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A COMPARATIVE STUDY BETWEEN EPIDURAL 0.5% BUPIVACAINE WITH NALBUPHINE AND EPIDURAL 0.5% BUPIVACAINE WITH FENTANYL IN LOWER ABDOMINAL AND LOWER LIMB SURGERIES"

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ABSTRACT **Aim:** To compare the effects of Epidural 0.5% Bupivacaine with Nalbuphine and 0.5% Bupivacaine with Fentanyl in lower abdominal and lower limb surgeries. **Introduction:** Epidural analgesia is the gold standard technique for providing postoperative analgesia, local anaesthetic medications along with opiods as an adjuvant for epidural analgesia were effective and had various benefits over conventional, intermittent IM/IV administered medications, as they have fewer respiratory complications. **Materials And Methods:** A prospective, randomised single-blinded study was undertaken in patients posted for lower abdominal and lower limb surgeries. 100 patients aged 20-60 years with ASA class I and II were randomly grouped into two groups, Group N(Epidural bupivacaine+Nalbuphine) and Group F(Epidural bupivacaine+Fentanyl) with 50 patients in each group. **Results:** There was statistically significant difference in the onset of sensory and motor block, mean duration of analgesia, level of highest sensory block achieved, time to achieve two segment regression, VAS score ,side effects among two groups with Group N showing superiority over Group F. **Conclusion:** Epidural Nalbuphine with 0.5% Bupivacaine significantly prolongs the total duration of analgesia with lesser requirement for rescue analgesic, less time for onset of sensory and motor block when compared to Epidural Fentanyl with 0.5%bupivacaine.

KEYWORDS : Nalbuphine, Fentanyl, Bupivacaine, Post operative analgesia

INTRODUCTION

Epidural anaesthesia is a technique commonly used to provide relief from perioperative pain. It is most commonly used as an adjuvant for pain management. It can be given as a single shot or a continuous infusion for prolonged pain relief. Apart from providing excellent analgesia, its use decreases exposure to other anaesthetic medications and analgesics, reducing the incidence of side effects. It also reduces cortisol levels, helps in quick recovery of bowel function, reduces the incidence of pulmonary embolism (PE) and Deep Vein Thrombosis (DVT) during the postoperative period, and decreases the length of in-hospital stay.

Epidural analgesia is the gold standard technique for providing postoperative analgesia in lower abdominal and lower limb surgeries. Local anaesthetic medications along with opioids, as an adjuvant for epidural analgesia, were effective. Epidural opioids have various benefits over conventional, intermittent IV/IM administrated medications, as patients will have fewer respiratory complications. Also, patients can be mobilized earlier during the post-operative (PO) period.

AIMS AND OBJECTIVES

To evaluate the efficacy and compare onset of sensory and motor blockade ,highest level sensory blockade achieved ,duration of analgesia, time for two segment regression, side effects ,VAS scores, bromage scale ,requirement of rescue analgesic among two groups undergoing lower abdominal and lower limb surgeries.

MATERIALS & METHODS

Study Design: A prospective randomized single blind study

Method Of Data Collection: The data will be collected in the pre-tested proforma consisting of age, sex, and weight meeting the objectives of the study.

Study Population: Adult patients with ASA PS I & II patients aged 20-60 years posted for lower abdominal and lower limb surgeries.

Sample size: 100 patients in the department of anaesthesiology at Santhiram Medical College and General Hospital,Nandyal for a duration of 6 months (July 2023- December 2023)

Sampling criteria:

Inclusion Criteria

- Patients with ASA class I and II
- Patients aged between 20 to 60 years undergoing infraumbilical surgeries under epidural anaesthesia
- Males and females
- Patients who gave written informed consent.

Exclusion Criteria

- Patients belonging to ASA III and IV.
- Patients who have not given written informed consent.
- Patients with incomplete data
- Known case of hypersensitive reaction to any of the drugs used
- Patients with abnormal BT, CT or on anticoagulation therapy.
- Local infection at the site of proposed puncture

Statistical Analysis:

Data was collected and entered into Microsoft Excel 2019 and analysed using Microsoft excel 2019 and statistical software called Epi info version 7.2.5 free version. Quantitative data was analysed by using the student 't' test. Qualitative data was analysed using the chi-square test. A p-value of less than 0.05 was considered statistically significant.

