

THE VALUE OF DEXAMETHASONE IN SPINAL BLOCK FOR LOWER LIMB ORTHOPEDIC SURGERY

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ABSTRACT

Background: adjuvants are not only used to potentiate analgesic effect of local anaesthetic agents but also to reduce the side effects and complication that may arise during regional anaesthesia. Many were tried to improve efficacy of local anaesthetic agents but are not without complication. The aim of this study was to determining and compare incidence of complications with the use of hyperbaric bupivacaine alone and combination with dexamethasone in spinal anaesthesia for lower limb surgery.

Methodology: This was a prospective double blinded randomized study. It involved 68 consented ASA I and II patients, aged 18-75 years scheduled for lower limb ORIF. Ethical approval was obtained, NHREC/25/10/2013. Patients were randomly allocated. Monitoring of haemodynamic parameters was done. The data analyzed using SPSS. Student T test was used to compare the quantitative variables while Chi-squared (χ^2) test was used to compare the qualitative variables. Results were presented in the form of figures and $p<0.05$ was regarded as statistically significant.

Results: The mean preoperative haemodynamic parameters of the patients were not statistically significant. The incidence of hypotension was 24.60% and 4.61% in group BA and BD respectively with $p = 0.001$. Bradycardia were 7.70% and 0.00% in group BA and BD respectively, with $p=0.003$ which was also statistically significant. For Inadequate block; 3.10% and 1.54% for groups BA and BD respectively, with $p=0.15$ showing no significant difference, while for nausea; was 09.20% and 4.62% for BA and BD respectively, with no significant difference, $p=0.26$. There was only one patient in Group BA that had shivering and none in group BD.

Conclusion: This study revealed that addition of 4 mg dexamethasone to 10 mg of 0.5% heavy bupivacaine was found to be associated with fewer incidences of complications compared with the use of 10 mg 0.5% heavy bupivacaine alone in spinal anaesthesia for lower limb ORIF in the immediate postoperative period.

Keywords: unilateral spinal anaesthesia, complications, dexamethasone

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INTRODUCTION

Unilateral spinal anaesthesia is a technique that exclusively blocks the sensory, motor and sympathetic functions on one side of the body and offers the advantages of a spinal block without the typical adverse side effects seen with a bilateral spinal block.¹ Intrathecal local anaesthetics have been found to be associated with limited duration of action, hypotension, bradycardia, nausea and vomiting, urine retention, high spinal and total spinal anaesthesia.² Adjuvants are not only used to potentiate analgesic effect of local anaesthetic agents but also to reduce the side effects and possible complication that may arise during regional anaesthesia.³ Many adjuvants were used to obtund such effects; opioids,⁴ adrenaline,⁵ dexmedetomidine,⁶ clonidine,⁷ ketamine,⁸ midazolam,⁹ neostigmine,¹⁰ and magnesium sulphate.¹¹ However, all these adjuvants were not without complications. Respiratory depression was seen with opioids, hypertension and tachycardia with ketamine, sedation as observed with clonidine and dexmedetomidine, while secretion was seen with the use of neostigmine and ketamine. The purpose of this study was to determine whether the addition of dexamethasone to intrathecal bupivacaine would prevent such complications or not during unilateral spinal anaesthesia for lower limb open reduction and internal fixation.

MATERIALS AND METHOD

The study was carried out at Federal Teaching Hospital Gombe, Gombe state, Northeastern part of Nigeria. This was a prospective experimental study that involved adult patients between the age of 18-75 years of American Society of Anesthesiologists (ASA) physical status I and II that fulfilled the inclusion criteria and were scheduled for unilateral lower limb ORIF at Federal Teaching Hospital Gombe, Gombe state, Nigeria. The data was collected over a period of 6 months with subsequent data cleaning. The study was conducted in a randomized double-blind manner. Patients were allocated to a group according to the drugs to be injected by picking a paper from a sealed

envelope which carried an equal number of BA (who received 10 mg of 0.5% intrathecal hyperbaric bupivacaine 2ml with 1ml of normal saline) and BD (who received 10 mg of 0.5% intrathecal hyperbaric bupivacaine 2ml with 4mg, 1ml dexamethasone) in the pre-anaesthetic room. It was prepared by a trained research assistant who was not involved in any other perioperative management of the patients. All the drugs were in 5ml syringe containing 3ml of prepared drugs.

