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A Randomized Controlled Trial Comparing the Efficacy of the Transversus Abdominus Plane Block with Two Concentrations of Bupivacaine in Patients Undergoing Cesarean Delivery

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Abstract

Background: To investigate whether Transversus Abdominis Plane (TAP) block using either 0.5% or 0.25% bupivacaine confers additional analgesia for Cesarean section patients when compared to placebo.

Methods: 60 parturients undergoing elective Cesarean delivery under combined spinal epidural anesthesia were enrolled and randomized into 3 groups. Bilateral TAP block was performed postoperatively using 15 ml solution on each side. Arm 1 received 0.5% bupivacaine, arm 2 received 0.25% bupivacaine and arm 3 received normal saline. All patients received epidural morphine after the umbilical cord was clamped. Pain and other parameters were assessed at 0 h, 3 h, 6 h, 24 h, and 48 h postoperatively. The primary outcome is the number of PCA boluses used by the patients postoperatively within 24 h. Appropriate statistical tests were used.

Results: The pain scores at 3 h, 6 h, 24 h, and 48 h were significantly lower in both bupivacaine groups compared to the placebo group (p-value between 0.0281-0.0066). Fewer PCA boluses (p-value between 0.0245-0.0011) and higher satisfaction (p-values between 0.0092-0.0009) were found in both bupivacaine groups compared to the placebo group. No significant difference was noted between bupivacaine groups. No significant differences were noted in secondary objectives among the three groups.

Conclusion: 0.5% and 0.25% bupivacaine TAP blocks were associated with reduced pain scores, decreased PCA requirements, and greater satisfaction than placebo. We conclude that 0.25% bupivacaine is ideal for use in TAP block as a part of multimodal analgesic regimen that includes neuraxial morphine in cesarean section patients.

Keywords: Cesarean section; Acute pain; TAP Block; Bupivacaine; Postoperative

Introduction

Transversus Abdominis Plane (TAP) blocks have been used for postoperative analgesia following lower abdominal surgery since first described by Rafi [1] in 2000. Originally, TAP blocks were performed without visualization, using tactile sensation to locate the fascial plane between the internal oblique and transversus abdominis muscles, within the landmark known as the Triangle of Petit. It is now possible to perform these blocks with in-plane needle localization under ultrasound guidance, which allows real-time visualization of the anatomy and the approaching needle. The result is a low risk abdominal wall nerve block which may improve postoperative conditions including pain, nausea, ambulation, and overall patient satisfaction, and which may potentially allow for earlier discharge.

Cesarean delivery is the most commonly performed operation in the United States [2]. Current postoperative pain management regimens typically include a combination of neuraxial opioids, intravenous opioids, Non-steroidal Anti-Inflammatory Drugs (NSAIDs), and acetaminophen. While generally being well tolerated, NSAIDs and acetaminophen have a limited ability to treat postoperative pain in major abdominal surgeries. Neuraxial and IV opioids often provide more complete analgesia, but cause an array of uncomfortable side effects, including nausea, sedation, ileus, pruritus and respiratory depression [3]. One analgesic strategy to reduce the incidence of these side effects is to reduce opioid dosing while using a supplemental technique such as a TAP block.

Pain after a Cesarean delivery is both somatic (incisional, body wall) and visceral (uterine and other intraperitoneal structures). In the neuritis, opioids have proven particularly effective at reducing the visceral component of postoperative pain. Neuraxial local anesthetics are generally considered to be more effective at blocking somatic pain but do not allow for ambulation and often require more monitoring and staff involvement. The TAP block is a single-shot, low-risk alternative to neuraxial local anesthetics for post-cesarean somatic pain control. Pfannensteil incision usually involves dermatomes from T11 to L1; TAP block usually covers the dermatomes from T7 to L4 [4].

Studies have been done to determine the efficacy of TAP block as a part of multimodal regimen [5] and McDonnell and colleagues demonstrated that a TAP block reduces morphine requirement after abdominal surgery, including Cesarean delivery [6,7]. However, a literature search did not reveal any investigation assessing the efficacy of different concentrations of bupivacaine in TAP blocks.

Methods

The study was approved by the hospital Institutional Review Board and registered with the United States clinical registry. www.clinicaltrials.gov, ID # 367620. Informed consent was obtained from each study participant.

