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Original Research Article

Efficacy of Epidural Infusion of 0.0625% Bupivacaine with 1µgm/Cc Fentanyl for Postoperative Analgesia After Major Abdominal Surgeries Using Elastomeric Infusion Pump (Infusor Baxter Health Care Usa) or Electronic (Emco) Infusion Pump: Quality of Sensory & Motor Block

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Abstract

Aim: To evaluate the use of electronic and elastomeric infusion pumps for administration of local anesthetics for post-operative analgesia in the major abdominal surgeries with regard to-quality of sensory and motor block.

Material & Methods: After institutional ethics committee approval, a prospective, observational, comparative study was carried out in 80 patients of either sex between ages of 18 to 65 years undergoing major abdominal surgery. The patients were into two groups of 40 patients each, elastomeric pumps (Group A) or electronic pumps (group B).

Results: The Mean sensory block remained comparable for 24 hrs and difference was not statistically significant. So the quality of sensory block in both the groups was same. The median value was also zero. Both the groups were comparable with respect to VAS Static at all-time intervals.

Conclusion: The quality of sensory block as assessed by Hollmen score, was comparable baseline and also throughout the study period. Three patients in Elastomeric group and two patients in Electronic group had higher degree of sensory block. Motor blockade was seen in 7.5% of patients in Elastomeric group and 5% of patients in Electronic group. At the end of 24 hours, percentage of motor blockade in both groups were comparable and the difference was statistically insignificant.

Keywords: epidural infusion, quality of Sensory & Motor Block, elastomeric infusion pump, electronic (emco) infusion pump

Introduction

The most common type of acute pain that the anesthesiologists deal with is postoperative pain with resultant neuroendocrine stress response causing protein catabolism, hyperglycemia, poor wound healing, decreased respiratory function, and increase in myocardial oxygen demand. [1]

Effective postoperative pain control is an essential component of care of the surgical patient. Surgical procedures are characterized by incisional damage to skin

and various tissues, application of thermal and chemical stimuli to wound and often prolonged traction, dissection and manipulation of somatic and visceral structures. Nociceptive pain is often regarded as the key feature of acute postoperative pain. This is caused by release of inflammatory mediators which activate peripheral nociceptors which initiate transduction and transmission of nociceptive information to CNS. There is also release of substance P and calcitonin which produce vasodilatation and extravasation. [2-5] Besides this, neuropathic pain mechanisms may contribute to the pain occurring during postoperative period.

Both bupivacaine and ropivacaine cause similar degree of sensory blockade. However, ropivacaine is reported to have a slower onset, lower intensity, and shorter duration of motor block with lesser propensity to produce the cardiac and central nervous system (CNS) toxicity as compared to bupivacaine. [6]

In this study, we aim to evaluate the use of electronic and elastomeric infusion pumps for administration of local anesthetics for post-operative analgesia in the major abdominal surgeries with regard to quality of sensory and motor block.

Material & Methods:

After institutional ethics committee approval, a prospective, observational, comparative study was carried out in 80 patients of either sex between ages of 18 to 65 years undergoing major abdominal surgery. The patients were into two groups of 40 patients each, elastomeric pumps (Group A) or electronic pumps (group B).

Place and area of study: general surgery and urology operation theatres of LTMGH

Inclusion criteria:

1. Age more than 18 years
2. Elective major abdominal surgical patients requiring epidural blockade for postoperative analgesia
3. Patient willing to consent

Exclusion criteria:

1. Patients with infection at the site of catheter insertion
2. Patients with coagulopathy, intra-cranial hypertension, severe hypovolemia
3. Patients for emergency surgery
4. Obstetric patients and lactating mothers
5. Any known allergy to the local anesthetic drug used

Methodology

80 adult patients undergoing elective major abdominal surgeries after written informed consent were included in the study. A thorough preoperative checkup was carried out which included physical examination and investigations according to institutional protocol.

