Improved pain control after cardiac surgery: Results of a randomized, double-blind, clinical trial

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Objective: We sought to determine whether a continuous regional infusion of a local anesthetic delivered to the operative site would result in decreased levels of postoperative pain and narcotic requirements for patients who undergo a standard median sternotomy for cardiac surgery.

Methods: A double-blind, randomized, controlled trial was conducted at a single center. Patients who were undergoing elective coronary artery bypass graft surgery alone or combined with laser transmyocardial revascularization received bilateral intercostal nerve blocks with either ropivacaine or saline. At wound closure, 2 catheters with multiple side openings were inserted percutaneously and placed directly over the sternum. The same agent (ropivacaine vs saline) was then administered as a continuous regional infusion for 48 hours through an elastomeric pump. Requirements for postoperative systemic narcotic analgesics and pain assessment scores were recorded for 72 hours after the operation. Secondary outcome measures were hospital length of stay and pulmonary function test results. Pain scores and narcotic use on the second postoperative day were also compared to avoid the confounding influence of anesthesia administered at the time of the operation.

Results: The total amount of narcotic analgesia required by the ropivacaine group was significantly less than that of the control group (47.3 vs 78.7 mg, respectively; $P = .038$). The ropivacaine group required less narcotics on postoperative day 2 as well (15.5 vs 29.4 mg, $P = .025$). The mean overall pain scores for the ropivacaine group were significantly less than the mean overall scores for the normal saline group (1.6 vs 2.6, respectively; $P = .005$). Patients receiving ropivacaine had a mean length of stay of 5.2 days compared with 8.2 days for patients in the normal saline group ($P = .001$). Excluding the data from outliers (length of stay = 39 days), the normal saline group mean length of stay was 6.3 days ($P < .01$). There was no difference in assessment of pulmonary function.

Conclusion: Continuous delivery of local anesthetics significantly improved postoperative pain control while decreasing the amount of narcotic analgesia required in patients who underwent standard median sternotomy. There was also a significant decrease in hospital length of stay, which is likely to result in significant cost reductions.

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Inadequate pain control after coronary artery bypass surgery and other thoracic and abdominal operations can result in increased morbidity and hospital length of stay (LOS).¹⁻⁴ Many factors have been found to contribute to unrelieved pain after an operation, including the reluctance or inability on the part of patients to ask for needed pain medication. The reluctance of physicians to prescribe or the nurses to administer adequate doses of analgesics also contributes to inadequate pain control.^{5,6} Standard management of postoperative pain is with opioid analgesics, such as morphine sulfate. However, opioid effects, such as respiratory depression, nausea, vomiting, decreased gastrointestinal motility, and peripheral vasodilation, can potentially worsen the patient's condition and result in unfavorable outcomes, extended hospital stays, and increased costs.^{1-4,7} Conversely, improved postoperative pain control has been demonstrated to have numerous physiologic benefits.^{8,9} In recognition of the need for improved pain management, the Joint Commission on Accreditation of Healthcare Organizations has recently developed new standards for the assessment and management of pain in accredited hospitals and other health care settings.¹⁰ The resurgence of interest in pain control and the recent attempts to fast-track patients stimulated our interest in postoperative pain control after routine median sternotomy, which is routinely used for cardiac surgery.

Multimodal analgesia, the combination of different modes of delivering analgesia, has been shown to be more effective than any single method of reducing pain. Multiple studies with regional anesthesia strategies in combination with systemic analgesics have demonstrated improved patient outcomes, including decreased LOS.^{3,11} One such strategy, the use of nerve blockade followed by a continuous infusion of a long-acting local anesthetic at the operative site, has shown improved outcomes in several randomized clinical trials.^{3,11} However, this approach has never been studied after a standard median sternotomy, which is routinely used to perform coronary artery bypass surgery and other cardiac surgery procedures. More than 700,000 median sternotomies are performed annually in the United States alone.¹² Improved pain control and subsequent improved patient outcomes would provide a substantial national health care benefit. We report the results of a randomized, double-blind, clinical trial of intercostal nerve blocks with either ropivacaine (a long-acting local anesthetic) or normal saline, followed by continuous regional infusion of the same agent (saline vs anesthetic) on outcomes after coronary artery bypass surgery.