Participants

Sixty consecutive eligible parturients (i.e. ASA 2) undergoing Cesarean delivery at New York Methodist Hospital were selected for this study from April to August 2013. Risks including infection, bleeding, peritoneal perforation, organ perforation, and unintentional femoral nerve block were explained to the patients. The parturients were given handouts regarding the TAP block. Patients were excluded if there was a history of relevant drug allergy, patient refusal, history of opioid abuse, weight <60 kg, contraindication to neuraxial anesthesia, ASA physical status 3 or 4, placental disease, multiple gestation, or preeclampsia.

Trial design

After informed consent was signed and inclusion/exclusion criteria were met, each patient was assigned a code number and was randomized *via* a computer generated randomization chart to one of the three arms.

Staff not directly involved with the block or data acquisition were un-blinded and prepared the medication. All staff providing direct care and the collection of data were blinded to the group assignment. The patients were randomized into 3 groups of 20 patients each. All received a TAP block with 15 ml of a study solution injected on each side (total 30 ml). Patients in Arm 1 received 0.5% bupivacaine, patients in arm 2 received 0.25% bupivacaine and patients in arm 3 received normal saline. Patients were not aware of which TAP block medication they received.

Anesthetic techniques

All patients received the same standardized treatment before and after the Cesarean delivery. Preoperatively patients received 30 cc of sodium citrate, 10 mg of oral metoclopramide and 300 mg of oral cimetidine. Patients received a combined spinal epidural anesthetic with 1.6 cc of hyperbaric 0.75% bupivacaine and 25 mcg of fentanyl injected intrathecally. Epidural lidocaine 2% was available for intraoperative pain. IV Ondansetron 4 mg was given for antiemetic prophylaxis and epidural morphine 3 mg was given after the umbilical cord was clamped. Postoperatively patients received IV acetaminophen 1 gm every 6 h and oral celecoxib 200 mg every 12 h for 48 h. They also received an intravenous morphine PCA for 48 h with the following settings: basal rate zero, bolus dose 1 mg, lockout time 10 min, maximum hourly dose 6 mg.

Intervention

TAP blocks were performed by one of the two investigators (PB or JF); both had significant prior experience with ultrasound-guided TAP blocks. Following completion of the Cesarean delivery, the abdomen was aseptically prepped with ChloraPrep®. A Sonosite ultrasound machine (S-nerve) with a 14-8 MHz linear probe was used to visualize the lateral abdominal wall muscles and transversus abdominis plane. A 2 or 4 inch stimuplex (Braun) needle was advanced under ultrasound guidance to the transversus abdominis plane. After negative aspiration, 15 ml of study solution was incrementally injected on each side. The spread of solution within the transversus abdominis plane was visualized with the ultrasound.

Outcomes

The primary outcome was the number of PCA boluses used by the patients within 24 h. The number of PCA boluses taken by the patient within 0 h, 3 h, 6 h, 24 h, and 48 h after the TAP block was reported. A graduated 100 mm visual analogue scale was used to subjectively assess the pain score at 0 h, 3 h, 6 h, 24 h, and 48 h. The scale is divided in millimeters with short lines, with long lines every 5 millimeters and longer lines for the tens with the number next to the line of tens to easily quantify the pain score.

Secondary outcomes included nausea, pruritus, ability to tolerate food, ability to walk, and patient satisfaction. Nausea and pruritus were assessed at 0 h, 3 h, 6 h, 24 h, and 48 h, and ability to tolerate diet and ability to walk were assessed at 24 h and 48 h using a Yes/No type questionnaire. Patient satisfaction was assessed at 24 h and 48 h using a visual analogue scale with 11 divisions with "extremely dissatisfied" and "extremely satisfied" at the extremes.

Sample size

The sample size was determined by considering an institutional statistics report that showed the mean number of PCA boluses used by patients after Cesarean delivery within 24 h was 18 (SD 12).

Randomization

The randomization table (4 blocks of 15) was generated and the allocation assigned to cases accordingly, written in paper for each case and sealed in an opaque envelope with the case number on it. The envelopes were kept in a safe place, and viewed only by the unblinded investigator preparing the study drugs.

