Incorporating dexamethasone with heavy bupivacaine in unilateral spinal anesthesia for lower limb Open Reduction and Internal Fixation

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Abstract

The use of additives in regional anesthesia, regardless of the local anesthetic agent used, the type of surgery, or the method of pain assessment, provides superior analgesia to parenteral opioids and, when used appropriately, reduces both opioid consumption and opioid-related adverse effects in the immediate postoperative period and therefore better recovery profile and patient satisfaction. Therefore, this study aimed at determining and comparing analgesic consumption between the use of 10 mg of 0.5% hyperbaric bupivacaine alone and in combination with dexamethasone for unilateral spinal anesthesia for lower limb Open Reduction and Internal Fixation (ORIF). This was a prospective double-blinded randomized study. It involved 68 consented American Society of Anesthesiologists (ASA) I and II patients, aged 18-75 years, scheduled for unilateral lower limb ORIF. Ethical approval was obtained, NHREC/25/10/2013. Patients were randomly allocated accordingly. Monitoring of hemodynamic parameters was done during the perioperative period. Visual Analogue Scale (VAS) and Bromage scores were regularly assessed, and rescue analgesia was utilized in patients with VAS greater than or equal to 4. The data obtained were analyzed using the Statistical Package for Social Sciences (SPSS; Armonk, USA). Student T-test was used to compare the quantitative variables, while Chi-squared (X^2) test was used to compare the qualitative variables. Results were presented in tables and figures, and $p<0.05$ was regarded as statistically significant. The mean age of the patients in groups BA and BD were 39.97 ± 11.22 and 39.12 ± 12.37 years, respectively, and was not statistically significant, $p=0.77$. The male-to-female ratio for groups BA and BD was 19:15 and 21:13, respectively, $p=0.64$. The mean VAS score in the first two hours was not significant. However, in the third hour, the mean VAS was 2.97 ± 1.00 and 0.18 ± 0.56 ($p=0.001$); in the fourth hour, it was 2.85 ± 1.58 and 0.94 ± 1.34 ($p=0.001$), and the eighth hour was 1.79 ± 0.41 and 3.82 ± 1.49 ($p=0.001$) which were statistically significant. The mean total analgesic consumption was 226.66 ± 45.52 and 148.79 ± 40.58 in groups BA and BD, respectively, which was statistically significant ($p=0.000$)

This study revealed that the addition of 4 mg dexamethasone to 10 mg of 0.5% heavy bupivacaine intrathecally was associated with less opioid consumption compared with the use of 0.5% heavy bupivacaine alone in unilateral spinal anesthesia for unilateral ORIF.

Introduction

The use of additives in regional anesthesia, regardless of the local anesthetic agent used, the type of surgery, or the method of pain assessment, provides superior analgesia to parenteral opioids and, when used appropriately, reduces both opioid consumption and opioid-related adverse effects in the immediate postoperative period and therefore better recovery profile and patient satisfaction.[1] Many additives have been tried, such as opioids,[2] adrenaline,[3] clonidine[4] and neostigmine,[5] ketamine,[6] dexmedetomidine,[7] but all these additives have their complications. Like respiratory depression seen with opioids, hypertension and tachycardia with vasoconstrictors and ketamine, secretions with the use of neostigmine, and sedation as observed with clonidine and dexmedetomidine. However, considering the benefits of dexamethasone, there is an increasing trend toward its use, not only for preventing postoperative nausea and vomiting but also for good analgesic action both intravenously, epidurally, or perineurally. Patients have enhanced recovery profiles after surgery.[8] Dexamethasone is a synthetic glucocorticoid that has minimal mineralocorticoid activity. Its anti-inflammatory potency is 30 to 40 times that of hydrocortisone, and up to 16 times that of prednisolone. Several studies demonstrated the analgesic effect of steroids in neuraxial and peripheral nerve blocks.[8] Unilateral spinal anesthesia is a technique that exclusively blocks the sensory, motor, and sympathetic functions on one side of the body.[9] The procedures that can be done using unilateral spinal block include unilateral arthroscopy, open reduction internal fixation of fractures, excision of tumors, amputations, debridement, and unilateral inguinal repairs, among others. The aim of this study was to determine and compare analgesic consumption with the use of 10 mg of 0.5% hyperbaric bupivacaine alone *vs* combination with 4 mg of dexamethasone in unilateral spinal anesthesia for lower limb Open Reduction and Internal Fixation (ORIF).

