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A Clinical Comparision – Between 0.125% Bupivacaine With Fentanyl-25µg And 0.0625% Bupivicaine With Fentanyl-25µg In Post-Operative Analgesia Through Epidural Route In Elderly Patients

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Abstract: *The pain in the postoperative period demands relief not only on humanitarian ground but also to reduce physical morbidity following the operation. In postoperative period when the effect of the anesthetic disappears, the tissue injury persists and pain producing substances which are liberated during the operation greatly reduce the normally high threshold of the nociceptors, so that innocuous stimulation produces pain. Moreover the cut ends of axons further contribute to nociception. A wide range of options exist to combat pain both pharmacologically and non-pharmacologically. However, despite the increasing complex armamentarium that we have at our disposal, the satisfactory alleviation of pain remains difficult goal. Thus the extent of our pharmacological alternatives is rather a reflection of our constant efforts to obtain more effective and safer analgesics.*

Hence forth the above study showed that low dose of Bupivacaine(0.0625%) almost equal to bupivacaine(0.125%) definitely improves the quality of analgesia by reducing the overall pain score, prolonging the duration of the need for first rescue analgesia and causing reduction of total analgesic consumption in the postoperative period without any hemodynamic instability.

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I. Introduction

The international Association for the study of pain defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage‖. The father of the field of pain management as we know it today was John. J. Bonica and he founded the international association for study of pain in 1974. Other than psychological trauma, pain is shown to affect the physiology of almost all the system including respiratory, cardiovascular and metabolic profile there by increasing the morbidity.[2] Regional anesthesia has lot of advantages compared to GA for lower limb surgeries.

A local anesthetic–opioid combination provides superior analgesia during peri-operative and postoperative period.[4]

This combination limits rapid regression of sensory blockade and possibly decreases the dose of local anesthetic administered. Analgesia provided by epidural opioids is superior to that with systemic opioids.[5]

Bupivacaine is a widely used drug in epidural anesthesia; it was first synthesized by Ekenstam in 1956 but was introduced in clinical practice by Telivuo and Widman 1963. It is a type of amide group of Local Anesthetic and characterized as pipecoloxylidedes as the molecule possess an asymmetric carbon atom.

Fentanyl is a phenylpiperidine-derivative synthetic opioid agonist; it is 75 to 100 times more potent than morphine.

II. Material And Methods

This is a **prospective, random, single blinded study** conducted at S.V. Medical College and Hospital, Tirupati. from August 2017 to August 2018. A total 60 adult subjects (both male and females) of aged ≥ 50, years were for in this study.

Study Design: P**rospective, random single blinded study**

Study Location: This was a tertiary care teaching hospital, S.V. Medical College and Hospital, Tirupati, Andhra Pradesh.

Study Duration: August 2017 to August 2018.

Sample size: 60 patients.

Sample size calculation: The sample size was estimated on the basis of a single proportion design. The target population from which we randomly selected our sample was considered 200. We assumed that the confidence interval of 10% and confidencelevel of 95%. The sample size actually obtained for this study was 96 patients for each group. We planned to include 60 patients (Group I- Control, Group II- Cases of 30 patients for each group) with 4% drop out rate.

Subjects & selection method: A prospective, randomized, single blinded study would be undertaken. 60 patients **posted and underwent surgery with Bupivacaine-17.5mg Heavy by spinal route** for lower limb surgeries under CSE anesthesia would be assigned to two groups, each containing 30 patients.
Group – Group A : Would receive 10ml bupivacaine 0.125% with Fentanyl-25 **µ**g
Group – Group B : Would receive 10ml of mixture of bupivacaine 0.0625% with Fentanyl-25 **µ**g
All the study drugs used were preservative free. 10ml solution for 'single shot' would be administered.

Inclusion criteria:
- Patients aged between 50-years & Above.
- Patients of either sex.
- Patients with ASA Grade I & II.
- All Patients posted for elective lower limb surgeries.

Exclusion criteria:
- Patients refusal
- Pregnant women.
- Patients with H/o Cardio-Respiratory disorders
- Patients with Hepatic and Renal diseases.
- Patients with H/o convulsions & neurological deficits.

Procedure methodology

After written informed consent was obtained, a well-designed questionnaire was used to collect the data of the recruited patients retrospectively. The questionnaire included socio-demographic characteristics such as age, gender, height, weight, and consanguineous marriage, physical activity and lifestyle habits like smoking and alcohol.

