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ORIGINAL RESEARCH REGIONAL ANESTHESIA

Comparison of ultrasound guided transversus abdominis plane block with different concentrations of ropivacaine combined with fentanyl: a randomized double-blind trial

Srinivasa Rao Nallam [1], Anila Darsi [2], Pooja Veeramalla [3], Abdullah Sunkesula [4], Sunil Chiruvella [5]

Author affiliations:

1. Srinivasa Rao Nallam, Associate Professor, Department of Anesthesiology, Critical Care & Pain Medicine, Government Medical College, Pulivendula, India; E-mail: drvaasu@gmail.com; {ORCID:0009000826248051}
2. Anila Darsi, Post Graduate, Department of Anesthesiology, Critical Care & Pain Medicine, Government Medical College, Kadapa, India; E-mail: aniladarsi2@gmail.com {ORCID:0009000409366030}
3. Pooja Veeramalla, Post Graduate, Department of Anesthesiology, Critical Care & Pain Medicine, Government Medical College, Kadapa, India; E-mail: aniladarsi2@gmail.com ; {ORCID:0009000102266799}
4. Abdullah Sunkesula, Post Graduate, Department of Anesthesiology, Critical Care & Pain Medicine, Government Medical College, Kadapa, India; E-mail: abdullah.svmc.2k10@gmail.com; {ORCID:000900003040301
5. Sunil Chiruvella, Professor, Department of Anesthesiology, Critical Care & Pain Medicine, Government Medical College, Kadapa, India; E-mail: drchiruvellasunil@gmail.com

Correspondence: Srinivasa Rao Nallam, **E-mail:** drvaasu@gmail.com; {**ORCID:** 0009000826248051}

ABSTRACT

Objectives: This study was conducted to assess the duration of analgesia using different concentrations of ropivacaine (0.2%, 0.375% and 0.5%) combined with fentanyl in Transversus Abdominis Plane (TAP) block. In addition to analgesic effects, hemodynamic effects, sedation and side effects were also evaluated in this study.

Methodology: A total of 90 patients scheduled for elective total abdominal hysterectomy (TAH) surgery under spinal anesthesia were randomly allocated to one of the three groups: R1 group received - 29 mL 0.2% ropivacaine combined with 50 µg fentanyl (1 mL) to make a total of 30 mL in TAP block; R2 - 29 mL 0.375% ropivacaine combined with 50 µg fentanyl (1 mL) to make a total of 30 mL; and group R3 - 29 mL 0.5% ropivacaine combined with 50 µg fentanyl (1 mL) to make a total of 30 mL. With the help of visual analogue scale (VAS) duration of analgesia was assessed also total rescue analgesic requirement was recorded.

Results: Duration of analgesia was significantly increased in group R3 (410.52 ± 70.18 min vs. 353.17 ± 92.03 min vs. 309.28 ± 83.66 min; [R3 vs. R2 vs. R1 respectively ($P > 0.05$)]. Significantly fewer patients in the R3 group required rescue analgesia. (23.3% vs. 36.6% vs. 63.3%; [R3 vs. R2 vs. R1 respectively ($P > 0.05$)].

Conclusion: We conclude that higher concentration of ropivacaine provided prolonged analgesia compared to lower concentrations in TAP block. However, 0.2% ropivacaine provides statistically similar postoperative analgesia to 0.375% ropivacaine.

Abbreviations: ASA - American Society of Anesthesiologists; LAST - local anesthetic systemic toxicity; PONV - post-anesthesia care unit; RSS - Ramsey sedation scale; TAP block - Transversus Abdominis Plane block; TAH - total abdominal hysterectomy;

Keywords: Anesthesia, ropivacaine, spinal cord, fentanyl, hysterectomy.

