Original Article

Quality of recovery and analgesia after total abdominal hysterectomy under general anesthesia: A randomized controlled trial of TAP block vs epidural analgesia vs parenteral medications

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Abstract

Background and Aims: Parenteral analgesics and epidural analgesia are two standard options to treat postoperative pain after total abdominal hysterectomy (TAH). Fascial plane blocks such as transversus abdominis plane (TAP) block have gained popularity recently. However, effect of these analgesic regimens on quality of postoperative recovery (QoR) has not been studied. Hence we aimed to assess and compare the QoR with three different postoperative analgesic regimens---parenteral analgesia, epidural analgesia, and TAP block in patients undergoing TAH under general anesthesia.

Material and Methods: Sixty female patients undergoing TAH were randomized into three groups of 20 each for postoperative analgesia. Epidural group received boluses of 0.125% bupivacaine for 24 h, parenteral group received injection diclofenac and injection tramadol alternately every 6 h for 24 h, and TAP group received bilateral TAP block with 0.25% bupivacaine at end of operation. QoR was assessed postoperatively by 40-item questionnaire-QOR-40 and pain was assessed by numerical rating scale (NRS).

Results: QOR-40 score was comparable across the three groups at 24, 48, and 72 h postoperatively. TAP block prolonged the time to first rescue analgesic ($P = 0.02$) and reduced the total 24-h postoperative morphine consumption by 2.4 (95% CI: 1.0, 3.8) mg ($P = 0.002$) and 7.8 (95% CI: 6.4, 9.1) mg ($P < 0.001$) when compared with epidural and parenteral groups, respectively.

Conclusion: The QoR after abdominal hysterectomy is similar with either intravenous analgesics or epidural analgesia or TAP block when used with rescue analgesia to manage postoperative pain. TAP block provides superior analgesia and reduces 24-h morphine consumption when compared with parenteral and epidural analgesia.

Keywords: Epidural analgesia, postoperative analgesia, quality of recovery, total abdominal hysterectomy, transversus abdominis plane block

Introduction

Total abdominal hysterectomy (TAH) is the most common nonobstetric major surgical procedure performed in Indian women,[1] and is associated with significant postoperative pain and discomfort.[2] Traditionally, postoperative pain relief following TAH is provided by intravenous opioid/nonopioid medications or epidural analgesia. Transversus abdominis plane (TAP) block is increasingly used for both upper and lower abdominal surgeries.[3-7] Although originally described as a blind technique,[3] advent of ultrasound has

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aided popularization of TAP block. An important component of the pain after TAH is from the abdominal wall incision which can be relieved by blocking abdominal wall afferent fibers with TAP block.[8]

Analgesia being an important component of anesthetic plan, effective management of postoperative pain is expected to impact perioperative quality of recovery (QoR) positively.[9] QoR-40 score has been shown to be a valid, reliable, responsive tool in variety of surgical settings[10-12] and, therefore, the best instrument to measure the complex and multidimensional process of postoperative recovery.[13]

A few authors have studied the analgesic efficacy of TAP block in TAH with varying analgesic efficacy.[7,14] However, it would make sense only if the analgesic effect translates into better QoR, which has not been studied so far. Therefore, we designed a study to evaluate QoR as assessed by QoR-40, following three different postoperative analgesic regimens-epidural local anesthetics, TAP block, and parenteral analgesics in patients undergoing total abdominal hysterectomy under general anesthesia. The secondary outcome measures were postoperative pain scores, postoperative analgesic requirement, time to first morphine requirement, and side effects of morphine.

Material and Methods

After obtaining approval of the Institutional Ethics Committee, a prospective, randomized double-blind controlled trial was registered in the Clinical Trial Registry of India (CTRI/2011/06/001823). Sixty female patients aged between 18 and 60 years of ASA physical status I/II and scheduled under general anesthesia for elective TAH with or without bilateral salpingo-oophorectomy through Pfannensteil incision were included. Written informed consent was obtained from all enrolled patients. The exclusion criteria were body mass index ≥30 kg/m^2; moderate to severe cardiopulmonary disease (ASA ≥III); history of addiction to either drug or alcohol; history of chronic pain; history of regular consumption of analgesics; contraindications to use of NSAIDs, local anesthetics or opioids; and contraindications to insert an epidural catheter. The enrolled patients were randomized to three groups of 20 each-epidural, parenteral, and TAP block groups by using computer-generated random number table. The group allocation was concealed in sealed, opaque envelopes.

