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Comparitive Study of Epidural Fentanyl and Bupivacaine with Epidural Clonidine and Bupivacaine for Postoperative Pain Relief in Lower Abdominal and Lower Limb Surgeries: RCT

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Abstract

Postoperative pain and discomfort are the major concerns in all patients undergoing any surgery. Delay of discharge is mainly due postoperative pain. So, postoperative pain relief becomes very important. Epidural anal gesiaisone of many recent evidence-base dregimens for postoperative pain relief after surgeries particularly surgeries of abdomen. The objective of this study is to compare the efficacy, onset and duration of epidural analgesia of Bupivacaine - Clonidinecombination Vs. Bupivacaine-Fentanyl combination for post-operative analgesia in lower abdominal and lower limb surgeries.

Materials and Methods: 50 patients belonging to ASA 1 and 2 were assigned into two groups (25 each). Group F received epidural Fentanyl with 0. 25% Bupivacaine and Group C received epidural Clonidine with 0.25% Bupivacaine.

Results: With regard to anxiolysis, increased sedative property with easy arousal, longer and better quality analgesia and patient comfort, epidural clonidine and Bupivacaine combination was found to be superior to epidural Fentanyl and Bupivacaine. Various parameters like HR, Blood pressure (both systolic and diastolic), SPo_2, Visual Analogue Scale (VAS) and Ram say Sedation Score (RSS) were observed for 24 hours post operatively. It was follow edup at 15 minutes, 30 min, 120 min, 240 min, 360 min, 480 min, 600 min, 720 min, 840 min, 960 min, 1080 min, 1200 min, 1320 min and 1440 min. Incidencesof side effects were also noted.

Conclusion: Clonidine has proved to be very efficient compared to Fentanyl in postoperative analgesia.

Keywords: Epidural; Postoperative; Pain; Clonidine; Fentanyl; Analgesia.

Introduction

Proper pain management is crucial for ideal care of surgical patients. Adequate postop pain relief facilitates early ambulation, reduces postop morbidity in terms of infection, neurological, cardiovascular and thrombo embolic sequelae caused by immobility. Also it leads to shorter hospital stay, decreased hospital costs, better patient outcome.[1–4] Pain elevates the degree of indisposition after surgeries due to a decrease in the breathing effort and cough reflex suppression, there by interrupting bowel function [5] and mobility.

Epidural analgesia is one of many recent evidence based regimens for postop pain relief after surgeries particularly abdominal surgeries . Advantages with epidural analgesia in high risk patients were[6]

1. Significant decrease in surgical stress response.
2. Hemodynamic stability and reduction in cardiac and pulmonary morbidity.
3. Early recovery of gastro intestinal function.[7]
4. Early ambulation thereby reducing thrombo embolic events.

Local anaesthetics are useful and effective in treatment of acute and chronic post-perative pain, but the limitations like short duration of action, adverse effects on Cardiovascular System (CVS) and Central Nervous System (CNS) curb its use in recent times.[8]

Local anesthetics and adjuvants are the frequently used combination for their synergistic and additive analgesic effects. Also, the increased dose of local anesthetics is being avoided whenever an adjuvant is used.[9]

The commonly used additives range from opiods like Morphine, Fentanyl and Sufentanil to Hydromorphone, Buprenorphine, Tramadol, Alpha 2 adrenergic agonists like Clonidine and Dexmeditomidine. Steroids, anti inflammatory agents, Midazolam, Ketamine, Magnesium sulphate and Neostigmine have also been used.

This study was undertaken with an aim to find out whether Clonidine and Bupivacaine combination has a better efficacy in epidural analgesia compared to Fentanyl –Bupivacaine combination.

Materials and Methods

After obtaining instituitional ethical committee approval and informed written consent, 50 adult patients belonging to ASA 1 and 2 class, scheduled for elective lower abdominal and lower limb surgeries under combined spinal epidural technique were enrolled for this study.

