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A Comparative Study Between Epidural Isobaricropivacaine with Dexmedetomidine and Ropivacaine with Clonidine for Epidural Anesthesia for Lower Abdominal and Lower Limb Surgeries

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ABSTRACT

Aim of the study is to compare the onset, duration and intensity of analgesia between the two groups Ropivacaine+Dexmedetomidine and Ropivacaine+clonidine administered by epidural route. Sixty ASA 1 and 2 physical status patients in the age group 15-60 yrs, posted for elective lower abdominal and lower limb orthopedic surgeries were included in the study. Patients were randomly divided into two groups namely Group RD and Group RC. Group RD (n=30) received 0.75% Ropivacaine 15 ml + Dexmedetomidine 1µg/kg. Group RC (n=30) received 0.75% Ropivacaine 15 ml + Clonidine 1.5 µg/kg. Ropivacaine 0.75% with Dexmedetomidine 1 µg/kg and Ropivacaine 0.75% with Clonidine 1.5µg/kg has same time to reach peak sensory block of T10 level. Ropivacaine 0.75% with Dexmedetomidine 1µg/kg and Ropivacaine 0.75% with Clonidine 1.5µg/kg has same peak sensory block. Ropivacaine 0.75% with Dexmedetomidine 1µg/kg and Ropivacaine 0.75% with Clonidine 1.5µg/kg has same time to reach peak sensory level. Ropivacaine 0.75% with Dexmedetomidine 1 µg/kg and Ropivacaine 0.75% with Clonidine has same time to reach complete motor block.

INTRODUCTION

Over the last two decades surgical methods and anaesthetic techniques have evolved and improved drastically. From time to time many techniques and drug regimens with partial or great success, have been tried to calm the patients and to eliminate the anxiety component during regional anaesthesia. In many patients the intense sensory and motor block, continuous supine position for a prolonged duration and the inability to move the body during regional anaesthesia brings a feeling of discomfort and phobia. In neuraxial anaesthesia sedation, stable hemodynamics and an ability to provide smooth and prolonged intra operative and post operative analgesia are the main desirable qualities of adjuvant^[1-4]. In modern anaesthesiology the epidural blockade is becoming one of the most useful and versatile procedure. It is more versatile than spinal anaesthesia, giving the opportunity to provide quality anaesthesia, postoperative analgesia, as well as enabling diagnosis and treatment of chronic disease syndromes. Epidural anaesthesia can reduce the adverse physiologic response to surgery such as cardiovascular stress, autonomic hyperactivity, tissue breakdown, increased metabolic rate, immune system dysfunction and pulmonary dysfunction. Epidural anaesthesia is very useful to patients as it can provide a pain relief for a longer duration, continuous infusion of the analgesic drugs, the facility of further top- ups through epidural catheter thus providing an uneventful and smooth recovery. In 1944 Edward Tuohy of the Mayo Clinic introduced two important modifications of the continuous spinal techniques. He developed the now familiar Tuohy needle as a means of improving the ease of passage of lacquered silk ureteral catheters through which he injected incremental doses of local anesthetic. In 1949, Martinez Curbelo of Havana, Cuba, used Tuohy's needle and a urethra catheter to perform the first continuous epidural anesthetic^[5-7]. One of the most important properties of a long-acting local anesthetic in different types of surgeries is to reversibly inhibit the nerve impulses, thus causing a prolonged sensory or motor blockade appropriate for anaesthesia. Bupivacaine is a well established long acting regional anaesthetic, which like all amide anaesthetics has been associated with cardiotoxicity when used in high concentration. Epidural bupivacaine has been replaced by Ropivacaine because of its similar analgesic properties, less cardiotoxicity and lesser motor blockade^[8-10]. Ropivacaine is a long acting amide local anaesthetic agent and first produced as a pure S(-) enantiomer. It produces effects similar to other local anaesthetics via reversible inhibition of sodium ion influx in nerve fibers. Ropivacaine is less lipophilic than Bupivacaine and is less likely to penetrate large myelinated motor fibers, resulting in a relatively reduced motor blockade. Thus reduced lipophilicity is

