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Original Research Article

Comparative Study of Inj. Ropivacaine (0.2%) v/s. Inj. Ropivacaine (0.2%) with Hyaluronidase in Transversus Abdominis Plane Block for Post Operative Analgesia

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Abstract

Background and Aim: The nerves of the anterior abdominal wall are employed in the TAP block, a common analgesic method. An enzyme called hyaluronidase aids in the distribution of local anaesthetic throughout the tissue surrounding the eye. In order to compare the effectiveness of injecting ropivacaine (0.2%) against injecting ropivacaine (0.2%) with hyaluronidase in tap block for postoperative analgesia, this study focused on that topic.

Materials and Methods: A total of 60 patients with ASA classes I and II who were scheduled for lower abdomen surgery were included in the study. With 30 patients apiece, the research populations were split into two groups. Using a blind approach on each side, 20 ml of 0.2% (preservative-free) ropivacaine was administered to Group R (n=30) together with 2.5 ml of distilled water, and 20 ml of 0.2% ropivacaine was administered to Group H (n=30) along with 750 IU of hyaluronidase diluted in 2.5 ml of distilled water.

Results: Between the two groups, there is no statistically significant difference up to 30 minutes and 1 hour postoperatively. ($p>0.05$) However, following that, Group R continually has a lower mean VAS score than Group H, which was statistically significant after 2, 4, 6, and 12 hours. after surgery. ($p\leq0.05$). In comparison to Group H's 5.471.48 hrs, Group R's mean analgesic duration was 8.944.22 hours, which is longer and statistically significant. In both groups, nausea had the highest percentage of problems, followed by vomiting, bradycardia in Group R, and bradycardia, hypotension in Group H.

Conclusion: In group H compared to R, the visual analogue scale (VAS) SCORE was lower. Traditional analgesia is less effective than Group H at lowering the pain score. Group H consumes fewer analgesics overall than Group R. The use of 0.2% ropivacaine with hyaluronidase in TAP block offers significant promise as an analgesic regimen following lower abdominal procedures, it can be concluded.

Keywords: Analgesia**,** Hyaluronidase, Ropivacaine, TAP block,

Introduction

A long-acting local anesthetic's ability to reversibly stop nerve impulses, which results in a prolonged sensory or motor blockade suitable for anaesthesia in various types of procedures, is one of its most crucial qualities. The sensory blockage that causes postoperative and labour patients to experience acute pain relief at lower doses is occasionally tainted by the concomitant motor blockade, which has no useful function and is highly undesired.[1,2]

An excellent localised anaesthetic for surgical anaesthesia and the reduction of postoperative pain, ropivacaine is well tolerated. Although it may be slightly less potent than bupivacaine when delivered epidurally or intrathecally, equi-effective doses have been found, and ropivacaine's effectiveness for peripheral nerve blocks is comparable to that of bupivacaine and levobupivacaine. A decreased incidence or grade of motor block seems to be linked to clinically acceptable dosages of ropivacaine.[3,4]

The nerves of the anterior abdominal wall are employed in the TAP block, a common analgesic method. As a result, TAP block relieves pain in the skin, anterior abdominal wall, and parietal peritoneum. The effectiveness of the Transversus Abdominis Plane (TAP) Block and TAP catheter-based continuous blocks, which are relatively recent procedures, has been well established in the scientific literature.[5] They are methods of localised anaesthesia that relieve pain in the muscles and skin of the anterior abdominal wall. Another benefit is that they can be applied to patients who would not benefit from neuraxial procedures, such as those who have modest platelet or coagulation problems. It has a high success rate and a low risk of complications, although it is not widely used.[6,7]

Various medical procedures employ hyaluronidases. This class of substances mostly degrades hyaluronic acid, although they can also break down chondrotin and chondrotin sulphate. An enzyme called hyaluronidase aids in the distribution of local anaesthetic throughout the tissue surrounding the eye. To provide a more fast onset of anaesthesia and to lessen or block eye movement, it is frequently used as an addition to local anaesthetic eye blocks.[8-10]

