

Comparison of Post Operative Analgesic Efficacy of Dexamethasone as an Adjuvant with Ropivacaine 0.25% and Plain Ropivacaine 0.25%, Using Ultrasound Guided Tap Block after Total Abdominal Hysterectomy: A Randomized Controlled Trial

Ashutosh Parihar, Nidhi Shukla¹, Atul Saxena², Shuchi Nigam

Department of Anaesthesiology, Uttar Pradesh University of Medical Sciences, Etawah, ¹Department of Anaesthesiology, Integral Institute of Medical Sciences,

²Department of Plastic Surgery, Uttar Pradesh University of Medical Sciences, Etawah, Uttar Pradesh, India

Abstract

Introduction: Following abdominal surgery, transversus abdominis plane (TAP) block, a peripheral nerve block, can be a useful supplement to multimodal postoperative analgesia. The aim was assessment of postoperative analgesic effectiveness of 0.25% ropivacaine with 4 mg of dexamethasone on each side and 0.25% ropivacaine alone in the management of postoperative pain following total abdominal hysterectomy (TAH). **Materials and Methods:** Sixty adult patients planned for elective TAH with ASA Grades I–II under general anesthesia participated in this prospective, randomized, double-blinded study. Patients of Group A were given 20 mL of 0.25% ropivacaine on both the sides and Group B patients were given 20 mL of 0.25% ropivacaine with dexamethasone 4 mg on each side. The primary objective of this study was a comparison of Visual Analog Scale (VAS) scores between the groups and comparison of mean time of first rescue analgesia. The secondary objectives of this study were a comparison of hemodynamic parameters, postoperative analgesic requirement, patient satisfaction, and incidence of side effects. **Results:** VAS shows no discernible variation in 1 and 4 h after administration of block in Groups A and B. However, a significant difference appeared in VAS 8 h ($P = 0.007$), VAS 12 h ($P = 0.000$), and VAS 24 h ($P = 0.000$) after the administration of block between Groups A and B. The median time for first rescue analgesia was 2.75 h (interquartile range [IQR] = 1 h) and 5.8 h (IQR = 1.6 h) in Groups A and B, respectively, which was highly significant. **Conclusion:** We concluded that, after abdominal hysterectomy, dexamethasone added to ropivacaine TAP block tends to prolong postoperative analgesia and decrease the need for analgesics.

Keywords: Analgesics, postoperative period, ropivacaine, ultrasonography

INTRODUCTION

Severe somatic, neuropathic, and visceral pain is experienced after lower abdominal procedures.^[1,2] Inadequate analgesia causes severe neurohumoral, immunological, and catabolic alterations that affect organ function physiologically. Postoperative pain after an abdominal hysterectomy might range from moderate to severe.^[3] Postoperative pain management aims to reduce pain while minimizing side effects.

A multimodal strategy is frequently the most effective way to do this. There are different agents (opioids and nonopioids), routes (oral, intravenous [IV], neuraxial, and regional) as well as modes (patient controlled and “as needed”) that are able to

Address for correspondence: Dr. Shuchi Nigam,
Department of Anaesthesiology, Uttar Pradesh University of Medical
Sciences, Saifai, Etawah, Uttar Pradesh, India.
E-mail: shuchinigam@gmail.com

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manage postoperative pain.^[4] Transversus abdominis plane block (TAP block) could be a useful addition to multimodal postoperative analgesia following abdominal surgical operations.^[5,6]

Using the least concentration of local anesthetics (LAs) is possible in peripheral nerve blocks.^[7] In TAP block, several combinations of LAs and dexamethasone were investigated. The quantity of dexamethasone and LAs used in earlier researches was associated with variations in pain levels. It was unclear if the difference in analgesia was brought on by dexamethasone or by a higher LA concentration. Furthermore, the evaluation of pain score for procedures performed under subarachnoid block may also be inaccurate. Recent investigations were not able to demonstrate a statistically meaningful prolonging of LA effects.^[8-10] Determining the analgesic effectiveness of dexamethasone as a TAP block adjuvant was our goal. 0.25% ropivacaine was used for the investigation because it provides a better sensory blockage than bupivacaine and has a lower toxicity profile. To properly evaluate the quality of TAP block while under general anesthesia, we reduced the concentration of LAs and utilized 4 mg of dexamethasone.

