Original Article

Comparison of patient controlled epidural infusion versus physician controlled epidural infusion for postoperative analgesia in patients undergoing major abdominal surgeries

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Abstract

Background and Aims: For effective patient-controlled epidural analgesia (PCEA) without many systemic effects after major intra-abdominal surgeries, optimal analgesic solution, background infusion rates, and settings need to be determined. The primary aim was to compare the efficacy of PCEA versus physician-controlled epidural analgesia (PhCEA) in terms of pain relief after major intra-abdominal surgeries. The secondary aim was, to establish an acceptable PCEA regime, to compare the vitals, amount of drug used, acute pain service (APS) interventions, rescue analgesics, and side effects.

Material and Methods: This prospective randomized study was conducted on consenting 102 adult patients undergoing major intra-abdominal surgeries. The study drug was levobupivacaine 0.125% with fentanyl 2 ug mL^{-1}. Trained nursing staff assessed patients and data were collected at fixed intervals (0, 1, 2, 4, 8, 12, and 24 h) till 24 hours post-surgery. Chi-square test, independent 't' test, and Mann–Whitney U test were used and P value < 0.05 was considered as significant.

Results: Pain scores were comparable in between the groups. Patients in the PCEA group had significantly ($P = 0.000$) fewer APS interventions (2.2 vs. 1.4 times) and need for rescue analgesics (1.8 vs. 0.8 times). There was no incidence of deep sedation, pruritus, hypotension, numbness, or complete motor block in either group.

Conclusion: PCEA with background infusion is better than PhCEA after major intra-abdominal surgeries as it requires lesser pain team interventions and rescue analgesics. Epidural administration of lower concentration of opioid and local anesthetic gives adequate pain relief without any untoward side effects.

Keywords: Epidural analgesia, pain relief in major intra abdominal surgeries, patient-controlled epidural analgesia, physician controlled epidural analgesia

Introduction

Pain is a protective mechanism but if not treated well, it causes anxiety, depression, and anger, which can increase postoperative morbidity.[1] Opioids, non-opioids, and local anesthetics administered alone or in combination via various routes have been the mainstay of postoperative pain relief for a long time. While the routes of administration might vary, the method of administration via patient-controlled tools is gaining increased popularity due to its advantages like patient autonomy, minimization of drug dose, optimal analgesia with minimal side effects, high patient satisfaction, reduced demand on professional time, prevention of chronic post-surgical pain and avoidance of fluctuations in analgesia.[2,3]

While systemic drugs are effective, local anesthetics with opioids administered via epidural route are found to be

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more effective in reducing pain[4,5] after thoracoabdominal surgeries and the combination reduces the dose requirement and adverse effects of each drug.[6,7] Epidural also helps in early mobilization; prevention of deep vein thrombosis and good pulmonary functions postoperatively.[4-7]

A majority of studies done so far have included a higher concentration of fentanyl (4–5 ug mL^{-1}) along with bupivacaine.[6,8-10] There is also no consensus on the use of background infusion in patient-controlled epidural analgesia (PCEA). We designed this study to explore the advantages and disadvantages of PCEA with background infusion technique over physician-controlled epidural analgesia (PhCEA) in a group of patients undergoing major intra-abdominal surgeries using a lower concentration of fentanyl at 2 ug mL^{-1} along with levobupivacaine 0.125%.

Material and Methods

Following ethical committee approval (IEC-KIMS/2016/ANES), this prospective randomized study was conducted on patients undergoing major intra-abdominal surgeries (surgical incision extending above the umbilicus) at a tertiary care hospital in south Kerala (India). The primary aim of the study was to compare the efficacy of PCEA versus physician-controlled epidural analgesia (PhCEA) in terms of pain relief after major intra-abdominal surgeries. The secondary aim was to establish an acceptable PCEA regime, to compare the vitals, amount of drug used, acute pain service (APS) interventions, rescue analgesics, and side effects.

Sample size ($n = 51$) was calculated based on a prospective study done by Liu SS *et al.*[8] by using the standard formula [$n = (Z1\text{-}\alpha\backslash 2 + Z1\text{-}\beta)^2 (\sigma 12+\sigma 22)/\delta 2$] wherein, level of significance ($Z1\text{-}\alpha\backslash 2$) is 1.96 (at 5%) and power of the study ($Z1\text{-}\beta$) is 0.842 (at 80%). The patients were randomized into two groups by using a simple randomization technique.

