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A comparative study between 0.2% ropivacaine with dexmedetomidine and 0.125% levobupivacaine with dexmedetomidine for post-operative epidural analgesia in patients undergoing total abdominal hysterectomy

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Abstract

Introduction: TAH is associated with significant post-operative pain. Epidural analgesia with a variety of local anaesthetics and adjuvants is widely used for TAH as it provides both intra and post-operative analgesia. The aim is to compare the effect of post-operative epidural analgesia with 0.2% ropivacaine and dexmedetomidine versus 0.125% levobupivacaine and dexmedetomidine in patients undergoing TAH.

Method: Afterobtaining ethical committee permission and patient consent, 50 women aged 35-65 years of ASA 1&2 were included in the study. We have excluded patients with hypersensitivity to local anaesthetics, infection at the site of injection. Patients were divided into 2 groups of 25 each. Group RD-received 10ml of 0.2% ropivacaine and dexmedetomidine 1 mcg/kg. Group LD-received 10ml of 0.125% levobupivacaine and dexmedetomidine 1mcg/kg. Using chi-square test and student t-test statistical results were obtained.

Results: The mean onset of analgesia in Group RD was 11.86min and in Group LD was 8.468min which is statistically significant ($P<0.05$). Mean duration of analgesia in Group RD was 210min and in Group LD was 271min which is statistically significant ($P<0.05$).

Conclusion: We conclude that 0.125% levobupivacaine with dexmedetomidine as adjuvant was found to have faster onset and prolonged duration of analgesia than 0.2% ropivacaine with dexmedetomidine.

Keywords: Epidural, ropivacaine, levobupivacaine, dexmedetomidine

Introduction

Background

Total Abdominal Hysterectomy (TAH) is a surgical procedure which is associated with significant postoperative pain [1]. Use of regional blocks for lower limb and lower abdominal surgeries has increased during last decade because of increase in demand for postoperative pain relief and decrease in the need for intravenous analgesic drugs during postoperative period [2].

Epidural anaesthesia is a versatile technique used both for providing anaesthesia and postoperative analgesia. Epidural drug route provides excellent analgesia and is associated with decreased occurrence of respiratory depression, reduces the surgical stress by blocking the nociceptive impulses from the operative site and helps in early mobilization by relieving postoperative pain thus decreases incidence of thromboembolic events, but it is frequently associated with hemodynamic fluctuations due to use of large volumes of local anaesthetic drug[3,4].

Levobupivacaine and ropivacaine are newer local anaesthetics that have effects similar to bupivacaine. New amide local anaesthetics like Ropivacaine has less propensity of motor

block with minimum cardiovascular and central nervous system toxicity during postoperative epidural analgesia[5]. Stereoisomers of the local anaesthetics are coming up instead of the isomers, in order to avoid the toxic effects as much as possible. Levobupivacaine, an amide local anaesthetic, showed a profile close to bupivacaine in terms of onset, qualityand duration of sensory block, but with lesser cardiac and neurotoxic adverse effects due to its faster protein binding rate. The clinical data showed its efficacy and safety for regional anaesthetic techniques with minimal hemodynamic fluctuations. Its low lipid solubility leads to greater sensory-motor differentiation by blocking sensory nerve fibres more readily than motor fibre[3].

Various adjuvants are being used along with local anaesthetic to decrease adverse effects of high doses of local anaesthetic and to prolong the duration of intraoperative and postoperative analgesia[2]. Epidural administration of α2 agonist in combination with local anaesthetics in low doses offers new dimensions in the management of postoperative pain[6].

Dexmedetomidine a newer highly selective alpha 2 adrenergic agonist has sedative, analgesic, and sympatholytic effects that blunt many of the cardiovascular responses and decreased oxygen demand seen during the perioperative period. Patients remain sedated when undisturbed but arouse readily with stimulation. This property of Dexmedetomidine makes it a very useful adjuvant. Based on earlier studies it was found that this drug produces prolonged postoperative analgesia with minimal side effects. It does cause a manageable hypotension and bradycardia but the striking feature of this drug is the lack of opioid-related side effects like respiratory depression, pruritus, nausea and vomiting. Dexmedetomidine have been evaluated epidurally without any report of neurological deficit in human being[2,5,7].

