warmed, humidified CO_2) using a computer model initiated by the surgical scrub nurse at the time of anesthetic induction. Only 1 surgical scrub nurse per procedure was privy to which method of CO_2 insufflation was being used, and they collected none of the data. The Insuflow device was attached to our insufflation equipment in all of the patients but was only activated by the single scrub nurse in those patients randomized to group B. The patients, surgeons, surgical trainees, students, operative and hospital floor nurses, and study coordinator were masked. Masked anesthesiologists used an external warming device at their discretion. Patients converted intraoperatively to open cholecystectomy or those undergoing a concomitant procedure were excluded from the study. The study coordinator accumulated all data and contacted patients postoperatively by telephone. Main variables studied during hospitalization included intraoperative patient core temperature (via esophageal probe), camera lens fogging (subjective evaluation by the surgeon, on a 1- [severe fogging] to 5-point scale [no fogging]), early postoperative pain rating (11-point Likert scale, 0 [no pain] through 10 [worst pain]), and medication usage. Analgesic medication usage was converted to morphine equivalents (**Table 1**)[6,7] to allow comparison of not only narcotic vs nonnarcotic medications, but also oral and parenteral variations. Per standard Mayo Clinic nursing protocol, all patients were asked to use the same 11-point Likert scale to rate abdominal, shoulder, and other pain after LC. Patients were contacted 2 weeks postoperatively to assess their ability to return to normal activities, their pain rating (Likert scale, 0-10), and usage of pain medication.

The study sample was calculated to be at least 100 subjects, with approximately 50 in each arm. A sample this size provides 80% power (based on historical data at the Mayo Clinic) to detect differences in means of continuous variables at greater than or equal to 0.57 SD. This implies that we could reasonably detect differences of 0.31°C in the mean intraoperative core temperature between groups A and B and of 0.35°C in the mean core temperature change during the operation; a difference of 14 minutes in the mean postanesthesia care unit (PACU) time; and a difference in means of 1.3–Likert points of perceived pain. Patient accrual occurred from November 1, 2001, through June 30, 2002.

Statistical analyses between groups A and B were performed for demographic and preoperative, intraoperative, and postoperative data. Subset analysis of groups A and B based on age (<65 years vs 65 year) was similarly performed. Variables that were continuous in nature were compared using 2-sample *t* tests if the data were normally distributed; if not, the Wilcoxon rank sum tests were used. Discrete, nominal data were analyzed using χ^2 tests, while discrete, ordinal data were compared using Mantel-Haenszel χ^2 tests. All statistical tests were 2-sided, and the threshold of significance was set at $P<.05$.

RESULTS

One hundred seventeen patients gave written consent, were randomized, and underwent LC. Sixteen patients were excluded from further analysis (11 were converted to open cholecystectomy, 3 underwent an additional operation that increased the duration of the procedure [umbilical hernia repair, 2 patients; extensive lysis of adhesions, 1 patient], and 2 patients had the Insuflow device removed during the operation for technical reasons). This allowed 101 blinded patients (69 women, 32 men) completing LC to be randomized into 2 groups: 52 receiving standard CO_2 insufflation (group A) and 49 receiving warmed, humidified CO_2 (group B). Mean patient age was 52 years (age range, 19-86 years). The groups were comparable demographically (**Table 2**). Hospital-generated data were complete on all 101 patients, but only 78 patients were able to be reached for telephone data acquisition 2 weeks postoperatively. Operative data between groups were similar (**Table 3**). A statistical difference between groups was seen with 1 of 6 temperature assessments (**Table 4**), 2 of 18 pain assessments (shoulder pain on entry to the PACU: group A, 0.8; group B, 0.2; $P=.05$; abdominal pain at 14 days: group A, 1.0; group B, 0.3; $P=.02$), and morphine equivalent usage at 14 days (**Table 5**). While data were similar between groups, sufficient differences in a few patients generated statistical differences between groups A and B (**Figure**). All other variables (core temperature while in the recovery room, number of times the camera lens needed to be cleaned intraoperatively, pain medications, hospital stay, time to return to baseline activity level, and others) were not statistically different. Overall mean (SD) duration in the PACU (group A, 82 [29] minutes; group B, 74 [29] minutes; $P=.14$) and overall mean (SD) hospital stay (group A, 29 [25] hours; group B, 31 [22

Table 3. Operative Data*

Operative Variable	Group A	Group B	P Value
Use of Bair Hugger,† No. of patients	34	32	>.99
Operative time, mean (SD) [median], min	91.2 (22.3) [87]	91.2 (22.7) [90]	>.99
Episodes of bile spillage	18 (35)	10 (20)	.13
Cases of acutely inflamed gallbladder	14 (27)	8 (16)	.23
Camera lens fogging			
Severe	0	1 (2)	
Moderate	2 (4)	4 (8)	
Minimal	5 (10)	7 (14)	.83
Rare	20 (43)	14 (29)	
None	20 (43)	23 (47)	
Times camera lens cleaned, mean (median), No.	1.6 (3.2)	1.1 (2.1)	.37
Amount of CO_2 used, mean (median), L	67 (79)	63 (62)	.20

Abbreviation: CO_2, carbon dioxide.
*Data are given as the number (percentage) of patients unless otherwise indicated.
†A Bair Hugger is an external warming device made by Augustine Medical, Eden Prairie, Minn.

