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A Comparative Study Of Epidural Butorphanol And Tramadol For Post Operative Analgesia Using Combined Spinal Epidural Anesthesia Technique In Lower Limb Surgeries.

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ABSTRACT

Effective control of pain is essential for postoperative patients especially those undergoing orthopedic surgeries. Combined spinal and epidural anesthesia technique is a regional anesthesia technique which combines the benefits of spinal anesthesia and epidural anesthesia and analgesia**.** This study has been conducted to compare epidural butorphanol and tramadol for postoperative analgesia , sedation and side effects using CSEA technique for orthopedic surgeries. This study was done in 80 patients who were undergo orthopedic surgeries of ASA physical status 1 and 2. Group A : Butorphanol was used as an analgesic agent epidurally to provide postoperative analgesia. Group B : Tramadol was used as an analgesia agent epidurally to provide postoperative analgesia. All patients were given spinal anesthesia for the surgical procedure one space lower then the site of epidural catheter, using 25G Quinckes needle with inj. bupivacaine 0.5% 2.5 to 3 ml. And at the end of surgical procedures sensory level and motor level were determined Butorphanol (11.13±1.9) has significantly rapid onset of action as compared to Tramadol (13.23±2.1), p value < 0.001 (Independent sample t-test). The mean duration of action for tramadol (284.3±46.9) was significantly higher than the mean duration of action for butorphanol (213.5±27), p value < 0.001 (Independent sample t-test). In conclusion epidural butorphanol (1mg) is a safe and efficacious drug for post-operative analgesia.

Keywords: Butorphanol, epidural, tramadol.

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INTRODUCTION

Effective control of pain is essential for postoperative patients especially those undergoing orthopedic surgeries. combined spinal and epidural anesthesia technique is a regional anesthesia technique which combines the benefits of spinal anesthesia and epidural anesthesia and analgesia [1]. Postoperative analgesia is essential for immediate postoperative pain reliefusing systemic analgesia, oral, parenteral and epidural analgesia [2]. Epidural analgesia using opioids is a popular, simple, effective and economical way of providing postoperative analgesia [3]. Use of newer opioids like Tramadol, Butorphanol, fentanyl has produced effective pain relief with minimal side effects compared to conventional drugs [4]. Butorphanol, a synthetic morphine derivative is a phenantherene series while tramadol is a centrally acting opioid agonist of amino cyclohexanol group. Both butorphanol a mixed opioid agonist and antagonist and tramadol hydrochloride a moderately potent opioid agonist has been used for postoperative pain relief in epidural analgesia [5]. This study has been conducted to compare epidural butorphanol and tramadol for postoperative analgesia, sedation and side effects using CSEA technique for orthopedic surgeries.

MATERIALS AND METHODS

This is a single center prospective randomized double blind study that was conducted at Orthopedic operation theatre, Department of anesthesiology, Tirunelveli medical college and hospital from January 2019 to January 2020.This study was done in 80 patients who were undergo orthopedic surgeriesof ASA physical status 1 and 2. Ethical committee approval and written informed consent from patients involved in this study are obtained before starting the study. Inclusion Criteria: Patients in the age group of 18 to 60 years belonging to ASA physical status 1 and 2 undergoing elective lower limb surgeries. Exclusion Criteria: Infection at the site of injection Patients with bleeding disorders Patients with neuromuscular disordersPatients with spinal deformities Patients taken for emergency surgeries. Group A : Butorphanol was used as an analgesic agent epidurally to provide postoperative analgesia. GroupB: Tramadol was used as an analgesia agent epidurally to provide postoperative analgesia. Perioperative assessment was done and written informed consent was obtained from all the patients who full filled the inclusion criteria. Patients was randomly assigned into any of the two groups. Patient was shifted to operation theatre and an intravenous line was secured and all monitors were connected. After positioning the patients and taking all aseptic precautions, epidural needle was introduced and after confirming the epidural space the epidural catheterwas placed and fixed. All patients were given spinal anaesthesia for the surgical procedure one spacelower than the site of epidural catheter, using 25G Quinckes needle with inj. bupivacaine 0.5% 2.5 to 3 ml. And at the end of surgical procedures sensory level and motor level were determined. In the group A patients, when the visual analogue scale for pain reaches 4,then bolus of inj.butorphanol 2mg in 9ml normal saline was given epidurally. Thereafter for top up 2mg of inj.buorphanol is dissolved in 19ml of normal saline (total volume of 20ml) and out of that 10 ml is given as top up for postoperative pain relief for 24rhours.In the group B patients, when the visual analogue scale for pain reaches 4,thenbolus of injection of inj.tramadol 100mg dissolved in 8ml of normal saline is given epidurally. Thereafter for top up 100mg of inj.tramadol is dissolved in 19ml of normal saline (total volume 20ml) and 10ml of this solution is given as top up for postoperative pain relief for 24 hours. Either of the group were then assessed for pain, heart rate, blood pressure, respiratory rate, sedation and side effects.

