A COMPARATIVE STUDY OF DEXMEDETOMIDINE AND FENTANYL WITH ROPIVACAINE 0.75% IN EPIDURAL ANALGESIA IN LOWER LIMB ORTHOPAEDIC SURGERIES

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Abstract:

The addition of an adjuvant not only increases the effectiveness of a local anesthetic by prolonging and intensifying the sensory blockade but also causes reduction in dose of local anesthetic agents. However, addition of adjuvant can lead to certain side effects eg. epinephrine can cause serious side effects if inadvertently injected intravenously or intrathecally, opioids can be given but they can cause side effects like confusion, itching, nausea, vomiting, and respiratory depression. Ketamine can cause neurotoxicity if accidentally injected in cerebrospinal fluid (CSF) and neostigmine is associated with a higher incidence of vomiting.

Fentanyl is partial agonist () on opioid receptor. Epidural fentanyl has been widely used as analgesic adjuvant. Its main site of action is the substantia gelatinosa on the dorsal horn of spinal cord. It blocks fibers carrying nociceptive impulses both pre and post synaptically.

Dexmedetomidine is a selective-2 agonist which provides sedation, anxiolysis, hypnosis, analgesia and sympatholysis. Dexmedetomidine has an eight-fold greater affinity for α2 adrenergic receptors than clonidine and much less α1 effects. A major advantage of dexmedetomidine is its higher selectivity compared with clonidine for α2Areceptors, responsible for the hypnotic and analgesic effects of such drugs.

Therefore we performed a randomized, control prospective study to compare the effect of dexmedetomidine and fentanyl as adjuvant to ropivacaine 0.75% for epidural Anaesthesia in patient undergoing elective orthopaedic lower limb surgery and concluded that dexmedetomidine is a better adjuvant to ropivacaine than fentanyl for epidural analgesia with better quality of analgesia, prolonged duration of analgesia, higher sedation scores and no significant side effects

Keywords: Dexmedetomidine, Fentanyl, Ropivacaine, Epidural Anaesthesia

Introduction:

Epidural anaesthesia has advantages like flexibility in adjusting the block intraoperatively, in case of prolonged surgery and ability to provide postoperative analgesia via use of epidural catheter. Improvement in equipments, drugs and techniques have made it a popular and versatile anaesthetic technique. Its versatility means it can be used as an anaesthetic, as an analgesic adjuvant to general anaesthesia, and for postoperative analgesia in procedures involving the lower limbs, perineum, pelvis and abdomen.

Fidel Pages described a lumbar epidural in abdominal surgery in 1921. Achile Dogliotti[1] described the ―loss of resistance technique to locate epidural space in 1931. The next important event in the history of regional anaesthesia was the adaptation of Tuohy's catheter technique(1945) developed for continuous spinal anaesthesia to lumbar epidural anaesthesia by Curbello[2] in 1949.

In comparison to bupivacaine, ropivacaine is known to have lesser cardiotoxicity[3,4] and motor blockade[5,6], with similar pain relief[6,7] at equivalent analgesic doses. The addition of an adjuvant not only increases the effectiveness of a local anesthetic by prolonging and intensifying the sensory blockade but also causes reduction in dose of local anesthetic Introduction[2] agents. However, addition of adjuvant can lead to certain side effects eg:- epinephrine can cause serious side effects if inadvertently injected intravenously or intrathecally, opioids can be given but they can cause side effects like confusion, itching, nausea, vomiting, and respiratory depression[8-10]. Ketamine can cause neurotoxicity if accidentally injected in cerebrospinal fluid (CSF)[11] and neostigmine is associated with a higher incidence of vomiting.

Fentanyl is partial agonist (μ) on opioid receptor. Epidural fentanyl has been widely used as analgesic adjuvant. Its main site of action is the substantia gelatinosa on the dorsal horn of spinal cord. It blocks fibers carrying nociceptive impulses both pre and post synaptically[12].

Dexmedetomidine is a selective -2 agonist which provides sedation, anxiolysis, hypnosis, analgesia and sympatholysis. Dexmedetomidine has an eight-fold greater affinity for α2 adrenergic receptors than clonidine and much less α1 effects. A major advantage of dexmedetomidine is its higher selectivity compared with clonidine for α2 A receptors, responsible for the hypnotic and analgesic effects of such drugs[13,14].