Inclusion criteria:

1. ASA 1 and 2 patients.
2. Age 20 –70 years.
3. Patients undergoing elective lower abdominal and lower limb surgeries.

Exclusion criteria

1. Patient refusal
2. ASA 3 and 4
3. Morbidly obese
4. Patients with spinal deformities, neurological disease
5. Patients with local or systemic infection
6. Coagulation disorders.

Study groups: The patients were randomized and allocated into two groups.

Group F 25 patients who received 0.25% Bupivacaine and Fentanyl (2 micrograms fentanyl/ml bupivacaine).

Group C 25 patients who received 0.25% Bupivacaine and Clonidine (2 micograms clonidine/ml bupivacaine).

Pre anesthetic evaluation

All patients were subjected to a thorough pre anesthetic evaluation, in which procedure was explained to the patients and all patients were educated about the visual analogue scale (VAS) pain score of 0–10. The patients were fasted for 8 hrs before surgery. In all patients, age, body weight and baseline vital parameters were recorded. A common conduct of anesthesia was followed in all patients which included alprazolam 0.25 mg orally at night before surgery and ranitidine 150 mg orally at night and on the morning of surgery.

Procedure Details

Standard monitoring included pulse oximetry, non invasive blood pressure, end tidal CO_2 and three lead electrocardiogram.

The i.v access was secured with 18G cannula in a suitable vein on the dorsum of non dominant hand. Ringers lactate was started. Baseline parameters i.e heart rate, NIBP, Spo_2, end tidal CO_2 and ECG were monitored.

Epidural block was performed in sitting position in T_{11}-T_{12}/T_{12}-L_1 interspace with 18G Tuohy needle. After ensuring epidural space by LOR technique, catheter is placed at around 9 to 10 cm at skin and epidural test dose was given .Spinal sub arachnoid block given with 0.5% Bupi vacaine heavy (volume calculated according to patient characteristics and type of surgery) without any adjuvant. After injection, patient was put back in supine position and 3L per min of O_2 given by facemask .After attainment of adequate level of sensory block , the surgery was proceeded.

After 90min of spinal anesthesia, study drug was given via epidural catheter after negative aspiration for CSF and blood.

Volume was calculated according to the required level analgesia.

Group F–received Bupivacaine (0.25%) with Fentanyl 2mcg/ml.

Group C-received Bupivacaine (0.25%) with Clonidine 2mcg/ml.

Parameters observed and analysed

Patients were observed in the OR for 15 minutes and then shifted to PACU (Post anesthesia care unit) for monitoring.

Various parameters like HR, Blood pressure (both systolic and diastolic), SpO_2, VAS (visual analogue scale) and RSS (Ramsay sedation score were observed for 24 hours postoperatively.

It was followed up at 15 minutes, 30 min., 120 min., then every 2 hrs upto 1440 min. Incidences of side effects were also noted. Injection Tramadol 50 mg i.v was used as rescue analgesia when pain score was more than 4 (i.e VAS≥4).

Statistical tools

The information collected regarding all the selected cases were recorded in Master charts 1 and 2. Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2008).

Using this software, range, frequencies, percentages, means, standard deviations, chi square and 'p' values were calculated. Kruskal Wallis chi square test was used to test the significance of difference between quantitative variables and Yate's test for qualitative variables. A 'p' value less than 0.05 was taken to denote significant relationship.

Observation and Results

Results of this study are described under the following headings:

A. Comparison of baseline characteristics
   1. Age, Sex and ASA - PS distribution
   2. Weight distribution
   3. Distribution of surgery done among study subjects.

B. Inferential statistics:
   1. Comparison of duration of analgesia between two groups.
   2. Comparison of time for First Rescue Analgesia between two groups.
   3. Comparison of Visual Analogue Scale between two groups.
   4. Comparison of Ramsay Sedation Score between two groups.
   5. Comparison of Hemodynamic variables like SBP, DBP, Heart rate and Pulse oximetry between two groups.
   6. Comparison of side effects between two groups.
   7. Comparison of patient acceptance between two groups.

There was no statistically significant difference found between the two groups with respect to age, ASA PS and gender distribution.

Table 1: Age, Sex and ASA PS distribution.

