Analgesic Efficacy and Safety of Ultrasound Guided Transverse Abdominis Plane Block in Postcesarean Section Patients—A Randomized Control Trial

Abstract

Context: Following cesarean section, pain is anticipated. An important component of pain after cesarean section is from abdominal wall incision. Transverse abdominis plane (TAP) block can be used as a part of multimodal analgesia for cesarean section. Aims: To assess the analgesic efficacy and safety of ultrasound-guided TAP block in postcesarean section patients. Methods: Sixty patients undergoing cesarean section under spinal anesthesia were included in this randomized control study. They were divided into three equal groups, A, B, and C. All patients received diclofenac suppository 100 mg 12th hourly and intravenous paracetamol 1g 8th hourly after surgery. Group A patients underwent TAP block after the surgery using a total of 40 ml of 0.25% bupivacaine bilaterally. Group B patients underwent TAP block using 20 ml of 0.25% bupivacaine with clonidine 2 µg/kg. Group C patients did not undergo any block. Postoperative blood pressure, heart rate, nausea, vomiting, sedation, and pain score were noted. Kruskal–Wallis test, Chi-square test, and Mann–Whitney test were used for statistical analysis. Results: Patients who received TAP block had prolonged analgesia. The mean time to rescue analgesia was 8.6 ± 2.8, 7.9 ± 3.8, and 3.5 ± 3.1h for groups A, B, and C, respectively. The pain scores in group A and B were less than group C. Comparison of pain score between group A and B did not show any statistical difference. Conclusion: Ultrasound-guided TAP block is a safe and effective method of providing postoperative analgesia in caesarean patients. Addition of clonidine does not provide any additional benefit.

Keywords: Cesarean section, clonidine, postoperative analgesia, spinal anesthesia, transverses abdominis plane block, ultrasound-guided

Introduction

Following cesarean section, postoperative pain is anticipated. An important component of pain after cesarean section is from abdominal wall incision. By transverse abdominis plane (TAP) block, the sensory nerves of the anterior abdominal wall from T6 to L1 are blocked. TAP block can be used as a part of multimodal analgesia for cesarean1 and abdominal surgeries.[1] There are a number of studies comparing the analgesic effects of TAP block with conflicting results.[4,5] In our study, the analgesic efficacy of ultrasound-guided TAP block and the hypothesis that clonidine administered as an additive will increase the duration of action of TAP block was tested.

Methods

This randomized single-blinded study was conducted after obtaining the approval of the hospital ethical committee and the written informed consent of 60 patients undergoing elective lower segment cesarean section under spinal anesthesia in a tertiary care teaching hospital over a period of three years [Figure 1]. Patients undergoing elective cesarean section under subarachnoid block belonging to ASA physical class I and II were included in the study. Patients not willing for TAP block, allergic to any medication in the study, patients with unsatisfactory view of abdominal layers as seen in the ultrasound were excluded from the study. The patients were recruited by computer-generated random sequence of numbers and divided into three equal groups: A, B, and C by closed envelope technique. Group A patients received bilateral TAP block through 20 ml of 0.25% bupivacaine on each side and group B patients received TAP block through 20 ml of 0.25% bupivacaine with clonidine 2 µg/kg. Group C patients did not undergo any block. Postoperative blood pressure, heart rate, nausea, vomiting, sedation, and pain score were noted. Kruskal–Wallis test, Chi-square test, and Mann–Whitney test were used for statistical analysis. Results: Patients who received TAP block had prolonged analgesia. The mean time to rescue analgesia was 8.6 ± 2.8, 7.9 ± 3.8, and 3.5 ± 3.1h for groups A, B, and C, respectively. The pain scores in group A and B were less than group C. Comparison of pain score between group A and B did not show any statistical difference. Conclusion: Ultrasound-guided TAP block is a safe and effective method of providing postoperative analgesia in caesarean patients. Addition of clonidine does not provide any additional benefit.

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How to cite this article: Leeladharan SP, Puthenveettil N, Rakhi B, Nair SS, Kumar L. Analgesic efficacy and safety of ultrasound guided transverse abdominis plane block in postcesarean section patients—A randomized control trial. J Obstet Anaesth Crit Care 2020;10:16-20.
of 0.25% bupivacaine with clonidine 2 µg/kg added to the total 40 ml of local anesthetic. Group C control patients received only routine postoperative analgesia.

