Open Journal of Surgery

Research Article

Effect of Continuous Local Anesthetic use for Pain Control and Narcotic use after Cesarean Section: A Randomized Trial

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Submitted: 09 November 2017; **Approved:** 18 December 2017; **Published:** 20 December 2017

Cite this article: Yaklic JL, Maxwell RA, Urschel KB, Robinson S, Dearmond MK, et al. Effect of Continuous Local Anesthetic use for Pain Control and Narcotic use after Cesarean Section: A Randomized Trial. Open J Surg. 2017;1(1): 026-030.

ABSTRACT

Background: Post-operative pain control after Cesarean delivery is a major concern for both patients and physicians. The current literature provides mixed results on the effectiveness of the local continuous infiltration of anesthesia for pain control and reduction of morphine use.

Methods: This was a randomized, double-blind, placebo controlled trial with a 1:1 group allocation. Fifty women who had a Cesarean delivery were randomly assigned to receive bupivacaine (Bupivacaine group) or saline (Saline group) delivered via locally placed catheters at the sub-fascial plane and at the uterine incision. Forty women (20 per group) completed the study. Total post-operative narcotic use and analog pain scale scores were used to evaluate efficacy of treatment at 6, 12, 24 and 48 hours after surgery.

Results: There was a reduction in pain and narcotic use in the Bupivacaine group at 6, 12, and 48 hours ($p < 0.09$). Regardless of group assignment, women who had a prior Cesarean section, versus primagravida women, had a higher total narcotic use (58.06 mg vs. 38.28 mg, respectively; $p < 0.03$).

Conclusions: Dual catheter placement and infusion of bupivacaine has potential to decrease the use of narcotics and decrease pain following cesarean section, however, given the small sample size in this study, a significant difference between groups could not be delineated. Further study is indicated to investigate catheter placement and its effects on pain control and narcotic use.

Keywords: Bupivacaine; Cesarean Delivery; Continuous Local Anesthesia; C-Section; Narcotic Use, On-Q™; Pain Control

INTRODUCTION

Cesarean delivery occurs in approximately 32% of deliveries in the United States [1]. The most conventional methods for postoperative pain control for these patients include IV narcotic pain medication (either intermittent or through Patient Controlled Analgesia (PCA)), intrathecal long-acting narcotics and/or oral narcotic with or without NSAIDs. These methods provide acceptable pain relief but are nursing intensive and have the potential for adverse effects including patient sedation, reduced mentation, respiratory depression, and decreased bowel function [2]. Moreover, narcotics have the disadvantage of being excreted into breast milk [3]. Patients often desire to withhold or minimize narcotic administration due to these side effects and concerns including safety and addiction potential. These issues and other extraneous factors result in postoperative obstetrical pain control that is often suboptimal. High quality postoperative analgesia is very important for the recovery of the patient. There are many options available, but tailoring the method of choice to each patient can be problematic. In addition, predicting the severity of an individual's post-operative pain or the patient's response to the regimen continues to be a challenge [4]. A locally delivered, patient controlled method would be advantageous. The use of the iFlow On-Q™ wound irrigation system for localized pain control has been shown to be effective for reducing narcotic use after abdominal surgery [5-8]. Randomized controlled trials have demonstrated the effectiveness of wound irrigation versus placebo for reducing narcotic use after Cesarean delivery [9]. There is a growing literature examining its use after obstetrical surgery where placement of the catheter has been examined at several positions including at the fascial or below the sub-fascial planes. However, differences in study designs and the inconsistency in the catheter placement hampers interpretation of the findings [7]. To our knowledge, when the wound irrigation system catheter has been placed at the subcutaneous tissue above the fascial plane, patients receiving bupivacaine had lower narcotic use when compared to patients receiving saline, however the medication group did not report lower pain scores [2]. When the wound irrigation system catheter was placed at the sub-fascial plane, it was superior in reducing narcotic use and pain when compared to postoperative multimodal systemic analgesia that included acetaminophen, nefopam, celecobix, and patient controlled intravenous morphine for 24 hours [10]. In contrast, with placement at the sub-fascial plane, patients receiving levobupivacaine by epidural (and saline by catheter) had lower pain scores during the first four hours after surgery than patients receiving levobupivacaine by catheter (and saline by epidural), though after four hours, both groups had similar pain scores and both had similar total narcotic use [11]. In a randomized study by Rackelboom et al, patients who received the wound irrigation system catheter placement below the fascia, had lower narcotics use and lower pain scores compared to those patients with catheter placement above the fascia [12]. To date, no study has examined pain control using a local wound irrigation to both the sub-fascial plane and uterine incision via placement of a dual catheter system. The purpose of the study was to investigate the efficacy of continuous wound irrigation system with local anesthetic to both the sub-fascial plane and the overlying uterine incision in the peritoneal cavity after Cesarean section for the reduction of post-operative pain and narcotic use.

