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A Randomized Trial of Bupivicaine Pain Pumps to Eliminate the Need for Patient Controlled Analgesia Pumps in Primary Laparoscopic Roux-en-Y Gastric Bypass

Daniel R. Cottam, MD; Barry Fisher, MD; James Atkinson, MD; Daniel Link, MD; Peter Volk, MD; Clifford Friesen, MD; Daniel Link , MD; Brian Grace, PAC; Robin Trovar, RN

Surgical Weight Control Center, Las Vegas, NV, USA

Background: The use of a bupivicaine pain pump has previously been reported to lower costs to hospitals, while providing similar pain relief to opioid-based patient controlled analgesia (PCA) pumps. However, these benefits have not been investigated in laparoscopic bariatric surgery.

Methods: We prospectively randomized 40 laparoscopic Roux-en-Y gastric bypass (LRYGBP) patients into two groups. The first group received the ON-Q® bupivicaine pain pump placed subxiphoid and radiating in both directions caudally beneath the lowest rib. The second group was treated with a meperidine PCA, which was initiated in the PACU and discontinued at 06:00 hrs the following morning. Both groups had identical surgery, anesthesiologists, anesthesia protocol and postoperative nausea prophylaxis.

Results: There were no significant differences between the groups with regard to age, sex, pain scores, nausea scores, gas pain scores, antiemetic use throughout their stay, or opioid use in the PACU. However, there was a dramatic decrease in opioid use between the two groups over the time interval from leaving the PACU to 06:00 hrs (meperidine by PCA mean 217 mg vs ON-Q® 129 mg meperidine equivalents, P=0.008).

Conclusions: The use of a bupivicaine pain pump offers the opportunity to dramatically reduce the use of opioids postoperatively in all bariatric patients by eliminating PCA. This change could potentially reduce the incidence of respiratory failure from oversedation, while offering the same levels of pain control.

Key words: Laparoscopic Roux-en-Y gastric bypass, morbid obesity, bupivicaine, patient controlled analgesia

Correspondence to: Daniel R. Cottam, MD, Surgical Weight Control Center, 3802 Meadows Lane, Las Vegas, NV 89107, USA. E-mail: drdanielcottam@yahoo.com

Introduction

For many types of abdominal surgery, the laparoscopic approach is one of the factors resulting in a dramatic increase in the numbers of cholecystectomies, Nissen fundoplications and obesity surgery performed. A primary consideration is the postoperative pain reduction and quicker return to activities of daily living. However, despite the dramatic increase in laparoscopic surgery, there have been few studies dealing with methods to reduce the residual postoperative pain. There have been even fewer studies investigating modalities to reduce pain in bariatric surgical patients after laparoscopic Roux-en-Y gastric bypass (LRYGBP).

We decided to investigate the ON-Q® pain pump (I-Flow Corporation, Lake Forest, CA) as a method to reduce postoperative pain in our morbidly obese patients. To further enhance analgesia, we implemented an adjunctive opioid-sparing regimen. We felt strongly that reducing the aggregate dosage of opioids would be potentially beneficial, as this patient population has a high incidence of obesity hypoventilation syndrome, COPD and sleep apnea.

Methods

This study was approved by the Western Institutional Review Board. All patients received an approved informed consent.

Forty patients undergoing LRYGBP were prospectively randomized into two groups. Each group was subjected to the identical surgical procedure from one of three surgeons. Each patient had an antecolic, antegastric approach, with patients having a BMI ≥50 kg/m^2 receiving a 150-cm Roux limb and those with BMI <50 kg/m^2 receiving a 100-cm Roux limb. The jejunostomy defect was closed, but not the Peterson defect. Gastrojejunal anastomosis was performed using an EEA technique (Ethicon). To allow passage of the EEA stapler, the port-site where the EEA was inserted was enlarged with a cervical dilator. The fascia at this site was closed with a port closure device. No other port-sites (Ethicon Excel ports were used for all cases) were closed with fascial suture, as per the recommendations of the manufacturer (Ethicon). All port sites were infiltrated with 0.5% bupivicaine at the end of each case: 20 mL to the working trocar site where the EEA stapler was placed, and an additional 20 mL was divided between the other sites.

In order to compare patients, we standardized the anesthetic protocol (Table 1) and limited the study to three anesthesiologists and three post-anesthesia care unit (PACU) nurses. All postoperative opioid use was converted to meperidine equivalents. Analgesia by the oral route consisted of 5 mL of an oxycodone-acetaminophen (5 mg oxycodone + 325 mg acetaminophen) elixir, the oxycodone portion of which is equivalent to 15 mg to 20 mg of intravenous (IV) meperidine.