Therefore we performed a randomized, control prospective study to compare the effect of dexmedetomidine and fentanyl as adjuvant to ropivacaine 0.75% for epidural analgesia in patient undergoing elective orthopaedic lower limb surgery.

Material And Methods:

Selection Of Cases:

Patients undergoing lower limb orthopaedic surgeries of both genders age ranging from 21 to 56 years belonging to American Society Of Anaesthesiologist (ASA) grade 1 or 2 were screened in all 100 patients included in the study.

A thorough preanaesthetic check up was done including the detailed history and physical examination. Airway examination was done.

All the necessary investigation was done like haemoglobin, total leucocyte count, diffrential leucocyte count, bleeding time, clotting time, platelet count, blood sugar ,serum urea, serum creatinine.

Chest X-ray and electrocardiogram in patient over 40 years of age was done.

Exclusion Criteria:

1. Patient refusal for the procedure.
2. Any contraindication to epidural anaesthesia.
3. Patient with diseased or deformed spine, or history of trauma to spine.
4. Patient's with history of diabetes, hypertension, coagulation abnormalities or any other severe systemic illness like severe respiratory, cardiovascular, and neurological disorder.
5. Patient who had history of low back surgery.

Informed consent was taken for study. The patient was kept fasting as required for surgery. Procedure was explained to the patient. The patient was premedicated with tablet Alprazolam 0.25mg and Ranitidine 150mg the night before and again 7a.m on morning of surgery with sips of water.

Allocation of Study Groups-

The study was divided into two groups.

Group I - (n=50) 15ml ropivacaine(Ropin,Neon) (0.75%) with 50mcg fentanyl (1 ml).

Total volume = 16 ml Material and Methods 45

Group II – (n =50) 15ml ropivacaine (0.75%) with 50 mcg dexmedetomidine (1 ml) (made by adding, 0.5 ml NS in dexmedetomidine)

Total volume = 16 ml

Drug preparation:

Dexmedetomidine(Dextomid Neon) available as 100mcg/ml so 50mcg Dexmedetomidine (1 ml) made by adding 0.5 ml NS in 0.5ml dexmedetomidine.

Fentanyl (Trofentyl troika) 50mcg/ml, 1ml (50mcg).

Randomization:

The patients were randomly allocated and prepared 100 coded slips and divided these 100 slips into two different groups and were kept inside a plastic box.

Blindness Of The Study:

Random selection of patients by plastic box and preparation of drug was done by one of helping colleague to maintain the blindness of the study.

By blinding a study, we can exclude the possibilities of different biases and this improves the outcome of the study. Helping colleague randomly allocated patients to one of the groups and prepared the study drug accordingly. He handed over the prepared drug with a unique code of identification on it. All the observations and recordings of the cases were completed without knowing the group of the patient. Only after completion of the study, the group of the patient was revealed with help of the code. This reduced the observer bias.

Anaesthetic Technique

After shifting the patient to OT the procedure was explained again. Then multipara monitor was attached and reading of all vitals HR,SBP,DBP,MAP,SPO2 and marked as baseline values were recorded.Then 18G of IV canula was inserted into a peripheral vein and patient was hydrated with 10ml/kg body weight of Lactate ringer's solution.The patient was placed in sitting position on the OT table with stool provided as foot rest. The assistant was asked to maintain the patient in a vertical plain while flexing the patient neck and arms over the pillow to open up the lumber vertebral space.With all aseptic precautions part was prepared, painted and draped.At space L3-L4 a small skin wheal was raised with 2% lignocaine.The Tuohy Epidural needle was used and it is 18G, 3 or 3.5 inch long, with blunt bevel with gentle curve of 15-30 degree at the tip.Through the wheal 18G epidural needle was inserted into the skin then supraspinous ligament, with needle pointing in a slightly Material and Methods 47 cephaled direction then into the interspinous ligament, which is encountered at a depth of 2-3 cm until distinct sensation of increased resistance was felt as the needle passed through the ligamentum flavum.At this point the needle stylet was be removed and the plastic syringe was attached into the hub of the needle. The loss of resistance technique will be used by filling syringe with 2ml of air.The needle was advanced, millimetre by millimetre, with either continuous or rapidly repeating attempts at injection.As the tips of needle just enter the epidural space there is a sudden loss of resistance and injection is easy. Then the syringe was removed and catheter was introduced gently via the needle into the epidural space.The catheter has markings showing the distance from its tip and should be advanced to15cm at the hub of the needle to ensure that sufficient length of the catheter has entered the epidural space. The needle was removed carefully.Epidural catheter was secured and patient placed in supine position. Test dose 3ml of 2% lignocaine with epinephrine was administered into epidural space.