METHODS

This study was a randomized, double-blind, placebo controlled trial that was conducted under a research protocol (IRB # 3179) approved by the Wright State University Institutional Review Board (Dayton, Ohio). Informed consent was obtained from all patients prior to their involvement in the trial and the study was compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Patient Selection

Fifty patients were recruited from the house staff service at Miami Valley Hospital in Dayton, Ohio from May 2013 to February 2015. Inclusion criteria included individuals undergoing non-emergent low transverse Cesarean section via pfannensteil incision under epidural or spinal anesthesia who were between 16 and 45 years old. Patients were excluded from participation if they were known to have a coagulopathy, sensitivity to any medications used in the study, or received Duramorph (long-acting morphine) as part of their pre-delivery anesthetic regimen. A resident or faculty physician counseled patients about participation in the study prior to the procedure. Those interested in participating provided informed consent and signed the appropriate consent forms for their procedure and for participation in the study. Minors participating were granted permission from a guardian. Patients were randomized in a 1:1 group allocation to receive an anesthetic system filled with normal saline or 0.25% of

bupivacaine. Randomization using a random numbers generator was performed by the pharmacy staff at Miami Valley Hospital. Physicians performing the surgery, researchers, nursing staff, and patients were all blinded regarding the assignment to local anesthetic or placebo. Systems were labeled only with participant's study identification number. Resident physicians, under supervision from attending physicians, performed all Cesarean sections and placed the wound irrigation system catheter in a standardized fashion.

On - Q™ Wound Irrigation System Catheter

A dual catheter iFlow On - Q™ wound irrigation system was placed with one catheter between the fascia and the rectus muscles and one catheter overlying the uterine incision in the peritoneal cavity. The catheters were introduced in the usual fashion through the skin utilizing separate skin punctures approximately 5 cm superior and/or lateral to the skin incision. All patients received either bupivacaine or saline solution via the wound irrigation system. Additionally, each patient received ketorolac on a scheduled IV basis (30mg immediately post-operative and every 6 hours for the first 24 post-operative hours). Narcotic pain control was achieved through the use of a morphine PCA for the first 24 hours and oral hydrocodone/acetaminophen (Lortab 5/325mg) tablets thereafter with intermittent IV morphine dosing if needed for breakthrough pain. The amount of morphine used was documented for the first 24 hours. After 24 hours, total opioid use was calculated using an opioid equivalence of 3mg PO hydrocodone to 1mg IV morphine. Postoperative pain was assessed in the recovery room and at 6, 12, 24, and 48 hours post-operatively using an 11 - point Likert visual analog pain scale. Nursing staff who were educated in the study protocol documented patient reported pain on the visual analog pain scale and documented total narcotic use in the medical record. All catheters were removed on the morning of Post Operative Day #3 by the house staff, if the patient was still hospitalized, or by the patient at home if she had already been discharged home. Catheters were removed in accordance with the recommendations of the manufacturer. If patients were discharged home with catheters in place, a resident or attending physician, prior to discharge, instructed them how to remove the catheters. Patients were also provided with the preprinted On - Q™ patient guide to catheter removal. If a patient had difficulty removing the catheter or did not feel comfortable removing the catheter themselves at home they were given an appointment for catheter removal in the office.