Methods

Study Screening and Enrollment

The study population included adult patients who underwent elective coronary artery bypass graft (CABG) surgery or CABG with the addition of transmyocardial revascularization (CABG/TMR).

All patients underwent a standard median sternotomy. The exclusion criteria included a left ventricular ejection fraction of less than 35%, severe acute or chronic lung disease, acute or chronic renal insufficiency (creatinine level of $>176.8 \mu\text{mol/L}$ [2.0 mg/dL]), congestive heart failure, level of liver disease (bilirubin level of $>1.8 \times$ ie, the upper limit of normal at screening), inadequate hematologic function (defined as a hemoglobin level of $<95 \text{ g/L}$, white blood cell count of $<3.0 \times 10^9/\text{L}$, neutrophil count of $<1.2 \times 10^9/\text{L}$, and platelet count of $<100 \times 10^9/\text{L}$), or the inability to understand and sign an institutional review board-approved consent form. These exclusion criteria were chosen to allow for the exclusion of high-risk patients who might require prolonged intubation and therefore not be able to complete the study protocol.

Each patient was given a face-to-face detailed study explanation by the surgeon before the initiation of any protocol-mandated procedure. After informed consent was obtained, patients were introduced to the visual analog pain scale used to rate their incision pain on a scale ranging from 0 (no pain) to 10 (maximum pain imaginable). Study participants were informed that they would receive intravenous narcotics by means of a patient-controlled analgesia (PCA) pump. Patients were instructed the day before the operation on how to use the PCA pump. Patients were also instructed on the use of a microspirometer and a peak flowmeter. Baseline measurements of forced expiratory volume in one second (FEV₁) and peak expiratory flow were measured the evening before operative therapy was started.

This study did not incur any additional cost to the patient. All costs associated with the cardiac surgery were considered standard of care and were billed to the patient's insurance carrier. The ON~Q Pain Relief System (I-Flow Corp, Lake Forest, Calif), which provides the continuous infusion of local anesthetic or saline control, was provided by the manufacturer. The local anesthetic (ropivacaine [Naropin]; AstraZeneca, Wilmington, Del) was provided free of cost by the manufacturer. The manufacturers did not contribute to the design of the study or the correction, analysis, or interpretation of the data. Also, they did not participate in the decision to submit the study for publication. The standard hospital cost for the ON~Q7 Pain Relief System, which includes the catheters and elastomeric pump, priming syringes, and patient carrying case, is \$180 to \$375 per patient. The cost for the local anesthetics in the dose used for the duration of the study is approximately \$80.

Operative Procedures

Anesthetic management was standardized in an attempt to eliminate the effects of different anesthetic regimens on postoperative pain levels. Short-acting anesthetics were used to minimize the presence of residual anesthetic agents in the postoperative period. Patients were medicated on call to the operating room with up to 0.15 mg/kg morphine sulfate administered intramuscularly, 2 to 5 mg of Versed (midazolam HCl; Roche Laboratories, Nutley, NJ) administered intramuscularly, and scopolamine (American Pharmaceutical Partners, Schaumburg, Ill). Younger patients received 0.4 mg of intramuscular scopolamine, patients older than 65 years of age received 0.2 mg of intramuscular scopolamine, and patients greater than 70 years of age did not receive scopolamine. Induction of anesthesia was begun with administration of 10 $\mu\text{g/kg}$ intravenous fentanyl. In addition, a 0.5 to 3 mg/kg intravenous bolus of

propofol, a 0.2 to 0.3 mg/kg intravenous bolus of etomidate, or a 1 to 2 mg/kg intravenous bolus of sodium thiopental was administered. Succinylcholine chloride (INN: suxamethonium), 1.5 mg/kg, was administered for intubation. Pancuronium bromide was used for defasciculation and maintenance of neuromuscular blockade. Maintenance anesthesia was with isoflurane and fentanyl as needed to maintain the bispectral index (BIS) at less than 50. During cardiopulmonary bypass (CPB), isoflurane alone was given to maintain the BIS at less than 50. Before weaning from CPB, patients received 2 mg of Versed intravenously. After CPB, anesthesia was with 25 to 250 $\mu\text{g} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ isoflurane and propofol as needed to maintain the BIS at less than 50.

