A COMPARATIVE STUDY OF ROPIVACAINE AND ROPIVACAINE WITH DEXMEDETOMIDINE AS POSTOPERATIVE ANALGESIA FOR LOWER ABDOMINAL SURGERIES UNDER ULTRASOUND-GUIDED TRANSVERSUS ABDOMINIS PLANE BLOCK

S. Ramesh Kumar¹, R. Vasanthageethan², G. Selvaraju³

¹Assistant Professor, Department of Anaesthesiology, Government Mohan Kumaramangalam Medical College Hospital, Salem.

²Assistant Professor, Department of Anaesthesiology, Government Mohan Kumaramangalam Medical College Hospital, Salem.

³Senior Resident, Department of Anaesthesiology, Government Mohan Kumaramangalam Medical College Hospital, Salem.

ABSTRACT

BACKGROUND

Ultrasound-guided Transversus Abdominis Plane block for providing postoperative analgesia for lower abdominal surgeries are performed commonly nowadays. Injection of alpha-2 adrenergic agonist drugs have been suggested for improving the quality of nerve block.

The aim of this study was to compare the efficacy of Ropivacaine and Ropivacaine with Dexmedetomidine in providing postoperative analgesia for lower abdominal surgeries under ultrasound-guided TAP block.

MATERIALS AND METHODS

This study was done in sixty patients of age group 18 - 60 years under ASA I and II randomly allotted into two groups of thirty each undergoing lower abdominal surgeries. Group A received only Ropivacaine, while Group B received Ropivacaine with Dexmedetomidine.

RESULTS

Patients in Group B had extended duration of analgesia with minimal sedation.

CONCLUSION

The study showed that the addition of Dexmedetomidine to Ropivacaine in TAP block extended the duration of analgesia with minimal sedation without significant changes in haemodynamic parameters or complications.

KEYWORDS

TAP - Transversus Abdominis Plane, VAS - Visual Analogue Scale, BMI - Body Mass Index, SAB - Subarachnoid Block.

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BACKGROUND

Lower abdominal surgeries are performed most commonly and are associated with significant postoperative pain and discomfort. Pain free postoperative period is necessary to give better care to the patient and in aiding early ambulation and it should be safe with minimal adverse effects.

Postoperative pain is treated usually with systemic and neuraxial opioids. In spite of the effective analgesia produced by neuraxial opioid technique, it is usually associated with side effects like nausea, vomiting and pruritus. The opioid side effects can be avoided by regional anaesthesia with local anaesthetic solutions.⁽¹⁾ Adequate postoperative pain relief can be achieved by blocking the nerves supplying the anterior abdominal wall like iliohypogastric, ilioinguinal nerve and by field block of the abdomen.⁽²⁾ This has given one new approach for the effective pain relief.

The surgical incision over the abdominal wall causes significant pain in the postoperative period. The abdominal wall supplied by nerves lying between the internal oblique

and transversus abdominis muscles can be blocked by injecting local anaesthetic drugs in the transverse abdominal plane in the region of Petit's triangle (TAP Block).⁽³⁾ Andrew et al⁽⁴⁾ in their study had shown the effects of TAP block.

First transversus abdominis plane block was described by Rafi in 2001.⁽⁵⁾ McDonnell et al⁽⁶⁾ described about TAP block in cadavers and humans in 2004. Curley et al,⁽⁷⁾ French et al⁽⁸⁾ and Carvello et al⁽⁹⁾ in their studies have shown the beneficial effects of TAP block in post LSCS patients. Hebbard et al⁽¹⁰⁾ described about the TAP block by using ultrasound-guided technique in 2007. Walter et al⁽¹¹⁾ in their study showed that the results were better in ultrasound guidance technique with posterior approach. TAP block success depends on injection of local anaesthetic drugs between transversus abdominis and internal oblique muscle where the neurofascial plane lies. There are many techniques for the nerve blocks and among them ultrasound-guided technique seems to be the most reliable. It helps to guide the needle towards the nerves or structures targeted and to see the spread of injected local anaesthetic drugs.⁽¹²⁾ The dose of local anaesthetic and opioid requirement is reduced with this technique.