Sample size estimation: The minimum sample size (n) for this study was calculated using the formula by Charan et al.¹² The Standard deviation of the duration of the pain-free period was 72.64 in the Dexamethasone group using the study by Bani-Hashem et al.¹³ This calculation resulted in a sample size of 31.

Thus, 31 subjects were recruited in each group. To allow for 10% attrition, the sample size of each group was made up to 34, resulting in a total number of 68 subjects for the entire study.

All consenting subjects aged 18-75 years, with ASA status of I and II who were scheduled for unilateral lower limb ORIF, and who had no contraindications, were included in the study

All subjects who were ASA III and above, diabetic, had evidence of cardiovascular disease or disease/injuries of the vertebral column were excluded from the study. Subjects who had local or systemic infection, who were chronic steroid therapy, had neurological deficits or psychiatric illnesses were also excluded. Un-cooperative patients, patients with allergies to bupivacaine, those with other contraindications to spinal anaesthesia, history of drug addiction or alcohol abuse as well as those with partial block on the contra-lateral limb, inadequate block or failed block were all excluded from the study.

Ethical issues: Ethical approval was obtained on 1st December, 2020 from the Health Research and Ethics Committee (HREC) of Federal Teaching Hospital, Gombe NHREC/25/10/2013. Written informed consent was obtained from each patient after adequate

counselling and an information note was given to each subject and their relations for clarity.

ANAESTHETIC MANAGEMENT: all patients booked for ORIF, whose names were on the surgery list were seen a day before surgery, to confirm diagnosis, establish rapport, allay anxiety and assess their clinical condition. The subjects were optimised and pre-medication prescribed including the establishment of fasting guideline and informed consent. The socio-demographic data of the subjects were collected, including age, sex, height, weight and BMI. Baseline vital signs, including pulse rate, blood pressure, respiratory rate, temperature and oxygen saturation were documented. Relevant investigation results were reviewed and documented. The Patient's physical status was assigned according to the American Society of Anesthesiologists (ASA) and physical status classification. Fasting guidelines were established based on 8, 6, and 4 hours for solid, semi-solid and clear fluid respectively. Oral benzodiazepine diazepam 5-10 mg was prescribed based on the patient's anxiety. Patient was educated how to use VAS (visual analogue score). On the day of surgery, patient was randomly allocated to either Group BA or BD according to the drugs to be injected, by picking a paper from a sealed envelope which carried an equal number of BA and BD in the pre-anaesthetic room.

INTRAOPERATIVE MANAGEMENT: a quick check for the availability and functionality of the anaesthetic machine and other essential anaesthetic equipments was carried out. In the operating room, the patient was placed on the operating table, 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 heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SPO₂), temperature and ECG. Intravenous access was secured using a size 18G cannula and Ringers lactate was given at 15 mls 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 1.5 mcg per kilogram body weight but not more than 100 mcg to position the patient well without much pain. Patients were placed in lateral position with the limb to

be operated on in the dependent position. The vertebral column position was accurately visualized and maintained as horizontal 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 mls 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 (Tuffier's line). Lumbar puncture was performed at the same level in the centre with a 25G disposable Whitacre spinal needle with 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 mls) diluted with preservative-free normal saline (1ml) made up to 3.0 mls was administered slowly to those in group BA while 2 mls (10 mg) of 0.5% heavy bupivacaine mixed with 4 mg (1ml) of dexamethasone making a total of 3.0 mls 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 twenty (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 (4) consecutive tests then every five (5) minutes till thirty (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, NIBP, mean arterial blood pressure (MAP), respiratory rate (RR) and ECG were recorded for every one (1) minute in the first 15 minutes, then every five (5) minutes for the remaining period of the surgery. The onset time was defined as the time interval between the end of injection of the drug into the intrathecal space and the time patient has total abolition of response to 'cold' at T10 on a target limb with a complete response on the other limb.

DATA ANALYSIS: All the data obtained were analyzed using statistical package for social sciences (SPSS Chicago, USA). Student T test was used to compare the quantitative variables while Chi-squared (χ^2) test was used to compare the qualitative variables. Results were presented in the form of tables, figures and graphs and $p < 0.05$ was regarded as statistically significant.

DEFINITIONS: Hypotension: is a decrease in systolic arterial blood pressure by over 20% or diastole 15% compared to the baseline value.

Bradycardia: reduction in heart rate by 20% from the baseline.

