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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: Haemodynamic Parameters

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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-Haemodynamic Parameters.

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: There was no statistically significant difference in the heart rate between the two groups throughout the duration of study. Throughout the duration of study, there was a steady fall in the SBP in both the groups, though the values were within normal range.Overall the Mean SBP remained stable throughout the postoperative period and the difference between both the groups was statistically insignificant.

Conclusion: Haemodynamic stability was maintained throughout the infusion in both the groups. In our study the baseline hemodynamic parameters, which included heart rate, systolic blood pressure and diastolic blood pressure were comparable, and difference was statistically insignificant. Overall, the hemodynamic parameters remained stable throughout the postoperative period in both the groups. The mean drug delivered over 24 hours was comparable in both the groups and the difference was statistically insignificant.

Keywords: epidural infusion, hemodynamic parameters, elastomeric infusion pump, electronic (emco) infusion pump

Introduction

Effective analgesia for postoperative pain relief after major surgery has been a practical proposition with epidural administration of local an aesthetic (LA) and opioid drugs since the early 1980s. Although epidural administration is perceived by 80% of anesthetists as the ideal analgesic technique for upper abdominal surgery, [1] there are many

patients undergoing major surgery who do not receive this form of analgesia.

The main factor which has limited the use of epidural analgesia has been the difficulty in making a reasonable risk/benefit analysis about the technique, which has resulted in clinicians constantly asking whether epidurals are effective for postoperative pain relief and whether the technique is safe. [2]

The epidural administration of local an aesthetic with opioids and patient-controlled analgesia (PCA) by intravenous (IV) opioid administration are commonly used for postoperative pain management. [3-8]

The routine use of epidural clonidine up to 900 mg as boluses of 100 mg is likely to produce significant hemodynamic depression and sedation. [9] When infused at 20 mg/h±1 with bupivacaine and fentanyl, it was shown to improve analgesia at rest and during coughing but, again, was associated with significant hemodynamic changes. [10]

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.

Postoperatively, patients were shifted to recovery room. Patient's hemodynamic stability was confirmed; the rate of infusion was increased or decreased as per the hemodynamic parameters.

In our study, the data was analyzed for normalcy of distribution and was expressed as mean and standard deviation. Categorical data was analyzed by Chi-square test, parametric data was analyzed 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:

Table 1 reveals postoperative baseline Mean heart rate was **93.83** in Elastomeric group which was comparable to **89.68** in Electronic group. **(P = 0.273).** At the end of 18 hrs. Mean heart rate was **87.60** in Elastomeric group and **87.33** in Electronic group. The difference was not clinically significant. **(P= 0.913).** At the end of 24 hrs. the Mean heart rate was **85.08** in Elastomeric group and **84.08** in Electronic group. Both the groups were comparable and the difference was insignificant. **(P = 0.671).** There was no statistically significant difference in the heart rate between the two groups throughout the duration of study.

Table no.2 reveals that the postoperative baseline Mean systolic blood pressure was **126.23 mmHg** in Elastomeric group and **129.45 mmHg** in Electronic group and the difference was statistically not significant.**(P = 0.288).** Throughout the duration of study, there was a steady fall in the SBP in both the groups, though the values were within normal range. Overall the Mean SBP remained stable throughout the postoperative period and the difference between both the groups was statistically insignificant.

Table no. 3 reveals that postoperative baseline mean diastolic blood pressure was **81.18 mmHg** in Elastomeric group which was comparable to **83.20 mmHg** in Electronic group, the difference was not significant. **(P = 0.385).** Throughout the study, the diastolic blood pressure showed a steady decline. At the end of 24 hrs. the Mean diastolic blood pressure was steadily reduced from baseline to **69.73** in Elastomeric group and **71.80** in Electronic group, both the groups were comparable and the difference was insignificant **(P = 0.290)**

Table 1: Comparison of mean heart rate between two groups

HR (per min)	ELASTOMERIC PUMP		ELECTRONIC PUMP		P VALUE
	Mean	Std.Dev.	Mean	Std.Dev.	

