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COMPARATIVE STUDY OF DIFFERENT DOSES OF EPIDURAL BUTORPHANOL FOR POSTOPERATIVE ANALGESIA IN ORTHOPAEDIC PATIENTS

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ABSTRACT

Introduction: Previously studied epidural narcotic agonist such as fentanyl and morphine are capable of producing post-operative analgesia with undesirable side effects such as pruritis, nausea and respiratory depression that have limited their use. The objective of our study was to compare the duration and quality of postoperative analgesia offered by two different doses of epidural butorphanol.

Methods: Our study comprised of Group A & B of 30 patients each, receiving 1mg & 2mg of butorphanolrespectively, diluted upto 10ml of normal saline and given by epidural catheter.

Results: The study was a prospective randomized double blind study.In bothgroups A & B, epidural butorphanol in doses of 1mg and 2mg, both provided good quality of postoperative analgesia as determined by the Visual Analogue Scale scores in the postoperative period.

Conclusion: The duration of postoperative analgesia provided by 2mg of epidural butorphanol is slightly longer than that provided by 1mg, but the difference is statistically not significant.

Keywords: Pain, Epidural Butorphanol, Postoperative analgesia, Orthopaedic, Visual Analog Scale (VAS) score, Hemodynamic effects, Sedation

INTRODUCTION

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage as defined by the International Association for Study of Pain.

Surgical trauma causes severe tissue damage.Intra-operative and postoperative pain management should be an essential and integral part of the care given to the patient. Severity of postoperative pain varies with site of operation, age, sex, premedication employed, anaesthetic agent used, psychological makeup of the patient and quality of postoperative care given.

Attenuation of postoperative pain, especially using certain type of analgesic regimens may decrease peri-operative morbidity and mortality.

Anaesthesia administered for orthopaedic lower limb surgery is quite frequent and a routine practice for anesthesiologist.The importance of such intervention and effective pain control for ambulation of operated patients is essential.

Epidural anaesthesia, has become a safe technique with advancement in procedures as well as in equipments (needle, catheter) etc. It is particularly

preferred to administer intraspinal or epidural narcotic along with local anaesthetic. The addition of opioid to an epidurally administered local anaesthetic has been suggested to improve the quality of analgesia provided by a local anaesthetic like bupivacaine alone.

A drug such as butorphanol a mu-agonist / antagonist and S / K agonist might be expected to be useful in the management of post-operative pain. Our aim was to study and compare the duration of postoperative analgesia offered by two different doses (1mg and 2mg) of epidurally administered butorphanol; to compare the hemodynamic changes & the incidence of side effects of two different doses of epidural butorphanol. And our objective was to compare the duration and quality of postoperative analgesia offered by two different doses of epidural butorphanol.

MATERIALS AND METHODS

The study was a prospective randomized double blind study conducted in orthopaedic operation theatre ofGrant Medical College, Mumbai. It comprised of 60 patients, aged 20- 70 years, of either sex and of ASA grade I and II posted for elective orthopaedic surgery of lower limb and hip.

Patients were evaluated preoperatively. Detailed history was taken and the procedure of spinal/ epidural and visual analogue scale was explained to the patients. Thorough physical examination was carried out. Patients' height and weight were recorded.All routine investigations such ashaemoglobin, complete blood count, blood sugar, kidney and liver function tests, coagulation profile, Echocardiography (ECG) and Chest X-ray were done. The study was approved by the Ethical committee &a written valid informed consent was taken from all the patients.

Patients with ASA grade III, IV,V; those with age <20 years or >70 years; those with co-existing systemic diseases like Hypertension, Asthma, Diabetes, Heart disease, renal and hepatic diseases, and psychiatric diseases; those undergoing surgery with operative time more than 3 hours; and uncooperative patients were excluded from the study.

Baseline pulse rate, blood pressure, respiratory rate and oxygen saturation were recorded. Intravenous access with 18 gauge cannula was established.Preloading was done with Ringer lactate at the rate of 10 ml/ kg.