Observation And Results

1. Maximum sensory level achieved-
   Assessed by pin prick.
2. Time to achieve the sensory level at T10.
   Time was recorded when sensory level comes at T10.
3. Time taken for complete motor blockade-
   Time taken to achieved Bromaze level-3
4. Intraoprative Hemodynamic Parameters (assessed just before and after the epidural block, 2,4,6,8,10,15 min and at an interval of 15 min. after that till 150 min.)

Heart rate (HR)-

Blood pressure- Systolic blood pressure

Diastolic blood pressure
Mean blood pressure
SPO2

5. First feeling of pain post operatively-
    Time is recorded when patient first
    Complain pain, VAS ≥ 3
6. Side effects such as

Hypotension:

If fall more then 20%, ephedrine was given, and if fall more then 30-40% continuous inotropic support (with dopamine) was started.

Bradycardia:

If pulse rate below 60beat/min I/V atropine 0.2mg in increments was given.

Nausea and vomiting

Respiratory depression

It was defined as decrease in SpO2 of less than 90% requiring supplementary oxygen.

Sedation

Urinary retention

- Any other side effects if will be noted

Degree of motor block- James Modified Bromage Scale

Bromage-0 - No weakness,able to straight leg raise against resistence
**Bromage-1 -** Patient is unable to straight leg raise, but able to flex knee.
Bromage-2 - Patient is unable to flex knee,but with free movement of feet.
Bromage-3 - Patient is unable to move leg or feet.

Ramsey Sedation Scale

Findings	Points
Anxious and agitated or restless, or both	1
Co-operative, oriented, and calm	2
Responsive to commands only	3
Exhibiting brisk response to light, glabellar tap or loud auditory stimulus	4
Exhibiting a sluggish response to light ,glabellar tap or loud auditory stimulus	5
Unresponsive	6

Visual Analogue Scale:
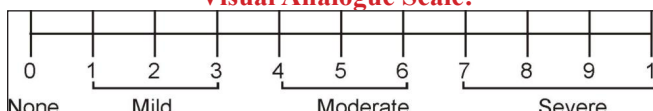
The patient will be shown a 10cm line marked as above they were asked to put a mark across the line that indicate the severity of their pain. Then measure the distance from 1 to 10 mark in cm.

Pain will be further graded as :

a) (VAS ‗0') Patient is comfortable.

b) (VAS ‗1-3') Mild pain.

c) (VAS ‗4-6') Moderate pain.

d) (VAS ‗7-10') Severe pain.

Nausea and Vomiting- were graded as-

0- No nausea and vomiting.

1- Nausea only.

2- Vomiting once in last hour.

3- Vomiting more then once in last hour

Results:

The present study was undertaken to compare the effect of dexmedetomidine and fentanyl as adjuvant to ropivacaine 0.75% when given in epidural anaesthesia in lower limb orthopaedic surgeries.

A total of 100 Patients undergoing lower limb orthopaedic surgeries of both genders, age ranging from 21 to 56 years belonging to American Society of Anaesthesiologist (ASA) grade 1or 2 were screened for the purpose of study.

The study popultion was randomly divided into two groups (having 50 patients each), group I (receiving15 ml Ropivacaine + 50 mcg Fentanyl) and group II (receiving 15 ml Ropivacaine + 50 mcg Dexmedetomidine).

Though higher proportion of males were found in Group II (78.0%) as compared to Group I (66.0%) but this difference was statistically non-significant (p=0.181). Age wise distribution of subjects in both the groups did not show any statistically significant difference (p=0.216), which indicate that there was no bias of age in the two groups. Weight of study subjects ranged between 50-66 kg in group I and 50-67 kg in group II. Both the groups did not show any statistically significant difference (p=0.979).

This indicates that the subjects in both the groups were demographically and anthropometrically matched.

