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Original Research Article

A STUDY TO EVALUATE AND COMPARE THE CLINICAL EFFECTS OF DEXMEDETOMIDINE AS AN ADJUVANT TO EPIDURAL BUPIVACAINE 0.5% FOR PATIENTS UNDERGOING TOTAL ABDOMINAL HYSTERECTOMY

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ABSTRACT

Background: Epidural anesthesia provides effective surgical anesthesia and can meet the extended duration of surgical needs and provides prolonged post operative analgesia. Bupivacaine is a long acting amide local anesthetic which is commonly used, produces better intensity of motor blockade and longer duration of action compared to other local anesthetics. Dexmedetomidine is a highly selective α 2 adrenergic agonist with an affinity of eight times greater than clonidine and it prolongs the duration of analgesia, motor blockade and post operative analgesia making it a very useful adjuvant. **Aim:** Hence we compared 0.5% bupivacaine with dexmedetomidine and 0.5% bupivacaine alone. The aim of this study is to evaluate and compare the clinical effects of Dexmedetomidine as an adjuvant to epidural bupivacaine 0.5% for patients undergoing total abdominal hysterectomy.

Materials and Methods: Sixty patients, scheduled for total abdominal hysterectomy belonging to ASA class I and II were included in the study. They were randomly divided into two groups with 30 patients in each group. 1. Group C - 20ml of 0.5% bupivacaine , 2.Group D - 20ml of 0.5% bupivacaine with1µg/kg of dexmedetomidine. (not exceeding 50 µg) Epidural anaesthesia was given at L3-L4 level in right lateral decubitus position using 18G tuohy's needle and catheter inserted 4 cms. The onset time and the maximum level of sensory and motor block, haemodynamic parameters, sedation, sensory and motor regression and post operative analgesia were recorded.

Results: Dexmedetomidine group had rapid onset of sensory block ($p<0.05$), prolonged duration of sensory and motor block ($p<0.05$), better sedation score and postoperative analgesia ($p<0.05$), better haemodynamic stability and lesser occurrence of side effects (shivering, nausea and vomiting).

Conclusion: There is clear synergism between dexmedetomidine and bupivacaine compared with plain bupivacaine in epidural anesthesia in terms of sensory and motor blockade, post operative analgesia, with hemodynamic stability with lesser side effects.

Keywords: Bupivacaine, Dexmedetomidine, Epidural.

INTRODUCTION

Intrathecal anesthesia and epidural anesthesia are the most popular regional anesthesia techniques used for lower abdominal surgeries. Epidural blockade is one of the most useful and versatile procedure in modern anesthesiology. It is unique in that it can be administered virtually at any level of

intervertebral space, allowing more flexibility in clinical practice. It is more versatile than spinal anesthesia, giving the anesthetist the opportunity for providing continuous surgical analgesia and anesthesia. It can also be utilized for post operative pain control and more rapid recovery from surgery.[1]

Epidural anesthesia can reduce the adverse physiologic responses to surgery such as autonomic hyperactivity, cardiovascular stress, increased metabolic rate, pulmonary dysfunction and immune system dysfunction. Epidural anesthesia also reduces the incidence of hyper coaguability, deep vein thrombosis (DVT), pulmonary embolism (PE) and also decreases intraoperative blood loss. Epidural anesthesia reduces venous blood pressure (measured in the operative wound), and this is the significant factor in determining surgical bleeding. Intrathecal anesthesia also called as sub arachnoid block has few limitations like, short duration of anesthesia, extension of anesthesia cannot be made for prolonged surgeries, rapid onset of sympathetic blockade, shorter duration of post operative analgesia and troublesome complication of postdural puncture headache (PDPH). Hence epidural anesthesia is the most preferred anesthetic technique for lower abdominal surgeries these days.[2]

Different local anesthetics are used for epidural anesthesia, most popular in India being Lidocaine and Bupivacaine. The drawback of lidocaine is its intermediate duration of action, thus bupivacaine, a long acting local anesthetic was used in the study.[3,4]

The intense sensory and motor block, continuous supine position for a prolonged duration and the inability to move the body during regional anesthesia brings a feeling of discomfort and phobia in many of the patients.[5] The high cephalic spread of analgesia with local anesthetics may be significant but still its quality sometimes may not correlate with the level of sensory analgesia. At this stage, the impulsive use of large doses of sedation or even general anesthesia with mask, defeats the novel purpose of regional anesthesia, whereby a continuous verbal contact with the patient is lost. Sedation, stable haemodynamics and an ability to provide smooth and prolonged post-operative analgesia are the main desirable qualities of an adjuvant in

neuraxial anesthesia. Epidural opioids produce good sedation but has serious side effects like late and unpredictable respiratory depression, post operative nausea and vomiting, pruritis and urinary retension.