Statical Analysis

This study included 80 patients who have undergone lower limb surgeries. Data was entered in Microsoft excel and analysed using Statistical Packages for Social Services (SPSS v.21). Baseline characteristics of the two were compared using appropriate tests of significance to ensure comparability between the groups. Duration of analgesia, pain scores and sedation scores were compared between the two groups using independent sample t-test. A p value of less than 0.05 was considered as a statistically significant difference between the two groups.

RESULTS

Among the study group, 63 patients (78.8%) were male and 17 patients (21.2%) were female. The mean age of the study group was 45.2 years with a standard deviation of 12.9 years. The minimum age was 20 years and the maximumage was 60 years. The proportion of female patients were much less in

the age group 20 to 49 years when compared to male patients of the same age group. As the age of the study group, the proportion of female patients also increased.

Table 1: Baseline Characteristics Of The Study Group

Age category	Number (N=80)	Percentage (%)
20 to 29 years	12	15%
30 to 39 years	16	20%
40 to 49 years	13	16.3%
50 to 59 years	23	28.8%
60 years and above	16	20%
Total	**80**	**100**

The preoperative readings of the study group was given in the table below

Table 2: Pre-Operative Readings Of The Study Group

Pre-operative readings	Mean	(±) SD	Minimum	Maximum
Pulse rate	80.8	5.4	68	92
Systolic blood pressure	117.8	6.6	102	130
Diastolic blood pressure	79.2	6.8	64	92
Respiratory rate	14.8	1	13	17
Sedation score				
Saturation	98.8	0.7	97	100

The mean age of the patients in group I was 45.7 years with a standard deviation of 12.2 years. The mean age of the patients in group II was 44.7 years with a standard deviation of 13.7 years. This difference in mean age between the two groups was not statistically significant. Similarly, there was no significant differencein the sex distribution between the two groups.

Table 3: Comparison Of Baseline Characteristics Of The Two Groups

Baseline character		Group I (Butorphanol)	Group II (Tramadol)	p value
Mean age in years (SD)		45.7 (12.2)	44.7 (13.7)	0.26 (Independent sample t-test)
Sex	**Male**	34 (54%)	29 (46%)	0.28 (Chi square test)
	Female	6 (35.3%)	11 (64.7%)	

The difference between the preoperative readings of group I and II patients were found to be statistically insignificant with p value > 0.05, Independent sample t-test. This shows that the groups were comparable to study the effectiveness of butorphanol and tramadol.

Table 4: Comparison Of Preoperative Readings Of Both Groups

Mean preoperativereadings (±SD)	Group I (Butorphanol)	Group II (Tramadol)	p value (Independent sample t test)
Pulse rate (bpm)	80 (6.6)	81.6 (4)	0.06
Systolic blood pressure (mmHg)	117.2 (7)	118.4 (6.4)	0.48
Diastolic blood pressure (mmHg)	77 (7)	81.2 (6.2)	0.12
Respiratory rate (per minute)	15 (1)	14.7 (1)	0.92
Saturation (SpO2)	98.8 (0.8)	98.8 (0.6)	0.15

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The mean postoperative pulse rate was higher for Tramadol at 0.5, 1, 1.5, 2 and 12 hours. There was a statistically significant difference in the mean postoperative pulse rate between the groups at 1 hour and 2 hours (p value < 0.05, Independent sample t-test).