Age (in yrs)	Grp C	%	Grp F	%	P value
<50 yrs	5	20	3	12	
51–60 yrs	11	44	13	52	0.480
61–70 yrs	9	36	9	36	
Total	25	100	25	100	
Male	14	56	13	52	
Female	11	44	12	48	1.00
Total	25	100	25	100	
ASA PS 1	12	48	14	56	
ASA PS 2	13	52	11	44	0.575
Total	25	100	25	100	

*p value calculated by independent sample t test, p value<0.05 is significant

This study found that mean age of participants in Clonidine group (57.56±6.634 years) was comparable to that of Fentanyl group (58.84±8.067yrs) t value=.712, p value: 0.48. No significant difference between two groups with respect to age.

Among 50 subjects, 8 belonged to <50 years of age group, 24 belonged to 51–60 years of age group, 18 belonged to 61–70 years of age group. 5(20%) of <50 years were in clonidine group and 3(12,%,) were in fentanyl group. 11(44%) were in clonidine group in 51–60 yrs and 13(52%) in fentanyl group. Clonidine and Fentanyl group had equal number of persons 9(36%) in 61–70 years of age group. (Table 1)

For gender,*p value was calculated by Chi square test. p value<0.05 is significant.

Among 50 subjects, 27(54%) of subjects were males and 23(46%) were females.

Out of 27 males 14 were in Clonidine group and 13 in Fentanyl group. Among 23 females, 11 were in Clonidine group and 12 in Fentanyl group. Both groups were comparable according to gender.

Table 2: Weight distribution between the groups.

	No. of cases	Mean ±S. D	t value	p value*
Group C	25	65.36± 6.975	1.51	0.13
Group F	25	61.68 ± 9.949		

*p value calculated by independent sample t test, p value<0.05 is significant This study found that mean weight of participants in Clonidine group (65.36± 6.975 Kg) was comparable to that of Fentanyl group (61.68 ± 9.949 Kg) t value= 1.51, p value: 0.13. No significant difference between two groups with respect to weight.(Table 2)

Table 3: Distribution of Surgery Done Among Study Subjects.

Surgeries done	Frequency	Percentage
B/B Leg fractures	7	14.0
Bilateral inguinal hernia	5	10.0
Femur shaft fracture	1	2.0
Incisional hernia	8	16.0
Pelvis fracture	1	2.0
TAH BSO	9	18.0
THR	7	14.0
TKR	4	8.0
Umbilical hernia	8	16.0
Total	50	100.0

About 9(18%) of 50 subjects had undergone Total Abdominal Hysterectomy and Bilateral Salphingo Oophorectomy (TAH BSO), 8(16%) undergone surgery for Umbilical Herniation, 8(16%) for incisional hernias. 7(14%) for surgeries of B/B leg fractures, 7(14%) undergone Total Hip Replacement (THR) Surgeries.(Table 3)

Table 4: Duration of Analgesia among Subjects.

	No. of Cases	Mean±S.D	t value	p value
Group C	25	415 ± 63.7	7.63	0.0001
Group F	25	231 ± 30.754		

*p value calculated by independent sample t test, p value<0.05 is significant.

The mean duration of analgesia was 415 ± 63.7 minutes in Group Clonidine and 231.00 ± 30.754 minutes in Group Fentanyl. There was statistically significant difference among two groups in the mean duration of analgesia (P<0.05). Higher duration of analgesia for the group who received Clonidine.(Table 4)

Table 5: Time For First Rescue Analgesia.

	No. of Cases	Mean±S.D	t value	p value*
Grou P Clonidine	25	427.6 ± 62.168	13.374	<0.001
Grou P Fentanyl	25	240.4 ± 32.143		

*p value calculated by independent sample t test, p value<0.05 is significant.

The mean time for 1st rescue analgesia (defined as the time at which patient demands some mode of pain relief i.e. when VAS score more than 4) was 427.6 ± 62.168 minutes in Group Clonidine and 240.4 ± 32.143 minutes in Group Fentanyl. There was significant difference among two groups in the duration of time for rescue analgesia (p<0.05). (Table 5)

Table 6: Visual Analogue Score (VAS) Between Clonidine and Fentanyl Group at Different Times in Minutes.