MATERIALS AND METHODS

Study design

This was a prospective, randomized, double-blind study.

Study setting

This study was conducted at the Department of Anesthesiology in collaboration with the Department of Obstetrics and Gynaecology, Vivekananda Polyclinic and Institute of Medical Sciences, Lucknow.

Sample size

The sample size was 30 in each group.

Following clearance from the Institutional Ethical Committee, this study was conducted (Ethical clearance no: 47/2019) and the procedures were carried out in compliance with the 2013 Helsinki Declaration over a year. The formula used for sample size calculation was:

$$n = 2(Z\alpha/2 + Z\beta)^2 SD^2/d^2$$

where n : Sample size in each group

SD: Pooled standard deviation = 2

d : Difference in the means (effect size) = 1.5

$Z\alpha/2$: Critical value of z at 95% confidence = 1.96

$Z\beta$: Critical value of z at 80% power = 0.84

Now, putting these values in the above equation, we get:

$$n = 28.76-28.$$

Assuming 80% power and 95% confidence interval, a minimum of 28 participants is needed in each group. However, after making provisions for contingency at 8%, we propose that each group has a sample size of 30.^[7]

Sixty patients between the ages of 35 and 55 years, ASA Class I or II who were planned for total abdominal hysterectomy, were included in this study. Participants who declined to take part in the trial, had a history of amide LA allergy, had hepatic or renal insufficiency, or had any condition that prohibited them from receiving regional anesthetic were not allowed to participate in the study. Two groups of patients were formed, each of which had 30 patients, using computer-generated random numbers. Every patient received a thorough description of the procedure before providing informed written consent. The computer-generated random sequence numbers were divulged in the operating room by an anesthesiologist who did not participate in the process of gathering data. All the blocks were given by the same individual with experience in nerve blocks guided by ultrasound (USG). The time when the block was supplied, the data recorder was not present. As a result, they were ignorant of the assigned group.

Following a preanesthetic evaluation, patients were instructed to use the Visual Analog Scale (VAS) (0–10), where 0 denoted no pain and 10 denoted the most intense agony they had ever felt. The patients were then asked to choose the measurement on the scale that most closely represented how uncomfortable they were. Individuals were kept nil per oral 6–8 h before surgery and were premedicated with oral 150 mg ranitidine and 0.25 mg alprazolam in the night before and the day of the procedure.

Once the anesthetic technique was explained to the patients, each one gave signed informed consent. Standardized general anesthesia was administered to both the groups. A premedication of 0.02 mg/kg of midazolam was administered intravenously to each patient approximately 20 min before induction of general anesthesia in the preoperative holding room. They were attached to standard monitoring including noninvasive blood pressure, pulse oximetry, capnography, and continuous electrocardiography. Vital parameters were recorded at baseline. Fentanyl (2 µg/kg) and propofol (1–2 mg/kg) were used to induce the patients. Vecuronium 0.08 mg/kg was administered to aid in tracheal intubation. The following doses were used to maintain anesthesia: 1 vol% of isoflurane, 0.02 mg/kg of vecuronium every 30 min, 65%:35% of N₂O with O₂, and 1 µg/kg/h of fentanyl. The end-tidal CO₂ concentration in the patients was maintained between 35 and 45 mmHg by mechanical ventilation.

The blinded anesthesiologist used a Fujifilm SonoSite M Turbo USG machine with a high-frequency linear array probe of 8–12 MHz to execute the TAP block on each side after the procedure was complete and before the patient was extubated.

The posterior technique was applied to approach the TAP plane. While the patient was in the supine position, the anterolateral abdominal wall on both the sides was disinfected with an antiseptic solution and draped. The anesthesiologist who gave the TAP block received the prepared medication mixture. A sterile transparent adhesive tape was used to cover the USG probe after it had been cleansed with antiseptics.

