

Comparative evaluation of 0.5% Ropivacaine and 0.5% Bupivacaine for day case inguinal herniorrhaphy in a Nigerian Tertiary Health Institution.

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ABSTRACT

Background: Day case inguinal herniorrhaphy is a common surgical procedure performed in our environment with lidocaine used for field block. The study was aimed at comparing 0.5% ropivacaine and 0.5% bupivacaine for the field block, determine their effectiveness and safety in our environment.

Methods: In a double-blind randomized study, 52 ASA physical status I-II patients (age >18yrs) scheduled for field block for day case inguinal herniorrhaphy were assigned to two study groups to receive 0.5% ropivacaine 25ml (n = 26) or 0.5% bupivacaine 25ml (n = 26). Onset of analgesia, adequacy of block, duration of postoperative pain relief and pain score at first requirement of analgesic were recorded.

Results: One patient in the bupivacaine group did not complete the study. Patient demographic characteristics and surgical times were similar in the two groups. Mean onset time of anaesthesia was shorter in the bupivacaine group than the ropivacaine group (5.37 ± 0.50 min vs 5.48 ± 0.45 min) although this was not significant ($P = 0.44$). Adequacy of block was similar in the two groups ($P = 0.55$). Postoperative pain relief was significantly longer for the ropivacaine group 6.83 ± 0.57 hr than for the bupivacaine group 6.32 ± 0.35 hr ($P = 0.0004$, unpaired t-test). Mean pain score at the first requirement for analgesic was lower in the ropivacaine group 1.38 ± 0.49 than the bupivacaine group (1.56 ± 0.51), but this was not significant ($P = 0.22$). Few untoward effects of nausea and dizziness were observed in this study.

Conclusion: Ropivacaine and bupivacaine have comparable onset of actions and adequacy of anaesthesia when used for day case inguinal herniorrhaphy and are safe.

Key words: Blood glucose, fasting, elective surgery.

INTRODUCTION

Recent advances in anaesthetic and surgical techniques, along with escalating healthcare costs, have resulted in an ever-increasing number of surgical procedures being performed on a day-case basis worldwide. The cost-effectiveness of day-case surgery is well recognized¹. Top priorities for successful outpatient surgery are the four 'A's: alertness, ambulation, analgesia and alimentation. Excessive fatigue, nausea, vomiting or unrelieved pain will delay discharge. The potential cost saving of outpatient surgery may be negated by unanticipated hospital admission for poorly treated pain². Inguinal herniorrhaphy is a routine procedure in our environment and it is frequently done under field block with lidocaine. The drug is cheap, readily available and surgeons are skillful in its use. However, its low cost does not necessarily translate to favourable prolonged

postoperative analgesia and patient satisfaction which are desirable features in day case surgery. Bupivacaine and ropivacaine are other amide local anaesthetic agents with long durations of action when compared with lidocaine which has a moderate duration of action³. These longer acting agents are not in routine use in our environment because they are expensive and many surgeons, especially those practicing outside the tertiary health institutions, may not be familiar with their use. On the other hand, ropivacaine is not readily available in our environment. Prolonged postoperative analgesia provided by these agents are particularly suited to the ever-growing population of patients (particularly high risk elderly patients, those with respiratory compromise) presenting for day case surgery. Ropivacaine has a higher threshold than bupivacaine and the former was produced in order to address the issue of bupivacaine cardiotoxicity⁴.

Levobupivacaine is a better alternative to bupivacaine because of its better safety profile^{5,6}. However this new local anaesthetic agent is not available in our environment.

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Ropivacaine has been used successfully for postoperative analgesia in patients undergoing inguinal herniorrhaphy⁷.

Equal doses (100mg) of ropivacaine and bupivacaine have been shown to provide similar analgesia after inguinal hernia surgery⁸. There is no available record in our environment with the use of both local anaesthetics for hernia surgery. The study compared 0.5% ropivacaine and 0.5% bupivacaine for the field block and determined their onset of action, effectiveness, duration of postoperative analgesia and safety in our environment.