Preoperative assessment:
- Routine clinical examination, Biochemical investigations, Electrocardiogram and chest x-ray were examined thoroughly for the conduct of anesthesia.
Pre-anesthetic check up was done and informed about the procedure. Patients were fasted over night. IV line secured and patients would be connected to monitors to record pulse, O_2 saturation , NIBP and ECG.Premedication with inj. Midazolam 0.05mg/kg body weight before the procedure the surgery .

Conduct of anesthesia:

On arrival in the operating room, baseline cardio-respiratory parameters viz., Heart Rate(HR), Systolic blood pressure (SBP), Diastolic blood pressure(DBP),Mean arterial pressure (MAP) and Respiratory rate(RR) were recorded.
With the patient in sitting posture, after informing the procedure to the patient & under strict aseptic precautions, epidural space was identified at L3-L4 interspace using 17G Tuohyn needle by **loss of resistance technique to air and saline**.
The patients were given 17.5 mg of Heavy Bupivacaine through spinal needle in one space below(L4-5). The surgery was performed under Combined spinal epidural Anesthesia. Intra-operatively the patient was monitored with ECG, BP and SpO2.

POST- OPERATIVE MONITORING:The study starts in PACU

The epidural catheter was retained in position. Postoperatively the patient was transferred to the Post Anaesthetic Care Unit(PACU).
The appropriate drug given into epidural catheter after ascertaining it's position as mentioned below and studied the effects : (All the study drugs used were preservative free).
- Control group – Group A : ➔10ml bupivacaine 0.125% with Fentanyl-25 **µ**g
- Study group – Group B : ➔10ml of bupivacaine 0.0625% with Fentanyl-25 **µ**g

B*upivacaine—(0.5% plain without preservative)*
- *0.0625%- (1.25+8.75ml sterile water) 10 ml– 6.25mg==1/8th of usual dose*

- *0.125% - (2.5+7.5ml sterile water) 10ml—12.5mg==1/4th of usual dose*
- *Opioids — Fantanyl----25µg---1/4th of usual dose*

All patients were given oxygen supplementation (4-5 L/min) through Hudson's face mask. No intravenous opioid analgesics were supplemented during the study.

RAMSAY SEDATION SCALE:

1. Patient is anxious and agitated or restless, or both.
2. Patient is co-operative, oriented and tranquil.
3. Patient responds to commands only.
4. Patient exhibits brisk response to light glabellar tap or loud auditory stimulus.
5. Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus.
6. Patient exhibits no response.

The intensity of pain was measured by using the verbal rating pain scale.

Pain Score (Verbal Rating Score):

Grade 0 - No complaint of pain
Grade 1 - Patient complaints of pain but tolerable (mild pain)
Grade 2 - Patient complaining of severe pain and demands relief(Moderate pain)
Grade 3 - Patient restless and screaming with pain(Severe pain)

When the patient complained of pain , the pain intensity was assessed based on verbal rating scale & if pain score reaches 1.

The time of first rescue analgesia(TFA) was calculated from the time of injection of study drug in the epidural space to the time when the verbal rating pain score reached 1 in the post-operative period.

SENSORY BLOCK:

- Sensory block was assessed by alcohol swab / toothpick method
- The time from epidural injection to loss of sensation of alcohol swab / toothpick was taken as onset of sensory block
- Highest level of loss of sensation of alcohol swab / toothpick was taken as level of sensory block
- Time interval from onset of sensory block to first complain of pain was recorded as duration of analgesia.

Definitions:

Onset of sensory blockade: is taken as, the time taken from the completion of the injection of the study drug till the patient does not feel the pin prick at T_{12} level.

Time for maximum sensory blockade: is defined as, the time taken from the completion of the injection of the study drug to the maximum sensory blockade attained.

Onset of motor blockade: is defined as, time taken from the completion of the injection of study drug till the patient develops modified Bromage scale grade 1 motor blockade.

Time for maximum motor blockade: is defined as, time taken from the completion of the injection of the study drug to the maximum motor blockade attained.

Duration of motor block: is defined as, time taken from the time of injection till the patient attains complete motor recovery (Bromage 0).

Duration of analgesia: is defined as, time taken from the time of injection till the patient complains of pain at the site of surgery.