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1. INTRODUCTION

After total abdominal hysterectomy (TAH), postoperative pain is a major problem for both anesthesiologists and obstetricians; mainly due to its abdominal wall incision and abdominal muscle dissection.[1] Incompetent control of postoperative pain following TAH surgery causes a delay in the course of recovery and increasing the risk of thromboembolism.[2] A multidisciplinary procedures to postoperative analgesia that combines regional analgesia techniques with parenteral analgesia can adequately control postoperative pain and reduce its side effects. [3]

The transversus abdominis plane block (TAP) is widely practicing and an important regional component of the analgesic technique in a multimodal approach to postoperative analgesia. TAP block mainly acts by blocking 7th to 11thintercostal, thoracic 12th nerve (subcostal) and iliohypogastric/ilioinguinal nerves.[4] This procedure was first described by Rafi in 2001 as a landmark based procedure utilizing Petit's triangle surface indicators. Later on this procedure was further tested and improved by McDonnell.[5,6] Hebbard later introduced the ultrasound-guided approach.[7]

In many previous studies several local anesthetic agents in various concentrations was studied in TAP block to ensure adequate analgesia. Bupivacaine is the most commonly used local anesthetic agent in TAP block. It has good analgesic properties and the duration of its effect is 6-8 hours when used in a concentration of 0.25-0.5%. However, high concentrations of bupivacaine can be problematic. Concentrations of bupivacaine greater than 0.5% increase the risk of systemic toxicity of the local anesthetic due to the increased possibility that the drug is absorbed into the bloodstream in larger quantities. Close monitoring of patients is recommended even after bupivacaine TAP blockade, especially when higher concentrations have been used.

In comparison to bupivacaine, ropivacaine has a lipid solubility that is 2-3 times lower, along with a reduced volume of distribution, increased clearance, and a shortened elimination half-life.[8] Ropivacaine is a long-acting amide local anesthetic. It is the S-enantiomer of bupivacaine with a lower toxicity profile and similar properties to bupivacaine.

The main objective of this study was to evaluate the duration of analgesia of three different concentrations of ropivacaine (0.2%, 0.375% and 0.5%) combined with fentanyl in ultrasound-guided TAP block in patients scheduled for TAH surgery under spinal anesthesia. Secondary outcomes measured were hemodynamic variables, total number of analgesic doses required in the first 24 hours, and adverse events in the three groups.

2. METHODOLOGY

This prospective, double-blinded (patient and assessor-blinded), parallel-group trial was conducted from November 2023 to April 2024. The approval for this research was obtained from the institutional ethics committee (vide no. IEC NO: 06/GMC/KDP/2023, Dated: 29/09/2023), and the trial was registered at the Clinical Trials Registry-India (vide no. CTRI/2023/11/075653; URL: https://ctri.nic.in/Clinicaltrials). The study followed the guidelines as laid down in the Declaration of Helsinki (2013).

A total of 90 patients with American Society of Anesthesiologists (ASA) physical status I and II between the age groups 50-65 years are enrolled. TAH surgeries scheduled under spinal anesthesia were included in this prospective randomized study. Patients known to be sensitive to local anesthetic drugs, allergic to investigational drugs, infections at injection area, coagulation disorders, uncontrolled diabetes and hypertension, hepatic and renal disorders, obesity (body mass index >25 kg/m2) and patients who were not unable to interpret visual analogue scale (VAS) before surgery were excluded from the study. Before surgery, all patients underwent proper pre-anesthetic check-ups and all routine laboratory investigations were performed. Patients were informed about the study procedure and advised to fast for 6 hours preoperatively. About 10 cm visual analogue scale (VAS) were also clarified at the preoperative visit.

Block randomization was performed using a computer-generated block random number table. Sequentially numbered, opaque, sealed envelopes were used for random sequence generation and concealment. To protect the allocation sequence, the assigned random group was sealed in an envelope. An anesthesiologist not involved in the trial opened the sealed envelope to prepare the study solution in accordance with the randomization protocol. The anesthesiologist who performed the block and monitored the patient was not aware of the treatment group. The same anesthesiologist collected the data and was uninformed of the group allocation.