PATIENTS AND METHODS

This prospective randomized double-blind study was carried out in the University of Ilorin Teaching Hospital, Ilorin, Nigeria which is a reference centre for patients from the state of location and five neighbouring states. After institutional approval and informed, written consent, 52 ASA physical status I–II patients (age >18years) scheduled for day case inguinal herniorrhaphy were included in the study.

Exclusion criteria were: patient refusal, previous hypersensitivity to local anaesthetics and patients on chronic analgesic therapy. Others excluded from the study were those with uncontrolled respiratory, cardiovascular and metabolic diseases, and, those with neuropathies. Patients were seen at the clinic visit where the study was explained to them. They were taught on the verbal rating score (VRS) for pain to respond as follows: 0 = no pain, 1 = mild pain, 2 = moderate pain 3 = severe pain, 4 = excruciating pain (while the native language, 'Yoruba' translation as validated by Soyannwo *et al*⁹ was used for those who could not communicate in the English language). Patients were instructed to inform the nursing staff or unit intern in the recovery room or the ward respectively as soon as they felt pain in the postoperative period. Surgery was scheduled early on the list to allow time for assessment later in the day before discharge home.

Premedication on the day of surgery consisted of 5mg of oral diazepam 2 hours before the commencement of surgery. In the operating room, patients were randomly allocated, using a draw of lots technique, to one of two groups of 26 each according to the local anaesthetic used – ropivacaine group (R) or bupivacaine group (B). Patients' sociodemographic characteristics including age, sex, weight and height were documented. Availability of functional anaesthetic machine, good supply of oxygen, resuscitation drugs (e.g. adrenaline, atropine) and suction machine was ascertained before each surgery. The following physiological parameters were monitored using the "Nellcor-Puritan-Bennett NPB 4000" multiparameter patient monitor (Nellcor-Puritan-Bennett, Inc. Pleasanton CA, 94588, USA) - non-invasive blood pressure (NIBP), arterial oxygen saturation (SpO₂), pulse rate (PR), electrocardiogram (ECG) and peripheral temperature. Patients were allocated to either receive 25ml, 0.5% ropivacaine (R group) or 25ml, 0.5% bupivacaine (B group) for inguinal field block using the technique described by

Pinnock *et al*¹⁰ i.e. performing block of the iliohypogastric, ilioinguinal and genitofemoral nerves. The block was completed by injecting the agent subcutaneously, on negative aspiration in a fanwise distribution (a point 1cm medial to the pubic tubercle towards the anterior superior iliac spine) to block innervations from the subcostal nerve. Sterile syringes containing the local anaesthetic solutions were prepared by one of the researchers who did not participate further in the management of the patients. The field block was performed by other researchers (surgeons) blinded to the local anaesthetic being used. The same researchers assessed the onset of surgical anaesthesia and adequacy of the block. The start time for clinical assessment was from completion of the injection of the local anaesthetic. The pin-prick test (22-gauge hypodermic needle) was used to assess sensory block. Onset of surgical anaesthesia was defined as loss of pin prick sensation at the skin dermatomes involved in the surgical field (determined from the time of completion of injection of local anaesthetic to loss of pin prick sensation).

The adequacy of block was judged according to the need for supplementary i.v. analgesics or general anaesthesia as follows: 1. adequate nerve block = no analgesic required to complete surgery. 2. inadequate nerve block = need for additional i.v. analgesic (i.v. pethidine 50mg) to complete surgery. 3. failed nerve block = general anaesthesia required to complete surgery. Fluid therapy consisted of normal saline infused intravenously at the rate of 5ml/kg/h. Duration of surgery was recorded.

At the end of surgery, patients were admitted into the recovery room for a period of 45-60 minutes and the Post-Anaesthesia Recovery Room Scoring System (PRS)¹¹ in use in our centre was used for discharge criteria (Appendix 1). This was assessed by the recovery room nurse every 15 minutes. A minimum score of 9 was required for discharge to the ward. Rescue analgesia with i.m. pethidine 1mg/kg was planned for any patient that had breakthrough pain in the recovery room and such patient was removed from the study.

