ORIGINAL ARTICLE

Postoperative pain relief following hysterectomy: A randomized controlled trial

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ABSTRACT

Background: Women experience moderate to severe postoperative pain following total abdominal hysterectomy (TAH). The transversus abdominis plane (TAP) block is a new modality for providing postoperative pain relief in these patients.

Materials and Methods: The present study was a single center, prospective randomized trial. After the Institutional Ethics Committee approval and informed consent, patients were randomized to either epidural group: Epidural block placement + general anesthesia (GA) or TAP group: Single shot TAP block + GA. Patients in both the groups received standard general anesthetic technique and intravenous tramadol patient-controlled analgesia in the postoperative period. Patients were monitored for tramadol consumption, visual analog scale (VAS) both at rest and on coughing, hemodynamics, and side effects at 0, 2, 4, 6, 8, 12, and 24 h postoperatively.

Results: The total consumption of tramadol in 24 h was greater in TAP group as compared to epidural group (68.8 [25.5] vs. 5.3 [11.6] mg, $P < 0.001$). The VAS scores at rest and on coughing were higher in TAP group as compared to the epidural group at 6, 8, 12, and 24 h postoperatively ($P < 0.05$). None of the patients in either group had any adverse effects.

Conclusion: Epidural analgesia provided greater tramadol-sparing effect with superior analgesia postoperatively as compared to TAP block in patients up to 24 h following TAH.

Key Words: Epidural block, postoperative pain relief, total abdominal hysterectomy, transversus abdominis plane block

INTRODUCTION

Total abdominal hysterectomy (TAH) is a major surgical procedure associated with a significant postoperative pain and morbidity.[1] The epidural analgesia has been widely used in patients following TAH except in those with raised intracranial tension, coagulopathy, patient refusal, local sepsis, inability to maintain stillness during needle puncture, and limited expertise.[2,3] Transversus abdominis plane (TAP) block is a new modality and requires injection of local anesthetic solution in the anterior abdominal wall.[2] Widespread adoption of TAP has been overwhelmingly underutilized, especially after TAH as it is technically challenging and labor intensive.[4] The advantages of TAP block include preservation of lower limb motor-sensory function, hemodynamic stability, and less invasiveness.[5]

Literature supports the use of tramadol patient-controlled analgesia (PCA) in patients undergoing upper abdominal and gynecological surgery for postoperative analgesia

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as compared to morphine PCA[6-8] due to little effect on respiration.[5,6] The optimal management of postoperative pain is essential for avoiding the development of chronic pain.[1] So far, no study has prospectively compared postoperative tramadol consumption in women receiving epidural or TAP for postoperative pain relief following TAH under general anesthesia (GA).

MATERIALS AND METHODS

After the Institutional Ethics Committee approval and written informed patient consent, we enrolled women with American Society of Anesthesiologist physical Status I–II patients, aged 40–70 years, weight 60–90 kg, and scheduled for TAH in this prospective randomized trial. Patients were excluded if they had a history of relevant drug allergy, inability to use PCA device, contraindication to epidural anesthesia, history of psychiatric illness or substance abuse, and were receiving medical therapies considered to result in tolerance to opiates.

The study was conducted in a tertiary care hospital after approval of the Institutional Ethics Committee. After fulfilling inclusion and exclusion criteria, the women were recruited a day prior to the surgery. The women were explained regarding the use of PCA pump (Master PCA pump, Fresenius Kabi Company, Bad Homburg, Germany), visual analog scale (VAS), nausea, and sedation scales a day prior to surgery and on the morning of surgery. The patients had the right to opt out of the study during any stage of the study if they wish to which would not have any influence on their management during the perioperative period and would continue to receive the standard anesthesia care.

The patients had nothing by mouth overnight and premedicated with alprazolam 0.25 mg and ranitidine 150 mg orally the night before and 2 h prior to surgery. In the operating room, an intravenous (IV) access was secured and 500–1000 ml of 0.9% saline was infused. Standard monitoring including electrocardiogram, noninvasive arterial blood pressure, arterial oxygen saturation, and end-tidal carbon dioxide monitoring were started. A resident not involved in the study opened the opaque sealed envelope and women were allocated to either of the two groups according to the computer-generated random number.

Anesthesia technique

In the epidural group, an epidural catheter was placed at L_2–L_3 interspace and 10–15 ml of 0.5% ropivacaine was administered to ensure a sensory block up to T_8 dermatome by 30 min, failing which an additional 5 ml of 0.5% ropivacaine was injected.

In the TAP group, TAP block was performed under ultrasound guidance with a high-frequency (5–10 MHz) probe (Sonosite, Inc., Bothell. WA 98021, USA) and an in-plane technique using 23 gauge spinal needle after the institution of GA. Following the placement of the needle, 1.5 mg/kg of 0.75% ropivacaine (maximum dose of 150 mg on each side) was injected between internal oblique and the transversus abdominis muscle. The same procedure was repeated on the other side, and a single investigator performed blocks in all the patients.