Respiratory depression: defined as respiratory rate ≤ 8 cpm,

High and total spinal: these manifest with loss of consciousness, apnoea and hypotension as a result of the high level of the block. It occurs when the level of sensory block extends to the second/third thoracic or cervical dermatomes.

Failed block: occurs when there is no sensory block, $VAS \geq 4$ or Bromage score > 2 on the target limb 20 minutes after giving the unilateral spinal block.

Inadequate block: occurs when the motor block based on the Bromage score is 2 on the target limb after 20 minutes from the onset time.

RESULTS

A total of sixty-eight (68) ASA I and II patients aged between 18-75 years who had unilateral lower limb ORIF at the Federal Teaching Hospital Gombe, were recruited for this study, which lasted for eleven months. The mean age of the patients in group BA was 39.97 ± 11.22 and BD was 39.12 ± 12.37 years, $p=0.77$.

The male to female ratio for groups BA and BD were 19:15 and 21:13 respectively, $p = 0.64$ as shown in table I. The mean preoperative haemodynamic parameters of the patients were not statistically significant as shown in table II. The mean onset time for sensory block were 4.48 ± 1.44 minutes and 4.44 ± 0.88 minutes in groups BA and BD respectively, $p=0.92$. While the mean onset time for the motor block were 7.24 ± 2.09 minutes and 6.59 ± 1.56 minutes for groups BA and BD respectively, $p=0.16$. The mean VAS score in the first two hours were not significant. However, in the third hour, the mean VAS was 2.97 ± 1.00 and 0.18 ± 0.56 ($p=0.001$), fourth hour 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 intra-operative complications observed during the study were hypotension, bradycardia, inadequate block, nausea and shivering. Those that had hypotension were 16 (24.60%) and 03 (4.61%) patients in group BA and BD with $p=0.001$. This showed a statistically significant difference. Bradycardia were 05 (7.70%) and 0 (0.00%) in group BA and BD respectively, with $p=0.003$ which was also statistically significant. For Inadequate block, 2 (3.10%) and 01 (1.54%) for groups BA and BD respectively, with $p=0.15$ showing no significant difference, while the patients that had nausea; were 06 (09.20%) and 03 (4.62%) for BA and BD respectively, with no significant difference, $p=0.26$. One of the subjects in Group BA experienced shivering. The mean dose of Ephedrine given in those that had hypotension was 3.889 ± 1.906 and 5.500 ± 3.969 for groups BA and BD respectively with no significant difference ($p=0.26$). There were no statistically differences in the postoperative PR, SBD, DBP, MAP, SPO₂ and RR between the two groups, as shown in table II.

Table I: Comparison of socio-demographic data of the patients

Variable	Group BA Mean ± S.D	Group BD Mean ± S.D	p-value
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/m ²)	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%)	08(11.80%)	
SEX (M:F)	19:15	21:13	0.64

BA: bupivacaine alone, BD: bupivacaine with dexamethasone, SD: standard deviation, p-Value <0.05 statistically significant. BMI: body mass index, ASA: American society of anaesthesiologists, M: F male to female ratio

Table II: Comparison of mean preoperative haemodynamic parameters of the subjects

Variable	Group BA Mean ± S.D	Group BD Mean ± S.D	p-value
HR (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
SPO ₂ (%)	99.18 ± 0.99	99.71 ± 0.72	0.08
RR (cycle/min)	18.00 ± 0.888	18.235 ± 1.103	0.34

BA: bupivacaine alone, BD: bupivacaine with dexamethasone, SD: standard deviation, p- value <0.05 statistically significant. SBP: systolic blood pressure, DBP: diastolic blood pressure, MAP: mean arterial pressure, RR: respiratory rate, SPO₂:

oxygen saturation

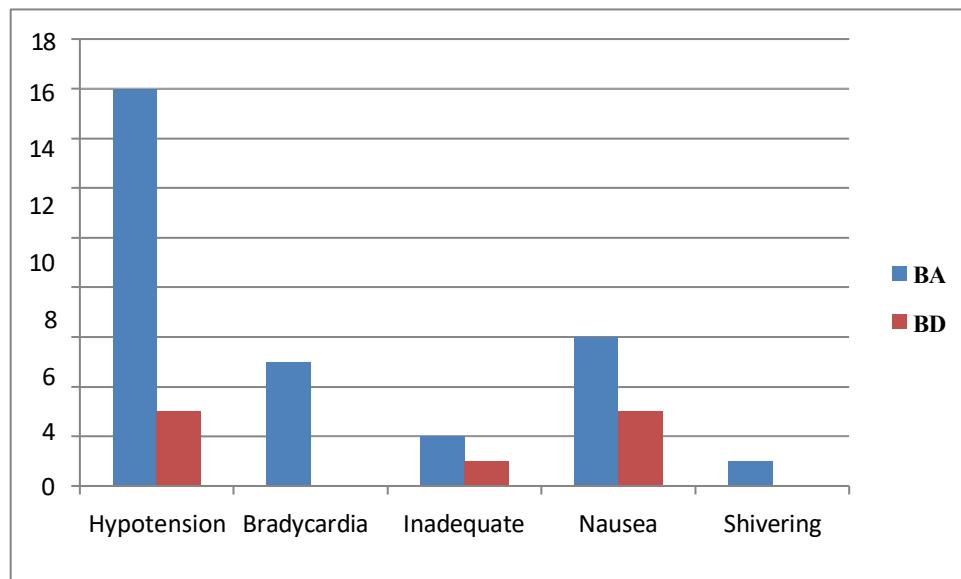


Figure 1: Incidence of Complications observed among the study groups

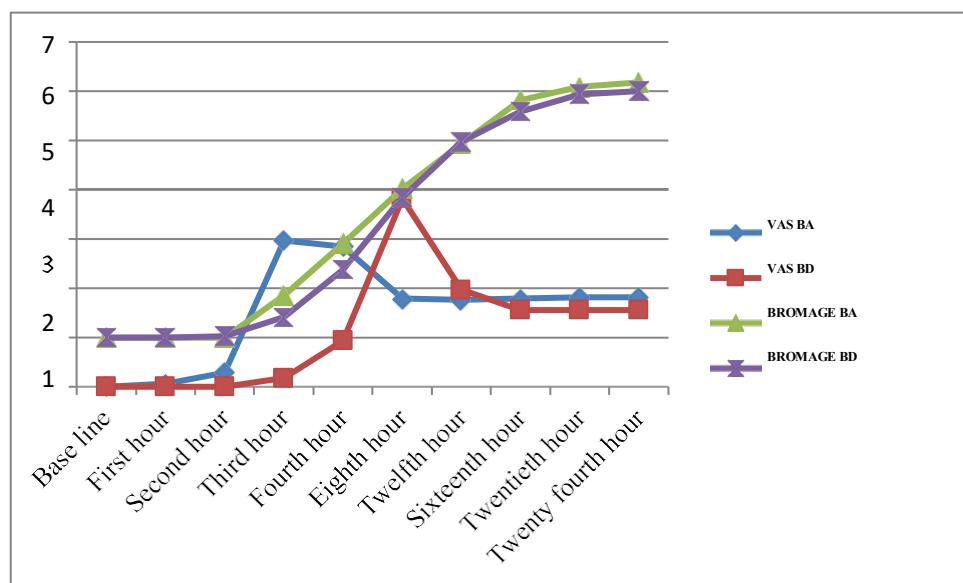


Figure 2: Bromage and vas scores among the study groups

DISCUSSION

Incidence of hypotension was observed in 16 (24.60%) and 03(4.61%) patients in groups BA and BD respectively, which showed a significant difference statistically, with $p=0.001$. Thus, the addition of 4 mg of dexamethasone to 0.5% heavy bupivacaine for unilateral spinal block reduced the incidence of hypotension compared to 0.5% heavy bupivacaine alone. This was a similar finding to the study of Takachenco et al,¹⁴ that found those who received 4 mg dexamethasone intrathecally with bupivacaine had reduced the hypotensive effect of spinal anaesthesia when compared with bupivacaine alone, $p=0.48$. Khaleel et al,¹⁵ also in a clinical trial study found out that when dexamethasone was mixed with heavy bupivacaine 0.5% it prevents hypotension which occurred in spinal anaesthesia compared with bupivacaine alone, with blood pressure 68.70 ± 6.46 and 85.44 ± 6.73 mmHg in control and dexamethasone groups respectively. In addition, a study by Ashoor et al,¹⁶ revealed that the addition of dexamethasone 8 mg intravenously 2 hours preoperatively decreased hypotension after spinal anaesthesia. Similarly, Esmat et al,¹⁷ in their results showed that the hypotensive effect of spinal anaesthesia was significantly reduced in patients that received 8 mg of dexamethasone intravenously 8 (8%) when compared with the control group 25 (25%, $p<0.00$). Incidence of bradycardia were 05 (7.70%) and 0 (0.00%) in groups BA and BD respectively with $p=0.003$, which was statistically significant. Thus intrathecal addition of dexamethasone significantly decreased incidence of post spinal bradycardia in unilateral spinal anaesthesia for ORIF. Nashwa et al,¹⁸ reported incidence of bradycardia following spinal anaesthesia in 2 (10%) patients in both dexamethasone and control, with $p=0.56$.