Vital parameters such as the heart rate, blood pressure, respiratory rate, and oxygen saturation were continuosly monitored for every 5 min for first 15min and every 15min throughout surgery during intra-operative period and every half an hour in the post-operative period for 2 hours.

Postoperatively complications, like nausea, vomiting, bradycardia, hypotension, respiratory depression and pruritus noted, treated and tabulated.

1) Duration of post-operative analgesia.
2) Quality of post-operative analgesia (VNS).
3) Hemodynamic monitoring (NIBP & HR).
4) The need for rescue analgesic supplementation.
5) Episodes of postoperative side effects such as hypotension (>30% of baseline or<100 SBP), bradycardia (>20% of base line or <50 BPM), desaturation (SpO2 <90%) and respiratory depression (<10 breaths per minute), pruritis, nausea vomiting, urinary retention noted and treated.

In every subject, a semi-quantitative food frequency questionnaire was administered to collect detailed information on dietary intake over the past year. Dietary fat and oil intake was assessed as the amount of fat/oil used during cooking and/or added at the table.

III. Result

A total of 60 patients of either sex randomly selected for the study. Statistical data was analysed using Microsoft Excell

- **Qualitative data will be analyzed Chi-square test** :A statistical method assessing the goodness of fit between a set of observed values and those expected theoretically (complications of epidural analgesia-hypotension, bradycardia, vomiting, motor blockade and urinary retention).
- **Quantitative data will be analyzed Student t-test** (Paired and unpaired t-test): Distribution under the null hypothesis
- A P value of < 0.05 significant <0.01 – Highly significant, <0.001 – Very highly significant, >0.05 not significant.

Table – 4: Group-A: 0.125% bupivacaine with 25mcg of Fentanyl

No. of patients	Age (in yrs)	Weight (kgs)	No. of male patients	No. of female patients
30	50 & above	46-72	19	11
Mean	53.77	57.90	63.3	36.7

Table – 5: Group B: 0.0625% bupivacaine with 25mcg of fentanyl

No. of patients	Age (in yrs)	Weight (kgs)	No. of male patients	No. of female patients
30	50 & above	45-74	23	7
Mean	69.43	56.56	76.6	23.3

Table 6: AGE DISTRIBUTION

AGE	Group A	Group B
51-60	3	5
61-70	6	13
71-80	14	9
81-90	7	3

Table 7: SEX DISTRIBUTION

GENDER	Group A	Group B
Male	19	23
Female	11	7

Table 8: WEIGHT DISTRIBUTION

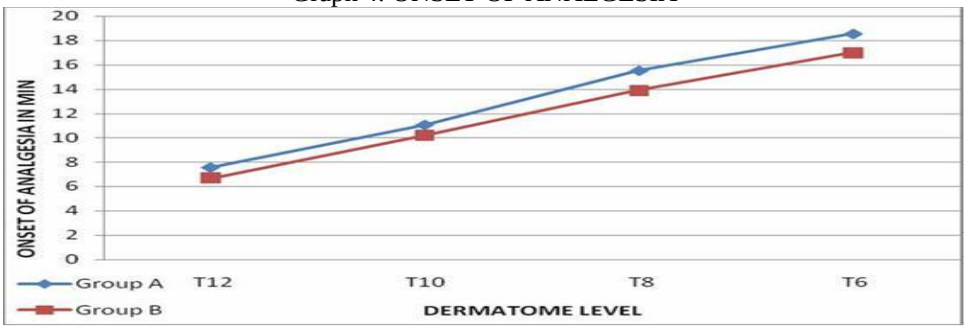
Groups	Weight in Kgs
Group A	57.9
Group B	56.56

Table 9: ONSET OF ANALGESIA

	ONSET OF ANALGESIA					
DERMATOME LEVEL	GROUP B (in min)	SD	GROUP A (in min)	SD	t	Significance
T12	7.56	3.11	6.66	2.44	1.246	

T10	11.06	3.08	10.20	2.80	1.138	P>O.O5 (NOT SIGNIFICANT)
T8						
	15.51	3.14	13.88	3.20	1.940	
T_6	18.54	2.76	17.00	3.19	1.101	

Graph 4: ONSET OF ANALGESIA



SD: Standard Deviation - It is observed that onset of analgesia in Group-A (0.125% bupivacaine + 25mcg Fentanyl) was 7.56 min. When compared to Group-B (0.0625% bupivacaine + 25 mcg fentanyl) which was 6.6 min, which is statistically insignificant (P<0.05). It shows that there was no difference in the onset of action.

