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Original Research Article

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 Side Effects, Patient Satisfaction and Rescue Analgesia

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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 side effects, patient satisfaction, rescue analgesia.

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: 3 patients out of 40 patients in Elastomeric group, needed Rescue analgesia. 6 hrs. Mean satisfaction score was 7.30 in Elastomeric group and 7.00 in Electronic group. The Median and IQR was 8 and 1 in Elastomeric group and 7 and 2 in Electronic group. The difference was statistically insignificant. (P = 0.168). The side effects noted in both the groups were mild, clinically not incapacitating and responded readily to treatment.

Conclusion: None of the patients in either group had any severe or incapacitating adverse effects. However, elastomeric group had hypotension and 10.0% in electronic group. One patient had bradycardia in electronic group.

Keywords: epidural infusion, rescue analgesia, elastomeric infusion pump, electronic (emco) infusion pump, patient satisfaction

Introduction

Postoperative pain plays a major role in the recovery following surgery especially in major abdominal surgeries. It causes tachycardia, hypertension and may lead to myocardial ischemia in a vulnerable subject. Pain prevents deep breathing, causes splinting

of diaphragm and promotes basal atelectasis leading to postoperative pulmonary complications. It prevents early mobilization of patients and contributes to deep vein thrombosis. In addition, uncontrolled postoperative pain can produce a neuroendocrine stress response which in turn causes release of catabolic hormones like catecholamine, cortisol, glucagon, and renin. [1]

There are many methods available to provide analgesia, including systemic analgesics (i.e. Opioid and non-opioid) and regional (i.e., neuraxial and peripheral) analgesic technique, but epidural analgesia using local anesthetics forms the gold standard for abdominal, thoracic and lower extremity surgeries.

Epidural analgesia decreases the incidence of postoperative gastrointestinal, pulmonary, and possibly cardiac complications. Analgesia for high-risk patients via the epidural route may result in shorter intensive care unit (ICU) stays. [2]

Addition of opioids to local anesthetics causes improved dynamic pain relief and reduces the dose of local anesthetic required. [3]

Use of lipophilic opioid (Fentanyl) is preferred to hydrophilic opioids as it provides rapid onset of action and rapid clearance and lesser side effects such as delayed respiratory depression. [4]

For many years electronic infusion pumps are being used to deliver the infusion of vasoactive drugs, insulin, IV fluids and local anesthetics. These infusion pumps are expensive, may not be always available and may be complicated to set up.

Since last 25-30 years, the elastomeric pumps are being used widely for delivery of chemotherapy, antibiotics and local anesthetics in peripheral nerve blocks and are found to be safe. They are economic, portable and easy to use. But they do have few shortcomings like inability to measure accuracy and no alarms system to indicate obstruction to flow. Also it can be used only at fixed rate of delivery. The flow through the device may be affected by operating temperature and pressures, viscosity of fluid and back pressure.

It is our common practice to use either electronic pump or elastomeric pumps for post-operative pain relief by continuous epidural analgesia for major abdominal general surgeries. In this study, we compared the two with respect their efficacy in reducing side effects, need for rescue analgesia and patient satisfaction.

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. Patient satisfaction score was assessed by numerical rating scale (0-dissatisfied, 10-most satisfied).

Need for rescue analgesia: if VAS score found to be > 3, the rate of infusion was increased to 7ml/hr. If VAS score was still > 3, the rate of infusion was increased to 12ml/hr. If VAS score was still >3, then rescue analgesia was given in the form of 50mg of inj TramadoI IV. Or inj paracetamol 1 gm IV. Total dose of rescue analgesia required over 24 hours was noted.

Side effects if any, were treated appropriately

1. High level of block (If Bromage score >1, the infusion was stopped temporarily).

2. Hypotension (if BP < 25% of baseline) was managed by adequate fluid resuscitation and if did not respond, by giving inj ephedrine.

3. Bradycardia – was managed by inj atropine.

Results:

In both the groups, the analgesia was managed by stepping up the infusion rate of the local anesthetic. Whenever, the VAS score did not respond to maximum rate of infusion i.e. 12ml/h, the rescue analgesia was given. As per Table 1, 3 patients out of 40 patients in Elastomeric group, needed Rescue analgesia. Over 24 hours, one patient required 1 gm inj paracetamol IV, one patient required 2 gm inj paracetamol IV and one patient required 2 gm inj paracetamol + inj tramadol 100mg IV. Out of 40 patients in Electronic group, 4 patients required Rescue analgesia. Over 24 hours, among 4 patients one patient required 1 gm inj paracetamol IV, Two patients required 1 gm inj paracetamol IV +

inj tramadol 100 mg IV and one patient required 2 gm inj paracetamol IV + inj tramadol 100 mg IV.

