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A Comparative Study between Ropivacaine with Dexmedetomidine and Ropivacaine with Fentanyl in Lower Abdominal and Lower Limb Surgeries for Postoperative Epidural Analgesia

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Abstract

AIM: Clinical evaluation of efficacy of adding Dexmedetomidine and Fentanyl to Ropivacaine in lower abdominal and lower limb surgeries . *Method:* This was a randomized double blind study of postoperative epidural analgesia was done in 100 patients divided into 50 patients each, Group-A Patients received 15ml of 0.2% Ropivacaine + 1mcg / kg of Dexmedetomidine and Group-B Patients received 15ml of 0.2% of Ropivacaine + 1mcg / kg of Fentanyl and onset, duration of analgesia, sedation score, visual analogue scale(VAS) were assessed. *Results:* The onset of analgesia in Group A was 8.21min and in Group B it was 10.23 min, which is statistically significant (P<0.05). Duration of analgesia in Group A was 336 min when compared to Group B which was 260min (p<0.05). No. of Patients with Sedation score of grade 2 and 3 are more in Group-A than in Group-B. There was a significant difference of VAS score between the two groups at 15 minutes, 30mins, 45mins, 60mins, 120 min, 180 min, 240 min and 330mins post operatively (p value < 0.05) that the A group had lower VAS score then B group. *Conclusion:* Dexmedeto-midine as an adjuvant to Ropivacaine in epidural analgesia seems to be a better alternative to Fentanyl, as it provides comparable stable hemodynamics, early onset of analgesia, prolonged post-op analgesia, and much better sedation levels.

Keywords: Dexmedeto-midine; Hemodynamics; Analgesia; Visual Analogue Scale.

Introduction

Use of regional blocks for lower limb and lower abdominal surgeries has increased during last decade because increase in demand for postoperative pain relief and decrease in the need for intravenous analgesic drugs during postoperative period. Various adjuvants are being used along with local anaesthetic to decrease adverse effects of high doses of local anaesthetic and to prolong the duration of intraoperative and postoperative analgesia [1]. Alpha$_2$ adrenergic agonist have dual property of analgesia and sedation when used as a adjuvant in regional anesthesia [2].

Dexmedetomidine a newer highly selective alpha$_2$ adrenergic agonist has property of stable hemodynamics and decreased oxygen demand because of its enhanced sympathoadrenal stability [3,4].

This property of Dexmedetomidine makes it a very useful adjuvant. Based on earlier studies it was found that Dexmedetomidine produces prolonged postoperative analgesia with minimal side effects been added to Ropivacaine in epidural anaesthesia [5,6,7,8].

New amide local anaesthetics like Ropicavaine has less propensity of motor block with minimum cardiovascular and central nervous system toxicity during postoperative epidural analgesia [9,10].

In combination with low dose local anaesthetic adjuvants like Fentanyl have been used in epidural anaesthesia [11].

The addition of opiods like Fentanyl provide superior analgesia and dose sparing effects of local anaesthetics but there is increased incidence of nausea, vomiting, pruritis, urinary retension and respiratory depression [12,13].

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Materials and Methods

This study was conducted in Narayana Medical College Hospital from November 2016 to February 2017. This was a randomized double blind study of postoperative epidural analgesia was done in 100 patients, posted for elective surgeries selected randomly, after approval from Ethical committee.

Inclusion Criteria

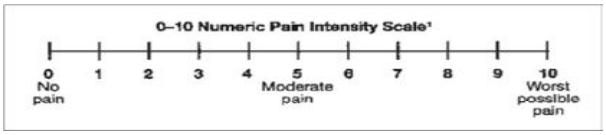
- Patients of either sex.
- ASA grades I and II.
- Age between 18 to 60 years.
- Elective lower limb Orthopaedic and lower Abdominal surgery.

Exclusion Criteria

- Patient's refusal
- Spinal deformities.
- Bleeding disorders.
- Neurological deficit.
- Local skin infection around the site of needle insertion.
- 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. After obtaining written informed consent, initial pre-operative counseling and reassurance was given to gain the confidence of the patient. Emotional component of pain was thereby minimized. The nature of the procedure was explained and the patients were taught to assess the intensity of pain using the visual analogue scale (VAS).