Aim

The present study was conducted with the primary aim of assessing the duration of postoperative analgesia between epidural 0.2% ropivacaine with dexmedetomidine and 0.125% levobupivacaine with dexmedetomidine for total abdominal hysterectomies. The secondary outcomes measured were the onset of analgesia, hemodynamic variables, VAS score and adverse effects in both the groups.

Methods

This randomized control study was conducted in Mamata General Hospital from January 2021 to June 2021 after obtaining ethical committee permission and informed patient consent. Fifty adult female patients of American Society of Anaesthesiologists (ASA) physical status Classes I and II between the age of 35 and 65 years undergoing total abdominal hysterectomies were enrolled for the study. The patients with hematological disease, bleeding or coagulation test abnormalities, psychiatric diseases, second or third-degree heart block, renal and hepatic insufficiency, uncontrolled diabetes and hypertension, history of drug abuseand allergy to local anaesthetics were excluded from the study.

Preanaesthetic evaluation was done on the day prior to surgery. Patients were explained about the study purpose, merits and demerits of the procedure and were taught to assess the intensity of pain using the visual analogue scale (VAS) and instructed to demand analgesia as per need and informed written consent was obtained. All the patients were premedicated with oral alprazolam 0.5 mg and oral pantop40 mg the night before surgery and IV pantop 40mg on the morning of surgery and were advised adequate fasting as per ASA guidelines.

All patients were preloaded with 10 ml/kg of ringer lactate. After shifting into the operating room, ASA standard monitors were connected, which included pulse oximetry, electrocardiogramand non-invasive blood pressure monitoring. The baseline values were recorded and documented.

With all aseptic precautions, patient in sitting position L1-L2 space was identified and local infiltration of 2% lignocaine was given subcutaneously. With 18G Touhy needle by loss of resistance using air injection technique epidural space was identified and an 18G epidural catheter was threaded and fixed with the aim of the tip being at T10 level. A test dose of 3

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mL 2% lignocaine with 5mcg/mL adrenaline was given to rule out intrathecal and intravascular placement of the catheter. Spinal anaesthesia was given in L3-L4 space with 3.5cc 0.5% Hyperbaric Bupivacaine. All the patients were continuously monitored for pulse rate, blood pressure, respiratory rate and oxygen saturation and recorded in the anaesthesia chart, every 5mins till the end of the surgery. In case of prolongation of surgery, anaesthesia was maintained by administering 5ml of 0.25% Bupivacaine epidurally after negative aspiration.

When the effect of subarachnoid local anaesthetic wears off and the patient complains of pain, first assessment of intensity of pain was done by visual analogue scale, when the visual analogue pain score touched the >5 mark, the intended drugs were given through the epidural catheter.

The test drug was given for postoperative analgesia as a single dose, whenever the patient complained of pain, the VAS score considered as >5 at that time.

Patients were divided into 2 groups of 25 each.

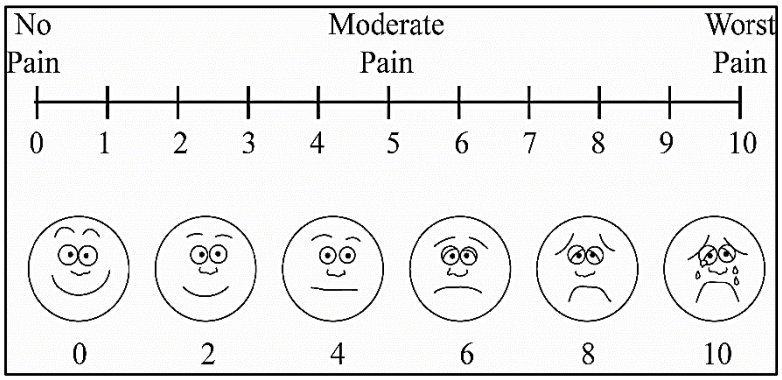
Group RD: Received 10ml of 0.2% ropivacaine and dexmedetomidine 1 mcg/kg.

