

A randomized clinical comparative trial to study the efficacy of adding Clonidine or Dexamethasone to Bupivacaine(0.5%) in prolonging the duration of post operative analgesia with ultrasound guided TAP block in cesarean delivery

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Abstract

Introduction: With dramatic rise in the rate of cesarean deliveries in the last two decades, post-operative pain management of these patients has become a major medical challenge. We studied the efficacy of adding dexamethasone and Clonidine as adjuvants to bupivacaine using USG guided TAP block.

Material and Methods: 60 patients posted for elective cesarean delivery under spinal anesthesia were selected for the study. Patients received 20ml of 0.125% Bupivacaine with Dexamethasone (4mg), Clonidine(25µg), Saline(2ml) on each side, in groups D,C and B respectively. Post-operatively pain scores using VAS score, time to first rescue analgesic, and 48hr analgesic consumption were studied.

Results: VAS scores were comparable in all the three groups in the first 12hr, it was higher in group B in the next 36hrs. Time to first rescue analgesic was prolonged by 2hrs in all three groups. Tramadol requirement was significantly lower in the group C and group D after 12hrs.

Conclusion: We conclude that USG guided TAP block using either clonidine or dexamethasone as adjuvants to bupivacaine will equally help in alleviating the somatic pain for extended period of time thereby providing substantial improvement in quality of pain care and breast feeding experiences.

Keywords: Dexamethasone, Clonidine, TAP block, VAS score, Somatic pain

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Introduction

With dramatic rise in the rate of cesarean deliveries in the last two decades, post-operative pain management of these patients has become a major medical challenge.⁽¹⁾ Cesarean delivery patients have compelling reasons to achieve optimal post-operative pain relief, as they present with unique challenges; such as, a higher risk of thromboembolic events, which may be precipitated by immobility, inadequate pain control or excessive sedation associated with opioids.⁽¹⁾ Moreover these women want to be alert and energetic enough, to care for, interact with, and breastfeed their newborn.⁽²⁾

Transverse Abdominis Plane[TAP] block is an established technique to manage post-cesarean delivery pain. More recently, ultrasound guided TAP block has been described with promises of better localization and deposition of the local anaesthetic with improved accuracy.⁽³⁾

TAP blocks with local anaesthetics only, offer no analgesic benefits compared to intrathecal morphine.⁽⁴⁾ Different adjuvants have been used to intensify the quality and increase the duration of action of local anaesthetics.⁽⁵⁾

The aim of the present study was to evaluate and compare the effect of adding Dexamethasone or Clonidine to Bupivacaine on the quality and duration of post-operative analgesia using USG guided TAP block.

We hypothesized that adding either clonidine or dexamethasone to bupivacaine did not show much difference in the duration and quality of post-operative analgesia.

Material and Methods

After approval from the institutional review board[SSIMS & RC Davangere] and a written informed consent, 60 patients posted for elective cesarean delivery were selected for the study. Eligible participants were pregnant patients with ASA physical status II aged between 20-40yrs posted for elective cesarean delivery under spinal anesthesia.

Patients with ASA physical status III and IV, history of severe chronic pain, history of hypersensitivity or allergies to any drugs and patients with contraindications for spinal anaesthesia were excluded from the study.

The recruited patients were randomly assigned to one of the three groups with 20 in each group by computer generated random number table, concealed in an envelope, which was opened just before cesarean section. The patients received USG guided TAP block with

20ml of 0.125% Bupivacaine+50micro gm Clonidine[group C] or

20ml of 0.125% Bupivacaine +4mg Dexamethasone[group D]or

20ml of 0.125% Bupivacaine plain[group B] on each side.

All patients received IV ranitidine [50mg] and metoclopramide[10mg] 20-30 min before surgery. Cesarean section was performed under spinal anaesthesia in left lateral position. Dural tap done using a 25G spinal needle and 2ml of 0.5% bupivacaine heavy was injected in L3-L4 space.

At the end of surgery the level of block was recorded. USG guided TAP block[posterior approach] was performed under all aseptic precautions The patient being in supine position, area painted and draped, aseptically prepared USG probe was placed in the mid-axillary line transverse to abdominal wall midway between iliac crest and costal margin. The image produced showed [from superficial to deep]skin and subcutaneous tissue, fat, external oblique, internal oblique, and lastly the peritoneum. Transversus abdominis plane was reached using Sono TAP cannula for single-shot techniques[22G*80mm]. The needle was advanced using in-plane technique and once the needle tip was visible in the plane between the internal oblique and transverses abdominis muscle, drug was deposited in the plane after negative aspiration. The technique was repeated on the opposite side. Visualization of the hypochoic spread of drug, with the fascial layer above and the muscle layer below, was considered a sure sign of proper deposition.