Materials and Methods

This was a prospective double-blinded randomized study on adult patients aged 18-75 years who met the inclusion criteria and had unilateral lower limb ORIF. The study groups included Group BA, who received 10 mg of 0.5% intrathecal hyperbaric bupivacaine (2 mL) with (1 mL) of normal saline, and Group BD, who received 10 mg of 0.5% intrathecal hyperbaric bupivacaine (2 mL) with 4 mg (1 mL) dexamethasone. Approval to conduct the study was obtained from the Ethical Research Committee of Federal Teaching Hospital Gombe. Informed written consent was obtained from each patient after adequate counseling. An information note was given to a patient and his relations for clarity. All data obtained were treated with the utmost confidentiality. Inclusion criteria were American Society of Anesthesiologists (ASA) I and II, patients aged 18-75 years, patients scheduled for unilateral lower limb ORIF, and patients who accepted the procedure after excluding contraindications. Exclusion criteria were unstable ASA III and above, diabetic patients, patients with heart diseases, patients with disease/injuries of the vertebral column, local or systemic infection, patients on chronic steroid therapy, patients with neurological deficits, patients with hypotension, patients with psychiatric illness, uncooperative patients, patients with other contraindications to spinal anesthesia, patients with a history of allergies to bupivacaine and dexamethasone, alcohol abuse, drugs addict, patient with a partial block on the other limb, inadequate block and failed block.

Pre-anesthetic review

All patients booked for ORIF whose names were on the surgery list were seen a day before surgery, rapport was established, anxiety was allayed, the diagnosis was confirmed, the clinical condition of the patient was assessed, optimization was done, premedication was prescribed, fasting guideline was established and informed consent was obtained. The socio-demographic data included age, sex, height, weight, and Body Mass Index (BMI). The height and weight were measured using tape and a bed scale, respectively. Relevant history was based on the inclusion and exclusion criteria. The patients were examined. Baseline vital signs were obtained: Heart Rate (HR), Non-Invasive Blood Pressure (NIBP), Respiratory Rate (RR), Temperature (T), and Oxygen Saturation (SPO$_2$). Relevant investigation results were reviewed and included Electrolytes, Urea and Creatinine (E/U/Cr), urinalysis, Random Blood Sugar (RBS), Full Blood Count (FBC), and Electrocardiogram (ECG). The patient's physical status was assigned according to the ASA. Fasting guidelines were established based on 8, 6, and 4 hours for solid, semi-solid, and clear fluid, respectively, and informed consent was obtained and signed. Oral benzodiazepine, diazepam 5-10 mg, was prescribed based on the patient's anxiety. The patient was educated on how to use the VAS. On the day of surgery, the patient was randomly allocated to a group according to the drugs to be injected into groups BA or BD by picking a paper from a sealed envelope that carried an equal number of BA and BD in the pre-anesthetic room. It was prepared by an informed anesthesia resident who was not involved in other perioperative management of the patients. The medication was prepared by a research assistant who was not involved in other aspects of the study. Neither the patient nor the researcher knew the group to which the patient belonged.

Intra-operative management

A quick check for the availability and functionality of equipment was done. Facilities for resuscitation drugs and general anesthesia were made available in case of any complications that might arise. The patient was placed on the operating table in the operating room, the multi-parameter patient monitor was attached to the patient, and the baseline vital signs were taken and documented. Subsequently, the patient was monitored for HR, NIBP, SPO$_2$, temperature, and ECG. Intravenous access was secured using a size 18G cannula, and Ringer's lactate was given at 15 mL per kilogram body weight over 20 minutes as preloading, and all the patients in both groups were given intravenous short-acting opioid, fentanyl at the dose of 50-100 mcg to position the patient well without much pain. The researcher was responsible for the lumbar puncture and sub-arachnoid injection. Patients were placed in a lateral position with the limb to be operated on in the dependent position. The vertebral column position is accurately visualized and maintained as horizontally as possible. The back of each patient was prepared with antiseptic lotion and the patient was draped aseptically. A skin wheal was raised with an injection of 2 mL solution of lidocaine 1% at the plane of needle puncture at L3/L4 intervertebral space. That level was identified by an imaginary line passing through the two iliac crests (known as the Tuffier's line). Lumbar puncture was performed at the same level in the center with a 25G disposable Whitacre spinal needle with a bevel facing the dependent side. After a free flow of clear cerebrospinal fluid is seen, an injection of 10 mg of 0.5% bupivacaine (2 mL) diluted with preservative-free normal saline (1 mL) made up to 3.0 mL was administered slowly to those in group BA or 2 mL (10 mg) of 0.5% heavy bupivacaine mixed with 4 mg (1 mL) of dexametha-