Visual Analogue Scale



In the operation theatre, the basal pulse rate, blood pressure and respiratory rate of the patient were recorded. An intravenous infusion was started and the patients were preloaded with 500 ml of Ringerlactate solution and connected with monitors like pulse-oximeter, ECG leads and noninvasive blood pressure monitor. With all aseptic precautions, epidural space was found with 18G Touhy needle at L2-L3 space by loss of resistance using air injection technique in sitting position and an 18G epidural catheter was threaded. Spinal anaesthesia was given in L3-L4 space and 3.5cc 0.5%. Bupivacaine was injected into subarachnoid space. All the patients were continuously monitored for pulse rate, blood pressure, respiratory rate and oxygen saturation and recorded in the anaesthesia chart, every 5mins till the end of the surgery.

In case of prolongation of surgery, anaesthesia was maintained by administering 5ml of 0.25% Bupivacaine epidurally after negative aspiration. When the effect of subarachnoid local anaesthetic wears off and the patient complains of pain, first assessment of intensity of pain was done by visual analogue scale, when the visual analogue pain score touched the >5 mark, the intended drugs were given through the epidural catheter 52. The test drug was given for postoperative analgesia as a single dose, whenever the patient complained of pain, the VAS score considered as >5 at that time.

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.

Onset of action and intensity and duration of pain relief were recorded at 15 minutes intervals for first one hour and then hourly monitoring done till the end of study. After completion of study if patient complains of pain, at this point rescue analgesia was given on demand by patient, in the form of inj. Bupivacaine 0.125% 8ml + Inj.Tramadol 50mg through epidural catheter .

In the post-operative period the following parameters were studied: Vital parameters such as the heart rate, blood pressure, respiratory rate, sedation score and visual analogue score were recorded:

Onset of Analgesia

Duration of Analgesia

The visual analogue scale

Side effects like nausea, vomiting, hypotension, respiratory depression and pruritis, allergic reactions were looked for.

Sedation score: Graded from 1 to 6

1. Deep sleep – Does not respond to verbal commands.

2. Sleepy – Responds to verbal commands.

3. No complaint on body movement – Calm.

4. Complaints with body movement – But Calm.

5. Complaining on body movement – Not Calm.

6. A great degree of complaining and body movement, accompanied by some excitement.

Statistical Analysis

A total of 100 patients of either sex selected in this study. Statistical data was analysed using • Chi-square test • Student t-test (Paired and unpaired t-test) • P value of < 0.05 was taken as significant and >0.05 was taken as not significant

Results

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 60 years respectively. In Group-A the mean age was 36.28 (±8.76) and in Group-B the mean was 38.73 (±9.23) There was no significant difference in the age of patients between the Group-A and Group-B. Both groups were similar with respect to age distributions. 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 2 & Figure 1 shows the onset of analgesia. In Group-A it was 8.21min. In Group-B it was 10.23 min, which is statistically significant (P<0.05).

Table 3 & Figure 2 shows the duration of analgesia. In Group-A it was 336 min when compared to Group-B which was 260min. This is statistically significant (P<0.05).

Table 4 & Figure 3 shows heart rate. In Group A the mean baseline heart rate was 94.96 with a standard deviation of 9.01. In Group B the mean baseline heart rate was 93.72 with a standard deviation of 10.11. On comparing the two groups there was statistically significant difference (p value > 0.05) between the groups at 1st (88.74 ± 8.37) 2nd (92.26 ± 7.38) and 3rd (92.44 ± 7.68) hour.

Table 5 & Figure 4 shows the systolic blood pressure changes. In Group-A the mean baseline systolic blood pressure was 133.92 with a standard deviation of 9.75. A fall in systolic blood pressure was recorded in Group-A, from 15min up to 45min, which was statistically significant (p value < 0.05). In Group-B, the mean baseline systolic blood pressure was 132.24 with a standard deviation of 10.85. A fall in systolic blood pressure was noted in Group-B from 30 min up to 45 min, which was statistically significant (p value < 0.05).

Table 6 & Figure 5 shows diastolic blood pressure changes in Group-A, the mean baseline diastolic blood pressure was 78.62 with a standard deviation of 10.67. There was no fall in diastolic blood pressure which was statistically not significant (p value < 0.05). In Group-B, the mean baseline diastolic blood pressure was 78.74 with a standard deviation of 10.25 there was no fall in diastolic blood pressure which was statistically not significant (p value < 0.05). On comparing the two groups, the fall in diastolic blood pressure was statistically not significant (p value > 0.05).

Figure 5 shows sedation score in Group-A and Group-B. No.of Patients with Sedation score of grade-2 and 3 are more in Group-A than in Group-B.