METHODOLOGY:

After getting approval from the institutional ethics committee, this study was conducted, assurance was provided regarding the maintenance of confidentiality ,thorough history from every patient was taken. Personal and family histories were elicited, details on previous allergies, drug histories were noted, Clinical examination findings were noted, demographics like age, gender, occupation were recorded. Data was entered in a case record form designed for the study and it was subjected to statistical analysis. All the patients were asked to fast for at least six hours before the surgery. In the surgery room, we monitored for patient's electrocardiograph (ECG), heart rate, oxygen saturation (SpO2) and blood pressure. Premedication with Alprazolam 0.5mg is given one night before surgery. After shifting the patient to the operation theatre (OT), monitors were connected, and IV line was secured. Intravenous paracetamol is used as a rescue analgesia depending on the visual analogue scale (VAS) pain score .Hypotension or low BP was treated with Mephentermine 6 mg IV, Bradycardia was treated with injection Atropine 0.6 mg IV. We observed all patients for next the 24 hours for side effects like hypotension, nausea, vomiting, respiratory depression bradycardia, and managed them accordingly.

Groups: Patients were randomised into two groups Group N and Group F.

Group N included 50 patients who received Epidural Bupivacaine with Nalbuphine and Group F included 50 patients who received Epidural Bupivacaine with Fentanyl. Patients were divided into two groups by randomization during computer software.

RESULTS:

There were statistically no significant difference between mean age, weight, gender and ASA grading(**(Table-1)** and types of surgeries performed in both groups **(Table-2),** Time of onset of sensory blockade ,motor blockade **(Table-3)** and highest level of sensory block achieved **(Table-4)**,duration of analgesia **(Table-5)** are statistically significant ($p<0.05$), There is significant difference in time to achieve two segment regression**(Table-6)** incidence and types of side effects seen in both groups**(Table-7)** ,as per chi-square analysis($p=0.000$). There is significant difference in VAS scores in both groups **(Table-8)** as per T test ($p=0.00$), There is no significant difference in the modified Bromage grade between both groups **(Table-9)**, as per T-test($p=0.2$), more patients from Group F required rescue analgesia in post operative period **(Table-10).**

Table-1 : Comparision Of Demographic Data In Both Groups

Demographic Parameters		Group N(n=50)	Group F(n=50)	P value
Age in years (Mean ±S.D)		43.1 ± 10.92	41.36±8.66	0.37
Weight in kg (Mean±S.D)		63.66±9.67	63.3±11.4	0.86
Sex	Male	21(42%)	18(36%)	0.53
	Female	29(58%)	32(64%)	0.53
ASA	Grade 1	31(62%)	26(52%)	0.31
	Grade 2	19(38%)	24(48%)	0.31

Table 2: Comparision Of Surgeries Among Two Groups

Type of surgery	Group N		Group F	
	Frequency	Percentage	Frequency	Percentage
Appendicectomy	4	8%	3	6%
Below knee amputation	3	6%	7	14%
Herniorrhaphy/ plasty	28	56%	25	50%
Hysterectomy	3	6%	0	0%
Varicose veins	6	12%	10	20%
Others	6	12%	5	10%
Total	50	100	50	100

Table -3: Onset Of Sensory And Motor Blockade Between Two Groups

		Mean	S.D	P-value
Onset of sensory blockade	Group N	192.4200	8.4999	0.00
	Group F	258.3400	23.7415	
Onset of motor blockade	Group N	14.5800	4.0360	0.00
	Group F	18.1600	0.7384	

Table 4- Highest Level Of Sensory Blockade Achieved

	Group		
Highest sensory block achieved	F	N	Total
T4	28	14	42
T5	13	21	34
T6	9	15	24
TOTAL	50	50	100

Single Table Analysis

Chi-squared	df	probability
8.049	2	0.0179

Table- 5 : Duration of Analgesia

Duration of Analgesia	Group N(Mean±S.D)	Group F(Mean±S.D)	P value
	66.92±2.96	62.50±2.375	0.000

Table 6: Time To Achieve Two Segment Regression

Time to achieve two segment regression	Group N(Mean±S.D)	Group F(Mean±S.D)	P value
	52.7400±1.6637	57.2000±1.9166	0.000

Table 7 : Side Effects In Both The Groups

Chi-squared	df	probability
22.871	7	0.0018

Table 8: VAS Score

VAS score	Group N(Mean±S.D)	Group F(Mean±S.D)	P value
	4.700±0.7354	5.700±0.7354	0.000

Table 9: Modified Bromage Scale Grade:

Bromage scale grade	Group N(Mean±S.D)	Group F(Mean±S.D)	P value
	1.8000±0.7284	1.9600±0.7814	0.2922