Consenting 102 adults (18–70 years) undergoing major abdominal surgeries under general anesthesia with epidural analgesia were included in the study. Patients in whom epidural was contraindicated or not used postoperatively due to complications, allergic to study drugs, or have to be put on ventilator support postoperatively, were excluded from the study [Figure 1]. Preoperatively, patients were allotted into two groups randomly: Group A [PhCEA] and Group B [(PCEA) and the patients in Group B were familiarized with PCEA pump use and numerical rating scale (NRS)[11] for pain. All patients received general anesthesia with epidural block as per the routine protocol and no interference was made in the intraoperative use of epidural. The study drug was levobupivacaine 0.125% with fentanyl 2 ug mL^{-1}. Immediately after shifting to the postoperative care unit, both the groups received 5 mL of the study drug as epidural priming dose. Later, Group A received an infusion at the rate of 6 mL h^{-1} via a syringe pump (Perfusor compact B/BRAUN) and Group B received the drug at the rate of 6 mL h^{-1} as background infusion, 3 mL bolus on demand with 20 min lockout period with a maximum hourly dose of 15 mL h^{-1} via PCEA pump (CADD-Legacy® pump).

On complaint of pain or NRS >4 at rest or on deep breathing, Group A received 5 mL of the study drug as epidural bolus and the rate of infusion was stepped up by 2 mL h^{-1} (up to 15 mL h^{-1}) whereas, in Group B, the patient was encouraged to press the demand button. When there was no response within 5-10 minutes after boluses, the APS team was informed and either injection tramadol (Tramazac-Alidac Corza) 2 mg kg^{-1} or injection paracetamol (Kabimol) 1 gm intravenous (IV) was given. The APS team included the duty anesthesiologist and pain nurse who were well-informed about the study [Figure 1].

Patients were assessed by trained nursing staff for pain at rest and on deep breathing, sedation, pulse rate, respiratory rate, blood pressure, oxygen saturation (SpO2), and side effects such as nausea, vomiting, pruritus, hypotension, respiratory depression at fixed intervals (0, 1, 2, 4, 8, 12, and 24 h) till 24 h postoperatively. After 24 h, total dose of levobupivacaine and fentanyl used, number of additional epidural boluses, and intravenous analgesics given were noted.

Methods of measurement of outcome: Pain was assessed by using, NRS,[11] wherein score of 0 is no pain, 1–4 is mild, 5–7 is moderate and 8–10 is scored as severe pain. Sedation was assessed by using the scoring system[12] wherein the awake and alert patient was given a score of 1, asleep and easily arousable score 2, asleep, arousable but unable to stay awake score 3 and patients who were not easily arousable were scored 4. Bromage scoring[13] was used to assess motor block (Score 1: no block, Score 2: partial block, Score 3: almost complete block, and Score 4: complete block). Hypotension was defined as a drop of systolic blood pressure of more than 20% of preoperative value or less than 90 mmHg during the study period.[8] Respiratory depression was defined as respiratory rate of less than 8–10/min.[8]

Mann–Whitney U test to compare pain, sedation, and Bromage scores, Chi-square test to compare total volume of drug used, number of APS team interventions and need for systemic analgesia and independent 't' test to compare demographic and hemodynamic variables between the groups