All patients underwent preanesthetic evaluation and were instructed to report pain on the 11-point numerical rating scale (NRS) with zero equaling "no pain" and 10 indicating "the worst imaginable pain." A standardized general anesthetic management with standard monitoring was employed in all the three groups. Epidural catheter was inserted in all patients at lower thoracic interspace followed by a test dose of 3 ml of 2% lignocaine with adrenaline 5 μg/ml. Injection morphine 0.1 mg/kg and propofol 2 mg/kg were administered to induce general anesthesia and tracheal intubation was facilitated by vecuronium 0.1 mg/kg, intravenously. Subsequently, anesthesia was maintained using isoflurane in a mixture of nitrous oxide and oxygen to achieve end-tidal concentration of 0.9-1.2%. Intraoperative analgesia was provided with 6-8 ml boluses of epidural lignocaine (2%) with adrenaline (5 μg/ml) every 90 min. In the event of inadequate analgesia as judged by increase in heart rate or systolic blood pressure by more than 20% of the baseline, a further bolus of IV morphine 0.05 mg/kg was administered. Injection ondansetron 0.1 mg/kg was given prophylactically 30 min before the surgery ended. At the end of procedure, isoflurane inhalation and nitrous oxide was stopped. In all patients, bilateral TAP block was performed by an experienced anesthesiologist using double loss-of-resistance technique as described by McDonnell *et al.*[3,4] before reversing the neuromuscular blockade with 50 μg/kg neostigmine and 20 μg/kg atropine. The trachea was extubated after recovery of neuromuscular blockade and patient was shifted to postanesthesia care unit after regaining consciousness.

For postoperative analgesia, patients were randomly allocated to one of three groups. Patients in epidural group received 8 ml boluses of 0.125% bupivacaine at 6-h interval for 24 h. They received placebo (0.9% sodium chloride) in TAP block and IV boluses at 0, 6, 12, 18, and 24 h. Parenteral group patients received injection diclofenac 1 mg/kg IV at 0, 12, and 24 h alternating with injection tramadol 1.5 mg/kg IV at 6 and 18 h. They received placebo (0.9% sodium chloride) in epidural and TAP blocks. The TAP block group patients received TAP block with 0.25% bupivacaine, 15 ml on each side or upto a maximum of 2 mg/kg body weight, whichever was lesser. They received placebo (0.9% sodium chloride) in the epidural space and IV boluses. The drug solutions for TAP block, postoperative epidural, and IV analgesic boluses were prepared according to randomization and labeled appropriately at the end of surgery by an anesthesiologist not involved in the study.

Postoperative pain was assessed by a blinded investigator by NRS at 0, 30, 60, and 90 min and 2, 4, 6, 12, 18, and 24 h postoperatively. Rescue analgesia was provided by IV morphine 0.05 mg/kg boluses whenever the NRS exceeded a score of >3. Metoclopramide 10 mg was administered if the patient complained of nausea. The sedation scores were assessed by modified Ramsay scale at time intervals of 0, 30,

60, and 90 min and 2, 4, 6, 12, 18, and 24 h. QoR-40, the 40-item questionnaire specifically validated to measure patient's health status after surgery and anesthesia, was used to assess QoR at 24, 48, and 72 h postoperatively. These 40 items are rated on a 5-point Likert scale and are drawn from five domains, viz. 12 items of physical comfort, nine items of emotional state, five items of physical independence, seven items of psychological support, and seven items of pain. The minimum possible score is 40, indicating extremely poor quality of recovery and maximum score is 200 indicating excellent quality of recovery.[10]

Statistical analysis

A pilot study was conducted in 5 patients who underwent elective total abdominal hysterectomy wherein injection diclofenac and injection tramadol were administered for postoperative analgesia. The QoR score (mean ± SD) at 24 h postoperative was found to be 162 ± 10 with this IV analgesic regimen. In order to achieve an improvement of QoR score by 10 points with an alternative intervention, it was found that at least 20 patients should be studied to achieve a power of 90% with an alpha error of 0.05.

The parametric data are expressed as mean ± standard deviation and nonparametric outcomes are expressed as median (IQR). Intraoperative hemodynamic parameters at different time intervals were compared between the groups by ANOVA with appropriate posthoc testing with Bonferroni correction. Intergroup comparisons of pain scores, sedation scores, dose of morphine consumption at different time intervals, time to first rescue analgesic, nausea, vomiting, and QoR scores were evaluated by using Mann-Whitney U-test. The difference in total postoperative morphine requirement between the groups was calculated by paired *t*-test. All tests were evaluated for 95% confidence limits. P value < 0.05 was considered significant. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 15.0 for Windows).

