Original Article

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A Prospective Randomized Study of Local Infiltration of Two Different Concentrations of Ropivacaine for Postoperative Analgesia in Inguinal Hernia Repair

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Abstract

Background: Postoperative pain management by surgical site infiltration has an edge over other methods of analgesia as it is simple and has lesser side effects. This study was designed to compare the analgesic effects provided by two different concentrations 0.25% and 0.50% of Ropivacaine, a new amino amide local anesthetic agent. **Subjects and Methods:** Ninety six patients in each group scheduled for elective inguinal herniorrhaphy were randomly allocated by chit and box method to Group A(0.50%) and Group B(0.25%), spinal anesthesia was given. The surgical site was infiltrated after the end of surgery with 20 ml of drugs; Ropivacaine 0.5% in group A, Ropivacaine 0.25% in group B. Postoperatively hemodynamics were recorded from every 0 h to until 12 h. Postoperatively, rest pain, pain on coughing, and pain on movements were assessed using visual analog scale (VAS) score immediately at the end of the surgery and 2 hourly up to 12 h. The time of the first request for rescue analgesia was noted. **Results:** VAS scores at rest($P<0.027$*), during coughing($P<0.001$) and movements ($P< 0.04$) were higher in group B 0.25% and the time of rescue analgesia was higher with group B 0.25% when compared with other group A ($P<0.001$). **Conclusion:** Ropivacaine as an anesthetic in inguinal hernia repair for surgical infiltration is safe and effective in pain reduction, with very few adverse reactions at the concentration of 0.5%.

Keywords: Ropivacaine, Inguinal hernia, Pain, Postoperative.

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Introduction

Repair of inguinal hernia is one out of the most common surgeries performed worldwide. The age group most susceptible to the development of hernia is the geriatric group as the elderly patients have weak abdominal wall and lax inguinal canal which makes anesthetic management in these cases way more demanding and challenging.[1] It can be performed under many anesthetic techniques including spinal anesthesia, inguinal field block, local infiltration and general anesthesia. Repair of inguinal hernia is a superficial surgery without much complexity, which can be completed in 60–90 min and does not have many intra and postoperative complications. Hence, it is an ideal procedure for outpatient setting.[2]

Postoperative pain is one of the main limitations encountered while dealing with this surgery. Taking into consideration the age group we are dealing with postoperative discomfort can lead not only to physiological consequences but also psychological ones. Lack of relief in pain may lead to hemodynamic changes in the form of tachycardia, tachypnea and hypoxemia, altered gastrointestinal motility, frequent urinary tract infection. Postoperative pain may lead to delay in home discharge as well as prolonging the postoperative recovery. The goal of postoperative pain control is reduction or even elimination of pain and discomfort with minimum unwanted side-effects along with least possible cost.[2]

Various methods in combination to anesthetic technique like opioids, NSAID's, acetaminophen have been used to

combat with post-surgical pain as it is an integral part of patient's care. Surgical site infiltration in comparison to other technique has an edge because it is not only easy to perform but also has minimal side effects. In local infiltration since it inhibits the build-up of local nociceptive receptors, hence it provides longer postoperative pain relief. The only limitation of this technique if any could be that only long-acting local anesthetics can provide sufficient duration of pain free interval. In the past researches various sophisticated techniques have been used for postoperative analgesia using older local anaesthetics side lining the simple technique of local infiltration. In our study we have tried to reintroduce this method using different concentrations of Ropivacaine to determine the effective dose for the same.

Ropivacaine is a s-enantiomer of bupivacaine with greater safety profile the propyl homologue has lower lipid solubility, short elimination half-life and rapid plasma clearance. Ropivacaine is a long-acting drug with less cardio toxicity. It has anti-inflammatory activity and is a potential vasoconstrictor too. These properties of the drug may make it a suitable choice for progressive reduction of pain when given locally.[3,4] Hence, the study was designed to test degree of analgesia provided postoperatively and potential side effects of the two different concentrations of drug Ropivacaine. The rationale of the study was to determine the best possible concentration of Ropivacaine for post-operative pain in inguinal hernia patients.