Time in Minutes	Clonidine Mean ± SD	Fentanyl Mean ± SD	t value	p value
15	0	0	0	0
30	0	0	0	0
120	0.16±.55	0	1.4	.15
240	2.44±1.19	4±0	6.53	0.001
360	2±0	2.08±0	1.45	.16
480	2.04±.2	2.2±.41	1.76	.08
600	2.16±.45	2.28±.374	1.014	.316
720	2.64±.49	2.68±.47	.294	.771
840	3±0	3±0	0	0
960	3±0	3.04±.2	1	.327
1080	3±0	3.36±.49	3.67	.001
1200	3±0	4±0	4.6	.001
1320	3±0	4±0	3.8	.001
1440	3.26±0.3	4±0	4.6	.001

At 240 minutes, the mean VAS score in Group C was 2.44±1.19 and in Group F was 4 ± 0; there was statistically significant difference in both groups (p<0.05).

At 1080, 1200, 1320 minutes the mean VAS score between Clonidine group and Fentanyl group were statistically significant.(Table 6)

Table 7: Ramsay Sedation Score between Clonidine and Fentanyl Group at Different Times in Minutes.

Time in Minutes	Clonidine Mean ± SD	Fentanyl Mean ± SD	t value	p value
0	3±0	3±0	0	0
60	2.88±.332	3±0	1.8	.08
120	2.72±.458	3±0	3.05	.005
180	2.64±.490	3±0	3.67	.001
240	2.52±.51	2.88±.34	2.88	.006
300	2.04±.2	2.75±.44	7.19	<0.001
360	2±0	2.5±.51	4.79	<0.001

There was no statistical significance in Ramsay Sedation score at 0 minutes and 60 minutes. The mean Ramsay sedation scores of Clonidine group is gradually decreasing starting from 60 minutes. The mean score of Clonidine group at 120 minutes was 2.72±.458 and that of Fentanyl group 3±0 which was statistically significant. (Table 7)

The mean scores of Clonidine group at 180, 240, 300 and 360 minutes were 2.64±.490, 2.52±.51, 2.04±.2, 2±0 respectively compared to Fentanyl group where the scores were 3±0, 2.88±.34, 2.75±.44, 2.5±.51 respectively and this was statistically significant.

Table 8: Systolic Blood Pressure (Sbp) between Clonidine and Fentanyl Group at Different Times in Minutes.

Time in Minutes	Clonidine Mean ± SD	Fentanyl Mean ± SD	t value	p value
15	120±9.09	115.6±9.61	1.9	0.05
30	119.6±8.88	106.8±7.483	5.5	<0.001
120	114±11.55	120.8±8.62	2.36	.02
240	122±7.64	121.6±6.88	.195	.847
360	122±8.165	124.8±6.532	1.33	.187
480	101.6±3.47	105.2±5.09	2.85	.007
600	102.8±4.58	108.8±7.25	3.49	.001
720	104.4±7.12	112.8±7.37	4.09	<0.001
840	105.2±6.53	110.8±7.024	2.91	.005
960	106±7.07	112.4±7.789	3.04	.004
1080	104.4±6.51	111.2±8.327	3.22	.002
1200	104.78±6.53	111.2±8.327	3.024	0.004
1320	105.2 ±6.53	114.4±8.21	4.386	<0.001
1440	103.6±6.37	108.8±7.26	2.69	.010

*p value calculated by independent sample t test, p value<0.05 is significant.

Table 8 There was statistically significant reduction in SBP in Clonidine group compared to Fentanyl group. The mean Systolic Blood Pressure reduction in Clonidine group wasmore compared to Fentanyl group and the relation was significant from 480 minutes after surgery.

At 480 minutes, the mean SBP was 101.6±3.47 in Clonidine group compared to 105.2±5.09 in Fentanyl group and is statistically significant with p value. 007.