TABLE 10: BROMAGE SCALE

MOTOR BLOCKADE						Significance
BROMAGE SCALE	GROUP A (in min)	SD	GROUP B (in min)	SD	t	
0	6.1	2.6	0	0	0	P> 0.05 NS
1	10.3	2.84	0	0		
2	13.83	2.78	0	0		
3	18.9	3.55	0	0		

NS –Not significant

The onset of motor blockade, degree and time required to achieve complete blockade were recorded. The degree of motor blockade was graded according to modified Bromage scale.

The mean time to achieve complete motor blockade was 18.9 min in group A and 18.63 in group B which was statically insignificant in both the groups.

Table 11: MEAN PULSE RATE OF GROUP A AT DIFFERENT TIME INTERVALS

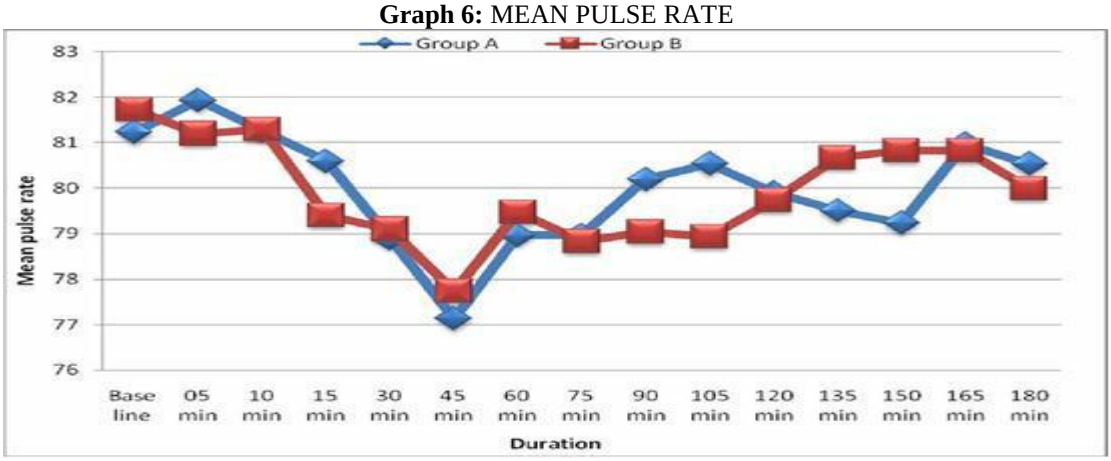
TIME INTERVALS	PULSE RATE	
	MEAN	SD
Base line	81.2333	8.98
05 min	82.9333	8.54
10 min	83.2667	7.81
15 min	80.6	7.10

30 min	78.9	7.07
45 min	77.1333	7.55
60 min	78.9667	5.01
75 min	78.9667	5.13
90 min	81.2	4.51
105 min	80.5333	3.91
120 min	79.9	4.14
135 min	79.5	4.65
150 min	78.2333	5.51
165 min	77.9667	5.03
180 min	77.5333	4.82

Table 12: MEAN PULSE RATE OF GROUP B AT DIFFERENT TIME INTERVALS

TIME INTERVALS	PULSE RATE	
	MEAN	SD
Base line	81.7333	9.33
05 min	81.2	9.14
10 min	82.3	8.62
15 min	79.4	7.62
30 min	79.1	6.789
45 min	77.73	6.71
60 min	79.46	6.39
75 min	78.83	6.04
90 min	79.03	5.48
105 min	78.93	5.33
120 min	79.73	5.72
135 min	81.66	6.74
150 min	81.83	6.51
165 min	80.83	5.79
180 min	80	4.82

