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Original Research Article

A Prospective and Randomized Study to Compare Postoperative Analgesic Effect of Ropivacaine with or without Dexamethasone in Ultra Sound Guided Transversus Abdominis Plane Block for Patients Undergoing Lower Abdominal Surgeries

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Abstract:

Background: An effective abdominal field block for the transversus abdominis is ultrasound guidance. In patients undergoing lower abdominal surgeries, the intention was to ascertain the impact of adding dexamethasone to 0.375% ropivacaine on the analgesic duration of TAP block.

Methods: Total 60 patients double-blinded randomised control study with 30 patients in each group was done. Group A: 20 ml total, 20 ml for each side of 0.375% ropivacaine and 1 ml of dexamethasone, 4 mg. Group B: Following lower abdominal surgery, 20 ml of 0.375% ropivacaine and 1 ml of normal saline were injected into the TAP block on each side. The primary objective is to assess the duration of postoperative analgesia provided by the block, and the secondary objectives are to compare the total amount of rescue analgesia required in the first 24 hours following surgery and any side effects from the ropivacaine in the TAP block. The intensity of the two groups' pain was compared using scores on a numeric rating scale.

Results: When compared to group B (10.69 ± 1.79 h), group A analgesia duration was substantially longer (12.44 ± 1.60 h) at the time of the first analgesic need, P < 0.001. In comparison to group B, group A required less total rescue analgesic ampoules after surgery (1.27 ± 0.64 vs. 1.63 ± 0.56 ampoule, P = 0.024) (P < 0.005). At 1 hour, 2 hours, and 4 hours postoperatively, group B NRS scores for pain were significantly higher than those of group A.

Conclusion: The duration of postoperative analgesia increases significantly when dexamethasone is added to ropivacaine in a TAP block.

Keywords: USG, Ropivacaine, Dexamethasone, Analgesia, Lower Abdominal Surgery.

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Introduction

The transversus abdominis plane block (TAP block) with 0.375% ropivacaine and dexamethasone has only been studied in a few cases under ultrasound guidance. The goal of the current study is to support and add to the body of literature already available on

the subject by demonstrating that Ropivacaine, when Dexamethasone was added as an adjuvant during an ultrasound-guided transversus abdominis plane block, increased analgesia duration and reduced the need for overall rescue analgesics. This was done without having any significant systemic side effects. The patients who were scheduled for lower abdominal surgery were the subjects of this study at our facility.

Material and Methods

A prospective, randomized, double-blind, controlled trial with 60 ASA I or II patients undergoing lower abdomen surgery was recruited. Participants' ages ranged from 18 to 65. 60 patients in all were split into two groups of 30 each. This study was done at Darbhanga Medical College and Hospital, Laheriasarai, Bihar from November 2022 and April 2023.

Computer generated random number sequences were used for randomization, and they were distributed using sequentially numbered opaque sealed envelopes. In order to prevent bias, the patient and the outcome assess or were both blinded. Patients with known drug allergies to study group drugs, local pathology at the injection site, anticoagulation therapy, inherited or acquired coagulopathy, taking medication for chronic pain, ASA class III or above, serum creatinine more than 1.2mg/dl, and patients with diabetes mellitus were among the patients who were excluded from the study.

Routine investigations (CBC, RFT, PT/INR, Blood sugar, Chest X-ray, ECG), as well as any additional necessary tests unique to the treatment and patient, were completed.

The patients were told about the surgery, and their written informed consent was obtained.

Each patient's baseline heart rate, noninvasive blood pressure, ECG, respiratory rate, and oxygen saturation were recorded and reported when they entered the operating room. A suitable IV fluid was begun after securing an intravenous cannula. Based on a prior study, the sample size was estimated using an alpha error of 0.05, an 80% study power, and a standard deviation of 7.6 hours for the duration of analgesia in the ropivacaine and dexamethasone group.

25 patients in each group are needed as the sample size for the current study, which is enhanced and rounded off to 30 patients in each group as the final sample size, assuming 15% dropouts/loss to follow-up/attrition, in order to detect a minimum detectable mean difference in duration of analgesia of 6.1 hours as found in the reference study1.

