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

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Abstract

Background: Open surgical procedures are associated with substantial postoperative pain; an alternative method providing adequate pain relief with minimal side effects is very much required. Aim: The aim of this study was a comparative evaluation of the efficacy of continuous thoracic paravertebral block (PVB) and thoracic epidural analgesia (EA) for postoperative pain relief in patients undergoing open nephrectomy. Settings and Design: Prospective, randomized, and single-blind study. Materials and Methods: Sixty adult patients undergoing open nephrectomy under general anesthesia were randomized to receive a continuous thoracic epidural infusion (Group E) or continuous thoracic paravertebral infusion (Group P) with bupivacaine 0.1% with 1 μg/ml fentanyl at 7 ml/h; both infusions were started after induction of anesthesia. The primary outcome measures were postoperative pain during rest (static pain), deep inspiration, coughing, and movement (getting up from supine to sitting position); the secondary outcome measures were postoperative nausea and vomiting, requirement of rescue antiemetic, hypotension, sedation, pruritus, motor block, and respiratory depression. These were assessed till the morning of the third postoperative day. Statistical Analysis: Results were analyzed by the one-way ANOVA, Chi-square test, and Mann–Whitney U-test. P < 0.05 was considered significant. Results: Both the groups were similar with regard to demographic factors (P > 0.05). The visual analog scale scores at rest, deep breathing, coughing and movement, and postoperative fentanyl consumption were similar in the two groups (P > 0.05); the incidence of side effects was also similar in the two groups (P > 0.05). Conclusions: Continuous thoracic PVB is as effective as continuous thoracic EA in providing pain relief in patients undergoing open nephrectomy in the postoperative period. The side effect profile of the two techniques was also similar.

Keywords: Dynamic pain, epidural analgesia, open nephrectomy, paravertebral block, postoperative nausea and vomiting, postoperative pain, static pain

Introduction

Open nephrectomy is associated with substantial postoperative pain; pain relief in patients undergoing this procedure is usually provided either by thoracic epidural analgesia (EA) or systemic analgesics. EA is a very useful option for the management of postoperative pain in patients undergoing abdominal surgeries, but the risks and contraindications linked to EA may limit its use.¹ ² Systemic analgesics in the form of opioid analgesics may give rise to side effects and often provide insufficient analgesia. ³ Hence, other methods of postoperative pain management are desired.

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Thoracic paravertebral block (PVB) provides good pain relief in patients undergoing thoracic and abdominal surgeries. There is enough evidence that thoracic PVB provides effective pain relief which is equally efficient to the EA; it is also associated with a lower incidence of side effects commonly associated with EA such as hypotension, nausea, and vomiting. It is because of these facts that PVB has been more frequently used in the present scenario for the treatment of postoperative pain. Thoracic PVB has been reported to be effective in open nephrectomy; however, the comparison of the effectiveness of continuous thoracic PVB with continuous thoracic EA has not been done in patients undergoing open nephrectomy so far.

In thoracic PVB, a local anesthetic is injected near the thoracic spinal nerve at its exit from the intervertebral foramina; this results in unilateral somatic and sympathetic nerve blockade in multiple continuous thoracic dermatomes above and below the site of injection. Hence, with PVB, one can accomplish a unilateral, band-like, segmental blockade similar to epidural block; however, the EA blocks the spinal nerves bilaterally giving rise to more prominent hemodynamic changes as compared to PVB.

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

**Materials and Methods**

**Study design**

Prospective and randomized study; the protocol of the study was approved by the Institute’s Ethics Committee. All the patients included in the study have given written informed consent for participation.

**Inclusion criteria**

Adult patients (18–65 years of age); American Society of Anesthesiologists physical status Classes I or II, planned for open nephrectomy under general anesthesia were included in the study.

**Exclusion criteria**

Coagulopathy, evidence of local or systemic infection, history of regular intake of analgesics, patient not willing to participate, and anatomical abnormalities.

**Randomization, group allocation, and study intervention**

Patients satisfying the criteria of inclusion for study during preoperative evaluation for anesthesia fitness were randomly distributed into two groups; each group contained thirty patients, and the randomization was done with the help of a table of random numbers developed by computer; Group E patients received intraoperative and postoperative epidural infusion of a solution containing 0.1% bupivacaine with 1 μg/L fentanyl at 7 ml/h; Group P patients received intraoperative and postoperative paravertebral infusion of a solution containing 0.1% bupivacaine with 1 μg/ml fentanyl at 7 ml/h. The infusions in both the groups were provided by an elastomeric pump (Baxter Healthcare Corporation, California, USA).