All subjects were randomly allocated to one of three equal groups. Patients in R1 group received 0.2%

ropivacaine (29 mL) plus 50 µg of fentanyl (1 mL) in TAP block under ultrasound guidance (15 mL on each side, a total of 30 mL), patients in R2 group received 0.375% ropivacaine (29 mL) plus 50 µg of fentanyl (1 mL) in TAP block under ultrasound guidance (15 mL on each side, a total of 30 mL) and patients in R3 group received 0.5% ropivacaine (29 mL) plus 50 µg of fentanyl (1 mL) in TAP block under ultrasound guidance (15 mL on each side, a total of 30 mL).

Upon arrival in the operating room, a wide bore intravenous (i.v.) cannula was secured and preloading was done with 10 mL/kg crystalloid solution. All noninvasive ASA monitors [electrocardiography (ECG), noninvasive blood pressure (NIBP) and oxygen saturation (SpO_2)] were attached and baseline recordings were noted.

Following institutional standard protocols, under strict aseptic precautions, spinal anesthesia was administered with 15 mg of 0.5% bupivacaine heavy (3 mL) without any adjuvant to all patients in the lateral position and without any table tilt. Using pinprick method level of sensory block was recorded. Surgery was started when the level of T6 blockade was reached. Patients were monitored intraoperatively. None of the patient required any analgesic or sedation dose during surgery.

After completion of surgery, an experienced investigator performed a bilateral TAP block. After thoroughly sterilizing the insertion site, which is situated in the mid axillary line halfway between the costal margin and the iliac crest, a 100-mm Stimuplex needle (B-Braun Medical, Bethlehem, PA, USA) was inserted using the in-plane technique into the neurofascial plane between the internal oblique muscle and the transverse abdominis. 15 mL of the test solution were given once the needle tip placement was confirmed in correct plane. The endpoint of block success was defined as imaging a hypoechoic layer between the two muscles after the local anesthetic solution was injected.[9] The opposite side underwent the same process again.

After successful bilateral TAP block all patients were transferred post-anesthesia care unit (PACU). In PACU patients were monitored for any possible adverse effects. Post-operative pain severity was assessed using a 0-10 cm (0 = no pain and 10 = worst pain) visual analog scale (VAS) at 2, 4, 6, 12, and 24 hours. Adverse effects like postoperative nausea & vomiting (PONV), sedation, bradycardia and hypotension were also recorded. Using Ramsey sedation scale (RSS), sedation scores assessed.[9] More than 20% fall in basal heart rate or an absolute heart rate less than 50 bpm was considered as bradycardia and was effectively managed with 0.6 mg atropine i.v bolus dose. A decrease in blood pressure of more than 20% of base line or an absolute mean arterial pressure (MAP) less than 60 mmHg was considered as hypotension and was treated with i.v crystalloid solutions (200 mL of ringer lactate/normal saline) or injection mephenteramine sulphate 3 mg i.v supplements.

Time from the completion of TAP block procedure at the end of surgery to the time when patient experiencing VAS ≥3 cm was defined as duration of analgesia. Injection paracetamol 1 gram was administered as rescue analgesia when VAS was equal or more than 3. Total number of rescue analgesics required in the first 24 hr postoperative period, for each patient was also noted.

Statistical analysis:

Based on a pilot study with fifteen patients (five in each group) sample size was determined. In three groups, the analgesia durations were279.4 ± 46.2 minutes, 327.12 ± 81.4 minutes, and 358.69 minutes respectively. To observe a 30 minutes difference in analgesia duration between three groups with 5% type 1 error and 80% of power, a minimum sample size of 37 patients in each group was required. For better validation of results, we included 40 patients in each group. Using Statistical Package for the Social Sciences (SPSS, IBM, Armonk, NY, USA) version 23.0 for Windows, data was analyzed. Continuous variables and categorical variables are represented as mean [standard deviation (SD)] and frequencies (percentages), respectively. To determine the association between quantitative continuous variables, one-way ANOVA, followed by Bonferroni's multiple comparison test was used. To assess the association between qualitative variables, the Chi-square test followed by pair wise comparison was used. P value of <0.05 was considered statistically significant.