All patients received spinal anesthesia using bupivacaine heavy 0.5% 1.8–2 ml as per standard practice in our obstetric theater. All patients received diclofenac suppository 100 mg 12th hourly and iv paracetamol 1g 8th hourly after surgery. The TAP block was also performed for groups A and B patients in the operating room by a single consultant anesthetist after surgery, prior to shifting to recovery room using a Sonosite portable ultrasound machine (Bothell, WA, USA) with a high-frequency probe. Ultrasound-guided TAP blocks were performed under strict aseptic precautions with an ultrasound probe in the transverse plane to the lateral abdominal wall. The probe was placed in the mid-axillary line, between the lower costal margin and iliac crest. After visualizing the external and internal oblique, transverse abdominis muscle and fascia, a 23G, 90-mm-long spinal needle (BD, Madrid, Spain) was introduced in the plane of the ultrasound probe directly under the probe and advanced until it reaches the plane between the internal oblique and the transverse abdominis muscle. After aspiration to rule out intravascular injection, the drug was injected under ultrasound guidance. The procedure was performed bilaterally. During the postoperative period, when the pain score recorded was more than 4, a rescue therapy with intravenous tramadol 1 mg/kg was given along with 4 mg ondansetron as antiemetic.

The patients were monitored in the recovery room by a blinded nursing staff, who was unaware which group the patient belonged. The postoperative parameters recorded were blood pressure, heart rate, nausea and vomiting, sedation score, and pain score. These parameters were recorded at 0, 2, 4, 6, 8, 10, and 12 hours after wound closure up to the time when rescue analgesia was administered or whichever was earlier. Patients were asked to rate pain experienced by using a ten-point numeric pain scale where zero represented no pain and ten represented worst possible pain. The severity of nausea, vomiting, and drowsiness were rated using a four-point scale (0-none, 1-mild, 2-moderate, and 3-severe). Sedation was assessed using POSS–Pasero opioid induced sedation scale (1- awake and alert, 2-slightly drowsy, 3-arousable but drifts off to sleep during conversation, and 4- No response to verbal or physical stimulation). Any local complications associated with TAP block were noted. We also looked for potential local complications like adverse drug reactions and inadvertent intravascular injection. Patients were given rescue analgesia for pain scale rated four or above. The study was terminated once the patient was administered rescue analgesia. The parameters were recorded up to the time when rescue analgesia was administered. The time to rescue analgesia was also noted for all the three groups.

Sample size calculation

Since no information was available in the existing literature on the exact dose that was studied, a pilot study with ten patients in each group was carried out. From this collected
data, with 95% confidence and 80% power the minimum sample size was calculated to be 20 in each group.

**Statistical analysis**

The data was analyzed using SPSS statistics version 17. Data were expressed as mean ± SD. Median was derived for variables without normal distribution. Statistical significance of the difference of mean values of measurable parameters among the three groups was done using Kruskal–Wallis test. To test the statistical significance of the difference in the percentages with respect to categorical variable among the three groups, Chi-square test was done. A *P* value of <0.05 was considered significant.

**Results**

The distribution of age and weight amongst the three groups were comparable. On comparing the heart rates at 0, 2, 4, 6, 8, 10, and 12 hours, it was found that the values obtained at 0, 2, and 8h had significant difference. At 0h, the mean heart rate of group A had mean of 86.5 ± 7.2 while that of group B and control group were 77.6 ± 7.3 and 89.3 ± 11.2, respectively (*P* < 0.001). At 2h, mean heart rates were 83.4 ± 4.8, 78.9 ± 6, and 91.2 ± 14 for groups A, B, and C, respectively (*P* = 0.005). At 8h also, a significant difference in heart rate was obtained, 82.9 ± 6 for group A, 77.4 ± 4.9 for group B, and 78.5 ± 0.046 for group C (*P* = 0.046) [Figure 2].

On comparing the systolic blood pressure (BP) between the three groups at 0, 2, 4, 6, 8, 10, and 12 h, it was found that there was a statistically significant difference at 0, 2, and 12h. Group B had significantly lower systolic BP at 0 and 2h as compared to groups A and C. At 0h, groups A, B, and C had a mean systolic BP of 123.3 ± 16.1, 114.8 ± 12.0, and 129.9 ± 18.3 mm of Hg, respectively (*P* = 0.025). At 2h, groups A, B, and C had a mean systolic BP of 121.4 ± 9.6, 115.0 ± 12.9, and 131.5 ± 14.0 mm of Hg (*P* = 0.004), respectively. At 12h, group A had a lower BP compared to the other two groups, the values being: group A, 113.8 ± 5.3 as compared to 128.8 ± 6.4 in group B and 125 ± 7.1 mm of Hg in group C [Figure 3].