A project nurse prepared sixty sealed envelopes as per the computer-generated random allocation sequence for the purpose of group distribution. The envelopes were opened by a nurse in the preoperative area before the patient was shifted to the operation theater; this nurse was not involved in the study.

An 18-gauge epidural catheter was placed in the epidural space at T8–T9 or T9–T10 inter-space in Group E patients or in the paravertebral space at T10–T11 or T11–T12 level in Group P patients, under local anesthesia, by an anesthesiology resident not involved in the study; the paravertebral catheter was placed utilizing loss-of-resistance technique as proposed by Eason and Wyatt. The paravertebral or epidural infusion via elastomeric pump was started after induction of anesthesia. General anesthesia with endotracheal intubation was induced in all the patients using a uniform approach; for this, we utilized fentanyl 2–3 μg/kg, propofol 1.5–2.5 mg/kg, and vecuronium 0.1 mg/kg. The maintenance of anesthesia was done with propofol, isoflurane, and oxygen air mixture. A reduction in systolic blood pressure of >20% or <90 mm Hg was considered as hypotension and was treated by normal saline infusion or mephenteramine 5 mg intravenously (IV) in incremental doses. At the end of the surgery, residual neuromuscular paralysis was reversed with neostigmine 0.04 mg/kg and glycopyrrolate 0.01 mg/kg. Following extubation, patients were taken to the postanesthesia recovery area. In the postoperative period, IV fentanyl via patient-controlled analgesia device was provided to all the patients for pain relief, with 5 min lockout interval and maximum hourly fentanyl dose of 2 μg/kg/h.

**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 postoperative 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 the patients were assessed on arrival to postanesthesia care unit (0 h), then at 2 pm, 6 pm, and 10 pm on the day of surgery postoperative day 0 (POD 0); 8 am, 2 pm, and 8 pm on postoperative day 1 (POD 1); 8 am and 8 pm on postoperative day 2 (POD 2); and 8 am on postoperative day 3 (POD 3). The evaluation of pain was done by a 100 mm visual analog scale (VAS): 0 = no pain and 100 mm = worst possible pain. Acetaminophen 1 g IV every 6 h was given to all patients during this period. Modified Bromage scale was utilized for the assessment of motor block. The assessment of PONV was done a four-point ordinal scale with 0 = no nausea or vomiting and 3 = severe nausea with vomiting. All the patients with PONV grade of two or more received rescue...
antiemetic ondansetron 4 mg IV. The sedation of patients was evaluated using the Ramsay sedation scale; patient having Ramsay sedation scale of >4 was designated as sedated.[12] Patients having respiratory rate <8 breaths/min and oxygen saturation of <90% without oxygen supplementation were defined as having respiratory depression.

Sample size estimation
The size of sample size was decided depending on the findings of a pilot study performed at our institute; it was assumed that the study drug would decrease postoperative pain VAS scores by 30% as compared to placebo; this was possible with 25 patients in each group (with \( \alpha = 0.05 \) and power = 80%). We recruited thirty patients in each group so that dropouts can be taken care of.

Statistical analysis
For the analysis of demographic data, the \( t \)-test was used for continuous variables and Chi-square test was used for categorical variables. The Kruskal–Wallis test was used for the analysis of VAS scores and sedation scores; the incidence of PONV, sedation, motor block, and respiratory depression were analyzed with Fisher’s exact test. We have decided the method of analysis prospectively and applied the intention-to-treat principle. For statistical analysis, the SPSS 22.0 (SPSS Inc., Chicago, IL, USA) package was used and for the purpose of significance, we have defined \( P < 0.05 \).

Results
Eighty-three patients were evaluated for eligibility between July 2015 and January 2016, out of which sixty patients were distributed into the two study groups; 57 patients, i.e., 95% of the randomized patients completed the present study [Figure 1]. The patients which were not randomized included: sixteen patients were not willing for participation in the study, two patients were consuming analgesics for a long duration, and five patients were unable to operate patient-controlled analgesia device.

Three patients were not included in the clinical trial after initial randomization; these subjects were not included in the formulation of study results (epidural catheter placement was deferred on account of a dural puncture in one patient and two patients were re-explored due to bleeding postoperatively). There was no difference among the groups as regards to age, sex, weight distribution, duration of anesthesia, duration of surgery, and intraoperative fentanyl consumption \( (P > 0.05) \) [Table 1].