Figure 6 shows the visual anologue scale score.The mean baseline VAS score in Group A was 5.80 with a standard deviation of 0.60, whereas in Group B it was 5.50 with a standard deviation of 0.50. On statistical analysis there was significant difference between the two groups at 15 minutes, 30mins, 45mins, 60mins, 120 min, 180 min, 240 min and 330mts post operatively (p value < 0.05) that the A group had lower VAS score then B group.

Table 7 shows the side effects. We observed that nausea and vomiting, shivering, pruritus, retention of urine were more in Group-B and dizziness and dry mouth were more in Group-A

Table 1: Demographic profile

Parameters	Group-A	Group-B
Age (in yrs)	36.28 (±8.76)	38.73 (±9.23)
Sex (M / F)	36 / 14	33 / 17

Table 2: Onset of analgesia (mins)

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

Table 3: Duration of analgesia (mins)

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

Table 4: Comparison of mean pulse rate between group-a and group-b

Time interval	Pulse rate group A		Pulse rate group B		P value
	Mean	SD	Mean	SD	
Base value	94.96	9.01	93.72	10.11	0.42
15 min	88.72	9.64	85.86	9.84	0.15
30 min	83.18	8.85	82.24	9.12	0.60
45 min	81.16	7.22	81.92	8.04	0.62
1 hr	88.74	8.37	84.58	8.28	0.01
2 hr.	92.26	7.38	86.46	7.60	<0.00
3 hr	92.44	7.68	88.34	7.55	0.01
4 hr	91.12	7.94	89.97	7.35	0.45
5 hr	91.88	7.89	89.43	6.79	0.10
6 hr.	90.81	7.58	91.35	6.30	0.7

Table 5: Comparison of systolic blood pressure in group a and group b

Time interval	Systolic blood pressure mm Hg Group-A		Systolic blood pressure mm Hg Group-B		P value
	Mean	SD	Mean	SD	
Base value	133.92	9.75	132.24	10.85	0.56
15 min	125.66	12.94	130.72	12.80	<0.00
30 min	128.52	11.14	124.10	11.30	0.04
45 min	128.68	10.62	123.40	11.30	0.02
1 hr	128.54	10.46	128.32	12.51	0.92
2 hr.	130.68	10.67	130.20	12.63	0.84
3 hr	131.35	9.44	130.62	12.60	0.74
4 hr	132.52	8.03	129.96	11.25	0.19
5 hr	128.52	11.14	130.79	10.69	0.30
6 hr.	128.55	9.35	133	10.39	0.02

Table 5: Comparison of diastolic blood pressure in group a and group b

Time interval	Diastolic blood pressure mm Hg group A		Diastolic blood pressure mm Hg group B		P value
	Mean	SD	Mean	SD	
Base value	78.62	10.67	78.7	10.25	0.95
15 min	77.94	11.18	76.48	10.35	0.5
30 min	78.30	11.06	75.02	9.16	0.10
45 min	78.24	11.53	76.54	10.16	0.41
1 hr	78.54	10.88	74.98	9.20	0.08
2 hr.	77.88	10.78	75.04	9.17	0.16
3 hr	79.24	11.53	76.58	10.17	0.22
4 hr	79.58	11.56	76.10	8.03	0.08
5 hr	78.04	11.12	76.92	8.67	0.58
6 hr.	76.76	8.15	78.21	9.10	0.40

Table 7: Comparison of sedation score in between group a and group b

Grade	Group A [No (%)] (RD)		Group B [No (%)] (RF)	
1	6	(12)	39	(78)
2	21	(42)	8	(16)
3	20	(40)	2	(4)
4	3	(6)	1	(2)
5	0	(0)	0	(0)

Table 8: Comparison of vas between group a and group b

Time interval	VAS score group A		VAS score group B		P value
	Mean	SD	Mean	SD	
Base value	5.80	0.60	5.60	0.50	<0.00
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	<0.0

Table 9: Comparison of side effects between group a and group b

Side effects	Comparison of side effects observed in both the groups in postoperative period			
	Group A N=50	Percent %	Group B N=50	Percent %
Nausea and vomiting	9	18	13	26
Shivering	2	4	2	2
Pruritus	0	0	3	6
Dizzines	3	6	2	4
Dry mouth	7	14	2	4
Respiratory depression	0	0	0	0
Urinary Retention	3	6	5	10