The main primary objective of our study was to determine the VAS score at rest, coughing and movements at two different concentrations of ropivacaine and to determine the total rescue analgesic dose required, the secondary objectives were to determine the changes in hemodynamics in two groups and to note if any adverse event occurred. The null hypothesis of our study was that there will be no significant difference in any of the parameters noted between the two groups.

Subjects and Methods

This prospective randomized study was carried on after obtaining clearance from institutional ethical committee in the Department of Anesthesia in tertiary care center from December. 2018-March 2020.

The Study has been registered in clinical Trial Registry India, CTRI/2019/03/017888. After obtaining CTRI approval recruitment of patients planned for inguinal hernia repair was started.

Randomization

Patients chosen for the study were randomized into two groups using chit & box method. The chit and Box method was done using the Cr.No. of the patients.

- Group A - 20 ml 0.5% ropivacaine subcutaneously,
- Group B - 20 ml 0.250% ropivacaine subcutaneously

Blinding Technique- It was a double blind study, the patient was not aware in which group he is being included. The drug was prepared by our nursing staff who was handed over the chit from the preoperative room. Senior Anesthetist/Investigator posted in the Operation theater performed the technique of local infiltration unaware of the concentration used and observer recorded the observation and further analysis was done.

The study participants were selected according to our inclusion and exclusion criteria after taking written informed consent from each patient or their attendant before undergoing the procedure. Patients aged between 18-60 years with BMI 18.5-22.9 kg/m^2 and American Society of Anesthesiologists (ASA) grade I & II patients were included in the study. Patients who refused to give consent and patients with hypersensitivity to local anesthetics, giant inguinoscrotal hernias, any absolute contraindications to spinal anesthesia, hernia with hydrocoele,[5] and patients on chronic analgesic therapy were excluded.

For all patients, a thorough history, full physical examination and routine & appropriate laboratory tests (complete blood count, urine r/m, blood sugar, blood urea, serum creatinine level, erythrocyte sedimentation rate, coagulation profile) were performed. Baseline systolic, diastolic, mean blood pressure and heart rate were tabulated in excel sheet. All patients were preloaded with 10 ml/kg of ringer lactate solution within 15– 20 min prior to administration of spinal anesthesia in operation theatre. Spinal anesthesia was administered by the investigator /observer to patients with injection bupivacaine 0.5% heavy 10 mg (2 ml). After adequate sensory effect was obtained, checked with the help of pin prick method, surgery was started.

Study drug of 20 ml ropivacaine was administered subcutaneously at the time of skin closure on both sides of incision by double blind technique. i.e. the patient as well as the investigator didn't know which concentration of drug was being admininstered. The study drug was prepared by a junior/colleague/nursing staff of the investigator. Once surgery was over all patients were shifted to the recovery room. All standard monitoring like electrocardiogram (ECG), non-invasive blood pressure (NIBP), SpO2 were attached.

Patients were observed in the recovery room for 60 min and were assessed every 15 min. Postoperative hemodynamic parameters including non-invasive blood pressure and saturation of oxygen in blood were observed and documented.

Postoperatively, the visual analogue score was documented in different situations i.e. at rest, on limb movements and on expiratory maneuvers like coughing immediately after the completion of the surgical procedure and then every 2hour upto 12 hour. Side effects such as headache, nausea,

vomiting, allergic reactions and convulsions were observed. Total duration spent before the need of first rescue analgesia and intravenous injection tramadol (1 mg/kg) was used as rescue analgesia once VAS score was more than 4 or patient demanded for analgesia. The total rescue analgesia dose administered within 12 h was reported.

Online software "G-Power" version 3.1.9.2 was used to calculate total sample size in our study, Minimum total sample size required was found to be 96 in each group when one tailed significance was 5% ($\alpha = 0.05$), power of study ($1-\beta$) was 0.90 and effect size was taken as 0.8.

The data was entered into the Microsoft excel sheet. All the data were analysed by statistical software SPSS version 21.0. The student t-test was used for comparing the mean values of the continuous variables between the 2 groups. The chi-square test was applied for comparing the categorical variables such as gender, adverse events between the 2 groups. The p-value was considered to be significant when less than 0.05.

Results

In this study 192 patients were enrolled and analysed as shown in consort flow diagram [Figure 1] Demographically and with respect to ASA status there was no difference between the two groups [Table 1].