Table 4. Patient Core Temperature*

Core Temperature, °C	Group A	Group B	P Value
Mean intraoperative	36.0 (0.6)	36.0 (0.6)	.61
Change in the OR	−0.03 (0.3)	+0.29 (0.6)	.01
Entering PACU	36.0 (0.6)	35.9 (0.6)	.28
Hour on floor			
1st	36.3 (0.6)	36.3 (0.7)	.52
4th	36.7 (0.5)	36.6 (0.5)	.34
Change, PACU to 4th hour	0.6 (0.7)	0.7 (0.6)	.71

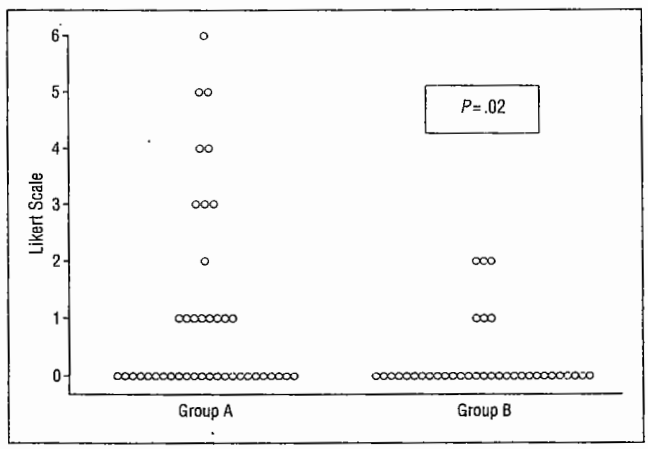
Abbreviations: OR, operating room; PACU, postanesthesia care unit.
*Data are given as the mean (SD).

Table 5. Pain Medication*

Total Morphine Equivalents†	Group A	Group B	P Value
PACU	2.6 (5.2)	2.8 (5.8)	.94
1st Hour	2.5 (4.5)	2.4 (4.4)	.80
4th Hour	2.7 (4.3)	3.5 (5.5)	.33
Post-PACU	26.7 (35.3)	20.4 (26.4)	.52
PACU and post-PACU	29.2 (35.4)	23.2 (27.1)	.53
2 Weeks postoperatively	0.8 (2.8)	0.0	.02

Abbreviation: PACU, postanesthesia care unit.
*Data are given as the mean (SD) equivalent daily dose.
†See asterisk footnote in Table 1 for explanation of morphine equivalents.

hours]; $P=.55$) were similar. The percentage of patients having returned to normal activities at 2 weeks postoperatively in groups A and B were similar (group A, 44%; group B, 56%; $P=.17$). Subset analysis of all patients younger than 65 years (group A, 37; group B, 33) found no difference between the groups except for statistically significant differences of the following: less camera lens fogging (mean number of lens cleanings required, 0.59 vs 1.22; $P=.05$), less shoulder pain on arrival to the PACU (Likert score, 0.0 vs 1.2; $P=.02$), shorter mean stay within the PACU (66 vs 83 minutes, $P=.01$), and less abdominal pain 2 weeks postoperatively (Likert score, 0.2 vs 1.1; $P=.02$) for group B. Patients aged 65 years or older harbored 1 difference on subset analysis: intraoperative patient mean core temperature change was 0.47°C warmer for group B ($P=0.02$).



Abdominal pain 2 weeks postoperatively.

COMMENT

The statistically significant findings in this double-blinded, prospective, randomized study of patients undergoing LC with warmed, humidified CO_2 vs standard CO_2 were 4-fold: patients were warmer intraoperatively using the Insuflow device, they harbored slightly less shoulder pain on PACU entry, they had less abdominal pain at 2 weeks postoperatively, and they used less pain medication at 2 weeks postoperatively. None of the other main variables studied showed a statistically significant difference between groups A and B. Other studies have similarly attempted to quantitate the benefits, or lack thereof, for using warmed, humidified CO_2 insufflation.