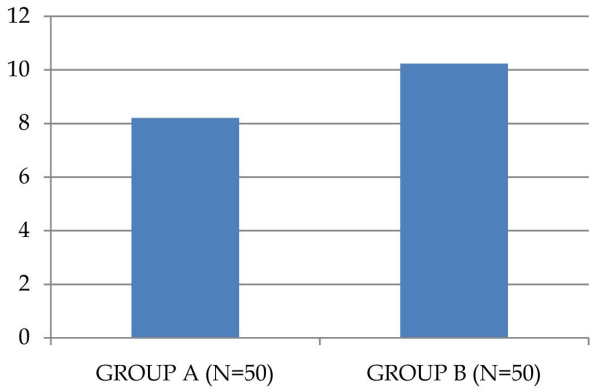


Fig. 1: Onset of analgesia (mins)

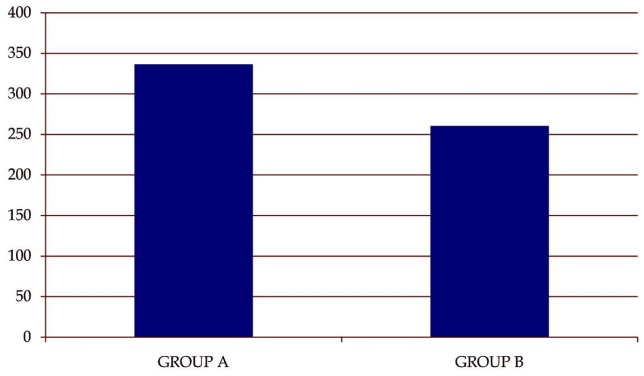


Fig. 2: Duration of analgesia (mins)