Hemodynamic parameters and arterial oxygen saturation at 0 h, 2 h, 4 h, 6 h, 8 h, 10 h and 12 h when compared between GROUP A (0.50%) and GROUP B (0.25%) which showed no significant difference [Figure 2].

Mean VAS score was significantly different at rest after 8 hr of surgery between GROUP B (0.25%) in comparison to GROUP A (0.50%) [Table 2].

Difference was significant when VAS score (at Coughing) was noted at 6,8 and 10 h between GROUP B (0.25%) in comparison to GROUP A (0.50%) [Table 3].

At movement also the mean VAS score was significantly different between the two groups at 8, 10 and 12 h [Table 4].

The total dose required as rescue analgesia was significantly increased in Group B (0.25%) when compared to Group A (0.50%) [Table 5].

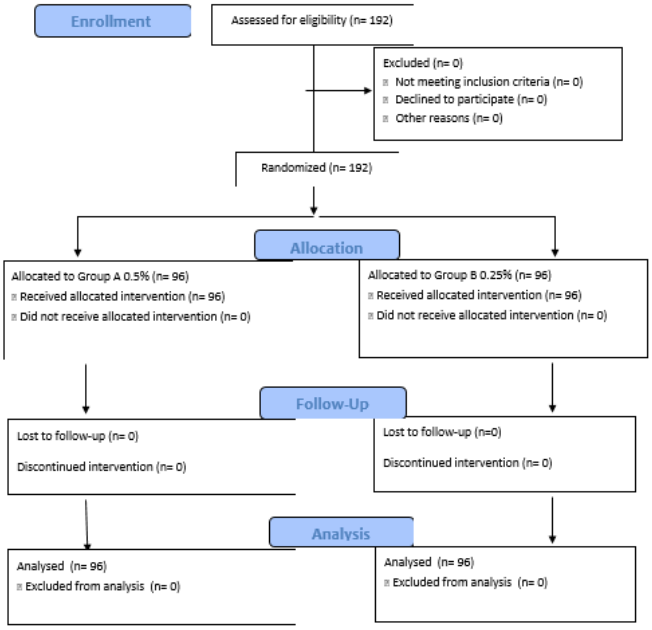


Figure 1: CONSORT flow statement for the present study

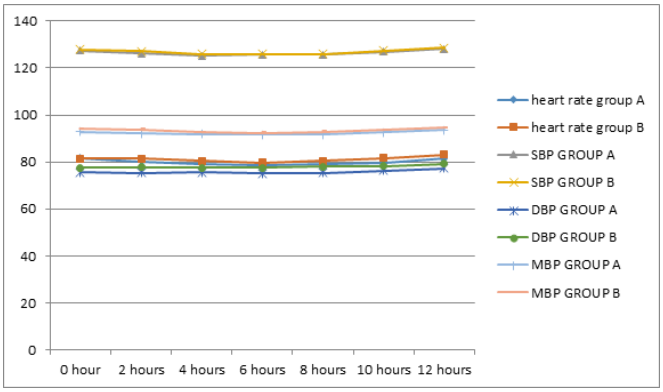


Figure 2: Comparison of Mean heart rate, Systolic blood pressure, Diastolic blood pressure and Mean blood pressure between Group A and Group B at different time intervals

Discussion

The advantage of local infiltration technique is its safety, cost effectiveness, easy technique, prolonged analgesia, early ambulation with no or minimal side effects. Hence it can be employed in day care surgeries reducing the requirement of narcotics postoperatively. Since local anesthetics do not hinder the respiratory and cardiovascular system in allowed dosage, good respiratory stability and hemodynamic stability are achieved, decreasing the discharge time and increasing the patient turnover rate.[1]

Many research works related to ropivacaine 0.5% local infiltration in various surgeries revealed that it provided adequate postoperative pain relief, but its cost hinders its routine use, thus we studied a lower concentration of Ropivacaine in comparison to a higher one to analyze the difference between the two.[6,7]

Table 1: Demographic and physical features of participants in groups

	GROUP A (number/ percentage)	GROUP B (number/ percentage)	P Value
Male	84 (87.5%)	81 (84.4%)	0.84
Female	12 (12.5%)	15 (15.6%)	0.64
BMI	21.7	21.73	0.838
ASA grade1	69 (71.9%)	70 (72.9%)	1
ASA grade2	27 (28.1%)	26 (27.1%)	0.92
Age group (mean ± SD)	43.44 ± 10.744	41.63 ± 11.554	0.26
P Value < 0.05 = significant, P Value >0.05 = Non significant			