also associated with decreased potential for cardiotoxicity and central nervous system toxicity. The plasma concentration of Ropivacaine depends on route of administration the total dose administered as well as the haemodynamic and circulatory condition of the patient and vascularity of the administered site. The stable haemodynamics and the decreased oxygen demand due to enhanced sympathoadrenal stability make them very useful pharmacologic agents. Clonidine, an imidazoline, was synthesized in the early 1960s and found to produce vasoconstriction that was mediated by receptors. During clinical testing of the drug as a topical nasal decongestant, Clonidine was found to cause hypotension, sedation and bradycardia. Clonidine may be useful in selected patients receiving anaesthesia because it may decrease the requirement for anesthetic and increase hemodynamic stability. Other potential benefits of Clonidine and related drugs such as Dexmedetomidine (a relatively selective α_2 receptor agonist with sedative properties) in anaesthesia include preoperative sedation and anxiolysis, drying of secretions and analgesia. Clonidine is a prototypal α_2 -adrenergic agonist having 200 fold selectivity for α_2 over α_1 adrenoreceptors^[11,12]. Dexmedetomidine, an imidazole compound, is the pharmacologically active dextroisomer of medetomidine that displays specific and selective α_2 -adrenergic receptor agonism. Dexmedetomidine is 8 times more specific for α_2 adrenergic receptors. One of the highest densities of α_2 receptors has been detected in the locus ceruleus. The sedative and hypnotic effects of α_2 adrenergic receptor activation have been attributed to this site. (α_2 : α_1 =1620:1). Dexmedetomidine has analgesic, sedative and sympatholytic effects that blunt many of the cardiovascular responses seen during the perioperative period. Patients remain sedated when undisturbed but arouse readily with stimulation.

MATERIALS AND METHODS

60 ASA 1 and 2 physical status patients in the age group 15 -60 yrs, posted for elective lower abdominal and lower limb orthopedic surgeries were included in the study. Exclusion criteria were patient refusal to participate in this study, patient's weight >120kg and height <150 cms, history of Diabetes Mellitus, hypertension, or psychiatric illness, ECG changes showing any degree of heart block, patients on beta blockers or Alpha 2 antagonists, patients with coagulation abnormality, pregnant and lactating mothers and patients allergic to any of the drugs used in the study. After obtaining informed written consent, patients were randomly divided into two groups namely Group RD and Group RC. Group RD (n=30) received 0.75% Ropivacaine 15 ml + Dexmedetomidine 1 μ g/kg. Group RC (n=30) received 0.75% Ropivacaine 15 ml + Clonidine 1.5 μ g/kg. Materials used for performing

an epidural block were placed in a sterile tray which contained antiseptic solution in a bowl, gauze sponges, sponge holding forceps and sterile towel and drapes to prepare the area for asepsis. A sterile epidural kit was kept ready with a 18G Tuohy needle, 20G calibrated epidural catheter and a 10 ml glass syringe for appreciating loss of resistance. Plain Lignocaine 2%, 25G 1.5 inch needle and 5 ml disposable syringes were used for local infiltration and freshly prepared 2% Lignocaine with adrenaline (5µg/ml) solution for the test dose. Emergency drugs and equipments were kept ready.