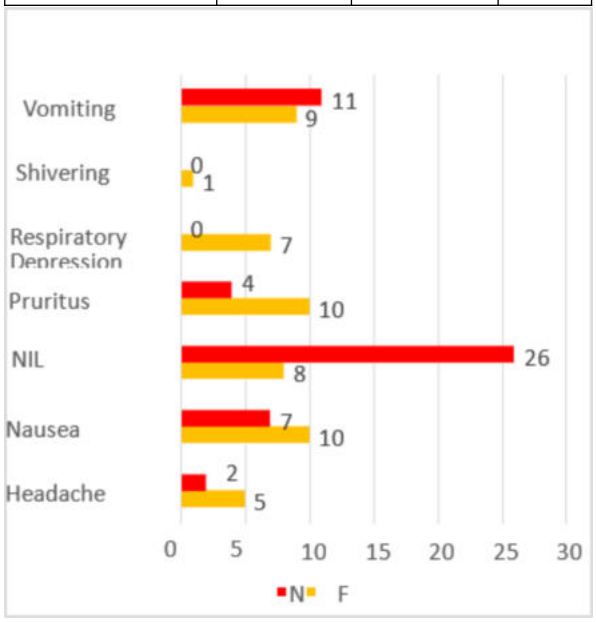

Figure 1: Side Effects In Both Groups

Table-10 : Need For Rescue Analgesia During Post Operative Period

	Group		
Rescue PO	F	N	Total
No	42	47	89
Yes	8	3	11
Total	50	50	100

DISCUSSION:

In the current study, 100 patients who were undergoing lower limb and lower abdominal surgeries were included, There is no significant difference in the mean age between two groups,61% (most) of the patients were females,39% were males. 57 patients belonged to ASA Grade I and 43 belonged to ASA Grade II. There is no significant difference in the body weight among patients belonging to groups N and F. The most common surgery done was herniorrhaphy or plasty done in 53 patients. There is a significant difference in the mean duration of analgesia in both the groups. The mean duration of analgesia in the Fentanyl group was 62.5 min and in the nalbuphine group was 66.9 min . **Verma**[38] *et al*. in their study found that PO analgesia was improved significantly by adding nalbuphine.

There is a significant variation in the onset of sensory block, as per the T-test ($p=0.000$). The mean onset of sensory block in the nalbuphine group was 192 seconds and in the fentanyl group was 292 seconds . There is a significant variation in the onset of motor block, as per the T-test ($p=0.000$). The mean onset of motor block in the nalbuphine group was 14.5 min and in fentanyl group was 18 min in the current study. This indicates that nalbuphine acts quickly compared to fentanyl. In the study done by **Borah TJ**[40]the authors assessed the effect of combining nalbuphine with ropivacaine and ropivacaine with normal saline,results obtained were in contrast to current study.

Headache, nausea, and pruritus were commonly seen in the fentanyl group compared to the nalbuphine group, respiratory depression and shivering were seen only in the fentanyl group.34 patients had no side effects. Among them, 26 belonged to the nalbuphine group. It was less in fentanyl group In the study done by **Sharma Ankit**[27], there is no incidence of pruritus, respiratory depression, headache, bradycardia or excessive sedation in nalbuphine or fentanyl groups and other side effects were similar to our current study.

Group F had higher VAS scores indicating pain is least with Nalbuphine group. In the study done by **Umesh**[41], the mean PO VAS score was 4.8 ± 1.12 in the Group bupivacaine nalbuphine, and in the bupivacaine fentanyl group, it was 3.86 ± 1.04.This indicates that pain was more in the nalbuphine group compared to the fentanyl group, which is in contrast to the current study findings.

There is no significant difference in the modified Bromage grade between both groups. There is significant difference between the time

to achieve two segment regression between both the groups less with nalbuphine compared to fentanyl. In the study done by **Shagufta[42],** 90 patients who were scheduled for lower limb surgeries were included. Time of two segment sensory regression were found to be comparable between groups nalbuphine and fentanyl and it was significantly less (p=0.03) in nalbuphine group when compared to the fentanyl group similar to our study. Analgesic requirement was significantly more in fentanyl group compared to nalbuphine group. In the current study also, more patients in fentanyl group required rescue analgesia compared to nalbuphine group. Side effects are least with nalbuphine group, similar to the current study.

CONCLUSION:

Side effects were more with fentanyl compared with nalbuphine when given by epidural route, combined with 0.5% bupivacaine which indicates that nalbuphine is safer than fentanyl.The mean duration of analgesia is more with nalbuphine, onset of sensory and motor blocks was less with nalbuphine and VAS score was less with nalbuphine. This shows that nalbuphine was superior in efficacy compared to fentanyl.

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