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Heated and Humidified Insufflation During Laparoscopic Gastric Bypass Surgery: Effect on Temperature, Postoperative Pain, and Recovery Outcomes

MOHAMED A. HAMZA, MD,[1] BENJAMIN E. SCHNEIDER, MD,[2]
PAUL F. WHITE, MD, PhD,[1] ALEJANDRO RECART, MD,[1] LEONARDO VILLEGAS, MD,[2]
BABATUNDE OGUNNAIKE, MD,[1] DAVID PROVOST, MD,[2]
and DANIEL JONES, MD[2]

ABSTRACT

Background: **Controversy exists regarding the efficacy of heated and humidified intraperitoneal gases in maintaining core body temperature. We performed a sham-controlled study to test the hypothesis that active warming and humidification of the insufflation gas reduces intraoperative heat loss and improves recovery outcomes.**

Patients and Methods: **Fifty morbidly obese patients undergoing laparoscopic Roux-en-Y gastric bypass procedures using a standardized anesthetic technique were randomly assigned to either a control (sham) group receiving room temperature insufflation gases with an inactive Insuflow® (Lexion Medical, St. Paul, MN) device, or an active (Insuflow) group receiving warmed and humidified intraperitoneal gases. Esophageal and/or tympanic membrane temperature was measured perioperatively. Postoperative pain was assessed at 15 minute intervals using an 11-point verbal rating scale, with 0 = none to 10 = maximal. In addition, postoperative opioid requirements, incidence of nausea and vomiting, as well as the quality of recovery, were recorded.**

Results: **Use of the active Insuflow device was associated with significantly higher mean ± standard deviation (SD) intraoperative core body temperatures (35.5 ± 0.5 *vs.* 35.0 ± 0.4°C). Postoperative shivering (0 *vs.* 19%) and the requirement for morphine in the postanesthesia care unit (5 ± 4 *vs.* 10 ± 5 mg) were both significantly lower in the Insuflow *vs.* control groups. Patients in the Insuflow group also reported a higher quality of recovery 48 hours after surgery (15 *vs.* 13, $P < 0.05$).**

Conclusion: **The Insuflow device modestly reduced shivering and heat loss, as well as the need for opioid analgesics in the early postoperative period. However, it failed to improve laparoscopic visualization due to fogging, and provided improvement in the quality of recovery only on postoperative day 2.**

INTRODUCTION

COMPARED TO OPEN LAPAROTOMY, laparoscopic surgery has been reported to decrease the risk of intraoperative heat loss. However, during longer laparoscopic procedures (e.g., Roux-en-Y gastric bypass) patients are exposed to large volumes of insufflation gas and irrigation fluids which can decrease body temperature.[1–3]

The standard laparoscopic insufflation gas is 20–21°C and contains <200 parts per million (ppm) water vapor. The insufflation of such dry gas has been reported to cause peritoneal tissue drying and cell death in the peri-

Departments of [1]Anesthesiology and Pain Management and [2]Surgery, University of Texas Southwestern Medical Center at Dallas, Dallas, Texas.

toneal lining.[4] It has been alleged that the use of standard carbon dioxide (CO_2) insufflation gas can lead to the development of hypothermia and increased postoperative abdominal pain.[5,6] Preliminary studies have suggested that heated and humidified insufflation gas could reduce pain after laparoscopic procedures.[6–8] Moreover, the prevention of hypothermia has been claimed to reduce surgical wound infections, shorten postoperative recovery, and decrease the cost and length of hospitalization.[1,9,10]

If the use of heated and humidified insufflation gas minimizes heat loss and peritoneal tissue damage,[7] we hypothesized that it would reduce postoperative pain and improve patient outcome. Therefore, this sham-controlled study was designed to evaluate the effect of the Insuflow® (Lexion Medical, St. Paul, MN) endoscopic gas heating, filtering, and humidifying system on perioperative body temperature, postoperative opioid analgesic requirements, and recovery outcomes in morbidly obese patients undergoing laparoscopic Roux-en-Y gastric bypass surgery.