At baseline no statistically significant difference in hemodynamic variables of both the groups was found (p>0.05).

Table 1: Maximum Sensory Level Achieved by Study Population

Sensory level	Group I		Group II	
	Number	Percent	Number	Percent
T4	2	4.0	8	16.00
T5	4	8.00	18	36.00
T6	26	52.00	22	44.00
T7	12	24.00	1	2.00
T8	6	12.00	1	2.00
Median level of block	T6		T5	

z=5.496; p<0.001 (Mann-Whitney U test)
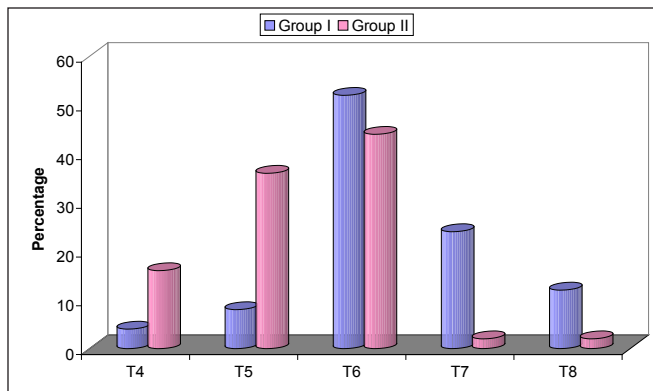
→Sensory level

Maximum sensory level of T6 or above was achieved by significantly higher proportion (p<0.001) of subjects in Group I (52%) as compared to Group II (44%). In Group I median level of block was T6 as compared to T5 in Group II.

Table 2: Time to Achieve the Sensory Level at T_{10}

	Group I	Group II
Number of subjects	50	50
Minimum time (min)	10	8
Maximum time (min)	14	11
Median (min)	11	9
Mean (min)	11.30	9.22
Standard Deviation	0.99	0.86
Statistical significance	't' = 11.162; p<0.001	
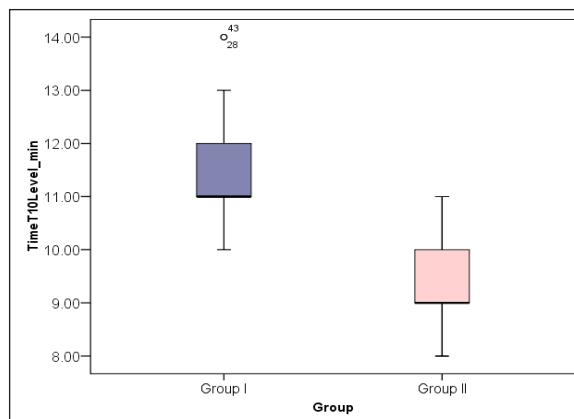
Time to achieve sensory level at T10 was found to be significantly lower in Group II (9.22+0.86 min) as compared to Group I (11.30+0.99 min) (p<0.001).

Table 3: Time to Achieve the Complete Motor Block

	Group I	Group II
Number of subjects	50	50
Minimum time (min)	21	18
Maximum time (min)	26	24
Median (min)	24	20
Mean (min)	24.02	20.00
Standard Deviation	1.12	1.53
Statistical significance	't' = 15.042; p<0.001	
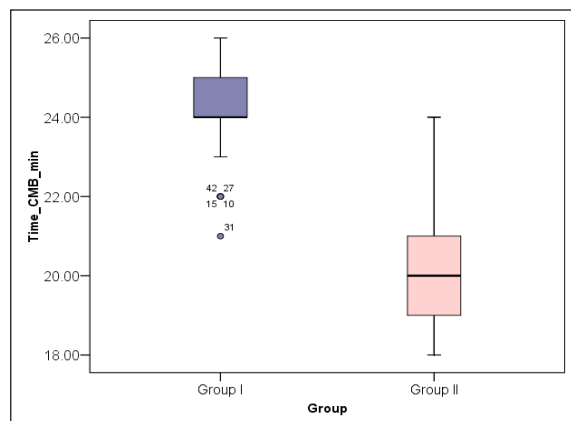
Time to achieve complete motor block in Group II was 20.0+1.53 minutes and in Group I it was found to be 24.02+1.12 minutes. Complete motor block was achieved in significantly lower time by Group II subjects as compared to Group I subjects (p<0.001).