Outcomes

The primary outcome was total narcotics used for the first 48 hours post-operatively. An opioid equivalence of 3mg PO hydrocodone to 1mg IV morphine was used to convert PO hydrocodone before calculation of the total narcotics used. Secondary measures included subjective assessment of post-operative pain at 6, 12, 24, and 48 hours. Baseline characteristics included age, race, gravidity, parity, and Body Mass Index (BMI) were recorded.

Statistical Analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (version 23.0) [13]. Student's t-test and Chi Square were used to compare group characteristics. Repeated measures ANOVA was used to assess change over time for primary outcomes, total narcotics use, and secondary outcomes, pain scores, and to compare the treatment assignment groups. Significance was defined as $p < 0.05$.

Sample Size

Sample size was limited by the number of devices (n = 50) provided by the Sponsor.

RESULTS

Fifty patients were enrolled in the study ranging in age from 16 - 40 years old and with a gestational age of 37 + 3 to 41 + 0 weeks. Forty patients were included in the data analysis. Ten patients were excluded from the analysis, including six who had premature catheter removal prior to the 48-hour time point related to excessive catheter leaking at skin insertion point or accidental or intentional patient self-removal, one due to an allergy requiring changes in narcotic medication, one for postpartum Ogilvie's syndrome, and two who never had the wound irrigation system catheter placed due to complications at the time of surgery. Ten patients received epidural anesthesia, 28 patients received spinal anesthesia, and 2 patients received general anesthesia. All patients were followed for a period of 48 hours. Comparison of the Bupivacaine and Saline groups revealed no differences with respect to clinical characteristics (see Table 1). Average total narcotic use at 6, 12, and 48 hours was lower in the Bupivacaine group compared to the Saline group, although these differences were not statistically significant ($p < 0.15$, see Figure 1). At 6, 12, and 48 hours post-operatively, the Bupivacaine group reported less pain than the Saline group, although not statistically significant ($p < 0.19$; See Figure 2). The average narcotic use and pain scores at 24 hours were higher in the Bupivacaine group than in the Saline group but failed to achieve significance (narcotic use: 21.2mg ± 13.8

Table 1: Clinical Characteristics of Bupivacaine versus Saline Groups.

	Bupivacaine Group (n = 20)	Saline Group (n = 20)	*p* value
Age (mean ± sd)	25.1 ± 6.1	27.6 ± 5.9	ns
Gravida	3.8 ± 2.4	3.8 ± 2.6	ns
BMI	37.5 ± 5.9	35.5 ± 6.6	ns
Number Prior C - Sections	1.2 ± 1.3	1.0 ±1.1	ns
African American (% (n))	50% (10)	60% (12)	ns
Caucasian	35% (7)	25% (5)	ns
Smoker	25% (5)	30% (6)	ns
Epidural Anesthesia	25% (5)	25% (5)	ns
Spinal Anesthesia	75% (15)	65% (13)	ns

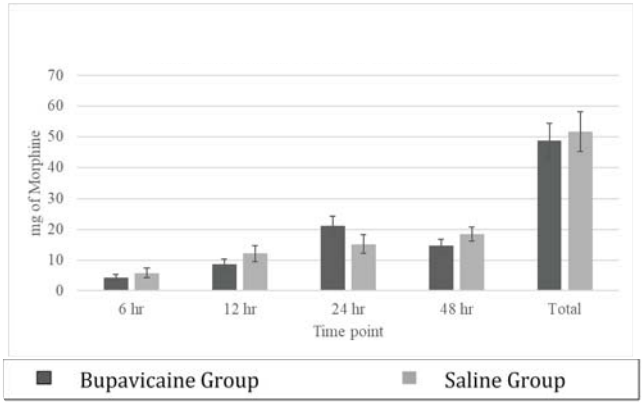

Figure 1: Average Narcotic Use at 6, 12, 24, and 48 Hours Post C-Section for Bupivacaine Versus Saline Groups.