The VAS scores at 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 two groups \( (P > 0.05) \); the incidence of side effects was also similar in the two groups \( (P > 0.05) \) [Table 4].

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

The standard techniques of postoperative pain management in this group of patients include EA and systemic analgesics in

Figure 1: Study design. Group E = Epidural analgesia group, Group P = Paravertebral block group
the form of opioids. EA is recommended as a gold standard modality for the management of POP in patients undergoing abdominal surgeries; however, it is associated with side effects and risks, which prevents its use in some patients. 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%.[13-15]

Opioids contribute an important role in the treatment of POP as it carries a low-risk profile; however, opioids do not reduce dynamic pain and surgical stress[16] and develop clinically relevant resistance in hours.[17,18] Opioids are associated with side effects such as PONV, itching, bowel ileus, and abdominal distension;[19] hence, the management of postoperative pain without opioids helps in minimizing postoperative pain and PONV.[3]

Alternatives to EA, such as PVB, offer the advantage of providing pain relief on one hand and favorable side effect profile on the other hand.[6] A meta-analysis of small, nonblinded trials compared thoracic PVB with thoracic EA in patients undergoing thoracic surgery and concluded that both techniques provided comparable analgesia with a higher incidence of side effects such as nausea, vomiting, urinary retention, failed blocks, hypotension, and pulmonary complications associated with EA.[11,19] In addition, an observational cohort study found that thoracic PVB was associated with lower incidence of major complications in patients undergoing pneumonectomy as compared to thoracic EA.[6]

PVB is used for a number of surgical interventions both as an anesthesia technique[20] and for postoperative pain management.[1] Because of the unilateral sympathetic blockade, PVB produces smaller effects on the cardiovascular system as compared to other regional anesthetic techniques like a spinal or epidural block.[21] PVB produces superior blockade of somatic nerves along with sympathetic nerves compared to EA; this results in better pain relief along with better conservation of lung physiological functions, neuroendocrine stress response, side effects, and respiratory complications in the postoperative period.[21]

Open nephrectomy involves a subcostal flank incision which offers a wide operative field, but it requires a considerable amount of muscle cutting giving rise to significant postoperative pain and longer recovery period owing to large painful scar. This also hampers effective coughing, deep breathing, and patient’s mobility. Chronic pain occurs in approximately 20–26% of cases undergoing open nephrectomy; highlighting that current methods which are being used for postoperative pain management following nephrectomy are inadequate.[22,23]

### Table 1: Demographic data

| Variables                  | Group E (n=28) | Group P (n=29) |
|----------------------------|----------------|----------------|
| Age (years)                | 56.5±8.4       | 52.7±11.5      |
| Weight (kg)                | 54.6±10.2      | 58.0±10.7      |
| Sex (male/female)          | 18/10          | 16/11          |
| Duration of anesthesia (min)| 213.5±25.2    | 224.8±21.4     |
| Duration of surgery (min)  | 183.6±23.1     | 191.4±18.9     |
| Intraoperatively fentanyl consumption (µg)| 228.1±32.1 | 249.6±46.7 |

*P=0.05 during intergroup comparison. Data are presented either as mean±SD or numbers. Group E=Epidural analgesia group, Group P=Paravertebral block group, SD=Standard deviation.