The data offer experimental support for the effects of various local anaesthetic and interventional pain treatment methods. However, it must be remembered that hyaluronidase is affected in various ways by the presence of corticosteroids, contrast media, and the concentration of NaCl.11 Since local anaesthetics have little to no impact on hyaluronidase activity, they can be combined without having a deleterious impact, in contrast to corticosteroids, which have a beneficial impact.[11]

The overall anaesthetic time before surgery is shortened when hyaluronidase is used as an adjuvant to ropivacaine. This is because it takes less time for the axillary brachial plexus block to achieve complete sensory block.[12]

Hyaluronidase has a little impact on the total analgesic duration or the intake of postoperative analgesics, despite the fact that it also shortens the block length. Additionally, 1% ropivacaine with 300 IU/ml of hyaluronidase is an effective combination for peribulbar block, with an anaesthetic onset and quality comparable to those attained with bupivacaine/lidocaine.[13] The quality of the block is improved by adding hyaluronidase to the traditional concoction of local anaesthetics. It offers improved hemodynamic regulation. Early postoperative recovery is much easier and the initial request for analgesics is delayed because to the analgesic impact. There are no obvious side effects when hyaluronidase is used in conjunction with local anaesthesia. In

order to compare the effectiveness of injecting ropivacaine (0.2%) against injecting ropivacaine (0.2%) with hyaluronidase in tap block for postoperative analgesia, this study focused on that topic.

Material and Methods

The goal of the current study was to compare the effects of injecting ropivacaine (0.2%) against injecting ropivacaine (0.2%) with hyaluronidase in tap block for post-operative analgesia. Prior to the study's launch, the ethics committee was made aware of it and the ethical clearance certificate was obtained.

A total of 60 patients with ASA classes I and II who were scheduled for lower abdomen surgery were included in the study. With 30 patients apiece, the study population was split into two groups.

1. Group R (n=30) – 20 ml of 0.2% ropivacaine (preservative free) with 2.5 ml distilled water is given in TAP block by using blind technique on each side. Total 45ml volume (40ml 0.2% Ropivacaine + 5ml distilled water) is injected.

2. Group H (n=30) -20 ml of 0.2% ropivacaine 750 IU Hyaluronidase diluted in 2.5ml distilled water i is given in TAP block by using blind technique on each side. Total 45ml volume (40ml 0.2% Ropivacaine + 1500 IU Hyaluronidase diluted in 5ml distilled water) is injected.

The determination of the sample size was based on a preliminary pilot study with 10 patients, with "total number of analgesic doses consumption" as the study's main outcome. 1.40 0.79 analgesic doses were consumed overall in group H, compared to 1.69 0.40 in group R. has a power of the study of 80% and a 0.05 error rate.

The standard visual analogue score (VAS) was introduced to all patients. All patients had surgery in accordance with hospital policies and procedures after being told of the advantages and side effects of the medications being studied. Written informed permission was also obtained from all patients.

Inclusion criteria for the study:

The following standards were met: Adult patients, of either sex, between the ages of 18 and 65 Patients with ASA classes I and II posted for elective lower abdomen and lower limb surgeries, patients weighing more than 50 kg, and patients standing between 150 and 180 cm.

Exclusion criteria for the study:

The following conditions were observed: refusal of regional anaesthesia by the patient, females who are pregnant or nursing, Patients who requested urgent operations, BMI > 30 obese patients Patients with the following symptoms were not allowed to participate in the study: increased intracranial pressure, severe hypovolemia, bleeding coagulopathy, local infection, uncontrolled hypertension/diabetes mellitus, neurologically disturbed spinal deformities, and allergy to local anaesthetics.

The evening before surgery, a standard pre-anaesthetic assessment was performed to evaluate the patient's medical history and overall health. Alprazolam 0.5 mg and ranitidine 150 mg tablets were administered orally to the patients the night before the procedure. On the prior night, from 10 p.m. on, they were kept nil orally.