During transportation to the recovery area and for the first 2 hours postoperatively, the patients received 25 to 250 $\mu\text{g} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ propofol as needed to maintain adequate sedation for mechanical ventilation. Fentanyl (a short-acting opioid) was given as needed until the patients were awake in the recovery room and able to use a PCA pump. Morphine sulfate was delivered intravenously through the PCA pump for 72 hours. Patients who were allergic to morphine sulfate received meperidine (Demerol; INN: pethidine) through the PCA pump at equivalent doses. PCA orders were written stating the loading dose (2-4 mg), the PCA dose (0.6-1.5 mg) with a lockout time (6-10 minutes), the continuous dose (1-4 mg/h), and the dose limit (30 mg maximum) in 4 hours. Patients did not receive nonsteroidal anti-inflammatory agents. In our experience these drugs are often stopped because of concerns about bleeding and especially renal dysfunction. Therefore these drugs were not used for this study.

CABG was performed by using standard techniques. Laser TMR was performed in patients who had areas with left ventricular myocardium that were ischemic but not amenable to bypass grafting. Before wound closure, bilateral intercostal nerve injections from T1 to T12 were performed by using 20 mL of either 0.2% ropivacaine (AstraZenca) or normal saline (placebo). After reapproximation of the sternum with wires, two 20-gauge catheters with multiple side openings were placed anterior to the sternum (Figure 1). These catheters were connected to a pressurized elastomeric pump (ON~Q7 Pain relief system, I-Flow Corp) that contains a flow regulator, which allowed for delivery of placebo or 0.2% ropivacaine at approximately 4 mL/h. These catheters were removed in both groups after 48 hours. Figure 2 shows the participant flow from first contact with study referral staff until completion of the study.

Assignment of the local anesthetic or placebo was made on the basis of a random table created in advance of patient enrollment. All investigators and study staff, including the nurses, were blinded to the identity of the injected solution. Both drugs were prepared by the research pharmacy team. There was no difference in the physical appearance of the study drug or placebo. Ropivacaine is a long-acting amide-type local anesthetic that has a chemical structure similar to that of bupivacaine. However, there is significantly less cardiotoxicity with ropivacaine than with other similar agents, such as bupivacaine.¹³

Postoperative Evaluation

All subjects were evaluated postoperatively in the cardiac intensive care unit (ICU) per hospital standard-of-care guidelines. Routine invasive and noninvasive monitoring was performed. Routine

Figure 1. Intraoperative placement of the pressurized elastomeric pump and catheters.

laboratory tests, chest radiography, and electrocardiographic monitoring were performed per ICU standard-of-care guidelines.

Pain was assessed every 4 hours after the patient was awake and alert by using the same visual analog scale (VAS) administered preoperatively. Patients in both groups received morphine sulfate intravenously or meperidine intravenously through the PCA pump, as ordered by the physician. The total amount of systemic analgesics delivered through the PCA pump in both groups was recorded. Pulmonary function tests were performed after extubation and every 4 hours until discharge from the intensive care recovery area and then daily for 3 days by respiratory therapists trained in the measurement of FEV₁ and peak expiratory flow. Continuous need for supplemental oxygen was based on clinical evaluation and measures of arterial saturation with pulse oximetry. All patients were assigned nurses experienced in the care of patients after cardiac surgery and the conduct of clinical research trials. At the end of each nursing shift, the patient's assigned nurse was asked to fill out a form indicating whether he or she believed the patient had usual pain levels or improved pain control on the basis of an overall clinical evaluation.

Study End Points and Statistical Analysis

The primary end points were postoperative requirements for systemic narcotic analgesia and postoperative pain assessment scores on visual analog pain scales for the first 3 days after the operation. Our secondary end points were narcotic requirements on the second postoperative day; postoperative pulmonary function as measured on the basis of FEV₁ and peak expiratory flow, need for supplemental oxygen, and time to removal of mechanical assisted ventilation; total LOS in the ICU; and total LOS in the hospital.

Figure 2. Participant flow during the study. PCA, Patient-controlled analgesia.

Patients were also evaluated for adverse events that occurred after being enrolled in the study during their hospitalization.