In the PACU, pain care was provided by one of three pre-designated PACU nurses. Pain was treated using meperidine via IV bolus. No patient left the PACU until pain scores were less than 5 (visual analogue scale (VAS)). Overall pain scores, using a VAS from 1 to 10, nausea scores from 1 to 10, and gas pain scores from 1 to 10, were recorded in the PACU, and thereafter at 4 hours, 12 hours and 18 hours postoperatively. Noon on the first postoperative day, was the time chosen to end this study, because 80% of our patients are discharged after lunch in the late morning.

After discharge from the PACU, the control group received our standard therapy, consisting of a meperidine-PCA. Because of its lower incidence of nausea in our post-LRYGBP population, meperidine is preferred over morphine sulfate, and is clearly our drug of choice. The PCA pump was continued until 06:00 hrs the next morning; thereafter, patients were placed on the oxycodone-acetaminophen elixir, 5 to 10 mL every four hours. This regimen was continued until noon. If patients experienced breakthrough pain, they could request IV meperidine until discharge.

Table 1. Anesthesia protocol

Preoperative	
± midazolam	
famotidine	
metoclopramide	
dexamethasone	
oxygen	
Induction	
lidocaine	
propofol	
rocuronium/cisatracurium*	
± succinylcholine	
fentanyl	
oxygen	
Maintenance	
sevoflourane	
oxygen	
Fentanyl	prn
Emergence	
neostigmine	
glycopyrrolate	
ondansetron	
Post Anesthesia Care Unit (PACU)	
meperidine	prn
ondansetron	prn
albuterol	prn
labetalol	prn

*cisatracurium is occasionally substituted for rocuronium.

The study group received an ON-Q® pain pump with 300 mL of 0.5% bupivicaine without epinephrine, and meperidine via IV bolus (25-75 mg every 2 hours), if needed for pain. Meperidine via IV bolus was continued until 19:00 hrs the evening of surgery. Patients in this group were then switched to oxycodone-acetaminophen elixir (5 to 10 mL as needed for pain every 4 hours) until their discharge at noon the following day. If they had breakthrough pain, these patients received meperidine via IV bolus.

The Soaker® catheters of the ON-Q® pain pump were placed sub-xiphoid in a subcutaneous/subfascial

position. The catheters radiated caudally and beneath the inferior margin of the rig cage, bilaterally. While the manufacturer of the device recommends that catheters be placed subfascially, we found this position difficult to achieve, due to the thick abdominal wall. Therefore, we only attempted to position the tip of the catheters into the subfascial plane. This resulted in segments of the soaker (fenestrated) portion of the catheter being embedded subfascially and the remainder, subcutaneously. The dual catheters were placed above the working ports (Figure 1). The continuous infusion of local anesthetic provides local/regional anesthesia for about 72 hours. When the pump is empty, it is removed by the patient at home.

Demographic information collected on each patient included age, sex, BMI, time of surgery, and the number of co-morbid conditions. Patients were excluded from participation in the study if they had a history of prior gastric surgery or were chronically dependent on pain medications.

Statistical Analysis was performed with Sigma Stat Software. Mann-Whitney Rank Sum test was used to compare the preoperative groups wherever the groups were not normally distributed, and *t*-tests were used to compare data between normally distributed groups. Z-tests were used to compare percentages between groups.

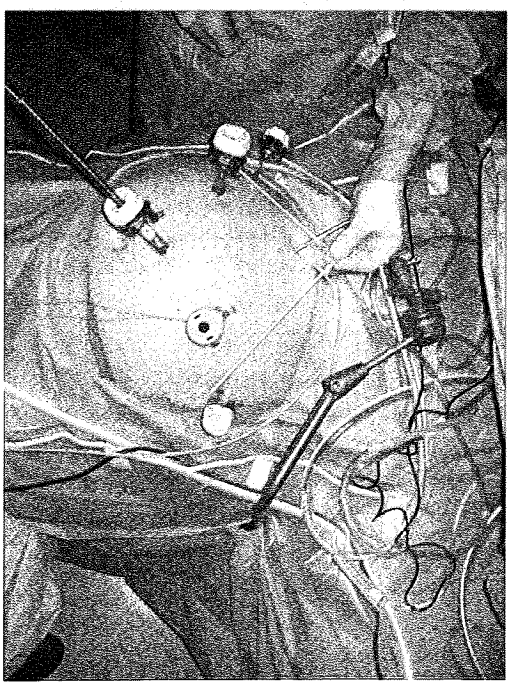

Figure 1. The subcostal pattern that we use to place the On-Q® pain pumps is shown.