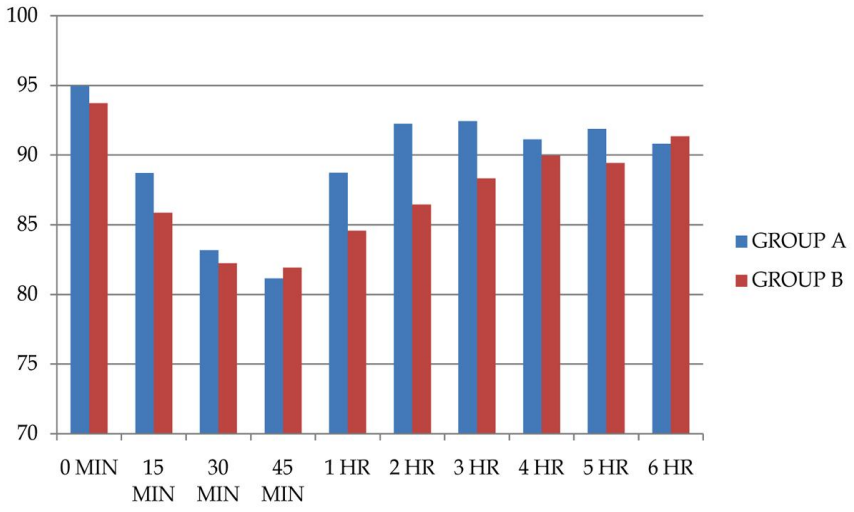


Fig. 3: Comparison of pulse rate

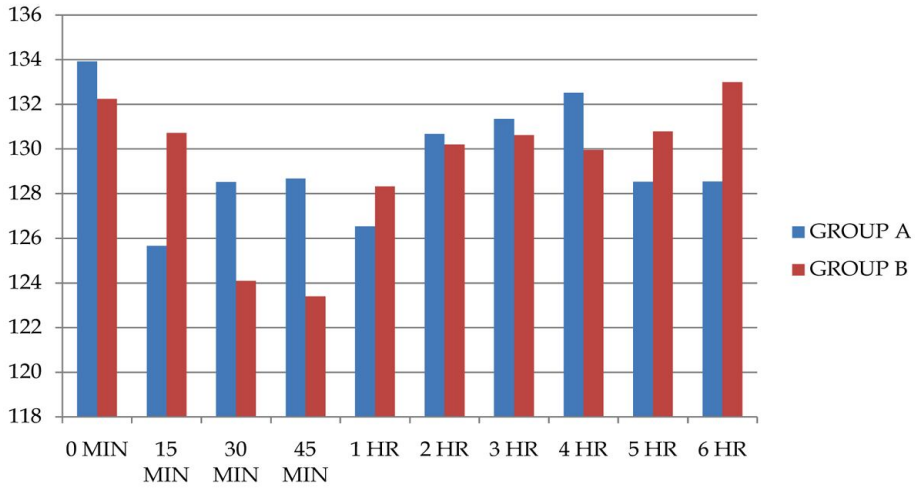


Fig. 4: Comparison of systolic blood pressure

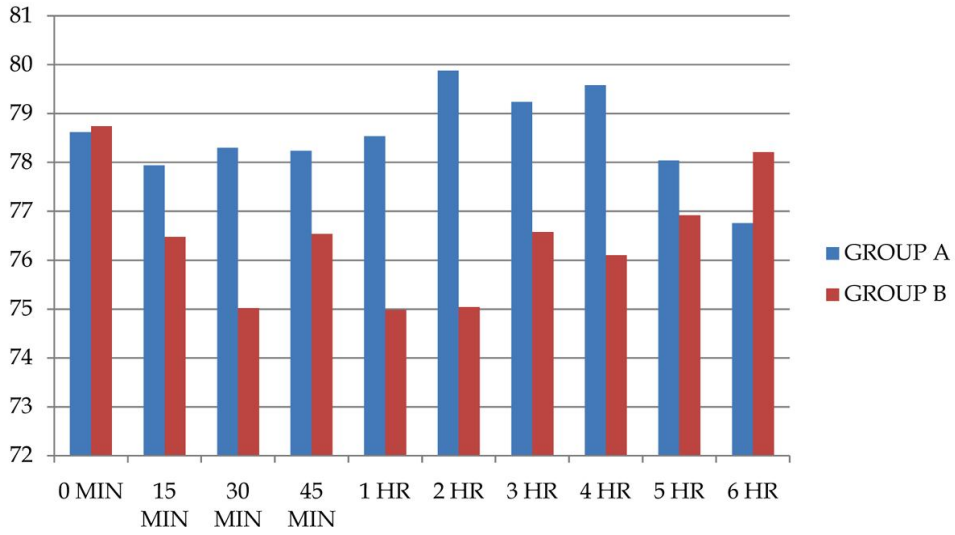


Fig. 5: Comparison of diastolic blood pressure

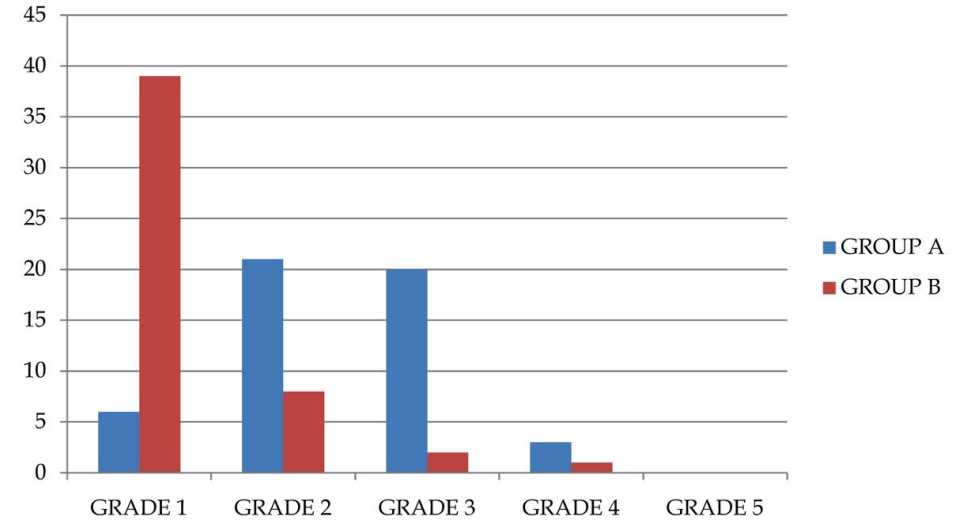


Fig. 6: Comparison of sedation score

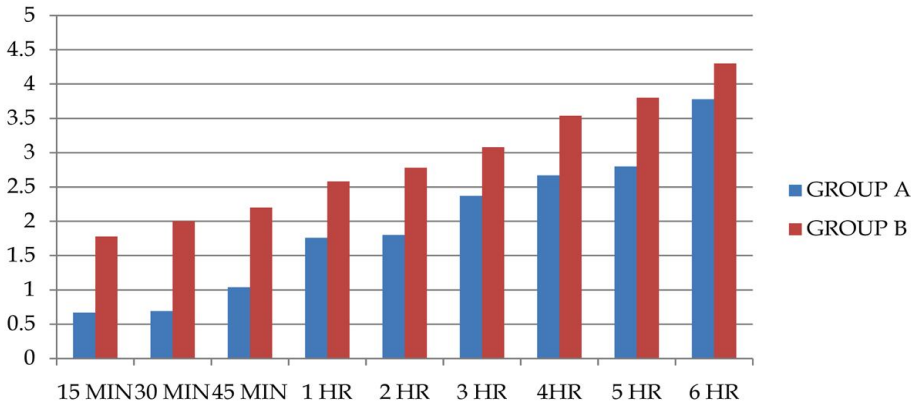


Fig .7: Comparison of vas score

Discussion

The minimum age in both groups was 18 years. The maximum age in both groups was 60years respectively. In Group-A the Mean age was 36.28 (±8.76) and in Group-B the mean was 38.73 (±9.23) There was no significant difference in the age of patients between the Group-A and Group-B. Both groups were similar with respect to age distribution. No significant difference was observed in sex wise distribution of the cases between two groups.

In the present study the onset of analgesia in Group-A was 8.21mins and Group-B was 10.23mins, where as in study of Bajwa et al [8] the onset of analgesia in Group-A was 7.12 minutes and in Group-B was 9.14mins. This may be due to the increased concentration and the volume of the of the drug used in Bajwa et al [8] 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 [8] 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 [8] study.

A statistically significant ($p<0.05$) increase in the mean and maximum duration of analgesia was found in Group II [324 and 480 min] in comparison to Group I [149 and 210 min] was found in the study conducted by Sandip Sinha, MD et al [14].

In the present study there was fall in pulse rate during first 35 - 40 minutes. Thereafter, the heart rate remained stable in both the groups with is comparable with other two studies.

Pulse Rate in Bajwa et al [8] 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 [15] 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.

In the present study we observed decrease in blood pressure from the base line till 45 minutes to 1 hour thereafter it maintained, which is comparable with above two studies.

In the study of Bajwa et al [8] there was decrease in blood pressure from the base line at 30 – 50 minutes after epidural injection.

In the study of Kaur Sarabjit et al [15] patients had fall in blood pressure during first 40 minutes interval which was corrected by giving oxygen and intravenous fluids and some required injection ephedrine hydrochloride 3-6mg intravenously for correction of blood pressure.