MATERIALS AND METHODS

After obtaining institutional review board approval and written, informed consent, 50 morbidly obese patients scheduled for elective laparoscopic-Roux-en-Y gastric bypass surgery were enrolled in this study over a period of 4 months. Using a computer-generated random number sequence, patients were randomized to either a control (sham) group where patients received standard CO_2 insufflation gas using an inactive Insuflow device, or an Insuflow group which received heated (37°C) and hydrated (95% relative humidity) intraperitoneal CO_2 insufflation gas. Patients were excluded if they were pregnant or lactating, or had clinically significant heart, liver, or renal disease.

All patients were approached on the morning of their operation to explain the study procedures and to instruct them in the use of the verbal rating scales (VRS) for assessing pain and nausea. Upon entering the operating room (OR), warm cotton blankets were applied to the upper chest and arms to minimize surface cooling in all cases. Forced air warming blankets or fluid warmers were not used. However, if the patient's core body temperature decreased to ≤34°C during the operation, a forced air warming blanket was applied to the upper body. Patients were withdrawn from the study if they required an external warming device during surgery (due to a decrease in core temperature <34°C), required conversion to an open procedure, or had to return to the OR because of surgical complications in the early postoperative period.

All patients received a standardized general anesthetic protocol consisting of midazolam (2–3 mg i.v.) for premedication, propofol (1.5 mg · kg^{-1}) and fentanyl (1–2 μg · kg^{-1}) for induction, and desflurane 3–6% (inspired concentration) in combination with air (1 L · min^{-1}) and oxygen (1 L · min^{-1}) for maintenance of anesthesia. All patients received antiemetic prophylaxis with droperidol (0.625 mg i.v.) after induction of anesthesia and ondansetron (4 mg i.v.) at the end of surgery. Morphine, 0.07–0.15 mg · kg^{-1} i.v., was given at the onset of surgery for intraoperative analgesia. Residual neuromuscular blockade was reversed with neostigmine (2.5–5 mg i.v.) and glycopyrrolate (0.3–0.6 mg i.v.). All patients received intraoperative fluids at a rate of 12–18 mL · kg^{-1} · h^{-1}.

The Insuflow device is a sterile, single-use device that adds heat and humidity to the CO_2 gas through a chamber connecting the insufflator to the laparoscopic ports. Before connecting the active device to the insufflator, sterile water was injected into a special chamber for humidification, and the heating unit was connected to a power source by a co-investigator not involved in the patient assessments. The insufflation tubing was always connected to the same 10–12 mm port. The patient, surgeon, anesthesiologist, data-collecting personnel, and recovery nurses were all blinded to the treatment group. An OR nurse was responsible for connecting the Insuflow device to the insufflator, and the operating surgeons were further blinded by covering the indicator light on the heating unit and the plastic tubing connecting the unit to the patient (to prevent detection of humidification due to condensation within the tubing). All operations were performed by the same surgical team using a standard laparoscopic procedure. The maximum intraperitoneal pressure was set at 15 mm Hg, and an insufflation flow rate of 10 L · min^{-1} was used. The thermostat in the OR was set at 20°C, and the intra-abdominal irrigation fluid was maintained at room temperature.

Esophageal (core) temperature was measured after induction of anesthesia but before starting the CO_2 insufflation (baseline), intraoperatively at 10 minute intervals, and at the end of gas insufflation, using a calibrated device. Tympanic membrane temperature was also measured at the end of surgery and postoperatively at 15 minute intervals during the postanesthesia care unit (PACU) stay. The ambient OR and PACU temperatures and humidity were similarly recorded at 10–15 minute intervals. Heart rate, blood pressure, and urine output were also measured at 10–15 minute intervals during the perioperative period. The duration of anesthesia and surgery, total insufflation time and volume of gas, total intraperitoneal irrigating fluids, and degree of peritoneal adhesions were recorded. The degree of laparoscopic lens fogging during the surgery was recorded at the end of the operation by the surgeon on a 5-point scale, with 1 = best and 5 = worst.