Postoperative pain relief (duration of analgesia) was defined as the time lasting from completing the block to the first requirement for pain relief and the pain score at this time was assessed using the VRS by a dedicated unit intern who was blinded to the local anaesthetic used. Each patient was then given i.v. paracetamol 600mg and i.m. ketoprofen 100mg for further postoperative pain relief. Any pain score greater than 2 was treated with im pethidine 1mg/kg. Vital signs were monitored by the ward nurse every 15 minutes for the first 1 hour, and then every 30 minutes until the patient was discharged home. Before discharge home, each patient satisfied the minimum requirement of readiness for discharge using the Post Anaesthesia Discharge Scoring System.¹² A minimum score of 9 was required for discharge home. At discharge, patients were questioned regarding complications such as nausea, vomiting, dizziness and headache. Postoperative pain relief at home consisted of oral paracetamol 1000mg 8hourly

daily for 72 hours. Such complications occurring within the first 24 hours after discharge home were documented on the first postoperative follow up clinic visit. Sample size was determined using the proportion of surgical patients presenting for inguinal herniorrhaphy in our hospital over a period of 5 years which was 3% (0.03 per 100)

Using Fisher's formula¹³ sample size was calculated thus $n = z^2pq/d^2$, where n = sample size, z = standard normal deviate, set at 1.96 (approximately 2.0 which corresponds to 95% confidence interval or 5% significant level), p = proportion of surgical patients presenting for inguinal hernia repair, q = 1.0 - p and d = degree of accuracy = 0.05. A minimum sample size of 47 patients was required for the study. Fifty two (52) patients were recruited into the study allowing for attrition rate of 10% (5 patients).

Data were presented as frequencies and means. The Statistical Package for Social Sciences (SPSS) version 15.0 was used for statistical analysis of data. The student's t-test (2-tailed) was used to analyze the means of continuous data (age, weight, height, onset of analgesia, postoperative pain relief and pain score) while categorical data were analyzed using the Chi-square (adequacy of block) or the Fisher's exact test (immediate postoperative and post-discharge complications). A P-value of less than 0.05 was taken as significant.

RESULTS

Fifty one patients (R group, n = 26, B group, n = 25) completed the study. All the patients were males. One patient in the bupivacaine group was excluded from the study as a result of bladder rent which was repaired and the patient was subsequently admitted into the ward. Nineteen (73.1%) patients had right inguinal hernia and 7 (26.9%) patients had left inguinal hernia in the ropivacaine group. Twenty (80.0%) patients had right inguinal hernia and 5 (20.0%) had left inguinal hernia in the bupivacaine group. The two groups of patients were similar in age, weight and height (Table I). Surgery times were also similar

Table I: Patients' characteristics, means (SD or range)

	Ropivacaine 0.5% n = 26	Bupivacaine 0.5% n = 25	P value
Age (yr)	44.27 (18-82)	43.48 (21-74)	0.89
Weight (kg)	64.98 (9.13)	64.46 (7.83)	0.83
Height (m)	1.69 (0.08)	1.17 (0.07)	0.77

in the two groups (Table II).

Onset of anaesthesia was faster with the bupivacaine group (mean = 5.37 ± 0.5min) than with the ropivacaine group (mean = 5.48 ± 0.45min), however there was no significant difference in the onset times (P = 0.44). Five (19.2%) patients in the ropivacaine group and 7 (28.0%) patients in the bupivacaine group had inadequate anaesthesia during their surgeries and the procedures were completed with the use of i.v. pethidine 50mg. There was no significant difference between both groups in adequacy of anaesthesia (P = 0.55). No failed blocks were reported in this study. No patient had breakthrough pain in the recovery room.