Results

Sixty patients were enrolled and randomized out of 65 patients who were assessed to be included. The data of all these 60 patients were analyzed. All the three groups had comparable characteristics, including patient demographics and intraoperative usage of anesthetic and analgesic drugs [Table 1].

The QOR-40 score was similar across the three study groups at 24 (P = 0.47), 48 (P = 0.82), and 72 h (0.34) postoperatively [Figure 1a-c].

The mean total morphine consumption in the first 24 h postoperative was 6.1 ± 1.8 mg in TAP block group, which was significantly less than that used in epidural (8.5 ± 2.6 mg) and parenteral group (13.9 ± 2.4) (P < 0.01) [Table 2]. The mean difference (95% confidence interval) in 24-h morphine consumption following TAP block was 7.8 (6.4, 9.1) mg less than that in parenteral group (P < 0.001) and 2.4 (1.0, 3.8) mg less than that in epidural group (P = 0.002). Overall, the time interval to administration of first rescue analgesia was significantly different across the three groups (P = 0.02). On intergroup comparison, the difference between TAP block group (105 (67.2-360) minutes) and parenteral group (60 (30-90) minutes) was statistically significant (P = 0.01), whereas the differences between TAP block group and epidural group (P = 0.14) or epidural and parenteral groups (P = 0.10) were not significant [Table 2].

The pain score (NRS) was significantly less in TAP block group patients at 1 h postoperatively as compared with the other two groups (epidural vs TAP block P = 0.02, TAP block vs parenteral P < 0.01). At 18 h postoperatively, the NRS scores were statistically significantly better in epidural and TAP block groups (epidural vs parenteral P < 0.01, TAP block vs parenteral P < 0.01) [Table 3].

There was higher incidence of postoperative nausea and/or vomiting in the epidural (45%) and parenteral group (50%) than TAP block group (30%), although the difference was statistically not significant (P = 0.4). Sedation scores were similar across groups. None of the patients reported any complication arising from either epidural or TAP block.

Discussion

The current study has shown that the QoR after total abdominal hysterectomy after general anesthesia is similar, while employing any of the three different regimens for postoperative analgesia, viz. intravenous analgesics alone, epidural analgesia, or TAP block. This is the first study to evaluate both analgesic efficacy and pattern of recovery using QoR-40 following TAP block and epidural local anesthetics in patients undergoing TAH. QoR-40 scores QoR in five dimensions: physical comfort (12 items), emotional state (9 items), physical independence (5 items), psychological support (7 items), and pain (7 items).[10] Five-point Likert scale is used to grade each item such that the global scores range from 40-200. QoR-40 has the advantage of being a composite recovery score incorporating multidimensional aspects of postoperative recovery and is validated in a range

Table 1: Patient Characteristics

	Epidural group (n=20)	Parenteral group (n=20)	TAP block group (n=20)	P
Age (years)	50.2±6.7	46.7±5.4	45.5±6.7	0.1
Weight (kg)	61.5±10.7	60.1±10.3	59.3±8.5	0.8
Height (cm)	156.4±4.9	156.8±4.1	155.5±3.6	0.6
BMI (kg/m^2)	24.8±3.3	24.6±3.2	24.4±3.2	0.9
ASA I/II, n	16/4	18/2	16/4	0.6
Surgical diagnosis				
Fibroid uterus	9	11	10	0.8
Endometrial carcinoma	6	6	5	0.9
Adnexal mass	4	3	4	0.9
DUB	1	0	1	0.6
Total intra-op morphine (mg)	5.8±1.3	6.0±0.9	6.4±1.4	0.4
Total intra-op propofol (mg)	112±24.4	112.5±25.9	111.5±19.5	0.9
Total intra-op vecuronium (mg)	8.5±1.8	8.8±1.2	8.5±0.9	0.7

ASA=American Society of Anesthesiologists Category, BMI=Body Mass Index, DUB=Dysfunctional Uterine Bleeding. Values are expressed as mean±SD or number. The parametric data in this table was analysed with ANOVA and categorical variables using Chi-square test