This study was designed to have 80% power to detect a 50% difference in total morphine equivalent dose between groups, with a 2-sided significance level set at .05. A sample size of 40 randomized to ropivacaine or normal saline in a 1:1 manner by using an analysis of variance model with local anesthetic group as the fixed effect in the model was determined adequate to detect a 50% difference in means, assuming a ropivacaine group morphine mean of 30 mg and a control group morphine mean of 60 mg, a common SD of 30, and a 7.5% dropout rate.

Analysis of variance models with local anesthetic group as a fixed effect in the model were used to analyze the primary end points. Repeated-measures analysis of variance models were used to test for differences between groups over postoperative days 1 to 3 for total morphine and postoperative pain scores. The Mantel-Haenszel χ^2 test with standardized midranks was used to analyze LOS (in days). Analysis of variance models with local anesthetic group as a fixed effect in the model were used to analyze the pulmonary function test results and change from baseline data. Demographic and baseline characteristics were analyzed by using

analysis of variance, whereas differences between categorical parameters were tested by using either the Pearson χ^2 or Fisher exact tests. All parameters had descriptive statistics calculated.

Regression models were used to describe the relationship between postoperative pain and total morphine. The models were generated as a descriptive measure of effects within groups and not intended for inferential distinction among groups.

Nonparametric tests were performed when assumptions for a parametric test were violated. Specifically, the Wilcoxon rank sum test was used for between-group testing when analysis of variance assumptions did not apply. When nonparametric tests were reported, the parametric results were included as confirmation of the analysis. All inferential and descriptive analyses were performed at the .05 significance level for a 2-sided test by using SAS (Statistical Analysis Systems) version 8.2 software.

Results

Screening and enrollment for the study began in April 2000 and continued until May 2001. Five patients initially enrolled in the study were excluded from evaluation. Two

TABLE 1. Baseline characteristics (per protocol population)

Characteristic	Ropivacaine (n = 16)	Normal saline (n = 19)	P value
Age (y), mean (95% CIM)	60 (55-66)	60 (56-64)	.861
BSA, mean (95% CIM)	1.9 (1.6-2.2)	2.1 (2.0-2.2)	.201
Sex			
Male	13 (81.2%)	14 (73.7%)	
Female	3 (18.8%)	5 (26.3%)	
Smoking status	4 (25.0%)	9 (47.4%)	.293
Diabetes mellitus	7 (43.8%)	10 (52.6%)	.601
Hypertension	14 (87.5%)	17 (89.5%)	1.000
Myocardial infarction	9 (56.3%)	10 (52.6%)	.831
Hyperlipidemia	12 (80.0%)	16 (84.2%)	1.000
History of coronary artery disease	13 (81.3%)	16 (84.2%)	1.000
Prior history of operation	9 (56.3%)	6 (35.3%)	.227
Ejection fraction (%)			—
35%-45%	6 (37.5%)	7 (38.9%)	—
50%-70%	10 (62.5%)	11 (55.8%)	
Missing/unknown	0	1 (6.3%)	
Time of anesthesia (h:min), mean (95% CIM)	4:36 (4:08-5:03)	4:31 (4:12-4:50)	.748
Time to extubation (h:min), mean (95% CIM)	8:16 (6:10-10:21)	7:17 (5:01-9:32)	.509

CIM, Confidence interval of the mean; BSA, body surface area.

patients who were randomized to the ropivacaine group were excluded before treatment because of abnormalities on the intraoperative echocardiogram (severe mitral regurgitation in one and left ventricular ejection fraction of <35% in the other). Three patients required prolonged intubation and received additional sedation. Two of these patients were randomized to ropivacaine and one to placebo. Because of the additional sedation, these patients were not able to operate a PCA pump or perform other outcome measurements.

Participants in the 2 groups were similar in all clinical and demographic respects (Table 1). The majority of participants were male, with a history of hypertension, hyperlipidemia, coronary artery disease, and a previous myocardial infarction. There was no difference in the 2 groups in the use of the left internal thoracic artery or the use of TMR. All patients had use of the left internal thoracic artery, and additionally, one patient had use of both internal thoracic arteries. There was no difference in the incidence of arrhythmias between the 2 groups. Specifically, there was no difference in the incidence of postoperative atrial arrhythmias.