Group LD: Received 10ml of 0.125% levobupivacaine and dexmedetomidine 1mcg/kg.

Onset of analgesia and duration of pain relief were recorded at 15 minutes intervals for first one hour and then hourly monitoring done till 6hrs during postoperative period. After completion of study if patient complains of pain, at this point rescue analgesia was given on demand by patient, in the form of inj. Bupivacaine 0.125% 8ml through epidural catheter.

In the post-operative period, the following parameters were studied:

Vital parameters such as the heart rate, blood pressure and visual analogue score, onset of analgesia and duration of analgesia were recorded.



Sample size

Power of study was calculated by using software G power 3.0.10, taking mean value for onset of sensory blockade from and considering a probability level of 0.05 (α-error) and power of 0.80 (1-β) yielded a sample size of 25 patients in each group.

Statistical analysis

Statistical data was analysed using SPSS version 23. Comparisions between groups were done using independent student-t test. P value <0.05 was considered statistically significant.

Results

Basic demographics

The minimum age in both groups was 35 years. The maximum age in both groups was 65 years respectively. In Group-RD the mean age was 52.28 (±6.93) and in Group-LD the mean was 49.48 (±7.85).

Table 1: Comparision of demographics between the groups

Parameters	Group RD	Group LD	P value
Age	52.28±6.93	49.48±7.85	0.18
Weight	54.48±5.44	55.24±5.98	0.64

In this there was no significant difference in age and weight between the groups (p>0.05).

Onset of analgesia

The onset of analgesia was significantly higher in group RD as compared to group LD and it was significant (11.86±0.96 vs 8.47±0.66mins; p=0.000). The results were shown in table 2.

Table 2: Comparison of onset of analgesia between the groups

Parameter	Group RD (n=25)	Group LD (n=25)	P value
Onset of analgesia (mins)	11.86±0.96	8.47±0.66	0.000*

The data are represented as mean ± SD.*denotes p value < 0.05.NS-Non-significant.

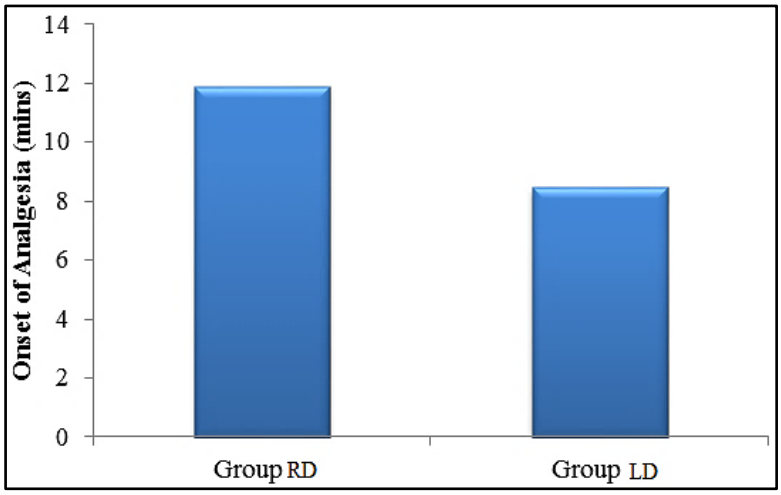


Chart 1: Onset of analgesia between the groups

Duration of analgesia

The duration of analgesia was significantly lower in group RD as compared to group LD and it was significant (210.04±5.29 vs 271.52±3.65mins; p=0.000). The results were shown in table 3.

Table 3: Comparison of duration of analgesia between the groups

Parameter	Group RD (n=25)	Group LD (n=25)	P value
Duration of analgesia (mins)	210.04±5.29	271.52±3.65	0.00

The data are represented as mean ± SD.*denotes p value < 0.05.NS-Non-significant.