At 600 minutes, the mean SBP was 102.8±4.58 in Clonidine group compared to 108.8±7.25 in Fentanyl group and is statistically significant with p value. 001.

At 720 minutes, the mean SBP was 104.4±7.12 in Clonidine group compared to 112.8±7.37 in Fentanyl group and is statistically significant with p value <0.001.

At 840 minutes, the mean SBP was 105.2±6.53 in Clonidine group compared to 110.8±7.024 in Fentanyl group and is statistically significant with p value 0.005.

At 960 minutes, the mean SBP was 106±7.07 in Clonidine group compared to 111.2±7.789 in Fentanyl group and is statistically significant with p value 0.004.

At 1080 minutes, the mean SBP was 104.4±6.51 in Clonidine group compared to 111.2±8.327 in Fentanyl group and is statistically significant with p value 0.002.

At 1200 minutes, the mean SBP was 104.78±6.53 in Clonidine group compared 111.2±8.327 in Fentanyl group and is statistically significant with p value 0.004.

At 1320 minutes, the mean SBP was 105.2 ±6.53in Clonidine group compared to 114.4±8.21 in Fentanyl group and is statistically significant with p value <0.001.

At 1440 minutes, the mean SBP was 103.6±6.37 in Clonidine group compared to 108.8±7.26 in Fentanyl group and is statistically significant with p value.010.

Table 9: Diastolic Blood Pressure (Dbp) Between Clonidine and Fentanyl Group at Different Times in Minutes.

Time in Minutes	Clonidine Mean ± SD	Fentanyl Mean ± SD	t value	p value
15	68±15.34	62.05±10.652	1.56	0.126
30	62.80±14.89	63.23±8.04	.124	.902
120	54.60±4.77	55.23±3.93	.49	.62
240	57±5.59	56.14±4.86	.56	.57
360	53.6±3.68	52.5±2.56	1.2	.24
480	53±2.5	53.41±2.38	.57	.57
600	53.8±3.32	53.41±2.384	.47	.642
720	55.4±3.79	53.18±2.46	2.40	.02
840	54.4±3.63	53.41±2.38	1.12	.27
960	55.6±3.33	52.73±2.548	3.34	.002
1080	55.2±4.44	52.95±2.52	2.16	.03
1200	55.6±4.64	53.41±2.84	1.97	.051
1320	55.4±4.77	53.64±3.513	1.45	.15
1440	55.6±4.16	55.45±5.09	.11	.91

*p value calculated by independent sample t test, p value<0.05 is significant.

Table 9 There was reduction in DBP in Clonidine group and Fentanyl group., but nostatistical significant difference between two groups.

At 720 minutes, the mean DBP was 55.4±3.79 in Clonidine group compared to 53.18±2.46 in Fentanyl group and is statistically significant with p value .02.

At 960 minutes, the mean DBP was 55.6±3.33 in Clonidine group compared to 52.73±2.548 in Fentanyl group and is statistically significant with p value 0.002.

At 1080 minutes, the mean DBP was 55.2±4.44 in Clonidine group compared to52.95±2.52 in Fentanyl group and is statistically significant with p value 0.03.

Table 10: SPO_2 between Clonidine and Fentanyl Group at Different Times in Minutes.

Time in Minutes	Clonidine Mean ± SD	Fentanyl Mean ± SD	t value	p value
15	99.68±.476	99.52±.510	1.14	.257
30	95.88±17.901	98.72±.792	.792	.436
120	99.28±.614	98.28±.542	6.108	<0.001
240	99.20±.764	98.76±.879	1.89	.065

360	99±.957	99±.71	.00	1.00
480	99±.71	99±.866	.00	1.00
600	99±.71	98.84±1.18	.582	.564
720	98.84±.943	98.76±.926	.303	.763
840	98.64±.810	98.64±.995	.00	1.00
960	98.76±.926	98.68±.945	.302	.764
1080	99±.764	98.88±.726	.569	.572
1200	99.12±.726	99.16±.800	.185	.854
1320	98.76±.663	99.36±.569	3.434	.001
1440	98.76±.663	99.36±.569	3.434	.001

*p value calculated by independent sample t test, p value<0.05 is significant

There was no statistical significance in mean SPO_2 in Clonidine group comparedto Fentanyl group.

