http://jmscr.igmpublication.org/home/
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v10i3.11

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Role of Dexmedetomidine or Fentanyl as Adjuvant to Ropivacaine in Trans versus Abdominis Plane Block for Postoperative Pain in Caesarean Section under Spinal Anaesthesia: A Comparative Study

Authors
Dr Anita Pareek[1], Dr Praveen Kumar[2], Dr Jinesh Baid[3*]
[1]Senior Professor, [2]Resident, [3]Senior Resident
*Corresponding Author
Dr Jinesh Baid
Department of anaesthesia, Sardar Patel Medical College & AGH, Bikaner, Rajasthan, India

Abstract

Introduction: *Cesarean section (CS) is one of the most common surgical procedures in India. The abdominal wall incision and soft tissue dissection associated with this procedure may result in moderate to severe post-operative pain. Postoperative pain management is usually multimodal including oral or intravenous (IV) acetaminophen, nonsteroidal anti-inflammatory agents (NSAIDs) and opiates, epidural analgesia, and peripheral nerve blocks. The transversus abdominis plane (TAP) block is a regional technique for analgesia, which provides satisfactory post-operative pain relief and reduces certain side effects associated with the use of opioids or epidural block[(9,10)]. The objectives of this study was to evaluate the potential benefits of dexmedetomidine or fentanyl when added to ropivacaine in TAP block for postoperative pain management and patient recovery after Cesarean section (CS).*

Material & Methodology: *We conducted a comparative prospective randomized controlled double-blind study on 90 patients of ASA grade I and II, 18 to 35 years of age undergoing elective and emergency Caesarean section under spinal Anaesthesia in Department of anaesthesia, S. P. Medical college and A.G. of Hospitals, Bikaner after taking approval from Institutional Ethical committee and valid written informed consent from patient and their close relatives.*

90 patients were randomised into 3 groups and 30 patients were included in each group randomly. Group A, B & C received 0.375% ropivacaine, 0.375% ropivacaine + 1 µg/kg dexmedetomidine, 0.375% ropivacaine + 1 µg/kg fentanyl (total volume 20 ml each side) respectively.

Results: *We observed that the group receiving combination of ropivacaine with dexmedetomidine (Group B) & Ropivacaine with Fentanyl (Group C) has significantly lower pain scores postoperatively compared to group receiving only ropivacaine (Group A). There was a significant difference in the terms of VAS over time (p = <0.001) & total Analgesic Consumption (mg) (p = <0.001) between the three groups in twenty four hours.*

Conclusion: *From our study we concluded that dexmedetomidine or fentanyl as adjuvant to ropivacaine in transversus abdominus plane block significantly decreases the Post-Operative pain after caesarean section under spinal anaesthesia .*

Keywords: *Ropivacaine, Dexmedetomidine, Fentanyl.*

Introduction

Recent estimates show that C-section rates in India range from 20% to 24% of all deliveries depending on the institution.[1-2]

The abdominal wall incision and soft tissue dissection associated with this procedure may result in moderate to severe post-operative pain. Pain is one of the most common symptom experienced postoperatively and poorly controlled pain is associated with patient distress, suffering, respiratory complications, increased blood pressure and chances of myocardial infarction, prolonged hospital stay, adversely affects early ambulation and breastfeeding[3] and increased likelihood of chronic pain. Appropriate pain relief leads to shortened hospital stays, reduced hospital costs and increased patient satisfaction[4].

Postoperative pain management is usually multimodal including oral or intravenous (IV) acetaminophen, nonsteroidal anti-inflammatory agents (NSAIDs) and opiates, epidural analgesia, and peripheral nerve blocks.

The transversus abdominis plane (TAP) block is a regional technique for analgesia, which provides satisfactory post-operative pain relief and reduces certain side effects associated with the use of opioids or epidural block[5,6]. Transverse abdominis plane (TAP) block, first described by Rafi in 2001.[7] Ultrasound-guided TAP block first described by Hebbard helps in effectively blocking the lower thoracic, iliohypogastric, and ilioinguinal nerves.[8]

Previous trials have demonstrated the efficacy of TAP block in providing post-operative analgesia following abdominal surgery[9,10]. However, a limitation of TAP block is its relatively short duration of analgesia due to the short duration of action of local anesthetics used in this technique. To resolve this issue, various adjuvants such as fentanyl, dexamethasone and clonidine have been used in combination with local anesthetics[11-13].