Graph 6: MEAN PULSE RATE



Not Significant, HS: Highly Significant, S: Significant

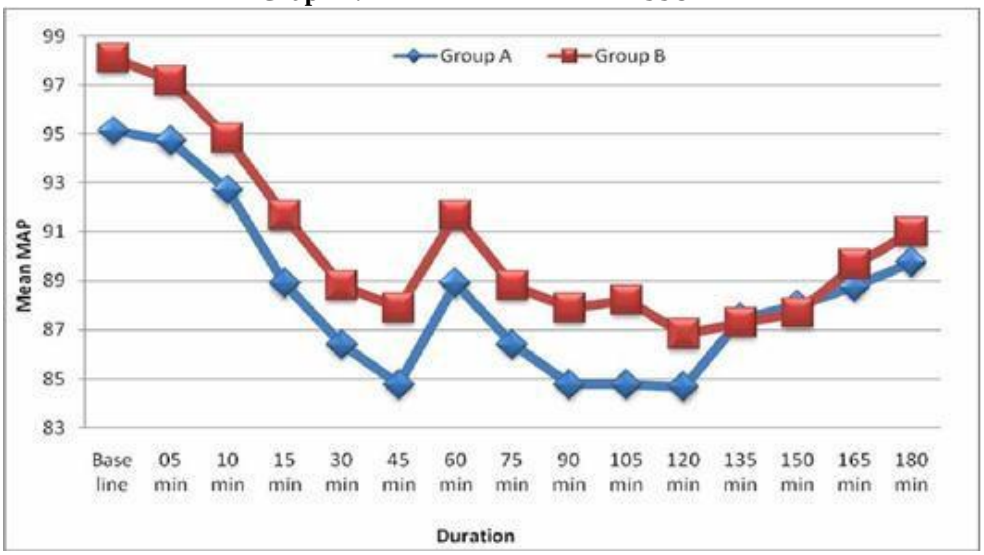
F_{Change} = 5.094 P>0.05 insignificant $F_{Change \times groups}$ = 2.156 P>0.05 insignificant

Variation of pulse rate in group -A and group -B was studied at different time intervals upto 3 hrs. There was moderate change in the pulse rate in 30 min and 45 min in the both the groups which was statically insignificant.

Table 13: MEAN OF MEAN ARTERIAL PRESSURE IN BETWEEN GROUP-A AND GROUP-B AT DIFFERENT TIME INTERVALS

TIME INTERVALS	MAP			
	Group A		Group B	
	MEAN	SD	MEAN	SD
Base line	95.13	6.92	98.1	5.10
05 min	94.73	6.98	97.2	5.25
10 min	92.7	7.64	94.83	6.04
15 min	88.9	7.16	91.66	5.63
30 min	86.4	6.68	88.8	6.01
45 min	84.76	6.00	87.9	4.53
60 min	88.9	7.16	91.66	5.63
75 min	86.4	6.68	88.8	6.01
90 min	84.76	6.00	87.9	4.53
105 min	84.76	5.94	88.2	4.29
120 min	84.66	6.36	86.83	4.19
135 min	87.46	6.16	87.3	4.92
150 min	88	7.16	87.7	5.12
165 min	88.76	7.06	89.66	4.55
1801 min	89.76	8.05	91	5.87

Graph 7: MEAN ARTERIAL PRESSURE



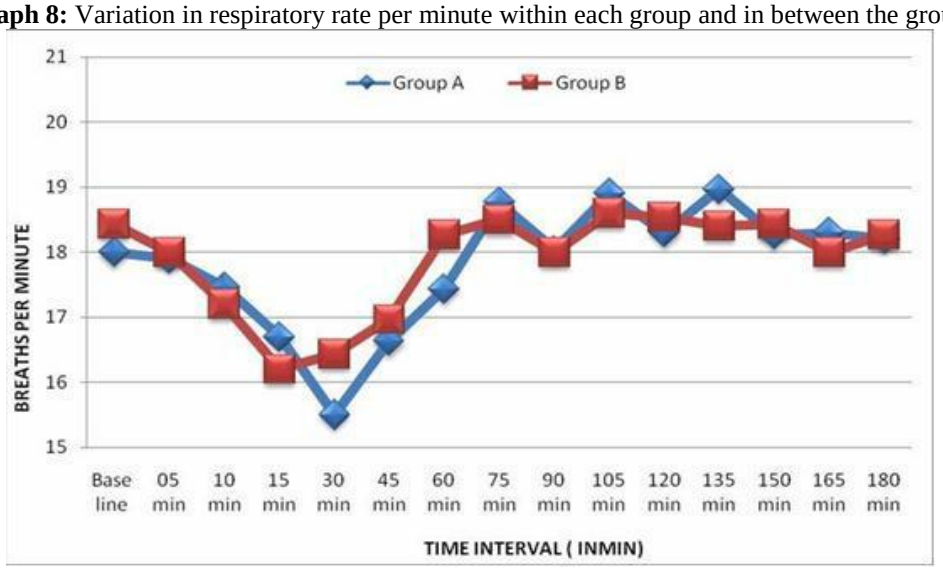
F_{Change} = 35.694 P>0.05 insignificant $F_{Change\ x\ groups}$ = 0.993 P>0.05 insignificant

It can be seen from the table no. 10 that change in MAP was not significant at any time interval in between the two groups.

