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# Does the Addition of TAP block to Intrathecal Buprenorphine Improve Analgesia and Patient Satisfaction after Caesarean Section under Spinal Anesthesia? A Randomized Controlled Study

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## Abstract

**Background and Objectives:** Intrathecal opioids are widely used to provide post-operative analgesia after caesarean section, but breakthrough pain requiring additional analgesia is not uncommon. TAP block, as a regional technique in addition to opioids intrathecally might improve analgesia after caesarean section.

**Methods:** In this randomized controlled study, 60 patients undergoing elective caesarean section were divided into two groups. 30 patients received 60 mcg intrathecal buprenorphine along with 0.5% hyperbaric bupivacaine and TAP block (intervention group) and 30 patients received 60mcg buprenorphine along with hyperbaric bupivacaine (control group). The primary outcome measures were the difference in pain at rest and on movement, as measured by the Numerical Rating Scale (NRS) and over all patient satisfaction with the pain relief.

**Results:** The pain scores at 6, 12, 24 hours at rest and on movement at 24 hours were not statistically significant between the two groups (p=0.80), but there was a significant difference in the satisfaction scores between the two groups (Control - 5.5 ±0.51; TAP - 8.57 ±0.5; p = 0.0001).

**Conclusions:** The addition of TAP block to intrathecal opioids does not improve analgesia, but might improve the overall patient satisfaction. More studies are needed to recommend the addition of TAP block to intrathecal opioids for routine practice.

**Keywords:** Caesarean section; TAP block; Spinal anesthesia; Analgesia;

## Introduction

Adequate analgesia after caesarean section helps the mother ambulate early, so she can care for, and establish an early bonding with the neonate1. Early ambulation also reduces the risk of thromboembolic complications in the post-operative period [1]. Generally, a multimodal approach involving paracetamol, non-steroidal anti-inflammatory drugs and opioids, either intrathecal or parenteral, is used to provide analgesia after caesarean section. Even with this approach, acute breakthrough pain requiring opioids remains a common clinical problem [2]. TAP block has been proposed as one of the techniques to provide analgesia after lower abdominal procedures, including caesarean section [3]. It has been shown to improve somatic analgesia and reduce analgesic requirement in the post-operative period. Although high dose intrathecal opioids provide adequate analgesia after caesarean section, the unpleasant side effects prompt us to lower the dose to just prevent intraoperative analgesic supplementation [4]. Therefore, it would be logical to combine an intrathecal opioid with TAP block to provide adequate somatic and visceral analgesia after caesarean section. The results of the published studies involving intrathecal opioids and TAP block thus far have been mixed with some favoring the addition of TAP block [5, 6] to the multimodal analgesia and others disapproving by concluding it does not improve analgesia any further [1]. Buprenorphine when given at a dose of 60 mcg intrathecally has been shown to provide analgesia for an average of 12 hours [7] with minimal side effects. TAP block when administered for caesarean section, has been shown to provide somatic analgesia for 18-24 hours [8]. Therefore, we hypothesized that the additionof TAP block might prolong the duration of analgesia further when combined with buprenorphine intrathecally.

## Methods

After approval from the local ethics committee, written informed consent was obtained from sixty ASA I - II pregnant women scheduled to undergo elective caesarean section under spinal anesthesia. All the patients were 18 years or older and the exclusion criteria were patient refusal, multiple previous abdominal operations and booking weight <50 kgs (since it limits the total bupivacaine dose). None of the patients refused to have spinal anesthesia or had any contraindications. Consecutive patients were randomized sequentially to receive TAP block (group T, n=30) or standard care (group C, n=30). Patients in both the groups underwent routine preoperative evaluation and were pre-medicated with intravenous ranitidine 50 mg and metoclopramide 10 mg, 60 minutes before anesthesia, as per the hospital guidelines. Baseline vitals (heart rate, blood pressure, respiratory rate and SpO2) were recorded and all the patients were preloaded with 500ml of Lactated Ringer's solution prior to anesthesia. Spinal anesthesia was performed in the sitting position and 2.0 ml of 0.5% heavy bupivacaine with 60mcg of buprenorphine, to a total of 2.2ml was injected intrathecally. In addition, patients randomized to the TAP group received bilateral TAP blocks in the operating theatre

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immediately after completion of the surgery. TAP block was performed under real time ultrasound guidance using the approach described by Hebbard and colleagues [9]. 20 ml of 0.25% bupivacaine was injected using a 9cm 22g injection needle on either side, after confirmation of the needle position using ultrasound.