Injection of alpha-2 adrenergic agonist drugs like Clonidine and Dexmedetomidine has been suggested for improving the quality of nerve block. Dexmedetomidine is a selective agonist for alpha-2 receptors with some agonistic property on alpha-1 receptors as well. The onset time, block

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Corresponding Author:

Dr. S. Ramesh Kumar,

Flat A2, Sri Vijayanand Paradise, 95/9 Gandhi Road, Salem-636007, Tamilnadu.

E-mail: esaarkay@yahoo.com

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efficacy and postoperative analgesic duration is prolonged with usage of Dexmedetomidine with local anaesthetic drugs.

Aim of the Study

A comparative study of Ropivacaine and Ropivacaine with Dexmedetomidine as postoperative analgesia for lower abdominal surgeries under ultrasound-guided Transversus abdominis plane block.

MATERIALS AND METHODS

Study Type - Interventional.

Study Design - Prospective randomised study.

Study Population

Sixty patients who were posted for lower abdominal surgeries at Govt. Mohan Kumaramangalam Medical College and Hospital, Salem, were taken up for the study.

Case Definition

Patients of age group 18 - 60 years with ASA I and II undergoing lower abdominal surgeries.

Groups

Group A - (Contains 30 patients): SAB with Inj. 0.5% hyperbaric Bupivacaine 15 mg, then TAP block with Inj. 0.375% Ropivacaine 20 mL.

Group B - (Contains 30 patients): SAB with Inj. 0.5% hyperbaric Bupivacaine 15 mg then TAP block with Inj. 0.375% Ropivacaine 20 mL + Dexmedetomidine 0.5 mcg/kg body wt.

Outcome Measures for this Clinical Trial

To evaluate the analgesic efficacy of Ropivacaine and Ropivacaine with Dexmedetomidine by using Visual Analogue Scale pain scores in 1, 2, 3, 4, 5, 6, 12 and 24 hrs. after surgery and to evaluate the sedation score of the patient.

Inclusion Criteria

1. ASA Class I and II patients.
2. 18 to 60 years of age.

Exclusion Criteria

1. Patient refusal.
2. Patient with known allergic reaction to local anaesthetics.
3. History of bleeding diathesis.
4. Known psychiatric illness.
5. Patients on chronic analgesics.
6. BMI > 40 kg/m².
7. Liver failure and Renal failure.

Probability Sampling

60 lots were randomised (30 in each group) from the people who were willing to take part in the study. All the patients stand an equal chance of getting into any group. All the patients were aware of the study and informed consent was obtained.

Data Collection

Age, BMI, duration of surgery, time to regression of sensory block to T10 level, VAS (In 1, 2, 3, 4, 5, 6, 7, 8, 10, 12 and 24 hrs.), heart rate, systolic BP, diastolic BP, SpO₂, respiratory rate, duration of analgesia and sedation score.

Materials

1. Ultrasound machine with high frequency transducer probe.
2. Sterile gel, antiseptics.
3. 23-G Quincke spinal needle.
4. Inj. 0.5% Bupivacaine Heavy.
5. 18-G Tuohy needle.
6. Inj. 0.375% Ropivacaine.
7. Sterile normal saline.
8. Inj. Dexmedetomidine.
9. 10 mL and 20 mL syringes.
10. Swabs, swab holding forceps and sterile towel.

Method of Study

The Hospital Ethical Committee approval was obtained first with proper explanation and written informed patient consent was obtained. The study was conducted in 60 ASA status I and II patients undergoing lower abdominal surgeries in a prospective, randomised, double-blinded, controlled trial. In the preoperative waiting room, detailed history and physical examination was done. Baseline data like pulse rate, blood pressure, respiratory rate and basic investigations were collected.