In the Present study we observed Group-A 42% and 40% of patients exhibited grade-II and grade -III sedation as compared to Group-B 16% and 4%, respectively.

Bajwa et al [8] study in Group-A observed 38% and 42% of patients exhibited grade-II and grade-III sedation as compared to Group-B 16% and 2% respectively.

All our sedation scores are comparable with Bajwa et al [8] study.

The mean baseline VAS score in Group-A was 5.80 with a standard deviation of 0.60, whereas in Group-B it was 5.50 with a standard deviation of 0.50. On statistical analysis there was significant difference between the two groups at 15 minutes, 30mins, 45mins, 60mins, 120 min, 180 min.240 min and

330mts post operatively (p value < 0.05) in that the Group-A had lower VAS score than Group-B

Sandip Sinha, MD et al [14] shows VAS were comparable in the immediate post operative period but after that it became significantly higher VAS in Group-A on all the post operative recordings.

In the present study the comparative incidence of various side effects in both the groups which were observed in the post-op period. Nausea and vomiting (26%) were observed to a significant extent in the Group-B compared to 18%, respectively, in the Group-A. The incidence of dry mouth was significantly higher in the Group-A (14%) as compared to the Group-B. The incidence of other side effects like pruritus, shivering, dizziness, and urinary retention were comparable in both the groups.

In Bajwa et al [8] shows the comparative incidence of various side effects in both the groups which were observed in the intra-op and post-op period. Nausea and vomiting (26%) were observed to a significant extent in the RF group when compared to RD Group (14%). The incidence of dry mouth was significantly higher in the RD (14%) group as compared to the RF group (2%). The incidence of other side effects like Pruritus, shivering, dizziness and urinary retention were comparable in both the groups

Conclusion

Dexmedetomidine as an adjuvant to Ropivacaine in epidural analgesia seems to be a better alternative to Fentanyl, as it provides comparable stable hemodynamics, early onset of analgesia, prolonged post-op analgesia, and much better sedation levels.

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