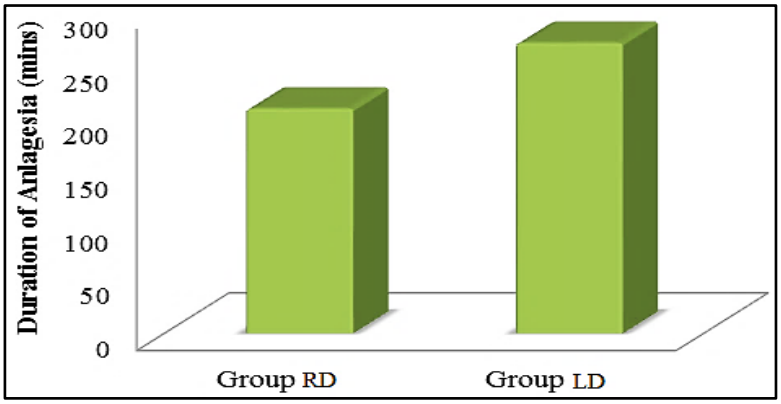


Chart 2: Duration of analgesia between the groups

Heart rate

In this study, the mean heart rate in group RD was 80.12± 8.65 and in group LD it was 89.08± 13.40 and found to be significant (p=0.007). Further, the heart rate was significantly lower in group RD as compared to group LD at 30, 45 minutes and at 1, 2,3,4,5 and 6 hours (p<0.05). However, the heart rate was not significant at 15 mins between the groups (75.64±9.16 vs 81.48±13.32; p=0.07). The results were shown in table 4.

Table 4: Comparison of mean heart rate between the groups

Heart rate (BPM)	Group RD (n=25)	Group LD (n=25)	P value
Baseline	80.12±8.65	89.08±13.40	0.007*
15 mins	75.64±9.16	81.48±13.32	0.07^{NS}
30 mins	74.92±8.41	81.28±12.99	0.04*
45 mins	73.64±7.91	80.80±12.56	0.02*
1 Hour	74.84±7.48	80.32±10.59	0.04*
2 Hours	76.60±6.14	81.44±9.22	0.03*
3 Hours	78.28±6.05	84.52±7.61	0.002*
4 Hours	78.84±6.47	87.40±8.26	0.000*
5 Hours	78.96±5.99	87.48±8.38	0.000*
6 Hours	79.44±5.97	86.12±8.50	0.002*

The data are represented as mean ± SD.*denotes p value < 0.05.NS-Non-significant.

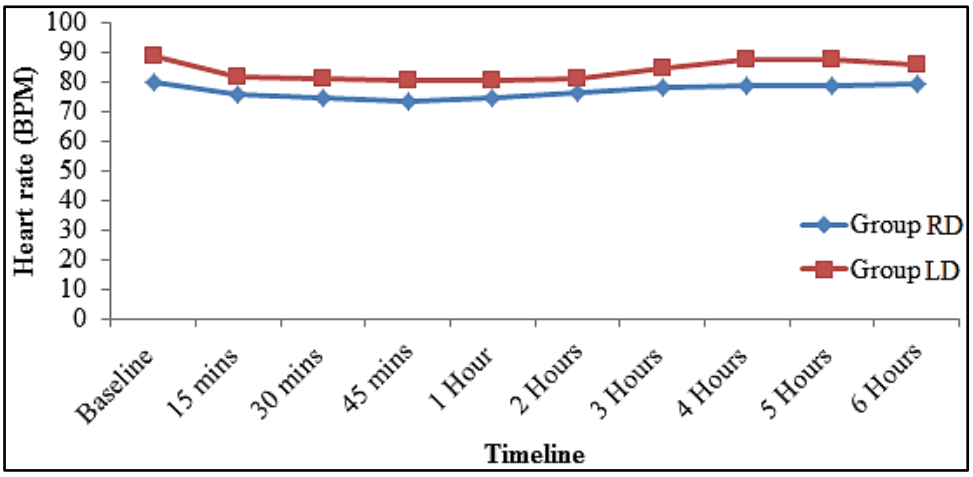


Chart 3: Comparison of mean heart rate between the groups

Systolic blood pressure

The mean systolic BP in group RD was 129.76±6.6 and in group LD was 126.60±9.46 and found to be non-significant (p=0.17). Further the SBP at 15, 30 and 45 mins, 1, 2, 3 and 6 hours was not significant (p>0.05). The SBP was significantly lower in group RD as

compared to group LD at 4 hour (116.88±7.04 vs120.36±6.54; p=0.004) and 5 hour (115.72±6.22vs 120.88±5.76; p=0.000). The results were shown in table 5.