Intergroup Change In Hemodynamic Variables

The difference in heart rate of subjects of both the groups was statistically non-significant at all the intervals except at 45 minutes.

The difference in systolic blood pressure of subjects of both the groups was statistically non-significant at all the intervals except at 30 minutes and 45 minutes.

The difference in diastolic blood pressure, difference in mean arterial pressure and difference in SpO2 of subjects of both the groups was statistically non-significant at all the intervals.

Intragroup Change In Hemodynamic Variables

In both the groups, change in heart rate from baseline was statistically significant at all the time intervals upto 120 minutes except just before epidural block, after epidural block and at 135 minutes.

Change in Systolic blood pressure and change in mean arterial pressure (from baseline) in Group I was statistically significant at all the time intervals except at 135 minutes.

Similarly in Group II, Change in Systolic blood pressure and change in mean arterial pressure from its baseline values was statistically significant at all the intervals.

In both the groups, change in diastolic blood pressure from its baseline values was statistically significant at all the time intervals.

In Group I, change in SpO2 from baseline was statistically significant at all the time intervals from 2 min after intubation upto 60 minutes after intubation while in Group II change in SpO2 from baseline was statistically significant at all time intervals upto 120 minutes except just before epidural block and at 135 minutes post intubation.

Table 4: Duration of Analgesia (minutes)

	Group I	Group II
Number of subjects	50	50
Minimum time (min)	240	346
Maximum time (min)	300	430
Median (min)	270	390
Mean (min)	270.30	384.02
Standard Deviation	19.34	20.84
Statistical significance	't' = 28.288; p<0.001	
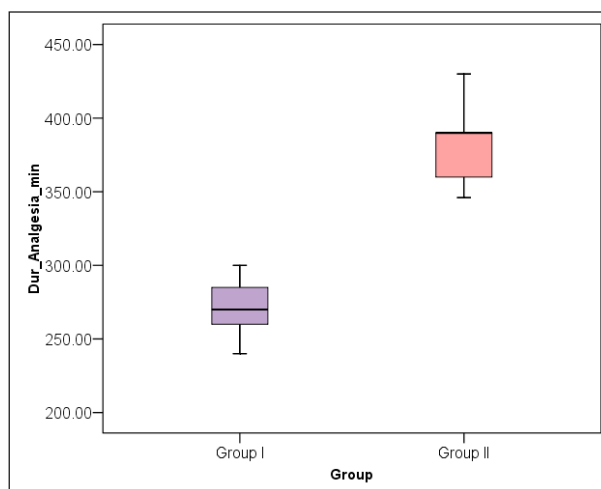
Above data shows that duration of analgesia was significantly higher (p<0.001) in Group II (384.02+20.84

206

minutes) as compared to Group I (270.30+19.34 minutes).

Though nausea and vomiting was found to be in higher proportion of subjects from Group I as compared to Group II but this difference was statistically not significant (p=0.181).

Though hypotension, bradycardia and urinary retention were found in higher proportion of Group II subjects as compared to Group I, but this difference was statistically non-significant (p=0.695, 0.646 and 0.249 respectively).

Table 5: Comparison of Sedation Point in Study Population

Sedation Point	Group I		Group II	
	Number	Percent	Number	Percent
2	44	88.00	6	12.00
3	6	12.00	20	40.00
4	0	0.00	23	46.00
5	0	0.00	1	2.00

$\chi^2 = 54.236$; $p < 0.001$
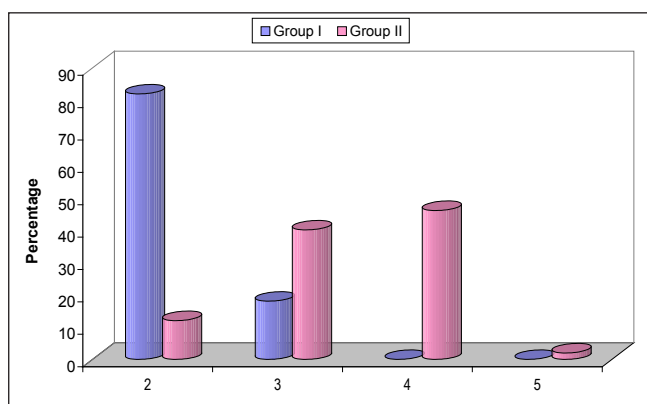
Sedation point 2 was found in significantly higher proportion of subjects from Group I (82%) as compared to Group II (12%). None of the subjects from Group I reported Sedation point 4 and 5.