Post-operatively pain scores using VAS (visual analogue scale)score, 0-10[0-no pain to10-unimaginable pain], at 2, 4, 6, 8, 12, 24, 36 and 48hrs, time to first rescue analgesic, 48hr analgesic consumption and incidence of nausea and vomiting were studied. Inj Tramadol 50mg IM along with tab ondansetron was used as rescue analgesic at VAS>4. The data were collected by a nurse who was unaware of the anaesthetic technique.

Statistical analysis: Statistical analysis was done using Descriptive statistics, graphics and One Way Analysis of Covariance[ANOVA].

Results

All three groups were comparable with respect to the demographic characteristics like age, ASA physical status, weigh, BMI and height.

Table 1: Descriptive statistics for age

| ASA | Group-B | Group-C | Group-D | Total |
|-------|---------|---------|---------|-------|
| I | 17 | 17 | 16 | 42 |
| II | 3 | 3 | 4 | 18 |
| Total | 20 | 20 | 20 | 60 |

VAS scores were comparable in all the three groups[group B, group C & group D] from 2h upto 8h, and were not statistically significant[P>0.05]. At 16th hr, 24th hr, 36th hr and 48th hr VAS scores were comparable in group C and group D (as shown in Fig. 1 and Table 1), while patients in group B showed higher pain scores, P values being statistically significant[P<0.05]. Total requirement of rescue analgesia was comparable upto 48hrs in group C and group D as shown in Table 2.

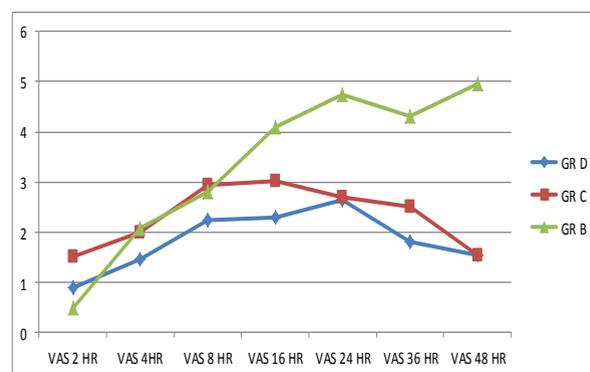


Fig. 1 : mean scores at various times

Table 2: VAS Scores at 4Hrs, 8Hrs and 16Hrs

| VAS | Group | N | Mean | STD-Deviation | Minimum VAS score | Maximum VAS score | P-Value |
|-------|-------|----|-------|---------------|-------------------|-------------------|---------|
| 4hrs | B | 20 | 0.500 | 0.88 | 0 | 2 | 0.07 |
| | C | 20 | 0.80 | 0.99 | 0 | 3 | |
| | D | 20 | 0.900 | 1.19 | 0 | 4 | |
| 8hrs | B | 20 | 2.8 | 0.76 | 1.00 | 4 | 0.3 |
| | C | 20 | 2.9 | 1.79 | 1.0 | 6 | |
| | D | 20 | 2.2 | 2.1 | 0.0 | 8 | |
| 16hrs | B | 20 | 4.1 | 0.85 | 3 | 6 | 0.02 |
| | C | 20 | 0.9 | 1.11 | 1 | 4 | |
| | D | 20 | 0.8 | 0.99 | 0.0 | 3 | |

Time to first rescue analgesic dose [TFA] of tramadol 50mg IM, was prolonged by almost 2hrs in all the groups [P>0.05]. Tramadol requirement in all the three groups in the first 12hrs was comparable[P>0.05], but was

significantly higher in the group B when compared to group C and group D upto 48hrs[P<0.05]as shown in Table 2. Mothers in the groups C and D were more comfortable during breast feeding in comparison with group B[Table 3].

