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A COMPARATIVE STUDY OF SINGLE SHOT EPIDURAL BLOCK AND POST OPERATIVE PAIN RELIEF CAUSED BY BUPIVACAINE AND FENTANYL, BUPIVACAINE AND TRAMADOL, BUPIVACAINE AND MIDAZOLAM COMBINATION IN LOWER LIMB ORTHOPEDIC SURGERY.

Anesthesiology

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ABSTRACT

Background and aims: - Epidural technique has opened a new horizon to the medical profession. It is an advanced technique in modern anesthesia for relieving various types of pain such as cancer pain, labor pain, postoperative pain and pain of surgery

Method: - Forty-five patients of the American society of anesthesiologists' physical status grad II, or I scheduled for lower limb orthopedic, randomly allocated into three group-I, group-II and group-III. Group-I, group received bupivacaine 0.5 %, 15 ml with fentanyl 50 micro gram. Group-II, received bupivacaine 0.5%, 15 ml with tramadol 100 mg. Group III- received bupivacaine 0.5%, 15 ml with midazolam 2.5 mg. Single shot epidural was given of lumbar region including L-3, L-4, L-5 inter spines space. Data were analyzed. The categorical data was presented as number (percent) and were compared among group using chi-square test. The quantitative data was presented as mean and standard deviation and were compared by student t-test and anova test. Probability was considered to be significant if p-value less than 0.05.

Result:-Operation in all three groups were performed without difficulty. There were good analgesia and muscular relaxation. Pulse rate, blood pressure and respiratory rate were normal throughout the operation and postoperative period and group-II (Tramadol) showed longer duration of analgesia. Retention of urine of urine was seen in 20% of cases in group-I, 6.67% in group-II and group -III respectively and other complications were nausea, vomiting, shivering and hiccup.

Conclusion: - GROUP-II(Tramadol) showed longer duration of analgesia as compared to group III(Midazolam)and group -I(Fentanyl) patients

KEYWORDS

Epidural block, bupivacaine, fentanyl, tramadol, midazolam.

Introduction: - The provision of good quality analgesia in the post operative period is important, benefit of good quality epidural analgesia include improved respiratory function, decreased Perioperative cardiac complication, earlier mobilization, return of bowel function and shorter hospital stay. Epidural analgesia was introduced by siccard and cathelin of France in 1901. The subatmospheric or negative pressure in the extradural space was described by Janoh 1926. Touhy in 1945 developed "Touhy's Needle" for epidural anesthesia. A Totally new concept of extradural analgesia arises following the description of opiate receptors in the spinal cord by Pert and by Snyder in 1973 and Snyder in 1977. Bupivacaine was the first local anaesthetic that combined the properties of an acceptable onset, long duration of action, profound conduction blockade and significant separation of sensory anaesthesia and motor blockade; Telivuo used bupivacaine first epidurally in 1963. In this study, Fentanyl, Tramadol and midazolam were used as adjuvants in respective group to improve efficacy of epidural anaesthesia and post operative analgesia duration.

Methods: -This prospective, randomized, double blind study was done at tertiary care Centre after approval of the institutional ethical committee and obtaining written informed consent from all patient. Pre anaesthetic check up was carried out the day before operation. Forty-five patients scheduled to undergo infraumbilicus surgery, Aged between 30 to 80 years with American society of anaesthesiologist (ASA) physical status grade I or II, height more than 140 cm, weight between 40 to 80 kg. Contraindication to epidural anaesthesia was major neurological, cardiovascular, metabolic, respiratory, renal disease or coagulation abnormalities excluded from this study. All the patients were fasted for at last 6 hour before the procedure. In the operative room, a multi-parameter monitor for electrocardiograph, heart rate, oxygen saturation and invasive blood pressure was attached and base line vital parameters were recorded. Intravenous line was secured with 18-gauge cannula and ringer lactate solution 10 ml/kg was administered