Povidone-iodine solution served as the scanning medium. The scanning probe was positioned transversely over the lateral abdominal wall between the iliac crest and the costal margin over the midaxillary line to identify the structures from superficial to deep, including skin, subcutaneous tissue, fat, external and internal oblique muscles, transverse abdominis muscles, peritoneal cavity, and bowel loops.

Using an in-plane approach, a 23G Quincke spinal needle was introduced into the neurofascial plane between the internal oblique and transverse abdominis muscles to open the fascial plane separating them. Following proper placement of the needle, Group A patients ($n = 35$) received 20 mL of 0.25% ropivacaine + 8 mg of dexamethasone on each side, while Group B patients ($n = 35$) received 20 mL of 0.25% ropivacaine + 2 mL saline on each side.

Neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg were used to reverse any remaining neuromuscular blockade following the block. After comprehensive oral cavity suctioning and restoration of airway reflexes, patients were extubated and moved to postanesthesia recovery room, where they were observed by the nursing staff, which was otherwise blind to the study group.

Postoperatively, the patients were evaluated by an independent observer for pain, sedation, nausea, vomiting, pruritus, and urinary retention. Arrival at the postanesthesia care unit was

taken as time 0; the patients were subsequently assessed at 1 h, 4 h, 8 h, 12 h, and 24 h. The pain was assessed using VAS. The level of sedation was assessed using a modified Wilson sedation scale 1 – oriented, 2 – drowsy, 3 – arousable, and 4 – Unarousable. On the first request for analgesia, injection diclofenac sodium 75 mg i/v and/or injection tramadol 100 mg IV was given. The time for first rescue analgesic request and supplemental analgesic requirements over 24 h was recorded. Twenty-four hours after surgery, patients were asked to rate on a three-point scale measure of how satisfied they were with the pain management 1 – highly satisfied, 2 – satisfied, and 3 – dissatisfied.

Statistics

IBM SPSS (Statistical Package for the Social Sciences) Version 21.0. Statistical Analysis Software was used to perform the statistical analysis. The values were denoted in number (%) and median and interquartile range. $P < 0.05$ was taken to be statistically significant.

RESULTS

Sixty patients were enlisted for the study and split into two groups of 30 each. Not a single patient was excluded in the study [Figure 1].

The two groups were equivalent in terms of age, body mass index, ASA grading, and vital parameters [Table 1].

