

POSTOPERATIVE ANALGESIA AFTER MAJOR ABDOMINAL SURGERY: INFLUENCE OF FENTANYL- BUPIVACAINE PATIENT CONTROLLED EPIDURAL ANALGESIA VS FENTANYL PATIENT CONTROLLED INTRAVENOUS ANALGESIA

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ABSTRACT

Background - Patient-controlled epidural analgesia with Local anaesthetics either alone or in combination with opioids and patient controlled analgesia with intravenous opioids are two clinical ways to tackle postoperative pain after major surgeries. This prospective, randomized clinical study was conducted to compare these two ways in regards to pain control, sedation score, overall patient satisfaction & complications after major abdominal surgeries. **Methods:** 70 patients with ASA grade I & II aged 25-65 yrs of either sex were randomized to EPCA group - patient-controlled epidural analgesia with fentanyl-bupivacaine IVPCA group - patient controlled intravenous analgesia with fentanyl. Parameters monitored were pain scores, rescue analgesia required, sedation scores, complications & overall patient satisfaction. **Results:** Both the groups were comparable with regards to demographic characteristics, hemodynamic variables at baseline, duration of surgery. While in Group IVPCA, immediate postoperative pain was statistically significantly less observed ($p < 0.05$). In Group EPCA, pain was statistically significantly less noted at 2hr, 4hr, 8hr & 12 hrs as compared to Group IVPCA ($p < 0.05$). In context to sedation scores, Group IVPCA observed higher sedation scores, at immediate postoperative period, with no difference statistically at 2, 4, 8, 12 & 24 hrs ($p < 0.05$). Minimal adverse events of nausea, vomiting, pruritis & shivering were noted. The average overall patient satisfaction score in Group EPCA & Group IVPCA was 9 and 6 respectively. The overall patient satisfaction was statistically significantly higher in Group EPCA ($p < 0.05$). **Conclusion:** Both epidural & intravenous groups were effective in postoperative pain management after major abdominal surgery. The patient controlled analgesia via epidural route provided better pain relief, less sedating effects, minimal side effects & enhanced overall patient satisfaction.

Keywords- Patient controlled analgesia, Epidural analgesia, Intravenous analgesia, Patient satisfaction



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INTRODUCTION

The Adequate post operative pain relief is desired by Clinicians after major abdominal surgeries failing which can lead to induction of various hormones in turn affecting the physiologic responses, hospital stay, organ impairment, quality of care, expenses & chronic pain. A good postoperative pain control leads to better, patient satisfaction, early enteral feeding, mobilization, cardiovascular stability. Major

abdominal surgeries include hysterectomy, abdominal mass, perforation, laparotomy etc (1).

Several studies have used local anaesthetics epidurally with or without opioids in management of postoperative pain (2). Bupivacaine was commonly used local anaesthetics (LA) (3). Fentanyl as an adjunct have long been used as an adjunct to

bupivacaine to enhance improved & quicker onset of blockade, enhanced duration of action and postoperative analgesia with minimized dose of LA. It is partial agonist (μ) on opioid receptor. It mainly acts on the dorsal horn of spinal cord in substantia gelatinosa. It blocks pre and post synaptic nociceptive impulses (4). Epidural administration is better as compared to general anaesthesia. It has various advantages as the block can be adjusted intraoperatively, in major surgeries & can provide postoperative analgesia via infusion pump (patient controlled analgesia) or epidural catheter. It has become a popular technique with the advancements in technique, equipments & drugs. It can be used either alone or in combination with general anaesthesia, and also as postoperative analgesia in major abdominal surgeries (5).

Patient controlled analgesia (PCA) is aimed at adequate pain relief & administers a predefined bolus of medication for treatment of acute & chronic pain, postoperative surgical pain. Philip H. Sechzer developed the first PCA pump in 1960s. In 1971 it was completely described & made commercially available in 1976 (6). In this a programmable infusion pump is used by patients and provides self titrated bolus analgesic dose, to their desired level of pain relief on demand by pressing a button. Predetermined boluses are administered either alone or in combination with medication infusion (7). In association to PCA, routes of administration can be intravenous, epidural, through a peripheral nerve catheter, or transdermally. Most commonly used drugs are LA & opioids, also analgesics & dissociatives can be used (8).

McNicol ED et al showed PCA to give an optimum pain relief than non-patient opioid injections and resulting in a higher patient overall satisfaction (9). A meta analysis by Walder et al., including 32 trials using different opioids administered through different techniques PCA or, intravenously/ intramuscularly/ subcutaneously. The analysis witnessed opioid PCA to enhance analgesia reduced risk of pulmonary complications as compared to conventional methods and preferred by the patients (10).