Upon arrival in the PACU, morphine was administered in 1–2 mg incremental doses when the patient complained

of pain. All patients had access to patient-controlled analgesia (PCA) with 1–2 mg i.v. morphine bolus doses. Pain and nausea scores were assessed using an 11-point VRS, with 0 = none to 10 = maximal, at 15 minute intervals until discharge from the PACU. During the postoperative period, the time to achieve a White fast-track recovery score ≥12,[11] and a modified Aldrete PACU discharge score of 10,[12] as well as the actual length of the PACU stay, were recorded. The time interval from the end of anesthesia until the first complaint of pain or nausea was also recorded. The total opioid analgesic requirement during the postoperative period was recorded. Finally, the maximum pain score, opioid analgesic requirement, and the incidence of postoperative nausea and vomiting, as well as the quality of recovery (using a standardized 18-point questionnaire),[13] were recorded on postoperative days (POD) 1, 2, 3, and 4.

Statistical analysis

An *a priori* power analysis based on a 50% reduction in the opioid analgesic requirement in the PACU (assuming 10 ± 5 mg morphine utilization by the control group) suggested that 23 patients would be required in each group to achieve a power of 0.9 ($\alpha = 0.05$). Continuous data were analyzed and compared using repeated-measure analysis of variance followed by Bonferroni's corrections for multiple comparisons. Categorical data were analyzed using the Chi-square test, with Fisher's exact test where appropriate. Power and probability levels were analyzed using NCSS software (Number Cruncher Statistical Systems for Windows, Kaysville, UT). P values <0.05 were considered statistically significant.

RESULTS

A total of 50 patients were enrolled in the study. However, 4 patients were converted to open procedures and were not included in the final statistical analysis. In addition, 2 patients in the control group were "rescued" during the operation with a forced air warming blanket when their core body temperature decreased <34°C.

The demographic characteristics, as well as the anesthesia and the surgery times, were comparable in the two study groups (Table 1). The two study groups were similar with respect to the volume of insufflated gas and the mean duration of pneumoperitoneum. The laparoscopic lens view remained unchanged during the operation, and there was no difference between the two groups with respect to lens fogging.

Use of the active Insuflow device was associated with significantly higher mean core body temperatures after 1 hour of insufflation, as well as at the end of surgery, compared to the control group, $P = 0.01$ (Fig. 1A). Compared to baseline values, intraoperative core temperatures were consistently decreased in the control group. In the Insuflow group, core temperatures were only decreased at the end of surgery after discontinuing the insufflation. Al-

TABLE 1. PATIENT DEMOGRAPHICS

	Control (n = 21)	*Insuflow* (n = 23)
Age (years)	45 ± 12	44 ± 10
Weight (kg)	128 ± 17	125 ± 15
Gender (F/M)	19/2	22/1
Anesthesia time (minutes)	152 ± 46	136 ± 30
Operative time (minutes)	132 ± 48	120 ± 24
Insufflation time (minutes)	120 ± 43	108 ± 21
Insufflation volume (L)	348 ± 218	267 ± 113
Irrigation volume (mL)	594 ± 435	694 ± 480
OR temperature (°C)	20 ± 0.7	19.5 ± 0.5
OR humidity (%)	44 ± 8	43 ± 8
PACU temperature (°C)	22 ± 0.6	21.7 ± 0.6
PACU humidity (%)	45 ± 8	43 ± 10
Propofol (mg)	181 ± 32	182 ± 27
Desflurane (end-tidal concentration) (%)	4.5 ± 1.2	4.9 ± 1.1
Intraoperative fentanyl (μg)	469 ± 147	393 ± 115
Total intravenous fluid (mL)	4836 ± 990	4217 ± 1093
Urine output (mL)	357 ± 230	381 ± 253
Fogging of laparoscopic lens[a]	2 (range, 1–4)	2 (range, 1–3)