Postoperative pain relief (duration of analgesia) was significantly longer in the ropivacaine group than in the bupivacaine group (6.83 ± 0.57 hr versus 6.32 ± 0.35 hr, P = 0.00). Pain scores ranged between 1 (mild) and moderate (2) for both groups at the first requirement of analgesic. While mean pain score was less in the ropivacaine group, this was not statistically significant (R 1.38 ± 0.49 versus B 1.56 ± 0.51, P = 0.22). No patient had breakthrough pain (i.e. pain score greater than 2) in the ward before discharge home, therefore rescue analgesia was not administered to any patient in both groups.

Few untoward effects were recorded in this study. In the immediate postoperative period, 2(7.7%) patients and 1(3.8%) patient had nausea and dizziness respectively in the ropivacaine group while 2(8.0%) patients and 2 (8.0%) patients had nausea and dizziness respectively in the bupivacaine group. There was no significant difference in the occurrence of these effects in the two groups (P=0.61). There were also few untoward effects at home in the 24hr following discharge. Only 1(3.8%) patient in the ropivacaine group had nausea while 1(4.0%) patient had headache and 1(4.0%) had nausea in the bupivacaine group without any significant difference between the two groups (P = 1.24). No patient was admitted as a result of any side effect arising from the use of the two local anaesthetics.

Table II: Onset of anaesthesia, duration of surgery and postop pain relief

	Ropivacaine 0.5% n = 26	Bupivacaine 0.5% n = 25	P value
Onset of anaesthesia (min)	5.48 (0.45)	5.37 (0.50)	0.44
Surgery time (min)	70.70 (17.26)	70.20 (11.50)	0.91
Postop pain relief (hr)	6.83 (0.57)	6.32 (0.35)	0.00

APPENDIX 1: Post Anaesthesia Recovery Scoring System (PRS) ¹¹

	0	1	2
COLOUR	Cyanosed	Dusky or pale	Pink
CONSCIOUSNESS	Unconscious	Semi-conscious	Conscious
CIRCULATION	BP change 50% of preop value	BP change 20-50% of preop value	BP change within 20% of preop value
RESPIRATION	Apnoeic or gasping	Shallow or labored	Good
MOVEMENT	Cannot move any Limb	Moves some but not all the limbs	Moves all limbs

DISCUSSION

Our results show that 25 ml of ropivacaine 0.5% has an onset time and adequacy of block that is similar to those of 25 ml of bupivacaine 0.5% when used for field block for inguinal herniorrhaphy. Day case inguinal herniorrhaphy in our environment is done under ketamine, field block with local anaesthetic (LA), regional anaesthesia (RA) e.g. subarachnoid block and occasionally general anaesthesia (GA). It has been shown that in specialist hernia centres, LA is used in more than 95% of cases^{14,15}. When economic resources and medical personnel are scarce as in our environment, LA has obvious advantages and this has been demonstrated in Nigeria and Ghana^{16,17,18}. It is advocated that uncomplicated inguinal hernia in the adult should be repaired under LA. Giant inguinoscrotal hernias, recurrent and strangulated hernias should be excluded from LA.

Only 1 patient (1.9%) had unplanned admission as a result of bladder rent and was excluded from the surgery. Unplanned hospital admissions for day cases following inguinal hernia repair is less in LA when compared with RA and GA¹⁹. The local anaesthetic most commonly available for field block for inguinal hernia repair in our environment is lidocaine. It is cheap, readily available and surgeons are familiar with its use. Lidocaine has a rapid onset and a short duration of analgesia making it unsuitable for prolonged postoperative pain relief in day case inguinal hernia repair.

There is no record of the use of either bupivacaine or ropivacaine for inguinal hernia repair in our environment to date. Though bupivacaine is available, it is used for central neural axial blockade and postoperative wound infiltration to provide postoperative analgesia. It is about four times more expensive than lidocaine and generally, surgeons are not yet familiar with its use in our environment for inguinal hernia repair. Both local anaesthetics have similar physico-chemical properties but ropivacaine is reported to have decreased cardiovascular and central nervous system toxicity⁴.