Two techniques of PCA are used after major surgeries i.e. epidural patient-controlled analgesia (EPCA) & intravenous patient controlled analgesia (IVPCA). PCA is observed to be a gold standard in providing analgesia with minimized opioid & LA related side effects. Administering PCA helps in reducing the dose of opioids, number of hospital

days, efficient pain control, minimal side effects & sedation, early mobilization and discharge (11).

Very few studies have been conducted comparing EPCA & IVPCA. Use of EPCA with opioids to be more effective than IVPCA but with minimal side effects of nausea, vomiting, pruritus, hypotension, motor blockade, and urinary retention. bupivacaine with opioid have been compared epidurally & intravenously for gynaecological surgeries but the optimal drug dosage has not been clearly defined (12). Thus, this prospective randomised clinical study was designed to compare the effectiveness of fentanyl bupivacaine PCEA with fentanyl PCIVA after major abdominal surgeries. Also the two groups were compared for hemodynamic variables, duration of hospital stay & complications, quality of postoperative analgesia, the incidence of side effects, dose of analgesia and the patient overall satisfaction.

MATERIAL & METHODS

This prospective randomized clinical study was conducted on 70 patients with ASA grade I & II aged 25-65 yrs of either sex scheduled to undergo major abdominal surgeries. The study was approved by ethical committee and written informed consent obtained from all patients.

Exclusion criteria: Patients on chronic analgesics or corticosteroids therapy, history substance abuse, allergy to LA or opioids, mental disability & disorders, neurological disorders, patient refusal, contraindication to regional anesthesia (coagulopathy or localized infection) and major spine deformity/ surgery.

Randomisation: Patients were randomly divided into two groups;

Group I – patient-controlled epidural analgesia with fentanyl–bupivacaine (EPCA group) (n=35)

Group II - patient controlled intravenous analgesia with fentanyl (IVPCA group) (n=35)

Complete preanaesthetic evaluation was attempted & patients instructed to not eat or drink 6 hrs before surgery. The day before surgery every patient was explained to describe pain using Numeric pain rating scale and the procedure to use PCA device. Premedication with midazolam 0.05mg/kg and glycopyrrolate 0.2 mg was completed. Patient after shifting to operating room, multipara monitor attached blood pressure, ECG, SpO₂ & end tidal carbon dioxide (ETCO₂) were monitored.

In EPCA group, under complete asepsis, in lateral decubitus position, epidural catheter (18G) inserted through midline approach at level T 10-12, using loss of resistance technique with air. A skin wheal was raised using 2% lignocaine & catheter was inserted 5cm in the epidural space. After which GA was induced. After completion of surgery neuromuscular blockage was reversed with glycopyrrolate 0.2 mg & neostigmine 0.04 mg/kg. Patients were extubated and shifted to wards & monitored for 24 hr. In Group EPCA, postoperative analgesia was administered through PCA pump, epidurally with 2-3 µg/mL fentanyl & 0.15% bupivacaine at a continuous rate of 3mL/h, & 2 mL bolus dose with lockout time of 15 min. In Group IVPCA, postoperative analgesia intravenous fentanyl 20 µg/ml solution was administered using PCA pump. The pump was programmed to give 2 mL bolus dose with lockout time of 15 min. If NPRS more than 3, rescue analgesia of 0.5µg/kg fentanyl was given intravenously in both groups.

Parameters monitored :

1. Postoperative pain assessment- using Numeric pain rating scale (NPRS), where

0- no pain

10- unbearable pain

Noted at time interval- immediately after surgery, at 2h, 8h, 12h and 24 h.

2. Rescue analgesia- frequency noted

3. Sedation assessment – using 5 point sedation score

0= aware

1= drowsy

2= asleep/easily respond to verbal command

3= asleep/difficulty responding to verbal command

4 =asleep/no respond to verbal command

4. Adverse events - nausea, vomiting, shivering, pruritus or respiratory complications were recorded postoperatively.

5. Overall patient satisfaction -assessed on a 10-point scale

0-extremely unsatisfied

10- extremely satisfied.

Statistical analysis: The tabulated data was statistically analyzed using SPSS version 22.0 for Windows (IBM Corp, India). Quantitative data are presented as mean ± SD or proportions. Intergroup comparisons were made using Student's paired *t*-test. P-value 0.05 at 90% confidence interval was considered to be statistically significant. Values were expressed as number (n) and percentage(%).