0 min	93.83	17.13	89.68	16.52	0.273
10 mins	91.88	16.94	88.40	13.67	0.316
20 mins	92.03	15.48	88.25	13.15	0.243
30mins	91.23	16.42	87.83	12.33	0.298
60 mins	90.93	15.36	86.03	12.16	0.118
90 mins	91.30	15.49	85.45	11.48	0.059
2hrs	90.00	14.18	85.75	11.72	0.148
3hrs	88.58	12.17	84.48	11.73	0.129
4hrs	89.60	11.89	85.50	11.88	0.127
5hrs	89.30	11.38	85.68	10.34	0.140
6hrs	89.30	10.85	85.88	10.89	0.163
7hrs	89.75	10.13	86.38	11.86	0.175
8hrs	88.25	10.65	85.03	11.03	0.187
9hrs	88.30	12.43	85.28	10.47	0.243
10hrs	88.18	12.79	86.60	10.98	0.556
11hrs	87.80	12.65	87.13	11.80	0.806
12hrs	88.33	12.63	87.03	10.44	0.617
13hrs	89.48	14.19	87.33	11.39	0.457
14hrs	88.70	13.38	87.20	9.96	0.571
15hrs	87.63	12.59	86.03	11.33	0.552
16hrs	88.43	12.56	87.30	11.93	0.682
17hrs	88.45	12.65	88.38	12.37	0.979
18hrs	87.60	11.40	87.33	11.14	0.913
19hrs	87.33	11.40	87.35	10.91	0.992
20hrs	85.88	10.75	86.58	10.91	0.773
21hrs	85.58	10.14	85.65	10.45	0.974
22hrs	85.35	11.29	84.93	11.10	0.866
23hrs	85.98	11.77	84.38	10.42	0.522
24hrs	85.08	10.98	84.08	9.94	0.671

Unpaired t-test

Table 2: Comparison of mean systolic blood pressure

SBP (mmHg)	ELASTOMERIC PUMP		ELECTRONIC PUMP		P VALUE
	Mean	Std.Dev.	Mean	Std.Dev.	
0 min	126.23	13.99	129.45	12.95	0.288
10 mins	125.45	11.91	128.48	13.66	0.295
20 mins	124.35	12.58	127.45	12.37	0.270
30mins	123.85	11.89	127.08	11.95	0.230
60 mins	124.00	11.21	126.00	11.39	0.431
90 mins	123.50	12.08	123.90	13.63	0.890
2hrs	121.90	12.80	122.05	13.33	0.959
3hrs	120.95	12.33	121.08	12.95	0.965
4hrs	116.08	20.48	122.03	11.57	0.114
5hrs	119.50	13.20	122.78	12.40	0.256
6hrs	118.78	12.30	121.53	11.65	0.308
7hrs	118.83	12.89	121.55	11.20	0.316
8hrs	118.88	13.06	121.85	11.79	0.288
9hrs	116.58	13.61	120.93	11.00	0.120

10hrs	116.58	12.62	119.78	12.07	0.250
11hrs	118.28	12.94	121.23	11.44	0.283
12hrs	116.90	13.78	119.93	10.13	0.267
13hrs	117.43	12.62	119.55	12.29	0.448
14hrs	118.38	11.49	118.18	11.38	0.938
15hrs	118.98	11.14	119.38	10.73	0.871
16hrs	116.55	12.14	118.05	11.94	0.579
17hrs	117.20	12.87	118.43	12.03	0.661
18hrs	116.23	11.57	116.53	10.97	0.906
19hrs	116.23	11.85	117.20	12.04	0.716
20hrs	115.30	13.05	117.20	11.98	0.500
21hrs	116.95	13.13	116.20	12.55	0.795
22hrs	113.88	11.64	115.83	12.20	0.467
23hrs	114.68	13.62	116.18	12.73	0.612
24hrs	114.20	10.78	115.98	11.51	0.479