Both groups were explained about the procedures (Both SAB and TAP Block) and postoperative followup pattern. The VAS was explained as 0 - 10 cm scale reading and patient was asked to tell the number.

Patients were divided randomly and allotted in either Group A (n = 30) or Group B (n = 30).

The investigator, patients and postoperative care physicians were blinded to group assigned. Common to both groups, an 18-G IV cannula was secured and preloading done with 1000 mL of crystalloid. Under asepsis, patient in lateral position, subarachnoid block was given with Inj. 0.5% Bupivacaine 15 mg using 23-G Quincke's spinal needle to all the patients in both groups. Patients were monitored intra-operatively and after the surgical procedure was over patient's sensory level was assessed, and once when the sensory level reached T10 TAP was performed.

Under asepsis, TAP Block was performed. An ultrasound-guided posterior TAP block technique was used to locate the Transverse abdominis plane. Patient was positioned supine; syringe containing local anaesthetic was prepared with asepsis. Syringes either contain Ropivacaine 0.375% 20 mL or Ropivacaine 0.375% with Dexmedetomidine 0.5 mcg/kg 20 mL. Investigators were blinded to the injected solution. A high frequency (10 - 15 Hz) Ultrasound probe was placed midway between the costal margin and iliac crest along the mid-axillary line. The satisfactory image was aimed to visualise the subcutaneous fat and all the three anterior abdominal wall muscles with peritoneum and intra-peritoneal cavity. An 18-G Tuohy needle was inserted anterior to the ultrasound probe. This wide bore needle was used for better visualisation and will not cause much discomfort to the patients, as they were still under residual analgesia from the SAB. With continuous monitoring of needle advancement in the fascial plane between transverse abdominis muscle and internal oblique muscle, a small volume of drug was injected to confirm the correct plane and needle tip and then 20 mL of prepared solution was injected. Injection was said to be successful when an echo-lucent lens-shaped (bi-convex) area come into view between the two

muscles. After observing closely for signs of toxicity, patients were shifted to postoperative ward.

Total Duration of Analgesia

The presence and severity of pain assessment was done with visual analogue scale (VAS score 0: no pain and 10: worst pain) in 1, 2, 3, 4, 5, 6, 7, 8, 10, 12 and 24 hrs. by an investigator blinded to group assigned. Sedation was monitored using Ramsay sedation score. Vital parameters and symptoms and signs of local anaesthetic toxicity and complications were recorded till the VAS score was equal to 4 in the immediate postoperative period after TAP block.

Sedation Score

Sedation was monitored using six point Ramsay sedation score. The primary end point of the study is when the VAS score reached = 4.

Rescue Analgesia

Inj. Tramadol 100 mg IM was used as first rescue analgesia either on demand or when the VAS score was = 4.

Data Analysis

In this study, the analgesic efficacy of Ropivacaine and adjuvant Dexmedetomidine in ultrasound-guided Transversus abdominis plane block for lower abdominal surgeries for postoperative pain relief is evaluated. The observation and results were analysed. Data analysis was done with the help of computer using Epidemiological

Information Package (EPI 2010) developed by Centre for Disease Control, Atlanta. Results were considered statistically significant when "p" value was = 0.05. In order to ascertain the significance of demographic features, Kruskal Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate's chi square test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

RESULTS

Age	N	Mean	SD	T	P
Ropivacaine	30	50.77	13.95	1.75	0.085
Ropivacaine with Dexmedetomidine	30	45.00	11.43		
Age Distribution					

Group	Sex				Total
	Male		Female		
	N	%	N	%	
Ropivacaine	25	83	5	17	30
Ropivacaine with Dexmedetomidine	26	87	4	13	30
Total	51	0.85	9	0.15	60
Gender Distribution					

The two groups were similar with respect to age and gender distribution and the difference was statistically insignificant.