vs. 15.2mg ± 13.3, $p < 0.15$ and pain scores: 4.3 ± 2.5 vs. 3.5 ± 2.4, $p < 0.20$). Additional analyses of women with prior C-section compared to those who were primagravida, revealed that in both Bupivacaine and Saline groups, women with a prior C-section had higher total narcotic use (38.3mg ± 20.8 vs. 58.1mg ± 27.5; $p < 0.02$) compared to primagravida women (Figure 3). The two groups did not differ with respect to total narcotic use when race, age, smoking status, and BMI were controlled. Clinical characteristic for these two groups are presented in Table 2. With respect to anesthesia type, there were no differences in total narcotic use or average pain scores. The type of anesthesia dummy variables were entered into stepwise multiple regressions predicting total narcotics use and average pain scores, however, these variables did not enter the prediction equation. Only a history of previous Cesarean delivery predicted higher total narcotics use and higher average pain scores.

DISCUSSION

Our study demonstrated that women who received the On-Q™ wound irrigation system at the sub-fascial and uterine incision planes demonstrated lower, but not statistically significant, narcotics use and reduced pain across three of the four time points assessed (6 hr, 12 hr, and 48 hr) leading to lower total narcotic use during the study.

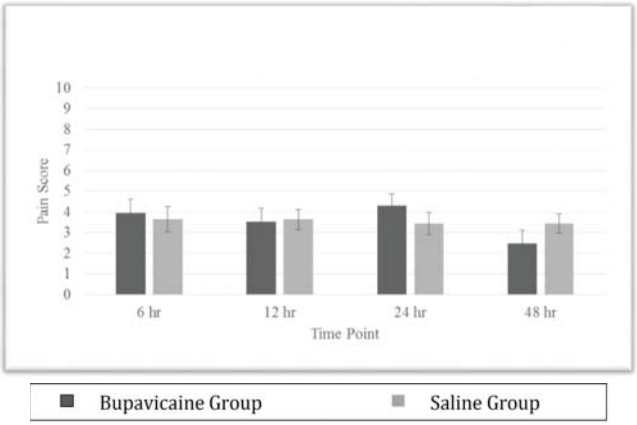

Figure 2: Average Pain Score at 6, 12, 24, and 48 hours Post C-Section for Bupivacaine Versus Saline Groups.

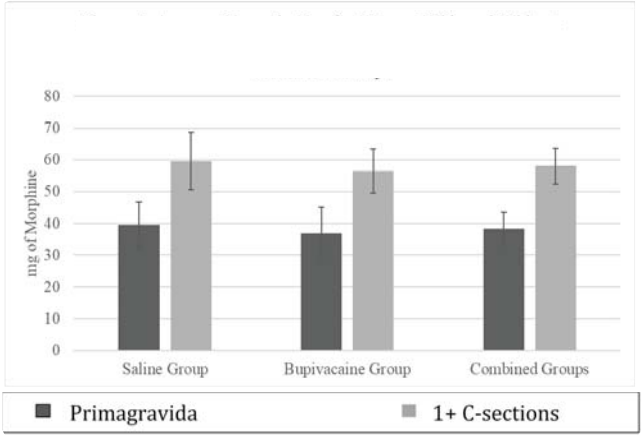

Figure 3: Average Narcotic Use for women with and without Prior C-Section for Bupivacaine Saline Groups and combined Groups.
Women with Prior C-Section had higher narcotics use than Primagravida women (p<0.02 for the Combined Group comparison).

Table 2: Clinical Characteristics of Primagravida versus Prior Cesarean Section.

	Primagravida (n = 16)	1+ Prior C - Section (n = 24)	*p* value
Age (mean ± sd)	24.1 ± 6.6	27.8 ± 5.3	< 0.07
Gravida	2.6 ± 2.5	4.6 ± 2.1	< 0.01
BMI	35.1 ± 5.4	37.4 ± 6.7	ns
Number Prior C - Sections	0.0 ± 0.0	1.8 ± 1.0	n/a
African American (% (n))	50% (8)	58% (14)	ns
Caucasian	37% (6)	25% (6)	ns
Smoker	25% (4)	29% (7)	ns
Epidural Anesthesia	63% (10)	0% (0)	< 0.002
Spinal Anesthesia	37% (6)	92% (22)	< 0.002