3. RESULTS

We assessed 101 patients for eligibility and randomized 90 patients equally to the three study groups. Eleven patients were not randomized as they either did not meet all eligibility criteria or declined to consent. No patient in any group experienced block failures.

Demographic data, in terms of age, weight, height, ASA physical status and duration of surgery were comparable among all groups (Table 1). Baseline hemodynamic parameters were not statistically significant in all three groups. (P > 0.05).

The overall analgesia duration was shorter in group R1 (309.28 ± 83.66 min) compared to group R2 (353.17 ± 92.03 min) and group R3 (410.52 ± 70.18 min), which is statistically significant (P < 0.001; Table 2). The duration of analgesia in group R3 was also clinically lengthened compared to group R2, but this was not statistically significant. (P < 0.05) About 19 out of 30 patients (63.3%) in group R1 required paracetamol

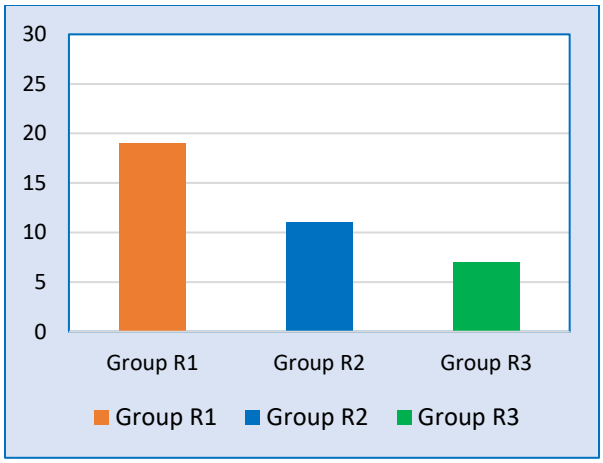

Figure 1: Rescue analgesic requirement in postoperative period (P = 0.0027)

injection as rescue analgesia, while in group R2 11 out of 30 patients (36.6%) and 7 patients out of 30 patients (23.3%) in group R3 required rescue analgesia within the first 24 hr after surgery (P = 0.037; Figure 1). During first 6 hours after TAP block, patients receiving greater concentrations of ropivacaine reported much less pain, but there was no statistically significant difference in pain scores were observed at 12 and 24 hr. (Table 3).

Complications such intestinal perforation, hematoma, femoral nerve palsy, liver damage, local anesthetic systemic toxicity (LAST), or intestinal perforation were not reported in any patient among all groups. No statistically significant difference in the effect of sedation was found between the three groups (Table 4).

No patient in either group experienced an episode of bradycardia. Only one patient in the R3 group developed hypotension and was managed effectively with 200 mL of crystalloids bolus and 3 mg of injection mephenteramine sulphate i.v. without any further deduction. There was no clinical difference between nausea scores at any time. One patient from group R1 and two from group R3 reported severe nausea at some point during the evaluation.

4. DISCUSSION

The results of this prospective, double-blind study demonstrated that single-shot ultrasound-guided TAP blockade provides effective postoperative pain relief as part of multimodal analgesia in patients undergoing TAH surgery under spinal anesthesia. We found statistically significant differences between groups R1, R2 and R3 ($P < 0.05$) concerning the mean duration of analgesia, the requirement of rescue analgesia, and the VAS score. However, the duration of postoperative analgesia was not statistically significant between groups R2 and R3 (P = 0.090). Compared to patients receiving 0.2% and 0.375% ropivacaine for TAP block, those getting 0.5% ropivacaine experienced superior analgesia and a decreased requirement for rescue analgesia. We observed no significant complications in the three groups.