This was followed with the standard anesthetic protocol including IV morphine 0.1 mg/kg, thiopentone sodium 5–7 mg/kg, vecuronium bromide 0.1 mg/kg, and tracheal was intubated. Maintenance of anesthesia was provided with N_2O in 40% oxygen, isoflurane, and vecuronium. IV tramadol 1 mg/kg and ondansetron 0.1 mg/kg were administered 20 min prior to the completion of surgery. Neuromuscular blockade was reversed and the patient was extubated. Following surgery, the patients in both the groups were shifted to Post-Anesthesia Care Unit (PACU). Irrespective of the group allocation, patients received PCA tramadol analgesia (bolus 2 ml, tramadol 10 mg/ml, 5 min lockout time) with the upper safe limit of 400 mg tramadol consumption in 24 h.[5] In the epidural group, continuous epidural infusion 0.2% ropivacaine at 10 ml/h was started in the postoperative period.

Outcome measures

Patients were monitored for tramadol consumption, VAS at rest and on coughing, hemodynamics, and any other adverse effects by a nurse in PACU at 0 h, 2, 4, 6, 8, 12, and 24 h. A VAS of 0 meant no pain and 10 worst imaginable pains.[7] The categorical scoring system of nausea and vomiting; 0 = no nausea/vomiting, 1 = slight nausea resolving without treatment, 2 = slight nausea and/or vomiting resolves on treatment, and 3 = nausea and/or vomiting not resolving on treatment was carried out in all the patients.[2] Sedation scale; 0 stands for completely alert, 1 for sleepy occasionally but arousable, 2 for asleep often but arousable, and 3 for asleep and unarousable.[2] Side effects such as shivering, pruritus, nausea, and vomiting were observed during the study period.

Sample size calculation and statistical analysis

The sample size was calculated based on a previous study[8] using "sample size calculation for the difference of two mean" in which a mean 24 h consumption of PCA tramadol was 267 mg with a standard deviation of 90 mg. In the present study, assuming a 25% absolute reduction in 24 h tramadol consumption as clinically important with an alpha value of 0.05 and a power of 80%, 29 patients were required per group. We planned to enroll thirty patients in each group.

Statistical analysis was performed using statistical package Sigma stat 3.5, Systat Software, San Jose, CA, USA. The demographic data were analyzed with Student's *t*-test or Fisher's exact tests as appropriate. For testing normality, the data were tested using Kolmogorov–Smirnov normality test. Repeated measurements were analyzed by repeated measures analysis of variance where normally distributed (ANOVA). For nonnormally distributed data, between group comparisons at each time point was made using Wilcoxon's ranked sum test. Tramadol consumption in each group was analyzed with Student's *t*-test. Categorical data were analyzed using χ^2 analysis or Fisher's exact test. Normally, distributed data were presented as a mean ± standard deviation, nonnormally distributed data were presented as median (interquartile range), and categorical data were presented as frequencies. $P < 0.05$ was considered statistically significant.

RESULTS

Sixty-two patients were screened for the study. Two patients, one from each group, were excluded due to nonfulfillment of inclusion criteria. We enrolled sixty women after written informed consent and all completed the study [Figure 1]. Groups were comparable in baseline demographic data [Table 1]. The total 24 h consumption of tramadol was significantly higher in women of TAP group as compared to epidural group (68.8 [25.5] vs. 5.3 [11.6] mg, $P < 0.001$). The postoperative VAS scores were similar in both the groups up to 6 h, but at 8, 12, and 24 h the mean VAS score was greater in TAP group, both at rest and on coughing ($P < 0.05$) [Tables 2 and 3]. There were no significant differences in hemodynamics in both the groups. At 24 h, 10% women in TAP group reported greater nausea as compared to epidural group (Median, IQR, 0 [0–0] vs. 0 [0–1], $P < 0.001$). There was no difference in mean consumption of antiemetics, sedation score, and side effects.