	Group	N	Mean	SD	T	P
Duration of Analgesia	Ropivacaine	30	352.17	22.88	12.33	< 0.001**
	Ropivacaine with Dexmedetomidine	30	482.00	52.94		
Sedation Score	Ropivacaine	30	2.23	0.43	0.29	0.770
	Ropivacaine with Dexmedetomidine	30	2.27	0.45		
Duration of Analgesia and Sedation Score						

The duration of analgesia was significantly increased with 130 mins in Ropivacaine with Dexmedetomidine group, which was statistically significant. Even though the sedation score was more in Ropivacaine with Dexmedetomidine group than plain Ropivacaine group, it was not clinically significant.

	Group	N	Mean	SD	T	P
VAS Score 5 hrs.	Ropivacaine	30	4.60	0.56	22.64	< 0.001
	Ropivacaine with Dexmedetomidine	30	0.17	0.91		
VAS Score 6 hrs.	Ropivacaine	30	4.70	0.60	17.07	< 0.001
	Ropivacaine with Dexmedetomidine	30	0.33	1.27		
VAS Score 12 hrs.	Ropivacaine	30	4.57	0.50	1.69	0.004
	Ropivacaine with Dexmedetomidine	30	4.30	0.70		
VAS Score 24 hrs.	Ropivacaine	30	4.70	0.75	0.933	0.003
	Ropivacaine with Dexmedetomidine	30	4.53	0.63		
VAS Score						

The duration of analgesia was significantly increased with 130 mins in Ropivacaine with Dexmedetomidine group

	Group	N	Mean	SD	T	p
PR0	Ropivacaine	30	86.97	9.34	0.79	0.430
	Ropivacaine with Dexmedetomidine	30	88.90	9.50		
PR 30 mins	Ropivacaine	30	86.67	8.62	1.31	0.195
	Ropivacaine with Dexmedetomidine	30	89.47	7.90		
PR 1 hr.	Ropivacaine	30	84.43	9.29	0.68	0.500
	Ropivacaine with Dexmedetomidine	30	86.03	8.95		
PR 2 hrs.	Ropivacaine	30	90.23	7.70	0.20	0.845
	Ropivacaine with Dexmedetomidine	30	89.83	8.05		
PR 3 hrs.	Ropivacaine	30	85.40	8.09	0.37	0.711

	Ropivacaine with Dexmedetomidine	30	84.60	8.52		
PR 4 hrs.	Ropivacaine	30	86.13	9.37	0.28	0.783
	Ropivacaine with Dexmedetomidine	30	86.80	9.29		
PR 5 hrs.	Ropivacaine	30	84.67	8.76	0.46	0.649
	Ropivacaine with Dexmedetomidine	30	85.70	8.75		
PR 6 hrs.	Ropivacaine	30	86.13	9.37	0.39	0.695
	Ropivacaine with Dexmedetomidine	30	87.07	9.01		
PR 12 hrs.	Ropivacaine	30	84.67	8.76	0.62	0.538
	Ropivacaine with Dexmedetomidine	30	86.03	8.32		
PR 24 hrs.	Ropivacaine	30	88.43	8.79	0.13	0.894
	Ropivacaine with Dexmedetomidine	30	88.76	9.80		

Changes in Pulse Rate

Both the groups were comparable on measuring pulse rate and the difference was statistically insignificant.