However, there was a peak of increased narcotic use and pain scores at the 24 hour time point. Regardless of study group assignment, patients with prior Cesarean sections had higher total narcotic use than women for whom this was their primary Cesarean section. The findings of our study are consistent with the literature demonstrating no differences in total narcotics use and no difference in pain scores between patients receiving continuous wound irrigation and patients receiving intrathecal narcotics [14,15]. While our study is suggestive of lower narcotics use in the Bupivacaine group, the difference in pain scores was minimal. This is important because if patients are experiencing similar pain control and lower narcotics use, then the benefits of using the continuous wound irrigation method for post-operative pain control will be evident through a decrease in narcotic side effects, including nausea and vomiting, but also by minimizing patient concerns regarding narcotic transmission in breastmilk and addiction potential. The sharp increase in narcotic use at the 24 hr time point and the accompanying spike in pain was an interesting finding, which may be accounted for by the earlier post-operative pain control. Some studies have noted that increased pain occurs around the time when IV medications are transitioned to oral therapy [16]. It is possible that earlier mobility at the 24-hour time point caused an increase in pain sensation, however, mobility parameters were not documented or included in data collection. The impact of prior Cesarean section on total narcotic use regardless of study group assignment, may be attributed to increased pain related to previous scar tissue and increased manipulation during surgery or anticipated pain based on their previous experience during their prior Cesarean section leading to a tendency to over-medicate to avoid pain. The strengths of our study include that it was a randomized placebo controlled trial and that its approach included placement of the dual catheter at the uterine incision and between the fascia and rectus muscle. The study was designed to be executed in real time within the standards of post Cesarean wound management. The study was conducted on a resident service where all patients underwent standardized surgical procedures and postoperative care. Nursing staff underwent study specific training to ensure that the required study information was recorded in the medical record. Placement of the wound irrigation system was informed by the current literature showing that placement below the fascia was more effective than placement above the fascia [12]. However, we acknowledge that there are study limitations including that not all cases were performed by the same surgeon and not all of the surgeons had extensive experience prior to the study for the placement or use of pain catheters at the time of Cesarean section. This likely contributed to some variance due to the learning curve associated with catheter placement. We

experienced a large number of cases that were excluded from analysis which impacted power to detect differences. Our post hoc power analysis (power = 80%, $p < 0.05$) indicated that we would need 114 patients per group to detect a difference in narcotics use (based on the group difference at the 48 hour time point) and 99 patients per group to detect a difference in pain score (based on the group difference at the 48 hour time point) for the small effect sizes we had. Another possible limitation in this study was that we allowed different anesthesia options including epidural, spinal, and general were used and not controlled. The study was executed in the standard labor and delivery setting in which anesthesia was determined according to patient desire and physician decision regarding what was in the best interest of the mother and infant. Further research is necessary with larger numbers of patients to allow inferences of no difference in pain scores using the dual catheter placement approach. Future studies will need to include specific assessment of side effects as this is an important area of patient concern with narcotics use. While patients may have experienced side effects, they may not have mentioned them to the nursing staff. If patients reported experiencing side effects, it is not known whether nurses would have recorded these in their notes unless the side effects were particularly bothersome and/or required intervention. As the culture of medicine changes over the next few years, it is important to improve patient satisfaction with their birthing experience for many reasons, including provider reimbursement. The nationwide rate of Cesarean section remains steady and pain control after surgery can be a major factor in patient satisfaction. Local infusion of anesthetic may allow patients to bond better with their babies, mobilize earlier, and possibly shorten length of stay when compared to traditional pain control methods. Our results show promise for the dual catheter placement for the management of postoperative pain and use of post-operative narcotics. However, our study had insufficient power, and we were unable to demonstrate a significant difference between the Bupivacaine group and the Saline group. Further clinical trials with larger sample sizes are needed to address those patients at high risk of postoperative pain issues including individuals with substance abuse or undergoing repeat, classical or emergent Cesarean sections under general anesthetic. Furthermore, the optimal site for the On-Q wound irrigation system at either or both the sub-fascial and uterine incision warrants further investigation.

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