[a]Fogging scale: 1 = best to 5 = worst
Values are mean ± standard deviation (SD), and inter-quartile range medians
OR, operating room; PACU, postanesthesia care unit
No significant differences were found between the two groups

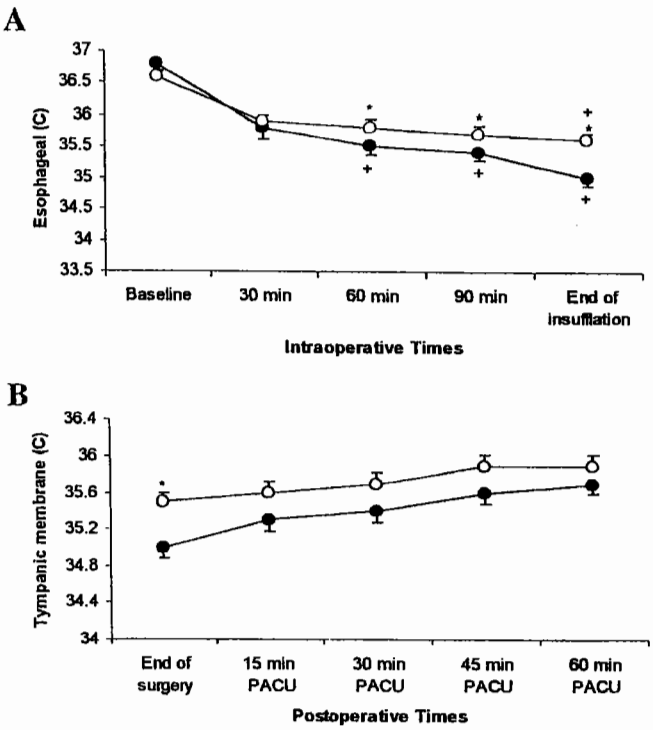

FIG. 1. **A.** Esophageal core temperature in °C at baseline (start of insufflation), 30 minute intervals during surgery, and at the end of gas insufflation upon removal of cannula. **B.** Tympanic membrane temperature in °C at the end of surgery, and 15 minute intervals in the postoperative care unit (PACU). Values shown are mean ± standard error of the mean (SEM).

—●— = Control group
—○— = Insuflow group
* = $P < 0.05$ *vs.* baseline
+ = $P < 0.05$ *vs.* control group

though not reaching statistical significance between the two groups, postoperative tympanic membrane temperatures remained higher in the Insuflow group throughout the PACU stay (Fig. 1B). None of the patients in the Insuflow group developed postoperative shivering, compared to 4 patients (19%) in the control group ($P = 0.03$).

Although the maximum VRS pain scores and morphine consumption in the PACU were significantly lower in the Insuflow group, there were no significant differences in the VRS nausea scores or in the need for rescue antiemetics after surgery (Table 2). The time to reach an Aldrete recovery assessment score of 10 (88 ± 37 minutes in the Insuflow group *vs.* 119 ± 81 minutes in the control group, $P = 0.09$), and the length of stay in the PACU (83 ± 30 minutes *vs.* 107 ± 69 minutes, respectively, $P = 0.08$) were nonsignificantly reduced in the Insuflow group (Table 3). Moreover, the median times to discharge from the hospital were similar: 2 days for patients in the Insuflow group *vs.* 2 days (range, 2–3 days), in the control group. The follow-up assessment of the quality of recovery during the first 4 days after surgery suggested that the patients in the Insuflow group had improved recovery compared to the control group only on POD 2.

DISCUSSION

Laproscopic-induced hypothermia and its prevention are highly controversial topics. Earlier studies suggested that during laparoscopic surgical procedures the core body temperature decreases linearly depending on the volume of insufflated gas, with a 0.3°C decrease per 50 L of dry gas.[14,15] The current sham-controlled study suggests that insufflation of the peritoneal cavity with dry CO_2 at room temperature caused a significant fall in the core body temperature after 1 hour of gas insufflation. The use of heated and humidified insufflation gas not only resulted in significantly higher intraoperative mean core body temperature, but also reduced postoperative pain and shivering, and led to improvement in the patients' assessment of their quality of recovery on POD 2.