The mean time to rescue analgesia was found to be 8.6 ± 2.8, 7.9 ± 3.8, and 3.5 ± 3.1h for groups A, B, and C, respectively [Figure 4]. We then compared the three groups with each other. When group A was compared to group C, the difference was found to be significant (*P* < 0.001). When group B was compared to group C, a significant difference was obtained (*P* < 0.001). When group A was compared to group B, the difference was not statistically significant. This shows that group C had a shorter time to rescue analgesia compared to both group A and B. However, there was no statistically significant difference in time to rescue analgesia between groups A and B.

We compared the median pain score of groups A, B, and C at 0 and 2h. In the later hours of the study, most patients from group C were excluded from the study as they received rescue analgesia. So in the later hours, we have compared the median pain scores of only group A and group B up to 8 hours. Comparison of pain scores of the three groups at 0h showed the median of 0 in groups A and B and two in group C (*P* < 0.0001). At 2h, the median of pain scores for the three groups were 0, 0, and 5 for groups A, B, and C, respectively (*P* < 0.001) [Table 1]. The three groups were then compared with each other. There
was no statistical difference between group A and B. But on comparing group B and C, a significant difference was obtained ($P < 0.0001$), the pain score of group B being lower than C. Upon comparing groups A and C also, a significant difference was obtained ($P < 0.0001$), the pain score of group A being lower than C. This shows that both the groups that received TAP block had significantly lower pain scores as compared to the control group with no TAP block [Table 2]. Group C was not compared as most of the patients in that group got terminated from the study as they received the rescue analgesia earlier. On comparing the median pain scores of group A and B, the results obtained had no statistical significance, thus showing that group A and group B had similar pain scores at these hours.

We did not encounter any complications while performing ultrasound-guided TAP block. The incidence of nausea and vomiting was compared in between the three groups. The patients had either mild or no nausea, vomiting at all. So they could be placed in 2 groups, either mild nausea and vomiting present or no nausea and vomiting at all and they were compared. In groups A, B, and C, 5%, 25%, and 50% patients had vomiting, respectively. The difference was statistically significant ($P < 0.006$). The sedation scores of the three groups were compared. The patients had either one or two sedation scores. The difference in sedation was not found to be statistically significant.

**Discussion**

Our study was primarily aimed at testing the analgesic efficacy and safety of TAP block in postcesarean patients. The primary outcome variables to test the analgesic efficacy were time to rescue analgesia and pain score. The secondary outcome variables were the hemodynamic parameters (heart rate and systolic blood pressure) nausea, vomiting, and degree of sedation. We looked for complications pertaining to the block such as hemodynamic instability, inadvertent intravascular injection of local anesthetic, accidental intraperitoneal injection, and any adverse reaction to study the drug. We also tested if addition of clonidine to local anesthetic had any effect on the duration of TAP block.

We compared the mean time to rescue analgesia between the three groups. Groups that received the TAP block had prolonged analgesia, showing that TAP block helps in prolonging analgesia. In a similar study by McDonnell et al.,[3] the effect of TAP block after cesarean section was evaluated and it was found that TAP block was effective in providing adequate analgesia. They also found that use of TAP block helps to reduce the opioid use in the postoperative period. In our study, we did not have to use opioids in groups A and B up to 12 hours. Increased use of opioids is associated with adverse effects like oversedation, respiratory depression, nausea, vomiting, and increased length of ICU stay.[7] Sharkey et al.[8] in their study found Tap block to be effective in prolonging analgesia in abdominal surgeries but it was not superior to that produced by epidural analgesia. TAP block may be useful when other modes of multimodal analgesia like epidural or nonsteroidal antiinflammatory drugs are contraindicated.[4]

There was no difference in the pain scores of patients belonging to groups A and B, while those of group C who did not receive TAP block had significantly higher pain scores. The fact that most of the patients in group C demanded rescue analgesia by 2 hours also indirectly indicates the analgesic benefit of TAP block over the control group with conventional analgesic regimes. Studies by Puddy et al.,[9] Marzouk et al.,[10] and McMorrow et al.[11] found that TAP block was not beneficial in patients who receive long-acting spinal opioids.