RESULTS

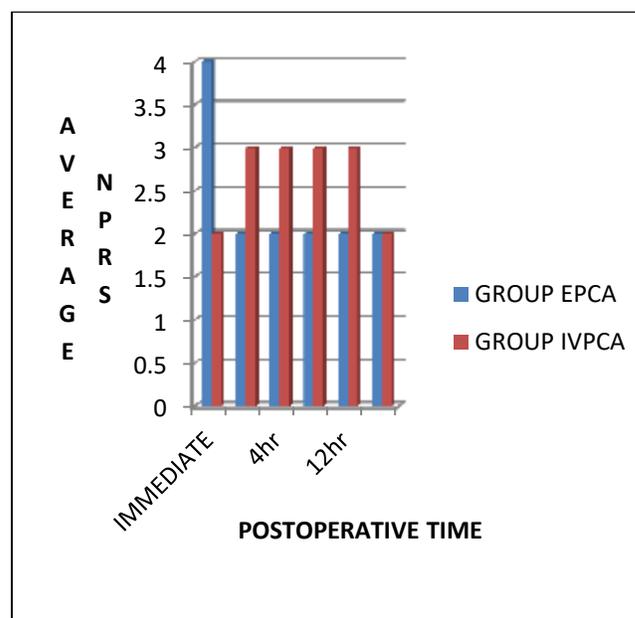
Both the groups were comparable with regards to demographic characteristics, hemodynamic variables at baseline, duration of surgery (Table 1).

While in Group IVPCA, immediate postoperative pain was statistically significantly less observed ($p < 0.05$). In Group EPCA, pain was statistically significantly less noted at 2hr, 4hr, 8hr & 12 hrs as compared to Group IVPCA ($p < 0.05$). (Fig 1).

Table 1 shows demographic characteristics

	Group EPCA	Group IVPCA	P value
Age (yr)	54.6±12.5	56.2±11.3	$p > 0.05$
Weight (kg)	61.4±3.42	60.3±2.41	$p > 0.05$
Sex (M/F)	24/11	26/9	$p > 0.05$
Duration of surgery (min)	118.3±26.7	120±24.8	$p > 0.05$
ASA 1/2	17/18	16/19	$p > 0.05$

Fig 1 shows Average Numeric pain rating scores of the study Groups



In context to sedation scores, Group IVPCA observed higher sedation scores, at immediate postoperative period, with no difference statistically at 2, 4, 8, 12 & 24 hrs (Fig 2). The average overall patient satisfaction score in Group EPCA & Group IVPCA was 9 and 6 respectively. The overall patient satisfaction was statistically significantly higher in Group EPCA ($p < 0.05$).

Fig 2 shows sedation scores of the study Groups

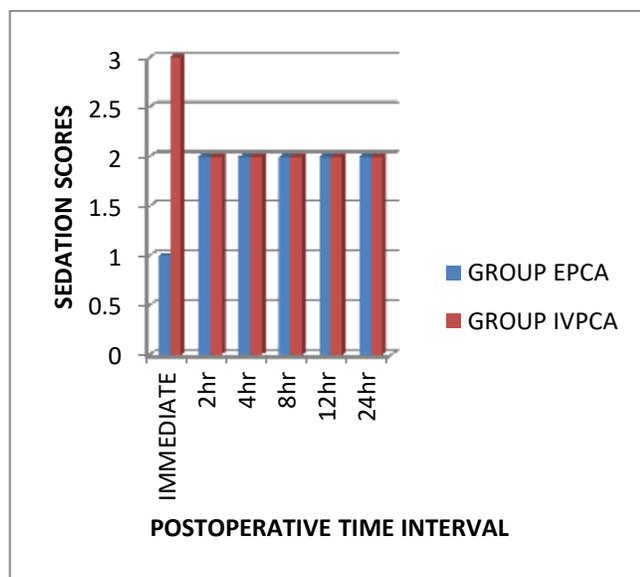


Table 2 Shows Postoperative Complications In Study Groups

Complications	Group EPCA	Group IVPCA	P value
Nausea	3	5	$p > 0.05$
Vomiting	2	3	$p > 0.05$
Pruritis	1	2	$p > 0.05$
Shivering	3	5	$p > 0.05$

DISCUSSION

The International Association for the Study of Pain (IASP) defined pain as "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage". It is a complex and subjective experience which is difficult to reproduce & apprehend. Earlier postoperative analgesia was assessed by measuring pain scores at rest & secondary measures like

respiratory spirometry. Recently pain is assessed on movement or coughing & VAS / NPR score to be 3 or more. (13)

PCA is a major advancement in the field of pain management. It permits self administration of small boluses of analgesic by patients, providing better titration and enhancing responsiveness in analgesic requirement. Liu et al (14) performed thoracic epidural analgesia with bupivacaine and morphine in healthy patients scheduled for colon surgery. There was a resultant earlier recovery of bowel activity, fulfillment of discharge criteria, minimal adverse effects. Cognitive dysfunction or delirium is commonly noted in the postoperative phase due to increased incidence adverse events and prolonged hospitalisation. Improved quality of postoperative analgesia can decrease incidences of delirium, expenses & duration of hospital stay (15).