Under all aseptic precautions epidural catheter was inserted through 16 G epidural needle at L3-L4 / L4 - L5 space and spinal anaesthesia was given with 3 ml of 0.5% heavy bupivacaine one space below (i.e. two level spinal – epidural) in sitting position.Patients were made to lie supine on the table. The sensory level by pin prick, Bromage scale and subjective pain score were recorded.

Intraoperative pulse rate, blood pressure, respiratory rate and oxygen saturation were recorded for every 2minutes for first 10minutes and every 10 minutes for next 20minutes and there after every 30minutes. Also intravenous fluids, blood given were recorded. On completion of surgery duration of surgery were evaluated.

Postoperatively the patients were observed in the recovery room. Patients complaining of discomfort or pain (Visual Analog Scale score of 1) were administered study drug.

GROUP A: 30 Patients receiving 1mg of butorphanol diluted upto 10 ml of Normal saline and given by epidural catheter.

GROUP B: 30 Patients receiving 2mg of butorphanol diluted upto 10 ml of normal saline given by epidural catheter for pain relief.

The patients were observed in the recovery room and later in their respective wards for 8 hours with written instructions to withhold any analgesic or sedative.

The patients were monitored for Pulse rate, Blood pressure (Systolic and Diastolic), Oxygen saturation (SpO2), Respiratory rate & Duration of analgesia.

Patients were assessed for pain by 0 – 10 cm linear Visual Analogue Scale (VAS). It is a 10 cm long

scale of which 0 end is marked as no pain while other end as worst possible pain. The patients were asked to point out the intensity of pain as experienced by them on the scale.

Duration of postoperative analgesia was calculated from the time of first dose of epidural Butorphanol to the time upto when patient again experienced pain (i.e. VAS score of 1).

Rescue analgesia was given in the form of 75 mg of Diclofenac Sodium given intramuscularly whenever the patients experienced visual analogue pain score ≥ 4.

The following parameters were noted in the postoperative period.

1. Pain score and duration of analgesia.
2. Vital parameters like pulse rate, systolic and diastolic blood pressure, respiratory rate and oxygen saturation.
3. Side effects like nausea, vomiting, pruritis, respiratory depression and urinary retention.

Patients were also observed post operatively for sedation caused by epidural Butorphanol for 8 hours by simple sedation score.

Sedation Scores

0 = Alert, conversant; 1 = mildly sedated; 2 = moderately sedated and drowsy; 3 = Asleep but arousal; 4 = Asleep and not arousal

At the end of study, all data were compiled and analyzed statistically using paired and unpaired statistical difference between the two groups. A P value of <0.05 was taken as statistically significant.

RESULTS

Demographic data in both the groups was comparable (Table 1).

The mean duration of analgesia was calculated from the time of first dose of epidural butorphanol to the time when patient experienced pain i.e.VAS score of 1. In group A, it was 187 ± 29.14and in group B, it was 201± 33.56 minutes. The difference between the two was statistically not significant (Table 2).

At the end of 2hours 30minutes, the number of patients who were pain free were 25 in group A and 27 in group B, the difference being statistically non significant. At 3hours, 22 patients had VAS score of 1 in group A and 16 in group B while 2 patients in both group had VAS score of 2.The result was statistically not significant.At 4 hrs, 28 patients had VAS score of 1-3 each in group A and group B.2 patients in both groups had VAS score ≥4 and were given rescue analgesia. The results were statistically not significant. At 5 hours, 15 patients in group A and 14 patients in group B had VAS score ≥4 and the results were statistically not significant.At 6 hours, 11 patients in group A and 14 patients in group B had VAS score ≥4 and were given rescue analgesia. The results were statistically not significant.None of the patients in both groups remained under observation for postoperative analgesia till 8 hours, which was the study period (Table 3 & Graph 1).

Postoperatively, nausea and vomiting was observed in 1 patient in both group A and group B. Pruritis was observed in 1 patient in group B & not observed in any patient in group A. No patient had urinary retention and respiratory depression in either group. The difference in incidence of these side effects was statistically not significant (Table 4).

