



COMPARATIVE STUDY OF ANALGESIC EFFECTS OF ROPIVACAINE AND DEXMEDETOMIDINE WITH THAT OF ROPIVACAINE AND FENTANYL FOR LOWER ABDOMINAL AND LOWER LIMB ORTHOPAEDIC SURGERIES

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ABSTRACT

Introduction: Epidural administration of various analgesics gained increasing popularity following the discovery of opioid receptors in the spinal cord capable of producing potent analgesia. The new amide local anaesthetic Ropivacaine has minimal cardio-vascular and central nervous system toxicity as well as a lesser propensity of motor block during post-operative epidural analgesia. Dexmedetomidine is a new addition to the class of alpha-2 agonist, which has numerous beneficial effects when used through epidural route.

Material And Methods: A clinical prospective comparative randomized study of postoperative epidural analgesia was done in 100 patients, posted for elective surgeries selected randomly, after approval from Ethical committee Kamineni Academy of Medical Sciences and Research Center conducted over a period of 6 months. All patients were thoroughly examined and assessed pre-operatively for any cardiovascular, respiratory or any other systemic illness and spinal deformities.

Results: A total of 100 patients of either sex selected in this study. The minimum age in both groups was 18 years. The maximum age in both groups was 60 years respectively. In group RD the Mean age was 36.28(±8.76) and in RF group the mean was 38.73 (±9.23). It is observed that onset of analgesia in Group-A (RD) (0.2% Ropivacaine + 1mcg/kg Dexmedetomidine) was 8.21 min. When compared to Group-B (0.2% Ropivacaine + 1mcg/kg Fentanyl) was 10.23 min, which is statistically significant (P<0.05). It shows Ropivacaine with Dexmedetomidine has faster onset of pain relief when compared to Ropivacaine with Fentanyl, given epidurally.

Conclusion: Dexmedetomidine seems to be a better alternative to fentanyl as an epidural adjuvant as it provides comparable stable hemodynamics, early onset and establishment of sensory anesthesia, prolonged post-op analgesia, and much better sedation levels. However further studies are required to evaluate both the drugs.

KEYWORDS : Ropivacaine, Dexmedetomidine, Fentanyl.

INTRODUCTION

The word pain is derived from the Latin word 'PONEA' meaning punishment. Pain following surgery is a universal phenomenon. Yet it is often underestimated and undertreated. Several factors contribute to this unhappy state of affairs. Being purely subjective, pain and its intensity varies widely among people. The anaesthesiologist, who is in the profession of alleviating the surgical pain, extends his services into the post operative period also.^[1]

Epidural analgesia is the most commonly used technique for providing not only peri-operative surgical anesthesia but also post-operative analgesia in lower abdominal and lower limb surgeries. Early postoperative mobilization and rehabilitation with minimally pain and discomfort is the most desirable feature in modern orthopaedic surgery. Many a time for achieving desired peri-operative anaesthetic effect, invariably large volumes of local anaesthetics are used, thereby increasing the possibilities of local anaesthetic toxicity and deleterious haemodynamic consequences.^[2]

The new amide local anaesthetic Ropivacaine has minimal cardiovascular and central nervous system toxicity as well as a lesser propensity of motor block during post-operative epidural analgesia. Opioids like Fentanyl have been used traditionally as an adjunct for epidural administration in combination with a lower dose of local anaesthetic to achieve the desired anaesthetic effect.^[3] The addition of opioid does provide a dose sparing effect of local anaesthetic and superior analgesia but there is always a possibility of an increased incidence of pruritis, urinary retention, nausea, vomiting and respiratory depression. The incidence of motor block after epidural analgesia with amide local anaesthetics and opioids is approximately 4-12% which itself defeats the purpose of early rehabilitation.^[4]