Table 14: Variation in respiratory rate per minute within each group and in between the groups

TIME INTERVALS	MAP			
	Group A		Group B	
	MEAN	SD	MEAN	SD
Base line	18	1.525	18.4333	2.523
05 min	17.9	1.843	18	1.29
10 min	17.4667	1.32	17.2	0.996
15 min	16.7	1.342	16.2	1.381
30 min	15.5	1.27	16.4333	1.381
45 min	16.6333	1.496	16.9667	1.3767
60 min	17.4333	1.381	18.2667	1.229
75 min	18.7667	1.165	18.5	1.252
90 min	18.0333	1.629	18	1.14
105 min	18.9	1.061	18.6	0.968
120 min	18.3	1.087	18.5333	1.166
135 min	18.9667	0.889	18.4	1.003
150 min	18.2667	0.827	18.4333	0.817
165 min	18.3	0.915	18	1.033
180 min	18.2	0.761	18.2667	0.944

Graph 8: Variation in respiratory rate per minute within each group and in between the groups



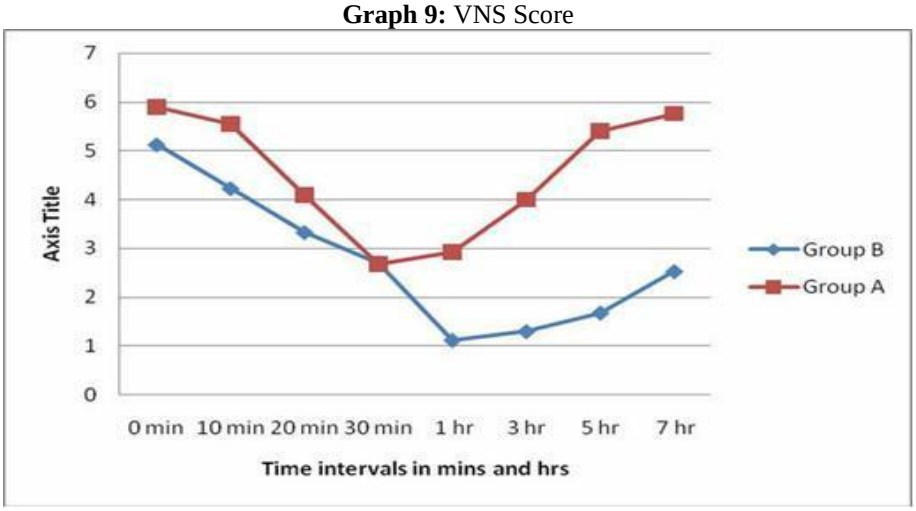
F_{Change} = 0.943 P>0.05 insignificant
$F_{Change\ x\ groups}$ = 1.182 P>0.05 insignificant

It can be seen from the table no.14 there was significant change in respiratory rate in between two groups at 10, 15, 30 min. This was due to the respiratory depressant action of both the drugs which was statically insignificant in both the groups.

Table 15: V N S Score

Time Intervals	Group A		Group B		t	Significance
	Mean	SD	Mean	SD		
0 min	5.13	0.63	5.9	0.88	-	-
10 min	4.23	0.72	5.55	0.65	4.78	P < 0.05 S
20 min	3.33	0.63	4.10	0.92	0.0006	P > 0.05 NS
30 min	2.7	0.89	2.68	0.855	0.941	P > 0.05 NS
1 hr	1.12	0.715	2.93	0.45	5.17	P < 0.05 S
3 hr	1.3	0.59	4.0	0.91	1.09	P > 0.05 NS
5 hr	1.68	0.61	5.4	0.56	2.49	P > 0.05 NS
7 hr	2.53	0.75	5.76	0.50	3.45	P > 0.05 NS

Graph 9: VNS Score



As seen from table 16 pain score (VNS) was compared between the two groups at different time interval for the first 7 hrs. It was found that VNS was significant at 20 min and 1 hr. This was due to the reduce VNS in group A when compared to group B.