α-2 adrenergic agonists have both analgesic and sedative properties without the adverse effects of opioids when used as an adjuvant in regional anesthesia. Dexmedetomidine is a highly selective α 2 adrenergic agonist with α 2/ α 1 selectivity ratio of (1600:1) which is eight times more potent than clonidine (200:1). It is shorter acting drug than clonidine with a distribution half- life of 9 min and elimination half- life of 2 hours.

The anaesthetic and the analgesic requirement get reduced to a huge extent by the use of dexmedetomidine because of its analgesic properties and augmentation of local anaesthetic effects as they cause hyperpolarisation of nerve tissues by altering transmembrane potential and ion conductance at locus coeruleus in the brainstem.[6]

The stable haemodynamics and the decreased oxygen demand due to enhanced sympathoadrenal stability make it a very useful pharmacologic agent. Apart from these, it has organoprotective effects, antiemetic properties and helps in reducing shivering. Hence a study was undertaken to study the effects of dexmedetomidine as an adjuvant to epidural 0.5% bupivacaine in patients undergoing total abdominal hysterectomy.

MATERIALS AND METHODS

A comparative study was conducted in Meenakshi Medical College Hospital and Research Institute, Kanchipuram during the period January 2024 to December 2025. The study was undertaken after obtaining ethical committee clearance as well as informed consent from all the patients. Sixty patients, scheduled for total abdominal hysterectomies belonging to ASA class I and II were included in the study.

The study population was randomly divided using computer generated randomization numbers into two groups with 30 patients in each group.

1. Group A (n=30) – 20 ml of 0.5% bupivacaine
2. Group B (n=30) – 20 ml of 0.5% bupivacaine + 1μg/kg of dexmedetomidine (not exceeding 50 μg)

The volume of bupivacaine is adjusted according to the height of the patient, < 150 cms received 15 ml 150 to 155 cms received 17 ml and >155 cms received 20 ml. All the patients were taken based on the inclusion and exclusion criteria. inclusion criteria includes adults patients aged between 30 to 65years, Weight above 45kgs and height above 145 cms.

The patients were premedicated with tablet alprazolam 0.5 mg and tablet ranitidine 150 mg orally at bed time on the previous night before surgery. They were kept nil orally 10 pm onwards on the previous night. On the day of surgery, patient's basal pulse rate and blood pressure were recorded. A peripheral intravenous line with 18 gauge cannula was secured. Multiparameter monitor was connected which records heart rate, non-invasive measurement of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure(MAP), continuous electrocardiogram (ECG) monitoring and oxygen saturation (SPO2). With the patient in right lateral decubitus position under aseptic precautions, epidural space was identified by loss of resistance technique using 18G Tuohy needle via the midline approach at L3-4 inter spinous space.

An epidural catheter was threaded and fixed at 4 cms inside the epidural space. A test dose of 3 ml of 2% lignocaine with 1:200000 adrenaline was injected through the catheter after aspiration.

After ruling out intrathecal and intravascular placement of the tip of the catheter, 10 ml of 0.5% bupivacaine was injected followed by study drug/ control followed by 10 ml again of 0.5 % bupivacaine.

Assessments of sensory and motor blockade were done at the end of each minute with the patient in supine position after completion of the injection of the drug, which is taken as the starting time. The onset time for sensory block, the maximum level of sensory block, time for complete motor block, sedation score and duration of post operative analgesia were recorded. Measurements of blood pressure, heart rate, and oxygen saturation was recorded every 5 minutes till the end of one hour and then every 15 minutes till the end of surgery.

Intraoperatively and postoperatively complications like fall in blood pressure, variation in heart rate were noted and treated. Hypotension is defined as reduction of systolic blood pressure more than 30% from basal systolic blood pressure or MAP less than 60 mmHg and was treated with intravenous fluids and if needed injection ephedrine 6 mg (I.V) Bradycardia (<50 beats/min) was treated with injection Atropine 0.6 mg (I.V).

