Research Paper

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Role of Fentanyl vs Dexmedetomidine as an Adjuvant to Ropivacaine in Epidural Anaesthesia for Infra-Umblical Surgeries.

Medical Science

KEYWORDS : post-operative analgesia,dexmedetomidine, ropivacaine, epidural anaesthesia

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ABSTRACT

Role of fentanyl vs dexmedetomidine as an adjuvant to ropivacaine in epidural anaesthesia for infra-umblical surgeries.

Background: Epidural fentanyl has been widely used in neuraxial blockades. However, the addition of opioids has an increased incidence of pruritus,nausea,vomiting and respiratory depression. Dexmedetomidine, a highly selective alpha 2 agonist can produce analgesia and sedation without compromising respiratory function.

Material and Methods: This is a prospective randomized double blinded case control study which included 120 adult ASA grade I and II patients requiring infra-umbilical gynecologic or orthopedic surgery. Patients were randomly divided into three groups. The patient received either 18.5 ml 0.75% Ropivacaine with dexmedetomidine 1mcg /kg(0.5 ml) (Group-1) or 18.5 ml 0.75% Ropivacaine with fentanyl 1 mcg/kg(1ml) (Group-2) or 18.5 ml 0.75% Ropivacaine with 0.5 ml of 0.9% normal saline (Group-3). Block characteristics along with hemodynamic parameters, sedation and adverse effects, if any were recorded.

Results: In our study, both dexmedetomidine and fentanyl as an adjuvant to ropivacaine provided better block characteristics compared to ropivacaine alone in relation to time of onset of sensory blockade at T10 level, maximum height of sensory block, time to reach maximum sensory blockade level, time to reach complete motor block, time to two segmental regression, time of segmental regression to L5 and time of complete motor recovery at the cost of increased incidence of hypotension and vasopressor use.

Conclusion: As compared to fentanyl, epidural dexmedetomidine provides better sensory motor block in patients of infraumblical surgeries but with increased yet manageable hypotension.

Introduction

Recently, early postoperative mobilization and rehabilitation with minimally associated pain and discomfort are the most sought after requirements in infraumbilical surgeries. For this, epidural anesthesia is one of the most versatile techniques available to the modern anaesthesia practice. A lot of clinical research has been done in order to find an ideal adjuvant to improve the quality of block. The latest candidates are short acting opioids and alpha-2 agonists. Ropivacaine, a long acting amino-amide type local anesthetic, differs from other amide-type local anesthetics in that it is a pure s-enantiomer, instead of a racemate. This feature improves its safety and studies have shown ropivacaine to have less cardiovascular and central nervous system toxicity than bupivacaine [1].

Dexmedetomidine, a highly selective alpha 2 agonist can produce analgesia and sedation without compromising respiratory function. It causes hyperpolarisation of nerve tissue by altering transmembrane potential and ion conductance at locus coeruleus in the brainstem. Thus, may lead to analgesia, augmentation of local anesthetic effects and reduced analgesic requirement when used as adjuvant in epidural anaesthesia [2].

Epidural fentanyl has been widely used in neuraxial blockades. The main site of action of fentanyl is the substantia gelatinosa in the dorsal horn of spinal cord, where it blocks the neural fibres carrying pain impulses both at pre-synaptic and post –synaptic levels. However, the addition of opioids has an increased incidence of pruritus,nausea,vomiting and respiratory depression [3].

Bajwa et al(2011,ija) showed that dexmedetomidine is a better neuraxial adjuvant compared to clonidine(both are alpha 2 agonists) for providing early onset of sensory analgesia, adequate sedation and a prolonged post-operative analgesia [2].

The present work "comparison of fentanyl or dexmedetomidine as an adjuvant to ropivacaine in epidural anesthesia for below umbilical surgeries" is done to attain and compare the suitability of both the combinations for perioperative anesthesia by epidural route.