Discussion:

The present study entitled "A comparative study of dexmedetomidine and fentanyl with ropivacaine 0.75% in epidural analgesia in lower limb orthopaedic surgeries" was designed to compare the effects of adding dexmedetomidine or Fentanyl as an adjuvant to Ropivacaine in Epidural Anaesthesia.

The present study was carried out on 100 patients, ranging from 21-56 years of age, there was no significant difference in the age of patient among the two groups.

Anaesthesiologists are specialized clinicians to treat pain by adopting various techniques and drugs. Pain is a very unpleasant and distressful condition to the patient. If not treated it may result into various physiological changes, including rise in heart rate, blood pressure, restricted physical activity and sleepless nights. Attenuation of perioperative pathophysiology that occurs during the surgery through reduction of nociceptive input into the CNS and optimization of postoperative analgesia may decrease complication and facilitates patients recovery in the immediate postoperative period and after discharge from the hospital.

Many options are available for treatment of postoperative pain, including systemic (opioid and non opioid) analgesics and regional (neuraxial and peripheral) analgesic techniques. Neuraxial blockade specially caudal epidural blocks assume an integral role in the management of lower abdominal and lower limb orthopaedics surgeries in pediatric patients as they are used not only to provide surgical analgesia but can be used in the postoperative period to provide effective pain relief. The use of lumbar epidural analgesia provides superior analgesia. It decreases the requirements of other anaesthetic agents intraoperativly and in post operative period it decreases the requirement of other systemic analgesic.

We decided to use Ropivacaine in our study because in comparison to bupivacaine, it has a wider margin of safety, less motor blockade, less cardiovascular or neurological toxicity.

Opioid analgesics are for the treatment of postoperative pain but their use is associated with side effects like nausea, respiratory depression, pruritis and urinary retention. Routine use of opioids for prolongation of ropivacaine analgesia has recently been challenged[15]. Although there is a risk of respiratory depression, less dramatic side effects such as itching, nausea and vomiting are more common. In an effort to avoid the side effects seen with opiods and to find a good alternative to it, we decided to compare the effect of dexmedetomidine (α-2 adrenoreceptor agonist) with fentanyl (a synthetic opioid) as adjuvant to ropivacaine in our study. Dexmedetomidine which has been used in spinal, epidural, caudal, oral and intraarticular routes to provide analgesia was used in the current study.

Dexmedetomidine have the following physiological properties: sedation , analgesia, it reduces the stress response to the surgery by reducing plasma catecholamine concentration, and prevents shivering via α2 adrenoceptors in the central nervous system[16].

The analgesic effect of the α2 agonists is a complex issue[17]. They can induce analgesia by acting at three different sites: in the brain and brainstem, spinal cord and in peripheral tissues. α2-adrenergic and opioidergic systems have common effector mechanisms in the locus coeruleus, representing a supraspinal site of action. In the spinal cord, their analgesic effect is related to activation of the descending medullospinal noradrenergic pathways or to the reduction of spinal sympathetic outflow at presynaptic ganglionic sites. Moreover, there is also significant interaction between opioids and α2 agonists at the spinal cord level[18].

The antihypertensive effect of dexmedetomidine results from stimulation of α2 inhibitory neurones in the medullary vasomotor center (nucleus reticularis lateralis) of the brainstem, which leads to a reduction in norepinephrine release and sympathetic nerve outflow from the CNS to the peripheral tissues. Moreover, caudally or epidurally administered dexmedetomidine decreases the electrical activity of preganglionic sympathetic nerves. Bradycardia is caused by an increase in vagal tone resulting from central stimulation of parasympathetic outflow, as well as a reduced sympathetic drive[19]. However in our study, in both the groups mean values heart rate and mean arterial pressure were lower than their respective baseline values.

Dexmedetomidine has unique sedative properties caused by hyperpolarization of excitable cells in the locus coeruleus[20]. It produces a unique form of sedation, in which patients become responsive as well as calm and cooperative when aroused, and then back to sleep when not stimulated. Confusion, cited as a common problem for other traditional sedatives, has not been described for Dexmedetomidine as it does not depend primarily on activation of the γ aminobutyric acid system[21].