After checking for starvation, consent and fitness, an intravenous line was established and IV fluids were started. Standard monitoring which includes ECG, blood pressure, pulse oximeter was initiated. Patients were explained the procedure, given position, back was scrubbed, painted & draped. An epidural catheter of 18G was inserted in the lumbar or lower thoracic area depending upon the surgical requirement. Standard protocol for general anesthesia with endotracheal intubation was followed.

Epidural analgesia was started before surgery using 0.125%bupivacaine 8cc by an anesthesiologist conducting the case, subsequent doses was given every 2 hrs. or when patient‘s physiologic parameters mandated it. The conduct of anesthesia and monitoring was as per standard protocol.

Patient was reversed and extubated on return of consciousness after meeting extubation criteria or mechanically ventilated.

After emergence from anesthesia patient was shifted to post-operative recovery

room. Pain was assessed by recovery room anesthetist and the epidural infusion was started. Epidural infusion used was local anesthetic solution containing 0.0625 % bupivacaine +1 mcg /cc fentanyl. The patients were divided into two groups:

Group A: in which epidural analgesia was delivered using elastomeric pump. 250 cc of 0.0625% bupivacaine + 1mcg/cc fentanyl was aspirated into the Infusor. The dead space volume of the Infusor tubing is 3 cc which was considered at the time of calculating volume delivered to the patient.

Group B: in which epidural analgesia was delivered using an electronic pump. 50 cc of 0.0625% bupivacaine + 1mcg/cc fentanyl (i.e.1cc =50 μ) total 51 cc; was aspirated in a 60 cc syringe. A high pressure line (PMO line) with capacity 0.90cc was connected to the syringe and primed with the solution.

In both the groups the drug was aspirated under aseptic precautions and the pumps was kept at the level of the patient‘s bed.

Sensory blockade assessed by **Hollmen’s test**

1. Normal sensation of pin prick,
2. Weaker pin prick sensation
3. Pin prick recognized as touch with blunt object,
4. No sensation of pin prick.

Motor block assessed by **Modified Bromage scale**

1. No motor block
2. Inability to raise extended leg but able to move knee and feet
3. Inability to move extended leg and knee but able to move feet,
4. Complete motor block.

In our study, the data was analysed for normalcy of distribution and was expressed as mean and standard deviation. Categorical data was analysed by Chi-square test, parametric data was analysed by unpaired t- test. Non-parametric data like VAS score at rest and dynamic, quality of sensory block, modified bromage score and satisfaction score was expressed as median and Inter-Quartile Range (IQR) and tested with Mann-whitney u test. P- value of ≤ 0.05 was considered as significant.

Results:

The present study is a prospective, observational study involving two groups viz, elastomeric pump group and electronic pump group having 40 patients each.

The age of the patients in the study ranged from 20.00 – 64.00 years. Table 1 reveal that the average age was **43.30 years** in Elastomeric group, which was comparable with **45.43 years** in Electronic group and the difference was not significant.(P = 0.424). **47.5%** of the patients were male in Elastomeric group and **65%** in Electronic group and difference was not significant. (P = 0.115). Hence, both groups were comparable demographically.

Most of the patients in both the groups had their normal pin prick sensation preserved throughout the study period. As per table no. 2, the Mean sensory block (assessed by Hollmen test) at baseline was 1.00 with median and IQR of 1 and 0 in both groups, i.e. they had normal sensation of pin prick. Thus baseline was comparable. Over the study period of 24 hrs.3 patients in Elastomeric group and 2 patients in Electronic group had higher grade of sensory block. The Mean sensory block remained comparable for 24 hrs. and difference was not statistically significant. So the quality of sensory block in both the groups was same.

Table no.3shows that in postoperative period at baseline, patients in both the groups had no motor blockade. During the period of study, most of the time the mean Bromage score in both the groups was zero. The median value was also zero. Both the groups were comparable with respect to VAS Static at all-time intervals.

