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Comparative Evaluation of Continuous Thoracic Paravertebral Block and Thoracic Epidural Analgesia Techniques for Post-operative Pain Relief in Patients Undergoing Open Cholecystectomy: A Prospective, Randomized, Single Blind Study

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ABSTRACT

Background: The aim of this prospective, randomized, single blind study was to compare the efficacy of post-operative pain relief provided by continuous thoracic paravertebral block with continuous thoracic epidural analgesia in patients undergoing open cholecystectomy.

Methods: Sixty four adult patients undergoing open cholecystectomy under general anaesthesia were randomized into two groups; Group EA patients received intra-operative and post-operative epidural infusion of a solution containing 0.1% bupivacaine with 1 µg ml-1 fentanyl at 7ml hr-1; Group PVA patients received intra-operative and post-operative paravertebral infusion of a solution containing 0.1% bupivacaine with 1 µg ml-1 fentanyl at 7ml hr-1. Primary outcome measures were postoperative pain during rest (lying supine), deep inspiration, coughing and movement (getting up from supine to sitting position); secondary outcome measures were post-operative fentanyl consumption, post-operative nausea and vomiting (PONV), requirement of rescue antiemetic, hypotension, sedation, pruritus, motor block and respiratory depression; these were assessed at 6 hourly intervals for a period of 48 hrs in the post-operative period.

Results: The two groups were similar with regard to demographic factors (P>0.05). The VAS scores during rest, deep breathing, coughing and movement (getting up from supine to sitting position) and postoperative fentanyl consumption were similar in the paravertebral and epidural analgesia groups (P>0.05); the incidence of side effects were also similar in the two groups (P>0.05).

Conclusions: We observed that continuous thoracic paraverterbal analgesia provides post-operative analgesia as effective as continuous thoracic epidural analgesia in patients undergoing open cholecystectomy.

KEYWORDS : Paravertebral Block Postoperative Pain Open Cholecystectomy Post-operative Nausea and Vomiting Dynamic Pain

Introduction

Open cholecystectomy is associated with substantial postoperative pain; pain relief is usually provided either by thoracic epidural analgesia or systemic analgesics in the form of intra-venous opioids and non-steroidal anti-inflammatory drugs (NSAIDs). Epidural analgesia (EA) is a highly effective option for postoperative pain management in abdominal surgeries, but associated complications and contraindications may limit its usage [1-3]. Systemic analgesics may cause side effects and often provide inadequate analgesia. Therefore, alternative approaches for post-operative pain management are desired.

Thoracic paravertebral block (PVB) is a useful alternative to thoracic epidural block with stable hemodynamic response and a lower side-effect profile [4]. PVB provides good quality analgesia in patients undergoing thoracic or abdominal procedures [5]; it offers several technical and clinical advantages and is indicated for anesthesia and analgesia when the afferent pain input is predominantly unilateral from the chest and abdomen [4].

Thoracic PVB is accompanied by lower incidence of hypotension, postoperative nausea and vomiting, and better pulmonary function [6, 7]. There is enough evidence that thoracic PVB provides effective analgesia and has been shown to be as efficient as epidural analgesia [4]. PVB has been reported to be effective in open cholecystecectomy [8, 9], however; the effectiveness of continuous thoracic PVB has not been compared with that of continuous thoracic EA so far.

In this prospective, randomized, single blind study we have compared the efficacy of post-operative pain relief provided by continuous thoracic PVB with continuous thoracic EA in patients undergoing open cholecystectomy.

Materials & Methods:

Study Design

The present study was a prospective, randomized, single blind study; the study protocol was approved from the institutional ethical committee and written informed consent was obtained from all the patients.

Inclusion Criteria

Adult patients (18-70 yrs) of either sex, ASA physical status I and II, scheduled for open cholecystectomy under general anesthesia were included in the study.

Exclusion Criteria

Patient refusal, coagulation disorders, signs of local or systemic infection, history of regular intake of analgesics, anatomical abnor malities.

Randomisation, Group Allocation and Study Intervention

Sixty four patients meeting the inclusion criteria during the pre-anesthetic evaluation were randomly assigned into two equal groups of 32 each with the help of a computer generated table of random numbers; Group EA patients received intra-operative and post-operative epidural infusion of a solution containing 0.1% bupivacaine with 1 µg ml-1 fentanyl at 7ml hr-1; Group PVA patients received intra-operative and post-operative paravertebral infusion of a solution containing 0.1% bupivacaine with 1 µg ml-1 fentanyl at 7ml hr-1; the infusion was provided by an elastomeric pump (Baxter Healthcare Corporation, California, USA).