After the surgery, patients shifted to post anaesthesia care unit where they were monitored until there was complete recovery of sensory and motor blockade. Epidural top up was given with 8ml of 0.125% inj. bupivacaine once the patient complains of pain. Postoperatively duration of sensory and motor blockade, and time for first epidural top up, any adverse events like nausea, vomiting, dry mouth, pruritis, shivering etc were noted. The results of the study were statistically analysed between the two groups.

RESULTS

Age wise Distribution

Table 1 indicates that age wise distribution of patients. There was no statistically significant difference in the distribution of age among the two groups, the p value being 0.756

Table 1: Study Group

Age group (years)	Group B		Group A		Total	
	N	%	N	%	N	%
31-40	4	13.3	3	10.0	7	11.7
41-50	17	56.7	15	50.0	32	53.3
51-60	9	30.0	12	40.0	21	35.0
Total	30	100.0	30	100.0	60	100.0

Chi-Square Tests	Value	P-Value
Fisher'sExactTest	0.696	0.756

ASA Status

Table 2 observed that There was no significant statistical difference between the two groups of ASA status P value being 0.78.

Table 2: ASA status

ASA	Study Group					
	Group B		Group A		Total	
	N	%	N	%	N	%
ClassI	20	66.7	21	70.0	41	68.3
ClassII	10	33.3	9	30.0	19	31.7
Total	30	100.0	30	100.0	60	100.0

Chi-Square Tests	Value	P-Value
Pearson Chi-Square	0.077	0.781

Weight, Height and Duration of Surgery

Table 3 shows that the weight, height and duration of the surgery patients. There is no significant statistical difference in weight, height and duration of surgery between the two groups.

Table 3: Weight, Height and Duration of Surgery

Variables	Study Group	N	Mean	Std. Dev	t-Value	P-Value
Weight(kgs)	Group B	30	58.27	7.575	0.317	0.753
	Group A	30	57.67	7.102		
Height (cms)	Group B	30	157.50	4.812	0.437	0.664
	Group A	30	156.97	4.642		
Duration of Surgery(mins)	Group B	30	113.30	10.681	0.404	0.688
	Group A	30	114.40	10.431		

Intraoperative Sensory and Motor Block Characteristics

Table 4 noted that the onset of sensory block at T10, time for maximum sensory level, time for motor blockade to Bromage 3 and RAM 5 are statistically highly significant with p<0.001.

Table 4: Intra operative Sensory and Motor Block Characteristics

Variables	Study Group	N	Mean	Std.Dev	t-Value	P-Value
Onset of Sensory Blockade10(Mins)	Group B	30	4.77	1.040	7.942	<0.001
	Group A	30	6.87	1.008		
Time for Max Sensory level (Mins)	Group B	30	9.50	1.137	5.421	<0.001
	Group A	30	11.13	1.196		
Time for motor Blockade to bromage 3(Mins)	Group B	30	14.37	1.217	6.127	<0.001
	Group A	30	16.33	1.269		
Time For Motor Blockade to ram 5 (Mins)	Group B	30	17.53	1.358	4.376	<0.001
	Group A	30	20.30	3.186		

Maximum Sensory Level Attained

Table 5 indicates that the sensory level of T2, T4, T6 and T7 were identified and maximum sensory level attained is T4 in Group B and T6 in Group A and are statistically highly significant with p<0.001.

Table 5: Maximum Sensory Level Attained

Maximum Sensory Level	Study Group					
	Group B		Group A		Total	
	N	%	N	%	N	%
T2	1	3.3	0	.0	1	1.7
T4	21	70.0	9	30.0	30	50.0
T6	8	26.7	19	63.3	27	45.0
T7	0	.0	2	6.7	2	3.3
Total	30	100.0	30	100.0	60	100.0

Chi-SquareTests	Value	P-Value
Fisher's Exact Test	11.794	0.002

Post-Operative Block Characteristics

Table 6. observed that the Time for two segment sensory regression, time for motor regression to Bromage 0 and RAM 3 and time for first epidural top up are all statistically highly significant with p<0.001.