Methods: All patients were kept nil per oral (NPO) state for eight hours and were premedicated with Tab. Ranitidine 150 mg the night before and two hours before the surgery. Tab. Alprazolam 0.5 mg was given night before surgery to reduce the anxiety. Peripheral venous line was accessed using and 18G intravenous cannula and all patients were preloaded with 10ml/kg of Ringer lactate solution 43 before performing the epidural block. ECG, pulse oximeter and NIBP monitors were connected and baseline parameters namely heart rate, blood pressure, SpO₂ and respiratory rate were recorded. Epidural block was performed by anaesthetist who was blinded to this study. The block was performed using 18G Tuohy needle at the L3-L4 or L4- L5 interspace level and 3-5 cm of 20G epidural catheter was inserted into the epidural space. Test dose of 3ml of 2% Lignocaine with 15µg adrenaline was given. After ruling out intra vascular and intrathecal placement, the bolus drug solution of either group was administered slowly. Vital parameters were continuously monitored and recorded every 5 minutes for the first 30 minutes, every 10 minutes for the first hour and every 15 minutes after 1 hour to the completion of surgery. Intravenous fluids were given based on the surgical requirements. Hypotension^[4] (SBP<100 mmHg) was treated with ephedrine 6mg iv. Bradycardia⁴ (HR<60 beats/minute) was treated with atropine 0.6mg iv. Respiratory depression (RR<8 breaths/min or SpO₂<90%) was managed with intermittent positive pressure ventilation with 100% O₂. Nausea or vomiting was treated with ondansetron 4mg iv. Sensory level of block was assessed bilaterally by pin prick method from distal to proximal dermatome level. Motor level of block was assessed by Modified Bromage Scale. Sedation level was assessed by Ramsay Sedation Scale. Surgical incision was made after achieving total loss of sensation at T10 level. At the end of surgery patients were shifted to the recovery room and subsequently to the post-operative ward. The patients were instructed to inform the onset of discomfort at incision site to the post-operative ward nurse who was also blinded to the study. Duration of analgesia was recorded from the onset of sensory block to the time of incisional discomfort as

reported by the patient. Study will end when duration of sensory blockade and motor blockade are confirmed and side effects observed. Rescue medication in the form of additional Dexmedetomidine or Clonidine was given to patients at the end of study.

Statistical Tools: The information collected regarding all the selected cases were recorded in a master chart. Kruskal Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate's chi square test was used for qualitative variables. A 'p' value <0.05 was taken to denote a significant relationship.

RESULTS AND DISCUSSIONS

Pain relief is necessary for both humanitarian and therapeutic reasons. Surgery produces tissue injury with consequent release of histamine and inflammatory mediators which activates peripheral nociceptors, which initiate transmission of nociceptive information to the central nervous system (CNS). Transmission of nociceptive stimuli from the periphery to the CNS results in the neuroendocrine stress response which may potentiate detrimental physiologic effects in other areas of the body. Therefore it is utmost important to block this transmission by adopting good anesthesia procedures of highest quality and safety. Epidural anesthesia is superior to spinal as the desired block levels can be achieved without significant haemodynamic disturbances and top-up doses of anaesthetics and analgesics can be given. In modern anesthesia practice, epidural anesthesia is widely being used especially in patients undergoing surgical procedures involving lower parts of the body. To fulfill this demand, there is a need for local anesthetic with desirable properties like longer duration of sensory blockade and shorter duration of motor blockade with adequate sedation. Ropivacaine is a well tolerated anaesthetic with an efficacy similar to that of Bupivacaine and much higher than that of Etidocaine. Indeed, studies have shown Ropivacaine to have less cardiovascular and CNS toxicity than Bupivacaine. Studies in human volunteers have shown that Ropivacaine is associated with at least 25% less CNS and cardiovascular adverse effects than Bupivacaine. Ropivacaine seems to have the greatest margin of safety of all long-acting local anaesthetics at present.

Thus Ropivacaine with its efficacy, lower propensity for motor block and reduced potential for CNS toxicity and cardio toxicity, is an important option for regional anaesthesia (Epidural anesthesia). Alpha 2 Selective adrenergic agonists are used primarily for the treatment of systemic hypertension. Alpha 2 adrenergic agonists like clonidine which acts on alpha 1 and alpha 2 receptors and Dexmedetomidine which acts on alpha 2 receptor have both analgesic and

Table 1: Heart Rate (bpm): A Comparison in Two Groups

HR(bpm)	Group RC	Group RD	P value
5 min	72.83±3.99	73.63±5.20	0.230
10	71.80±6.28	73.27±5.65	0.345
15	70.17±5.19	71.97±4.79	0.168
20	70.23±7.19	72.33±5.06	0.196
25	71.60±8.60	71.67±4.82	0.971
30	70.70±7.34	71.43±4.49	0.643
40	71.23±8.57	73.10±4.33	0.291
60	70.33±6.41	73.07±4.29	0.210
80	70.97±5.49	73.15±6.30	0.263
100	71.57±5.98	72.68±4.58	0.549
120	70.52±5.26	71.71±4.43	0.672
140	71.88±5.64	73.18±2.93	0.297
160	69.56±5.70	72.00±2.83	0.581
180	69.75±8.02	65.00±0.00	0.633