Grouping: - Group -I:-Fifteen patients belong to this group were given epidural injection of bupivacaine 0.5%, 15 ml with fentanyl 50µgm. Group-II:- Fifteen patients belonging to this group were given epidural injection of bupivacaine 0.5%, 15 ml with tramadol 100 mg. Group- III:- Fifteen patient belonging to this group were given epidural injection of bupivacaine 0.5%, 15 ml with midazolam 2.5 mg. Shaving of lumbar region was done L3-L4-L5 spine. Patient was taken on the operation table in supine position. Blood pressure, pulse rate,

respiratory rate was recorded. Preloading was done with 5% dextrose 500 cc and subsequently with ringers lactate solution. To identify the epidural space the loss of resistance method was used in sitting position. A syringe with 5 cc air connected to touhy's needle was advanced slowly with pressure on piston. There was almost resistance to injection of air through the needle as it was advanced through the supra spinous, inter spinous ligament and ligamentum flavum. As the tip emerged the epidural space, the resistance to air in the syringe disappeared dramatically. This was loss of resistance sign. The desired solution was given by another syringe through touhy's needle slowly. Then touhy's needle was removed and the site was sealed with tincture benzoin. The patient was given supine position and the time of injection of solution was noted. Onset of analgesia was conformed by pin prick method or cold swab method. Ringer lactate infusion was continuing during the intra operative period. Pulse rate, blood pressure, respiratory rate, pain scores and sedation scores were recorded every 15 minutes in first hour and then at 2,6,12,24 hours. Statistical analysis was done with the statistical programming software. The categorical data was presented as number (percent) and were compared among group using chi-square test. The quantitative data was presented as mean and standard deviation and were compared by student t-test and anova test. Probability was considered to be significant if p-value less than 0.05.

Result: -Three groups were comparable with respect to age, sex, weight and ASA status (table-1) Heart rates were analyzed as basal and through-out the surgery at 15 minute interval in intra operative as well as post operatively 2,6,12,24 hour. Which was not statistically significant across all measured time (table-2). There were no statistically significant differences in systolic blood pressure in three group (table-3).

There were no statistically significant differences in diastolic pressure among three groups in pre operative, intra operative and postoperative period (table-4). There were no statistically significant and comparable each group in respiratory rate (table-5). There were observed that incidence of nausea was one patient in group group-II and I and vomiting was one patient in each group. Urine retention was three patients in group-I and one patient was in group-II and group-III. Shivering was only one patient in group-I. No sedation was observed in any group. Hiccup was seen one patient in group-III. There were no statistical significant complications in three group (table-6).

Duration of analgesia was maximum in group- II, 11.84-hour mean,

6.68-hour standard deviation. Group-I, 7.13-hour mean, 5.14-hour standard deviation. Group-III, 9.96-hour mean, 7.62 standard deviation. Anova test p-value was 0.154. There were no statistical significant. (Table-7).

Discussion: - Epidural analgesia is development from intradural block and its main attraction over intradural block being that it never causes headache. Preservative free narcotic preparation in the epidural space because preservatives are presumed to be toxic to nerve tissue and may have anaesthetic properties of their own. Preservative free fentanyl, tramadol and midazolam were used in this study. Snyder -1977(1) spinal cord opiate receptors are found in substantia gelatinosa. Subarachnoid or epidural doses of opiates provide segmental analgesia by direct action on these sites. There were observed that pre-operative, intra-operative and post-operative the fall of blood pressure in all the three group is well within normal limits which is of no clinical significance. (Table-3, 4). There were also observed that pulse rate as well as respiratory rate remained in normal range. No change in respiratory indicates that no patient had any respiratory depression in any group. (Table-2,5). Christenson(1980)[2] found respiratory depression after 4 mg of morphine epidurally in a 83 old patient. Naloxone 0.4 mg intravenously was given and the patient respond well. Delikan et al (1993)[3] studied the effect of tramadol 50 mg, tramadol 100 mg and 10 ml of bupivacaine 0.25% given epidurally to 60 patient for post operative pain relief. In this study, there were no respiratory depressions of all groups. The dose of opioid is said to be important. Weightman (1991)[4] reported three case of respiratory depression in patients who received more than 1.5 gm/kg/hour fentanyl. Sedation has been reported with higher doses of epidural midazolam 75-100 g/kg (Nishiyama et al 1992)[5] and not with this dose of spinal midazolam (Serrao et al 1992)[6]. In the present study also no respiratory depression was observed in any patient in the three groups. There were observed in this study that the mean duration of analgesia in group-I was 7.13 hours, in group- II was 11.84 hours and in group-III was 9.96 hours.