Blood pressure and the patient's basal pulse rate were measured the day of the procedure. After local anaesthetic was applied, one of the upper limbs was fitted with an 18 gauge cannula for a peripheral intravenous line. All of the patients received 500 ml of Ringer lactate 30 minutes prior to treatment. A multi-parameter monitor was connected, recording heart rate as well as continuous electrocardiogram (ECG) monitoring, oxygen saturation (SPO2), mean arterial pressure (MAP), systolic and diastolic blood

pressure measurements performed without using any intrusive techniques, and heart rate.

A 25 gauge Quincke spinal needle was used to do a lumbar puncture in the L3-L4 space while the patient was seated, following all aseptic and antiseptic procedures. Bupivacaine heavy 0.5% 0.3mg/kg was injected after free flow of clear CSF. Patients were immediately placed in the supine posture after noting the time of the injection. The time of surgery's completion was recorded, and both groups underwent a TAP block at its conclusion.

Systolic blood pressure less than 90 mmHg or a reduction of more than 30% from the basal systolic blood pressure is referred to as hypotension. If necessary, mephentermine 3 mg (I.V.) is administered in incremental doses along with increased intravenous fluid intake. Atropine 0.6 mg (I.V.) injections were used to treat bradycardia (60 beats/min).

When the VAS was 4 or the patient requested pain relief, a rescue analgesic in the form of an injection, Tramadol 100mg i.v., was administered. The number of times analgesia was requested for the first time and the total number of times 100mg of tramadol was needed in 24 hours were both noted. Patients received an intravenous injection of 0.08 mg/kg ondansatron for nausea and vomiting. The results of the study were statistically analysed between the two groups.

Statistical Analysis

SPSS version 16.0 was used for the statistical analysis. By accurately computing the mean, standard deviation, range, and proportion, descriptive statistics were performed. Unpaired t-tests, two-way repeated measures ANOVA, and chi-square tests were used for the inferential statistics (test of significance).

Results

The goal of the current study was to compare the effects of injecting ropivacaine (0.2%) against injecting ropivacaine (0.2%) with hyaluronidase in tap block for post-operative analgesia. A total of 60 patients with ASA classes I and II who were scheduled for lower abdomen surgery were included in the study. The study participants were randomly split into two groups, each with 30 patients.

Age and weight data from the demographic profile revealed that Group R's mean age was 40.12 years and Group H's was 40.47 years and 13.21 pounds. In groups R and H, the mean weight was 59.21 kg and 59.65 kg, respectively. In groups R and H, the mean height was 164.22 23.45 cm and 165.47 31.02 cm, respectively. Their age, weight, and height distributions are not statistically different. ($p>0.05$)

There was no statistically significant pulse rate change found between Group R and Group H, according to the post-operative mean pulse rate changes in both groups at various time intervals. ($p>0.05$) Systolic and diastolic blood pressure in both groups were statistically similar at all times, including 30 minutes, 1, 2, 4, 6, 12, and 24 hours after surgery. ($p>0.05$). Between Group R and Group H, there was no discernible difference in mean Spo2 changes that was statistically significant. ($p>0.05$)

In the postoperative phase, changes in the mean VAS pain scores for Group R and Group H were noted. Between the two groups, there is no statistically significant difference up to 30 minutes and one hour postoperatively. ($p>0.05$) However, following that, Group H consistently has a lower mean VAS score than Group R, which was statistically significant at 2, 4, 6, 12, and 24 hours after surgery. ($p\leq0.05$). The length of the analgesia was recorded, and the mean length in Group H was 8.944.22 hours, which is greater and statistically significant than the mean in Group R, which was 5.471.48 hours. In both groups, nausea had the highest percentage of problems, followed by vomiting, bradycardia in Group R, and bradycardia, hypotension in Group H.