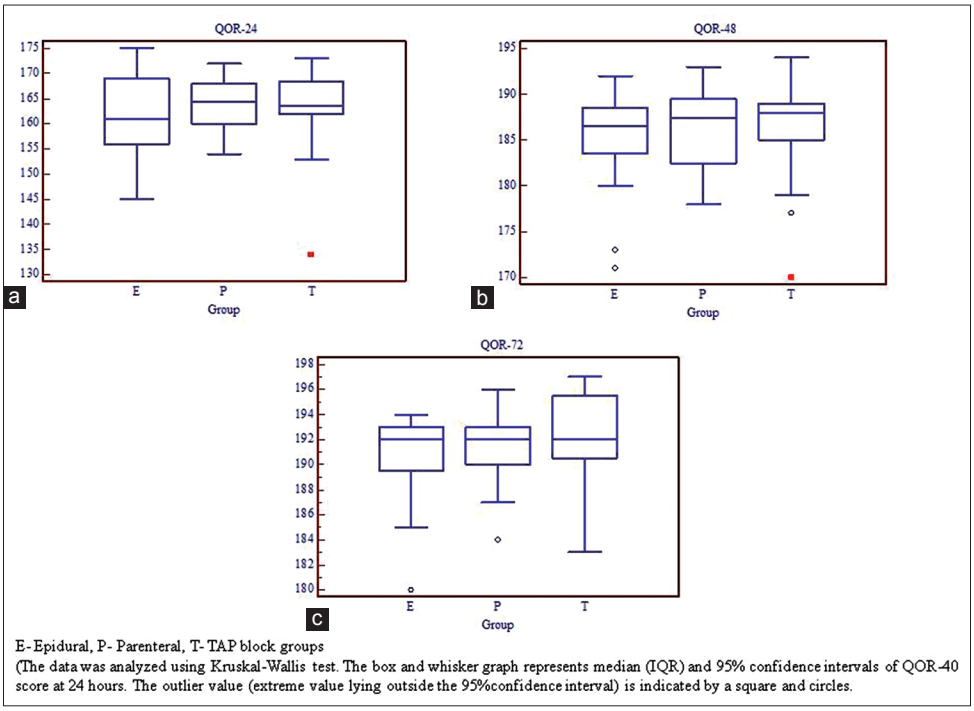

Figure 1: Quality of recovery score (a) QoR-40 at 24h, (b) QoR-40 at 48h and (c) QoR-40 at 72h after surgery

of surgical procedures.[10-12] Since recovery of cognition is essential to perform this scoring, QoR-40 cannot be used to assess emergence from anesthesia. In addition, QoR-40 does not perform repeated measures essential for assessing recovery over time nor does it include patient satisfaction in the scoring.

There is scanty data in our country to show the actual practice of postoperative pain management after major abdominal surgery. The recent survey on the practices of postoperative pain management in tertiary care centers in Maharashtra has identified some of the important barriers for effective acute pain management in Indian hospitals.[15] Epidural analgesia has a high-risk benefit ratio and therapeutic failure rate ranging from 13-27%.[16-18] Opioids have significant side effects such as sedation, nausea, and vomiting[19] that may be unsuitable for enhanced recovery programs. The TAP block being a regional technique offers logical advantage to provide analgesia without the risks of epidural technique and side effects of intravenous analgesics. Landmark-guided TAP block was chosen over ultrasound-guided TAP block in this study to simulate the possible practice of perioperative management in large sections of healthcare delivery system in our country, which includes private nursing homes, district hospitals, and government medical colleges where ultrasound-guided TAP block may not be a practical option.

Table 2: Post-operative morphine requirement

	Epidural Group (*n*=20)	Parenteral group (*n*=20)	TAP block group (*n*=20)	*P*
Post-op morphine requirement:				
0-24 hrs (mg)	8.5±2.6	13.9±2.4	6.1±1.8	<0.001*
0-6 hrs (mg)	5.2±2.2	5.9±2.3	3.2±1.8	<0.001*
6-24 hrs (mg)	3.4±2.8	7.4±3.3	3.0±2.3	<0.001*
Time of first rescue (minutes)	75 (60-120)	60 (30-90)	105 (67.2-360)	0.02

*Values are mean±SD or median (IQR).*Indicates P<0.05*

Table 3: Postoperative pain scores (NRS) at different time points

	Epidural Group (*n*=20)	Parenteral group (*n*=20)	TAP block group (*n*=20)	*P*
NRS 0	0.0 (0.0-1.0)	0.0 (0.0-1.8)	0.0 (0.0-0.0)	0.34
NRS 0.5	2.0 (1.0-3.8)	2.0 (1.0-3.0)	1.5 (0.0-2.0)	0.17
NRS 1	3.0 (2.0-4.8)	3.5 (3.0-5.0)	2.0 (1.0-3.0)	<0.001*
NRS 1.5	3.0 (2.0-4.8)	3.0 (2.0-4.8)	2.0 (2.0-3.0)	0.14
NRS 2	3.0 (2.0-3.0)	3.0 (2.0-4.0)	2.0 (2.0-3.0)	0.50
NRS 4	2.0 (2.0-4.0)	2.0 (1.0-3.8)	2.0 (1.0-4.8)	0.81
NRS 6	2.0 (1.3-3.8)	2.0 (1.3-4.0)	2.0 (2.0-4.0)	0.78
NRS 12	2.0 (1.0-2.8)	3.5 (2.0-4.8)	3.0 (1.0-4.0)	0.15
NRS 18	1.0 (0.0-1.8)	2.5 (1.0-4.0)	1.0 (0.0-1.0)	<0.001*
NRS 024	1.0 (0.0-1.0)	1.0 (0.0-1.8)	0.0 (0.0-1.0)	0.48