	Group	N	Mean	SD	T	p
SBP 0	Ropivacaine	30	115.57	10.41	0.27	0.787
	Ropivacaine with Dexmedetomidine	30	114.83	10.53		
SBP 30 mins	Ropivacaine	30	113.97	11.06	0.20	0.842
	Ropivacaine with Dexmedetomidine	30	114.53	10.92		
SBP 1 hr.	Ropivacaine	30	112.27	20.78	0.14	0.892
	Ropivacaine with Dexmedetomidine	30	111.53	20.79		
SBP 2 hrs.	Ropivacaine	30	111.03	10.18	0.73	0.466
	Ropivacaine with Dexmedetomidine	30	112.90	9.53		
SBP 3 hrs.	Ropivacaine	30	115.13	9.25	1.19	0.237
	Ropivacaine with Dexmedetomidine	30	117.63	6.78		
SBP 4 hrs.	Ropivacaine	30	116.47	9.64	1.55	0.127
	Ropivacaine with Dexmedetomidine	30	112.67	9.35		
SBP 5 hrs.	Ropivacaine	30	118.67	9.75	0.48	0.633
	Ropivacaine with Dexmedetomidine	30	117.60	7.27		
SBP 6 hrs.	Ropivacaine	30	118.67	9.75	0.48	0.633
	Ropivacaine with Dexmedetomidine	30	117.60	7.27		
SBP 12 hrs.	Ropivacaine	30	118.67	9.75	0.48	0.633
	Ropivacaine with Dexmedetomidine	30	117.60	7.27		
SBP 24 hrs.	Ropivacaine	30	117.27	8.83	0.31	0.757
	Ropivacaine with Dexmedetomidine	30	116.47	11.02		

Changes in Systolic Blood Pressure

Both the groups were comparable on measuring Systolic BP and the difference was statistically insignificant.

	Group	N	Mean	SD	t	P
DBP 0	Ropivacaine	30	83.37	8.43	4.96	< 0.001**
	Ropivacaine with Dexmedetomidine	30	101.83	18.55		
DBP 30 mins	Ropivacaine	30	83.93	9.42	0.83	0.411
	Ropivacaine with Dexmedetomidine	30	85.77	7.65		
DBP 1 hrs.	Ropivacaine	30	80.30	9.35	1.96	0.054
	Ropivacaine with Dexmedetomidine	30	84.90	8.78		
DBP 2 hrs.	Ropivacaine	30	83.80	7.25	0.33	0.739
	Ropivacaine with Dexmedetomidine	30	83.10	8.88		
DBP 3 hrs.	Ropivacaine	30	85.37	7.18	1.86	0.068
	Ropivacaine with Dexmedetomidine	30	81.90	7.28		
DBP 4 hrs.	Ropivacaine	30	84.20	8.41	0.05	0.960
	Ropivacaine with Dexmedetomidine	30	84.30	7.04		
DBP 5 hrs.	Ropivacaine	30	84.47	8.66	0.11	0.911
	Ropivacaine with Dexmedetomidine	30	84.23	7.39		
DBP 6 hrs.	Ropivacaine	30	84.20	8.41	0.02	0.987
	Ropivacaine with Dexmedetomidine	30	84.23	7.39		
DBP 12 hrs.	Ropivacaine	30	84.20	7.92	0.18	0.860
	Ropivacaine with Dexmedetomidine	30	84.59	8.77		
DBP 24 hrs.	Ropivacaine	30	84.20	7.92	0.23	0.816
	Ropivacaine with Dexmedetomidine	30	84.70	8.64		

Changes in Diastolic BP

Both the groups were comparable Diastolic BP and the difference is statistically insignificant.

DISCUSSION

Adequate pain relief has been shown to reduce stress postoperatively leading to a quick recovery, early mobilisation and reduced morbidity in the postoperative period. It has been shown that local anaesthetic used in various techniques reduces pain and analgesic requirements, which can improve the quality of postoperative recovery. The efficacy of TAP block by using local anaesthetics is proved in many studies. McDonnell J G⁽⁶⁾ et al in their study has proved the beneficial effect of Ropivacaine in TAP block for post caesarean section patients.

In order to increase the duration of block, Dexmedetomidine has been used as an adjuvant to local anaesthetics in different regional techniques. So Dexmedetomidine as an adjuvant in TAP block is expected to prolong the duration of block, thereby achieving a good postoperative analgesia.

D. Belavy and J. Cowlshaw⁽¹³⁾ et al has shown the efficacy of ultrasound-guided TAP blocks in post caesarean section patients. So this study was done to evaluate the postoperative analgesic efficacy of Ropivacaine alone or in combination with Dexmedetomidine in ultrasound-guided TAP block. In this study, the local anaesthetics were deposited in the correct plane under ultrasound guidance. Rachana Gandhi et al⁽¹⁴⁾ have shown in their study that Dexmedetomidine added to local anaesthetics prolongs the duration of analgesia.