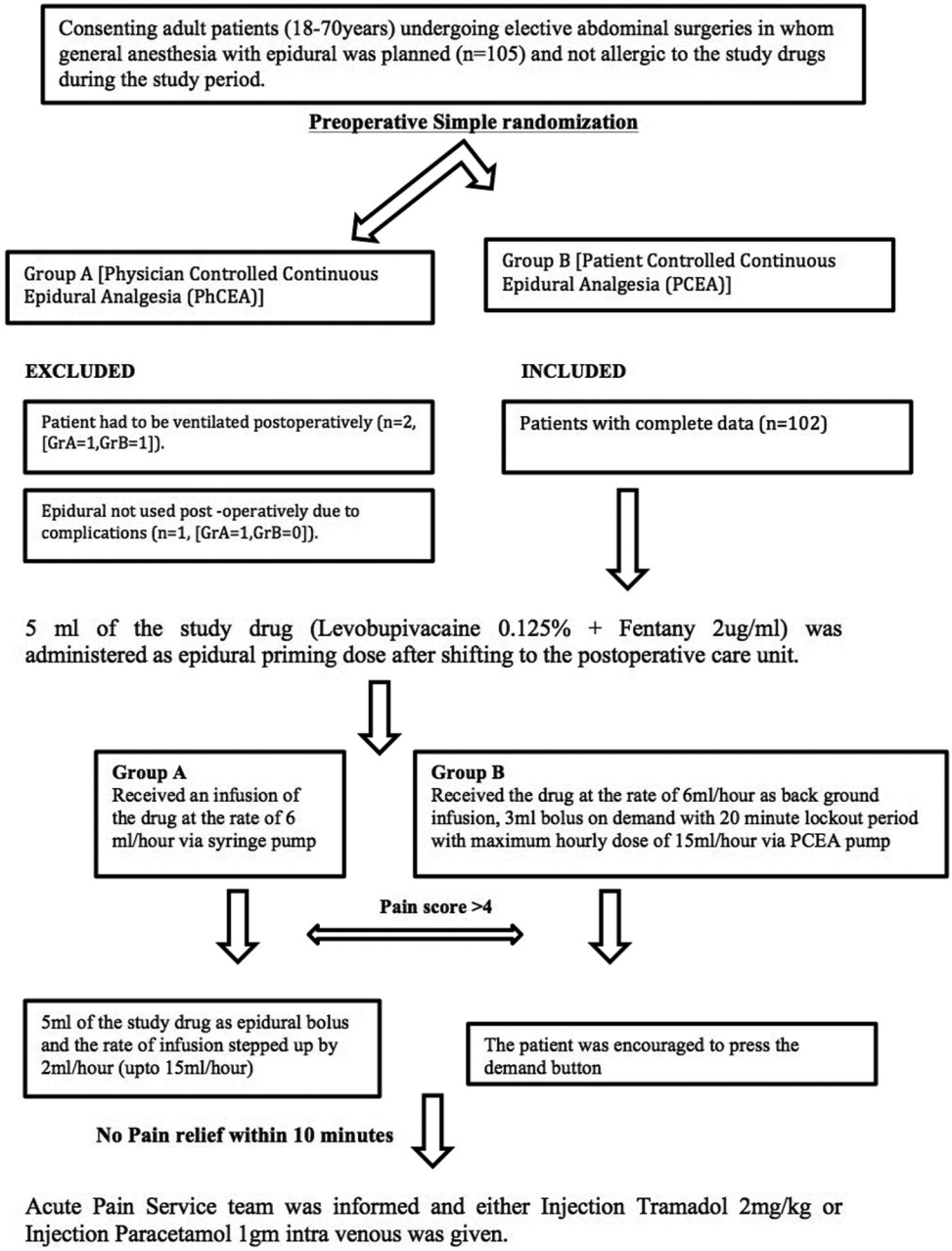

Figure 1: Flow diagram of methodology

were used. Statistical analysis was done using IBM SPSS 20.0 (Armonk, NY, USA) and P value < 0.05 was considered as statistically significant.

Results

Both the intervention groups were comparable in terms of demographic variables, respiratory rates, SpO2, and duration of surgery [Table 1]. Group A (PhCEA) required significantly more APS team interventions (2.2 ± 1.4 vs. 0.7 ± 0.6 times) and rescue analgesics (1.8 ± 1.1 vs. 0.8 ± 0.8 times) than PCEA group ($P = 0.000$). In both the groups (PhCEA vs. PCEA), a few patients had side effects like hypotension (2–7.8% vs. 0–2%) and lower limb numbness (2% vs. 0%) at different periods of observation. But the difference was not statistically significant ($P = 0.200$). Patients in the PCEA group took significantly ($P = 0.000$) more epidural boluses (14.4 ± 7.2 vs. 1.3 ± 0.9 times) and used more amount of drug (185.0 ± 24.3 mL vs. 172.5 ± 29.4 mL).

The PCEA group had a significantly higher heart rate at 12 h ($P = 0.004$) and 24 h ($P = 0.04$) after the surgery and mean blood pressure (MBP) was significantly lower at 0, 4, and 12 h ($P = 0.02$, 0.01, and 0.02, respectively) as compared to the PhCEA group [Figure 2].