The majority of studies show that the use of a mixture of local anaesthetic and opioid is associated with significant better dynamic pain relief after lower or upper abdominal [7, 8] orthopedic and thoracic surgery than the components of the infused alone.

The action of tramadol is probably at the spinal level (chrubasik-1987)[9] similar to other opiates like morphine.

Tramadol hydrochloride was given epidurally in our study, which was produced good pain relief in intra-operative and post-operative period as compared to fentanyl and midazolam group. In group-II, our result correlated with other studies. In a study on post-operative pain relief with epidural tramadol 100 mg (Delikan et al-1993)[3] found the mean duration of analgesia to be 9.36 hour.

Extradural administration of midazolam to post-operative adult patient and individual with chronic pain resulted in significant analgesia (Regoli et al 1983)[10]. Nishiyama et al (1992)[5] evaluated four dose (25,50,75, and 100 g/kg) of epidural midazolam mixed with saline in patients undergoing upper abdominal surgery. They were conducted that midazolam 50 g/kg was optimal dose for post-operative analgesia. Higher doses were associated with prolonged and deep sleep.

The most common complication in this study was urinary retention. Urinary retention was seen in 3(20%) patient in group-I, 1(6.67%) patients each in-group II and III. Nausea was seen in one patient in each group II and I in postoperative period. There was vomiting in one patient each in three groups. Shivering was seen in one patient in group-I and one patient complained of hiccup in group-III.

The dose of opioid is said to be important. Weightman [5] reported three case of respiratory depression in patients who received more than 1.5 g/kg/ml hour fentanyl. In their cases, the concentration of fentanyl was high. None of the patient in group-I given 50gm fentanyl had respiratory depression.

None of the patient was sedated with 2mg epidural midazolam sedation. Sedation has been reported with higher doses of epidural midazolam (75-100 g/kg) (Nishiyama et al 1992)[5] and not with this dose of spinal midazolam (Serrao et al 1992)[6].

Rathi et al (1998)[11], have shown that epidural injection of tramadol

has no significant effect on respiration. A maximum dose of tramadol 400 mg in 24 hour is recommended because of its analgesic ceiling effect and side effects like sweating, nausea and vomiting that may occur.

In our study patients were interviewed for pain they had at 4, 6, 12, 24 hours after epidural anaesthesia. Linear or visual analogue scale is now widely used as a sensitive and valid measure of pain intensity. It consists of a 10 cm line labeled at one end marked "0"("no pain") and the other end marked "10" the most intense pain that patient can imagine. The patients were considered to have mild, moderate and severe pain when their pain scores were 3, 4-6 and more than 7 respectively. Analgesic dose of tramadol 100 mg i.v. given when was score was more than three. Mild and moderate pain were complained by all groups in post-operative period. Severe pain were not complained by any patient in all groups.

Conclusion:-

From this study it seems that lumbar epidural technique gives good analgesia for lower limb orthopedic surgery and post-operative pain relief without major complication. It also shows that the patients belonging to group-II (Tramadol) showed longer duration of analgesia as compared to group-III (Midazolam) and group-I (Fentanyl) patients.

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Conflict of interest.

There are no conflicts of interest.

Table No. 1 Distribution of Demographic Variable

Variables	Group-I mean+/-sd	Group-II mean+/-sd	Group-III mean+/-sd	P-value
Age (years)	54.26 ± 16.86	51.73 ± 14.75	56.06 ± 16.69	0.763
Weight (Kg)	64.33 ± 8.4	65.53 ± 9.49	65.06 ± 10.25	0.940
ASA	I 14	13	11	0.306
Grade	II 1	2	4	
Male-Female Ratio	9:6	6:9	5:10	0.310

Values presented as meanSD, Group I =Fentanyl, Group II= Tramadol, Group III= Midazolam, ASA- American society of anaesthesiologists, SD- Standard deviation, op- operative

