ISSN: 0975-1556

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2022; 14(1);548-553

Original Research Article

Comparative Analysis of Epidural Ropivacaine 0.75% Versus Ropivacaine 0.75% with Clonidine for Vaginal Hysterectomy - Randomised Controlled Trial

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Received: 01-11-2021 / Revised: 29-11-2021 / Accepted: 23-12-2021
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Conflict of interest: Nil

Abstract

Aim: Comparative analysis of epidural ropivacaine 0.75% versus ropivacaine 0.75% with clonidine for vaginal hysterectomy.

Methodology: This prospective randomized study was conducted at department of anaesthesia, Jhalawar Medical College, Jhalawar in 80 ASA I and II patients scheduled to undergo Vaginal Hysterectomy. Patients were randomly divided in two groups with 40 patients in each group, group RS were given epidural 0.75% Ropivacaine 20ml and 1ml normal saline (total 21ml), group RC were given epidural 0.75% Ropivacaine 20ml and 1ml clonidine (75 mcg dissolved in NS upto1ml, total 21ml). Patients were observed for intraoperative and post operative duration of sensory block, motor block, regression of sensory and motor block, post operative analgesic requirement.

Results: It was observed that epidural ropivacaine in combination with clonidine (Group RC) provides earlier and prolonged sensory and motor block, prolonged duration of analgesia as compared to ropivacaine (Group RS) alone. Incidence of hypotension and bradycardia were comparable in both the groups. Incidence of sedation and dry mouth were more with clonidine. None of our patients in both the study groups experienced respiratory depression.

Conclusion: The findings of the study suggest that use of clonidine as adjuvant helps in achieving faster block onset, longer duration of block, and analgesia without any significant hemodynamic changes.

Keywords: Clonidine, Epidural, Hypotension, Motor block, Isobaric ropivacaine, Sensory block.

Introduction

Regional Anaesthesia like Spinal and Epidural Anaesthesia is an excellent option when the surgical site is located on the lower extremities, perineum, or lower abdomen. Regional anaesthesia has important advantages over general anaesthesia [2] including excellent pain control, no airway manipulations, minimum side effects and shortened stay in the post-anaesthesia care unit. Epidural Anaesthesia provides not only perioperative surgical anaesthesia but can also be used for post operative analgesia by placing a continuous epidural catheter, there is also low incidence of hemodynamic changes as a result of sympathetic blockade as it produces segmental anaesthesia unlike subarachnoid block anaesthesia. Amide local anaesthetic ropivacaine has minimal cardiovascular [1,2] and nervous system toxicity as well as a lesser propensity of motor block during postoperative epidural analgesia main limitation of local anaesthetic with epidural block is its slower onset of action and requirement of high dose [3,4,5]. Here comes role of an adjuvant. The pharmacologic properties of α2 agonist have been extensively studied and have been employed clinically to achieve desired effect in regional anaesthesia [11]. Epidural administration of these drugs is associated with sedation, analgesia, hypnosis and sympatholysis. The addition of Clonidine to local anaesthetics during epidural block can improve the quality of anaesthesia while providing adequate and prolonged analgesia with favourable intra operative condition for surgeon and anaesthesiologist. Along with providing post operative analgesia, it also reduces requirements of anaesthetic agent intra operatively thus avoiding excessive sedation [6,7]. This study was designed to evaluate the analgesic efficacy of Ropivacaine, and Clonidine mixture given through lumbar epidural route in patients undergoing elective vaginal hysterectomy.

Aims and objectives

This study was done to compare the duration of post operative analgesia, onset and duration of sensory and motor block, compare the vital parameters in terms of Heart Rate (HR), Blood Pressure (BP), Oxygen saturation (Sp02) and Respiratory Rate (RR), compare adverse effects of the drugs if any.

Material and methods

This prospective randomized study was conducted in Department of Anaesthesia, Jhalawar Medical College, Jhalawar after getting approval from ethical committee of the institution and informed written consent from the patients. The duration of study was 9 months, from February 2019 to October 2019. In this study 80 ASA grade I & II patients 35-65 years of age, 50-70 kg of weight, undergoing elective hysterectomy per vaginally scheduled to undergo Vaginal Hysterectomy were randomly divided in two groups with 40 patients in each group:

Group RS: Patients were given epidural 0.75% Ropivacaine 20ml and 1ml

Normal saline (total 21ml)

Group RC: Patients were given epidural 0.75% Ropivacaine 20ml and 1ml

Clonidine (75mcg dissolved in NS upto 1ml, total 21ml).