Normal distribution unpaired numerical variables were studied using unpaired T-tests, and categorical/nominal variables were analyzed using Chisquare tests/Fisher-exact tests. The Mann- Whitney U test was used to assess data that were not normally distributed, contained numerical variables, and were unpaired. P-values <0.05 were regarded as significant. All statistical computations were performed using Medcalc 16.4 software.

Results

In two equal groups of 30, a total of 60 adult patients with informed permission who were scheduled for lower abdominal surgery underwent randomization. The use of ultrasonic guiding enhances the block's overall quality and helps prevent complications because the diffusion of local anesthetic can be seen in the plane. All the blocks were successful. There were no adverse effects or problems. In terms of mean age, weight, gender, and ASA grade, the demographic statistics were comparable between the two groups and statistically insignificant. The group's baseline hemodynamic parameters were comparable and statistically insignificant.

With a significant P value <0.001, group A had a longer average time before needing a rescue analgesic ($12.44\pm1.60h$) than group B ($10.69\pm1.79h$).

With a significant P value of 0.024, group A total analgesic ampoule consumption is much lower (1.27 ± 0.64) than group B (1.63 ± 0.56). Given that one ampoule of diclofenac sodium aqua contains 75mg of the medication, this equates to 95.25 ± 48 mg in group A and 122.25 ± 42 mg in group B of diclofenac sodium.

Parameters	Group A	Group B	*P value	
	N=30	N=30		
Mean Age (Yrs.)	37.77 ± 10.21	37.40 ± 11.39	0.895	
Mean Weight (Kg.)	70.70±5.98	71.17±9.4	0.819	
Gender				
Male	6 (20%)	6 (20%)	1.000	
Female	24(80%)	24(80%)		
ASA Grade				
Ι	21(70.0%)	16(53.33%)	0.111	
IE	1(3.33%)	8(26.67%)		
II	5(16.67%)	3(10.00%)		
IIE	3 (10.00%)	3 (10.00%)		

Table 1: Demographic parameters

- Unpaired t test for mean age and mean weight.
- Fisher exact test for gender
- Chi-square = 6.620 with 3 degrees of freedom; P = 0.111 for ASA grade N= group E=emergency

NRS	Group	Ν	Mean	SD	Median	'p' value*	
0 Min	Α	30	0	0	0	-	
	В	30	0	0	0		
30 Min	А	30	0	0	0	-	
	В	30	0.13	0.35	0		
1 hour	А	30	0.37	0.49	0	0.017	
	В	30	0.73	0.64	1		
2 hour	А	30	1.00	0.37	1	< 0.001	
	В	30	1.67	0.61	2		
4 hour	А	30	1.47	0.51	1	< 0.001	
	В	30	2.47	0.57	2.5		
6 hour	А	30	1.90	0.55	2	0.296	
	В	30	2.07	0.69	2		
8 hour	А	30	2.33	0.55	2	0.305	
	В	30	2.07	1.26	2		
10 hour	А	30	2.60	0.86	2	0.559	
	В	30	2.43	1.33	2		
12 hour	А	30	2.63	1.27	2	0.323	
	В	30	2.93	1.05	3		
14 hour	А	30	2.43	1.28	2	0.111	
	В	30	1.97	0.89	2		
16 hour	А	30	1.97	0.81	2	0.628	
	В	30	1.87	0.78	2		
18 hour	А	30	2.23	0.63	2	0.877	
	В	30	2.20	0.85	2		
20 hour	А	30	2.37	0.81	2	0.142	
	В	30	2.73	1.05	2.5		
24 hour	А	30	2.73	0.94	3	0.390	
	В	30	2.50	1.11	2.5		

Table 2: Comparison of pain score on numeric rating score (NRS) at various time

*Mann-Whitney Rank Sum test. N= population SD= standard deviation

Table 3: Comparison of total analgesic ampoule consumption & duration of first rescue an	algesic used
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Duration of first	Group	Ν	Mean	SD	Median	Min.	Max.	p-value*
rescue analgesic	А	27	12.44	1.60	12	10	16	< 0.001
used	В	29	10.69	1.79	10	8	14	
Total analgesic	Group	Ν	Mean	SD	Median	Min.	Max.	p-value*
ampoule consump-	А	30	1.27	0.64	1	0	2	0.024
tion	В	30	1.63	0.56	2	0	2	



Figure 1: Sonographic View of Anatomy. EO-external oblique, IO-internal oblique, TAP-transversus abdominis plane, TA-transversus abdominis