Hence the objectives of this study was to evaluate the potential benefits of dexmedetomidine or fentanyl when added to ropivacaine in TAP block for postoperative pain management and patient recovery after Cesarean section (CS).

Material and Methodology

We conducted a comparative prospective randomized controlled double-blind study on 90 patients of ASA grade I and II, 18 to 35 years of age undergoing elective and emergency Caesarean section under spinal Anaesthesia in Department of anaesthesia, Sardar Patel Medical college and A.G. of Hospitals, Bikaner after taking approval from Institutional Ethical committee and valid written informed consent from patient and their close relatives. Patients having history of drug hypersensitivity to local anaesthetic and analgesic drug, local infection at the injection site of TAP block, ASA grade III and IV, spinal deformities, coagulation disorders, severe anemia were excluded from study. 90 patients belonging to ASA grade I and II were randomly divided into three groups:-

Group	Drugs and Route	No. of Patients
A	0.375% ropivacaine 20 ml each side	30
B	0.375% ropivacaine + 1 µg/kg dexmedetomidine (total volume 20 ml each side)	30
C	0.375% ropivacaine + 1 µg/kg fentanyl (total volume 20 ml each side)	30

Pre-anaesthetic check-up was done a day prior to surgery for elective cases and at recovery room in emergency which included a detailed history, complete general physical and systemic examination. Patient were kept nil by mouth for minimum 6-8 hours before surgery. Visual analogue scale (VAS) for pain was explained to every patient at the time of pre-anaesthetic evaluation. Routine investigations were done (Hb%, BT, CT, Urine analysis, Blood urea, Serum creatinine, ECG, viral markers).

Premedication with inj ranitidine 50 mg and inj ondansetron 4 mg was given in preoperative room. Baseline vitals (SBP, DBP, PR, $SPO_{2)}$ were recorded. Following arrival in the anaesthetic room, IV access was established and an infusion

of 500 mL Ringer's lactate commenced. After taking full aseptic precautions, patient was kept in left lateral decubitus position and lumbar puncture was performed at L3-L4 inter-space through mid-line approach using a disposable 25G Quinke's spinal needle and 2.2 ml of 0.5% hyperbaric bupivacaine without any additive was injected in subarachnoid space after free flow of CSF and patient was made supine with left lateral tilt by putting wedge.

Surgery was allowed only after the sensory blockage up to T4 (by pin prick method along mid clavicular line bilaterally) and motor block of modified bromage scale grade 3. Vitals were monitored & recorded intra-operatively every 5 mins up to 30 mins and every 15 mins till the end of surgery. Hypotension was taken as fall in systolic BP>30% of baseline and Bradycardia was taken as heart rate <60 beats/min.

Before administrating TAP block regression of sensory block was assessed by pin prick method and recession of motor block was noted by movement of ankle and knee joint. TAP block was performed bilaterally by landmark technique. The landmark for palpation was the 'TRIANGLE OF PETIT' which lies above the pelvic rim in the mid axillary line. Under all aseptic precautions a 23G spinal needle was inserted perpendicular to the skin. A loss of resistance technique was use to locate the TAP and study drugs were given bilaterally. Post-operative pain was evaluated by Visual analogue score (VAS). First dose of rescue analgesic was given on patients demand VAS score ≥3. For rescue analgesia intra muscular inj. Diclofenac 75mg was given. The total analgesic requirement for 24 hrs were recorded. The Duration of analgesia was taken as the time between administration of TAP block and first dose rescue analgesic. The study ended at 24 hours after TAP block and any complication and side effects were recorded during this period.

Data Analysis

To collect required information from eligible patients a pre-structured pre tested proforma was used. For data analysis microsoft excel and statistical software SPSS was used and data were analysed with the help of percentage, mean, SD in the form of tables, diagrams and tests of significance was applied wherever required.