Table 2: Comparison of mean VAS score at Rest between Group A and Group B at different time intervals

VAS at	Group A (0.50%)		Group B (0.25%)		Mean	t-test value	p-value
	Mean	SD	Mean	SD			
0 h	0.00	0.00	0.00	0.00	0.00	0.000	1.000
2 h	0.00	0.00	0.00	0.00	0.00	0.000	1.000
4 h	0.00	0.00	0.02	0.20	-0.02	-1.000	0.319
6 h	0.00	0.00	0.00	0.00	0.00	0.000	1.000
8 h	0.10	0.45	0.31	0.80	0.21	2.230	0.027*
10 h	1.31	1.02	1.49	1.21	0.18	1.099	0.273
12 h	2.53	0.81	2.71	1.16	0.18	1.228	0.221
* P Value < 0.05 = significant, P Value >0.05 = Non significant							

Table 3: Comparison of mean VAS score at Coughing between Group A and Group B at different time intervals

VAS at	Group A (0.50%)		Group B (0.25%)		Mean	t-test value	p-value
	Mean	SD	Mean	SD			
0 h	0.00	0.00	0.00	0.00	0.00	0.000	1.000
2 h	0.01	0.10	0.00	0.00	0.01	1.000	0.319
4 h	0.02	0.14	0.05	0.37	-0.03	-0.778	0.437
6 h	0.17	0.63	0.61	1.11	-0.45	-3.446	0.001*
8 h	1.00	1.38	2.11	1.23	-1.11	-5.916	0.001*
10 h	2.94	1.04	3.25	0.98	-0.31	-2.134	0.034*
12 h	4.13	1.14	4.28	0.87	-0.16	-1.066	0.288
* P Value < 0.05 = significant, P Value >0.05 = Non significant							

Table 4: Comparison of mean VAS score at Movements between Group A and Group B at different time intervals

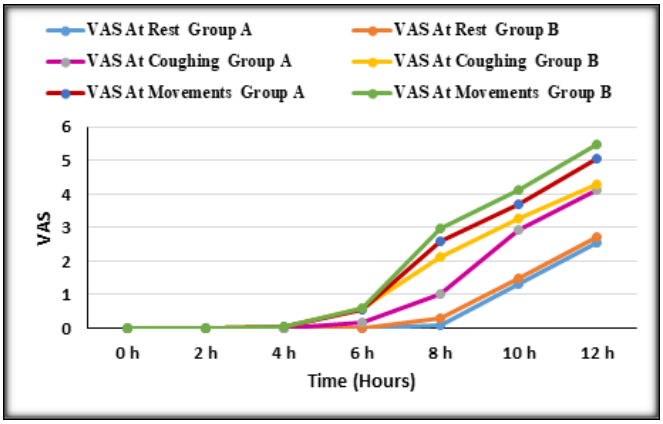
VAS at	Group A (0.50%)		Group B (0.25%)		Mean	t-test value	p-value
	Mean	SD	Mean	SD			
0 h	0.00	0.00	0.00	0.00	0.00	0.000	1.000
2 h	0.00	0.00	0.02	0.20	-0.02	-1.000	0.319
4 h	0.06	0.43	0.04	0.32	0.02	0.380	0.705
6 h	0.56	1.19	0.58	1.28	-0.02	-0.117	0.907
8 h	2.61	1.30	2.97	1.06	-0.35	-2.067	0.040*
10 h	3.71	1.15	4.14	1.09	-0.43	-2.638	0.009*
12 h	5.06	1.16	5.47	1.08	-0.41	-2.517	0.013*
*P Value < 0.05 = significant, P Value >0.05 = Non significant							

Table 5: Postoperative use (mean dose) of rescue analgesia in both groups

	Group A (0.50%)	Group B (0.25%)	t-value	p-value
Rescue analgesia	70.83±75.28	108.33±77.69	-3.397	< 0.001*
* P Value < 0.05 = significant, P Value >0.05 = Non significant				

In present study, the study groups were found to be comparable statistically in relation to the distribution of baseline characteristics such as the age, gender, BMI and ASA status.