Our results show that both agents had similar onset times and adequacy of block but ropivacaine had longer duration of analgesia. Bertini et al²⁰ found that ropivacaine showed a faster onset of sensory and motor block than ropivacaine but the duration of analgesia did not differ when used for brachial plexus blocks. However they concluded that ropivacaine showed advantages over bupivacaine for axillary brachial plexus block. The main advantage observed with ropivacaine over bupivacaine in our field block for inguinal hernia repair is the longer duration of action which is a desirable feature for day case inguinal hernia repair.

Studies using either bupivacaine or ropivacaine as sole anaesthetic for inguinal hernia repair are rare in the literature. However, there are studies that have compared both agents for postoperative pain relief after inguinal hernia repair done under GA^{21,22} while another study compared different concentrations of ropivacaine for

postoperative pain relief after inguinal hernia repair done under GA⁷. Pettersson et al²¹ found no statistically significant differences between pain scores in two groups when the operating field was infiltrated with either 40ml 7.5mg/ml ropivacaine or 2.5mg/ml bupivacaine following inguinal hernia repair under GA. They concluded that wound infiltration with long acting LA resulted in low pain scores after hernia surgery. While they used very differing concentrations (0.75% vs 0.25%), we used equal concentrations (0.5%) of the two local anaesthetics without any significant difference in the pain scores. Bertini et al²⁰ showed that the higher 0.75% concentration of ropivacaine added little value to its features while it could add an increased risk of systemic toxicity. Tsuchiya et al²² concluded that bupivacaine and ropivacaine were more effective than lidocaine in the prevention of postoperative pain following inguinal hernia repair in children. Their conclusion supports the use of these long acting local anaesthetics for day case inguinal hernia surgery, not only in their environment, but also in our environment.

Studies have also compared ropivacaine and bupivacaine for other nerve blocks. Fanelli et al²³ observed that 0.75% ropivacaine and 2% mepivacaine had shorter onset time than 5% bupivacaine but both ropivacaine and bupivacaine had significantly longer duration of analgesia than mepivacaine in combined sciatic and femoral nerve blocks. Marhofer et al²⁴ observed that onset time and quality of sensory block were similar between 0.5% ropivacaine and 0.5% bupivacaine during 3-in-1 block in patients scheduled for hip surgery. The Marhofer findings agree with similarity in onset times and adequacy of block observed in this study. However, the onset time in our study is considerably less compared to that reported in the Marhofer study. This may be due to infiltration of local anaesthetic into the skin and subcutaneous layers in our study, which are supplied by nerve fibres of small diameters that are more rapidly blocked than the larger nerve fibres of the 3-in-1 block. Mean onset times between 51-74 seconds have been reported for ropivacaine used for skin infiltration²⁵ while mean onset times between 1.4-10.7 minutes have been reported for inferior alveolar nerve block for molar tooth extraction with different concentrations of ropivacaine²⁶. The longer duration of analgesic action with ropivacaine reported in our study may be attributable to its intrinsic property of vasoconstriction which will reduce its rate of absorption into the circulation and therefore prolong its duration of action.

No patient in both groups required any rescue analgesia either in the recovery room or in the ward before discharge. Moreover, mean pain score for each agent was less than 2 (less than moderate pain) at the first requirement for analgesic which was over 6 hours for each agent. These results agree with the findings of Sanjay and Woodward²⁷ who reported that LA was associated with less postoperative analgesic requirements than GA in patients who had inguinal hernia repair. They also reported fewer

micturition problems with LA. Other studies have demonstrated the advantages of LA over GA or RA for inguinal hernia repair to include shortest time to home readiness, lowest pain score at discharge and highest patient satisfaction²⁸. Time to home readiness was not measured in this study because one of the outcome measures was duration of analgesia. Minimal to no pain in the postoperative period as demonstrated in this study are acceptable criteria for home readiness.

The general incidence of untoward effects in this study is low which makes both agents safe for day case inguinal herniorrhaphy with its added advantage of long duration of postoperative analgesia.

CONCLUSION

Ropivacaine and bupivacaine are safe for day case inguinal hernia repair in our environment, providing prolonged postoperative analgesia which is a desirable feature of day case surgery.

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