A random allocation sequence concealed in 64 consecutively numbered, sealed envelopes, determining group distribution, were computer generated by a project nurse not involved in the trial. The envelopes were opened on the morning of surgery by the preoperative nurse, not involved in the study.

An 18G epidural catheter was placed in the epidural space at T8-9 or T9-10 inter-space in group EA patients or in the paravertebral space at T 6 or T7 level in Group PVA patients, under local anesthesia prior to induction, by an anesthesiology resident not involved in the study; the paravertebral catheter was placed using loss-of-resistance technique according to Eason and Wyatt [10]; before catheter placement 15ml 0.1% bupivacaine with 1 µg ml-1 fentanyl was injected in the paravertebral space. The paravertebral or epidural infusion via

elastomeric pump was started after induction of anesthesia. The Anesthesia technique was standardized in all the patients. Patients were induced with fentanyl 2-3 g kg-1 and propofol 1.5-2.5 mg kg-1; orotracheal intubation was facilitated by vecuronium 0.1 mg kg-1. Anesthesia was maintained with propofol, isoflurane and oxygen air mixture. A reduction in systolic blood pressure of more than 20% or a systolic blood pressure below 90 mm Hg was considered as hypotension and was treated by infusion of isotonic sodium chloride or mephentramine 5 mg intravenously in incremental doses. At the end of surgery residual neuromuscular paralysis was antagonized with neostigmine 0.04 mg.kg-1 and glycopyrrolate 0.01 mg.kg1. Following satisfactory recovery, the patients were extubated and shifted to the post-anesthesia care unit. In the post-operative period patients received intravenous (IV) fentanyl via patient controlled analgesia device with patient activated dose of 10μg/mL, lock out interval of 5 minute; with a maximum allowable fentanyl dose being 2μg kg^{-1} hr^{-1}.

Outcome Measures and Patient Assessment

Primary outcome measures were postoperative pain during rest (lying supine), deep inspiration, coughing and movement (getting up from supine to sitting position); secondary outcome measures were post-operative fentanyl consumption, post-operative nausea and vomiting (PONV), requirement of rescue antiemetic, hypotension, sedation, pruritus, motor block and respiratory depression. All these measures were assessed by acute pain nurse blinded to group allocation.

All patients were assessed on arrival to post anaesthesia care unit (PACU) (0 hr), then at 6 hourly intervals for a period of 48 hrs in the post-operative period. Assessment of pain was done by a 100mm visual analogue scale (VAS); 0= no pain, 100mm= worst imaginable pain. All patients received acetaminophen 1 g (IV) every 6 hr during this period. Motor block was measured using the modified Bromage scale (0 = no motor block, 1 = inability to raise extended leg, 2 = inability to flex knee, 3= inability to flex ankle) [11]. The severity of PONV was graded on a 4 point ordinal scale (0 = no nausea or vomiting, 1 = mild nausea, 2 = moderate nausea, and 3 = severe nausea with vomiting) [12]. Rescue antiemetic ondansetron 4 mg IV, was given to all patients with PONV of grade >2. The Ramsay sedation scale (Awake levels were: 1- anxious, agitated or restless; 2- cooperative, oriented and tranquil; 3- responds to command; asleep levels were dependent on patient's response to a light glabellar tap or loud auditory stimulus; 4- brisk response; 5- a sluggish response; 6- no response) was used to assess the sedation; patients with a sedation scale of > 4 were considered as sedated [13]. Respiratory depression was defined as respiratory rate < 8 breaths/min and oxygen saturation < 90% without oxygen supplementation.

Sample Size Estimation

Sample size calculation was based on the findings of a pilot study performed at our institute. Assuming that the therapeutic drug would reduce postoperative pain VAS scores by 30% as compared to the placebo a sample size of 25 patients was required in each group for the results to be significant (with $\alpha = 0.05$ and power=80%); To take care of any drop outs we enrolled 32 patients in each group.

Statistical Analysis

Demographic data were analyzed with student's T-test for continuous variables and chi square test for categorical variables. The VAS scores were analyzed with Mann Whitney test; post-operative patient controlled fentanyl requirement was analyzed with student's T-test; the incidence of PONV, sedation, motor block and respiratory depression were analyzed with Fisher's exact test. The package SPSS 22.0 (SPSS Inc, Chicago, IL) was used for statistical analysis. $P < 0.05$ was considered significant.