Various factors affect the efficacy of epidural analgesia eg choice of drugs, the site of epidural insertion in relation to the surgical incision and the timing and method of drug delivery.

Epidurally infused fentanyl & bupivacaine minimizes the reversal of the sensory block and improves the quality of pain relief (16).

Both the groups were comparable with regards to demographic characteristics, hemodynamic variables at baseline, duration of surgery thus eliminating the selection bias.

At immediately after surgery, pain scores were relatively lower in Group IVPCA. Similar results have been observed by Moawad H et al 2019 (17). Shafer SL et al explained this by the pharmacokinetics of fentanyl as after i.v. bolus administration, peak effect of fentanyl is observed at 2–5min. After epidural administration analgesic effect takes around 10-20 min since fentanyl takes time to reach the opiate receptors in the neuraxis of spinal cord. Also some amount of delay takes place in systemic absorption (18).

Pain scores in both Groups observed statistically significant lower NPRS scores in Group EPCA at 2, 4, 8, 12, hrs than Group IVPCA. Similar results shown in studies of Moawad H et al 2019 (17).

No clinically significant difference was observed 24 hrs postoperatively as sufficient plasma levels of fentanyl were reached & maintained thereafter. A meta analysis by Block BM et al 2003 concluded epidural analgesia to be far superior to systemic opioids (19). Privado et al 2010 compared fentanyl iv & epidural analgesia & found epidural analgesia

to be more effective. Fentanyl interacts with pre synaptic & post synaptic opioid receptors in the dorsal horn of spinal cord thus inhibiting transmission of pain through afferent nerves (20). Zhu et al 2013 conducted a randomized clinical trial comparing postoperative analgesia epidural & iv administration of opioids after gastrectomy cases & found epidural analgesia to be more effective at same doses of drug (21).

Group IVPCA observed higher sedation scores, at immediate postoperative period, with no difference statistically at 2, 4, 8, 12 & 24 hrs (Table 3). Lower sedation scores can be explained since low dose of fentanyl was used in combination with bupivacaine epidurally in comparison to iv. Similar results observed by Moawad H et al 2019 (17).

The overall patient satisfaction was improved in Group EPCA since postoperative pain scores were lower than Group IVPCA.

Maan C et al 2000 concluded that after major abdominal surgery, epidural or intravenously administered PCA was effective. Epidural PCA with a combination of bupivacaine 0.125% and sufentanil enhances pain relief, improves mental stability and bowel activity in the elderly as compared to intravenous morphine (6).

Van Boerum et al concluded that in epidural PCA group patients started mobilization earlier, were discharged on an average of one & half day earlier & overall patient satisfaction was higher than intravenous group (22). Tsui S L et al in gynaecological laprotomy cases compared EPCA 0.0625% bupivacaine and 3.3µg/ml fentanyl & found EPCA to provide profound & better analgesia than IVPCA morphine (23).

A randomized crossover double blind study done on 80 patients after caesarean section, patients received Fentanyl by EPCA or IVPCA or pethidine by EPCA or IVPCA. Patients which received fentanyl showed lower pain scores with less consumption of fentanyl with EPCA than IVPCA at 12 hrs.

CONCLUSION

PCA is observed to be a gold standard in providing analgesia with minimized opioid & LA related side effects. PCA use by health care personnel's worldwide could reduce their patient workload. In spite of reduction of direct role of clinicians in pain management, a supervision is required to ensure adequate functioning of PCA device.

The study compared epidural patient controlled analgesia with 0.15% bupivacaine & 2–3 µg/mL fentanyl and intravenous patient controlled analgesia (fentanyl) in major abdominal surgeries and found EPCA to be more efficient in relieving pain at 2, 4, 6, 8, 12 hrs with less sedating effects, minimal side effects & enhanced overall patient satisfaction. Group IVPCA observed more sedation & reduced pain scores immediately after surgery.

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