sone making a total of 3.0 mL was administered slowly to those in group BD. The needle was removed at once, and the punctured site was covered with sterile gauze and plastered. The patient was kept in the lateral position for 20 minutes and then turned supine for the procedure. The sensory block was evaluated using temperature discrimination (by application of 'cold' alcohol skin prep) after the end of the injection. The dermatomal level was tested every two minutes till the level stabilized for four consecutive tests, then every five minutes till 30 minutes, then every 15 minutes until the point of regression of the sensory level to L3 on the dependent side. The motor block was evaluated using the Bromage scale at the time reaching the peak of sensory level on the operated and non-operated limb, and time to complete recovery of motor block was noted. HR, NIBD, MAP, RR and ECG were recorded for every one minute in the first 15 minutes, then every five minutes for the remaining surgery period. Analgesic consumption in this study is defined as the total amount of pethidine given to the patient during the study.

Data analysis

All the data obtained were analyzed using SPSS. Student T-test was used to compare the quantitative variables, while Chi-squared (X^2) test was used to compare the qualitative variables. Results were presented in tables, and $p<0.05$ was regarded as statistically significant.

Results

A total of 68 ASA I and II patients aged between 18-75 years who had unilateral lower limb ORIF at the Federal Teaching Hospital, Gombe, Nigeria, were recruited for this study, which lasted over seven months. The male-to-female ratio for groups BA and BD was 19:15 and 21:13, respectively, p=0.64, while the mean age of the patients in groups BA and BD were 39.97±11.22 and 39.12±12.37 years, respectively, and the difference was not statistically significant (p=0.77) as shown in Table 1. The mean preoperative hemodynamic parameters PR, MAP, RR, and SpO$_2$ were compared in both groups, and there was no statistically significant difference between the two groups, as shown in Table 2.

The mean VAS score in the first two hours was not significant. However, in the third hour, the mean VAS was 2.97±1.00 and 0.18±0.56 (p=0.001) the fourth hour, it was 2.85±1.58 and 0.94±1.34 (p=0.001), and the eighth hour was 1.79±0.41and 3.82±1.49 (p=0.001) which were statistically significant. The mean total analgesic consumption over the period of the study was 226.66±45.52 and 148.79±40.58 in groups BA and BD, respectively, which was statistically significant, p=0.000, as shown in Table 3.

Discussion

In this study, it was found that there were no significant differences in socio-demographic data and pre-operative parameters. However, it was found that the mean total analgesic consumed throughout the study (twenty-four hours) were 226.66±45.52 and 148.79±40.58 mg in groups BA and BD, respectively, which was statistically significant (p=0.000). Thus, the addition of dexamethasone to 0.5% heavy bupivacaine reduced opioid consumption compared to 0.5% heavy bupivacaine alone in unilateral spinal block. This is in keeping with a study by Tomar et al.,[10] who found

that the total dose of intravenous fentanyl consumed in the first 24 hours postoperatively in the dexamethasone group was 98.60±14.14 µg as compared with 147.6±18.22 µg in bupivacaine group, which was statistically significant as in this study. They used the thoracic paravertebral block technique, deposited a large volume of bupivacaine (19 mL) and a higher dose of dexamethamethasone (8 mg) during the block, which might have caused a more prolonged period of analgesia, thereby reducing the analgesics consumption more than in this study. Similarly, a study conducted by Ammar et al.[11] also showed that the addition of 8 mg dexamethasone to 20 mL bupivacaine 0.25% for bilateral transversus abdominis plane block significantly prolonged the duration of analgesia, delayed the analgesic request and therefore reduced morphine requirements; 4.1 and 19.2 mg for dexamethasone and control groups respectively with p<0.01 which was statistically significant. The similarity was the addition of dexamethasone to bupivacaine in the nerve block. It is also known that perineural steroids as an adjuvant to local anesthetics give good postoperative analgesia.[12] This may reduce the analgesic consumption.

Table 1. Comparison of socio-demographic data of the patient.

Variable	Group BA Mean ± SD	Group BD Mean ± SD	p
Age (years)	39.97±11.22	39.19±12.37	0.77
Weight (kg)	62.73±10.20	64.68±8.25	0.39
Height (m)	1.67±0.08	1.68±0.94	0.70
BMI (kg/m2)	22.85±3.55	23.35±3.79	0.58
ASA I	24 (35.30%)	26 (38.20%)	0.58
ASA II	10 (14.70%)	8 (11.80%)	
Sex (M:F)	19:15	21:13	0.64

p<0.05 is statistically significant. BA, bupivacaine alone; BD, bupivacaine with dexamethasone; SD, Standard Deviation; BMI, Body Mass Index; ASA, American Society of Anaesthesiologists; M:F male to female ratio.