After 30 minutes, 23 patients in group A and 15 patients in group B were mildly sedated (S1), while 11 patients in group B were moderately sedated(S2) compared to 0 patients in group A. The difference was found to be statistically significant. After 1 hour, 17 patients in group A and 11 patients in group B were mildly sedated (S1). At the same time, 1 patient in group A and 17 patients in group B were moderately sedated (S2). One patient in group B was asleep but arousal. This difference was found to be statistically significant. After 1 hour 30 minutes, 6 patients in group A and 14 patients in group B were mildly sedated (S1). At the same time, 10 patients in group B were moderately sedated (S2)

compared to 0 patients in group A. The difference is statistically significant. After 2 hours, 1 patient in group A and 3 patients in group B were mildly sedated(S1). At the same time, 1 patient in group B and no patient in group A was moderately sedated i.e(S2) .The difference was found to be statistically significant. Henceforth none of the patients in either groups complained of sedation(Table 5& Graph 2).

DISCUSSION

The present study was comprised of 60 patients of ASA class I or II, aged 20-70 years, weight between 40 – 80kgs and undergoing elective lower limb orthopaedic surgery. All patients were randomly assigned to one of the two groups of 30 patients each.

Group A - Comprised of 7 females and 23 male patients of mean age 44.70 ± 11.05 years, mean weight 59.93 ± 6.36 kg and height of 164.40 ± 7.74 cm who received 1mg of inj. Butorphanol diluted upto 10 ml of Normal Saline and given epidurally.

Group B – Comprised of 5 females and 25 male patients of mean age 47.17 ± 10.04 years, mean weight 60.73 ± 7.14 kg and height of 164.80 ± 6.74 cm who received 2mg of injection ofButorphanol diluted upto 10 ml of Normal Saline and given epidurally.

A drug such as butorphanol a mu-agonist / antagonist and S / K agonist might be expected to be useful in the management of post-operative pain (Bromage P. R. et al 1982 [17]).

Demographic data in both the groups was comparable (Table 1).

The time interval between the first dose of epidural butorphanol and the time of onset of pain in the patient (i.e. VAS score of 1) was taken as the duration of analgesia.

The patients underwent various types of lower limb orthopaedic surgeries which was comparable in both the groups.

The mean duration of analgesia in group A was 187 ± 29.14 mins and in group B was 201± 33.56 mins (Table 2). The difference in duration of analgesia between the two groups was statistically not significant.

Our study did not correlate with studies conducted by J. S. Naulty et al (1984)[8], Abboud et al (1987)[26], W.E. Ackerman et al (1988)[28], of epidurally administered butorphanol in different dosesfor postoperative analgesia in patients undergoing elective caesarean section which reported a stastistically significant post operative analgesia in patients receiving epidural butorphenol in doses of >1mg compared to doses of 1mg.

Our results correlated with the study conducted byCatherine. O. Hunt et al (1989)[1], Q.T. Palacios, M. M. Jones (1991)[19], J. L. Howkins et al(1991)[19] Pramila Malik et al (2006)[18], according to which it was evident that in both groups i.e. 1mg and 2mg butorphanol administered epidurally provided effective longer duration of analgesia..Slightly longer duration of analgesia in group B i.e. 2 mg group but the difference is statistically not significant (p value < 0.05).

In our study, the VAS score of 1-3 was considered as mild painandscore of 4 or >4 was considered as moderate painandrescue analgesia was given at this point of time.

On comparing the VAS scores of two groups(Table 3), which shows the number of patients at different time intervals and number of patients requiring rescue analgesia, at the end of 2 hours 30 minutes, 3 hours, 4 hours, 5 hours, 6 hours,were similarandresults were not statistically significant.

The findings in our study correlated with the studies conducted by D. Lawhorn et al (1991)[2], Q.T. Palacios, M. M. Jones et al (1991)[19], David R. Gambling et al (1994)[3], Pramila Malik et al (2006)[18], according to which there was no statistical significant difference in VAS scores at varying time intervals in patients receiving 1mg and 2 mg of epidural butorphanol.