Table 1: Post operative Spo2 changes in both the groups

Time	Group R	Group H	P value
0 min	98.54±0.23	97.35±0.9	0.19
30 min	97.56±0.56	97.54±0.8	0.71
1 hr	97.76±0.98	98.23±0.34	0.2
2 hr	98.45±0.49	97.12±0.76	0.08
4 hr	97.93±0.87	97.93±0.12	0.09
6 hr	97.85±0.49	97.62±0.04	0.71
12 hr	98.97±0.87	98.90±0.19	0.46
24 hr	97.83±0.65	97.60±0.43	0.09

Table 2: Post-operative VAS pain score comparison in both groups

Time	Group R	Group H	P value
30 min	0.33±0.28	0.23±0.19	0.08
1 hr	0.83±0.16	0.80±0.46	0.41
2 hr	1.60±0.26	1.30±0.52	0.02
4 hr	3.10±0.22	2.65±0.52	0.003
6 hr	3.30±0.27	2.30±0.14	0.001
12 hr	2.80±0.68	2.10±0.90	0.04
24 hr	1.97±0.90	1.40±0.52	0.02

Discussion

A good post-operative analgesia should generate a long-lasting, continuous analgesia that is effective and has few negative effects. The advantages of appropriate postoperative analgesia are obvious and include a decrease in the stress response after surgery, a decrease in postoperative morbidity, and in some cases, a better surgical result. Effective pain management also speeds up recovery following surgery and promotes rehabilitation. Effective localised analgesic treatments also lessen pain intensity, lower the likelihood of analgesic side effects, and enhance patient comfort.[14]

By injecting LA into the neurofascial plane between the internal oblique and transversus abdominis muscles, transversus abdominis plane (TAP) block blocks abdominal neural afferents. The TAP block is increasingly recognised as a major method for reducing post-operative pain after abdominal surgery due to the widespread availability of ultrasonography guidance for more precise localisation of TAP (than the 'blind' procedure).

The extracellular connective tissue matrix contains a lot of hyaluronic acid. It is a glycosaminoglycan molecule that facilitates cell motility and proliferation while serving as a lubricant. An enzyme called hyaluronidase breaks down hyaluronic acid in tissues. It has been demonstrated to promote LA tissue spread. This is thought to be accomplished by hyaluronic acid experiencing a reversible depolymerizing effect. Additionally, it has been shown to increase a LA preparation's pH, enhancing the effectiveness of LA blockage.[15]

An ultrasonography research found that the addition of hyaluronidase significantly improved the dispersion of sub-tenon lignocaine. According to a double-blind, randomised, controlled trial, adding hyaluronidase to lignocaine 2% in sub-tenon blocks dramatically reduced the amount of LA needed to produce a good block.

Although hyaluronidase side effects are uncommon, there have been case reports of allergic responses, including angioedema, in the context of ophthalmology. Previous exposure to hyaluronidase was reported in most cases.[16,17]

There is no statistically significant difference in the mean diastolic blood pressure between the two groups at any point in time, including 30 minutes, one, two, four, six, twelve, and twenty-four hours after surgery ($p>0.05$). The post-operative mean Spo2 changes in both groups were displayed in Table 1 at various time points.Between Group R and Group H, no statistically significant difference was seen. ($p>0.05$) The results of Dr. Dipika Patel *et al*., who compared 0.5% ropivacaine and 0.25% bupivacaine for TAP block in lower abdominal procedures, are identical to these.

At 6, 12, and 18 hours, they discovered that Group R had considerably lower blood pressure and pulse rates than Group B. ($p<0.05$) Because Group R's analgesia was maintained for a longer period of time, this difference was linked to a proportionate increase in pulse and systolic blood pressure in Group B. The difference between the mean pulse rate and the mean systolic and diastolic blood pressure between group B and group R at all points in the first 24 hours was statistically non-significant, according to Neha Fuladi *et al*. [18] who also compared 0.25% bupivacaine with 0.5% ropivacaine.

In Group R and Group H, the mean VAS pain score changed during the postoperative period, as shown in Table 2. Between the two groups, there is no statistically significant difference up to 30 minutes and one hour postoperatively. ($p>0.05$) However, following that, Group R continually has a lower mean VAS score than Group H, which was statistically significant after 2, 4, 6, and 12 hours. after surgery. ($p\leq0.05$) Iyad Abbas *et al*. [19] found that traditional therapy was superior in relieving pain only for the first two hours, while TAP block was superior for the next two, four, and twelve hours. This difference was extremely significant. M. Bhanu Lakshmi, *et al*.[20] found the pain scores were statistically lower at 0 and 4hrs period in Group T compared to Group D.