Results

Table 1-3 shows the demographic variables of the patients in the three groups. All three groups were comparable in respect to age, body weight, duration of surgery. The baseline vitals were comparable between all the groups.

Table 1: Comparison of the 3 Subgroups of the Variable Group in Terms of Age (Years) (n = 90)

Age (Years)	Group			
	A	B	C	p value
Mean (SD)	24.77 (2.36)	26.43 (2.67)	26.13 (2.93)	0.40
Range	19 - 30	22 - 33	22 – 32	

Table 2: Comparison of the 3 Subgroups of the Variable Group in Terms of Weight (n = 90)

Weight	Group			
	A	B	C	p value
Mean (SD)	65.27 (5.85)	67.87 (6.96)	67.77 (7.07)	0.235
Range	52 - 78	50 - 85	55 – 85	

Table 3: Comparison of the 3 Subgroups of the Variable Group in Terms of Duration (n = 90)

Duration	Group			
	A	B	C	p value
Mean (SD)	44.50 (4.27)	43.90 (4.79)	45.90 (5.12)	0.315
Range	35 - 50	35 - 55	38 – 55	

Table 4: Comparison of the 3 Subgroups of the Variable Group in Terms of Time to First Rescue Analgesia (Mins) (n = 90)

Time to First Rescue Analgesia (Mins)	Group			
	A	B	C	p value
Mean (SD)	458.17 (43.18)	615.00 (84.23)	509.00 (38.56)	<0.001
Range	370 - 520	420 - 750	430 - 570	

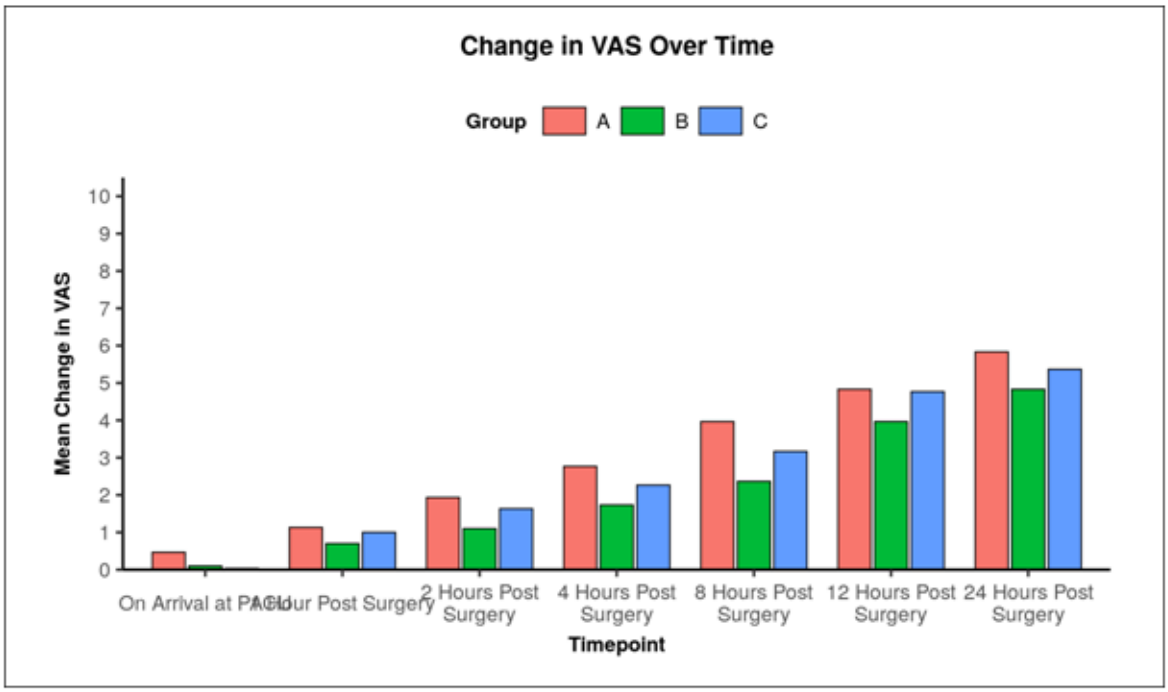
The mean (SD) of Time to First Rescue Analgesia (Mins) in the Group A was 458.17 (43.18, in the Group B was 615.00 (84.23) and in the Group C was 509.00 (38.56). There was a significant difference between the 3 groups in terms of Time to First Rescue Analgesia (Mins) (p = <0.001), with the mean Time to First Rescue Analgesia (Mins) being highest in the Group B.