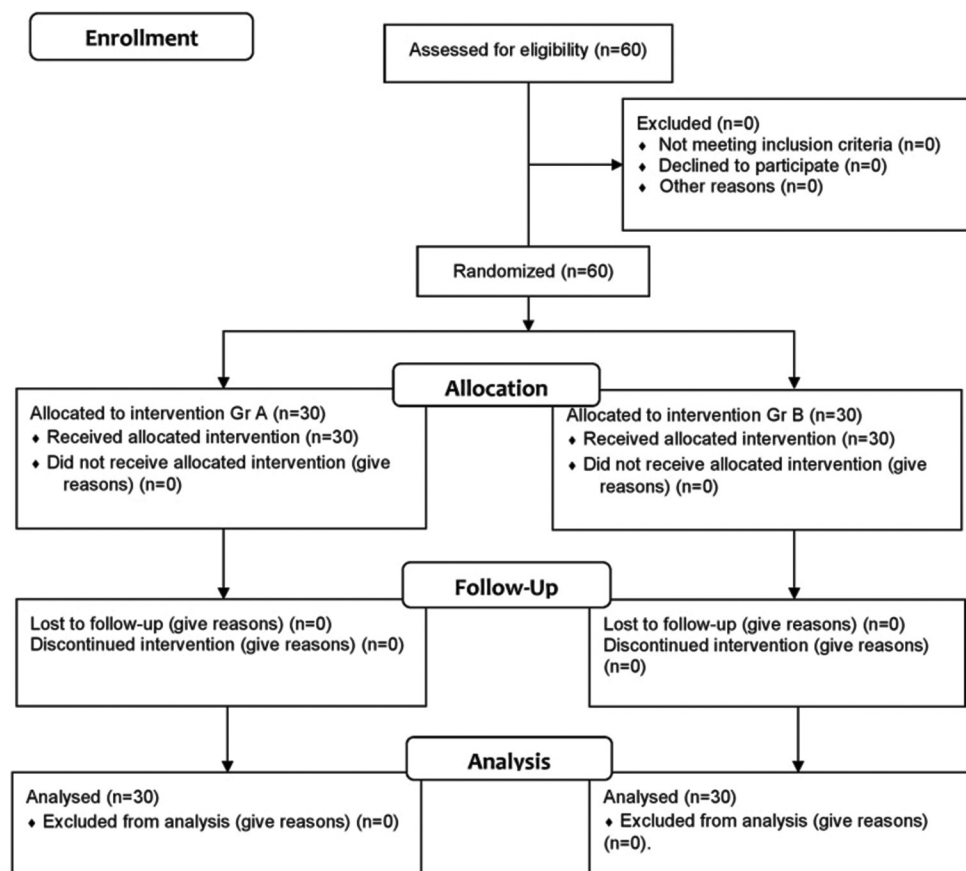


Figure 1: Consort flow diagram

VAS was used to measure postoperative pain at various intervals, including 1 h, 4 h, 8 h, 12 h, and 24 h. For VAS, there is not a noticeable difference in 1 and 4 h after administration of block in Groups A and B. However, a significant difference appears in VAS 8 h ($P = 0.007$), VAS 12 h ($P = 0.000$), and VAS 24 h ($P = 0.000$) after the administration of block between Groups A and B [Table 2].

On application of the Mann–Whitney U -test, there is no significant difference in sedation scores, i.e., after 1 h, after 4 h, after 8 h, after 12 h, and after 24 h, between Group A and B variables after intervention [Table 3].

In Group B, 70% of patients reported as satisfied after the block, whereas in Group A, only 50% stated to be satisfied following the block's application. Only 13.3% of the participants were dissatisfied in Group B, and in Group A, 43.3% reported to be dissatisfied. Highly satisfied response was given by 16.7% of participants in Group A and by 6.7% in Group B. On application of the Mann–Whitney U -test, there

Table 1: Association between sociodemographic profile of participants under Groups A and B

Sociodemographic factor Variables	Median (IQR)		P
	Group A	Group B	
Age	55.0 (12)	55.5 (15)	0.411
Body weight	56.0 (10)	56.0 (8.5)	0.755
Height	159.5 (8)	160 (6)	0.623
BMI	21.6 (5.7)	22.35 (4.6)	0.865

BMI: Body mass index, IQR: Interquartile range

Table 2: Association between Visual Analog Scale score after 1 h, 4 h, 8 h, 12 h, and 24 h in Group A and Group B

Variables (h)	Median (IQR)		P
	Group A	Group B	
VAS 1	3 (1)	2 (1)	0.155
VAS 4	5 (1)	4 (2)	0.051
VAS 8	6 (1.3)	5 (1.3)	0.007
VAS 12	8 (1)	6 (2)	0.000
VAS 24	9 (2)	8 (2)	0.000

IQR: Interquartile range, VAS: Visual Analog Scale

Table 3: Association between sedation score of participants after 1 h, 4 h, 8 h, 12 h, and 24 h between Groups A and B

Variables (h)	Median (IQR)		P
	Group A	Group B	
Sedation score 1	3 (0)	3 (0)	0.553
Sedation score 4	3 (1)	3 (0.3)	0.119
Sedation score 8	2 (1)	2 (0)	0.393
Sedation score 12	1 (1)	1 (1)	0.776
Sedation score 24	1 (0)	1 (0)	0.165

IQR: Interquartile range

is a substantial distinction ($P = 0.029$) in the satisfaction scale between both the groups between Group A and B variables after the intervention [Figure 2].