The patients that had nausea were 06 (09.20%) and 03 (4.60%) in groups BA and BD respectively in this study, with no significant difference, $p=0.26$. This may be connected with the use of unilateral spinal anaesthesia and a low dose of local anaesthetic agents in all the groups.¹⁹ Nashwa et al¹⁸ also reported that there was no statistically significant difference in the incidence of PONV during spinal anaesthesia for abdominal surgeries between dexamethasone group 1 (5%) patient and bupivacaine alone group 3 (15%) with $p=0.42$.

Similarly, El maurad et al²⁰ conducted a prospective randomized controlled study that evaluated the effect of the addition of 4 mg of dexamethasone as adjuncts to bupivacaine in TPVB and the results showed that the incidence of PONV in the study population was not statistically significant. In contrast, Ammar et al,²¹ found out that when dexamethasone was added to bupivacaine during transversus abdominis plane block for abdominal hysterectomy there was a reduced effect of PONV, 6 patients in the dexamethasone group and 14 patients in the control group, with $p=0.03$ which was statistically significant. Also, Deo et al²² in their study found that a single injection of dexamethasone, it has reduced the effect of nausea and vomiting in 14 patients in control and 2 patients in case groups which was statistically significant, $p<0.05$. Esmat et al,¹⁷ their results showed; 6 (6%) vs 27(27%) for nausea and 3(6%) vs (16%) for vomiting in dexamethasone and placebo with $p<0.001$.

Shivering was observed in one patient (1.50%) in group BA and none of the patients in BD, the $p=0.31$ which was statistically not significant. The reason may be due to the unilateral spinal technique given to all patients among the study groups. However, a study by Moeen et al²³ showed that intrathecal addition of dexamethasone was as effective in attenuation of shivering compared to bupivacaine alone in patients scheduled for prostate surgery under spinal anaesthesia. The number of patients with shivering was higher in bupivacaine alone group (13) than in dexamethasone group (2), with $p<0.01$ which was statistically significant.

None of the patients had failed block among the study groups. This may not be unconnected with the methodology used: patients were given the drugs in lateral decubitus, Whitacre spinal needle with the bevel directed distally, hyperbaric bupivacaine was used and patients were remained in that position for twenty minutes. These are the determinant factors for successful unilateral spinal block.²⁴ This was a similar finding with a study by Magar et al,²⁵ which reported that none of patients had failed block in unilateral spinal anaesthesia group, which may be due to the same reasons. Contrary to this findings, Kilinc²⁶ reported failure rate observed in the unilateral spinal anaesthesia group (5%) in their study, which may be as a result of the used of lower concentration of the drug: 0.5% hyperbaric

bupivacaine 7.5 mg and the lateral position was maintained for only 15 min before patients were turned to the supine position. Inadequate block was observed in 2(3.10%) patients in group BA compared to 1(1.50%) group BA with $p=0.15$ which showed no significant difference. This is in agreement with study by Colish et al,²⁷ which reported inadequate block rates of 3.9% and 3.8% among the study groups which were not statistically significant

CONCLUSION

The addition of 4 mg dexamethasone to 10 mg of 0.5% heavy bupivacaine was found to be associated with fewer incidences of complications compared with the use of 10 mg 0.5% heavy bupivacaine alone in unilateral spinal anaesthesia for unilateral lower limb ORIF in the immediate postoperative period.

Recommendation: 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 anaesthesia should be encouraged in unilateral lower limb ORIF as it minimizes even the little complications that may arise

Limitations: sample size of 68 patients is relatively small compared to a larger population covering the whole of north-eastern Nigeria and as a Referral Centre; multicenter approach to get

a larger population for the study is needed to ensure the findings of the studied drug. Secondly, there was limited availability of studies on unilateral spinal anaesthesia with dexamethasone to compare with this work.

Declaration: this study has not been previously presented in a conference or published in another journal

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