Table 5: Comparison of the 3 Subgroups of the Variable Group in Terms of Total Analgesic Consumption (mg) (n = 90)

Total Analgesic Consumption (mg)	Group			
	A	B	C	p value
Mean (SD)	217.50 (22.88)	161.67 (49.01)	195.00 (37.37)	<0.001
Range	150 - 225	75 - 225	150 - 225	

The mean (SD) of Total Analgesic Consumption (mg) in the Group A was 217.50 (22.88), in the Group B was 161.67 (49.01) & in the Group C was 195.00 (37.37). The Total Analgesic Consumption (mg) in the Group A ranged from 150 – 225, in the Group B ranged from 75 – 225 and in the Group C ranged from 150 - 225. There was a significant difference between the 3 groups in terms of Total Analgesic Consumption (mg) (p = <0.001), with the mean Total Analgesic Consumption (mg) being highest in the Group : A group.

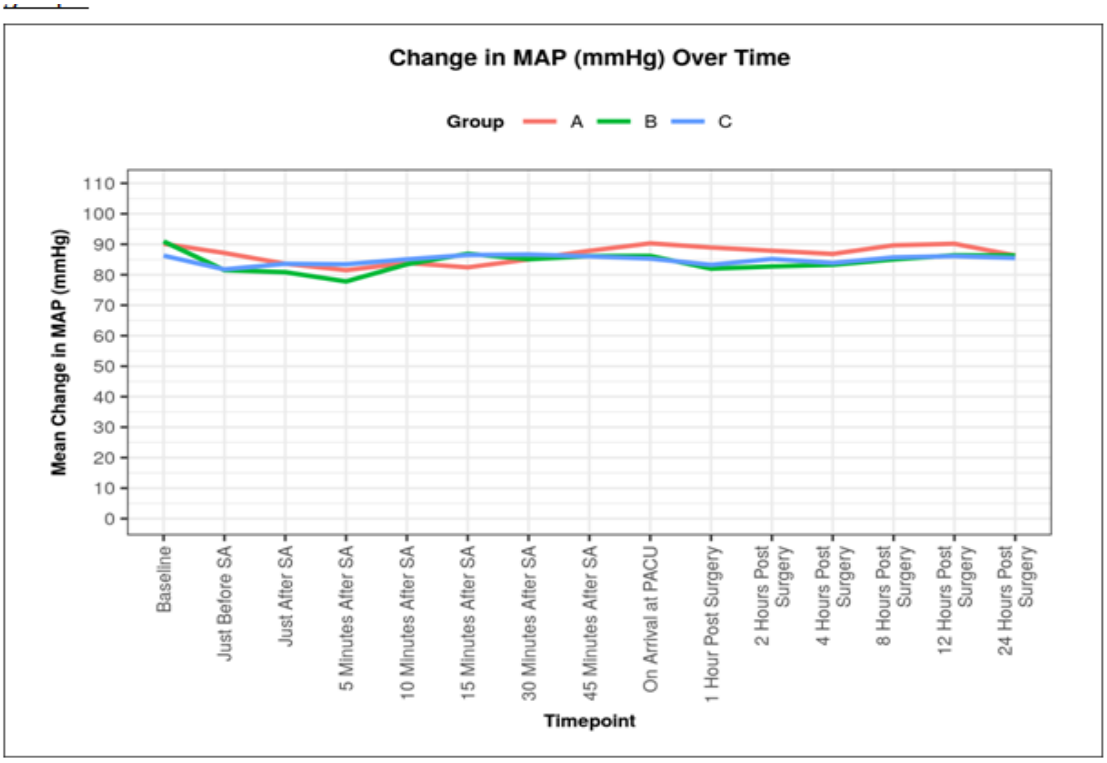
The following is a bar diagram depicting the change in VAS over time in the three groups.