DISCUSSION

Corticosteroids have been proven to lessen postoperative analgesia in the past. According to Kikuchi *et al.*, the decrease in interleukin-8 caused by methylprednisolone's intrathecal rather than epidural administration reduced patients' herpetic neuralgia continuous pain, and allodynia.^[11]

Similar to our findings, Gupta *et al.* concluded that the addition of dexamethasone to ropivacaine in TAP block significantly prolongs the duration of postoperative analgesia.^[12] Deshpande *et al.*'s study showed that Group ropivacaine and dexamethasone (RD) significantly reduced postoperative VAS pain scores at 4, 6, and 12 h in contrast to Group R (just ropivacaine) ($P = 0.05$).^[13] Comparable outcomes were observed in a research by Ammar and Mahmoud, where the VAS score was considerably lower in the dexamethasone + bupivacaine group than in the bupivacaine alone group at the postoperative 2 h (4.9 vs. 28.1, $P = 0.01$), 4 h (12.2 vs. 31.1, $P = 0.01$), and 12 h (15.7 vs. 25.4, $P = 0.02$).^[14] In their study, Naghipour *et al.* discovered that the dexamethasone and bupivacaine group had a sustained analgesic effect and a lower pain score.^[15] Similar results were also published by Gendy *et al.*, who found that in bariatric patients undergoing laparoscopic vertical band gastroplasty giving dexamethasone in a dose of either 4 or 8 mg with isobaric bupivacaine in TAP block considerably decreased discomfort following surgery, decreased the need for analgesics, and encouraged early ambulation.^[16]

In the study by Vieira *et al.*, the median patient satisfaction scores at 48 h (9.5 vs. 8.0, dexamethasone vs. control, respectively) did not substantially differ between the two groups.^[17] However, in our investigation, there was a considerable discrepancy between the two groups' satisfaction scales. Similar to our study, where there was a substantial difference between the two groups in the timing of the first rescue analgesic, the time of first rescue analgesia was also found to be considerably longer in the dexamethasone group in Ammar and Mahmoud's study (459.8 vs. 325.4 min, $P = 0.002$). In their study, Mirzai *et al.* also discovered that

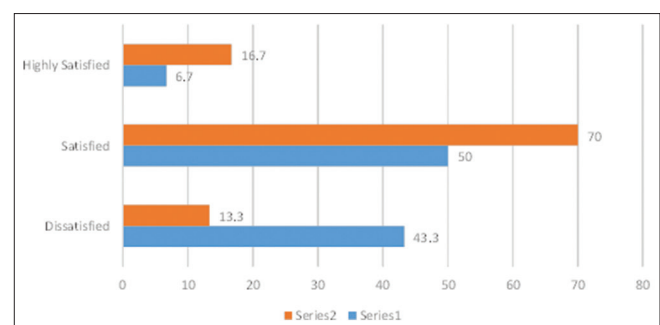


Figure 2: Bar graph representing satisfaction scale (by percent) for Groups A and B after intervention

the group receiving dexamethasone and corticosteroid used rescue analgesia significantly less frequently than the control group (patients in Groups 1 and 2 received 77.3 ± 48.8 mg of meperidine and 31.8 ± 45.5 mg of meperidine, respectively, for pain medication in the first 12 h ($P = 0.05$).^[18]

Similar to our study, Ammar *et al.*^[14] discovered that there were substantial differences between the adverse effects of the two groups (vomiting and nausea). Deshpande *et al.*^[13] observed a decreased adverse effect in the RD group in their trial, where the incidence of nausea or vomiting was statistically insignificantly different between the groups ($P > 0.05$). This is similar to our study, where also overall adverse effect was reduced in the dexamethasone group, but the difference in the adverse effects (nausea and vomiting) between the two groups was significant ($P < 0.05$).

CONCLUSION

Thus, from the aforementioned details, we can conclude that the addition of dexamethasone to ropivacaine in TAP block prolonged the postoperative analgesia, reduced the postoperative analgesic requirement, and increased patient satisfaction following abdominal hysterectomy.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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