Patients in both the groups received intravenous paracetamol after delivery and all patients were prescribed a standard postoperative analgesic regime of intravenous Paracetamol 1g sixth hourly. In the Post-Anesthesia Care Unit (PACU), in addition to the routine observations like blood pressure, heart rate, respiratory rate and oxygen saturation, the pain score using numerical rating scale (NRS) was also monitored and documented. Patients were monitored in PACU for a maximum of two hours and then shifted to the ward. Thereafter, NRS was recorded at 6, 12 and 24 hours. If the NRS was more than or equal to 3 or if the patient requests additional analgesia (whichever occurs first) at any time in the post-operative period, intravenous tramadol 50 mg was given as rescue analgesic. In the ward, along with pain score, postoperative nausea and vomiting, pruritus and total tramadol consumption in the first 24 hours were also monitored. Patients were asked to rate the overall satisfaction of the quality of postoperative pain relief on a scale of 1-10 with 'extremely dissatisfied' in one end and 'extremely satisfied' at the other and 'neither' at the center mark. Both nausea and pruritus were rated using a four-point scale (0- none; 1- mild, 2- moderate and 3-severe) and the degree of sedation was monitored using the standard sedation score (1- awake and alert, 2- drowsy, but easily roused, 3- somnolent and 4 - minimal or no response to stimulation). The primary outcomes were NRS at rest and on movement, defined as elevation of head and shoulders from the pillow, in the first 24 hours, and overall patient satisfaction with the pain relief. Secondary outcomes were tramadol consumption, sedation, nausea and vomiting, respiratory depression and pruritus.

Sample size was calculated using the results of an audit conducted earlier. It was calculated that a sample size of 28 for each group would be sufficient to detect a medium to large effect size (Cohen's d 0.75) difference between the groups for a significance level of 0.05 at 80% power. To account for withdrawals and dropouts, 30 patients were recruited to each group.

Quantitative data is expressed as mean and standard deviation (SD) and qualitative data is given as number and proportion. Statistical analysis was performed using Stats Direct software (Stats Direct, Altrincham, and Cheshire, UK). Student's t-test was used to compare means and Chi-square test was used for proportions. A p value of $<0.05$ is considered significant. The comparison of NRS scores between the two groups was done using two factors ANOVA with repeated measures on one factor (Vassar Stats, NY, USA).

## Results

All 60 patients completed the study. Baseline variables (age, ASA status, booking weight and height) were comparable between the two groups (Table 1). There was no statistically significant difference between the pain scores at 6, 12, 24 hours and pain score on movement at 24 hours (p= 0.80, table 2 and 3), but the patient satisfaction score was significantly higher in the TAP group compared to the control (8.57 vs 5.5; p 0.0001, table4).

None of the patients required tramadol for analgesia and none of them developed respiratory depression in the post-operative period. Other secondary outcome measures like nausea, vomiting, sedation and pruritus were not significantly different between the two groups (table 5).There were no local or systemic complications, minor or major, because of TAP block.

**Table 1:** Baseline variables

| | Control group | TAP group | *p* |
|---|---|---|---|
| Age (Mean±SD) | 28.17±4.03 | 29.3±4.14 | 0.29* |
| Height (Mean±SD) | 158.90±7.9 | 157.8±8.8 | 0.61* |
| Weight (Mean±SD) | 63.2±9.8 | 64.9±11.2 | 0.52* |
| ASA status 1/2 | 25/2 | 26/4 | 1.0† |

* Student's t test, †Fisher Exact test

**Table 2: NRS**

| Time | Control group (Mean NRS) | TAP group (Mean NRS) |
|---|---|---|
| 2 hours | 1.1±0.40 | 1.07±0.45 |
| 6 hours | 1.3±0.70 | 1.07±0.45 |
| 12 hours | 2.1±0.61 | 1.87±0.73 |
| 18 hours | 2.57±0.50 | 2.27±0.64 |
| 24 hours | 2.87±0.35 | 2.77±0.50 |

Comparison of NRS over time (2, 6,12,24 hours) between the two groups using the two factors ANOVA with repeated measures on one factor did not show significant difference between the two groups (p =0.80).