On analysis of the demographic profile the age and weight were comparable in both the groups.

Agewise distribution of subjects in both the groups did not show any statistically significant difference (p=0.216). Weight of study subject in both the groups did not show any statistically significant difference (p=0.979).

Maximum Sensory Level Achieved

In our study, we observed that maximum sensory level of T6 or above was achieved by significantly higher proportion (p<0.001) of subjects of Group I (52%) as compared to Group II (44%). In Group I median level of block was T6 as compared to T5 in Group II.

Cederholm l,et al[22] compared with Sensory, motor, and sympathetic block during epidural analgesia with 0.5% and 0.75% ropivacaine with and without epinephrine and showed that Onset time for analgesia was short (Th10 blocked after median 5.3-6.7 minutes), and maximum segmental level was median Th 2-3 (range, Th5-C4). A tendency toward a dose-response relationship (duration of sensory block) was noted for the 0.75% solutions (median, 258-264 minutes at Th10) compared to the 0.5% solutions (median, 228-234 minutes at Th10). Only about half of the patients exhibited a complete motor block of the lower extremities with a longer duration with the 0.75% solutions. The majority of patients had a marked or complete sympathetic block in the lower limbs. Ropivacaine given epidurally provided adequate sensory anesthesia and motor block for transurethral surgery. Addition of epinephrine did not provide any significant prolongation of the sensory or motor block, nor any influence upon the sympathetic block.

Niesel HC et al[23] Ropivacaine for peridural anesthesia. Studies on the dose-response relationship in orthopedic surgery administered ropivacaine Group 1 received 15 ml (112.5 mg); group 2 20 ml (150 mg); and group 3 25 ml (187.5 mg). The times to initial onset (6.7-7.9 min) and to the maximum level of sensory analgesia (25.7, 27.1, and 30.7 min) hardly differed. The mean maximum level of sensory analgesia increased from T6 (group 1), to T5 (group 2) and T3 (group 3), with an absolute maximum level of C3 (statistically not significant). Times for two-segment regression increased from 146 min and 169 to 192 min, for regression of analgesia to T10 from 193 and 189 to 246 min and to T12 from 220 min and 244 to 296 min (significant). The mean maximum durations were 239(+/- 54), 267(+/- 49.8) and 355(+/- 59.2) min. The degree of motor blockade varied with the volume. Motor block grade I was recorded in 100% of cases, and motor block grade II in 64% of patients in group 1, in 73% in group 2, and in 100% in group 3. Motor block grade III was only seen in 7.1% in group 1, 20% in group 2, and 47% in group 3.

The duration was 102 min, 133 min and 188 min for grade I, 158 min, 199 min and 263 min for grade III when this occurred.

Time to Achieve the Sensory Level at T10

In our study, we observed that Time to achieve sensory level at T10 was found to be significantly lower (p<0.001) in Group II (9.22+0.86 min) as compared to Group I (11.30+0.99 min).

Sukhminder Jit Singh Bajwa et al[24] Addition of dexmedetomidine to ropivacaine as an adjuvant resulted in an earlier onset (8.52 ± 2.36 min) of sensory analgesia at T10 as compared to the addition of clonidine (9.72 ± 3.44 min) comparison (P < 0.05)

Time to Achieve the Complete Motor Block

In our study, we observed that time to achieve complete motor block in Group II was 20.0+1.53 minutes and in Group I it was found to be 24.02+1.12 minutes. Complete motor block was achieved in significantly lower (p<0.001) time by Group II subjects as compared to Group I subjects.

Katz JA et al[25] compared 0.5% bupivacaine and 0.75% ropivacaine administered epidurally and found that maximum block height (median (range] was T4 (T2-T8) and T5 (T2-L1) for bupivacaine and ropivacaine, respectively, and maximum motor block scores were 4 (2-6) and 4 (0-6) using the modified Bromage scale. Times to maximum height of sensory block for bupivacaine and ropivacaine, respectively, were 28 +/- 12 and 28 +/- 13 minutes; times to onset of block to T12 were 6 +/- 4 and 9 +/- 10 minutes; times to onset of maximum motor block were 32 +/- 17 and 47 +/- 29 minutes; times to two-segment regression were 2.7 +/- 0.8 and 3.4 +/- 1.0 hours (p less than 0.05); times to regression to T12 level were 4.8 +/- 0.9 and 4.7 +/- 0.95 hours; times to total recovery of sensation were 6.5 +/- 0.9 and 6.6 +/- 1.0 hours, and times to recovery of motor function were 4.4 +/- 0.9 and 4.1 +/- 0.9 hours.