Table No. 2 Effect on Pulse Rate

	Group I mean+/- sd	Group II mean+/- sd	Group III mean+/- sd	P-value (Group I-II)	p-value (Group I-III)	P-value (Group II-III)
Basal	81.86 ± 9.92	89.33 ± 12.56	83.66 ± 12.47	0.081	0.665	0.225
Intra- OP-15 Minutes	82.13 ± 10.15	90.53 ± 13.96	83.73 ± 12.61	0.070	0.705	0.173
Intra- OP-30 Minutes	81.46 ± 10.48	88.8 ± 12.00	83.2 ± 15.37	0.085	0.720	0.275
Intra- OP-45 Minutes	81.66 ± 8.97	87.13 ± 11.7	81.46 ± 9.14	0.162	0.954	0.163
Intra- OP-60 Minutes	80.4 ± 7.89	82.6 ± 8.42	80.06 ± 8.19	0.466	0.909	0.409
Post- OP-2 Hours	78.4 ± 5.4	83.2 ± 8.34	80.06 ± 6.49	0.072	0.233	0.439
Post- OP-6 Hours	76.93 ± 3.01	80.2 ± 5.83	77.2 ± 6.53	0.064	0.885	0.195
Post- OP-12 Hours	75.86 ± 3.5	76.8 ± 4.45	77.73 ± 4.71	0.525	0.227	0.583
Post- OP-24 Hours	75.6 ± 4.35	77.4 ± 5.28	76.46 ± 4.01	0.317	0.578	0.587

Table No. 3 Effect on Systolic Blood Pressure

	Group I mean+/- sd	Group II mean+/- sd	Group III mean+/- sd	P-value (Group I-II)	P-value (Group I-III)	P-value (Group II-III)
Basal	124.53 ± 13.03	132.8 ± 14.45	132.73 ± 11.06	0.111	0.074	0.988
Intra- OP-15 Minutes	117.33 ± 30.74	133.33 ± 18.77	126.93 ± 11.28	0.096	0.264	0.270
Intra- OP-30 Minutes	119.86 ± 15.33	133.60 ± 18.48	124.46 ± 12.79	0.035	0.380	0.126
Intra- OP-45 Minutes	121.06 ± 10.36	127.06 ± 12.44	124.4 ± 13.73	0.162	0.458	0.583
Intra- OP-60 Minutes	120.26 ± 11.38	127.46 ± 10.83	124.2 ± 12.21	0.292	0.368	0.446
Post- OP-2 Hours	122.13 ± 9.17	126.4 ± 9.56	126.66 ± 9.43	0.222	0.463	0.620
Post- OP-6 Hours	122.93 ± 6.58	126 ± 8.91	126.13 ± 11.55	0.292	0.359	0.973
Post- OP-12 Hours	121.6 ± 6.05	122.93 ± 6.27	123.86 ± 12.31	0.559	0.529	0.796
Post- OP-24 Hours	121.86 ± 6.34	121.6 ± 7.21	125.73 ± 11.82	0.917	0.273	0.258

Table No. 4 Effect on Diastolic Blood Pressure.

	Group I mean+/- sd	Group II mean+/- sd	Group III mean+/- sd	P-value (Group I-II)	P-value (Group I-III)	P-value (Group II-III)
Basal	78.53 ± 6.73	84.93 ± 9.58	85.06 ± 6.58	0.043	0.012	0.966
Intra- OP-15 Minutes	78.26 ± 7.00	83.46 ± 8.08	83.53 ± 8.25	0.07	0.073	0.982
Intra- OP-30 Minutes	78.13 ± 5.68	82.4 ± 8.88	83.33 ± 8.19	0.128	0.053	0.768
Intra- OP-45 Minutes	79.06 ± 4.58	82 ± 8.45	81.46 ± 9.14	0.246	0.371	0.868
Intra- OP-60 Minutes	77.33 ± 5.78	82.13 ± 8.70	81.06 ± 6.58	0.376	0.110	0.707
Post- OP-2 Hours	78.8 ± 4.94	82.66 ± 8.33	82.26 ± 6.27	0.134	0.104	0.883
Post- OP-6 Hours	80 ± 0.47	81.86 ± 6.90	82.36 ± 6.68	0.376	0.306	0.324
Post- OP-12 Hours	80.93 ± 3.36	79.73 ± 7.36	80.66 ± 5.10	0.570	0.865	0.691
Post- OP-24 Hours	81.6 ± 4.08	81.33 ± 6.57	80.93 ± 6.36	0.893	0.734	0.867

Table No. 5 Effect on Respiratory Rate.