As per table 2; at 6 hrs the mean satisfaction score was 7.30 in Elastomeric group and 7.00 in Electronic group. The Median and IQR was 8 and 1 in Elastomeric group and 7 and 2 in Electronic group. The difference was statistically insignificant. (P = 0.168). At the end of 12 hrs. Mean satisfaction score was 7.65 with Median and IQR of8 and 2.5 in Elastomeric group and Mean satisfaction score was 7.80 with Median and IQR of 8 and 2 in Electronic group. The difference was statistically insignificant. (P = 0.726). At the end of 18 hrs. Mean satisfaction score was increased to 8.18 in Elastomeric group and 8.10 in Electronic group. The Median and IQR was 8.5 and 2 in Elastomeric group and 9 and 2 in Electronic group. Both groups were comparable and the difference was not statistically significant. (P = 0.760). After 24 hrs. the Mean satisfaction score was increased in both the groups to 9.20 in Elastomeric group and 9.10 in Electronic group. The Median and IQR was 9 and 1 in both the groups. The difference was statistically insignificant. (P = 0.466). The higher satisfaction score indicated higher degree of satisfaction of patient with the level of analgesia.

As per table no. 3 the Mean drug delivered over 24 hrs. is 5.88 ml/h in Elastomeric group and 5.95 ml/h in Electronic group. The difference was statistically insignificant. (P =0.8605).

As per table 4, the side effects noted in both the groups were mild, clinically not incapacitating and responded readily to treatment. 3 patients of Elastomeric group showed motor blockade with a Bromage score of 1 and 2 patients of Electronic group showed motor blockade with a Bromage score of 2 in one patient and 1 in other patient. The difference was statistically insignificant. (P = 0.664). In Elastomeric group 5 patients had hypotension and 4 patients in Electronic group. The difference was statistically insignificant. (P = 0.723). 1 patient had bradycardia in Electronic group and none of the patients had arrhythmias in Elastomeric group.

Table 1: Number of patients receiving rescue analgesia

RESCUE ANALGESIA		ELASTOMERIC PUMP	ELECTRONIC PUMP
Inj Paracetamol 2 gm IV	No	1	0
	%	2.5%	0%
Inj Paracetamol 1 gm IV	No	1	1
	%	2.5%	2.5%
Inj Paracetamol 2 gm iv + Inj Tramadol 100 mg iv	No	1	1
	%	2.5%	2.5%
Inj Paracetamol1 gm iv + Inj Tramadol 100mg iv	No	0	2
	%	0%	5%
No rescue	No	37	36
	%	92.5%	90.0%
Total	No	40	40
	%	100%	100%

Table 2: Comparison of mean satisfaction score

Satisfaction Score	Baxter Infusion Pump				Electronic Infusion Pump				P Value
	Mean	Std.Dev.	Median	IQR	Mean	Std.Dev.	Median	IQR	
6 hr.	7.30	0.99	8.00	1.00	7.00	1.28	7.00	2.00	0.168
12 hr.	7.65	1.19	8.00	2.50	7.80	1.24	8.00	2.00	0.726
18 hr.	8.18	1.22	8.50	2.00	8.10	1.22	9.00	2.00	0.760
24 hr.	9.20	0.91	9.00	1.00	9.10	0.96	9.00	1.00	0.466

Table 3: Drug delivery over 24 hours

Groups	Volume of Drug Delivered over 24 hours (ml/h)X± SD
ELASTOMERIC PUMP (N = 40)	5.88 ± 1.81
ELECTRONIC PUMP (N = 40)	5.95 ± 1.74
P value	0.8605

Table 4: Comparison of side effects

SIDE EFFECTS	ELASTOMERIC PUMP	ELECTRONIC PUMP	P Value
MOTOR BLOCKADE	3 pts.	2 pts.	0.644
HYPOTENSION	5 pts.	4 pts.	0.725
ARRHYTHMIAS	NONE	1 pts. (BRADYCARDIA)	1.00

Discussion:

In both the groups, whenever the VAS score did not respond to maximum rate of infusion i.e. 12ml/h, the rescue analgesia was given in the form of inj. paracetamol 1 gm IV or inj. tramadol 100 mg IV. In our study over 24 hours, 3 patients out of 40 patients in Elastomeric group and 4 patients out of 40 patients in Electronic group needed rescue analgesia. However study done by Capdevila, Xavier et al [5] in 2001studyout of 76 patients, 8 patients in Elastomeric pump and 11 patients in Electronic group used rescue analgesia (acetaminophen + codeine) twice during the studied period (not significant).

