

Comparison of Efficacy of 0.25 % Ropivacaine with Dexmedetomidine versus 0.25 % Ropivacaine Alone for Transversus Abdominis Plane Block for Post-Operative Analgesia in Patients Undergoing Lower Segment Caesarean Section - A Prospective Randomized Clinical Study

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ABSTRACT

BACKGROUND

Regional anaesthesia is an armamentarium in the hands of the anaesthesiologist to provide swift, effective and safe condition for surgery. However, local anaesthetics are characterised by slower onset and shorter duration of action, when used in larger doses can cause systemic toxicity. Hence, adjuvants are used to better the quality of blocks. Here, I have used dexmedetomidine as an adjuvant in transversus abdominis plane (TAP) block to assess duration of action, hemodynamic effects and side-effects.

METHODS

Our study is randomised double blinded comparative study, in which we have compared two groups, one received ropivacaine alone and another received ropivacaine with dexmedetomidine as an adjuvant. Assessment was done for duration of action, visual analog scale (VAS) scores, analgesic drug usage, sedation scoring and incidence of side-effects and complications. This study was conducted on 94 parturients with 47 patients in each group.

RESULTS

Dexmedetomidine has a statistically significant prolonged action and has given excellent analgesia post-operatively. Additional analgesics were required in a lesser number than the control group. There were no hemodynamic disturbances and complications.

CONCLUSIONS

Dexmedetomidine added to ropivacaine for ultra-sound guided TAP block is associated with prolonged and excellent analgesia with lesser requirement for additional analgesic usage, lower VAS scores, hemodynamic stability, and minimal sedation.

KEYWORDS

Caesarean Section, Dexmedetomidine, Analgesia, Post-Operative, Ropivacaine, Transversus Abdominis Plane Block

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BACKGROUND

Lower segment caesarean section (LSCS) is a major surgical procedure with significant post-operative pain.

1. Good control of pain is vital as it has a negative impact on ambulation, breast-feeding and even maternal bonding. Post-operative pain management is usually multimodal which includes oral or intra-venous acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), opioids, peripheral nerve block or epidural as patient-controlled analgesia (PCA).
2. Although opioids are most widely used to control post-operative pain effectively, unwanted effects are the major drawbacks. There is a potential risk of opiates being excreted in breast milk and these medications in high doses can lead to respiratory depression and death, high doses of NSAIDs can cause gastrointestinal injury.
3. Ultrasound-guided TAP block has recently come up as a peripheral nerve block which provides anaesthesia to the anterolateral abdominal wall derived from T6-T12 which is gaining (Rozen WM, et al.¹) popularity as a part of multimodal analgesia for post-operative pain relief during abdominal surgeries. It (Mishra M, et al.²) can avoid the use of intravenous opioids and its complications.

Bupivacaine with its cardiac and central nervous system toxic effects in some patients, prompted researchers to develop a newer local anaesthetic agent with a profile similar to bupivacaine without considerable cardiotoxic effects. One such possible replacement for bupivacaine was ropivacaine which was introduced into the market in 1996. Ropivacaine is a long acting amide which is less lipophilic than bupivacaine and minimal penetration of large myelinated motor fibres.

Thus, it has a greater degree of motor sensory differentiation, which could be useful when motor blockade is undesirable. Dexmedetomidine an imidazole compound is a selective α_2 adrenergic agonist with both analgesic and sedative properties. Its use with local anaesthesia (LA) in regional blocks is associated with prolongation of the LA effect (Yoshitomi T, et al.³ Marhofer D et al.⁴ Almarakbi WA et al.⁵) Dexmedetomidine has been used as an adjuvant to ropivacaine in TAP block to increase the duration of analgesia after various abdominal surgeries. However, there are very few studies using this (Mishra M, et al.⁶ Andurkar US et al.⁷ Ramya Parameswari A, et al.⁸) combination in comparison to ropivacaine alone for caesarean section.

The present study was conducted to compare the efficacy of 0.25 % ropivacaine with dexmedetomidine versus 0.25 % ropivacaine alone in TAP block for post-operative analgesia in patients undergoing LSCS.

Objectives

Primary Objectives

1. To compare the time taken for request of first rescue analgesic.

2. To assess total requirement of doses of rescue analgesia in first 24 hours, in both the groups:
 - a) TAP block with ropivacaine.
 - b) TAP block with adjuvant dexmedetomidine added to ropivacaine.

Secondary Objectives

1. To assess the side effects of opioids like nausea, vomiting, sedation etc.
2. To identify complications related to the technique.