The ropivacaine group reported significantly less pain than the normal saline group. The mean overall VAS score for the ropivacaine group was significantly less than the mean overall VAS score for the normal saline group (1.6 vs 2.6, $P = .005$). Total narcotic use was significantly less with the ropivacaine group (all narcotics were converted to morphine equivalence) versus the control group (47.3 vs 78.7 mg, respectively; $P = .038$). Because patient assessment of pain in the first 24 hours after surgical intervention might be

influenced by residual anesthetics administered during the operation, narcotic requirements on postoperative day 2 were also assessed as an independent measure. Significantly less narcotics were required by the ropivacaine group on postoperative day 2 (15.5 vs 29.4 mg, $P = .025$).

In the ropivacaine group the mean LOS was 5.2 ± 1.3 days, with a range of 3 to 7 days. Patients in the control group had a mean LOS of 8.2 ± 7.9 days, with a range of 4 to 39 days. The ropivacaine group had a significant decrease in mean LOS compared with the control group ($P < .001$). There was one patient in the placebo group who had a long LOS (39 days). The difference in LOS between the 2 groups remained significant, even if this datum was excluded from analysis (5.2 ± 1.3 vs 6.3 ± 2.8 days, $P < .01$). Narcotic use, pain score evaluations, and LOS are summarized in Table 2.

A regression model can be used to graphically demonstrate the difference between pain scores and narcotic requirements over the study period. These data are presented in Figure 3. The vertical axis represents an objective evaluation of pain, and the horizontal axis represents the total narcotic use (in morphine equivalents) over the length of the study. A steeper curve indicates the pain level is less responsive to the intravenous narcotics that were delivered by means of the PCA pump. A steeper curve is seen in the control group, and a relatively flat curve is seen in the ropivacaine group.

As noted, the patient's primary nurse indicated at the end of each shift whether he or she believed that the patient had usual pain levels or improved pain control. In the group

TABLE 2. Results of primary end points

Parameter evaluated	Ropivacaine (n = 16)	Normal saline (n = 19)	P value
Total morphine (mg)			.038
Mean (95% CIM)	47.3 (31.0-63.6)	78.7 (51.1-106.2)	
Median	45.1	76.1	
Min-Max	2.0-107.0	12.0-263.7	
Overall VAS scores, mean (95% CIM)	1.6 (1.2-2.1)	2.6 (2.1-3.1)	
VAS repeated measures			
Day			<.001
Treatment			.0195
Day by treatment			.9961
LOS, mean (95% CIM)	5.2 (2.2-8.2)	8.2 (5.4-10.9)	.001

CIM, Confidence interval of the mean; VAS, visual analog scale; LOS, length of stay.

treated with ropivacaine, pain control was evaluated as improved in 94% and usual in 6%. In the control group pain control was evaluated as improved in 54% and usual in 46%. These differences were statistically significant ($P < .01$).

There was a trend toward improvement in pulmonary function tests in the ropivacaine group that did not reach statistical significance. This trend was seen on the first 3 postoperative days. The mean FEV₁ was increased 20% on postoperative day 1, 14% on postoperative day 2, and 17% on postoperative day 3 in the treated group. The mean peak expiratory flow was increased 12% on postoperative day 1, 19% on postoperative day 2, and 10% on postoperative day 3 in the ropivacaine group. There was no difference in need for supplemental oxygen, time on mechanical-assisted ventilation, or LOS in the ICU.

There was no drug toxicity identified in either group. No patients were dropped from either arm of the study because of concerns about drug toxicity. There was no difference in wound infections or wound healing between the groups during hospitalization or after discharge. There were no complications related to placement of the catheters or performance of the intercostal nerve blocks.

Discussion

The effective relief of pain after operative therapies is of paramount importance to patients and health care providers. In addition to achieving pain control for humanitarian reasons, there is now increasing evidence that improved postoperative pain management has significant physiologic benefits. Conversely, inadequate pain control has been shown to result in an increased incidence of atelectasis and significantly lower tissue oxygen levels, which can predispose to infection.^{8,9} After ambulatory surgery, inadequate pain control is one of the leading reasons for hospital readmission.⁷ Recently, the Joint Commission on Accreditation of Healthcare Organizations has developed new standards for the

assessment and management of pain in accredited hospitals and other health care settings.¹⁰ The new standards definitively acknowledge that pain is a coexisting condition with a number of diseases and injuries and requires explicit attention.