Exclusion criteria

1. Patient’s refusal

2. Contraindication to epidural block like

a) Patients with coagulation disorders,

b) Patients with pre-existing neurological disease

c) Patients with anatomical abnormalities of spine

d) Infection at local site

e) Patients with known allergy to local anaesthetics

3. Patients with diabetes, received corticosteroids or immunosuppressant drugs in last 6 months

4. Patients having compromised renal, pulmonary and cardiac status

5. Patients on medication like hypnotics, narcotic analgesic or sedatives

6. Presence of hypotension or any vascular disease

7. Patients having known allergy to drugs used in study

8. History of seizure disorder

9. Patients with anticipated difficult intubation

All patients were examined on the day before surgery for complete history of patients including any known allergy, general physical and systemic examination, airway examination, ASAgrading and local examination of vertebral column area, baseline pulse rate, blood pressure, respiratory rate, height and weight of patient. All the patients were kept nil per oral as per fasting guideline

Investigations – Hb, TLC, DLC, BT, CT, RBS, Blood urea, Serumcreatinine, LFT, Chest X ray (PA view) and ECG to be done.

After thorough pre-anesthestic check-up and getting an informed consent from the patient, patient was taken inside OT. On arrival all standard monitoring were attached and baseline parameters were recorded IV line was secured by 18 G canula and infusion of Ringer Lactate was started under strict aseptic precautions, skin over thoraco-lumbar region was cleaned and painted using povidone iodine 5-10 % solution, then wiped away using spirit then allowed to air dried & then area of interest draped L3-L4 intervertebral space was identified & infiltrated with 2% lignocaine using 24 G hypodermic needle. Epidural needle 16G was inserted with bevel facing upwards and advanced into epidural space. Epidural space was identified using LOR technique careful aspiration was done to make sure that dura-mater is not punctured if no CSF aspirated LOR syringe was removed, and prepared drug is given in epidural space.

INTRAOPERATIVE OBSERVATIONS

1) Sensory block

Assessed by loss of sensation to pin prick test in the midline using a 22-gauge blunt hypodermic needle. Onset of sensory block to T10 dermatome level, maximum level of sensory block, time taken to achieve maximum sensory level and duration of sensory block (Interval from epidural administration of drug until regression of sensory block to L5 dermatome) was noted.

Pin prick test

0 = sensation

1 = analgesia (touch sensation)

2 = anaesthesia (no sensation)

2) Motor block

The degree of motor block was assessed by Modified Bromage Scale. Onset of motor blockade i.e. time required from injection to achieve Modified Bromage Score 1, time for maximum level blockade (modified Bromage score 3) and duration of motor blockade i.e. time required from onset of action to start of movement of feet or knee (Modified Bromage Score 1) was noted.

Modified Bromage Score

0 = No motor block (able to move feet or knees)
1 =Inability to raise extended leg, able to move knees and feet
2 =Inability to raise extended leg and move knee, able to move feet
3 =Complete block of motor limb (unable to move leg, knee and feet)

3) Sedation:

Patients were monitored for sedation by Ramsay sedation score.

Ramsay Sedation Score

1 Anxious or restless or both
2 Cooperative, oriented and tranquil

3 Responding to commands
4 Brisk responses to stimulus
5 Sluggish responses to stimulus
6 No response to stimulus

Mean arterial pressure (MAP), systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), oxygen saturation (SpO2) and respiratory rate was measured and recorded before and after epidural anaesthesia, every 5 minutes till 30 minutes and thereafter every 15 minutes till the end of surgery and then 2 hours postoperatively for next 24 hours. Quality of analgesia was assessed using visual analogue scale (VAS) on a 0-10 scale, where a score of 0 represents no pain and 10 is the worst pain.

VAS will be measured every ½ hour, till 2 hours, then every 1 hour, till 6 hours followed by every 2 hour, till next 24 hour post operatively. Duration of analgesia will be defined as time interval between activation of epidural block and time to first rescue analgesic requirement. Rescue analgesia will be given when the patient demands it or when the VAS score ≥ 4. Any adverse effects, e.g. nausea, vomiting, itching, bradycardia (fall in HR>30% from baseline or HR<50 beats/min), hypotension (fall in SBP > 20% from baseline or MAP < 60mm Hg), excessive sedation, shivering, respiratory depression (respiratory rate < 10/min or SpO2 < 90%) recorded.