In preliminary studies, MacFadyen[2] and Bessell et al.[15] suggested that laparoscopic-induced hypothermia might be prevented by the use of the Insuflow device. These investigators found that dry heated gas provided no benefit in maintaining core body temperature. However, the ability of warmed humidified insufflation gas to prevent intraperitoneal evaporation and provide a physiologically thermoneutral pneumoperitoneum have been the key factors in improving patient outcomes in previous studies.[5,16] Peritoneal desiccation may lead to superficial denuding of the peritoneum, with release of chemically active kinins, such as prostaglandins, which can contribute to increases in postoperative pain.[7] Therefore, use of dry insufflation gas at room temperature (20–21°C) may trigger the release of systemic acute-phase reactants, which can in turn increase postoperative pain, prolong recovery, and have a negative impact on patient outcome.[4] Mouton et al.[8] reported that humidification of the insufflation gas reduced postoperative pain in patients undergoing laparoscopic cholecystectomy, due to reduced peritoneal irritation by dry CO_2 gas. The current study also demonstrates that the use of the active Insuflow gas warming device was associated with a significant reduction in the opioid analgesic requirement in the early postoperative period.

On the other hand, a controlled trial utilizing dry and warmed insufflation gas reported no benefit in terms of postoperative recovery, and suggested that this approach might even increase pain in the early postoperative period following laparoscopic fundoplication surgery.[17] In addition to using dry CO_2, these authors used warmed saline for intraperitoneal lavage, and this may have obscured any benefit from the heated gas.[18] Slim and col-

TABLE 2. MEAN POSTOPERATIVE VERBAL RATING SCALE (VRS) PAIN AND NAUSEA SCORES AND THE NEED FOR ANALGESIC AND ANTIEMETIC RESCUE MEDICATIONS IN THE TWO STUDY GROUPS

	Control (n = 21)	*Insuflow* (n = 23)
Recovery period (PACU)		
Pain score at 15 min	4 (range, 0–6)	3 (range, 0–6)
Nausea score at 15 min	0 (range, 0–3)	0 (range, 0–4)
Pain score at 30 min	5 (range, 3–6)	4 (range, 2–6)
Nausea score at 30 min	0 (range, 0–2)	0 (range, 0–4)
Pain score at 45 min	5 (range, 4–5)	4 (range, 0–3)
Nausea score at 45 min	0 (range, 0–2)	0 (range, 0–3)
Pain score at 60 min	5 (range, 2–6)	3 (range, 1–5)[a]
Nausea score at 60 min	0 (range, 0–2)	0 (range, 0–3)
Morphine consumption (mg)	10 ± 5	5 ± 4[a]
Rescue antiemetic	4 (19%)	4 (17%)
Postoperative day 1		
Pain score	5 (range, 4–6)	5 (range, 4–6)
Nausea score	0 (range, 0–3)	0 (range, 0–4)
Rescue for nausea <24 h	10 (48%)	13 (57%)
Morphine consumption (mg)	37 ± 18	32 ± 20
Ketorolac usage (mg)	67 ± 33	53 ± 32
Postoperative day 2		
Pain score	4 (range, 3–5)	4 (range, 3–4)
Nausea score	0.5 (range, 0–2)	0 (range, 0–2)
Rescue for nausea <48 h	7 (33%)	7 (30%)
Morphine consumption (mg)	21 ± 18	15 ± 12
Ketorolac usage (mg)	62 ± 28	47 ± 24
Oral analgesic pills	2.5 ± 1.6	2.2 ± 1.2
Postoperative day 3		
Pain score	3.5 (range, 2–4)	3 (range, 2–3)
Nausea score	0 (range, 0–1)	0 (range, 0–0)
Oral analgesic pills	3 ± 1.6	3 ± 1.5

[a]$P < 0.05$
PACU, postanesthesia care unit

leagues[19] also reported that the use of dry heated gas in patients undergoing upper abdominal laparoscopic surgery was associated with increased postoperative shoulder and subcostal pain.