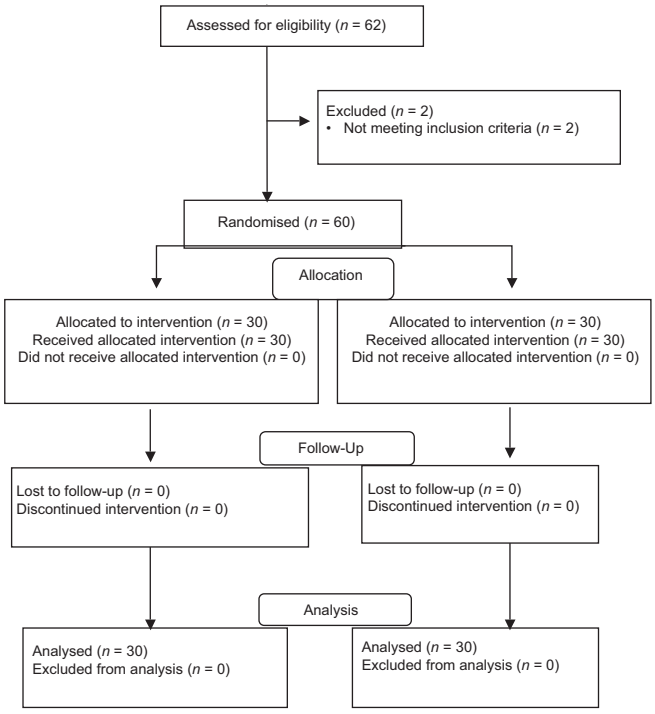

Figure 1: Consort diagram

DISCUSSION

We found greater total 24 h tramadol PCA consumption in TAP group as compared to the epidural group. Epidural analgesia treats both somatic (abdominal wall wound) and visceral (uterus) components of pain, whereas the TAP block covers pain derived from the abdominal wall only.[9] In a previous study,[8] comparison of tramadol, tramadol-metamizol, and tramadol-lornoxicam

Table 1: Comparison of baseline characteristics of patients

	Epidural group (*n*=30)	TAP group (*n*=30)	*P*
Age (years)	50.5 (7.1)	49.9 (5.5)	0.5
Weight (kg)	70.9 (9.3)	71.3 (5.8)	0.8
BMI (kg/m^2)	25.9 (3.8)	27.6 (2.5)	0.05
ASA I/II (%)	40/60	36.7/63.3	0.7

Data are represented as mean (SD), *P*<0.05 is considered statistically significant.
BMI: Body mass index, ASA: American Society of Anesthesiologist, SD: Standard deviation, TAP: Transversus abdominis plane

Table 2: Comparison of visual analog scale scores at rest during 24 h postoperative period in epidural and transversus abdominis plane group

	Epidural group (*n*=30)	TAP group (*n*=30)	*P*
0 h	0.5 (0-1)	0 (0-1)	0.14
2 h	1 (1-1)	1 (0-1)	0.20
4 h	1 (0-1)	1 (0-1)	0.49
6 h	1 (0-1)	1 (1-1)	0.01*
8 h	0 (0-1)	1 (1-2)	0.001*
12 h	0 (0-0.2)	2 (2-3)	0.001*
24 h	1 (0-1)	5 (4-5.2)	0.001*

Data are represented as (median, IQR), **P*<0.05 statistically significant.
IQR: Interquartile range, TAP: Transversus abdominis plane

Table 3: Comparison of visual analog scale on coughing during 24 h postoperative period in epidural and transversus abdominis plane group

	Epidural group (*n*=30)	TAP group (*n*=30)	*P*
0 h	2 (1-3)	2 (0-2)	0.1
2 h	2 (2-3)	2 (1-2)	0.06
4 h	2 (1.7-3)	2 (1-2)	0.1
6 h	2 (1-2)	2 (2-2)	0.02*
8 h	1 (1-2)	2 (2-3)	0.001*
12 h	1 (1-2)	3.50 (3-5.2)	0.001*
24 h	2 (1-2)	8 (7-8)	0.001*

Data is represented as (median, IQR), **P*<0.05 statistically significant.
IQR: Interquartile range, TAP: Transversus abdominis plane

administered by IV PCA in the management of postoperative pain relief after lower abdominal surgeries resulted in a 24 h tramadol consumption of 267 (91.4) mg which was much higher[8] as compared to the present study. TAP for postoperative pain has been used in cesarean section patients, but the results cannot be compared with women undergoing TAH due to different nociceptive inputs of the two surgeries.[10] Rao Kadam *et al*. compared epidural versus continuous TAP catheter technique for postoperative analgesia after abdominal surgery but did not find any differences in pain scores. The study was underpowered and authors suggested randomized trials with a larger numbers of patients.[11]

The mean VAS score at rest and coughing was higher in TAP group at 8, 12, and 24 h in the present study. This could be explained as an analgesic effect of TAP block starts to decrease at 6 h;[8] however, studies have reported an effective postoperative analgesia following a single shot TAP block for up to 24–36 h.[10,12] We used GA in the present study instead of spinal anesthesia,[12,13] which possibly prolongs the effect of TAP block. The benefits of single shot TAP block could be of advantage in situations where epidural analgesia is contraindicated or not desired. The hemodynamic parameters in the present study were within the normal physiological range with no adverse effects.[14,15]

Patients receiving TAP block for postoperative analgesia had been shown to exhibit reduced incidence postoperative nausea vomiting (PONV) by more than half (69% vs. 31%)[2,16] but in the present study, patients in TAP group at 24 h showed an increased PONV due to increased tramadol consumption.

The strength of the present study was that it was a randomized controlled trial, which is one of the cornerstones of any prospective clinical trial. The random assignment of subjects into one of the groups is the basis for establishing a cause-and-effect relationship for an intervention.

There are certain limitations of the present study; first, the study could not be blinded for risk of ethical issues (performing both epidural and TAP) for just the purpose of blinding and second, all the blocks were performed by the same investigator.

CONCLUSION

Epidural analgesia provided tramadol-sparing effect with superior analgesia postoperatively up to 24 h when compared to a single shot TAP block in patients following TAH.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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