Table 5: Comparison of Systolic blood pressure between the groups

SBP (mmHg)	Group RD (n=25)	Group LD (n=25)	P value
Baseline	129.76±6.6	126.60±9.46	0.17 NS
15 mins	120.64±7.1	117.56±10.74	0.24 NS
30 mins	114.36±7.3	115.84±9.95	0.14 NS
45 mins	111.64±5.12	114.96±9.83	0.72 NS
1 Hour	113.36±6.08	114.16±9.58	0.95 NS
2 Hours	113.68±5.42	113.56±8.26	0.78 NS
3 Hours	116.48±6.92	117.08±8.26	0.07 NS
4 Hours	116.88±7.04	120.36±6.54	0.004*
5 Hours	115.72±6.22	120.88±5.76	0.000*
6 Hours	118.16±5.92	122.08±6.75	0.34 NS

The data are represented as mean ± SD.*denotes p value < 0.05.NS-Non-significant.

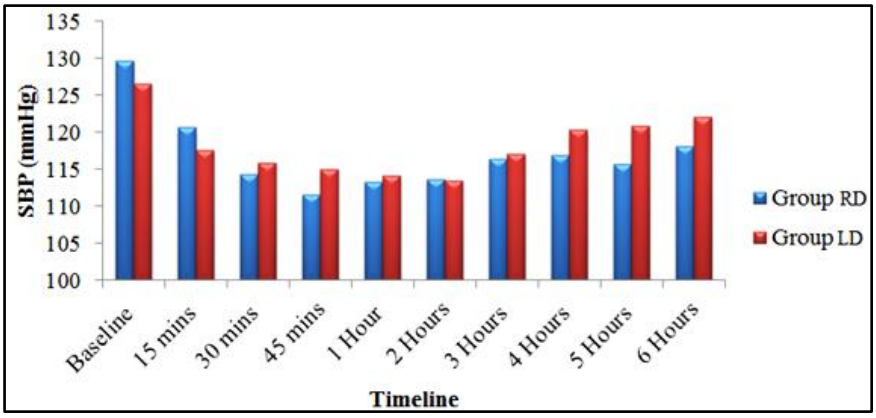


Chart 4: Comparison of SBP between the groups

Diastolic blood pressure

The mean diastolic BP in group RD was 80.28±7.78 and in group LD was 80.28±11.48 and found to be non-significant (p=1). Further, the DBP at 15 and 30 mins, 1, 2, 3, 4 and 6 hours was not significant (p>0.05) between the two groups. The results were shown in table 6.

Table 6: Comparison of diastolic blood pressure between the groups

DBP	Group RD (n=25)	Group LD (n=25)	P value
Baseline	80.28±7.78	80.28±11.48	1
15 mins	77.84±7.36	76.96±10.84	0.73
30 mins	77.20±7.45	76.16±10.68	0.69
45 mins	76.60±6.93	75.92±11.00	0.79
1 Hour	76.00±6.45	75.96±9.86	0.98
2 Hours	75.76±6.75	76.28±7.99	0.80
3 Hours	77.64±6.80	77.88±7.25	0.90
4 Hours	78.16±7.50	78.88±8.04	0.74
5 Hours	78.92±6.46	79.80±7.30	0.65
6 Hours	79.44±6.08	79.52±6.84	0.96

The data are represented as mean ± SD.*denotes p value < 0.05.NS-Non-significant.

