

A randomized trial of postoperative wound irrigation with local anesthetic for pain after cesarean delivery

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OBJECTIVE: The purpose of this study was to investigate the efficacy of continuous local anesthetic infusion system for pain control after cesarean delivery.

STUDY DESIGN: This was a randomized prospective double-blind study. Patients who underwent cesarean delivery had a pain system implanted subcutaneously after closure of the fascia. Patients were randomized to receive an infusion of either 0.25% bupivacaine (n = 20) or normal saline solution (n = 16) into the wound for 48 hours. Postoperative pain (determined with a visual analog scale) and postoperative morphine use were assessed at 12, 24, and 48 hours.

RESULTS: There were no significant differences in patient demographics or visual analog pain scores at any time interval between the bupivacaine versus the placebo group. However, narcotic requirements to produce this amount of pain relief were significantly less in patients who received bupivacaine infusion rather than normal saline solution at all time intervals.

CONCLUSION: The continuous local anesthetic infusion system appears to be effective in reducing postoperative morphine use after cesarean delivery. (Am J Obstet Gynecol 2002;186:1188-91.)

Key words: Pain control, cesarean delivery, local anesthetic

Treatment of postoperative pain continues to be an ongoing concern. The injection of local anesthesia into the wound has been shown to reduce postoperative incisional pain in several studies.¹⁻⁷ However, other studies have shown no benefit.⁸⁻¹³ Recently, the Federal Drug Administration has approved a device (On-Q Pain Management System; I-FLOW Corporation, Lake Forest, Calif) that provides continuous irrigation of local anesthesia into the incision; however, there are no data to support the efficacy of this device in the treatment of postoperative pain.

The purpose of this study was to investigate the efficacy of the On-Q Pain Management System for pain control after cesarean delivery.

Material and methods

After institutional review board approval, pregnant women who would undergo cesarean delivery with epidural anesthesia at the Regional Medical Center of Memphis and who met inclusion criteria were recruited for the study. Inclusion criteria included planned Pfannenstiel incision, the absence of coagulopathy, HELLP

(hemolysis, elevated liver enzymes, and low platelet count) syndrome, or infection. No patients with a history of narcotic use in the pregnancy or a history of narcotic abuse were enrolled. Participating patients were randomized to receive a system filled with either 0.25% bupivacaine (n = 20) or normal saline solution (n = 16), based on a computer-generated randomization schedule. Sealed packets that contained group assignments were shuffled and drawn randomly to further prevent knowledge of the contents of any 1 envelope. Before the operation, the pain pump reservoir was filled by 1 of the investigators with the assigned solution and delivered to the operating team. Surgeons, patients, and subsequent data recorders were blinded to the assignment of control versus study group. Obstetric and gynecology residents who were under attending staff supervision performed all cesarean deliveries and pain pump implantation. A member of the resident team recorded the patients' subsequent visual analog pain scores and the cumulative amount of morphine used.

The On-Q Pain Management System consists of an elastomer pump connected to one or two 20-gauge latex infusion catheters. The system used in this study uses 2 catheters to deliver a total of 4 mL of solution per hour. The terminal 2.5 inches of each catheter is perforated with holes to allow anesthetic delivery along the entire distal segment. After the fascia had been closed in the usual fashion, introducers were used to place the 2 infusion catheters into the incision. The catheters were initially introduced through the skin approximately 5 cm

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Table I. Demographics of patients who received bupivacaine versus normal saline solution therapy

Demographic	Bupivacaine (n = 20)	Normal saline solution (n = 16)	P value
Age (y)	24.0 ± 4.6	24.6 ± 5.5	.74
Gravidity (No.)	2.8 ± 1.3	2.9 ± 1.6	.80
Parity (No.)	1.5 ± 1.2	1.6 ± 1.7	.82
Body mass index (kg/m ²)	35.0 ± 9.3	33.0 ± 6.2	.49
Gestational age at delivery (wk)	38.0 ± 3.0	38.9 ± 1.0	.26
Birth weight (g)	3055.1 ± 769.4	3429.2 ± 569.0	.11

Data given as mean ± SD.

Table II. VAS for pain and amount morphine used by time interval

	Bupivacaine (n = 20)	Normal saline solution (n = 16)	P value
VAS			
12 h	3.8 ± 2.5	4.0 ± 2.9	.82
24 h	4.1 ± 2.7	4.1 ± 2.5	.97
48 h	1.8 ± 1.7	2.3 ± 3.1	.55
Morphine (mg)			
12 h	25.8 ± 13.4	43.3 ± 16.3	<.01
24 h	46.8 ± 23.6	78.9 ± 28.5	<.01
48 h	72.7 ± 43.7	128.4 ± 55.5	<.01

Data given as mean ± SD.

above the incision in the midline. They were then advanced into the subcutaneous space of the incision. Catheters were positioned directly over the fascia, with their tips extending to the ends of the incision. The subcutaneous tissue was then infiltrated with 25 mL of the assigned solution. The overlying skin incision was closed with staples. The system was left in place for 48 hours.

All patients were placed on morphine patient-controlled analgesia (PCA) pumps in the recovery room. Standardized orders for the PCA included an initial loading dose of 2 mg, followed by a 1-mg bolus every 6 minutes on demand. Lockout was set at 8 mg per hour. Inadequate pain relief with these settings resulted in 1-mg incremental increases of the boluses to a maximum of 4 mg every 6 minutes on demand. Lockout settings were not altered if the settings were increased. Basal rates were not used to determine the exact amount of narcotics needed for pain control.