Anderson with his associates gave local infiltration for inguinal hernia repair surgery on 160 patients who were divided into two equal groups according to local infiltration along with ilioinguinal block or without it. The author concluded that inguinal hernia surgeries can be carried out in infiltration given locally too.[8] Thus, supporting the use of this technique in our study.



Ausems et al evaluated 120 patients randomized into group of 60 each to note the postoperative requirement of analgesics after herniorrhaphy conducted on day care basis. One group was infiltrated at surgical incision site with 20 ml 0.5% levobupivacaine or 20 ml of 0.9% saline. Analgesic consumption and noting of VAS Score was done by the patients on their own and written in a diary for 5 days. The time required for the first analgesic to be taken, score of visual analogue scale, patients requiring no analgesic drug were lower significantly in the group receiving levobupivacaine for the first 24 h, but not after, therefore emphasizing strongly on our study results.[9] Our results also showed that mean VAS score at rest, movement or coughing was decreased as well as postop analgesia requirement also decreased in our patients more so in group receiving 0.5% concentration than 0.25%.

Quite identical findings were reported by Gupta et al,[4] where VAS score was compared among the 3 groups (Group 1 Ropivacaine (0.5%),Group 2 Ropivacaine(0.25%) and Group 3 Bupivacaine (0.5%)) at rest, during coughing and movement till the first request of analgesic at 4 h in the postoperative period after inguinal hernia repair. Pain ratings using VAS scores when taken at rest, during coughing and limb movements was more in group R (0.25) and difference was significant when compared with other groups. The time required for first rescue analgesia was much less with group R 0.25 as compared to other groups. Similar in our study too the total dose required as Rescue analgesia was significantly increased in Group B (0.25%) when compared to Group A (0.50%). The VAS score was significantly increased at 6,8,10 hrs in Group B in comparison to Group A.

Our results are also consistent with those obtained by Johansson et al who had shown that 40 ml of 0.25% or 0.5% ropivacaine injected preoperatively provided pain relief for 3 and 6 h, respectively.[10]

In discordance with our study, Jalil et al,[11] who found that ropivacaine 0.2% to be having almost equal amount of effectiveness as ropivacaine 0.5% for pain relief required postoperatively. There was a statistical difference in pain relief with extra amount of IV fentanyl used with 0.2% ropivacaine patients intra-operatively. These findings might not correlate so well clinically.

Mulroy et al,[12] studied 110 ASA grade 1 and 2 patients infiltrating their wounds with different concentrations of ropivacaine following their inguinal hernia repair under regional anesthesia. According to the study conclusion 0.25% and 0.5% ropivacaine were comparable with respect to adequate pain relief after surgery and superior to 0.125% ropivacaine or 0.9% saline which was in discordance to our study which concluded that 0.5% concentration was better than 0.25% for adequate pain relief.

A similar findings from our study were found in a study done by Su Y et al who found that postoperative VAS scores were lower and satisfactory scores higher among the higher concentration groups of ropivacaine which was significant. In brief it supported our study that 0.5%concentration of ropivacaine provides better postoperative pain management.[13]

The use of local infiltration technique for inguinal hernioplasty in postoperative analgesia might prove to be much more cost-effective as an anesthesia and analgesia technique.[14,15] Local anesthesia has been considered a conventional method of analgesia due to its various advantages and usage of limited amount of drug.[16–20]

Strength of the study- The study was randomized and comparative study between two drug doses, with adequate sample size. The main strength of this study was that on ethical grounds too none of the two groups was devoid of postoperative analgesia.

Future aspects- The study helped to open more spheres for dose calculation using Dixon massey method for future studies. This technique can be compared to other more sophisticated techniques to draw results.

Limitations- This technique needs to be compared with other techniques used for post-operative analgesia to prove its efficiency.

Conclusion

The local infiltration technique meets all the requirements needed for the control of postoperative pain i.e. adequate analgesia, adequate relaxation with good hemodynamic control and minimal side effects. Ropivacaine as a local anesthetic in 0.5% concentration provides better quality post-operative analgesia than 0.25% without any undesirable side effects.

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