At 120 minutes, the mean SPO_2 was 99.28±.614 in Clonidine group compared to 98.28±.542 in Fentanyl group and is statistically significant with p value .001.

At 1320 minutes, the mean SPO_2 was 98.76±.663 in Clonidine group compared to 99.36±.569 in Fentanyl group and is statistically significant with p value .001.

At 1440 minutes, the mean SPO_2 was 98.76±.663 in Clonidine group compared to99.36±.569 in Fentanyl group and is statistically significant with p value .001. (Table 10)

Table 11: Comparison of Patient Acceptance and Drugs used.

	Patient acceptance				Chi square	p value*
	Not Satisfied	Satisfied	Good	Excellent		
Group C	4(16%)	9(36%)	9(36%)	3 (12%)	7.79	0.005
Group F	0	4(16%)	16(64%)	5(20%)		

*p value calculated by Chi-square test. P value<0.05 is significant.

Among 25 patients who received Clonidine, patient acceptance was found to be 4(16%) were not satisfied, 9(36%) were satisfied, 9(36%) were good, 3(12%) were excellent. (Table 11)

In Fentanyl group, for patient acceptance, 4(16%) satisfied, 16(64%) were good, 5(20%) were excellent. This was statistically significant with p value=0.005.

Table : Mean Heart Rate between Clonidine and Fentanyl Group at Different Times in Minutes.

Time in Minutes	Clonidine Mean ± SD	Fentanyl Mean ± SD	t value	p value
30	55.12±3.66	54.36±3.87	.713	.48
120	54.84±4.42	55.4±3.862	.477	.636
240	54.72±4.512	55.92±4.481	.943	.350
360	55.16±4.298	56.96±4.605	1.43	.16
480	55.04±4.42	56.8±4.89	1.34	.188
600	54.76±3.6	57.12±4.65	1.99	.052
720	55.28±3.95	57.8±7.42	1.49	.143
840	55.28±3.70	57.04±3.87	1.64	.107
960	56.12±4.26	56.64±4.36	.426	.672
1080	57.68±4.72	57.08±5.42	.417	.678
1200	55.92±4.06	56.28±5.32	.269	.789
1320	55.64±4.42	56.28±4.198	.525	.602
1440	55.4±5.18	55.96±4.32	.415	.680

*p value calculated by independent sample t test, p value<0.05 is significant. There was no statistical significance in mean Heart Rate in Clonidine group compared to Fentanyl group.

Table 12: Comparison of Side Effects and Drugs used.

	Side effects				Chi square	p value*
	Nil	Hypotension	nausea	vomiting		
Group C	20(80%)	4(16%)	1(4%)	0	4.31	0.456
Group F	22(88%)	1(4%)	0	2(8%)		

p value calculated by Chi-square test. P value<0.05 is significant.

Among 25 patients who received Clonidine, Side effects was not in 20(80%) of subjects, 4(16%) had hypotension. (Table 12)

In Fentanyl group, side effects were not found in 22(88%), 2(8%) had vomiting.

This was not statistically significant with p value=.456

Discussion

In our study, the mean duration of analgesia was 415±63.7 minutes in group C (Clonidine) and 231.00±30.754 minutes in Group F (Fentanyl).There was statistically significant difference among two groups in mean duration of analgesia (p<0.05). Higher duration of analgesia was observed in Clonidine group. Clonidine as an adjuvant promotes faster onset and longer duration of action similar to the other studies done by El-Hennaway AM et al[10], Kambiyasashi et al.[11] This might be due to the dermatomal effect of clonidine. Another study done by Dobrydnjov et al[12] also had similar findings. Another study by Pooja Chopra et al[13], whereby adding 30 mcg of Clonidine to the mixture of 0.5% hyperbaric Bupivacaine and 15 µg Fentanyl significantly enhances the duration of adequate analgesia. They also showed that intra operative pain and requirement of postoperative analgesics and duration of analgesia are significantly lesser when Clonidine was added to Bupivacaine 0.5% or in mixture of Bupivacaine and Fentanyl,in comparison with the group which did not receive Clonidine.