TABLE 16: MEAN DURATION OF ANALGESIA

	NO OF PATIENTS	MEAN DURATION (inmin)	SD	t	SIGNIFICANCE
GROUP A	30	766.6	169.67	7.178	P<0.05 S
GROUP B	30	471	148.68		

SD: Standard Deviation, S: Significant

Graph 10: MEANDURATION OF ANALGESIA

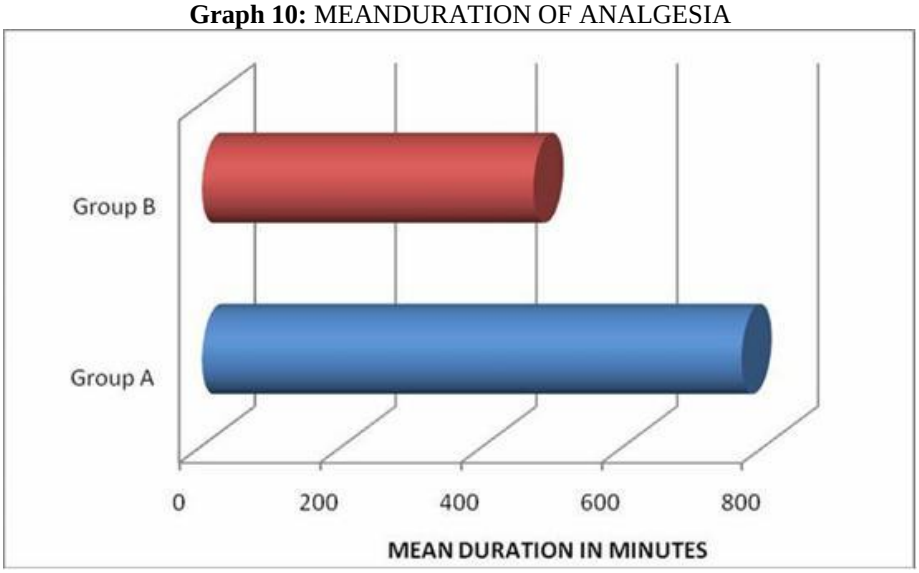


Table 17: SIDE EFFECTS

The incidence of side effects like nausea, vomiting, urinary retention, pruritus and hypotension was studied and results were as shown in the table.

SIDE EFFECTS	GROUP- A		GROUP- B	
	NO	%	NO	%
MOTOR BLOCKADE	9	30	Nil	nil
VOMITING	3	10	nil	nil
URINARY RETENSION	2	10	nil	nil
BRADYCARDIA	18	60	nil	nil
HYPOTENSION	18	60	nil	nil

IV. Discussion

Pain is a more terrible lord of mankind than death itself. Pain is a complex subjective experience, which has proved difficult to measure in reproducible way.[6] Pain perception can be sensory discriminative aspect that describes the location and quality of the stimulus called fast pain and motivational affective portion that leads to aversive aspect of pain, also known as slow pain. Satisfactory pain relief has always been a difficult problem in clinical practice.[5] It is found that post-operative pain is more severe after surgery and thereafter gradually diminishes over the next 24 hours. Existence of pain has been a constant stimulus to the discovery of both drugs and procedures for relief of pain.[7]

The pain in the postoperative period demands relief not only on humanitarian ground but also to reduce physical morbidity following the operation. In postoperative period when the effect of the anesthetic disappears, the tissue injury persists and pain producing substances which are liberated during the operation greatly reduce the normally high threshold of the nociceptors, so that innocuous stimulation produces pain. Moreover the cut ends of axons further contribute to nociception. A wide range of options exist to combat pain both pharmacologically and non-pharmacologically. However, despite the increasing complex armamentarium that we have at our disposal, the satisfactory alleviation of pain remains difficult goal. Thus the extent of our pharmacological alternatives is rather a reflection of our constant efforts to obtain more effective and safer analgesics.

A multimodal approach is recommended for post-operative pain management.

This usually consists of regional analgesic techniques, opioids, non-steroidal anti-inflammatory agents and paracetamol. All anesthesiologists at our hospital used multimodal analgesia for major abdominal surgeries; paracetamol being the most commonly used co-analgesic. The rationale for using multimodal analgesia is the achievement of effective analgesia with the additive or synergistic effects of different classes of analgesic agents with reduced doses of individual drugs and a decreased incidence of side-effects, improved recovery, shorter hospitalization times and better patient satisfaction.