*Values are expressed as median (IQR). *Indicates P<0.05*

The median NRS scores were comparable across the three groups of the current study at most times (except at 1 h and 18 h), implying that analgesia was adequate during the first 24 h postoperatively. This was achieved by provision of rescue intravenous morphine when the NRS exceeded a score of 3. Since pain management is indispensable to ensure good quality of recovery after major surgery, ensuring adequate analgesia in the study design probably explains that QoR-40 scores were similar across the three groups. Kane *et al.*[20] and Oliveria *et al.*[21] were the only other authors who evaluated the effect of TAP block on quality of recovery after hysterectomy, although in both studies laparoscopic hysterectomies were performed. Their findings were contrasting as Kane *et al.*[20] found no difference either in pain scores or QoR-40 scores with and without TAP block, and Oliveira *et al.*[21] observed positive effects of TAP block with better quality recovery, less postoperative pain, and lower opioid consumption.

As the current study protocol ensured adequate analgesia for all study subjects for ethical reasons by incorporating rescue medications, the total amount of rescue analgesia and the time to first rescue analgesia are indicators of efficacy of analgesic interventions studied. The total 24 h postoperative morphine consumption was reduced in TAP block group by an average of 2.4 mg compared with epidural group, and by 7.8 mg when compared with parenteral group. Similar findings are available in literature wherein Carney 2008[8] and Oliviera 2011[21] demonstrated less morphine requirement after TAP block as compared with intravenous analgesics. However, Raghvendra *et al.*[14] had found the analgesic efficacy of epidural analgesia superior to TAP block in women undergoing TAH. These authors had used epidural infusion to provide epidural analgesia, whereas our study had used epidural boluses for postoperative analgesia.

The nonavailability of an acute pain service team in our institution was a barrier to employ epidural infusion and during the study design, we were particular to implement a pragmatic study protocol, which is practicable in the setting of our country wherein acute pain service is not available even in majority of tertiary care centers.[15] Considering this factor in our set-up as well as in many other developing countries, single-shot TAP block may be a better alternative to epidural local anesthetic boluses or infusion, to maintain the quality of postoperative analgesia and thus QoR.

The sedation scores and the occurrence of opioid associated side effects were similar in three groups despite a statistically significant difference in the amount of opioids consumed. This may be explained as the sample size was not calculated to detect differences in the incidence of these secondary outcome characteristics. This finding may be another factor that contributed to similar QoR in the three groups studied.

The NRS score at 1 h postoperatively was significantly less in the TAP block group than in epidural or parenteral groups. This may be because of the effect of TAP block establishing earlier than the epidural or parenteral regimens,

as later values are all comparable between the three groups. This assumption is supported by the observation that the median (IQR) time for first rescue morphine requirement was longer in TAP block-105 (67.2--360) min as compared with epidural-75 (60--120) min, and parenteral groups-60 (30--90) min.

The strengths of current study include the randomized controlled double-blind study design and the homogeneous nature of study population, procedures and study protocols as close as possible to the real-life practice of anesthesia in our country. However, some of these aspects may be construed as drawbacks of the study, viz. (i) use of landmark technique for TAP block which has lesser predictability for success than ultrasound guided technique, (ii) lack of use of patient-controlled analgesia to administer intravenous morphine, and (iii) use of boluses of local anesthetics for epidural analgesia rather than an infusion because of lack of acute pain services. It could be argued that ultrasound-guided TAP block may provide even better analgesic efficacy. In addition, we acknowledge that the number of patients studied may be considered small, masking the potential complications with the TAP block.

In conclusion, the quality of recovery after abdominal hysterectomy under general anesthesia is similar whether intravenous analgesics or epidural local anesthetic boluses or TAP block are used with provision for rescue analgesia to manage postoperative pain for the first 24 h. TAP block provides superior analgesia and reduced 24 h morphine consumption when compared with parenteral group and may be a suitable alternative for epidural analgesia in situations where acute pain service is not available or the neuraxial blockade is contraindicated.

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Conflicts of interest
There are no conflicts of interest.

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