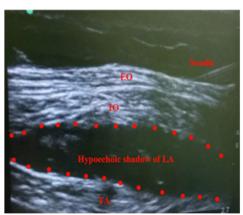


Figure 2: Desired spread of the local anesthetic in transverses abdominis plane. EO-external oblique, IOinternal oblique, LA- local anesthetics, TA-transversus abdominis

Discussion

Since many years ago, TAP Block has experimented with various local anesthetic agent concentrations, but no well-defined dose and concentration of local anesthetic agent has yet been discovered. Various studies examined various local anesthetic drug concentrations with various adjuvants to examine the quality of block.

In our randomized study we compared the analgesic efficacy of 0.375% Ropivacaine 19ml and 4mg Dexamethasone that is 1ml total 20ml each side with 0.375% ropivacaine 19ml and normal saline 1ml total 20ml each side in lower abdominal surgeries. Age, weight, sex, ASA grade, and kind of procedures were the only baseline variables that did not significantly differ between the two groups. The hemodynamic parameter, including heart rate, diastolic and systolic blood pressure, respiratory rate, and oxygen saturation, were similar in both groups pre and post block, indicating that the drug combination had no discernible impact on the patients' hemodynamic parameters in either group. When the two groups' numeric rating scale (NRS) scores were evaluated in our study, the scores were considerably lower in the dexamethasone and ropivacaine group than in the ropivacaine and saline group at 1 hour, 2 hours, and 4 hours. Due to the effects of spinal anesthetic, the NRS score was insignificant up until one hour. The average NRS score was lower in the ropivacaine with dexamethasone group than in the ropivacaine alone group over the course of the 24-hour observation period, but statistical significance was not discovered after the sixth hour. This may be because rescue analgesics were administered in both groups when the NRS score was more than 3, and pain was not permitted to increase on the NRS scale in either group.

Deshpande JP et al.[1] reported a conclusion that was similar: dexamethasone and ropivacaine in the TAP block significantly decreased the VAS score and were statistically significant at 4, 6, and 12 hours.

In their study, Sachdeva J, Sinha A, et al.[2] also discovered a similar outcome in which the VAS score was considerably lower at 2 hours, 4 hours, and 12 hours.

Pain scores

Due to its simplicity of use, the Numeric Rating Scale (NRS) (0-10) is a tool for measuring pain that is widely used. When measuring acute pain, it can take the place of a visual analogue scale.[3] We had trouble getting VAS pain scores from our patients, so we used the NRS Scale instead. NRS is easy to use and effective at determining how well an intervention worked.

Our study main goal was to compare the postoperative analgesia offered by the block in two groups, and we discovered that 19ml Ropivacaine (0.375%) with 4mg Dexamethasone total 20ml on each side in the TAP block offered a longer duration of analgesia in the postoperative period as compared to Ropivacaine (0.375%) with normal saline in terms of the time it took to administer the first rescue analgesic.

Similar results were found in the study by Gupta A et al.[4] where they found that the time to first rescue analgesic was significantly longer in the dexamethasone with ropivacaine 0.375% group compared to the ropivacaine 0.375% with normal saline group and that the mean time to first rescue analgesic use in both groups was longer than in our study. This may be because the block was filled with more volume than was necessary for our study; 25 ml plus 1 ml of adjuvant on each side.

While the mean duration of the first rescue analgesic used in both groups is less than in our study, M Raghu et al.[5] conducted a study with 0.375% ropivacaine with and without dexamethasone and discovered that the time of first rescue analgesic use is significantly longer in the dexamethasone group compared to the normal saline group.

The duration of the first rescue analgesic was significantly prolonged in the dexamethasone group in a study by Sachdeva J et al [2] using 0.2% ropivacaine in a TAP block with and without dexamethasone 8 mg. However, their study's duration of the first rescue analgesic was shorter overall in both groups than ours. This shows that ropivacaine 0.375% in a TAP block provides analgesia for a longer period of time than ropivacaine 0.2%.

Similar findings were made in a research conducted by Gnanasekar N et al.[6] using 0.25% ropivacaine in 20 ml with and without dexamethasone, concluding that 0.375% ropivacaine provides analgesia that lasts longer than 0.25% ropivacaine.