Table 1: Comparison of different parameters between the groups

Parameter	PhCEA Group (mean±standard deviation)	PCEA Group (mean±standard deviation)	*P*
Male (*n*)	29	32	
Female (*n*)	22	19	0.545
Age (years)	55.7±13.8	50.7±12.3	0.057
Height (cm)	161.5±8.3	163.1±7.1	0.284
Weight (kg)	62.6±10.4	64.8±10.1	0.268
BMI	24±3.4	24.3±3.1	0.573
Duration of surgery (h)	6.7±2.6	7.2±2.3	0.329
Respiratory rate (breaths min^{-1})	19±3.21	21±2.48	0.558
Number of times rescue analgesic administered	1.8±1.1	0.8±0.8	0.000
Number of APS interventions	2.2±1.4	0.7±0.6	0.0000
Number of times epidural boluses taken	1.3±0.9	14.4±7.2	0.0000
Total amount of drugs used in 24 h (mL)	172.5±29.4	185.0±24.3	0.022

The PhCEA group had a pain score >4 at rest at 1st and 2nd h and score >4 on deep breathing at 1st h. The scores decreased over time in both the groups; the trend is more pronounced in the PCEA group. None of the patients in either group had severe pain at rest but a few patients in either group had severe pain on deep breathing and there is no statistically significant difference between the groups [Figure 3].

None of the patients had deep sedation or complete motor block [Figure 4]. In the PCEA group, significantly fewer number of patients were having sedation score of 3 ($P = 0.002$) and the PhCEA group had a significantly higher ($P = 0.023$) number of patients with grade II power till 8 h postoperatively in comparison to the PCEA group where the majority had grade I power. There was no significant hypotension or numbness in either group [Figure 4].

Discussion

This study was conducted to compare the efficacy of PCEA with background infusion, over PhCEA in patients undergoing major intra-abdominal surgeries, using a lower concentration of local anesthetic and opioids. There is no doubt that, many high-risk patients including the elderly, undergoing major intra-abdominal surgery, will receive substantial benefit from combined general and epidural anesthesia intraoperatively with continuing postoperative epidural analgesia.[14] However, the drug and dosage regime remains different.

Local anesthetic alone is proven to be less effective with relatively high incidence of motor block and hypotension.[8,15] Use of combination of lower dose local anesthetic and opioids have advantages of providing superior postoperative analgesia (including improved dynamic pain relief), limiting regression of sensory blockade, improving mental status and bowel activity[14] and decrease in the dose of local anesthetic.[16]

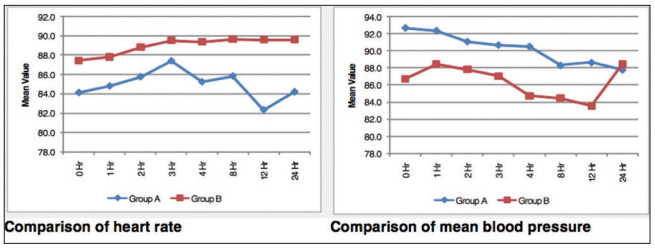

Figure 2: Comparison of vital signs between PhCEA and PCEA groups

A lipophilic opioid like fentanyl is usually chosen because of its rapid analgesic effect and shorter duration of action. The concentration of fentanyl used in various studies[6,8,10,17-19] varies between 4 and 5 ug mL^{-1} along with 0.1–0.125% bupivacaine.

Scott *et al.*[6] in their study of postoperative analgesia used three different concentrations of fentanyl (1, 5, and 10 ug mL^{-1}) along with 0.1% bupivacaine. There was no set initial infusion rate, set the maximum limit or background infusion. Liu *et al.*[8] used 0.05% bupivacaine with fentanyl 4 ug mL^{-1} with 2 mL bolus and lockout period of 10 min. There was no background infusion and no maximum limit set. Wigfull J *et al.*[19] used 0.1% bupivacaine with fentanyl 5 ug mL^{-1} without any fixed prescription. These studies targeted all post-surgical patients who underwent surgeries other than abdominal surgeries. are not necessarily abdominal surgeries. Previous studies have reported side effects like pruritus (10.2–16.7%), sedation (7.4–13.2%), nausea vomiting (3.1–14.8%), and respiratory depression (0.3–1.2%).[6,8,10,17-19] These studies recommend further studies to determine the optimal analgesic solution, background infusion rates, and settings for PCEA.