METHODS

Preanesthetic Preparation

After obtaining approval from hospital ethical committee (IEC No - NHMMI / ECIRB / 01 / 2018) along with written and informed consent, 94 adult patients of American society of Anaesthesiologist (ASA) grade I & II, who were undergoing Caesarean section from August 2018 to April 2020 with Pfannenstiel incision under spinal anaesthesia were included in this prospective randomized double blinded study.

Inclusion Criteria

1. Pregnant women more than 18 years of age undergoing lower segment Caesarean section under spinal anaesthesia via Pfannenstiel incision under spinal anaesthesia with 2 ml 0.5 % hyperbaric bupivacaine (both elective and emergency).
2. ASA grade I and II parturient.
3. Who could understand and rate their pain on Visual Analog Scale (VAS scale of 0 – 10)?

Exclusion Criteria

1. Patient refusal.
2. Allergy to study medications.
3. Patients with significant coagulopathies and with contraindications with regional anaesthesia.
4. Patients with history of cardiac, respiratory, renal or hepatic failures.
5. Psychological disorders.
6. Infection at the site of block.
7. Patients converted to general anaesthesia after giving subarachnoid block.

Group Allocation, Randomization, and Blinding

After obtaining informed consent, the patients were assigned to one of the two groups, i.e.,

Group A (N = 47): TAP Block with 20 ml of study medication 0.25 % ropivacaine on each side group B (N = 47): TAP block with 20 ml of 0.25 % ropivacaine with dexmedetomidine 0.5 μ g / kg added on each side A research assistant created a randomization schedule for 94 patients using Microsoft excel (Microsoft Corporation©, Seattle,

USA), assigned codes to the patient group, and put the coded group allocation information in sealed envelopes. Patient group allocation after enrolment was decided by opening consecutive sealed envelopes. The research assistant was not responsible for enrolling patients, direct patient care including postoperative analgesia administration, or final data analysis. The group codes were only shared with an anaesthesiologist who did not involve in outcome assessment, to prepare the respective drug combinations. The drug combinations were marked with group codes to maintain the double-blind nature of the study.

Procedure

Drugs and equipment necessary for resuscitation were kept ready. Intravenous line was secured with a 16 - 1 - 1 or 18-gauge (G) intravenous cannula in all patients and preoperatively 8 ml kg h NaCl 0.9 % was infused. Routine monitors were applied in the operating room (BP, HR, SpO₂) and values were tracked by non-invasive methods. All patients received Inj. Ondansetron 4 mg IV and Inj. Ranitidine 150 mg IV 30 minutes prior to the procedure as pre-medication.

All the patients received subarachnoid block by 26 G Quincke's needle at L4 - 5 / L3 - 4 inter-space with a total volume of 2.2 ml of 0.5 % hyperbaric Bupivacaine using a standard mid-line approach to achieve a block level of T6 for the Caesarean section. All patients were hemodynamically monitored and to allay anxiety, IV Midazolam 1 mg was given after delivery of the baby.

At the end of surgery after skin closure, ultrasound guided bilateral TAP block using In-plane technique was performed under strict aseptic conditions (gown, gloves, facemask, cling film drape to cover ultrasound probe) by placing the linear probe (3 - 12 MHz) in transverse plane to the lateral abdominal wall in the midaxillary line, between lower costal margin and iliac crest. The image produced shows (from downwards to above) moving peritoneum, transverse abdominis muscle, internal oblique muscle, external oblique muscle, fat, subcutaneous tissue and skin. The block was performed with a 22-G spinal needle attached with 10 cm flexible tubing to a syringe filled with the study solution. The needle is introduced in plane of the ultrasound probe directly under the probe and advanced until it reaches the plane between internal oblique abdominal muscle (IOAM) and transverse abdominal muscle (TAM). Upon reaching the plane, a negative aspiration of blood is confirmed and a test dose of 2 ml of drug is injected to confirm the correct needle position. The transversus abdominis plane was visualized expanding with the injection (appears as a hypo echoic space).

TAP block was performed bilaterally by injecting 20 mL of 0.25 % ropivacaine (prepared by diluting 10 ml of 0.5 % ropivacaine in 10 ml of normal saline) each side in group A and 0.5 µg / kg dexmedetomidine added to 20 ml of 0.25 % ropivacaine each side in group B. All TAP blocks were performed by the same anaesthesiologist. Patients as well as the anaesthesiologist who was performing TAP block were unaware of the allocated group.