In a study done by Deshpande JP et al.[1] using 20ml of ropivacaine 0.5% with and without 4mg of dexa-

methasone in the TAP block B/L side for total abdominal hysterectomy, they discovered that the duration of the initial rescue analgesic was considerably longer in the dexamethasone group than in the normal saline group. When compared to our study, their study's total mean duration of the first rescue analgesic utilized is marginally longer but nearly identical. This shows that the duration of the TAP block with ropivacaine 0.5% and dexamethasone is roughly equivalent to ropivacaine 0.375% and 4mg.

In a meta-analysis, Chen Q et al.[7] found that adding dexamethasone to local anesthetics increased the duration of analgesia following TAP block by a mean difference of 2.98 hours, which is consistent with our study's findings.

In our investigation, diclofenac aqua, a 1 ml ampoule containing 75 mg of medication, was used as a rescue analgesic when NRS pain scores in both groups exceeded 3. This is different from earlier trials that primarily employed opioids, such as tramadol, fentanyl, or morphine [2,5,6], to prevent postoperative nausea or vomiting associated with opioid analgesics.

With the addition of dexamethasone 4 mg to ropivacaine 0.375% in the TAP block, we saw a reduction in the initial 24-hour total analgesic demand. In the dexamethasone and ropivacaine group, the mean ampoule of diclofenac actua that was needed as a rescue analgesic was 1.27±0.64, which is equivalent to 95.25±48 mg if 1 ampoule of diclofenac aqua contains 75mg medication. The average amount of diclofenac aqua used in the ropivacaine and saline group was 1.63 ± 0.56 , or 122.25 ± 42 mg. Similar findings were seen in the study conducted by Gupta A et al.,[4] Deshpande JP et al.,[1] Sharma UD et al.,[8] Sachdeva et al [2] where tramadol were used as rescue analgesic and found significant reduction in total analgesic used when dexamethasone was added with ropivacaine compared to when ropivacaine used with normal saline in TAP block. In their study, Raghu M. et al.[5] employed fentanyl as a rescue analgesic and discovered that dexamethasone plus ropivacaine reduced the need for rescue analgesic use after surgery. In their study, Gnanasekar N et al.[6] observed that using dexamethasone with ropivacaine reduced the need for morphine as a rescue analgesic.

No adverse TAP block event, such as intravascular drug deposition or visceral needle injury, was discovered.

When used as an additive in the TAP block, ropivacaine 0.375% or dexamethasone did not cause any negative medication reactions, and additional research likewise came to a similar conclusion. [6,9,10]

The results of our study showed that 0.375% ropiva

caine with dexamethasone offered longer duration of analgesia than 0.375% ropivacaine with normal saline by delaying the need for the first rescue analgesic and lowering the overall amount of analgesics consumed during the first 24 hours following surgery.

The study had some restrictions. In some earlier investigations, the analgesic efficacy of TAP block has been shown to last for up to 48 hours; however, in this study, patients were only monitored for 24 hours. The analgesic efficacy of TAP block in the first several hours following surgery could have been increased by the various times that spinal anesthesia regresses in different people.

Dexamethasone may cause side effects include slow wound healing, hyperglycemia, and adrenal suppression, although these effects weren't examined. But prior research has shown that a single, insignificant dose of dexamethasone is not linked to any negative side effects. Since the sensory pattern of nerve blockage was not examined, it's probable that patients will feel numbness in their abdomen wall. Pressurized injection causes some loss of local anesthetic injection in the intramuscular plane that cannot be avoided and may have an impact on the effective volume used for TAP Block.

Conclusion

Transversus Abdominis Plane Blocking is a simple and efficient way to manage discomfort after lower abdominal surgery without causing any serious side effects. Our study showed that following lower abdominal surgeries, an injection of ropivacaine 0.375%+Dexamethasone 4mg provided longer duration of analgesia than an injection of ropivacaine 0.375% + Normal saline and was superior to 0.2% and 0.25% with nearly comparable to 0.5% in terms of need for first rescue analgesic. Additionally, it reduced the 24-hour total postoperative analgesic intake.

One crucial multimodal analgesic technique that is effective in delivering postoperative analgesia following lower abdominal surgeries with little to no side effects and simple to perform is the transversus abdominis plane block. This technique helps to reduce systemic analgesic consumption in the postoperative period and their potential side effects.

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