Unpaired t- test

Table 3: Comparison of mean diastolic blood pressure

DBP (mmHg)	**ELASTOMERIC PUMP**		**ELECTRONIC PUMP**		**P VALUE**
	Mean	Std.Dev.	Mean	Std.Dev.	
0 min	81.18	9.91	83.20	10.82	0.385
10 mins	80.35	9.09	81.88	10.36	0.486
20 mins	79.55	8.16	81.73	9.94	0.288
30mins	79.30	8.09	81.63	9.16	0.233
60 mins	79.00	8.24	80.73	9.57	0.390
90 mins	77.25	8.70	78.25	10.53	0.645
2hrs	75.40	9.62	75.55	15.57	0.959
3hrs	75.73	9.52	77.48	9.82	0.421
4hrs	74.78	9.86	77.30	9.17	0.239
5hrs	74.35	9.84	77.13	8.17	0.174
6hrs	74.50	8.98	76.30	8.17	0.351
7hrs	73.98	10.22	75.75	8.19	0.394
8hrs	72.08	14.41	76.48	13.87	0.168
9hrs	73.00	10.27	77.13	8.49	0.054
10hrs	73.78	9.54	75.50	9.63	0.423
11hrs	73.25	9.56	76.10	9.81	0.192
12hrs	72.50	9.90	76.03	7.26	0.073
13hrs	74.40	9.06	77.00	10.24	0.233
14hrs	73.53	8.35	74.80	9.01	0.514
15hrs	73.58	9.12	75.03	8.77	0.471
16hrs	71.83	9.89	74.75	9.16	0.174
17hrs	72.80	8.29	74.90	8.31	0.261
18hrs	72.68	9.03	74.50	8.25	0.348
19hrs	72.38	8.23	88.70	93.74	0.276
20hrs	71.30	8.34	72.90	7.74	0.376
21hrs	71.83	7.91	71.75	7.95	0.966
22hrs	70.73	8.10	73.15	9.10	0.212

23hrs	70.48	9.24	72.70	9.02	0.279
24hrs	69.73	8.70	71.80	8.73	0.290

Unpaired t-test

Discussion:

In our study the baseline mean heart rate was **93.83** in Elastomeric group which was comparable to **89.68** in Electronic group. **(P = 0.273)** At the end of 24 hrs., the mean heart rate was **85.08** in Elastomeric group and **84.08** in Electronic group, which was comparable and the difference was insignificant.**(P = 0.671)** Throughout the duration of study, there was steady fall in mean heart rate with no statistically significant variation in both groups.

The mean baseline systolic blood pressure was **126.23 mmHg** in Elastomeric group and **129.45 mmHg** in Electronic group which was comparable. This difference was statistically not significant. **(P = 0.288).** At the end of 24 hours mean SBP was **114.20 mmHg** in Elastomeric group and **115.98 mmHg** in electronic group, both the groups were comparable and the difference was not significant**(P = 0.479)**.Throughout the duration of study, there was a steady fall in the SBP in both the groups, though the values were within normal range. Overall the SBP remained stable throughout the postoperative period. **Few patients had fall in SBP in both the groups**. In Elastomeric group **5 pts i.e. 12.5%** of patients had hypotension which was treated with IV fluids and Inj epdhedrine if required and infusion was stopped temporarily for 2 to 3 hours. In Electronic group **4 pts i.e. 10.0%**of patients had fall in blood pressure. The difference was statistically insignificant.

Rachid cherkab et al [11] 2014 study revealed that in 11.5% out of 35 patients of electronic group experienced at least one episode of hypotension against 8.5% out of 35 patients in elastomeric group (P = 0.63). The difference was statistically insignificant.

The baseline mean diastolic blood pressure in both the groups was **81.18 mmHg** in Elastomeric group which was comparable to **83.20 mmHg** in Electronic group, the difference was not significant. **(P = 0.385)** Throughout the study, the diastolic blood pressure showed a steady decline in both groups and the difference was statistically insignificant.

Hemodynamic parameters remained stable in both the groups in the postoperative period. However, patients in the bupivacaine group developed hypotension, of which two patients required temporary withholding of infusion. This hypotension was mild and responded to intravenous fluid. Thus, when used in the said concentrations, both the drugs were found to be safe and had a similar effect on the patient's heart rate and blood pressure. **[12]**

This trend of hemodynamic parameters was similar to that observed by Akifumi *et al*., Pouzeratte *et al*., and Finucane *et al*. **[13-15]**

Delayed respiratory depression after administration of epidural opioids in infants and young children has been reported in the past. **[16-19]** However, these reports are associated with the use of high-dose morphine in the epidural space, and not fentanyl. In addition, most of these episodes of respiratory depression have been observed in infants who received supplemental intravenous opioids. **[20,21]**

Conclusion:

Haemodynamic stability was maintained throughout the infusion in both the groups. In our study the baseline hemodynamic parameters, which included heart rate, systolic blood pressure and diastolic blood pressure were comparable and difference was statistically insignificant. Overall the

hemodynamic parameters remained stable throughout the postoperative period in both the groups. The mean drug delivered over 24 hours were comparable in both the groups and the difference was statistically insignificant.

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