Warming the CO_2 insufflant, without adding humidity, seems to have little effect on the patient's core temperature and may actually cause more pain. Testing warmed vs standard CO_2 insufflation, Saad et al[8] (using CO_2 at 37°C vs 21°C) and Nelskyla et al[9] (using CO_2 at 37°C vs 24°C) found no difference in patients' core temperatures with small, prospective studies involving LC (n=20) and laparoscopic hysterectomy (n=37), respectively. Interestingly, Wills et al[10] (using CO_2 at 37°C vs 21°C) found more pain in patients undergoing laparo-

scopic fundoplication (n=21) with heated CO_2 than for standard CO_2 (n=19), but they noted core body temperatures increased 0.2°C with heated gas. Slim et al[11] found in 100 randomized patients undergoing laparoscopic upper gastrointestinal tract procedures that purely warming the CO_2 increased pain and had little effect on patient core temperature. In a rat model, Hazebroek et al[12] looked at the physiologic and actual peritoneal effects of 120 minutes of CO_2 insufflation of cold, warm, dry, humidified, and gasless combinations. Heat with humidity prevented hypothermia. Heat without humidity did not. Histologic analysis of the rat peritoneum showed definite changes in any group with CO_2 insufflation compared with the gasless method. Ott[13] found standard CO_2 insufflation (21°C) without humidity (and without external warming devices) will decrease the patient's core temperature by 0.3°C for each 50 L of CO_2 used. With 65% of all of our study patients having an external warming device applied in the operating room, we found no such drop in patient core temperature.

Combining humidity (95%) and heat (36°C), as the Insuflow device does, has been analyzed in numerous small studies. In a prospective, randomized, controlled, multicenter study of laparoscopic gynecologic procedures (n=72), Ott et al[4] suggested reduced hypothermia, shortened length of recovery room stay, and reduced postoperative pain occurred in patients receiving warmed, humidified CO_2 insufflation. Nguyen et al[1] found core temperatures increased by 0.4°C with Insuflow use (vs no core temperature change with standard CO_2) in patients undergoing laparoscopic Nissen fundoplication. Neudecker's literature search to support the European Association for Endoscopic Surgery's position on practice guidelines involving pneumoperitoneum for laparoscopic surgery found that "The clinical benefits of warmed, humidified insufflation gas are minor and contradictory."[14(p1121)] In 40 patients undergoing thoracoscopic procedures randomized to standard CO_2 vs warmed, humidified CO_2, pain was less at 6 hours, and at 1, 2, 3, and 14 days after operation for the warmed, humidified group.[2] While no difference in respiratory complications was seen, these investigators felt the Insuflow device was useful.

Core body and intra-abdominal patient temperatures do seem to be maintained better with the Insuflow device. The clinical significance of a mean benefit of 0.32°C ($P=.01$) as seen in our study is unclear, and statistical significance does not imply clinical importance. One might extrapolate that elderly patients, or patients tending toward hypothermia undergoing longer laparoscopic procedures might benefit from warmed, humidified CO_2 insufflation.

Although some studies have shown less patient pain using warmed, humidified CO_2 for laparoscopic procedures, we remain cautious about a small, but statistically significant difference ($P=.02$) in patients who reported abdominal pain at 14 days after the operation in our study. Pain perception was not different at other times of assessment. A mean difference of 0.77 (7.7%) between groups 2 weeks postoperatively using a 0- to 10-point Likert scale is small, and its clinical relevance is uncertain. The use of similar amounts of narcotic and nonnarcotic analgesics by both groups was noted, except for follow-up at day 14. Perhaps the benefit lies in just a handful of patients where peritoneal irritation is more sensitive or the immune system interactions of cytokines are more crucial (Figure).

We hypothesized that using warmed, humidified CO_2 would decrease camera lens fogging. We did not find this to be true. While Almeida[3] suggested there is less camera lens fogging and better visualization with use of the Insuflow device, Nguyen et al[1] found no such difference in a randomized trial of 20 patients undergoing laparoscopic Nissen fundoplication. Indeed, our larger, randomized trial of 101 patients undergoing LC seems to mirror Nguyen's findings: we both found patient core temperatures were greater (0.3-0.4°C) with warmed, humidified CO_2, but early pain, camera lens fogging, and narcotic requirements were equivalent to those who received standard CO_2 insufflation.

Patients returned to baseline activities in similar fashion in groups A and B. The hospital stay was similar, as were the recovery room stay, and narcotic usage. The cost of warming and humidifying CO_2 with the Insuflow device is less than $100, and if thermoregulation is vital and an all-out attempt at minimizing patient discomfort is desired, the Insuflow device may have a useful clinical role. However, better and larger randomized, blinded trials should be undertaken before the clinical utility of such a product can be recommended globally.

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Lexion Medical provided the Insuflow devices for this study.

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DISCUSSION

David W. Easter, MD, La Jolla, Calif: Congratulations go to the authors for attempting to shed some scientific light on the tangled subject of new devices in laparoscopic surgery. Dr Farley and colleagues accurately point out that since many, many laparoscopic procedures occur yearly in the United States, even small differences in outcomes may produce a large population-based benefit, for example, lower healthcare costs.