This study was funded by the I-Flow Corporation. The funds were used for data gathering only. The I-Flow Corporation did not participate in the writing of this paper, design of the study, or the analysis of data.

Results

There were no statistical differences in age, operating-room (OR) time, pain scores, gas pain scores, nausea scores, or use of anti-emetics throughout the course of the study (Table 2). The mean age of patients enrolled in this study was 41.1 in the ON-Q® group and 40.9 in the PCA group. The mean OR time was 71 minutes in the ON-Q® group and 63 minutes for the PCA group. The postoperative nausea scores, gas pain, and overall pain scores, did not differ between the two groups during any given study interval. Likewise, there was no statistically significant difference in the postoperative use of anti-emetics in the study (Table 2).

Opioid use was significantly different during the PACU to 06:00 hrs study interval. The total dose of opioids administered in meperidine equivalents was 217 mg for the PCA group and 129 mg for the ON-

Table 2. Results of gas pain, nausea and opioid use postoperatively

	ON-Q®	PCA	*P*
Age	41.1±13	40.9±10	NS
OR Time	71±13	63±8	NS
PACU gas	1.7±2	1.5±2.5	NS
4 hours gas pain	1.44±2.5	1.1±2.2	NS
12 hours gas pain	0.9±1.7	.5 ±1.2	NS
18 hours gas pain	0.27±.8	0.6±1.2	NS
4 hours nausea	0.42±1.4	0.1±0.4	NS
12 hours nausea	0.41±1.2	0.1±.2	NS
18 hours nausea	0±0	0±0	NS
4 hours overall pain	4.2±2.4	3.8±2.0	NS
12 hours overall pain	3.7±1.6	3.6±1.6	NS
18 hours overall pain	2.4±1.3	2.5±1.5	NS
PACU opioid use	42±21	61±35	0.176
PACU to 06:00 hrs opioid use	129±90	217±99	0.008
06:00 to 12:00 PO day 1 opioid use	15±17	18±11	0.227

All values expressed as mean ±sd

Q® group (P=0.008) (Table 2). Interestingly, opioid use was not significantly different while in the PACU or on the postoperative surgical unit from 06:00 hrs (when we removed the PCA) to noon (end of study).

Discussion

Pain is an ever present problem in the postoperative period for any type of surgical procedure, especially in the first 48 to 72 hours. In the postoperative LRYGBP patient, pain emanates principally from the abdominal wall and is often enhanced with co-existing nausea. Additionally, obese patients have numerous other co-morbid conditions, such as impaired mobility, cardiac disease, and arthritis, which contribute to disability and pain. Inadequate treatment of pain can lead to reduced mobility, resulting in pneumonia and phlebothrombosis.

In the past, physicians have relied heavily on opioid-based regimens. This usually involves morphine sulfate, which is typically administered using a PCA pump. The use of PCA pumps has proved superior to bolus-based regimens in previous studies. Strict opioid-based pain regimens, using PCA, can result in nausea, sedation, and respiratory depression. In the morbidly obese, these undesirable side-effects can result in serious morbidity and occasional death in the postoperative setting.

In order to decrease our reliance on postoperative opioids, we investigated the ON-Q® pain pump. The ON-Q® pain pump acts locally to reduce pain in the anterior abdominal wall through a continuous infusion of 0.5% plain bupivicaine for up to 72 hours. The anterior abdominal wall is vitally important to both pulmonary ventilation and ambulation. Inadequate use of the anterior abdominal wall can lead to decreased ambulation and inability to effectively use the incentive spirometer. The ON-Q® pain pump provides continuous pain relief (the most effective type of pain relief) for up to 3 days, without the requirement for refill or additional patient care. It is also associated with a very low side-effect profile.

Use of this device for the management of postoperative pain has been studied for more than 6 years. It has proven effective in reducing pain scores in every therapeutic area studied. Relevant to the bariatric surgeon, this study shows that the ON-Q® system effectively reduces opioid requirements, while not compromising pain control. This has previously been shown in orthopedic, urologic, gynecologic and thoracic applications.[1-10] However, to the present, there has been only one prior study which evaluated its efficacy in a laparoscopic model.[11]

At our institution, a multimodal opioid-sparing approach, using the ON-Q® pain pump, oral pain medications the night of the surgery, and meperidine boluses by patient request, is as effective as PCA in controlling postoperative pain in a LRYGBP model. In this study, the ON-Q® pain pump was shown to effectively control pain, while significantly reducing the aggregate dose of opioids administered.