Table 5: Postoperative Pulse Rate Of Two Groups

Time since first dose (inhours)	Mean pulse rate (SD) (bpm)		p value (Independent sample t test)
	Group I (Butorphanol)	Group II (Tramadol)	
0.5 hours	76.2 (6)	77.9 (4.2)	0.14
1 hour	73.3 (5.9)	75.8 (4.6)	**0.04**
1.5 hours	74.2 (5.9)	76.4 (5.6)	0.10
2 hours	76.4 (6.2)	79.4 (5.5)	**0.03**
4 hours	78.8 (6.3)	78.6 (12.7)	0.90
8 hours	81.2 (6.1)	81.2 (4.7)	0.97
12 hours	82.8 (5.7)	83.2 (4.7)	0.77
24 hours	83.4 (5.5)	83.4 (4.7)	0.63

The mean postoperative systolic blood pressure was higher for Tramadol at 0.5, 1, 1.5, 2, 8 and 12 hours. However, there was no statistically significant difference in the mean systolic blood pressure between the groups at any interval (pvalue > 0.05, Independent sample t-test).

Table 6: Postoperative Systolic Blood Pressure Of Two Groups

Time since first dose (inhours)	Mean systolic blood pressure (SD) (mmHg)		p value (Independent sample t test)
	Group I (Butorphanol)	Group II (Tramadol)	
0.5 hours	113.5 (6.7)	115.7 (6.5)	0.84
1 hour	113.7 (5.6)	114.1 (6.0)	0.57
1.5 hours	114.1 (6.5)	114.6 (6.0)	0.53
2 hours	116.5 (6.3)	116.8 (6.9)	0.49
4 hours	117.8 (6.0)	117.8 (6.2)	0.95
8 hours	117.9 (6.8)	118.8 (6.5)	0.52
12 hours	119.8 (6.5)	120.3 (6.2)	0.36
24 hours	121.9 (5.6)	121.5 (6.5)	0.69

The mean postoperative diastolic blood pressure was higher for Tramadol at all intervals of time. And the difference was statistically significant difference witha p value < 0.05, Independent sample t-test).

Table 7: Postoperative Diastolic Blood Pressure Of Two Groups

Time since first dose (inhours)	Mean diastolic blood pressure (SD) (mmHg)		p value (Independent sample t test)
	Group I (Butorphanol)	Group II (Tramadol)	
0.5 hours	74.3 (7.0)	78.4 (6.4)	**0.008**
1 hour	71.4 (6.2)	76.7 (5.4)	**<0.001**
1.5 hours	72.7 (7)	77.3 (5.5)	**0.001**
2 hours	74.9 (6.9)	78.5 (5.6)	**0.013**
4 hours	76.3 (6.8)	80.3 (6.1)	**0.006**
8 hours	77.2 (6.7)	80.4 (6.0)	**0.03**
12 hours	79.1 (6.2)	82.1 (5.1)	**0.02**
24 hours	79.5 (5.9)	83.1 (4.9)	**0.004**

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Table 8: Postoperative Respiratory Rate Of Two Groups

Time since first dose (inhours)	Mean respiratory rate (SD) (per minute)		p value (Independent sample t test)
	Group I (Butorphanol)	Group II (Tramadol)	
0.5 hours	14.2 (1.3)	13.8 (0.9)	0.10
1 hour	14.7 (1.1)	13.7 (0.9)	**<0.001**
1.5 hours	14.7 (1.3)	14.1 (1.1)	**0.012**
2 hours	14.9 (1.1)	14.3 (1.0)	**0.006**
4 hours	15.2 (1.0)	14.7 (1.2)	0.079
8 hours	15.3 (1.1)	14.9 (1.2)	0.09
12 hours	15.7 (0.8)	15 (0.9)	**0.001**
24 hours	15.6 (0.8)	15.2 (0.9)	0.09

No patients had sedation in group II whereas nearly 20% patients in group I had mild sedation at 0.5 hour and 1 hour; 10% patients in group I had mild sedationat 1.5 hour. At 2 hours, both group I and group II patients had no sedation or slept normally. All patients were alert at 4 hours, 8 hours, 12 hours and 24 hours. GroupsI patients had higher sedation score than group II patients. This difference was also statistically significant at 0.5, 1, 1.5 and 2 hours (p value < 0.05).

Table 9: Postoperative Sedation Score Of Both Groups

Time interval	Group	None	Mild	Sleeping normal	p value
0.5 hour	I	8 (20%)	8 (20%)	24 (60%)	**0.004 (Fishers exact test)**
	II	15 (37.5%)	-	25 (62.5%)	
1 hour	I	2 (5%)	8 (20%)	30 (75%)	**<0.001 (Fishers exact test)**
	II	26 (65%)	-	14 (35%)	
1.5 hour	I	9 (22.5%)	4 (10%)	27 (67.5%)	**<0.001 (Fishers exact test)**
	II	29 (72.5%)	-	11 (27.5%)	
2 hours	I	23 (57.5%)	-	17 (42.5%)	**0.002 (Chi square test)**
	II	36 (90%)	-	4 (10%)	

The mean postoperative oxygen saturation was higher for Tramadol till 1.5 hours. After 2 hours, the mean postoperative oxygen saturation was higher for Butorphanol. And the difference was statistically significant difference at 4 hours and 8 hours with a p value < 0.05, Independent sample t-test.