Table 4 shows that a total 3 patients i.e. 7.5 % of patients had motor blockade in Elastomeric group with a Bromage score of 1 and 2 patients i.e., 5.0 % of patients had motor blockade in Electronic group out of which 1 patient had Bromage score of 2 and other had Bromage score of 1.

Table 1: Demographical data

PARAMETERS	ELASTOMERIC PUMP	ELECTRONIC PUMP
No. of Cases	**40**	**40**
#Age(yrs.) Mean SD Range	43.30 12.30 20.00 - 64.00 yrs.	45.43 11.35 21.00 - 64.00 yrs.
@Sex (%) Male Female	19(47.5) 21(52.5)	26(65.0) 14(35.0)

#by unpaired T test Not Significant (P = 0.424)
@ By Chi Square test Not Significant (P = 0.115)

Table 2: Comparison of quality of sensory block

Sensory Block	ELASTOMERIC PUMP				ELECTRONIC PUMP				
	Mean	**Std. Dev.**	**Median**	**IQR**	**Mean**	**Std. Dev.**	**Median**	**IQR**	**P Value**
0 min	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	-
10 mins	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	-
20 mins	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	-
30mins	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	-
60 mins	1.00	0.00	1.00	0.00	1.03	0.16	1.00	0.00	0.317
90 mins	1.00	0.00	1.00	0.00	1.05	0.32	1.00	0.00	0.317
2hrs	1.00	0.00	1.00	0.00	1.03	0.16	1.00	0.00	0.317
3hrs	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	1.000
4hrs	1.00	0.00	1.00	0.00	1.03	0.16	1.00	0.00	0.317
5hrs	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	-
6hrs	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	-
7hrs	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	-
8hrs	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	-

By Mann-Whitney u test

Table 3: Comparison of level of motor blockade by bromage scale

Sensory Block	ELASTOMERIC PUMP				ELECTRONIC PUMP				
	Mean	**Std. Dev.**	**Median**	**IQR**	**Mean**	**Std. Dev.**	**Median**	**IQR**	**P Value**
0 min	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
10 mins	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
20 mins	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
30mins	0.00	0.00	0.00	0.00	0.03	0.16	0.00	0.00	0.3-17

60 mins	0.00	0.00	0.00	0.00	0.03	0.16	0.00	0.00	0.317
90 mins	0.00	0.00	0.00	0.00	0.05	0.32	0.00	0.00	0.317
2hrs	0.00	0.00	0.00	0.00	0.03	0.16	0.00	0.00	0.317
3hrs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
4hrs	0.00	0.00	0.00	0.00	0.03	0.16	0.00	0.00	0.317
5hrs	0.00	0.00	0.00	0.00	0.03	0.16	0.00	0.00	0.317
6hrs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
7hrs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
8hrs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
9hrs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
10hrs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
11hrs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
12hrs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
13hrs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
14hrs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
15hrs	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-

By Mann-Whitney u test

Table no. 4: Modified bromage score

Modified Bromage score	0	1	2	3
Elastomeric pump	37 patients	3 patients	None	None
Electronic pump	38 patients	1 patient	1patient	None

Discussion:

Paech et al demonstrated that adding bupivacaine to fentanyl reduced fentanyl dose requirement by 20%. [7] Although in many series, bupivacaine concentrations of 0.125 to 0.25% have been used, [8-10] a very low bupivacaine concentration of 0.0625% and fentanyl at 3.3 μg/ml, by adding 15 ml of plain bupivacaine 0.25% to 200 μg of fentanyl (2 2 2 ml ampoules) and mixing with normal saline to a total volume of 60 ml, in an attempt to provide good analgesia and minimize side-effects of either drug. With this mixture, the median VRS at rest was always less than 3 during all the observation periods from the fourth postoperative hour onward. This is comparable to a similar study using epidural infusion of a higher concentration of bupivacaine (0.15%) in diamorphine 0.01% for total abdominal hysterectomy. [11]

The degree of motor block was calculated according to Bromage scale. There is a greater degree of separation between motor and sensory blockade with ropivacaine. This can be due to it being less lipophilic than bupivacaine and is less likely to block large myelinated nerve fibers. [6]However, the motor block so developed is usually not incapacitating and does not hamper the patient's mobilization in bed or physiotherapy.