Bio statistical analysis

Statistical analysis was performed using STATA, version 13.1. The primary objective was to compare the analgesic effect of a TAP block using 0.5% bupivacaine, 0.25% bupivacaine or normal saline utilizing pain scores and the number of PCA boluses. It was assumed that the addition of the TAP block using 0.5% bupivacaine would reduce the mean use of PCA boluses to 9 (SD 6). We added the 0.25% bupivacaine arm to study the non-inferiority between the two concentrations of bupivacaine. The calculated sample size would then be 18 for each of three groups to prove the hypotheses with a type I error of 0.05 and a power of 80%. The sample size was further adjusted to 20 cases in each group for a total of 60 patients.

ANOVA test with Bonferroni correction was used to compare numerical data between the three arms, unpaired t-test was used to compare these data between the two bupivacaine arms. chi square or Fisher exact test were used to compare between categorical data. Two-sided tests were considered.

Results

Recruitment

Sixty consecutive eligible parturients (i.e. ASA 2) undergoing Cesarean delivery at New York Methodist Hospital were selected for

this study from April to August 2013. The trial ended in August 2013 as the adequate number of participants for the trial was reached.

Numbers analyzed

60 patients who were included the trial completed the study and all 60 patients were included in the analysis.

Outcomes and estimation

Sixty subjects were enrolled in the study. All of them completed the study. There were no significant differences in age, gestation, parity, or number of previous Cesarean sections among the groups (Table 1).

	Arm 1 (0.5% Bupivacaine)	Arm 2 (0.25% Bupivacaine)	Arm 3 (Placebo)	ANOVA Test (P-Value)
Age (Years)	32.5 (23-41)	34.5 (21-48)	33 (19-41)	0.3442
Parity	1 (0-3)	1 (0-2)	1 (0-3)	0.1943
Previous Cesarean delivery	1 (0-3)	1 (0-2)	1 (0-3)	0.3138
Gestational Age (Weeks)	39 (37-40)	39 (36-40)	39 (37-41)	0.2197

Table 1: Baseline characteristics of the study participants (Median (Range)).

Pain score

A statistically significant difference was noted in the mean pain scores between the arms at 3 h, 6 h, 24 h, and 48 h. No significant difference was noted between the two bupivacaine groups (Table 2). The mean pain scores at 24 h and 48 h in the placebo group were significantly higher than in the bupivacaine groups. There was no significant difference between the two bupivacaine groups. A bar graph is created to show the mean pain score on the 24th and 48th h for each arm (1, 2 and 3) (Figure 1).

	Mean (SE)			ANOVA (P-Value) B/W the three Arms	t-test (P-Value) B/W Arms 1 & 2
Pain Score	Arm 1	Arm 2	Arm 3		
At Time 0 (Start)	3 (1.638)	2 (0.917)	3 (2.064)	0.8798	0.5975
After 3 h	21.5 (4.935)	21.5 (4.429)	39 (5.021)	0.0163	1
After 6 h	22 (3.811)	20 (3.162)	33.5 (3.574)	0.0187	0.6886
After 24 h	19.5 (2.663)	20.5 (2.111)	30.5 (4.197)	0.0281)	0.7702
After 48 h	16.5 (2.086)	18.5 (3.015)	28 (2.675)	0.0066	0.5887

Table 2: Pain scores (Mean (SE)) and P values between (B/W) groups.

Number of PCA Boluses	Mean (SE)			ANOVA (P-Value) B/W the three Arms	t-test (P-Value) B/W Arms 1 & 2
	Arm 1	Arm 2	Arm 3		
Within 3 h	1.7 (0.447)	1.55 (0.351)	3.6 (0.815	0.0245	0.7936
Within 6 h	4.1 (0.721)	3.75 (0.652)	7.8 (1.236)	0.004	0.721
Within 24 h	9.45 (1.292)	8.95 (1.756)	17.65 (2.893)	0.0068	0.8199
Within 48 h	11.75 (1.859)	13.15 (2.116)	24.5 (3.351)	0.0011	0.6221

Table 3: Number of PCA boluses used [Mean (SE)] and P values between (B/W) groups.

PCA Bolus

A statistically significant difference was noted in the number of PCA boluses between the bupivacaine groups and the placebo group at 3 h, 6 h, 24 h and 48 h. No significant difference was noted between the two bupivacaine groups (Table 3). The mean number of PCA boluses at 24 and 48 h in the placebo group were significantly higher than in the bupivacaine groups. A bar graph is created to show the mean number of PCA boluses used within the 24 h and 48 h respectively for each arm (1, 2, 3) (Figure 2). It shows that there is no significant difference between the two bupivacaine groups.