Table 2: SBP (mm Hg): A Comparison in Two Groups

SBP (mm Hg)	Group RC	Group RD	P value
5 min	120.93±11.01	123.27±8.13	0.354
10	115.50±8.06	118.17±7.20	0.182
15	115.97±8.49	119.50±7.11	0.914
20	115.73±9.01	118.47±5.97	0.870
25	115.20±10.5	118.60±6.85	0.843
30	113.10±8.28	114.67±6.47	0.251
40	112.27±9.32	112.87±6.64	0.564
60	114.57±10.31	112.43±6.18	0.453
80	113.67±7.80	112.00±5.79	0.468
100	112.54±6.52	114.00±6.37	0.584
120	112.16±8.93	114.00±7.58	0.543
140	113.13±6.00	114.36±7.10	0.584
160	112.89±5.67	113.00±4.24	0.980
180	111.25±2.50	110.00±0.00	0.685

Table 3: DBP (mm Hg): A Comparison in Two Groups

DBP (mm Hg)	Group RC	Group RD	P value
5 min	74.33±7.28	72.93±4.35	0.370
10	71.27±7.29	71.27±4.22	1.000
15	68.17±9.16	70.87±4.70	0.452
20	68.13±6.43	70.07±4.26	0.646
25	68.30±7.72	70.93±4.57	0.546
30	67.30±8.96	70.40±4.97	0.248
40	67.80±6.13	69.20±5.29	0.641
60	69.07±7.27	69.67±6.50	0.288
80	68.27±5.30	69.58±4.58	0.875
100	67.61±7.11	68.90±5.60	0.842
120	69.12±6.41	71.88±5.50	0.155
140	69.25±6.19	69.91±4.04	0.726
160	67.78±6.67	70.00±0.00	0.662
180	67.50±5.00	70.00±0.00	0.685

Table 4: Respiratory Rate: A Comparison in Two Groups

RR	Group RC	Group RD	P value
5 min	12.60±0.93	12.57±1.10	0.951
10	12.80±1.00	13.13±1.20	0.246
15	13.13±1.01	13.03±1.16	0.723
20	13.17±1.18	12.80±1.13	0.223
25	13.10±1.06	13.60±1.07	0.744
30	12.80±1.10	12.33±0.92	0.792
40	13.13±1.11	13.20±0.81	0.648
60	13.23±1.33	13.23±0.73	1.000
80	12.88±0.99	12.27±0.69	0.692
100	12.91±1.19	12.36±0.78	0.548
120	12.82±1.01	12.72±0.75	0.871
140	13.20±1.03	13.25±0.68	0.787
160	13.00±1.41	12.44±0.88	0.476
180	-	-	-

Table 5: SpO2%: A Comparison in Two Groups

SpO2%	Group RC	Group RD	P value
5 min	99±0.56	99±0.49	0.956
10	99±0.47	98±0.50	0.567
15	99±0.49	99±0.50	0.987
20	98±0.54	98±0.50	0.979
25	99±0.50	98±0.50	0.456
30	99±0.48	99±0.47	0.964
40	99±0.49	99±0.49	1.000
60	99±0.57	99±0.46	0.798
80	99±0.48	99±0.46	0.876
100	99±0.65	99±0.50	0.774
120	99±0.46	98±0.56	0.654
140	99±0.49	99±0.46	0.967
160	99±0.48	99±0.46	0.764
180	99±0.47	99±0.50	0.648