Postoperative Monitoring

The presence and severity of pain, sedation, nausea, vomiting and any other side effects were assessed for all patients in both groups. These assessments were performed in the recovery room for 30 minutes and at 0, 2, 4, 6, 8, 12, 24 hrs postoperatively in the post-natal care room by an observer, who was unaware of the group to which patient has been allocated and record the pain score on visual analogue scale. Each patient was asked to rate the postoperative pain using VAS scale. Intravenous Tramadol 1 mg / kg was given as rescue analgesia for postoperative pain relief if pain score > 4 or when it was requested by the patients, the time to first dose of rescue analgesic given was recorded and worst pain score noted. Patients were closely observed postoperative for 24 hours for complications like nausea, vomiting, sedation etc. Nausea was assessed by using an ordinal scale and level of sedation by ASA grading. Occurrence of any complications (hematoma, bleeding, and infection) were also assessed.

Statistical Analysis

Categorical data was expressed in frequency and percentage and analyzed using Fisher's exact or Chi-square test depending on sample size. Continuous data was expressed as mean (standard deviation) and was analyzed using Independent T-test. Two-sided P-value of < 0.05 was considered significant. Data was analyzed using statistical packages for SPSS 16.0 for Windows (SPSS Inc., Chicago, IL, USA). The blind was opened at the end of data analysis for the purpose of reporting the results of the study.

Sample Size

94 patients sample size was calculated based on standard deviation (SD) and minimum difference (d) for the mean VAS score detected between the patients in which 0.25 % ropivacaine used and 0.25 % ropivacaine with dexmedetomidine

$$N = 2 * (Z\alpha + Z\beta)^2 \times \sigma^2$$

$Z\alpha = 1.96$ at 95 % confidence interval

$Z\beta = 0.84$ at 80 % power

Combined σ (SD) = (0.616 + 0.605 / 2)

d = difference between mean VAS score of 2 groups = 2.8 - 2.55 = 0.25 Substituting the values in formula we got total sample size (N) = 93

47 in each group

RESULTS

The results obtained were recorded and data was analysed. Intraoperative characteristics like heart rate, mean arterial pressure (MAP), oxygen saturation (SPO₂), duration of surgery and duration of anaesthesia also did not differ in both the groups. Characteristics like age, weight, height and ASA grading were comparable in both the groups.

Our study showed that addition of dexmedetomidine to ropivacaine resulted in a longer mean time to first rescue analgesia when compared with ropivacaine alone. Mean time to first rescue analgesic in patients who received ropivacaine was (7.57 ± 0.71 hrs) vs. (11.95 ± 0.88 hrs) in those who received ropivacaine + dexmedetomidine (P < 0.0001).

Assessment of results from data performing to the number of analgesic doses required in 24 hours showed a mean of 1.6 ± 0.57 (ropivacaine alone dose) and 0.78 ± 0.58 (ropivacaine + dexmedetomidine dose) in our study. 14 patients (30 %) in group B (ropivacaine with dexmedetomidine) did not require any rescue analgesia in comparison to only 1 patient (2 %) in group A (ropivacaine alone). This was found to be statistically significant.

On comparison of VAS scores in both groups we found that at 6 hrs. 8 hrs. 12 hrs. and 24 hrs the median VAS score was lower in group B (P < 0.05) which is statistically significant.

On comparing sedation between the two groups using Modified Ramsay Sedation score we found that there is significant sedation in group B as compared to group A at 1 and 2 hours following the block. Also, the overall sedation score in group B was 3 as compared to 2 in group A. All the patients with sedation score at 3 were arousable and did not have any respiratory depression.

In our study though there was numerical increase in nausea / vomiting in group B (5 vs. 4) this finding was not statistically significant. There were no complications related to the TAP block in both the groups in our study.

Characteristics	Group A	Group B	P-Value
	(N = 47)	(N = 47)	
	Mean ± S.D	Mean ± S.D	
Age (years)	24.71 ± 1.517	24.84 ± 1.261	0.65
Weight (kg)	64.07 ± 3.864	62.98 ± 4.382	0.21
Height (cm)	155.0 ± 4.497	157.1 ± 4.419	0.98
ASA status (grade I)	13 (28 %)	15 (32 %)	0.65
ASA status (grade II)	34 (72 %)	32 (68 %)	(chi-square)
Level of spinal L3 - L4	6 (13 %)	6 (13 %)	1
Level of spinal L4 - L5	41 (87 %)	41 (87 %)	(chi-square)