Material and Methods

This is a prospective randomized double blinded case control study which included 120 adult ASA grade I and II patients requiring infra-umbilical gynecologic or orthopedic surgery. Patients who were unable to comprehend or perform physical assessment, had neurological disorders, BMI >30 or any contraindication to epidural anaesthesia were excluded. Using computerized randomization enrolled patients were randomly divided into three groups. The patient received either 18.5 ml 0.75% Ropivacaine with dexmedetomidine 1mcg /kg(0.5 ml) **(Group-1)** or 18.5 ml 0.75% Ropivacaine with fentanyl 1 mcg/kg(1ml) **(Group-2)** or 18.5 ml 0.75% Ropivacaine with 0.5 ml of 0.9% normal saline **(Group-3)**.

Technique

Patients were thoroughly assessed and investigated during pre anaesthetic checkup. In the operating room after ensuring an iv assess using 18 gauge cannula, prehydration with 8-10 ml/ kg of ringer lactate over 15 min and standard monitoring lignocaine sensitivity was done. The standard midline approach in sitting position was used to place a 20 G epidural catheter in L2-L3 intervertebral space using 18 G Touhy needle. After giving epidural anesthesia, the quality of sensory block was assessed to pin prick using Visual Analgue Scale.

The onset of sensory block was taken from the time of epidural drug administration to loss of pain sensation to pinprick at T10 level. Onset and degree of motor blocks was determined using Modified Bromage Score. Duration of motor block was considered as time till achievement of bromage scale zero. Bilateral assessments were made every 5 min till 30 min post block and every 30 min till full recovery. Hemodynamic parameters, sedation and adverse effects, if any were recorded and accordingly treated.

Statistical analysis were performed using the SPSS software (ChicagoIL, vaersion 17). Hemodynamic changes were analysed with ANCOVA with Tukey-Kraemer corrections, sensory-motor block characteristics with Analysis of variance with Tukey- Kraemer test. Chi square test with corrections was used to analyse dichotomous variables.

Results

Table 1: comparison of demographic profile of the RD, RF and R ALONE groups

	RD(n=40)	RF(n=40)	R ALONE(n=40)
Age(years)	38.45±7.70	39.8±7.63	40.15±8.16
Height(cm)	160.10±4.47	160.23±4.08	160.30±4.40
Weight(kg)	60.47±5.01	61.20±4.67	60.02±4.24
Gender(M/F)	34/6	35/5	36/4
ASA(I/II)	31/9	31/9	32/8
Mean duration of surgery (minutes)	121.75	118.5	119.25

Table 2: comparison of initial block characteristics in RD,RF and R ALONE groups

Anesthetic characteristics	RD(n=40)	RF(n=40)	R ALONE(n=40)	intergroup comparison		
				RD-RF	RF-R ALONE	RALONE
0nset time at T10(minutes)	9.375±1.67	13.45±1.99	15.90±1.59	+	+	+
Maximum sensory level	T5-T7	T6-T8	T8-T10			
Time to maximum sensory blockade level(minutes)	15.55±1.43	20.17±2.48	33.25±6.15	+	+	+
Time to complete motor block (minutes)	25.42±3.36	36.50±4.96	45.50±5.75	+	+	+
Mephenteramine requirement(mg)	9.60±7.39	2.47±4.06	0.525±1.50	+	-	+

(-)sign shows the value of p>0.05, (+)sign shows the value of p<0.05 and is significant on statistical analysis

The onset of sensory block was taken from the time of epidural drug administration to loss of pain sensation to pinprick at T10 level. The mean time of onset of sensory blockade at T10 level was (9.37±1.67)min. in Group 1, (13.45±1.99)min. in Group 2 and (15.90±1.59)min. in Group 3. It showed that ropivacaine – dexmedetomidine combination had an earlier onset.(Table 2)

The median highest thoracic dermatomal level reached was T6 (T5-T7) in group 1, T8(T6-T8) in group 2 and T10(T8-T10) in group 3.(Table 2). This showed that ropivacaine - dexmedetomidine combination had reached the maximum height of sensory block.

The time to reach peak sensory level was (15.55±1.43)min. in group 1, (20.17±2.48)min. in group 2 and (33.25±6.155)min. in group 3 .(Table 2). This showed that earliest peak sensory level was achieved by dexmedetomidine group.