### Table 2: Postoperative pain (visual analog scale scores)

| Pain          | Rest          | Deep breathing | Coughing       | Movement       |
|---------------|---------------|----------------|----------------|----------------|
|               | Group E (n=28) | Group P (n=29) | Group E (n=28) | Group P (n=29) | Group E (n=28) | Group P (n=29) | Group E (n=28) | Group P (n=29) |
| POD 0         |               |                |                |                |                |                |                |                |
| 0 h           | 30 (10)       | 30 (18)        | 40 (14)        | 40 (15)        | NA             | NA             | NA             | NA             |
| 2 pm          | 30 (13)       | 25 (15)        | 45 (19)        | 30 (5)         | NA             | NA             | NA             | NA             |
| 6 pm          | 35 (16)       | 30 (20)        | 35 (15)        | 40 (20)        | 35 (14)        | 40 (10)        | NA             | NA             |
| 8 pm          | 30 (10)       | 25 (15)        | 40 (15)        | 35 (10)        | 35 (15)        | 35 (10)        | NA             | NA             |
| POD 1         |               |                |                |                |                |                |                |                |
| 8 am          | 35 (20)       | 30 (20)        | 35 (19)        | 30 (10)        | 35 (9)         | 30 (20)        | 45 (5)         | 40 (10)        |
| 2 pm          | 30 (20)       | 30 (15)        | 30 (23)        | 25 (5)         | 30 (10)        | 30 (5)         | 40 (18)        | 35 (5)         |
| 8 pm          | 40 (18)       | 30 (20)        | 30 (10)        | 25 (5)         | 30 (10)        | 25 (10)        | 40 (8)         | 40 (10)        |
| POD 2         |               |                |                |                |                |                |                |                |
| 8 am          | 25 (19)       | 30 (20)        | 30 (5)         | 30 (20)        | 25 (5)         | 25 (15)        | 35 (10)        | 30 (10)        |
| 8 pm          | 25 (5)        | 25 (15)        | 25 (13)        | 25 (10)        | 25 (20)        | 30 (15)        | 30 (5)         | 25 (5)         |
| POD 3         |               |                |                |                |                |                |                |                |
| 8 am          | 30 (10)       | 30 (10)        | 30 (10)        | 25 (5)         | 20 (10)        | 20 (10)        | 30 (8)         | 30 (10)        |

*P=0.05 during intergroup comparison. Data are presented as median (IQR). POD 0=Day of surgery, POD 1=First postoperative day, POD 2=Second postoperative day, POD 3=Third postoperative day, NA=Unable to do the maneuver, Group E=Epidural analgesia group, Group P=Paravertebral block group, IQR=Interquartile range.
Thoracic PVB has been used for the management of postoperative pain in open nephrectomy patients. Baik et al. concluded that a single preoperative dose of thoracic PVB in open nephrectomy patients reduced the postoperative pain scores and opioid consumption for a period of 24 h without any significant side effects,[6] in one case, series of thirty patients undergoing hand-assisted laparoscopic nephrectomy. Clendenen et al. concluded that thoracic PVB offered very good pain relief with a significant decrease in opioid requirements in the postoperative period.[9] A clinical trial comparing continuous thoracic PVB with continuous thoracic EA in open nephrectomy patients has not been done so far.

In the present study, it was observed that thoracic PVB reduces both the components of postoperative pain, i.e., static and dynamic pain scores in patients undergoing open nephrectomy; however, VAS scores in the paravertebral group were similar to that in the epidural group ($P > 0.05$). The incidence of side effects was 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 EA; 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 a single rate of drug infusion and local anesthetic concentration; comparison of different rates and different concentration would provide more valuable information. Second, 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.

**Conclusions**

We observed that continuous thoracic PVB provides postoperative analgesia as effective as continuous thoracic EA in patients undergoing open nephrectomy. We therefore suggest routine usage of continuous thoracic PVB over continuous thoracic EA for the management of postoperative pain in patients undergoing open nephrectomy owing to its likely better safety profile.

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**Conflicts of interest**

There are no conflicts of interest.

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**Table 3: Postoperative fentanyl consumption (µg)**

| Group E ($n=28$) | Group P ($n=29$) |
|------------------|------------------|
| POD 1 189.9±27.2 | 176.9±19.8       |
| POD 2 264.9±59.7 | 290.6±53.8       |
| POD 3 328.6±29.4 | 305.4±32.4       |

*P<0.05 during intergroup comparison. Data are presented as mean values±SD.

POD 0=Day of surgery, POD 1=First postoperative day, POD 2=Second postoperative day, POD 3=Third postoperative day, Group E=Epidural analgesia group, Group P=Paravertebral block group, SD=Standard deviation

**Table 4: Incidence of side effects**

| Side Effect                  | Group E ($n=28$) | Group P ($n=29$) |
|------------------------------|------------------|------------------|
| PONV                        | 2                | 3                |
| Hypotension                  | 2                | 0                |
| Motor block                  | 0                | 0                |
| Sedation                     | 0                | 0                |
| Pruritus                     | 1                | 0                |
| Respiratory depression       | 0                | 0                |
| Rescue antiemetic (required) | 5                | 4                |

*P<0.05 during intergroup comparison. Data are presented as numbers.

Group E=Epidural analgesia group, Group P=Paravertebral block group, PONV=Postoperative nausea and vomiting
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