Heart Rate:

Heart rate of subjects of both the groups was statistically non-significant at all the above intervals except at 45 minutes. In Group I, change in heart rate from baseline was statistically significant at all the above time intervals

upto 120 minutes except just before epidural block, after epidural block and at 135 minutes.

Similarly, in Group II change in heart rate from baseline was statistically significant at all the above time intervals upto 120 minutes except just before epidural block, after epidural block and at 135 minutes.

Systolic Blood Pressure:

Systolic blood pressure of subjects of both the groups was statistically non-significant at all the above intervals except at 30 minutes and 45 minutes. Change in Systolic blood pressure (from baseline) in Group I was statistically significant at all the above time intervals except at 135 minutes.

Similarly in Group II, Change in Systolic blood pressure from its baseline values was statistically significant at all the above intervals.

Diastolic Blood Pressure :

Diastolic blood pressure of subjects of both the groups was statistically non-significant at all the above intervals. In Group I, Change in diastolic blood pressure from its baseline values was statistically significant at all the above intervals. Similarly in group II change in diastolic blood pressure from its baseline values was statistically significant at all the above time intervals.

Mean Arterial Pressure:

Mean arterial pressure of subjects of both the groups was statistically non-significant at all the above intervals. Group I, change in Mean arterial pressure from its baseline value was statistically significant at all the above intervals except at 135 minutes.

Similarly in Group II, change in mean arterial pressure from its baseline value was statistically significant at all above intervals.

SpO2

In our study none of the subject at any interval reported spo2 level <90%, hence no statistical comparisons of both the groups.

Duration of Analgesia:

In our study we observed that duration of analgesia was significantly higher (p<0.001) in Group II (384.02+20.84 minutes) as compared to Group I (270.30+19.34 minutes).

Bang EC et al[26] Onset of labor epidural analgesia with ropivacaine and a varying dose of fentanyl ware randomly assigned 0, 50, 75, or 100 μg with 0.17% ropivacaine 12 ml. The onset of analgesia (mean ± SD) was shortened with an increasing dose of fentanyl (14.3 ± 5.4, 14.2 ± 6.5, 12.1 ± 5.1, and 8.7 ± 3.8 min with fentanyl 0, 50, 75, or 100 μg, respectively, P=0.001). The duration of analgesia was prolonged with an increasing dose of fentanyl (87.4 ± 20.8, 112.3 ± 19.5, 140.8 ± 18.8, and 143.6 ± 18.6 min with fentanyl 0, 50, 75, or 100 μg, respectively, P<0.001).The addition of increasing doses of fentanyl to 0.17% ropivacaine contributed to shortened onset as well as prolonged duration of labor epidural analgesia and improved patient satisfaction

Salgado PF at el[27] Epidural dexmedetomidine prolonged sensory and motor block duration time (p < 0.05) and postoperative analgesia (p < 0.05), and also resulted in a more intense motor block, l (p < 0.05).

Postoperative analgesia was prolonged significantly in RD group followed by the patient receiving fentanyl.

Side Effects:

In our study we observed that nausea and vomiting was found to be in higher proportion of subjects from Group I as compared to Group II but this difference was statistically not significant (p=0.181).

None of the subjects from either of the groups had suffered with respiratory distress i.e. SpO2 <90%. Hypotension, bradycardia and urinary retention were found in higher proportion of Group II subjects as compared to Group I,

but this difference was statistically non-significant.

Sedation:

In our study we observed that Dexmetedomidine is popular sedative agent. It produced profound sedation 46% of patients exhibited brisk response to light glabellas tap or loud auditory stimulus in Group II as compared to no sedation in fentanyl Group I.In Group II 40% of patients and 12% of patients in Group I were responsive to commands only. In Group I 88% of patients were found to be Co-operative, oriented, and calm as compared to12% of patients in Group II.

Sedation point was highly significant with administration of dexmetedomidine.

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