Dexmedetomidine is a new addition to the class of alpha-2 agonist, which has numerous beneficial effects when used through epidural route. It acts on both pre and post synaptic sympathetic nerve terminal and central nervous system thereby decreasing the sympathetic outflow and nor-epinephrine release causing sedative, anti-anxiety, analgesic, sympatholytic and haemodynamic changes.^[5] Dexmedetomidine does cause a manageable hypotension and

bradycardia but the striking feature of this drug is the lack of opioid-related side effects like respiratory depression, pruritis, nausea, and vomiting.^[6]

MATERIAL AND METHODS

A clinical prospective comparative randomized study of postoperative epidural analgesia was done in 100 patients, posted for elective surgeries selected randomly, after approval from Ethical committee of Kamineni Academy of Medical Sciences and Research Center, conducted over a period of 6 months.

Inclusion Criteria

Patients of either sex with age between 18 to 60 years. ASA grades I and II. Elective lower limb Orthopaedic and lower Abdominal surgery.

Exclusion Criteria

Patients' refusal, Spinal deformities. Bleeding disorders, Neurological deficit. Local skin infection around the site of needle insertion and Allergic to local anaesthetic drugs

All patients were thoroughly examined and assessed pre-operatively for any cardiovascular, respiratory or any other systemic illness and spinal deformities.

The nature of the procedure was explained and the patients were taught to assess the intensity of pain using the visual analogue scale (VAS). In the visual analogue scale the patients were shown a scale of 10 cm length. Zero end of the scale was taken as 'No pain' and 10 cm mark as 'Maximum pain'. Intensity of pain increases gradually from '0' to '10'. Patients were instructed to point the intensity of pain on the scale.

Procedure

With all aseptic precautions, epidural space was found with 18G Tuohy needle at L2 - L3 space by loss of resistance using air injection technique in sitting position and an 18G epidural catheter was threaded through this needle for 5-cms in the cephalad direction in epidural space and properly fixed. Afterwards using a 23G spinal needle lumbar puncture was done in L3-L4 intervertebral space. After appearance of CSF at the hub of spinal needle, 3.5cc 0.5% Bupivacaine was injected

into subarachnoid space, the spinal needle removed.

Group A: Patients received 15ml of 0.2% Ropivacaine + 1mcg/kg of Dexmedetomidine Group B: Patients received 15ml of 0.2% of Ropivacaine + 1mcg/kg of Fentanyl.

RESULTS

A total of 100 patients of either sex selected in this study.

Table 1: Age Distribution

Age(in yrs)	Group -A (N=50) RD		Group-B(N=50) RF	
	No. of patients	Percent%	No. of patients	Percent%
18 to 30	12	24	11	22
30 to 40	21	42	20	40
40 to 50	12	24	17	34
50 to 60	5	10	2	4
Total	50	100	50	100
Mean±SD	36.28 (±8.76)		38.73 (±9.23)	

Table: 1 Shows age distribution of the patients in both the groups. The minimum age in both groups was 18 years. The maximum age in both groups was 60years respectively. In group RD the Mean age was 36.28(±8.76) and in RF group the mean was 38.73 (±9.23) There was no significant difference in the age of patients between the Group RD and Group RF. Both groups were similar with respect to age distribution.

Table: 2 Sex Distribution Between Group A And Group B

Sex	Group -A (N=50) RD		Group-B (N=50) RF	
	No of patients	Percent %	No of Patients	Percent%
Male	36	72	33	66
Female	14	28	17	34

There were 36 males and 14 females in Ropivacaine + Dexmedetomidine group and there were 33males and 17 females in the Ropivacaine + Fentanyl group. No significant difference was observed in sex wise distribution of the cases between two groups

Table: 3: Onset Of Analgesia

	Mean duration for onset of analgesia (in min)	SD	Significance (p)
Group A(N=50)	8.21	±2.59	t Statistics=- 4.047
Group B(N=50)	10.23	±3.23	P= 0.00125 (S)

It is observed that onset of analgesia in Group-A (RD) (0.2% Ropivacaine + 1mcg/kg Dexmedetomidine) was 8.21 min. When compared to Group-B (0.2% Ropivacaine + 1mcg/kg Fentanyl) was 10.23 min, which is statistically significant (P<0.05). It shows Ropivacaine with Dexmedetomidine has faster onset of pain relief when compared to Ropivacaine with Fentanyl, given epidurally.