In Group A, B & C the mean VAS increased from a minimum of 0.47, 0.10 & 0.03 at the On Arrival at PACU time point to a maximum of 5.83, 4.83 & 5.37 at the 24 Hours Post Surgery time point respectively. This change was statistically significant (p = <0.001).

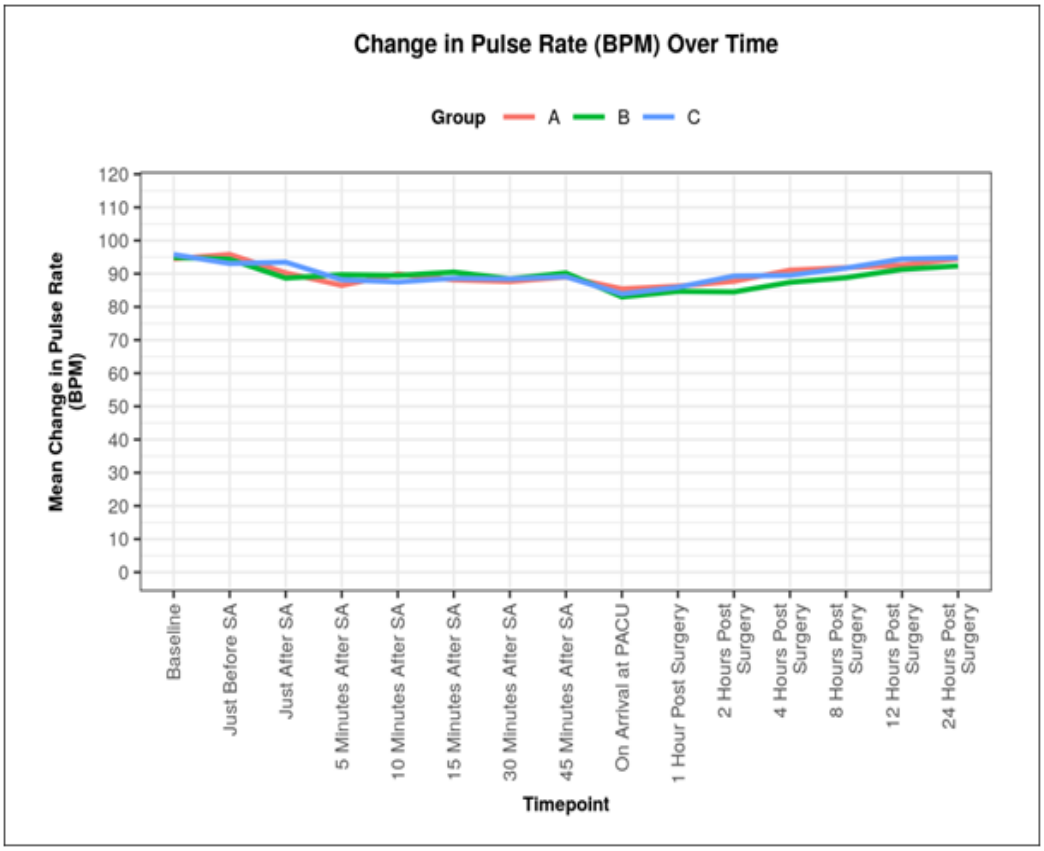
The three groups differed significantly in terms of VAS at the following time points: On Arrival at PACU, 1 Hour Post Surgery, 2 Hours Post Surgery, 4 Hours Post Surgery, 8 Hours Post Surgery, 12 Hours Post Surgery, 24 Hours Post Surgery. The overall change in VAS over time was compared in the three groups using the Generalized Estimating Equations method. There was a significant difference in the trend of VAS over time between the three groups (p = <0.001).