Table 6: Post-Operative Block Characteristics

Variables	Study Group	N	Mean	Std. Dev	t-Value	P-Value
Time for two Segment regression (Mins)	Group B	30	187.83	4.878	39.705	<0.001
	Group A	30	122.90	7.513		
Time For Motor Regression To RAM3 (Mins)	Group B	30	226.33	14.492	20.149	<0.001
	Group A	30	153.73	13.396		
Time for Regression to bromage 0 (Mins)	Group B	30	309.30	3.612	61.629	<0.001
	Group A	30	247.47	4.142		
Time for First Rescue Top Up (Mins)	Group B	30	503.60	6.112	133.06	<0.001
	Group A	30	311.03	5.048		

Ramsey Sedation Score (RSS)

There is statistically high significance in the sedation score between the two groups, Group B causing significant sedation and less requirement for additional need for sedation (p<0.001). [Table 7]

Table 7: Ramsey Sedation Score (RSS)

Variables	Study Group	N	Mean	Std. Dev	t-Value	P-Value
RSS 30mins	Group B	30	2.23	.504	9.264	<0.001
	Group A	30	1.17	.379		
RSS 60mins	Group B	30	2.93	.450	10.553	<0.001
	Group A	30	1.67	.479		
RSS 90mins	Group B	30	3.07	.450	11.440	<0.001
	Group A	30	1.80	.407		
RSS 120mins	Group B	30	3.10	.481	12.059	<0.001
	Group A	30	1.57	.504		

Adverse Effects

There was lesser incidence of nausea (p=0.02), vomiting (p=0.103), shivering (p=0.140) in Group D but greater incidence of dry mouth (p=0.01) which is statistically significant. [Table 8]

Table 8: Adverse Effects

Side effects	Group B(n=30)	Group A(n=30)	P value
Nausea	2(6.7%)	9(30%)	0.020
Vomiting	1(3.3%)	6(20%)	0.103
Shivering	2(6.7%)	7(23.3%)	0.140
Drymouth	7(23.3%)	0	0.010
Dizziness	0	0	0
Respiratory Depression	0	0	0
Headache	0	0	0

DISCUSSION

The hypothesis that was made before the study was that Bupivacaine will produce lesser duration of sensory and motor blockade than Bupivacaine + dexmedetomidine, as dexmedetomidine causes significant prolongation of sensory and motor blockade57 and improves the quality of anaesthesia and perioperative analgesia. In our study, the drugs selected for epidural anaesthesia were Bupivacaine and dexmedetomidine. Bupivacaine is being regularly used for epidural anaesthesia for various abdominal surgeries in our hospital. It has a greater duration of action as
well as greater intensity of motor blockade. Dexmedetomidine has been studied by various authors as an adjuvant to epidural local anaesthetic7. Few studies have compared bupivacaine and dexmedetomidine for epidural anaesthesia in India. Hence bupivacaine and dexmedetomidine combination was selected for our study to compare with bupivacaine alone. The volume of 0.5% bupivacaine used is calculated as 2 to .5ml/segment for thoracolumbar segments and block upto T6 is required for abdominal hysterectomies, so total volume required would be 15 ml and dose is adjusted according to the height of the patient adding 0.1ml/segment for every 5 cms of increasing height, height upto 150 cms received 15 ml, from 150 to 155 cm received 17ml and more than 155 cms received 20 ml of the drug.

Dexmedetomidine was selected as 1mcg/kg, not exceeding 50 mcg since it was found in our pilot study that higher than 50mcg caused significant sedation and fall in heart rate.[8]

Also, in the pilot study, dexmedetomidine was given initially followed by the bolus dose of 0.5% bupivacaine. This caused a delay in onset of sensory blockade probably due to the membrane stabilizing property of dexmedetomidine. Thus a bolus dose of 10 ml of 0.5% bupivacaine was given initially followed by the drug and then again 10 ml of 0.5 % bupivacaine which effectively reduced the sensory onset time.

All patients received epidural anaesthesia at the level of L3- L4 with the catheter inserted 4 cms inside the epidural space. In our pilot study conducted, epidural was given at a higher space which did not produce sufficient intensity of motor blockade, and there was ineffective lower abdominal relaxation. Thus the level of blockade was selected as L3- L4 as instructed by our chief.

Demographic data comparing age, sex, weight, height shows no statistically significant difference among both the groups. P>0.05

In our study the mean time for onset of sensory analgesia at T10 is 6.87 ± 1.08 mins in group A and 4.77±1.04 mins in group B. This is statistically highly significant (p<0.001). Saravia P.S.F, Sabbag AT et al,[9] found no significant change in the onset time for sensory block between control and dexmedetomidine groups.