Table 6: Motor Blockade (Bromage): A Comparison in Two Groups

Motor blockade (Bromage)	Group RC	Group RD	P value
5 min	1.00±0.26	1.00±0.00	1.000
10	1.47±0.51	2.00±0.00	<0.001**
15	1.97±0.18	2.20±0.61	0.049*
20	2.80±0.89	3.73±0.69	<0.001**
25	3.47±0.90	3.93±0.37	0.011*
30	3.73±0.69	4.00±0.00	0.039*
40	3.93±0.37	4.00±0.00	0.321
60	3.97±0.18	4.00±0.00	0.321
80	4.00±0.00	4.00±0.00	-
100	4.00±0.00	4.00±0.00	-
120	4.00±0.00	4.00±0.00	-
140	3.88±0.50	4.00±0.00	0.397
160	3.78±0.67	4.00±0.00	0.662
180	-	-	-

sedative properties when used as an adjuvant in regional anesthesia. The anesthetic and the analgesic requirement are reduced to a huge extent by the use of these two adjuvants because of their analgesic properties and augmentation of local anaesthetic effects as they cause hyper polarization of nerve tissues by altering transmembrane potential and ion conductance at locus caeruleus in the brain stem. The stable hemodynamic and the decreased oxygen demand due to enhanced sympathoadrenal stability make them very useful pharmacologic agents. The Alpha 2 adrenergic agonists produce clinical effects by binding to α_2 -receptors. The quality of sedation produced by α_2 -agonists differs from these sedation produced by drugs (Midazolam, Propofol) that act on γ -amino butyric acid (GABA) receptors. Sedation reflects decreased sympathetic nervous system activity, resulting in a calm patient who can be easily aroused to full consciousness. Clonidine, an imidazoline, was synthesized in the early 1960s and found to produce vasoconstrictor that was mediated by receptors. During clinical testing of the drug as a topical nasal decongestant, Clonidine was found to cause hypotension, sedation and bradycardia. Clonidine may be useful in selected patients receiving anesthesia because it may decrease the requirement for anesthetic and increase hemodynamic stability. Other potential benefits of Clonidine and related drugs such as Dexmedetomidine a relatively selective α_2 receptor agonist with sedative properties in anesthesia include preoperative sedation, anxiolytic, drying of secretions and analgesia. Clonidine is a prototypal α_2 -adrenergic agonist having 200 fold selectivity for α_2 over α_1 adrenoreceptors. Dexmedetomidine, an imidazole compound, is the pharmacologically active dextroisomer of medetomidine that displays specific and selective a 2-adrenergic receptor agonist. Dexmedetomidine is 8 times more specific for a 2 adrenergic receptors. Dexmedetomidine has sedative, analgesic and sympatholytic effects that blunt many of the cardiovascular responses seen during the perioperative period. Patients remain sedated when undisturbed but arouse readily with stimulation. This study is in partial agreement with our study where they have used the lower dose of drug for labour

analgesia but in our study we used for anesthesia in lower limb surgeries. In our study the duration of analgesia and duration of sensory and motor blockade was prolonged with epidural Ropivacaine and Clonidine, α_2 -adrenergic agonist. This study is in partial agreement with our study where they have used the intravenous route of drug for sedation but in our study we used for anesthesia in lower limb surgeries. In our study the duration of analgesia and duration of sensory and motor blockade was prolonged with epidural Ropivacaine and Dexmedetomidine, a α_2 -adrenergic agonist. This study is in complete agreement with our study where the epidural Dexmedetomidine prolonged sensory and motor block duration time. There was no difference in incidence of hypotension and bradycardia in our study. The above study is a comparison between fentanyl, a opioid and Dexmedetomidine, a α_2 - adrenergic agonist but in our study we have compared both α_2 -adrenergic agonists clonidine and Dexmedetomidine. Similar to our study there is synergism between epidural Dexmedetomidine and Ropivacaine.

CONCLUSION

- Ropivacaine 0.75% with Dexmedetomidine 1 μ g/kg and Ropivacaine 0.75% with Clonidine 1.5 μ g/kg has same time to reach peak sensory block of T10 level.
- Ropivacaine 0.75% with Dexmedetomidine 1 μ g/kg and Ropivacaine 0.75% with Clonidine 1.5 μ g/kg has same peak sensory block.
- Ropivacaine 0.75% with Dexmedetomidine 1 μ g/kg and Ropivacaine 0.75% with Clonidine 1.5 μ g/kg has same time to reach peak sensory level.
- Ropivacaine 0.75% with Dexmedetomidine 1 μ g/kg and Ropivacaine 0.75% with Clonidine has same time to reach complete motor block.

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