The effectiveness of TAP blockade with local anesthetics such as lignocaine, bupivacaine, levobupivacaine and ropivacaine for postoperative pain relief has been evaluated in many previous

Table: 1 Demographic data

Parameter	Group R1	Group R2	Group R3	P value
Age (yr)	54.30 ± 3.76	55.67 ± 3.77	53.41 ± 6.19	0.179
Weight (kg)	76.40 ± 6.96	74.04 ± 6.52	75.74 ± 8.41	0.44
Height (cm)	164.48 ± 4.28	163.71 ± 5.10	165.25 ± 4.11	0.42
ASA I/II	23/7	24/6	22/8	0.302
Duration of surgery (min)	78.2 ± 9.8	77.3 ± 8.2	76.7 ± 9.1	0.812

Data are represented as mean ± SD. BMI = Body mass index, ASA = American Society of Anesthesiologist, SD = Standard deviation

Table 2: Comparison of duration of analgesia between the three groups

Variable	Group R1	Group R2	Group R3	P value
Duration of analgesia (min)	309.28 ± 83.66	383.17 ± 92.03	419.52 ± 70.18	0.000056

Data are represented as mean ± SD. SD = Standard deviation

Table 3: Comparison of VAS score between three groups at different time intervals

Time interval (Hr)	Group R1	Group R2	Group R3	P value
2	0.69 ± 0.32	0.62 ± 0.11	0.52 ± 0.09	0.0063
4	2.32 ± 1.21	1.94 ± 0.69	1.12 ± 1.9	0.0033
6	4.89 ± 0.98	3.46 ± 1.06	2.67 ± 1.25	0.0000059
12	5.45 ± 2.82	4.01 ± 2.31	3.62 ± 4.77	0.104
24	6.79 ± 5.08	5.86 ± 4.07	4.29 ± 3.54	0.078

P < 0.05 was taken as statistically significant

Table 4: Comparison of the incidence of side effects in three groups

Side effect	Group R1 (n = 30)	Group R2 (n = 30)	Group R3 (n = 30)	P value
Sedation score (>3)	2 (6.66%)	2 (6.66%)	3 (10%)	0.041
Bradycardia (HR <50 bpm)	0	0	0	
Hypotension (MAP <60 mm Hg)	0	0	1 (3.33%)	0.034
PONV	3 (10%)	3 (10%)	4 (13.3%)	0.027

Values are expressed as number of patients. HR=Heart rate; MAP=Mean arterial pressure

studies.[10]According to the findings of these investigations, TAP block significantly reduced pain and reduced the need for rescue analgesic medications. The majority of research appear to support the usefulness of bupivacaine combined with TAP block for managing postoperative pain; however, none of them clearly indicate what dosage of ropivacaine is best. Our study's primary goal was to assess the safety and effectiveness of three ropivacaine concentrations in ultrasound-guided TAP block to relieve postoperative pain in patients undergoing TAH surgeries under spinal anesthesia.

In contrast to our study, Griffiths et al. found no discernible decrease in post-operative VAS scores in patients scheduled for gynecologic cancer surgeries, randomized into two groups with and without TAP blockade.[11] Moreover, Kane et al. found that TAP block did not reduce postoperative pain scores or reduce analgesic requirement after laparoscopic hysterectomies. It was also noted that there was no difference in the length of hospital stays between patients who received TAP blocks and those who did not.[12]

Similar to our study, Mohamed and team found a beneficial effect of ropivacaine in TAP block at 0.2% and 0.5% concentrations on management of postoperative pain following lower segment cesarean section.[13] Also De Oliveira et al. examined the efficacy of TAP block with ropivacaine 0.25% and 0.5% concentrations in the management of postoperative pain following laparoscopic hysterectomy surgeries. These studies conclude that the efficacy of higher concentration of ropivacaine is more in controlling postoperative pain when compared to lower concentrations. [14]