Results

A total of ninety four patients were assessed for eligibility between August 2016 to January 2017, out of which sixty four patients were randomized into two groups; sixty one patients i.e. 95% of the randomized patients completed the study (Fig. 1). The reasons for patients not being randomized were refusal to participate in the study (17 patients), chronic analgesic consumption (4 patients) and inability to operate patient controlled analgesia device (9 patients). Three patients were excluded from the study following initial randomization and were therefore not subjected for further analysis (2 patients needed re-exploration on account of postoperative bleed; epidural catheter placement was deferred on account of dural puncture in 1 patient). There was no difference amongst the groups as regards to age, sex, weight distribution, duration of anesthesia, duration of surgery and intra-operative fentanyl consumption (P>0.05) (Table 1).

The VAS scores during rest, deep breathing, coughing and movement (getting up from supine to sitting position) (Table 2) and postoperative fentanyl consumption (Table 3) were similar in the paravertebral and epidural analgesia groups (P>0.05); the incidence of side effects were also similar in the two groups (P>0.05) (Table 4). We observed hypotension in three patients in the epidural analgesia group as compared to none in the paravertebral analgesia group, but the difference was not significant.

Discussion

The aim of conducting this study was to explore a valid alternative for the management of postoperative pain in patients undergoing open cholecystectomy with minimal side effects; we observed that continuous thoracic paravertebral analgesia is as effective as continuous thoracic epidural analgesia in providing pain relief in patients undergoing open cholecystectomy in the post-operative period. The side effect profile of the two techniques was also similar.

The right subcostal incision of open cholecystectomy involves cutting of abdominal muscles including external oblique, internal oblique, transverse abdominis and anterior rectus sheath; hence, it give rise significant post-operative pain especially during abdominal wall movement, as in deep breathing and coughing. Chronic pain occurs in approximately 30-40% of cases undergoing open cholecystectomy [14, 15]; this is an indication of inadequate pain control in the post-operative period in these patients with currently existing methods of pain control.

The standard techniques of post-operative pain management in this group of patients include epidural analgesia and systemic analgesics in the form of opioids. Epidural analgesia is considered as the gold standard as it provides excellent analgesia. However, there are well known side effects and risks associated with this technique. The common side effects include hypotension, itching, vomiting/nausea and urinary retention; in addition, technical difficulties with insertion have been reported in up to 11% of patients along with a failure rate ranging from 17% to 37% [16-18].

Alternatives to EA, such as paravertebral block, offer the advantage of providing unilateral analgesia with lower incidence of side-effects. A meta-analysis of small, non-blinded trials demonstrated that PVB provided comparable pain relief and were associated with less nausea and vomiting, urinary retention, failed blocks, hypotension, and pulmonary complications compared with EA in patients undergoing thoracic surgery [7, 19]. In addition, paravertebral blocks were associated with fewer major complications in patients after pneumonectomy [20].

PVB is currently being utilized for many surgical procedures both as an anesthesia technique [7] and for postoperative pain management [21]. By providing unilateral analgesia it has minimal hemodynamic effects compared with spinal or epidural block. The deafferentation provided by PVB is superior to that of epidural block resulting in better preservation of physiologic function such as functional residual capacity of the lungs [22]. This intense deafferentation with resultant decrease in opioid requirements postoperatively helps in minimizing the incidence of chronic pain [23].

The literature on the usage of thoracic PVB in patients undergoing open cholecystectomy is limited at the moment and the results are inconclusive [8]. Giesecke et al. reported that a single preincisional thoracic paravertebral injection of bupivacaine 0.5%, 20 ml before cholecystectomy, attenuates the stress response to surgical stimuli during isoflurane anesthesia and provides complete pain relief for 1–6 h [24]. On the contrary, Bigler et al. [9] reported that TPVB with 0.5% bupivacaine, a 15-ml bolus dose followed by an infusion of 5 ml/h postoperatively, is inadequate as the only analgesic after cholecystectomy, whereas a thoracic epidural infusion of bupivacaine 0.5% (5 ml/h) and morphine (0.2 mg/h) produced total pain relief. Pain scores were higher in the paravertebral group, as was the use of systemic morphine [9].

In the present study it was observed that thoracic paravertebral block reduces both the components of post-operative pain i.e. static and

dynamic pain scores in patients undergoing open cholecystectomy; however, VAS scores in the paravertebral group were similar to that in the epidural group (P>0.05). The incidence of side effects were also similar in both the groups. The mean systolic blood pressures were lower in the epidural group as compared to the paravertebral group; but the difference was not significant (P>0.05). Thus the analgesia provided by continuous PVB was similar to that of continuous thoracic epidural block; the side effect profile of the two techniques was also similar.

One of the limitations of the present study is that the two techniques were compared at single rate of drug infusion and local anesthetic concentration; comparison of different rates and different concentration would provide more valuable information. Secondly, a number of comparisons of side effects in the two groups have been done; however, the sample size is not adequate to comment on these and we therefore suggest further studies with larger sample size which could adequately address these issues.