Various additives could be added to local anesthetics to prolong the duration of analgesia produced by blocks.[12] Clonidine, dexmedetomidine, fentanyl, sufentanil[13] are the commonly used additives. It has been shown in various previous studies that addition of clonidine to local anesthetic may prolong the action of peripheral nerve blocks.[14-17] Clonidine is an $\alpha_2$ adrenergic agonist. It enhances peripheral, epidural or spinal blockade when administered as an additive along with local anesthetics. But it is known to cause hypotension and bradycardia. It reduces heart rate by presynaptically mediated inhibition of norepinephrine release at the neuroreceptor junction and by vagomimmetic action.[14] In our study, group B patients, who received clonidine had lower heart rate and blood pressure as compared to other groups, probably because of the systemic absorption of clonidine. But

**Table 1: Comparison of pain scores between groups**

| Group | PS0  | PS2  | PS0  | PS2  |
|-------|------|------|------|------|
|       | n    | M    | R    | n    | M    | R    |
| A     | 20   | 0    | 0-10 | 20   | 0    | 0-10 |
| B     | 20   | 0    | 0-10 | 20   | 0    | 0-10 |
| C     | 20   | 2    | 0-10 | 17   | 5    | 1-10 |
| $P$   | $<0.0001$ | $<0.0001$ |

PS0: Pain score at 0h, PS2: Pain score at 2h, n: Number of patients, M: Mean, R: Range

**Table 2: Comparison of pain scores between group A and B**

| Group | PS0  | PS2  | PS4  | PS6  | PS8  |
|-------|------|------|------|------|------|
|       | n    | M    | R    | n    | M    | R    | n    | M    | R    | n    | M    | R    |
| A     | 20   | 0    | 0-10 | 20   | 1    | 0-10 | 18   | 1    | 0-10 | 16   | 2    | 0-10 |
| B     | 20   | 0    | 0-10 | 20   | 1    | 0-10 | 14   | 1    | 0-10 | 10   | 1.5  | 0-10 |
| $P$   | 0.382 | 0.462 | 0.101 | 0.354 | 0.912 |

PS: pain scores at 0, 2, 4, 6, 8h, n: number of patients, M: Median, R: Range
addition of clonidine at 2 μg/kg did not cause any drastic blood pressure or heart rate variations requiring intervention Singh et al. [18] found that addition of clonidine to bupivacaine in transverses abdominis plane block prolonged analgesia after cesarean section. But in contrast, this study found that there was no significant difference in the time to first rescue analgesia when clonidine was added. Niraj et al. [19] studied the analgesic efficacy of ultrasound-guided TAP block in patients undergoing open appendicectomy and found that the patients who received TAP block had better pain scores.

The incidence of nausea, vomiting was higher in-group C, probably because of the earlier need to rescue analgesia. We used Injection tramadol as rescue analgesic, which has emetic property. Antiemetic iv ondansetron was given along with tramadol. But still, patients had a higher incidence of nausea and vomiting. There was no significant sedation in patients who received clonidine in TAP block showing that addition of clonidine to bupivacaine in TAP block had no additive sedative effect. But sedation was noted in patients who did not receive TAP block. This could be attributed to the sedative effect of tramadol. The difference in sedation scores was not statistically significant.

Blind TAP blocks are associated with complications like accidental intraperitoneal, intravascular injections. Ultrasound guidance allows accurate deposition of local anesthetic in the correct neurovascular plane and avoids procedure related complications. In this study, we did not encounter any complication with ultrasound-guided TAP block. None of the patients in any group had any drug adverse reaction or overdose. The absence of significant nausea and vomiting, sedation, and other side effects probably suggests the safety of ultrasound-guided TAP block for routine clinical practice.

Our study has a number of limitations; we have assessed the pain relief up to only 12 hours. But the analgesia provided by TAP block has been shown to last longer. We did not add long-acting intrathecal opioids, which could have reduced the postoperative pain. We did not encounter any complication with ultrasound-guided TAP block. But the number of patients studied is too small to rule out a possibility.

**Conclusion**

Ultrasound-guided TAP block is a safe and effective method of providing postoperative analgesia in cesarean section patients as a part of a multimodal regimen. Addition of clonidine to bupivacaine had no added beneficial effect in prolonging analgesia.

**Financial support and sponsorship**

Nil.

**Conflicts of interest**

There are no conflicts of interest.