The faster action may be due to the spinal

cholinergic activation of Clonidine. Cholinergic interaction in spinal α-2 adrenergic receptors which are situated on downward route of nor adrenergic pathways produces nor adrenaline release that causes analgesia directly and also it releases Ach (acetyl choline) to produce analgesia. Clonidine also blocks A delta and C fibres at lamina V, thereby producing analgesia. This was similar to studies by Van Sujil et al[14] and Strebel et al.[15]

The mean time for first rescue analgesia (time at which patient demands some mode of pain relief i.e when VAS score more than 4) was 427.6 ±62.168 minutes in Clonidine group and 240.4 ± 32.143 minutes in Fentanyl group and this difference was significant. Other studies also showed similar studies declaring the longer duration of action of Clonidine.

There was no statistical significance in Ramsay sedation score at 0 minutes and 60 minutes. The mean Ramsay sedation score of Clonidine group is gradually decreasing starting from 60 minutes. The mean score of Clonidine group at 120 minutes was 2.72±.458 and that of Fentanyl group 3±0 which was statistically significant. The mean scores of Clonidine group at 180, 240, 300 and 360 minutes were lower compared to Fentanyl group and this was statistically significant. The results of our study clearly indicates the sedation score between the two groups was similar in the first two hours after study drug administration and they had profound sedation but arousable by gentle tactile stimulation-Ramsay sedation score-3. After 2 hours the mean Ramsay score in Clonidine group decreased compared to Fentanyl group at a faster rate. Overall decrease in Clonidine group is statistically significant showing a faster onset of anesthesia in Clonidine group, which was similar to another study done by Yoga narasimha et al and Celleno et al respectively.[16,17]

There was no difference in pain score at 15 and 30 minutes and was found to be statistically not significant ($p>0.05$). At 240 minutes, the mean VAS core in Group C was 2.44 ± 1.19 and in Group F was 4±0; there was statistically significant difference in both groups ($p<0.05$). At 1080, 1200, 1320 minutes the mean VAS score between Clonidine and Fentanyl groups were statistically significant. Pain scores in Clonidine group is significantly lower compared to Fentanyl group reinforcing the higher analgesic quality of Clonidine. The cause being attributed to the stimulation of post synaptic α 2 receptors in substantia gelatinosa of the spinal cord.

The vital signs appear to be normal throughout the period of study which confirms the established effects of α2 agonists in accomplishing a hemodynamically stable postoperative period. Although a slight decrease in heart rate and blood pressure (both systolic and diastolic) was observed in both the groups, in both the groups, It never fell down to more than 20% baseline values.

SBP was significantly lower in Clondine group during multiple follow up times (720, 960, 1080 minutes). Mean SpO_2 was higher in Fentanyl group at 1320 minutes and 1440 minutes. All these findings were similar to Yoganarasimha et al and Bajwa et al.[18,19]

Hypotension were observed more in 16% of Clonidine group patients corrected with bolus of IV fluids and ephedrine. None of patients in either groups had excessive sedation, vomiting, pruritus, post dural headache or transient neurological symptoms at intra operative period or during postoperative follow up.

The postop hemodynamic variables between the groups were comparable and statistically significant. The results of our observations show that in addition to prolonged analgesia and less pain scores, Clonidine has a favourable safety profile and stable hemodynamics over Fentanyl, which correlates with the reports published by other authors.

All the above results conclude that that the addition of Clonidine to Bupivacaine epidurally lengthens motor and sensory block and analgesia, without an amplified frequency of side effects which was estimated by study done by Gupta et al.[20]

Conclusion

From this study, it is concluded that 2µg/ml of Clonidine was found to be a better adjuvant to epidural Bupivacaine (0, 25%) in postoperative analgesia. The postoperative analgesic effect as well as the arousal sedation was excellent with lowest side effects .The hemodynamic stability well maintained with Fentanyl.

Conflict of interest: None

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