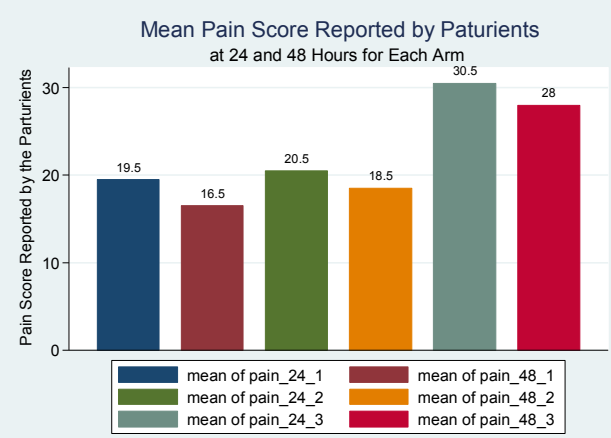

Figure 1: Comparison between mean pain scores at 24 h and 48 h after TAP block Mean pain scores at 24 h and 48 h were significantly lower in both bupivacaine groups when compared to the placebo group with no significant difference between the two bupivacaine groups.

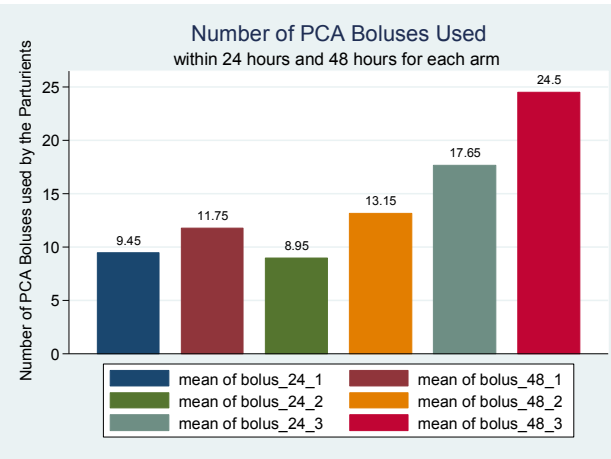

Figure 2: Comparison between mean PCA boluses at 24 h and 48 h after TAP block. Mean PCA boluses at 24 h and 48 h were significantly lower in both bupivacaine groups when compared to the placebo group with no significant difference between the two bupivacaine groups.

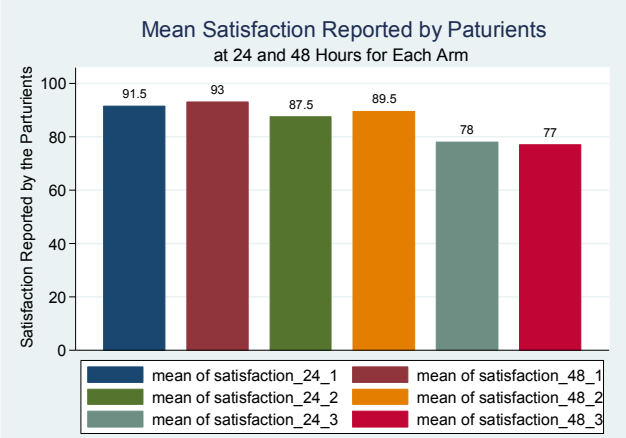

Figure 3: Comparison between mean satisfaction scores at 24 h and 48 h after TAP block Mean satisfaction scores at 24 h and 48 h were significantly higher in both bupivacaine groups when compared to the placebo group with no difference between the two bupivacaine groups.

Satisfaction

The mean satisfaction levels were significantly higher in each of the bupivacaine groups when compared to the placebo group at 24 h and 48 h. There was no difference between the two bupivacaine groups (Table 4).

A bar graph is created to show the mean satisfaction score on the 24th h and 48th h for each arm (1, 2, 3) (Figure 3).

Secondary measures

There was no significant difference noted among groups in the secondary measures such as nausea, pruritus, ability to ambulate, ability to tolerate food and the discharge readiness (at 48 h) of the patients.