In the TAP block, different local anesthetics or varying concentrations of the same local anesthetics have been utilized. Raghunath et al. demonstrated that, 0.5% ropivacaine sustained a longer period of postoperative analgesia compared with 0.25% levobupivacaine for TAP block in patients undergoing lower abdominal surgeries.[15] Another study by Sinha et al. found that 0.375% ropivacaine was superior to 0.25% bupivacaine in terms of analgesia in patients scheduled for laparoscopic cholecystectomy, however this difference was only observed an hour after surgery.[16] Also, in ropivacaine group, they observed a statistically significant reduction in pain score. Nonetheless, the total amount of rescue analgesia needed during the 24-hour postoperative period was comparable. In comparison to 0.375% ropivacaine, we discovered that 0.5% ropivacaine produces analgesia for a longer period of time and requires less rescue analgesia over the first 24 hours.

At the same time, a statistically significant difference in the first analgesic requirement was observed in the R2 and R3 groups compared to the R1 group. Gildasio S. De Oliveira compared postoperative opioid requirements in patients undergoing laparoscopic surgery who received TAP blockade with ropivacaine 0.25%, ropivacaine 0.5%, or saline.[17] Opioid consumption was significantly reduced in the ropivacaine group compared to the saline group. However, opioid requirements were comparable between ropivacaine 0.25% and ropivacaine 0.5%.

When evaluating postoperative pain, we found that VAS scores were significantly lower in the R2 and R3 groups for 6 hours after surgery. At six hours, VAS scores were lower in the R3 group and this trend continued up to 24 hours. Belavy et al reported no significant differences in

VAS scores in patients receiving TAP block with 0.5% ropivacaine or normal saline.[18] This is in contrast to other studies that reported lower VAS scores 24 hours postoperatively after TAP block. In another study of 88 women undergoing elective cesarean section under spinal anesthesia, a lower VAS score was observed in the TAP block group compared to the control group at 3, 6, and 12 hours postoperatively.[19]

Postoperative hemodynamic parameters were also investigated in our study. Systolic &diastolic blood pressures also SpO2 were comparable after surgery ($P < 0.05$). While one patient in group R3 experienced hypotension, the incidence was not statistically significant (P value > 0.05), and no patient in any group experienced bradycardia [Table 5]. Chakraborty et al. discovered, in line with our investigation, that there was never a statistically significant change in SpO2, blood pressure, or HR between the two groups.[20]

The TAP block approach has not been associated with any complications, including hematomas, infections, or visceral damage. This may be because the surgery is guided by ultrasonography, although it does not guarantee total safety. Following TAP blockage, Scharine observed colon puncture or hematoma formation at the entry site, whereas Farooq and Carey reported liver injury. [21, 22]

Numerous investigations, including one by Mane and colleagues, have demonstrated that the quality of peripheral nerve blocks was enhanced when fentanyl was added to local anesthetics.[23] Other research, such that conducted by Magistris et al., however, came to the conclusion that adding fentanyl or other opioids to local anesthetics does not significantly improve peripheral nerve blocks clinically.[24]

5. LIMITATIONS

Our study has two limitations. The first limitation was that the sensory block level was not assessed after TAP block. Another limitation was that the serum levels of ropivacaine was not assessed.

6. CONCLUSION

We conclude that 0.5% ropivacaine provided a longer duration of analgesia than 0.25% & 0.375% ropivacaine when used in TAP block for patients undergoing TAH surgeries. However, 0.2% ropivacaine provides postoperative statistically similar analgesia to 0.375% ropivacaine. Postoperative hemodynamics and the incidence of adverse effects were also comparable in all three groups.

7. Study data availability

De-identified data may be requested from authors for reasonable reasons (via email to the corresponding author) and will be shared after approval according to author institution policy.

8. Financial support and sponsorship

No industrial or organizational grant was availed. The study was conducted with the institutional resources only.

9. Conflicts of interest

There are no conflicts of interest.

10. Authors' contribution

All authors have contributed intellectually to the manuscript and the manuscript has been read and approved by all the authors. All authors read and approved the final manuscript.

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