Table 1. Demographic Data and Operative Characteristics between Groups
Independent T-test; P > 0.05 not significant

Characteristics	Group A	Group B	P-Value
	(N = 47)	(N = 47)	
	Mean ± SD	Mean ± SD	
Heart rate	74.98 ± 9.46	76.18 ± 7.60	0.48
MAP (mmHg)	75.72 ± 5.43	77.9 ± 7.47	0.09
SpO2	98.72 ± 0.99	99 ± 0.53	1.76
Duration of surgery (min)	56 ± 5.02	60.2 ± 5.94	0.15
Duration of anaesthesia (min)	240.56 ± 10.54	230 ± 10.52	0.77

Table 2. Comparison of Intraoperative Characteristics
Independent t test; P > 0.05 not significant

Rescue Analgesics (Tramadol) Doses in 24 hrs.	Group A (N = 47)	Group B (N = 47)	P-Value
0 (not required)	1 (2 %)	14 (30 %)	P < 0.001**
1 (one time required)	18 (38 %)	30 (64 %)	(Fischer's exact test)
2 (two times required)	27 (58 %)	3 (6 %)	
3 (three times required)	1 (2 %)	0 (0 %)	
Mean total number of rescue analgesics (tramadol) in 24 hrs.	1.6 ± 0.57	0.78 ± 0.58	P < 0.001**
Comparison of time to 1 st analgesic request (in hours)	7.57 ± 0.71	11.95 ± 0.88	P < 0.001**

Table 3. Comparison of Analgesic Efficacy
Independent t test; **P < 0.001 highly significant

Duration	Group A (N = 47)	Group B (N = 47)	P-Value
	Mean ± S.D	Mean ± S.D	
0 hrs.	1.9 ± 0.60	1.86 ± 0.61	0.74
2 hrs.	2.1 ± 0.89	2.12 ± 0.93	0.91
4 hrs.	2.2 ± 1.15	2.14 ± 0.70	0.76
6 hrs.	3.2 ± 0.69	2.6 ± 0.59	< 0.001**
8 hrs.	4.4 ± 0.59	2.7 ± 0.42	< 0.001**
12 hrs.	3.3 ± 0.53	2.4 ± 0.42	< 0.001**
24 hrs.	3.1 ± 0.62	2.2 ± 0.80	< 0.001**

Table 4. Comparison of VAS Scores in Both Groups
Independent t test; **P < 0.001 highly significant

Parameter	Group A (N = 47)	Group B (N = 47)	P-Value	
MRS score	0 hour	1.16 ± 0.37	1.96 ± 0.51	0.67
	1 hour	1.03 ± 1.5	0.18 ± 0.34	0.01*
	2 hours	0.96 ± 1.13	0.18 ± 0.52	0.025*
	4 hours	0.93 ± 0.83	0.253 ± 0.53	0.354
	6 hours	0.85 ± 0.94	0.71 ± 0.53	0.52
	8 hours	0.90 ± 0.86	0.30 ± 0.20	0.08
	12 hours	0.73 ± 0.70	0.44 ± 0.26	0.17
	24 hours	0.57 ± 0.67	0.46 ± 0.40	0.373
Nausea / vomiting	Yes	4 (8.5 %)	5 (10.6 %)	1.052
	No	43 (91.5 %)	42 (89.4 %)	(chi square)

Table 5. Comparison of PONV and Sedation in Both Groups
Independent t test; *P < 0.05 significant

DISCUSSION

Our study showed that addition of dexmedetomidine to ropivacaine resulted in a longer mean time to first rescue analgesia when compared with ropivacaine alone. Mean time to first rescue analgesic in patients who received ropivacaine was (7.57 ± 0.71 hrs.) vs. (11.95 ± 0.88 hrs.) in those who received ropivacaine + dexmedetomidine (P < 0.0001). This compares well with the study done by (Prannal Bansal et al.⁹) who gave TAP block with 3 mg / kg of ropivacaine diluted to total of 40 ml in normal saline with 20 ml on each side to the control group and 3 mg / kg ropivacaine plus 50 mcg of dexmedetomidine diluted to total of 40 ml in normal saline with 20 ml on each side to test group and found that the mean time to first rescue analgesia was 6.47 ± 1.22 hr. (ropivacaine) vs. 7.8 ± 2.29 hr. (ropivacaine + dexmedetomidine) (P < 0.05). Similarly in a study done by (RatiPrabha et al.¹⁰) it was found that the time for first analgesia in patients who received 20 ml of 0.5 % ropivacaine alone was 219.00 ± 27.31 minutes as compared to 555.07 ± 120.22 minutes in the group that received ropivacaine along with additional 0.5 µg / kg dexmedetomidine (P-value < 0.001).