In our study, pulse rate, systolic blood pressure and diastolic blood pressure remained stable in the

post operative period and difference between the 2 groups was not statistically significant ($p > 0.05$), which were well supported by the studies conducted by Catherine O' Hunt et al (1989)[1], Q.T. Palacios, M. M. Jones et al (1991)[19], Pramila Malik et al (2006)[18].

In our study, the incidence of nauseaandvomiting in both groups was minimalandstatistically not significant (Table 4).

The incidence of prutitis in patients who received 2mg of butorphanol was 3.3% which correlated with studies conducted by Ackerman et al (1988) [28] - 6.7%, Palacios et al(1991)[19]- 1.4 %, Pramila Malik et al(2006)[18]- 3% respectively.

According to our study (Table 5), the sedation scores at varying time intervals of 30 mins, 1 hour, 1hour 30 mins and 2 hrs were higher in patients receiving 2mg of butorphanol as compared to those receiving 1mg. Thus, the sedation scores were higher in group B when compared to group A, but none of the patients developed respiratory depression i.e. respiratory rate <10 breath /min and fall in peripheral arterial oxygen saturation i.e SpO2<90 %.

Our results correlated with the results of studies conducted by Catherine O Hunt et al (1989)[1], David R. Gambling et al (1994)[3], Tan P. H. et al (1997)[24], Pramila Malik et al (2006)[18], which reported higher sedation scores at varying time intervals in patients receiving epidural butophanol of 2mg or >2mg compared to those receiving 1mg.

SUMMARY AND CONCLUSION

The present study comprised of 60 patients of ASA class I or II, aged 20 – 70 years, weighing between 40-80Kgs and undergoing elective lower limb orthopaedic surgery and were randomly assigned to one of the two groups of 30 patients each to receive either.

Group A – 1mg of Butorphanol diluted up to 10ml of Normal saline and given by epidural catheter.

Group B – 2mg of Butorphanol diluted up to 10ml of Normal saline and given by epidural catheter.

The duration of postoperative analgesia was calculated from the time of first dose of epidural butorphanol to the time when patient again experienced pain (VAS score of 1).

Epidural Butorphanol, in doses of both 1mg and 2mg are effective means of providing postoperative analgesia. The duration of analgesia with 1mg of epidural Butorphanol is 187 ± 29.14 minutes and the duration of analgesia with 2mg of epidural Butorphanol is 201 ± 33.56 minutes. The duration of analgesia provided by 2 mg of epidural butorphanol is slightly longer than 1mg of epidural Butorphanol, but the difference is statistically not significant.

Epidural Butorphanol in doses of 1mg and 2mg, both provide good quality of postoperative analgesia as determined by the Visual Analogue Scale scores in the postoperative period.

Haemodynamic changes i.e. Pulse rate, Systolic B.P, Diastolic B.P. were comparable throughout the study period. On comparing the changes in these parameters in each group at various time intervals with the preoperative value, it was found that the difference is statistically not significant in both the groups. Therefore it can be concluded that the haemodynamic changes in both the groups were acceptable.

Epidural Butorphanol in doses of 1mg and 2mg had minimal incidence of side effects and the difference between the two groups was statistically not significant.

Sedation scores in 2mg Butorphanol group i.e. Group B were higher after 30 minutes, 1 hour, 1 hr 30 mins and 2 hours interval than in 1mgButorphanol group i.e. Group A. The difference is statistically significant.(p value < 0.05).But the duration of sedation in the two groups was comparable and the difference was not statiticallysignificant.

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Table 1: Demographic Data of Group A and Group B

DATA	GROUP A	GROUP B
Number of patients	30	30
Age (Mean ± S.D) (years)	44.70 ± 11.05	47.17 ± 10.04 N.S.
Weight (Mean ±S.D.) (Kgs)	59.93 ± 6.36	60.73 ± 7.14 N.S.
Height (Mean ± S.D.) (cms)	164.60± 7.74	164.80 ± 6.74 N.S.
Duration of Surgery (Minutes)	116.83±11.48	117.17± 8.27 N.S.