Sergio bertoglio et al [6] in 2012 compared efficacy of pre-peritoneal continuous wound infusion to epidural continuous infusion using Elastomeric pump with local anesthetic for postoperative analgesia after colorectal cancer surgery in 106patients. They showed that 16 patients in the CEI group and 14 patients in the CWI group required rescue analgesia, ketorolac 30 mg or paracetamol 1gm.

Satisfaction score was assessed by numerical rating scale every 6 hourly where 0 is dissatisfied, 10 is most satisfied. At 6 hrs Mean satisfaction score was 7.30 in Elastomeric group and 7.00 in Electronic group, both the groups were comparable and the difference was statistically insignificant. (P=0.168) Over period of study as VAS score decreased with time, satisfaction score increased. After 24 hrs the Mean satisfaction score was increased from baseline in both the groups to 9.20 in Elastomeric group and 9.10 in Electronic group. The median value of both the groups was same at the end of study (median = 9). Overall the patients in both groups were satisfied about the analgesia offered. However, Capdevilla Xavier et al in 2001, found in their study that median satisfaction score was 9 in elastomeric group, 8 in PCA group and 6 in electronic infusion group. When elastomeric group was compared to electronic infusion group, this was significant ($p< 0.05$).

Rachid cherkab et al in 2014 showed that the patient satisfaction was better in elastomeric group, 88.4% in electronic group against 94.3% in elastomeric group. However, this was without statistically significant difference: ($P = 0.8$). [7]

Remerand, Francis et al [8] in 2008 did a survey of 430 consecutive elastomeric pump device's reliability in postoperative regional anesthesia. Perineural infusion of local anesthetic of 0.2% ropivacaine was provided randomly with either Infusor LV5 (Baxter) or Easy pump, both set at 5ml/hr. Clinical assessment of elastomeric pump flow rate was done by weighing the devices at the bedside using a portable electronic scale several times a day, the difference between its first weight on the surgical ward and the last one, divided by the time (in min) between these two measures. During their study period after connection to the catheter, 88 devices did not deflate, 80 Easy pump of 300 and 8 Infusor of 130, $P < 0.0001$. The flow rates differed from those set by manufacturers (5 mL/h ± 15%) in 47% of Easy pump and in 34% of Infusor devices ($P = 0.01$).

In elastomeric group 3 patients i.e. 7.5% had motor blockade with a Bromage score of 1 and 2 patients i.e. 5.0% of Electronic group showed motor blockade with a Bromage score of 2 in one patient and 1 in other patient, but the difference was statistically insignificant. Motor blockade was managed by temporarily stoppage of infusion pump.

In Elastomeric group 5 patients i.e. 12.5% had hypotension and 4 patients i.e. 10.0% had hypotension in Electronic group, the difference was statistically not significant ($P = 0.723$) hypotension was treated with IV fluids and inj ephedrine if required.

1patient had bradycardia in electronic group which was managed by inj atropine 0.6 mg IV and none of the patient had arrhythmias in elastomeric group. Another side effect of using elastomeric pump we observed was the wastage of local anesthetic drug. Since, the elastomeric pumps are prefilled to a specific volume as per the instructions of the manufacturer, the drug which was not used after the study period was wasted.

A lipophilic opioid such as fentanyl is less likely to cause respiratory depression. It is more common with hydrophilic opioids such as morphine, which are capable of cephalad migration. Subarachnoid or intravenous migration of the epidural catheter can also result in respiratory depression. Furthermore, with continuous infusion, there is increase in protein binding (α1‑acid glycoprotein) and decreased clearance of the drug. In addition, the poor general condition and extensive surgery can also contribute toward respiratory insufficiency. [9-10]

Higher doses of ropivacaine as compared to bupivacaine are generally required to elicit equivalent analgesic effects.[11]Bupivacaine is said to be 40% more potent than ropivacaine. [12-13]

Studies by Casati et al., Pouzeratte et al., Jørgensen et al., and Surabathuni et al. reported that the need for rescue analgesia was more in the ropivacaine group than the bupivacaine group. [14-18]

Conclusion:

Throughout the study period the dynamic mean VAS score was comparable in both the groups. In our study over 24 hours, 3 patients in Elastomeric group and 4 patients in Electronic group needed rescue analgesia in the form of inj paracetamol 1 gm IV or inj tramadol 100 mg IV or both. The quality of sensory block as assessed by Hollmen score was comparable at 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 was comparable and the difference was statistically insignificant. Mean satisfaction score was comparable throughout the study period. At the end of 24 hours, the score was 9.20 in elastomeric group and 9.10 in electronic group. Both the groups were satisfied about the analgesia offered. None of the patients in either group had any severe or incapacitating adverse effects. However, elastomeric group had hypotensionand 10.0% in electronic group. One patient had bradycardia in electronic group.

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