Also (Sarvesh et al.¹¹) in their study found that demand of first rescue analgesic in 0.375 % of 20 ml ropivacaine group was 289.8 min and in 0.375 % of 20 ml ropivacaine with (0.5 mcg / kg) dexmedetomidine group was 485.6 minutes which has results similar to our study. Assessment of results from data performing to the number of analgesic doses required in 24 hours showed a mean of 1.6 ± 0.57 (ropivacaine alone dose) and 0.78 ± 0.58 (ropivacaine + dexmedetomidine dose) in our study. 14 patients (30 %) in Group B (ropivacaine with dexmedetomidine) did not require any rescue analgesia in comparison to only 1 patient (2 %) in group A (ropivacaine alone). This was found to be statistically significant. The analgesic dose provided was 1 mg / kg of Injection Tramadol given intravenously. This requirement was comparable to Gupta et al.¹² who reported a mean of rescue analgesics whilst using Tramadol at a dose

of 2 mg / kg in Ropivacaine alone group was 3.13 ± 0.86 and in ropivacaine with dexmedetomidine group was 1.9 ± 1.14 . Prashant et al.¹³ concluded that total doses of tramadol used in the first 24 hours were less among patients who received dexmedetomidine along with ropivacaine. Total dose of tramadol consumed by ropivacaine group was 98 mg and by ropivacaine with dexmedetomidine group was 71 mg ($P < 0.001$). This shows us that the addition of dexmedetomidine to ropivacaine has reduced the requirements of analgesia in the first 24 hours following surgery and is consistent with the findings of others. On comparison of VAS scores in both groups we found that at 6 hrs., 8 hrs., 12 hrs. and 24 hrs the median VAS score was lower in group B ($P < 0.05$) which is statistically significant. These findings are similar to the results of a study by Gupta et al.¹² who reported lower VAS score at 8 hrs., 12 hrs and 24 hrs but statistically significant score only at 24 hrs. In concordance to above (Qian H. et al.¹⁴) reported that postoperative VAS pain scores were significantly lower in ropivacaine and dexmedetomidine group at 6 and 8 hrs compared with those in ropivacaine alone. (Eldegwy et al.¹⁵) found similar results in their study done in patients undergoing herniorrhaphy.

TAP block with dexmedetomidine adjuvant had significantly lower VAS score at rest and on movement at 10, 18 and 24 hrs. ($P < 0.05$). On comparing sedation between the two groups using Modified Ramsay Sedation score we found that there is significant sedation in group B as compared to group A at 1 and 2 hours following the block. Also, the overall sedation score in group B was 3 as compared to 2 in group A. All patients with sedation score at were arousable and did not have any respiratory depression. A study done by (Prashant et al.¹³) sedation was found to be statistically insignificant in both groups (ropivacaine alone vs. ropivacaine with dexmedetomidine) except for the first hour where patients of group ropivacaine with dexmedetomidine were more sedated than group ropivacaine. In our study though there was numerical increase in nausea / vomiting in group B (5 vs. 4) this finding was not statistically significant. In concordance to our study (Sulagna Bhattacharjee et al.¹⁶) in their study compared analgesic efficacy of transversus abdominis plane block in providing effective perioperative analgesia in patients undergoing total abdominal hysterectomy reported no increase in nausea and vomiting. There were no complications related to the TAP block in both the groups in our study. This could be because of experienced personnel performing the procedure and the associated use of ultrasonography to reduce the margin of error in delivering the drug, in the correct plane. Gupta et al.¹² in their study evaluated 60 patients who underwent USG guided TAP block with 0.2 % ropivacaine (group A) or normal saline (group B) and did not report any complications in both the groups.

CONCLUSIONS

Dexmedetomidine is a newer α_2 agonist i.e. used as an adjuvant to local anaesthetic to improve the quality of regional blocks at a dose of 0.5 mcg / kg added to

Ropivacaine for ultra-sound guided TAP block which is associated with prolonged and excellent analgesia with lesser requirement for additional analgesic usage, lower VAS scores, hemodynamic stability and minimal sedation.

Hence, due to longer duration of action and stable haemodynamics, dexmedetomidine is a useful adjunct to local anaesthetic for the practice of regional anaesthesia by TAP block in lower abdominal surgeries. The use of ultrasound makes the procedure safer with a single intervention and drug administration.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.

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