Analogous to our findings, an earlier, uncontrolled study[20] reported that heating and humidifying CO_2 gas produced fewer complaints of postoperative shoulder pain (5 *vs.* 40%) and less shivering (0 *vs.* 55%) than in a dry CO_2 group, following awake microlaparoscopic surgery.

Although the reduction in opioid analgesic requirement in the PACU did not alter the incidence of postoperative

TABLE 3. POSTOPERATIVE RECOVERY TIMES AND PATIENT ASSESSMENTS OF THE QUALITY OF RECOVERY

	Control (n = 21)	*Insuflow* (n = 23)
Time from end of surgery to		
Eye opening (min)	16 ± 12	14 ± 9
Orientation (min)	39 ± 23	28 ± 14
White fast-track score ≥12 (min)	68 ± 38	57 ± 25
Aldrete score of 10 (min)	119 ± 81	88 ± 37
Duration of PACU stay (min)	107 ± 69	83 ± 30
Total hospital stay (days)	2 (range, 2–3)	2 (range, 2–2)
Quality of recovery (on 18 point scale)		
at 24 h	11 (range, 10–13)	12 (range, 10–14)
at 48 h	13 (range, 11–15)	15 (range, 14–16)[a]
at 72 h	15 (range, 12–17)	16 (range, 14–17)
at 96 h	16.5 (range, 14–18)	17 (range, 16–18)

[a]$P < 0.05$
PACU, postanesthesia care unit

nausea or vomiting in our sham-controlled study, this finding is not completely unexpected because all patients received a combination of droperidol and ondansetron for antiemetic prophylaxis.

The protocol design can be criticized because the control group received no active warming device. Although active warming is considered the standard of care for open intra-abdominal surgery, this has not been an established practice for laparoscopic surgery at most centers. To avoid any ethical concerns regarding the lack of any active surface warming in the control group, warm blankets were used to cover the upper chest and arms in all patients. In addition, the anesthesiologist was allowed to "rescue" patients experiencing a significant decrease in core body temperature at any time during the operation, using forced air warming and/or fluid warming. Given that 2 of the control patients were "rescued" during the operation, the temperature difference between the two study groups was actually minimized. A future study is planned to compare the Insuflow device directly to forced air warming for maintaining core body temperature during major laparoscopic surgery.

Although patients in the Insuflow group had reduced recovery times in the immediate postoperative period, these differences failed to achieve statistical significance because our study was underpowered with respect to these secondary endpoints. Protocol-driven dietary restrictions and the routine requirement for postoperative upper gastrointestinal contrast studies also affected the discharge time from the public hospital where this study was performed. Nevertheless, during the follow-up period, patients in the Insuflow group reported a higher quality of recovery score at 48 hours (POD 2). Since 2 of the patients in our control group had to be rescued with a forced air warming blanket due to a decrease in core temperature during surgery, the differences in the outcome parameters between the two study groups would likely have been of an even greater magnitude, had this provision not been part of the protocol.

In conclusion, heated and humidified laparoscopic insufflation gas using the Insuflow device significantly decreased heat loss during surgery, reduced postoperative shivering, pain, and the opioid analgesic requirement. However, the Insuflow device failed to improve laparoscopic visualization due to fogging, and provided improvement in the quality of patient recovery only on POD 2 after gastric bypass surgery.

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Address reprint requests to:
Paul F. White, MD, PhD
Department of Anesthesiology and Pain Management
University of Texas Southwestern Medical Center at Dallas
5161 Harry Hines Boulevard, CS 2.282
Dallas, TX 75390-9068

E-mail: paul.white@utsouthwestern.edu