More than 750,000 heart operations are performed annually in the United States alone.¹² Almost all of these operations are performed through a standard median sternotomy incision. Recent advances in operative therapies and improved anesthetic techniques have allowed for early extubation and fast-tracking of these patients. However, there have been no advances in methods to improve the control of pain after a median sternotomy. Isolated studies have advocated the use of epidural or intrathecal anesthetics in patients who undergo median sternotomy.^{14,15} However, these techniques have not been adopted because of concerns over respiratory depression and epidural hematomas in patients who require full anticoagulation during surgical intervention.

There has been a resurgence of interest in the use of continuous administration of local anesthetics to create a regional field block in other surgical specialties. This approach has resulted in a significant decrease in pain scores and narcotic use after elective cesarean delivery.¹⁶ Regional infusion of ropivacaine after colon and rectal surgery has resulted in significantly improved pain control, decreased narcotic requirements, and quicker return of bowel function.¹¹ Improved pain control with this approach has also been seen after orthopedic surgery, pelvic surgery, and thoracic operations performed through a standard thoracotomy.^{3,16,17} These studies also demonstrated that the regional infusion of anesthetic does not increase the incidence of wound complications. Most studies have shown a trend toward a lower infection rate, which has been hypothesized to be due to the antimicrobial action of bupivacaine.¹⁸ Regional anesthetics have been used after minimally invasive coronary artery bypass surgery performed through a limited left anterior thoracotomy incision.^{19,20} This technique decreased chest wall pain and had fewer complications compared with those seen in control subjects. However, the use of a thoracotomy for cardiac surgery is quite limited, and the vast majority of patients undergo a median sternotomy. These studies demonstrate the safety and efficacy of this technique. However, the pharmacokinetics of continuous regional infusion of anesthesia have not been well studied. One study showed that low levels of ropivacaine are seen in the serum with this technique.¹⁷ The use of regional anesthetic techniques has not previously been described after a standard median sternotomy for cardiac surgery.

This study demonstrates that the use of continuous regional infusion of a long-acting local anesthetic will result in less pain and less narcotic use after a standard median

Figure 3. Predicting mean postoperative pain for morphine levels in groups.

sternotomy for cardiac surgery. In an attempt to provide a clinical assessment of treatment outcome, the primary nurses were asked to assess the level of pain control for each patient. The nurses were blinded to the study and were significantly more likely to assess the patients in the treated group as having improved pain control. There was also a significant decrease in hospital LOS in the treatment group. Given the high volume of cardiac surgical procedures, any incremental improvement in LOS will likely result in substantial cost benefits. This study was powered to show a difference in postoperative pain levels and narcotic requirements, and therefore the small sample size precluded statistical analysis of other outcomes, such as hospital costs. The actual difference in hospital cost was 8% less in the treated group. Although the cost data did not reach statistical significance, cost savings of this magnitude would result in substantial national cost benefits. On the basis of an average cost of \$24,000 for coronary artery bypass surgery, a cost savings of 8% would result in savings of \$1.4 billion each year in the United States alone.

One concern with any new therapy is whether the approach will be adapted by practicing clinicians. The administration of bilateral intercostal nerve blocks and placement of the catheters at operation are straightforward and do not require the use of new techniques. After the operation, the elastomeric pump does not require any adjustment or care by physicians or the nursing staff. Our current practice is to use this system for essentially all patients who have median sternotomies. The exception is for patients who we anticipate will require prolonged intubation and intravenous sedation.

In summary, advances in operative therapy and anesthetic techniques have allowed for rapid recovery of patients after cardiac surgery. These advances, along with the increased emphasis on pain control, have highlighted the need for improved strategies of pain management after median sternotomy. In this double-blind, randomized, clinical trial we demonstrated that the use of continuous infusion of local anesthetic after standard median sternotomy results in less postoperative pain, decreased need for systemic narcotics, and decreased LOS. These results and the large number of patients who require median sternotomies for cardiac surgery indicate that this approach might provide substantial national health care benefits.

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