Postoperative pain was assessed with a visual analog scale (VAS) that consisted of a 10-cm horizontal line with vertical anchors at each end. One end was labeled “No Pain,” and the other end was labeled “Worst Pain Possible.” Patients were asked to mark the point on the scale that corresponded to their pain. The VAS was recorded at 12, 24, and 48 hours after the procedure. The amount of morphine used at 12, 24, and 48 hours was also recorded. Records were reviewed for the incidence of postoperative complications that included wound infection or wound breakdown.

Data were analyzed with the Student *t* test with a probability value of .05 considered significant.

Results

There was no difference in patient demographics between the 2 groups with respect to age, gravidity, parity, and body mass index (Table I). Twenty-six of the 36 patients (72%) had repeat cesarean deliveries. Fourteen of these 26 patients (54%) were randomized to receive bupivacaine solution, and 12 patients (46%) were randomized to received placebo. Of the patients who underwent a primary cesarean delivery, 6 of the 10 patients (60%) received bupivacaine. No patient had a failed epidural analgesia. A wound cellulitis developed in 1 patient in the bupivacaine group. This patient was a undergoing a repeat cesarean section and had no other risk factor for wound infection, except obesity. No wound breakdowns occurred in either group. No patients expressed any aesthetic concerns over the 2 catheter insertion sites after removal of the 20-gauge catheter.

There was no significant difference in VASs for pain perception at any time interval between the bupivacaine versus the placebo group. Mean pain scores were 3.8 versus 4.0 at 12 hours, 4.1 versus 4.1 at 24 hours, and 1.8 versus 2.3 at 48 hours for bupivacaine and saline solution, respectively. However, the amount of morphine required to effect the same degree of postoperative pain relief was significantly less with local infusion of bupivacaine than normal saline solution at all time intervals. Cumulative milligrams of morphine used were 25.8 versus 43.3 at 12 hours, 46.8 versus 78.9 at 24 hours, and 72.7 versus 128.4 at 48 hours for bupivacaine and normal saline solution, respectively. These data are reflected in Table II.

Comment

The most appropriate method for the treatment of postoperative pain after cesarean delivery remains uncertain. Options currently used include the use of periodic injections of parenteral narcotics either intramuscularly or intravenously, oral narcotics with or without concomitant nonsteroid anti-inflammatory agents, and continuous epidural anesthesia. Narcotic use in the postpartum patient is associated with decreased mentation, slow return of bowel function, and passage of narcotics in the breast milk. Unless PCA is used, delivery of the narcotic may be delayed by other demands on the nursing staff. Likewise, the time spent delivering narcotics may detract from the performance of other nursing services. Continuous epidural anesthesia requires an indwelling epidural catheter, with the increased possibility of infection and the need for trained anesthesia personnel. The injection of local anesthesia before or after incision has been shown in some studies to provide short-term pain relief after the operation.¹⁻⁷ Few studies have evaluated the use of local anesthesia after cesarean delivery.^{3,7,11} These studies have shown conflicting results. The bathing of subcutaneous tissue with local anesthesia before skin closure has been shown to reduce postoperative pain after inguinal herniorrhaphy.⁵ The use of a PCA machine to deliver local anesthesia into the wound on demand has not been shown to be effective in reducing postoperative pain after nonobstetric major abdominal operation.⁸ However, its use has been shown to reduce morphine requirements after cesarean delivery.³ Unlike a PCA machine, which provides local anesthesia only on demand, the device used in this study provides continuous local anesthesia into the subcutaneous tissue of the wound. Theoretically, it would provide more complete anesthesia than intermittent infusion on demand.

This study was performed in a randomized, blinded manner that would be expected to minimize most confounding variables. One potential variable that would not be eliminated is the possibility that the placebo was not inactive. The infusion of normal saline solution or the presence of the catheter alone might produce tissue irritation that could result in increased pain over baseline. In such a scenario, the bupivacaine infusion might have minimal or have no effect, although the placebo could cause additional pain. Although the results would appear similar (ie, less narcotic use in the bupivacaine group), the true effect would be the result of increased narcotic use in the placebo group.

The reported cost of the device to the hospital at the time of the study would have been \$140. The cumulative 56-mg decrease in morphine use would not alone be expected to offset the cost of the system and local anesthetic. However, this study did not attempt to address return to activities, return of bowel function, or length of

postoperative hospitalization. The decreased use of narcotics could favorably affect these variables. Although this system was only kept in place for 48 hours, it can supply local anesthetic for up to 5 days. Theoretically, the patient could be discharged with the system in place for continued outpatient pain treatment.

The system used here delivers local anesthetic through two 20-gauge catheters. The insertion sites are almost unnoticeable after removal of the system. However, leakage of the excess solution through the incision results in an increased need for dressing changes and patient reassurance, which this is not unusual. Although patients who require vertical incisions were not enrolled in this study (to avoid adding another variable), placement of the system could easily be performed through insertion sites lateral to the incision.

The use of subcutaneous local anesthesia after cesarean delivery would not be expected to have an effect on uterine pain. However, it is uncertain what proportion of pain after a cesarean delivery is produced by superficial structures and what proportion is produced by deeper visceral structures. Furthermore, according to some neural pain pathway theories, the stimulation of superficial pain receptors may further sensitize the nervous system to painful sensation. Thus, elimination of some of the superficial components of the pain after cesarean delivery could modulate the perception of deeper visceral pain.

The data from this study suggest that the use of a continuous infusion of local anesthesia into the wound after cesarean delivery appears to be effective in reducing postoperative narcotic requirements. Furthermore, the significant reduction in narcotic use that was associated with the infusion of local anesthetic in this study suggests that a substantial amount of this pain is superficial in origin.

On-Q Systems were provided by Ethicon Endosurgery.

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