Table 3: Percentage of mothers comfortable during breast feeding

| | | Group-B[n=20] | Group-C[n=20] | Group-D[n=20] |
|-----------------------------|------------|---------------|---------------|---------------|
| Rescue analgesia (Tramadol) | [0-12hrs] | 8% | 12% | 10% |
| | [12-24hrs] | 18% | 7% | 8 |
| | [24-48hrs] | 16% | 5% | 4% |

Table 4: Post-operative rescue analgesic requirement expressed in %

| Group | B | | C | | D | |
|----------|---------|----------|---------|----------|---------|----------|
| Duration | 0-24hrs | 24-48hrs | 0-24hrs | 24-48hrs | 0-24hrs | 24-48hrs |
| n | 85% | 90% | 90% | 100% | 90% | 100% |

Discussion

Managing pain following cesarean section is challenging. The analgesic regimen should be effective, safe and devoid of side effects. Transverse abdominis plane block performed in conjunction with USG for post-operative analgesia is more frequently used now in cesarean deliveries.^(6,7,8,9) Different drug combinations have been explored to determine the most efficient analgesic combination.^(4,7,10)

Our study was the first to compare the efficacy of dexamethasone and clonidine as adjuvants to local anaesthetic with USG guided TAP block for post-operative analgesia in cesarean delivery. We found that adding adjuvants to bupivacaine for TAP block decreases the total analgesic requirement in post-operative period.

The time to first rescue analgesia was comparable in all the three groups[group B, C, D] as most of our patients received the first rescue analgesia in the first 2 hrs. This was probably due to the visceral pain, since the somatic pain elicited by pressing on the incision site was negligible. Single injection TAP protects only against somatic pain whereas visceral pain is spared. TAP block blocks the abdominal wall neural afferents between T6-L1. Pain of cesarean section essentially has two components somatic and visceral but substantial amount of pain experienced by the patients is derived from abdominal wall incision. A randomized double-blind study by Uma Srivastava et.al. Using USG guided TAP block for cesarean section found that predominant somatic pain was very well relieved by TAP block and visceral pain at its worst did not appear to be prominent and was relieved by additional analgesic.⁽¹¹⁾

The VAS scores were comparable in all the three groups in the first 12hrs. The score was lesser in the group-C and group-D compared to group-B after 12 hrs, which was statistically significant.[P<0.05].

Cumulative requirement of rescue analgesics after 12hrs was comparable in group-C and group-D and was statistically significant [P<0.05]. The requirement in these two groups was significantly less when compared

to group-B. This can be attributed to the wearing off of TAP block in group B.

A study by Laurent Bollag et.al. concluded that adding clonidine to TAP did not enhance or extend the analgesic effect of TAP block.⁽⁴⁾ But this finding is questionable since the study also showed that TAP with plain bupivacaine enhanced the duration of post-operative analgesia.

A meta-analysis by Popping et.al. which included 20 trials showed that adding clonidine to local anaesthetic in nerve blocks prolonged the duration of post-operative analgesia by only about 122min which is comparable to our study. He also showed an association of side effects like arterial hypotension, bradycardia and sedation with clonidine use in higher doses. But this study included only peripheral nerve blocks where the visceral component of pain does not come into picture. We did not encounter any of the above said problem may be due to dose we selected. Also this meta-analysis did not include any TAP block studies. In another systematic quantitative review on role of adjuvants in peripheral nerve blocks by Meghan. A. Kirksey et.al. clonidine added to local anaesthetic was found to prolong peripheral nerve blocks to moderate degree, but however caused bradycardia and hypotension at higher doses⁽¹²⁾

A prospective double-blind study by Waleeda Abdalla showed that using dexamethasone as adjuvants in TAP block prolongs the duration of post-operative analgesia upto 22.4hrs.⁽⁶⁾ Also in another study by A. Akkaya et. al. It was found that adding dexamethasone to local anaesthetic increased the duration of post-operative analgesia upto 24hrs.⁽⁹⁾

Post-operatively, mothers in the dexamethasone and clonidine groups had better breast feeding experiences compared to the plain bupivacaine group. Also post-operative nausea was less or nil in the dexamethasone and clonidine groups in comparison to the bupivacaine group.

Conclusion

TAP block did not prolong the time to first rescue analgesia but the cumulative requirement of tramadol was less in the groups where adjuvants like dexamethasone or clonidine were used [group-C & group-D] compared to plane local anaesthetic[Group-B]. There was no difference in the two groups with respect to the parameters(VAS score, time to first rescue analgesic and number of analgesic doses) studied. So we conclude that TAP block is beneficial for post-operative analgesia in LSCS patients and using additives like clonidine or dexamethasone will help in alleviating the somatic pain for extended period of time, thereby providing substantial improvement in quality of pain care and breast feeding experiences . Hence, using either clonidine or dexamethasone as adjuvants in TAP block is equally effective in alleviating post-operative pain.

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