Adverse events

There were no adverse events noted during the course of the study.

Patient Satisfaction	Mean (SE)			ANOVA (P-Value) B/W the three Arms	t-test (P-Value) B/W Arms 1& 2
	Arm 1	Arm 2	Arm 3		
At 24 h	91.5 (1.817)	87.5 (3.151)	78 (3.879)	0.0092	0.2785
At 48 h	93 (1.933)	89.5 (2.348)	77 (4.173)	0.0009	0.2006

Table 4: Patient satisfaction (Mean (SE)) and P values between (B/W) groups.

Discussion

Cesarean delivery is one of the most commonly performed surgical procedures worldwide, with more than one million patients undergoing this procedure annually in the United States alone. There is considerable benefit in formulating an analgesic regimen that is safe and effective, with minimal side effects for the mother and her newborn. Regional anesthesia has been proven to provide reduced pain intensity, decreased incidence of analgesics side effects, and improved patient comfort level [9,10].

Our study demonstrated that the addition of TAP block to a multimodal post-Cesarean analgesic regimen results in improved analgesia and a reduction in opioid usage. Cesarean delivery patients are typically expected to recover quickly and start caring for their newborn baby. Unlike many other patients recovering from abdominal surgery, they do not have the luxury to rest extensively.

Many also want to minimize their systemic opioid intake so as to avoid transfer to the newborn in their breast milk. TAP block is clearly an effective way to enhance analgesia beyond that achieved with neuraxial opioids, while reducing systemic opioid requirements.

Overall patient satisfaction in the bupivacaine groups was greater than that in the placebo group. In this era of health care in which respecting patient autonomy is increasingly emphasized, patient satisfaction is becoming an important metric of clinical care. Hospitals and clinicians will be judged in part by the satisfaction of their patients. We demonstrated that TAP block is an effective way to improve satisfaction.

Our trial failed to show any advantage of TAP block over placebo in terms of nausea, which had been demonstrated in a previous trial6. This may be related to the use of epidural morphine in all of our study groups.

No randomized controlled trials have compared the efficacy of 0.5% and 0.25% bupivacaine in TAP blocks in cesarean delivery patients. Although there were some differences in the amount of opioid consumption and pain score, the differences between the two bupivacaine groups were not statistically or clinically significant. The recommended maximum dose of bupivacaine is 2.5-3 mg/kg as per the FDA11. For lower abdominal surgeries with a Pfannenstiel incision, 0.5% bupivacaine can be used so long as the toxic limit is not exceeded. However, for midline abdominal surgeries, where the volume for the TAP block needs to be greater in order to cover the lower thoracic segments, 0.25% bupivacaine may be preferred. Further trials might examine if there exists any difference between 0.5%, 0.25%, and 0.125% bupivacaine.

An initial hypothesis was that only patients who received a bupivacaine TAP block would meet the discharge readiness criteria at the end of 48 h. We were surprised that patients in all three study arms met the discharge readiness criteria at 48 h. This might be because the analgesic regimen used in all three groups included an aggressive analgesic regimen of IV acetaminophen q6 and celecoxib 200 mg q12 for 48 h, in addition to the epidural morphine and IV morphine PCA.

The TAP block should be particularly useful for patients who undergo emergency Cesarean delivery, requiring general anesthesia. Typically, these patients are given IV morphine PCA or other systemic opioids for pain control. TAP block in these patients will likely allow a significant reduction in opioid usage, with a reduction in opioid side effects, opioid transfer in the breast milk, and improved patient satisfaction.

In summary, our trial demonstrated the analgesic efficacy of ultrasound-guided TAP block in Cesarean delivery patients. Since there was no significant difference between 0.5% and 0.25% bupivacaine, 0.25% bupivacaine is the ideal choice of local anesthetic for use in the TAP block. This block has an opioid sparing effect, and improves patient satisfaction. TAP block may be considered as a part of multimodal analgesic regimen in all Cesarean delivery patients. Given appropriate training, it is easy to perform, provides reliable, long lasting analgesia, and improves patient satisfaction.

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Limitations

Since we used epidural morphine in all 3 groups, we were not able to assess whether TAP block in a multimodal analgesic regimen without the neuraxial opioids provide advantage over the multimodal analgesic regimen with neuraxial opioids.

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