Though statistically insignificant, pain was less in group T in the first 24 hrs. For a variety of abdominal procedures, including large bowel resection, open/laparoscopic appendectomy, caesarean section, total abdominal hysterectomy, laparoscopic cholecystectomy, open prostatectomy, renal transplant surgery, abdominoplasty with/without flank liposuction, and iliac crest bone graft, Mark J. Young *et al*. described TAP block as an effective component of multimodal postoperative analgesia.[21]

The difference between the mean total number of analgesics consumed in Group H and Group R, 1.71 ± 0.32, is statistically significant at 1.42 ± 0.74. ($p\leq0.05$) Iyad Abbas Salman and Hayder Saad Kamel observed that the parenteral group used greater incremental doses. The vicious loop that pain creates hinders the healing process and throws the body's physiology off. Effective surgical pain management helps patients feel less anxious and recover more quickly. In the initial postoperative phase, it reduces the problematic postoperative stress response and pain-induced hypoxia. For all surgical patients, post-operative analgesia is not only ideal but also very necessary.

In comparison to Group H's mean analgesia duration of 5.47 hours, Group R's mean analgesia duration of 8.94 hours is statistically considerably longer. The average duration of analgesia was 7.38 ± 2.35 hours in the bupivacaine group and 9.98 ± 2.38 hours in the ropivacaine group, according to Dipika Patel *et al*.'s comparison of 0.25% bupivacaine and 0.5% ropivacaine. When comparing the ropivacaine group to the bupivacaine group, the difference was statistically significantly different (p 0.05). Neha Fuladi *et al*. discovered that the

Ropivacaine group's mean duration of analgesia in their trial was longer than the Bupivacaine group's (9.924.81) by 2.690.52 hours, which was statistically significant. M.

Bhanu Lakshmi, D. Suresh Chander, G. Vinay Raj found that time for rescue analgesia was on an average 8 hours post-surgery in Group T (TAP) and 2.5 hours in Group D. Time To The First Dose Of Tramadol In Hours was 20.9(±4.12)in TAP group (Ropin 0.25%) compared to 3.55(±0.44) in control group, favouring our study. Sddiqui MR and his colleges in the UK conducted a clinical effectiveness study on TAP block in 2011 and found that it lengthens the period before the patient requests further analgesia. According to McDonnell JG *et al*., there was a longer interval between the initial requests for analgesia in the TAP group.

The patients who got a TAP block with ropivacaine 1.5 mg/kg experienced a median (interquartile range) delay to first request for analgesia of 220 (150, 380) min as opposed to the control group's 90 (55, 190) min. Similar results were reported by McDonnell JG *et al* who had observed the mean time to first request for rescue analgesic 24.1 ± 6.9 min in control group and 157.2 ± 27.9 min in study group. In contrast to our study, the duration of first demand of analgesia is shorter probably because this study involved In contrast to our analysis, which largely involved lower abdominal procedures carried out under spinal anaesthetic, upper abdominal surgeries were carried out under general anaesthesia.

Both Group R and Group H had the difficulties. In both groups, nausea had the highest percentage of problems, followed by vomiting, bradycardia in Group R, and bradycardia, hypotension in Group H. Clinical studies on the effectiveness of TAP block conducted by Sddiqui MR and his colleges in the UK in 2011 revealed that it decreases the need for postoperative opioid use, lengthens the interval before the first request for additional analgesia, offers more potent pain relief, and lessens opioid-related side effects. McDonnell JG *et al* reported that the incidence of postoperative nausea and vomiting was substantially reduced in TAP group than control group.

Conclusion

In group H compared to R, the visual analogue scale (VAS) SCORE was lower. Traditional analgesia is less effective than Group H at lowering the pain score. Group H consumes fewer analgesics overall than Group R. The use of 0.2% ropivacaine with hyaluronidase in TAP block offers significant promise as an analgesic regimen following lower abdominal procedures, it can be concluded.

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