The following is a line diagram depicting the change in MAP (mmHg) over time in the three groups.



The three groups differed significantly in terms of MAP (mmHg) at the following time points: 5 Minutes after SA, 1 Hour Post Surgery, 2 Hours Post Surgery. The overall change in MAP (mmHg) over time was compared in the three groups using the Generalized Estimating Equations method. There was a significant difference in the trend of MAP (mmHg) over time between the three groups (p = <0.001).

The following is a line diagram depicting the change in Pulse Rate (BPM) over time in the three groups.



The three groups differed significantly in terms of Pulse Rate (BPM) at the following time points: 2 Hours Post Surgery, 8 Hours Post Surgery, 12 Hours Post Surgery, 24 Hours Post Surgery. The overall change in Pulse Rate (BPM) over time was compared in the three groups using the Generalized Estimating Equations method. There was a significant difference in the trend of Pulse Rate (BPM) over time between the three groups (p = <0.001).

There was no significant difference between the various groups in terms of distribution of Complications (p = 0.438).

Table 6: Association Between Group and Complications (n = 90)

Complications	Group				
	A	B	C	Total	P Value
None	26 (86.7%)	29 (96.7%)	29 (96.7%)	84 (93.3%)	
Nausea And Vomiting	1 (3.3%)	1 (3.3%)	1 (3.3%)	3 (3.3%)	
Hypotension	2 (6.7%)	0 (0.0%)	0 (0.0%)	2 (2.2%)	0.438
Shivering	1 (3.3%)	0 (0.0%)	0 (0.0%)	1 (1.1%)	
Total	30 (100.0%)	30 (100.0%)	30 (100.0%)	90 (100.0%)	

Discussion

The management of postoperative pain is an important issue. The uncontrolled postoperative pain is the major limiting factor for early ambulation and thereby puts patient to the increased risk of various complications as well. The desirable properties of an analgesic agent are that it provides safe and effective analgesia, with

minimal side effects. The multimodal pain management is the answer of this. The TAP block is used for postoperative analgesia following abdominal surgeries. It provides blockade of the nociceptive inputs from the abdominal wall but not from the abdominal organs. Therefore, the block is used as a part of multimodal approach.

Yu N *et al.*[14] conducted a study titled, "TAP block versus LA wound infiltration in lower abdominal surgery: A systematic review and meta-analysis of randomized controlled trials." They found that TAP block and LA infiltration provide comparable short-term postoperative analgesia, but TAP block has better long-lasting effect, especially up to 24 h after surgery.

Ranjit S *et al.*[15] Compare the ultrasound-guided TAP block versus local wound infiltration for postoperative analgesia in patients undergoing gynecological surgery under general anesthesia found that bilateral TAP block was effective in reducing postoperative pain scores for 8–12 h postoperatively. This block was also successful in reducing postoperative opioid requirement.

Another study by Mishra M *et al.*[16] comparing TAP block versus wound infiltration of local anesthesia for postoperative analgesia concluded that TAP block and wound infiltration of local anesthesia both provide significant postoperative analgesia initially but the effects are more long-lasting in TAP block.

Therefore, we can presume that the potent prolonged analgesic effects of TAP block remain the issue beyond doubt. Now, the next issue of concern can be that how we can prolong the analgesic effects of TAP block even further. The current studies were performed on patients undergoing LSCS under spinal anesthesia and were offered landmark approch TAP block for postoperative analgesia. Study Group A were given only 0.375% ropivacaine 20 ml each side, Study group B were given 0.375% ropivacaine + 1 µg/kg dexmedetomidine (total volume 20 ml each side) and Study group C were given 0.375% ropivacaine + 1 µg/kg fentanyl (total volume 20 ml each side). To ensure blinding, the volume of the study medication was standardized at 40 mL which was divided into 20 mL and injected on each side by TAP block.

Hemodynamic parameters Mean pule rate and mean arterial pressure was comparable between the groups.