Table 10: Postoperative Oxygen Saturation Of Two Groups

Time since first dose (inhours)	Mean SpO2 (SD) (%)		p value (Independent sample t test)
	Group I (Butorphanol)	Group II (Tramadol)	
0.5 hours	97.4 (1.2)	97.6 (1.2)	0.56
1 hour	97.7 (0.9)	97.8 (1)	0.37
1.5 hours	98 (0.7)	98 (0.9)	0.79
2 hours	98.4 (0.7)	98.3 (0.7)	0.88
4 hours	98.8 (0.4)	98.4 (0.6)	**0.01**
8 hours	98.9 (0.2)	98.6 (0.6)	**0.003**
12 hours	98.7 (0.7)	98.6 (0.5)	0.61
24 hours	98.8 (0.5)	98.6 (0.5)	0.21

Table 11: Onset Of Action Of Both Drugs

Onset of action	Group I	Group II	p value
Mean (in min)	11.13	13.23	<0.001 (Independentsample t-test)
SD (in min)	1.9	2.1	

Butorphanol (11.13±1.9) has significantly rapid onset of action as compared to Tramadol (13.23±2.1), p value < 0.001 (Independent sample t-test).

Table 11: Duration Of Action Of Both Drugs

Duration of action	Group I	Group II	p value
Mean (in min)	213.50	27	**<0.001 (Independentsample t-test)**
SD (in min)	284.30	46.9	

The mean duration of action for tramadol (284.3±46.9) was significantly higher than the mean duration of action for butorphanol (213.5±27), p value < 0.001(Independent sample t-test).

Table 12: Side-Effects Of Both Drugs In The Study Group

Side effect	Butorphanol (n=40)	Tramadol (n=40)
Nausea	4 (10%)	12 (30%)
Vomiting	2 (5%)	9 (22.5%)
Sedation	3 (7.5%)	-

DISCUSSION

Post operative pain is a complex physiological response to tissue injury. The effective pain relief is important to patients undergoing surgeries. [6]The effective pain relief has significant physiological benefit and hence post operative pain relief is important for physical and emotional well being of the patients. The main aim of post operative pain relief is to reduce the pain with minimal side effects. [7]. Epidural opioids plays an important role in the management of postoperative pain [8]. The postoperative pain evaluation is essential for successful pain management. Both subjective and objective ways are there for assessment of pain. Subjective assessment by patients and objective assessment of parameters alteration in cardiovascular and respiratory system in response to pain are studied to judge the severity of pain [9]. Epidural is one of the method used for postoperative pain relief in patients undergoing abdominal and orthopaedic surgeries [10]. Combined spinal and epidural analgesia has the benefit of rapid onset of action of spinal anaesthesia and use of epidural for postoperative pain relief [11]. Despite the advances in pain management, opioids still remain the mainstay of therapy for postoperative analgesia. Opioids binds to receptors in the central nervous system and peripheral tissue and modulate the pain response. Tramadol an opioid analgesic is 1/5-1/10th as potent as morphine and analgesic doses of Tramadol may produce less respiratory depression because of its non-opioid receptor mediated actions [12]. Butorphanol is a mixed agonist and antagonist non-narcotic opioid analgesic. The analgesic potency of Butorphanol has been found to be greater than morphine and pethidine [13]. Butorphanol unlike morphine, exhibits a ceiling effect on respiratorydepression.Thus this study was conducted in an effort to assess efficacy of newer drugbutorphanol and compare it against well known drug tramadol [14,15].

CONCLUSION

In conclusion epidural butorphanol (1mg) is a safe and efficacious drug for post- operative analgesia. Epidural butorphanol provides a rapid, excellent but shorter duration of analgesia when compared to epidural tramadol. Epidural butorphanol had lesser side effects like nausea and vomiting but has sedation in milder degree which is an additional advantage in the post-operative period. Quality of analgesia in terms of patient satisfaction is also better with epidural butorphanol.

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