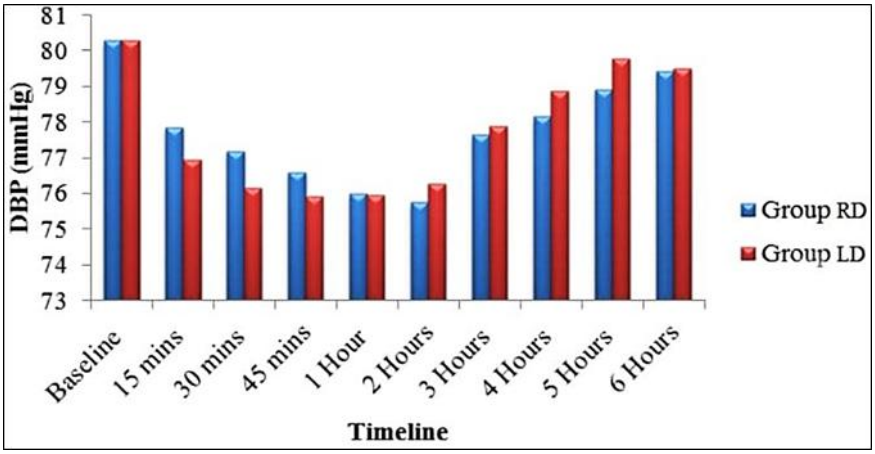


Chart 5: Comparison of DBP between the groups

Visual analogue scale

The mean baseline VAS score was not significant between the group RD and LD (5.39±0.48 vs 5.75±0.59; p=0.25). Meanwhile, VAS score at 15, 30 and 45 mins, 4 hours was not significant between the groups (p>0.05). The VAS score was significantly higher in group RD as compared to group LD at 1(p=0.03), 2 (p=0.01), 3 (p=0.02), 5 (p=0.000) and 6 hours (p=0.000). The results were shown in table 7.

Table 7: Comparison of Visual analogue scale score pressure between the groups

VAS	Group RD (n=25)	Group LD (n=25)	P value
Baseline	5.39±0.48	5.75±0.59	0.25
15 mins	0.3±0.15	0.27±0.14	0.57
30 mins	0.56±0.16	0.44±0.13	0.13
45 mins	0.77±0.17	0.68±0.15	0.57
1 Hour	1.16±0.25	0.98±0.15	0.003
2 Hours	1.45±0.23	1.30±0.16	0.01
3 Hours	1.84±0.33	1.64±0.24	0.02
4 Hours	2.43±0.30	2.28±0.21	0.05
5 Hours	3.04±0.39	2.68±0.24	0.000
6 Hours	3.53±0.25	3.11±0.45	0.000

The data are represented as mean ± SD.*denotes p value < 0.05.NS-Non-significant.

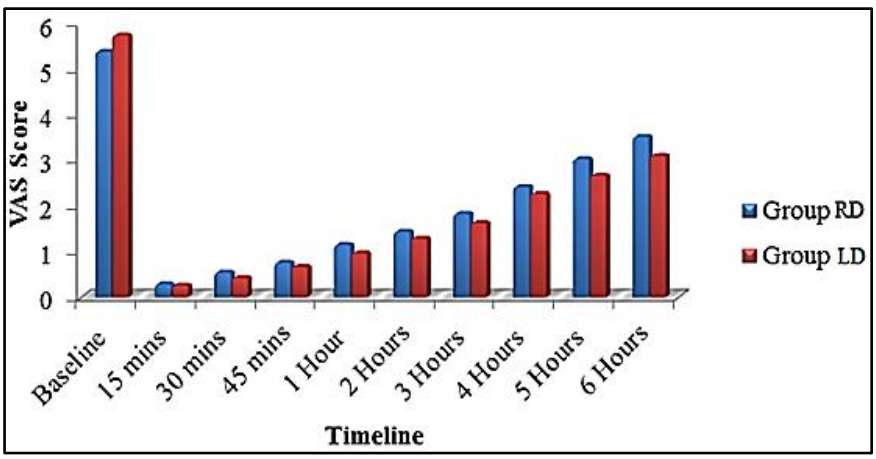


Chart 6: Comparison of VAS scores between the groups

Side effects

We observed that nausea, vomiting, shivering were more in group RD and dizziness was more in group LD. Urinary retention was seen equally in both the groups.