Brodner *et al*. reported bromage of >0 only in the bupivacaine group. [12] Furthermore, ability to mobilize was better in the ropivacaine group. Jørgensen *et al*. observed that 7% of patients in ropivacaine group and 15% in bupivacaine group had motor blockade. [13] Berti *et al*. and Paddalwar *et al*. also had similar findings. [14-15]

The quality of Sensory block was assessed by Hollmen score. In Hollmen scale, grade 1 represents normal pin prick sensation

and 4 indicates no pin prick sensation. Grade 2 indicates mild pin prick sensation and grade 3 is touch sensation. It was desirable to have adequate pain relief with intact sensations i.e. Hollmen score of one. The score at baseline was 1.00 in both the groups which was comparable and the difference was not significant. The mean and median sensory block in both the groups remained comparable for 24hrs and difference was not significant. Over the study period, 3 patients in elastomeric group had Hollmen score of 2 and in electronic group 1 patient had Hollmen score of 2 and one patient had score of 3, with simultaneous development of motor blockade, which was managed by temporarily cessation of infusion and the sensory block receded after 2 to 3 hours of stoppage of infusion. Most of the patients in both groups had adequate analgesia with intact normal pin prick sensation throughout the study period. Very few studies have elaborated on the sensory blockade accompanying the analgesia but have predominantly stressed on the motor blockade.

In our study, in postoperative period at baseline patients in both the groups had no motor blockade. Over the period of 24 hours, 7.5% of patients had motor blockade in Elastomeric group with a Bromage score of 1 i.e Inability to raise extended leg but able to move knee and feetand5.0 % of patients had motor blockade in Electronic group out of which 1 patient had Bromage score of 2 i.e. Inability to move extended leg and knee but able to move feet and 1 patient had Bromage score of 1. In Elastomeric group 2 patients developed motor blockade at rate of 7ml/h and one patient at rate of 5ml/h after 15 to 18 hours of infusion. In Electronic group, one patient developed motor blockade after 90 min at rate of 12ml/h and one patient after 4h of infusion at 7ml/h. Motor blockade was managed by temporary stoppage of infusion and the block recovered after 2 to 3 hours of stoppage of infusion in both the groups. At the end of study, percentage of motor blockade did not show any significant change in both the groups from baseline and difference was not statistically significant. (P = 0.644)

Christophe Dadure et al [16] in 2003 performed prospective descriptive study to evaluate the effectiveness of disposable elastomeric pumps for continuous peripheral nerve block in 25 children undergoing major orthopaedic surgery with 0.2% ropivacaine. A sensory block was noted at first hour in 18 of 25 children (72%) and this decreased from 6 hours onwards. This was also accompanied by motor block also noted at first hour in the postoperative period with a median of three and decreased totally from 6 hour onwards with the median of 0.5.

Rachid cherkab et al [17] in 2014 noticed motor block in 3% of the cases out of 35 patients in electronic group against 5.7% of cases out of 35 patients in elastomeric group but the difference was not significant. (P=0.48) [18]

Conclusion:

The quality of sensory block as assessed by Hollmen score, was comparable baseline and also throughout the study period. Three patients in Elastomeric group and two patients in Electronic group had higher degree of sensory block. Motor blockade was seen in 7.5% of patients in Elastomeric group and 5% of patients in Electronic group. At the end of 24 hours, percentage of motor blockade in both groups were comparable and the difference was statistically insignificant.

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