Among the studies targeting major abdominal surgeries, Standl *et al.*[9] and Silvasti M, *et al.*[10] did not use background infusion and patients could receive 5 mL bolus of the bupivacaine 0.1% with sufentanil 0.5 ug mL^{-1} or fentanyl 5 ug mL^{-1}

respectively with maximum three boluses in an hour whereas Komatsu H *et al.*[17] and Mann C *et al.*[14] recommend the use of background infusion. Mann C *et al.*[14] also report the inability of elderly patients to use PCEA pump in the initial postsurgical hours.

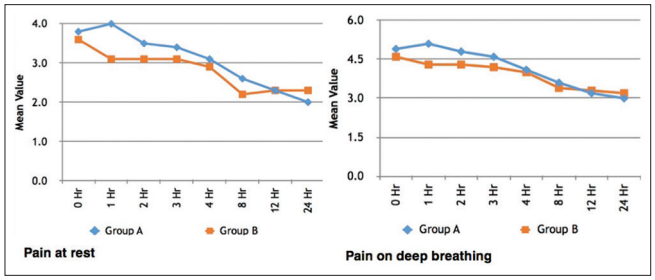

Figure 3: Comparison of postoperative pain between PhCEA and PCEA groups

As patients with major surgeries may be elderly, usually not well awake at the end of long hours of surgery, they will benefit from background infusion.

To avoid untoward effects, we used fentanyl 2 ug mL^{-1} with 0.125% levobupivacaine. Our regime for PCEA included set priming dose (5 mL), background infusion of 6 mL h^{-1} and set the maximum limit of 15 mL h^{-1} thus overcoming the limitations