The studies conducted by Bajwa SJ, Bajwa SK, Kaur J et al,[10] showed onset of sensory analgesia at T10 in dexmedetomidine group was 8.52 ± 2.36 min Vs 9.72 ± 3.44 min in clonidine group and this is statistically significant similar to our study.

Bajwa SJ, Bajwa SK, Kaur J et al 10 showed onset of sensory analgesia at T10 in dexmedetomidine group was 7.12± 2.44 mins VS 9.14 ± 2.94 mins in fentanyl group and this is also statistically significant similar to our study.

In our study, the maximum level of sensory block in group D was T4 (n=21) and time taken was 9.50 ± 1.13 mins and in group C,the maximum level was T6(n=19) and time taken was 11.13 ± 1.19 mins which was statistically significant between the two groups. (p<0.001) Saravia P.S.F, Sabbag AT et al,[9] found maximum level of sensory block at T6 between control and dexmedetomidine groups. The studies conducted by Bajwa SJ, Bajwa SK, Kaur J et al 10 showed maximum level of sensory block at T5-6 level in group B compared to T6-T7 in group A.

Bajwa SJ, Arora V, Kaur J et al,[10] showed maximum level of sensory block at T4-6 level in group dexmedetomidine compared to T5-T7 in group fentanyl which is similar with our study.

In our study, the time for sensory regression is longer with group B (187.83 ± 4.87) compared with group C (122.90 ±7.51). This is statistically significant(p<0.001). Our study concurs with the study conducted by Azemati S et al,[11] who observed the time for two segment regression to be 136.46±8.12 mins in group dexmedetomidine compared to 128.08±7.54 mins in group clonidine which is highly significant.

One patient in group B required supplemental analgesics intra-operatively whereas 10 patients in group C required supplemental analgesics. There was significant statistical difference in the requirement of supplemental analgesics. (p=0.003).

In our study motor blockade is assessed using modified Bromage scale and RAM scale and time for complete motor blockade is taken when the

patient developed grade 3 bromage and grade 5 RAM scale.

The onset of motor blockade to bromage 3 was 14.37 ±1.2 mins and time for RAM 5 was 17.53 ± 1.35 in group B whereas the time for bromage 3 was 16.33±1.26 mins and time for RAM 5 was 20.30 ± 3.18 mins in group A. This is statistically significant. Azemati S et al,[11] found that there is statistical significance for the onset of complete motor blockade between the two groups consistent with our study.

The duration of motor blockade was assessed in our study as the time taken for regression to Bromage 0 and RAM 3. In group B the time taken for regression to bromage 0 is 309.30±3.61 mins compared to 247.47±4.14 mins in group A and the time taken for regression to RAM 3 is 226.33 ± 14.49 mins in group B compared to 153.73± 13.39 mins in group A.

The duration of motor block with B group is more prolonged than with A group, which is statistically significant ($p<0.001$). In a study conducted by Saravia P.S.F, Sabbag AT et al,[9] found the duration of motor blockade was significantly higher in the dexmedetomidine group, averaging 30% higher than that observed in the control group similar to our study.

The studies conducted by Bajwa SJ, Bajwa SK, Kaur J et al,[10] showed the mean duration of motor blockade was 246.72 ± 30.46 mins in ropivacaine + dexmedetomidine group and 228.44 ± 27.18 mins in ropivacaine + clonidine group. This was not statistically significant.

Group A had the highest sedation score of 2 and in group B was 4. Dexmedetomidine had greater sedation scores at different time interval when compared to bupivacaine alone. This is statistically highly significant ($p=0.001$). Similar results were observed by Saravia P.S.F, Sabbag AT et al,[9] who studied bispectral index 30 mins after the execution of anaesthesia and before sedation or additional analgesia. They noted that bispectral values were lower and patients were more sedated in dexmedetomidine group than in the control group ($p<0.05$). Similar results were also observed by Bajwa SJ et al,[10] and Azemati S et al,[11] who studied five point sedation. Mean sedation scores were significantly higher in dexmedetomidine group compared to clonidine group ($p<0.0001$). Incidence of dry mouth was significantly higher in group B and there was significantly less incidence of nausea, vomiting and shivering when compared to group A.

CONCLUSION

In the present study we concluded that dexmedetomidine as an adjuvant to epidural bupivacaine produces a synergistic effect of profound and prolonged motor blockade, prolonged duration of sensory blockade and post operative analgesia, good sedation with maintenance of haemodynamic stability, and lesser incidence of intra and postoperative complications like nausea, vomiting and shivering.

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