V. Conclusion

This study entitled **"clinical study between post operative analgesia with different doses especially low dose of bupivacaine for postoperative pain relief in elderly persons undergoing lower limb surgeries"** was conducted to compare the effects of bupivacaine with fixed dose of Fentanyl as a single shot epidural block. Sixty persons of ASA grade I and II in the age group of 50 years and above coming for various lower limb surgeries were studied. They were randomly divided into 2 groups of 30 each.

Group A had the bupivacaine 0.125% (10ml-Single shot epidural). Group B had the with bupivacaine 0.0625% (10ml-Single shot epidural). The main parameters studied were hemodynamic changes, extent of postoperative analgesia and incidence of side- effects.

This randomized control study was designed to evaluate the analgesic efficacy of bupivacaine with Fentanyl mixture given through lumbar epidural route for postoperative analgesia in patients undergoing elective orthopaedic lower limb surgeries and the quality of analgesia was compared with epidural 0.125% bupivacaine.

Sixty ASA I & II patients undergoing elective orthopaedic lower limb surgical procedure under epidural anesthesia were randomly allocated into one of the two groups.

There was no complication encountered in technical skills in all sixty patients. Pain in the post-operative period was assessed using a verbal rating scale(VRS).

Time of first rescue analgesic(TFA) and the supplementary analgesic doses required for 48 hours were noted for the two groups. Pain score were significantly less in Group B at 2,4, hours (P <0.05) almost equal in group A. Overall pain score over 48 hours period also revealed better pain relief in group B (P<0.05) as compared to Group A. Time of first rescue analgesic (TFA) in group B was significantly prolonged as equally as with group A . The postoperative analgesic consumption was also significantly less in group B as well as in group A. The incidence of hypotension differ significantly between the two groups & there was no bradycardia in the group-B.

So this study demonstrates that low dose of Bupivacaine(0.0625%) almost equal to bupivacaine(0.125%) definitely improves the quality of analgesia by reducing the overall pain score, prolonging the duration of the need for first rescue analgesia and causing reduction of total analgesic consumption in the postoperative period without any hemodynamic instability.

Un wanted Effects:

The four classic side effects of neuraxial opioids are Pruritus, Nausea and vomiting, Urinary retention and Depression of ventilation. Side effects are caused by the presence of drug either in CSF or systemic circulation. Most side effects are dose dependant.

Opioids produce nausea and vomiting by direct stimulation of CTZ in the area postrema of the medulla. The effect is dose related and tolerance to it develops rapidly. The emetic effect can be treated by anticholinergic and phenothiazines, especially those which are antagonists at dopamine receptors.

Pruritus is the most common side effect with neuraxial opioids.

It may be generalized but is more likely to be localized to the face, neck, or upper thorax. Incidence varies widely; severe pruritus is rare and more common in obstetric patients.

Although opioids may liberate the release of histamine from mast cells, this does not appear to be the mechanism, instead pruritus is likely due to cephalad migration of the opioids in CSF and subsequent interaction with opioid receptors in trigeminal nucleus. An opioid antagonist naloxone is effective in relieving opioid induced pruritus.

Urinary retention is due to interaction of the opioid with opioid receptors located in the sacral spinal cord. This interaction promotes inhibition of sacral parasympathetic nervous system outflow, which causes detrusor muscle relaxation and an increase in maximum bladder capacity, leading to urinary retention. Nalaxone antagonizes these effects, promoting an increase in detrusor contractility, with a reduction in functional bladder capacity.

The patients were observed for side effects like nausea and vomiting, sedation, urinary retention, pruritus and hypotension in both the groups.

Nausea and vomiting

In this study 3 patients (10%) developed nausea and 3 patients (10%) had vomiting in group A and the group B - none of them developed nausea with no vomiting.

Urinary Retention:

In this study 2 patients (10%) developed in group A and the group B -none of them developed.

Bradycardia:

In this study18 patients (60%) developed in group A and the group B -none of them developed.

Hypotension:

In this study18 patients (60%) developed in group A and the group B -none of them developed.

Sedation:Patients were comfortable and and did not require any further medication in either of the groups.

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