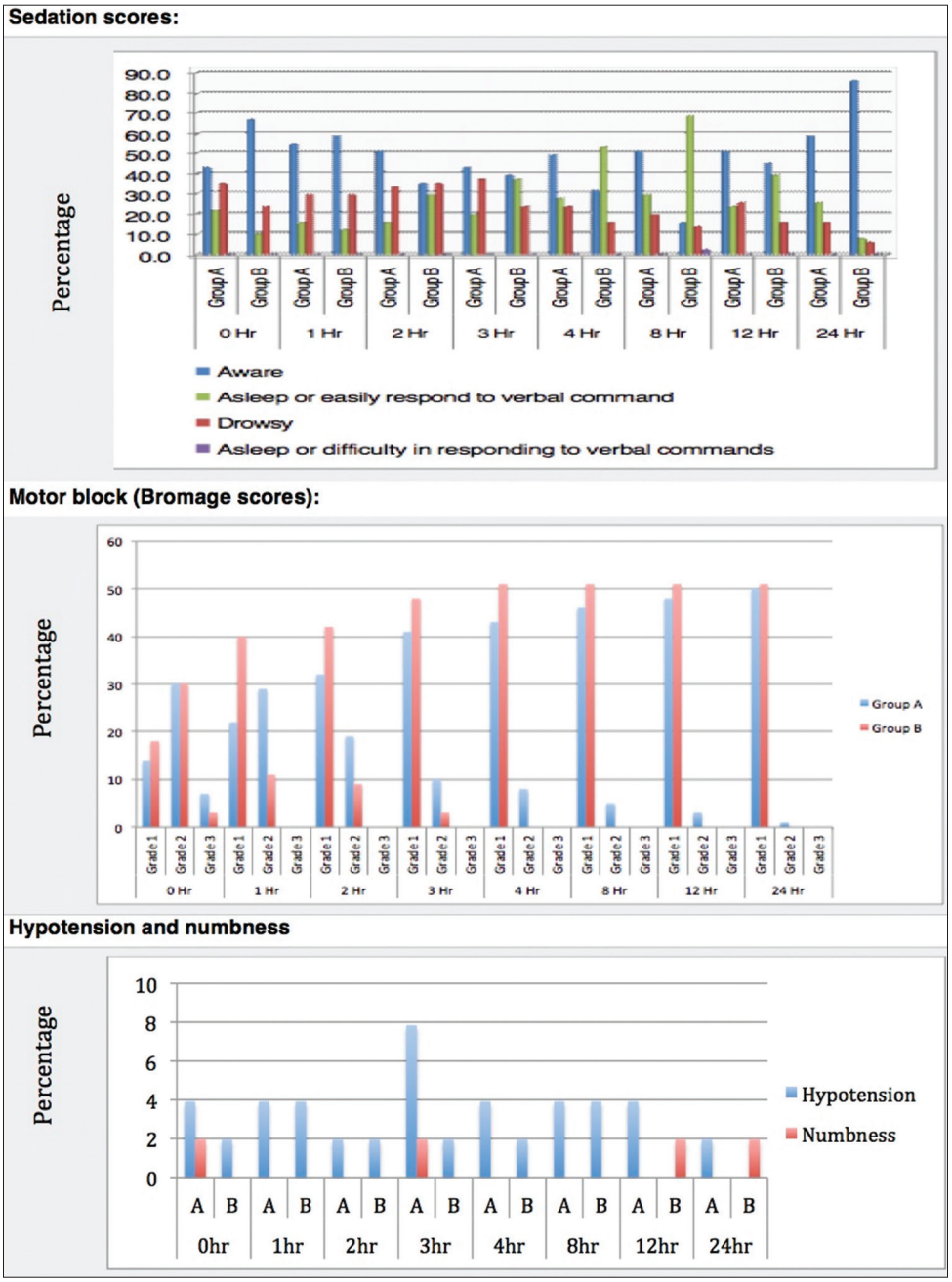

Figure 4: Comparison of side effects between PhCEA and PCEA groups

of previous studies. We did not encounter any pruritus, respiratory depression, nausea, and vomiting. A few patients in both groups had a sedation score of 3 but none had deep sedation [Figure 4].

A few of our patients had grade 4 motor block (7 in PhCEA vs. 3 in PCEA, $P = 0.215$) only at "0" hour of observation. Hypotension was seen in both the groups (2–7.8% vs. 2–3.9%, $P = 1.000$) at different times of observation.

A few studies have reported a significant motor block and hypotension (2–3% and 4.3–10%, respectively) for PCEA.[6,8,16,17-19] Higher incidence as compared to our incidence could be either because of the high maximum limit[8] or no set maximum limit.[6,17,19]

The pain was adequately managed in both groups as indicated by lower pain scores in both the groups. In the PCEA group, the patient could take the additional boluses and had the freedom to use 15 mL h^{-1} maximum from the beginning and had lower pain scores from the beginning itself. Whereas in the PhCEA, group the increment was done gradually as and when the patient complained of pain as is our routine protocol for this group. This might be the reason the patients in the PhCEA group had pain at rest or pain on deep breathing in the initial 1–2 h of the postoperative period ($P = 0.004$). Thereafter, there is no significant difference in the pain scores between the groups. PCEA provides better pain relief from the beginning of the infusion itself.

The number of times epidural boluses were taken were significantly higher ($P = 0.000$) in the PCEA group leading to lesser APS interventions, the lesser requirement of systemic analgesia, and lesser pain scores. Because of this, this group used a significantly higher amount of study drug ($P = 0.000$).

A few studies[8-10] show that the PCEA group required lower local anesthetic doses compared to the PhCEA group. The difference seen in our study is because of the use of background infusion and is similar to the Komatsu H *et al.*[17] study.

We conducted this study to set an acceptable drug regime for PCEA using a lower concentration of fentanyl (2 ug mL^{-1}) along with 0.125% levobupivacaine, background infusion, and set maximum hourly limit (15 mL h^{-1}). We also compared it with the already existing mode of epidural analgesia (PhCEA) at our institution. We did not study the patient satisfaction scores at the time of discharge from the postoperative care unit. This could have been a valuable asset.

In summary, PCEA with background infusion in comparison to PhCEA provides better pain control from the earliest time of the postoperative period with stable hemodynamics and lesser sedation and motor block. The group requires lesser APS team interventions and rescue analgesics, thus improving patient satisfaction. There is no increased incidence of side effects in the PCEA group even though the total amount of drug used is higher.

Conclusion

PCEA with background infusion is better than PhCEA after major intra-abdominal surgeries as it requires lesser pain team interventions and rescue analgesics. Epidural administration of a lower concentration of opioids and local anesthetic gives adequate pain relief without any untoward side effects.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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