**Table 3:** NRS on movement

| | Control group | TAP group | *p* |
|---|---|---|---|
| NRS 24 hours (movement) (Mean±SD) | 5.1±0.4 | 4.9±0.3 | 0.16* |

* Student's t test

**Table 4:** Satisfaction score

| | Control group | TAP group | *p* |
|---|---|---|---|
| Satisfaction score(Mean±SD) | 5.5±0.51 | 8.57±0.5 | 0.0001* |

* Student's t test

**Table 5**

| | Control group | TAP group | *p* |
|---|---|---|---|
| Nausea and Vomiting | 2/30 (6.7%) | 1/30 (3.3%) | 1.0† |
| Pruritus | 1/30 (3.3%) | 2/30(6.7%) | 1.0† |

†Fisher Exact test

## Discussion

It is well known that opioids, when added to local anesthetics in spinal anesthesia provide a synergistic effect and prolong analgesia [10]. Since preservative free morphine and diamorphine are not freely available in Asia, buprenorphine is widely used as anintrathecal opioid additive. Buprenorphine is a partial agonist at mu opioid receptors with a prolonged duration of action due to its high affinity for the receptor. The high lipophilicity of buprenorphine makes it suitable for intrathecal administration as it reduces the risk of delayed respiratory depression. As an intrathecal additive in spinal anesthesia, it has been widely studied. Due to the high lipophilicity, the duration of action of 60mcg buprenorphine intrathecally is not as prolonged as morphine, but probably comparable to 0.4 mg intrathecal diamorphine [8]. Previous studies have shown that buprenorphine provides good analgesia with less adverse effects at a dose

of 60-mcgintrathecally [10]; therefore, this dose was chosen for our study. At this dose, buprenorphine provides analgesia for an average of 12 hours after intrathecal administration.

Recent literature equally supports and questions the use of lateral TAP blocks for post-operative analgesia. It is beyond doubt that posterior TAP blocks described by Rafi et al. [11] provide prolonged analgesia compared to lateral TAP blocks12, but blind needle placement has its own risks; therefore, ultrasound guided lateral TAP block technique7was chosen for our study. TAP block when administered using ultrasound provides analgesia for 18-24 hours.

## Limitations

There are several limitations to this study. Lack of allocation concealment and blinding could have introduced substantial bias, but people blinded to the intervention performed data collection and analysis. Analgesic duration of lateral TAP blocks doesn't last as long as posterior TAP blocks [12]. This could have contributed to the lack of difference in NRS between the two groups, but there was no difference in the need for rescue analgesia indicating satisfactory analgesia with intrathecal opioid itself. Single center recruitment, lack of follow up after the first 24 hours and exclusion of patients with previous abdominal procedures are the other limitations of this study.

Although NRS was not significantly different, it is interesting to note that the patient satisfaction scores were significantly different between the two groups. This supports the argument that the process of pain management and the anesthetist's efforts to provide good pain relief, but not just adequate analgesia, determines the overall patient satisfaction. In fact, several small studies have shown that there is no correlation between the level of analgesia and patient satisfaction, which leads to an argument that patient satisfaction with pain control, must be included along with NRS while reporting analgesic outcomes [13]. The limitation in this study is that the control group patients didn't receive TAP injections with saline, which could have had an impact on the ultimate satisfaction scores. Therefore, the difference in satisfaction scores in our study must be interpreted with caution.

## Conclusion

Effective postoperative analgesia for caesarean delivery can be achieved using a multimodal approach including intrathecal buprenorphine and other oral and parenteral analgesics. The addition of TAP block to this approach adds very little to the overall pain relief, but might improve overall patient satisfaction. 167 Until further evidence investigating the overall patient satisfaction with TAP block after intrathecal opioids emerges, TAP block will not be recommended for the provision of routine post-operative analgesia after caesarean section under spinal anesthesia with intrathecal opioids.

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