One of the surprising results of this study was the observation that the incidence of nausea did not differ between the two groups, despite dramatically less opioid use in the ON-Q® pump group. Postoperatively, we found that low rates of nausea are achievable, not by utilization of the ON-Q® pain pump, but by our aggressive prophylactic use of anti-emetic agents on all patients and our extremely brief anesthetic times (our current average operative time for LRYGBP is under 1 hour). This finding is a departure from past studies, which showed that the ON-Q® pain pumps also reduced nausea. We also believe that our rates of nausea are lower, because we rarely use morphine sulfate. Morphine sulfate was originally part of the study, but was discontinued as part of the therapeutic regimen when the first three patients receiving it registered nausea scores that were much higher than those who received meperidine. The similar nausea scores of the two groups resulted from our aggressive perioperative anti-emetic regimen, which is predicated on prior studies in this surgical arena.[12,13]

Some may criticize our use of meperidine for postoperative pain control. The common belief is that it causes seizures. To the present, and having treated 2,000 patients with meperidine, we have never experienced this complication. Demographically, the majority of meperidine-induced seizures occur in patients with pre-existing chronic renal failure who receive both IV bolus and PCA meperidine.[14] Thus, in patients who have impaired renal function preoperatively, we use morphine sulfate postoperatively. In otherwise normal individuals, we continue to rely on meperidine, because it causes less nausea.

One criticism of this paper might be our use of an EEA stapler to perform the gastrojejunal anastomosis. This form of LRYGBP is potentially more painful than both the linear stapler technique or the completely hand-sewn technique, because it requires placement of the stapling device within the abdominal cavity through a larger incision. This incision must be dilated as we described, or, alternatively, the fascial incision must be enlarged. Using either technique, the fascial incision is obligatorily closed and this can be painful. With 12-mm ports that have dilating trocars, the manufacturer of our trocars (Ethicon) claims that these need not be closed. This clearly results in less pain. Therefore, proponents of hand-sewn or partially hand-sewn anastomoses could rightfully claim that those variations of the LRYGBP are less painful, as port-site closure is unnecessary. However, if all 10-mm (or greater) port-sites are closed with fascial sutures, then the pain that their patients experience would be greater than using our technique. As described above, our technique has been used on over 700 of our patients without an anastomotic leak. We have had only one leak in our last 1,400 patients and this patient had, as causation, an incarcerated umbilical hernia.

Another criticism of our pain regimen that others may find unusual was our use of oral pain medication on the evening of the operative day. This expedites the transition to a clear liquid diet, promotes a sense of well-being, and allows patients to accelerate more rapidly into activities of daily living. Additionally, oral pain medication has a smoother onset and longer duration of action, eliminating the need for frequent boluses. It also delivers acetaminophen to the patient, which exerts its synergistic pharmacologic effect on an alternative pain pathway.

Perhaps the greatest criticism of this paper is the acknowledgement that this study was funded by the I-Flow Corporation. However, all PACU and surgical unit nurses responsible for recording pain scores and administering pain medications, were unaware of I-Flow Corporation funding. Inasmuch as the authors did not participate in the pain evaluation or administration of opioids, charges of author-outcome-bias should be minimal.

In our experience, we found that eliminating the use of perioperative Foley catheters can further reduce patient discomfort. We are comfortable with this practice, because our operating times (mean 1 hour) and length-of-stay (mean 18 hours) are so brief. Postoperatively, this practice allows the patient to move easily in bed and ambulate to the bathroom without undue encumbrance. Corroborating this practice, a recent study showed lack of correlation between intraoperative urinary output (UOP) and postoperative renal failure.[15] Furthermore, reduced postoperative UOP is one of the last signs of an anastomotic leak, occurring long after fever and tachycardia. Despite this evidence, some surgeons and anesthesiologists are uncomfortable without measured UOP, and under these circumstances the practice of Foley catheterization should continue.

In conclusion, this prospective, randomized study found that use of the ON-Q® pain pump dramatically reduces the use of postoperative opioid analgesics from discharge in the PACU to the first postoperative morning at 06:00 hrs. Use of the ON-Q® pain pump accomplishes this postoperatively without compromising pain scores and without the use of a PCA pump.

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