The time to attain complete motor blockade in three groups was (25.42±3.36)min. in Group 1, (36.50±4.96)min. in Group 2 and (45.50±5.75)min. in Group 3. This showed that dexmedetomidine group had fastest motor blockade. (Table 2)

Table 3: comparison of per-op and post-op block characteristics in RD, RF and R ALONE groups

Anesthetic characteristics	RD(n=40)	RF(n=40)	R ALONE(n=40)	intergroup comparison		
				RD-RF	RF-R ALONE	RALONE-RD
Time to two segmental regression(minutes)	151.62±8.58	114.75±9.60	89.50±6.77	+	+	+
Time to segmental regression(L5)(minutes)	468.25±34.63	322.5±24.04	251.25±21.14	+	+	+
Time for regression to bromage 0(minutes)	328.50±31.82	235.00±21.84	174.25±13.18	+	+	+
Time of first analgesic demand(minutes)	395.50±23.42	276.50±19.81	205.00±10.13	+	+	+
Total dose of ropivacaine post-op(mg)	80±14.32	100±14.32	120±14.32	+	+	+

(-)sign shows the value of p>0.05, (+)sign shows the value of p<0.05 and is significant on statistical analysis

The mean time to two segmental regression of sensory blockade was (151.62±8.58)min. in Group 1, (114.75±9.60)min. in Group 2 and (89.50±6.77)min. in Group 3. This showed that dexmedetomidine Group had prolonged regression time. (Table 3)

The mean time of segmental regression to L5 was (468.25±34.63)min. in Group 1, (322.50±24.04)min. in Group 2 and (251.25±21.14)min. in Group 3. This showed that dexmedetomidine had prolonged regression time to L5. (Table 3)

The mean time of complete motor recovery (modified bromage scale 0) was (328.50±31.82)min. in Group 1, (235.0±21.84)min. in Group 2 and (174.25±13.18)min. in Group 3. This showed that dexmedetomidine Group had prolonged motor recovery.(Table 3)

The mean time of first analgesic demand (duration of analgesia) was (395.50±23.42)min. in Group 1, (276.50±19.81)min. in Group 2 and (205.0±10.13)min. in Group 3. This showed that dexmedetomidine Group had delayed first analgesic demand.(Table 3)

The mean total dose of analgesia (ropivacaine 0.2%) required in 24 hours was (80.0±14.32)mg in Group 1, (100.0±14.32)mg in Group 2 and (120.0±14.32)mg in Group 3. This showed that dexmedetomidine Group had lesser analgesic dose consumption. (Table 3)

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Table 4: SEDATION SCORE

P VALUE	RD VS RF	RF VS R ALONE	R ALONE VS RD
BEFORE BLOCK	-	-	-
30 MINUTES	+	-	+
1 HOUR	+	+	+
AT END OF SURGERY	+	-	+
AT PACU 1 HOUR	-	-	-

(-) sign shows the value of p>0.05, (+)sign shows the value of p<0.05 and is significant on statistical analysis

The sedation by modified Ramsay score pre-op, 30 min. intra-op, 1 hour intra-op, end of surgery and 1st hour of PACU was (1.075±2.67, 2.95±.503, 3.95±.503, 2.82±.549, 1.27±.452) in Group 1, (1.100±.304, 1.22±.422, 2.22±.422, 1.30±.464, 1.37±.490) in Group 2 and(1.25±.438, 1.27±.452, 1.67±.474,1.22±.422, 1.25±.438) in Group 3. This showed that dexmedetomidine group had excellent sedation and no patient required any other sedatives during the intraoperative period. (Table 4)

TABLE 5: Incidence of side effects in patients of all the three groups

Side effects	RD(n=40)	RF(n=40)	R ALONE(n=40)
Nausea	7	15*	3
Vomiting	3	7	1
Shivering	1	4	7
Headache	1	0	4
Hypotension	28*	12	5
Dry mouth	4	2	0
Urinary retention	0	0	0
Respiratory depression	0	0	0
Pruritis	3	7	1