Table 2. Comparison of mean preoperative hemodynamic parameters of the patients.

Variable	Group BA Mean ± SD	Group BD Mean ± SD	p
PR (b/min)	85.125±5.51	85.36±4.14	0.84
SBP (mmHg)	124.5±4.89	123.52±4.60	0.08
DBP (mmHg)	82.10±5.11	79.36±7.56	0.09
MAP (mmHg)	94.13±17.06	93.18±5.63	0.69
SPO2 (%)	99.18±0.99	99.71±0.72	0.08
RR (cycle/min)	18.00±0.888	18.235±1.103	0.34

p<0.05 is statistically significant. BA, bupivacaine alone; BD, bupivacaine with dexamethasone; SD, Standard Deviation; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; MAP, Mean Arterial Pressure; RR: Respiratory Rate; SPO$_2$, Oxygen Saturation.

Table 3. Comparison of total analgesic and ephedrine consumption among the study groups.

Variable	Group BA Mean ± SD	Group BD Mean ± SD	p
Analgesic consumption (mg)	226.66±45.52	148.79±40.58	*0.000
Ephedrine consumption (mg)	5.50±3.97	3.89±1.91	0.26

*statistically significant. BA, bupivacaine alone; BD, bupivacaine with dexamethasone; SD, Standard Deviation.

Bousabbeh *et al.*,[13] in a prospective controlled, randomized double-blinded clinical trial on patients proposed for surgery of the upper extremity of the femur under spinal anesthesia and evaluated the efficacy of dexamethasone added to bupivacaine and sufentanil in spinal anesthesia to improve postoperative analgesia after femur upper extremity surgery. There was a reduction in morphine consumption during the first six postoperative hours in the case group against the control group (p=0.02). They concluded that the addition of intrathecal dexamethasone in spinal anesthesia improved postoperative analgesia after femur upper extremity surgery and reduced opioid consumption. However, the sample size of 58 patients is relatively small. Moreover, patients on steroids or opioids for long periods were not mentioned in the exclusion criteria. Deo *et al.*,[14] also, in a randomized controlled trial, found out that a single injection of dexamethasone as an additive to local anesthetic reduced the total number of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) needed to provide rescue postoperative analgesia. The total number of analgesics consumed was 5.98±2.26 and 8.04±1.52 in dexamethasone and the control group, which was statistically significant between the study groups, p<0.05. Dexamethasone causes vasoconstriction, reduces inflammation, and blocks transmission of nociceptive C-fibres.[15] These combined effects may be responsible for the delayed analgesic request and reduced analgesic consumption. In contrast, Hassan *et al.*,[16] found that there was not much difference between dexamethasone and control groups. The analgesic consumption was 3.45±0.51 in dexamethasone and 3.50±0.51 in the control group, p=0.76, which was statistically not significant. This may be connected with the use of VAS ≥3, as the time of first analgesic request in their study compared with VAS ≥4 in this study, and the use of two different intravenous analgesics with different mechanisms of action in their study: when VAS was ≥3, the patient received ketolac (30 mg IV infusion) first, then VAS was reassessed 15 minutes later, nalbuphine (0.15 mg/kg IV) was given if VAS≥3 after giving ketolac, while in this study, only intravenous pethidine was given as rescue analgesia, then was given eight hourly. Also contrary to this study was a study by Kayalha *et al.*,[17] which found that the addition of 4 mg dexamethasone to bupivacaine in an ilioinguinal and iliohypogastric block at the end of surgery in patients undergoing inguinal herriorrhaphy under spinal anesthesia failed to prolong the time to the first analgesic request. The results showed the total analgesic consumption was higher in the dexamethasone group (51.1±32.4 mg) than in the control group (26.4±33.8 mg) and (p=0.018), which was not in agreement with this study. This may be because the block was given when the patients were under spinal anesthesia at the end of the surgery, so they might have missed failed blocks since patients were under spinal block.

Conclusions

This study revealed that the addition of 4 mg of dexamethasone to 10 mg of 0.5% heavy bupivacaine intrathecally was associated with less opioid consumption compared with the use of 0.5% heavy bupivacaine alone in unilateral spinal anesthesia for unilateral open reduction and internal fixation.

Recommendations

Based on the findings of the present study, the addition of 4 mg dexamethasone to 10 mg of 0.5% heavy bupivacaine in unilateral spinal anesthesia can be encouraged in unilateral lower limb ORIF as it significantly reduces opioid consumption.

Limitations

A sample size of 68 patients is relatively small, and there was limited availability of studies on unilateral spinal anesthesia with dexamethasone to compare with this work.

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