Observation and Results

The population in both the groups were comparable demographically and there was no statistically significant difference between the groups.

Table 1: Patient characteristics

Variables	Group RS	Group RC	P value
Age (years)	54.38±7.88	53.93±8.06	0.801
Weight (kg)	56.13±4.947	55.08±3.308	0.267
Height (cm)	157.625±3.417	157.975±4.560	0.698

Table 2: Spinal anaesthesia characteristics

Block characteristics	Group RS	Group RC	P value
1.Sensory block			
Onset of sensory block	15.62 ± 2.37 min	11.80 ± 1.85 min	<0.0001
Time to achieve max sensory block	22.97±2.36 min		
Duration of sensory block	389.25±44.28 min	433.75±40.29 min	<0.0001
2.Motor block			
Onset of motor block	18.97±2.62 min	16.12±1.84 min	<0.0001
Time to achieve max motor block	27.22 ±1.91 min	22.72±2.74 min	<0.0001
Duration of motor block	336.75±40.66 min	378.75±36.52 min	<0.0001
3. Duration of analgesia	418.75±43.27 min	464.25±37.61 min	<0.0001

Table 3: Adverse effects

Adverse effects	Group RS	Group RC
Hypotension	2 (5%)	3 (7.5%)
It	**0**	1 (2.5%)
Nausea/Vomiting	**0**	1 (2.5%)
Sedation	**0**	4(10%)
Respiratory depression	**0**	**0**
Shivering	2 (5%)	2(5%)
Dry mouth	**0**	2(5%)

Discussion

Addition of adjuvant to local anesthetic in epidurals increases the duration of analgesia and intensity of the block with minimal stress response, thereby resulting in early ambulation and less postoperative morbidity [8,9]. Clonidine, an α-2 adrenergic agonist, which produces analgesia through a non-opioid mechanism, is used as an adjuvant in regional anesthesia in various settings [10]. it also augments the action of local anesthetics in regional blockade. In our study patients were comparable in terms of age, height and body weight so as to ensure that there was no confounding bias.

The onset of sensory blockade was earlier in group RC (11.8±1.85 min) as compared to group RS (15.62±2.37 min). Maximum sensory level was also achieved earlier in group RC (17.25±1.80 min) than group RS (22.97±2.36 min).

Onset of motor blockade and max motor blockade was also achieved earlier in group RC. Onset time was 16.12±1.84 min in group RC and 18.97±2.62 in group RS. Time to max motor blockade was 22.72±2.74 in group RC and 27.22±1.91 in group RS.

Duration of analgesia is also prolonged in group RC (464.25±37.61 min) as compared to group RS (418.75±43.27 min). The difference was statistically highly significant ($p < 0.0001$).

With respect to HR during the study period, there was no significant differences among groups were observed for the initial 60 minutes, however from 60 min onward till 120 min, Group RC had significantly lower heart rate as compared to Group RS. The blood pressure showed statistically significant difference ($P < 0.05$) in both the groups from 10 to 30 minutes. Lower in RC group which coincided with the increasing sensory blockade in both the groups. But once the sensory and motor blocks were completely established, there was no significant difference in BP in either of the groups**.**

No significant adverse effects were noted between both the groups during study period. 4 patients of RC group experienced sedation, but it was not associated with respiratory depression, Incidence of hypotension was comparable in both the groups. 3 patients in group RC and 2 patients in group RS had hypotension. Bradycardia was experienced in only one patient in group RC. The interaction of clonidine with central α-2 receptors causes sedation while augmentation of parasympathetic system and inhibition of sympathetic outflow activity are mainly responsible for centrally mediated hemodynamic effects [11,12]. Incidence of shivering was comparable in both the groups with 2 patients in each group experiencing shivering, none of the patient in group RS had bradycardia.

Conclusion

From our study we concluded that ropivacaine in combination with clonidine provide prolonged duration sensory and motor block, postoperative analgesia as compared to ropivacaine alone. Incidence of sedation and dry mouth were more with clonidine group. Both the groups did not experience any severe side effects, incidence of hypotension and bradycardia were comparable in both the groups. This study suggests that use of clonidine as adjuvant helps in achieving faster block onset, longer duration of block, and analgesia without any significant hemodynamic changes.

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