*p<0.05

There was no significant change in mean pulse rate from the baseline in any of the groups during the study. (Table 5)

There was statistically significant decrease in systolic blood pressure in GROUP 1, as compared to GROUP 2 and GROUP 3 at 30 minutes and 60 minutes. Statistically significant decrease in systolic blood pressure was observed in GROUP 1 than GROUP 2/3 ,as compared to baseline. (Table 5)

There was statistically significant decrease in diastolic blood pressure in GROUP 1, as compared to GROUP 2 and GROUP 3 at 30 minutes and 60 minutes.Statistically significant decrease in diastolic BP was observed in GROUP 1 than GROUP 2/3 , as compared to baseline. (Table 5)

The mean mephenteramine dose required intraoperatively was (9.60±7.39)mg in Group 1, (2.47±4.06)mg in Group 2, (0.525±1.50) mg in Group 3. Group 1 had increased requirement as compared to Group 2/3(p<0.001), whereas no significant difference were seen between Group 2 and Group 3(p>0.05). (Table 5)

None of the patients in any of the groups required any additional epidural top-up dose during the surgical period. The analgesia was assessed using visual analogue scale (VAS) and patients in all the three groups showed 0 scores during the entire surgical period. None of the patients in either of the groups experienced any respiratory difficulty warranting any active intervention.

The incidence of nausea was significantly higher in Group 2 and it was statistically significant on comparison between Group1 and Group 3 ($P < 0.05$). The incidence of hypotension was significantly higher in Group 1 and it was statistically significant on comparison between Group 2 and Group 3 ($P < 0.05$). The incidence of other side effects like dry mouth, vomiting, headache, pruritis and shivering were comparable in all the three groups and found to be statistically non-significant (p value >0.05). Respiratory depression and urinary retention was not observed in any patient. (Table 57)

Discussion

Among the adjuvants, the synergism between epidural local anesthetics and opioids is well established but evidence regarding combination of LA with dexmedetomidine through epidural route is scarce in literature [4,5]. In our study, both dexmedetomidine and fentanyl as an adjuvant to ropivacaine provided better block characteristics compared to ropivacaine alone in relation to time of onset of sensory blockade at T10 level, maximum height of sensory block, time to reach maximum sensory blockade level, time to reach complete motor block, time to two segmental regression, time of segmental regression to L5 and time of complete motor recovery. Dexmedetomidine provided longer post-operative analgesia as compared to fentanyl. Along with lesser consumption of analgesia during first 24 hours, dexmedetomidine also provided intraoperative sedation precluding use of any sedatives. Thus, remarkable synergistic properties of local anesthetics and dexmedetomidine have come to the fore. However, intraoperative hypotension with dexmedetomidine needs consideration.

Selection of exclusive epidural route during this study was done deliberately to avoid invasive dural penetration technique with spinal needle as well as to provide post-op pain relief.

The absence of respiratory depression in the present study can be explained on the basis that fentanyl is less likely to induce respiratory depression as compared to its prototype morphine and we also used fentanyl in a lower dosage. As far as α-2 agonists are concerned, the respiratory depression is not a known feature of this group of drugs as depicted by earlier studies. [6,7,8]

There are certain limitations of this study. There may be difference in the level of surgical anesthesia required according to the site of surgical incision(higher for abdominal surgery as compared to limb surgery) creating bias in the observations. Also, the optimal dose of dexmedetomidine for epidural anesthesia and analgesia are not known due to lack of dose finding studies. The doses used in this study were arbitrarily selected on the basis of Lopez et al study [9].

Conclusion

Consequent to a careful appraisal of the observations we can conclude that dexmedetomidine provided better sensory block as compared to fentanyl in terms of earlier onset, higher and earlier maximum sensory block. The quality of motor block was also better when assessed in terms of earlier complete block, delayed regression of the block and decreased analgesic requirements. Better sedation scores without any respiratory depression were observed. However, increased incidence of hypotension and vasopressor use observed, indicates need for larger multicentric trials recommendation of routine usage of dexmedetomidine as adjuvant to epidural local anaesthetics.

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