The three groups differed significantly in terms of Pulse Rate (BPM) at the following time points: 2 Hours, 8 Hours, 12 Hours & 24 Hours Post Surgery. The overall change in Pulse Rate (BPM) over time was compared in the three groups using the Generalized Estimating Equations method. There was a significant difference in the trend of Pulse Rate (BPM) over time between the three groups ($p = <0.001$).

The three groups differed significantly in terms of MAP (mmHg) at the following timepoints: 5 Minutes, 1 Hour & 2 Hours Post Surgery. The overall change in MAP (mmHg) over time was compared in the three groups using the Generalized Estimating Equations method. There was a significant difference in the trend of MAP (mmHg) over time between the three groups ($p = <0.001$).

VAS In the study by *Rai et al.*[17], it was assessed that the addition of dexmedetomidine to ropivacaine in TAP block led to further prolongation of analgesia, less requirement of rescue analgesia, and lower VAS pain scores. The study done by *Marhofer et al.*[18] found that there was prolongation of ulnar nerve block duration after addition of dexmedetomidine in ropivacaine used for the block by approximately 60%. *Almarakbi and Kaki*[19] reported that the addition of dexmedetomidine to bupivacaine in TAP block in patients undergoing abdominal hysterectomy provides better pain control postoperatively. *Joseph B et al*[20] studied that Fentanyl and dexmedetomidine as adjuvants to ropivacaine were equally effective in both prolongation of analgesia and reducing the total consumption of analgesics in ultrasound-guided TAP block.

The results of our study reveals that the group receiving combination of ropivacaine & dexmedetomidine and Ropivacaine & Fentanyl has significantly lower pain scores postoperatively than that the group receiving only ropivacaine. The three groups differed significantly in terms of VAS at the following timepoints: On Arrival at PACU, 1 Hour Post Surgery, 2 Hours Post Surgery, 4 Hours Post Surgery, 8 Hours Post Surgery, 12 Hours Post Surgery, 24 Hours Post Surgery. VAS score was significantly lower in Group B > Group C > Group A. The overall change in VAS over time was compared in the three groups using the Generalized Estimating Equations method. There was a significant difference in the trend of VAS over time between the three groups (p = <0.001).

In the study conducted by *Chen Qi et al*[21] the VAS score was significantly lower in all TAP groups than in the control group at 1, 2, 4, and 8 hours postoperatively (P<0.05) and there were significant differences in scores between TAP-DEX and TAP-FEN groups only at 6 hours (P<0.01). *Haitao Qian et al*[22] found Post-operative VAS pain scores were significantly lower the RD group at 6 and 8 h compared with those in the R group. However, there was no significant difference in scores between groups at 2, 4, 10, 12 and 24 h.

Total Analgesic Consumption (mg)

The mean (SD) of Total Analgesic Consumption (mg) in the Group A was 217.50 (22.88), in the Group B was 161.67 (49.01) & in the Group C was 195.00 (37.37). There was a significant difference between the 3 groups in terms of Total Analgesic Consumption (mg) (p = <0.001), with the mean Total Analgesic Consumption (mg) being highest in the Group: A group.

First Rescue Analgesia (Mins)

The mean (SD) time to First Rescue Analgesia (Mins) in the Group A was 458.17 (43.18, in the Group B was 615.00 (84.23) and in the Group C was 509.00 (38.56). There was a significant difference between the 3 groups in terms of Time to First Rescue Analgesia (Mins) (p = <0.001), with the mean Time to First Rescue Analgesia (Mins) being highest in the Group B.

Haitao Qian et al[22] compared with the R group (Ropivacaine only), the pain-free duration and first request for analgesia were significantly prolonged in the RD (Ropivacaine + Dexmedetomidine) group. The number of patients who required rescue analgesia was also significantly lower in the RD group compared with that in the R group.

Distribution of Complications

There was no significant difference between the various groups in terms of distribution of Complications (p = 0.438). *Haitao Qian et al*[22] also found no patients developed hypotension or bradycardia in either group during this time period.

Conclusion

From our study, we concluded that dexmedetomidine or fentanyl as adjuvant to ropivacaine in transversus abdominus plane block significantly decreases the Post-Operative pain after caesarean section under spinal anaesthesia

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