Table 8: Comparision of side effects between groups

Side effects	Group RD (n=25)	Group LD (n=25)
Nausea and Vomiting	5 (20%)	4 (16%)
Shivering	6 (24%)	4 (16%)
Pruritus	0	0
Dizziness	3 (12%)	4 (16%)
Respiratory Depression	0	0
Urinary Retention	3 (12%)	3 (12%)

Discussion

Control of postoperative pain constitutes a major problem for physicians who take care of postoperative patients[6]. It is important to treat postoperative pain because it leads to impaired activity and function, thus increasing the healthcare cost. In addition, the treatment of postoperative pain is associated with better results in terms of early mobilization, early rehabilitationand complication prevention, such as deep vein thrombosis, pulmonary embolism, pneumoniaand atelectasis[8]. Several studies have shown that epidural analgesia with local anaesthetics combined with opioid provides better postoperative analgesia which improves the surgical outcome. However, the use of neuraxial opioids was associated with a few side effects, so various options including α2 agonists are being extensively evaluated as an alternative with emphasis on opioid-related side effects such as respiratory depression, nausea, urinary retentionand pruritus[6,9].

The use of α2 agonists for regional neural blockade in combination with local anaesthetic results in increased duration of sensory blockade with no difference in onset time. Dexmedetomidine when combined with spinal bupivacaine prolongs the sensory block by depressing the release of c-fibre transmitter and by hyperpolarization of post-synaptic dorsal horn neurons[10].

Results of this randomized control study demonstrate that 0.125% levobupivacaine with dexmedetomidine produced early onset of analgesia and prolonged duration of analgesia compared to 0.2% ropivacaine with dexmedetomidine.

In Group RD mean age was 52.28(±6.93) and in Group LD mean age was 49.48(±7.85). There was no significant difference in the age of patients between the Group RD and Group LD. Both groups were similar with respect to age distribution.

In Group RD mean weight was 54.48(± 5.44) and in Group LD mean was 55.24(±5.98). There was no significant difference in the weight of patients between two groups.

In the present study the onset of analgesia in Group RD was 11.86(± 0.96) mins, whereas in study of Prabhavati R *et al.*[2] (2017) onset of analgesia in Group A was 8.21min, this may be due to increased volume of drug [15ml of 0.2% ropivacaine with 1mcg/kg dexmedetomidine]. And onset of analgesia in Group LD was 8.47(±0.66) mins in the present study, whereas in study of Sunil Chiruvella*et al.*[6] (2018) onset of analgesia in Group LD was 7.26(±0.96) min which is comparable with the previous study as the drug volume and concentration is same in both the studies [10ml of 0.125% levobupivacaine with 1mcg/kg dexmedetomidine].

In the present study duration of analgesia in Group RD was 210.04(±5.29) mins, whereas in study of Prabhavati R *et al.*[2] (2017) duration of analgesia in Group A was 336min and in study of Sruthi Arun Kumar *et al.*[4] (2015) duration of analgesia in Group RD was 316(±31.5), this may be due to increased concentration and volume of drug [15ml of 0.75% ropivacaine with 1mcg/kg dexmedetomidine.

In the present study duration of analgesia in Group LD was 271.52(±3.65) mins, whereas in study of Pathak N *et al.*[1] [2020] the duration of analgesia in Group D was 384.02 min, which may be due to increased volume and concentration of drug [12ml of 0.5% levobupivacaine with 50mcg dexmedetomidine]. In the study of Manal N *et al.*[11] [2014] the duration of

analgesia in Group LD was 390mins, due to increased volume and concentration of the drug [20ml of 0.5% levobupivacaine with 1.5mcg/kg dexmedetomidine].

In the present study there was fall in heart rate, SBP, DBP during initial 45min, thereafter hemodynamics remained stable in both the groups.

In the present study VAS score was initially comparable but at 5th and 6th hour the score of significantly higher in Group RD when compared to Group LD.

In our study adverse effects like nausea, vomiting and shivering were seen comparatively more in Group RD, which were managed by antiemetics and low dose opioids(tramadol) and dizziness was comparatively higher in Group LD.

Conclusion

Both levobupivacaine and ropivacaine combined with dexmedetomidine as adjuvant provide effective postoperative analgesia. However, levobupivacaine has faster onset and significantly longer duration of analgesia compared to ropivacaine with a single dose and required lesser top-ups, resulting in lesser consumption of drugs and better patient satisfaction.

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