In this study, 20 mL of Inj. 0.375% Ropivacaine or Inj. 0.375% Ropivacaine with Dexmedetomidine 0.5 mcg/kg for ultrasound-guided TAP block was used, which is comparable to many studies.

Tramadol was selected for rescue analgesia, as several studies have confirmed that a single dose of intramuscular Tramadol 50 – 100 mg can provide effective analgesia in postoperative patients.

Ultrasound-guided TAP block has been shown to provide adequate analgesia to the skin and anterior abdominal wall musculature in patients undergoing lower abdominal surgeries. All patients in both groups breathed deeply, coughed freely, moved without limitation and showed good satisfaction. The Ropivacaine with Dexmedetomidine group showed increased duration of analgesia with minimal sedation.

Duration of Postoperative Analgesia

In this study, results had demonstrated that postoperative ultrasound-guided TAP block reduced VAS score in both the groups. In Group A (0.375% Ropivacaine alone) the VAS score was almost zero in the first 4 hours, while in Group B the VAS score was zero for about 6 hours which itself explains the effectiveness of TAP block.

In this study, the mean time to reach VAS score of = 4 was 482 minutes in Ropivacaine with Dexmedetomidine 0.5 mcg/kg group when compared with 352 minutes in the 0.375% Ropivacaine. The difference of 130 minutes with P value less than 0.001 was very significant statistically.

The reason for extended analgesic duration after TAP blockade may be due to the relatively reduced vascularisation and slower drug clearance from transversus abdominis plane and may be due to avoidance of central sensitisation by giving TAP block postoperatively. The prolonged action of Dexmedetomidine may be produced by the membrane hyperpolarisation due to opening of the potassium channels,

which increases the sodium channel blocking property of local anaesthetic. When added to local anaesthetic, it enhances the quality and reduces the time of onset of block.

Sedation

The mean sedation score of 2.27 was obtained in Ropivacaine with Dexmedetomidine group compared to 2.23 obtained in Ropivacaine group. Even though the sedation score was more in Ropivacaine with Dexmedetomidine group than plain Ropivacaine group, it is not clinically significant. Dexmedetomidine added to Ropivacaine for prolonging analgesic duration also had minimal sedative effect, but arousable sleep. Thus, TAP block as a component of multimodal analgesia has significantly increased the total postoperative analgesia and those who received Dexmedetomidine in addition to Ropivacaine had prolonged duration of analgesia with minimal sedation without any complications.

Haemodynamic Stability

Haemodynamic stability in terms of changes in pulse rate, oxygen saturation and blood pressure was compared in both groups and there were no significant difference between them.

Complications

In this study, the incidence of postoperative nausea and vomiting was very much reduced in both groups. This is similar to study conducted by Jumana M Baaj et al,⁽¹⁵⁾ where they reported reduced incidence of postoperative nausea and vomiting. Complications like peritoneal and visceral punctures related to TAP block were not encountered in this study. Thorough familiarity with anatomy, safe monitoring and injection technique, knowledge of local anaesthetic pharmacology and toxicity would prevent the possibility of complications and the technique of TAP block is further simplified by proper knowledge and correct use of ultrasound. These precautions will prevent major complications with TAP block. By using ultrasonography, real time needle position can be confirmed and is a promising approach that should further decrease the risk of visceral injury complication.

CONCLUSION

Ultrasound-guided TAP block as a technique for providing postoperative analgesia is highly effective for lower abdominal surgeries. The addition of Dexmedetomidine to Ropivacaine in TAP block extended the duration of analgesia with minimal sedation when compared to plain Ropivacaine without significant changes in haemodynamic parameters or complications. Ultrasound-guided TAP block is easier to perform and provides reliable and effective analgesia.

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