Adding to the mixed literature on this subject, the authors found statistically significant differences in the intraoperative change of core body temperature, but only by 0.3°C and, less subjective pain, but only by 0.7 points on an 11-point scale, only for abdominal pain, and only at 2 weeks postoperatively. Notably, it appears from their well-constructed manuscript that at least 43 variables were analyzed for differences between groups. At a *P* value of .05 significance, and the real possibility of a type I or II error, as the authors point out, we will not be surprised to find 1 or 2 false-positive results. The authors correctly point this possibility out when explaining the differences in pain medication usage at the 2-week interval. This difference was only 0.8 morphine equivalence units, and only at the last of 6 time points evaluated. Furthermore, of the 3 types of pain evaluated at 6 different time points, only the abdominal pain, not shoulder or other pain types, was measurably different.

As for patient temperature measurements, only 1 of 6 measurements was different between groups, that is, only the intraoperative change in core temperatures. It appears that there is no real clinical value from this device in keeping the laparoscope clean, that is, fogging, or other measured variables.

My questions relate to the clinical utility of this device given the authors' findings.

1. Was there any difference in measured variables if you sort by the use of patient warming devices, for example, the Bair Hugger? Sixty-five percent of the patients in each group received the Bair Huggers at the discretion of the many anesthesiologists. My suspicion is that this was a most important covariable.

2. What is the incremental additional cost of using this device? It looks like the device is the one major additional cost—what is the differential cost in using this device?

3. What difference, if any, exists between the device-delivered gases at the unit itself and the patient-received gas at the port site. Is it still 95% and 95°C at the entrance to the abdomen?

4. Did the authors learn anything from the 2 technical failures that they reported?

5. Were there any infections found in your patients, and if so, how many in each group?

6. Finally, regarding the ultimate utility of this device, are you recommending that we prescribe 2 fewer pain pills to our patients at discharge following the heat-humidified gas during LC? If not, I propose that the statistically significant differences are not clinically relevant.

In your next studies, you may want to return to an animal model using more extreme study conditions with more strictly controlled variables.

Dr Farley: Sorting the patients out by the Bair Hugger, again like with many others, is fraught with the hazards of subset analysis, but we did not see any difference between the two. The cost of the tubing is less than $100. The temperature within the tubing is consistent, at least from what I understand, its 95% humidity at the source and the actual water source is close to the abdominal wall so there is little change and the temperature is, indeed, 35°C to 36°C. We placed the device in each one of the 101 patients, but it was only turned on in 49 of them (group B). In 2 instances (group A), the connection did not fit well and the surgeons elected not to reconnect the device.

We had 1 superficial wound infection in each group. Since the clinical relevance remains to be proven, I would base my analgesic treatment on patient pain, not on whether they did or did not use this device.

While we have not studied the Insuflow in an animal model, we are doing a prospective randomized double-blind study with laparoscopic ventral hernia repair. This longer operation may show more or less benefit and we look forward to study completion.

Raymond J. Joehl, MD, Chicago, Ill: Did you exclude patients with acute cholecystitis?

Dr Farley: No.

Dr Joehl: Or, if you did not exclude them preoperatively, how many patients were found to have acute cholecystitis or even gangrene? The second question relates to the 7 patients converted to open cholecystectomy. Did you exclude those patients from the analysis postoperatively?

Dr Farley: Yes.

Dr Joehl: The next group of questions relate to anesthesia technique. Whenever we talk about pain in the postoperative period, especially the immediate postoperative period, we need to consider techniques and medications used by anesthesiologists. At the Mayo Clinic is there an ambulatory anesthesia program that everyone follows in which you avoid intravenous narcotics and use intravenous NSAIDs [nonsteroidal anti-inflammatory drugs] to control pain in the recovery room? Did all surgeons use bupivicaine to infiltrate port sites?

Dr Farley: First, there were patients in the study who had acute cholecystitis and they were not excluded—14 in group A and 8 in group B. The 4 conversions in group A and the 7 conversions in group B were eliminated from the study. We do not specifically have an ambulatory program and the anesthesiologists do have full autonomy. As I tried to allude to with a million different combinations of people coming and going in our institution, the variation is significant and it is certainly a warranted criticism of this paper. Port site infiltration is left up to each surgeon.

Thomas R. Huntington, MD, Boise, Idaho: You implied that there is a 0.30°C temperature drop intraoperatively due to heating and humidifying the gas flowing through the abdomen. The thermodynamic equations for this are well worked out, fundamental, and they have been published in the surgical literature. Basically, it takes 1 kilocalorie to heat and humidify 36 L of CO_2. Specific heat of the human body is 57 calories per degree of Celsius. When you run through that, it takes about 700 L to change the temperature of the human body one third of a degree. Your leak, I believe you said was 67 L. Laws