N.S.: Not Significant by students unpaired t-test

p< 0.05 : Significant.

Table 2: Comparison of Duration Of Analgesia In Group A & Group B

	DURATION OFANALGESIA (Mean ± SD) in minutes.	**P value**
GROUP A	187 ± 29.14	0.090
GROUP B	201 ± 33.56	

p< 0.05 = Significant.

Table 3: Comparison of Group A and Group B

Groups	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
R.A No.	-	-	-	-	-	-	2	2	15	14	11	14	0	0	0	0
V4	0	0	0	0	0	0	2	2	15	14	11	14	2	0	0	0
V3	0	0	0	0	0	0	0	2	1	2	1	0	0	0	0	0
V2	0	0	0	0	2	2	21	14	12	12	1	0	0	0	0	0
V1	0	0	5	3	22	16	7	12	0	0	0	0	0	0	0	0
C	30	30	25	27	6	12	0	0	0	0	0	0	0	0	0	0
TIME AFTER	2 hrs		2 ½ hrs		3hrs		4hrs		5hrs		6hrs		7hrs		8 hrs	

- P<0.05: Significant
- C: Pain free zone, V1-3: Mild pain, V>4: Moderate pain & rescue analgesia given.
- R.A. no.: Number of patients who required rescue analgesia.

Table 4: Comparison of Side Effects In Postoperative Period In Group A & Group B

SIDE EFFECTS	GROUP A	GROUP B	P VALUE
Nausea	1	1	0.797
Vomiting	1	1	
Pruritis	0	1	
Respiratory depression	0	0	-
Urinary retention	0	0	-

P <0.05: Significant.

Table 5: Comparison of Sedation Scores in Group A & Group B

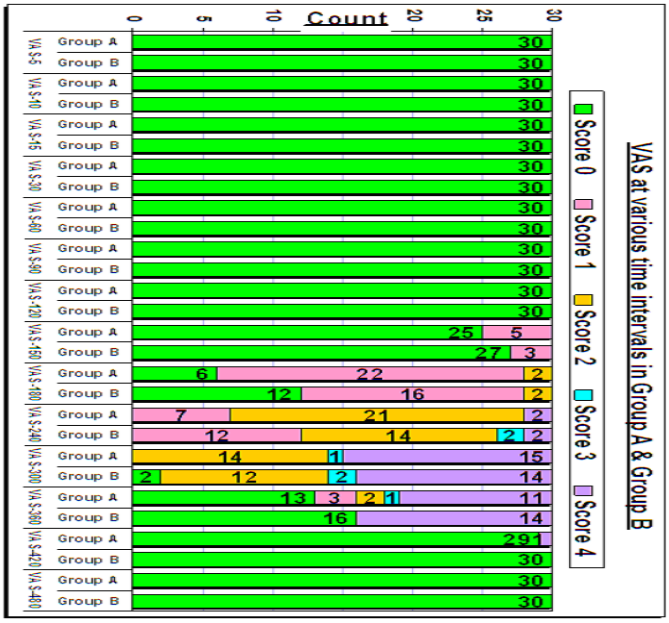
GROUPS	A	B	A	B	A	B	A	B	A	B	A	B	A	B
S4	0	0	0		0	0	0	0	0	0	0	0	0	0
S3	0	0	0	01	0	0	0	0	0	0	0	0	0	0
S2	0	11	01	17	0	10	0	01	0	0	0	0	0	0
S1	23	15	17	11	06	14	01	03	0	0	0	0	0	0
S0	7	4	12	01	24	06	29	26	0	0	0	0	0	0
TIME AFTER	30 mins		1 hour		1 hour 30 mins		2 hour		3 hour		4 hour		8 hour	

P <0.05: Significant.

S0—Alert, S1 –Mildly sedated, S2 –Moderately sedated,
S3 –Asleep, arousal, S4 –Asleep, not arousal

GRAPHS

Graph 1: Comparison of Group A and Group B



Graph 2: Comparison Of Sedation Scores in Group A & Group B