Table: 4 Duration Of Analgesia In Minutes

	Mean duration of analgesia (in min)	SD	Significance
Group A (N=50)	336.45	±26.21	T=15.5675 P=0.04
Group B (N=50)	260.63	± 22.34	(P<0.05)

Duration of analgesia in Group-A (Dexmedetomidine + Ropivacaine) was 336min compared to Group-B (Fentanyl + Ropivacaine), which was 260min. This is statistically significant (P<0.05). Mean duration of analgesia in group A was more compared to group B.

Table-5: Level Of Analgesia: (Chi-square Test)

LEVELS	Group-A (n)	%	Group-B (n)	%	p VALUE
T8	0	0	0	0	CHI-SQ = 3.787 D.F.= 2 P= 0.15
T9	2	4	0	0	
T10	15	30	13	26	
T11	22	44	17	34	
T12	11	22	20	40	

- In Group RD, the mean baseline oxygen saturation was 97.10 with a standard deviation of 2.16.
- In Group RF, the mean baseline oxygen saturation was 96.85 with a standard deviation of 1.53

- On comparing the two groups there was statistically significant difference from 15 to 30 minutes (p value>0.05) between the groups.
- It was observed that oxygen saturation decreased in RD group from 15 mins upto 30 mins compared to RF group.

Table-6: Comparison Of Oxygen Saturation In Between Group A And Group B

Time interval	Oxygen Saturation% Group A		Oxygen Saturation% Group B		Group A Vs Group B
	Mean	SD	Mean	SD	
Base value	97.10	2.16	96.85	1.53	
15 min	96.38	2.22	92.64	3.81	<0.00
30 min	96.50	2.13	93.68	3.39	<0.00
45 min	96.11	1.96	95.10	2.41	0.48
1 hr.	96.89	1.93	96.38	1.81	0.18
2 hr.	97.22	1.95	96.62	1.84	0.12
3 hr.	96.88	1.90	96.60	1.82	0.45
4 hr.	97.34	1.86	96.95	1.93	0.31
5 hr.	97.58	1.68	96.71	1.89	0.06
6 hr.	97.84	1.69	97.25	1.79	0.09

Table 7. Comparison Of VAS Between Group A And Group B

Time interval	VAS group A		VAS group B		P
	Mean	SD	Mean	SD	
Base value	5.80	0.60	5.60	0.50	
15 min	0.67	1.08	1.78	0.99	<0.00
30 min	0.69	0.89	2.00	0.72	<0.00
45 min	1.04	0.80	2.20	0.75	<0.00
1 hr.	1.76	0.96	2.58	0.78	<0.00
2 hr.	1.80	0.81	2.78	0.81	<0.00
3 hr.	2.37	0.90	3.08	0.77	<0.00
4 hr.	2.65	1.06	3.54	0.78	<0.00
5 hr.	2.80	1.37	3.80	0.65	<0.00
6 hr.	3.78	1.59	4.30	0.67	<0.00

- The mean baseline VAS score in Group RD was 5.80 with a standard deviation of 0.60, whereas in Group RF it was 5.50 with a standard deviation of 0.50.

DISCUSSION

The present study is undertaken to compare the efficacy of single epidural dose of Ropivacaine and Dexmedetomidine verses Ropivacaine and Fentanyl for postoperative analgesia in lower abdominal and lower limb surgeries. A clinical comparative study of postoperative epidural analgesia was done on 100 patients posted for elective surgeries selected randomly. Combined spinal epidural anaesthesia was given to all the patients.