	Group I mean+/- sd	Group II mean+/- sd	Group III mean+/- sd	p-value (Group I-II)	p-value (Group I-III)	p-value (Group II-III)
Basal	18.26 ± 1.62	19.13 ± 2.38	18.86 ± 3.06	0.252	0.426	0.789
Intra- OP-15 Minutes	18.4 ± 1.59	19.00 ± 2.36	18.6 ± 3.11	0.421	0.826	0.695
Intra- OP-30 Minutes	18.06 ± 1.09	19.06 ± 2.78	18.86 ± 3.13	0.205	0.358	0.855

Intra- OP-45 Minutes	18.33 ± 1.23	19.33 ± 2.43	19.13 ± 3.06	0.166	0.356	0.844
Intra- OP-60 Minutes	17.46 ± 1.95	19.26 ± 2.52	19 ± 2.97	0.067	0.104	0.798
Post- OP-2 Hours	17.4 ± 1.88	19.06 ± 2.28	18.46 ± 2.92	0.038	0.247	0.536
Post- OP-6 Hours	17.26 ± 1.86	18.66 ± 2.16	18.66 ± 2.60	0.067	0.101	1.000
Post- OP-12 Hours	17.33 ± 1.87	18.66 ± 2.23	18.46 ± 2.77	0.051	0.201	0.666
Post- OP-24 Hours	17.26 ± 1.86	18.73 ± 6.68	18.4 ± 2.66	0.059	0.185	0.714

Table No. 6 Distribution of patients according to complication.

	Group I		Group II		Group III	
	No.	%	No.	%	No.	%
Nausea	1	6.67	1	6.67	0	0
Vomiting	1	6.67	1	6.67	1	6.67
Retention of urine	3	20	1	6.67	1	6.67
Shivering	1	6.67	0	0	0	0
Sedation	0	0	0	0	0	0
Hiccup	0	0	0	0	1	6.67

Table No. 7 Duration of analgesia.

	Mean	SD	P
Group I	7.13	5.14	0.34 (Group I- II)
Group II	11.84	6.68	0.32 (Group II-III)
Group III	9.96	7.62	0.68 (Group I-III)

References :-

- Solomon H. Snyder, Robert R. Goodman: Differentiation of delta and mu opiate receptor localizations by light microscopic autoradiography. *Prac. Natl.Acad.Sct.USA* Vol77, No.10, 1980; 6239-6243.
- V.Christenson: Respiratory depression after extradural morphine. *BJA*, 1980,Vol.52, issue8; 841.
- Delilkan AE: Epidural tramadol for postoperative pain relief. *Anesthesia*, 1993; 48(4); 328-31.
- Weightman WM: Respiratory arrest during epidural infusion of bupivacaine and fentanyl. *Anesthesia & Intensive care* 1991; 19; 282-84.
- Nishiyama, T.Malsukawa, K.Hanoeka: Continuous epidural administration of midazolam and bupivacaine for postoperative analgesia. *Acta Anaesthesiologica Scandinavica* 1993; 43(5); 568-72.
- Serrao et al 1992: Intrathecal midazolam for the treatment of chronic mechanical low back pain: a controlled comparison with epidural steroid in a pilot study;48:4-12.
- Lowsom SM, Alexander JI, Black ams, Bambridge AD: Epidural diamorphine infusion with and without 0.167% bupivacaine postoperative analgesia 1994;11:345-52.
- Wiebalck A, Brondor G, Van Aken H: The effects of adding sufentanil to bupivacaine for postoperative patient controlled epidural analgesia. *Aneth Analg* 1997;85:124-9.
- Chrubasik J, Warth L, Zindler M: Analgesic potency of epidural tramadol after abdominal surgery. *Pain* 1987;(suppl4): 5154.
- Rigoli M, Tiengo M, Coision MJ: Epidural analgesia with benzodiazepines. *Pharmacological basis of anaesthesiology. Clinical pharmacology of new Analgesics and Anaesthetics*. New York Raven press 1983; 69-76.
- Rathie P, Verma RS, Jatav TS, Kabra A : Postoperative pain relief by epidural tramadol. *Ind J Anaeth* 1998; 42 : 26 .