Conclusion:

We observed that continuous thoracic paraverterbal analgesia provides post-operative analgesia as effective as continuous thoracic epidural analgesia in patients undergoing open cholecystectomy. We therefore suggest routine usage of continuous thoracic paravertebral block over continuous thoracic epidural analgesia for management of post-operative pain in patients undergoing open cholecystectomy owing to its likely better safety profile.

Table 1: Demographic data

Groups Variables	Group EA (N=30)	Group PVA (N=31)
Age (yr)	41.7 ± 9.9	43.8 ± 9.2
Weight (kg)	55.3 ± 8.7	57.5 ± 7.8
Sex (M/F)	13/ 18	10/ 20
Duration of anesthesia (min)	148.4 ± 27.1	155.9 ± 33.9
Duration of surgery (min)	129.8 ± 18.6	135.5 ± 24.5
Intra-operatively fentanyl consumption (g)	235.7 ± 52.9	238.3 ± 41.4

*Data are presented either as mean + SD or numbers; Group EA: Epidural Analgesia Group; Group PVA: Paravertebral Analgesia Group. *Denotes P<0.05 during intergroup comparison*

Table 2: Postoperative pain (Visual Analogue Scale Scores)

	Pain During Rest		Pain During Deep Inspiration		Pain During Coughing		Pain During Movement	
	Group EA	Group PVA	Group EA	Group PVA	Group EA	Group PVA	Group EA	Group PVA
0hr	30 (10)	30 (16)	40 (15)	35 (20)	NA	NA	NA	NA
6 hr	30 (15)	25 (15)	40 (20)	35 (10)	NA	NA	NA	NA
12 hr	35 (15)	30 (16)	40 (15)	35 (11)	40 (15)	35 (13)	NA	NA
18 hr	30 (10)	25 (18)	35 (15)	40 (18)	35 (10)	30 (23)	NA	NA
24hr	35 (15)	30 (23)	30 (25)	25 (10)	35 (15)	30 (10)	45 (5)	40 (15)
30 hr	30 (20)	25 (20)	35 (20)	30 (10)	30 (10)	25 (15)	40 (10)	30 (5)
36 hr	40 (20)	30 (23)	30 (10)	25 (15)	30 (10)	30 (16)	40 (10)	40 (10)
42 hr	30 (15)	30 (18)	30 (15)	25 (15)	30 (20)	30 (11)	30 (5)	30 (20)
48 hr	25 (15)	25 (8)	25 (13)	25 (10)	25 (15)	30 (15)	35 (10)	30 (19)

*Data are presented as median (inter-quartile range); Group EA: Epidural Analgesia Group; Group PVA: Paravertebral Analgesia Group; *Denotes P<0.05 during intergroup comparison*

Table 3: Post-operative Fentanyl Consumption (g)

	Group EA (N=30)	Group PVA (N=31)
0-24 hrs	669.7 ± 62.8	622.1 ± 122.7
24-48 hrs	860.7 ± 159.9	781.7 ± 241.9

*Data are presented as mean values + SD; Group EA: Epidural Analgesia Group; Group PVA: Paravertebral Analgesia Group. *Denotes P<0.05 during intergroup comparison*

Table 4: Incidence of side effects

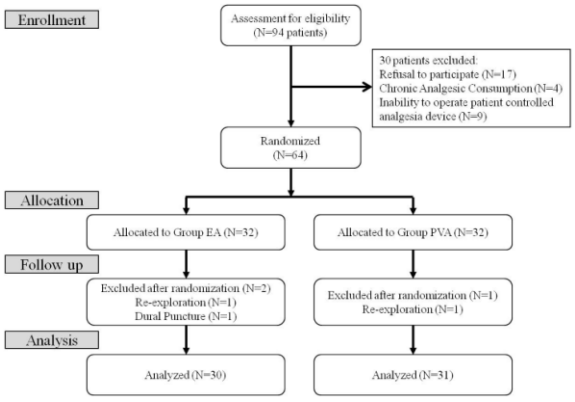
	Group EA (N=30)	Group PVA (N=31)
PONV	3	4
Hypotension	3	0
Pruritus	2	0
Respiratory Depression	0	0
Motor Block	0	0
Sedation	0	0
Requirement of rescue antiemetic	4	6

*Data are presented as numbers; Group EA: Epidural Analgesia Group; Group PVA: Paravertebral Analgesia Group; *Denotes P<0.05 during intergroup comparison*

Legend for Figures

Figure 1: Study Design

Group EA: Epidural Analgesia Group; Group PVA: Paravertebral Analgesia Group



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