Ropivacaine has been employed in various doses for postoperative epidural analgesia. In 2003, Kanai A, ^[15] did a comparative study on postoperative analgesia. They concluded that Ropivacaine with 0.2% was better in continuous epidural infusion for postoperative analgesia due to less systemic toxicity. In view of this in the present study we employed 0.2% of Ropivacaine.

In 2005, Paula F. Salgado et al ^[15] have conducted a double blinded study in which they have used Dexmedetomidine 1mcg/kg with Ropivacaine. They concluded that Dexmedetomidine increases sensory and motor block duration during epidural anesthesia with Ropivacaine, it prolonged analgesia in postoperative period and did not cause hemodynamic instability.

In 2014 Hanoura, Samy Elsayed, Rabei Hassanein Saad, and Rajvir Singh ^[16] conducted a study by adding 1mcg/kg Dexmedetomidine improved intraoperative conditions and quality of postoperative analgesia without maternal or neonatal significant side effects. In view of this in the present study we employed Ropivacaine with 1mcg/kg of Dexmedetomidine (Group RD).

In 2005, Kanai A, Kinoshita S, Suzuki A, Okamoto H, Hoka ^[17] studied the advantages of Ropivacaine for postoperative epidural analgesia following leg orthopedic surgery, Epidural Injection of Ropivacaine with fentanyl decreased postoperative pain with stable vital signs in patients undergoing leg orthopedic surgery.

In view of this in the present study we employed Ropivacaine with Fentanyl (Group B). The present study is compared to other recent studies done by Whiteside, R., et al in 2011^[18] studied epidural analgesia using Dexmedetomidine and Fentanyl as adjuncts to Ropivacaine. The study population was divided into 2 groups with 50 patients in each group.

Group RD Received 1mcg/kg Dexmedetomidine with 0.75% Ropivacaine 15 ml (n=50). Group RF Received 1mcg/kg Fentanyl with 0.75% Ropivacaine 15 ml (n=50). Kaur Sarabjit et al^[19] in 2014 studied intraoperative and postoperative epidural analgesia in lower limb Orthopaedic surgeries using Ropivacaine with Dexmedetomidine.

In the present study the age group taken was 18 to 60 years which is comparable with the study of Bajwa et al with age group of 20 to 65 years, the study of Kaur Sarabjit et al with age group of 20 to 65 years and in the study Whiteside, R., et al^[20] the age group taken was 26-65 years. In our study the onset of Analgesia was earlier in Group A than Group B which is comparable with the Bajwa et al study.^[21]

In the present study the onset of analgesia in Group A was 8.21mins and Group B was 10.23 mins, where as in study of Bajwa et al^[21] the onset of analgesia in Group A was 7.12 minutes and in Group B was 9.14 minutes. This may be due to the increased concentration and the volume of the drug used in Bajwa et al study (20 ml of 0.75% Ropivacaine).

In the present study the duration of analgesia in Group A was 336.45mins and Group B was 260.63mins, which is comparable with study of Bajwa et al^[21] where the duration of analgesia in group A of 366.62 minutes and in Group B of 242.16 minutes.

Duration of Analgesia was lasting longer in Group A than Group B which is comparable with the Bajwa et al study. Pulse Rate in Bajwa et al exhibited negative chronotropic effect by Dexmedetomidine approximately 30-35 mins after the epidural injection of the drug. Thereafter, the heart rate remained stable. Pulse rate in Kaur Sarabjit et al there was fall in pulse during first 40 minutes and was treated by giving injection atropine 0.6mg intravenously, after 40 minutes pulse was remained stable.

CONCLUSION:

The duration of action was longer in Ropivacaine with Dexmedetomidine (mean duration of analgesia was 336mins) when compared to Ropivacaine with Fentanyl group (mean duration of analgesia 260mins). Dexmedetomidine seems to be a better alternative to fentanyl as an epidural adjuvant as it provides comparable stable hemodynamics, early onset and establishment of sensory anesthesia, prolonged post-op analgesia, and much better sedation levels. However further studies are required to evaluate both the drugs.

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