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Original Article

Dexamethasone as an Additive to Heavy Bupivacaine in Unilateral Spinal Anaesthesia for Lower Limb Open Reduction and Internal Fixation

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ABSTRACT

Background: An ideal additive should shorten the speed of onset of action of the local anaesthetic drug and also reduce its dosage along with providing better hemodynamic changes. Therefore, the aim of this study was to determining the onset of action of unilateral spinal anaesthesia when intrathecal dexamethasone is added to heavy Bupivacaine for lower limb open reduction and internal fixation (ORIF).

Materials and methods: The study was carried out in Anaesthesia Department, Federal Teaching Hospital Gombe, Gombe State. It was a prospective experimental study in which patients were recruited using simple random sampling technique and balloted for the intervention given. The minimum sample size (n) for this study was calculate and resulted in a total number of 68 subjects for the entire study. Data was collected using modified questioner. Dependent variables; onset time, level of the block, HR, SBP, DBP, MAP and while the independent variables; height, age, weight. 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; age, height, weight, BMI, haemodynamic changes and the onset time. While Chi-squared (X^2) test was used to compare the qualitative variables; sex, ASA. Results were presented in the form of tables and $p < 0.05$ was regarded as statistically significant.

Results: 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 blockwere 7.24 ± 2.09 minutes and 6.59 ± 1.56 minutes for groups BA and BD respectively, p=0.16 which were all not statistically significant.

Conclusion: this study revealed that, addition of 4mg dexamethasone to 10 mg of 0.5% heavy Bupivacaine intrathecally does not affect both sensory and motor onset of action anaesthesia.

KEYWORDS: Unilateral Spinal Anaesthesia, Heavy Bupivacaine, Dexamethasone

INTRODUCTION

Unilateral spinal anaesthesia is a type of sub arachnoid block in which the block is restricted to the operative side only with the absence of a block on a non-operative side.[1] It has advantages of spinal block without the typical adverse side effects seen with conventional spinal anaesthesia.[2] Additives are drugs which, when administered along with local anaesthetic agents, may improve the latency of onset and duration of analgesia and counteract the undesirable effects associated with large doses of local anaesthetic. [3] The use of additives has the potential to improve the efficacy of central neuraxial blocks and decrease systemic toxicity by

prolonging the duration of sensory block, enhancing motor blockade, and limiting the overall dose requirement of drugs.[4] An ideal additives should shorten the speed of onset of action of the local anaesthetic drug and also reduce its dosage along with providing hemodynamic.[5] However, much consideration was not given on the effect of the additives on the onset of action. Therefore, this study aimed at determining the effect of dexamethasone on the onset of action with the use of 10 mg of 0.5% hyperbaric bupivacaine in unilateral spinal anaesthesia for lower limb open reduction and internal fixation (ORIF).

MATERIALS AND METHODS

Study Setting

Study was conducted in anaesthesia and critical care department, Federal Teaching Hospital, Gombe which was established in 1996. It has a 500 bed-capacity. Gombe is the capital city of Gombe State in Nigeria. It is located between latitude 100° and 110° north, within the savannah region.

Study Design

Double blinded prospective randomized experimental study.

Study Population

Study population include all adult patients between the age of 18-75 years of American Society of Anaesthesiologists (ASA) physical status I and II scheduled for unilateral lower limb ORIF at Federal Teaching Hospital Gombe, Gombe state, Nigeria.

Inclusion Criteria

ASA I and II, patients aged 18-75years, scheduled for unilateral lower limb ORIF.

Exclusion Criteria

ASA III and above, diabetic, patients with heart diseases, disease/injuries of the vertebral column, local or systemic infection, patients on chronic steroid therapy, with neurological deficits, hypotension, psychiatric illness, or uncooperative. Patients with other contraindications to spinal anaesthesia; history of allergies to bupivacaine, alcohol abuse, drugs addict, partial block on the other limb, inadequate block and failed block.

Sample Size Estimation

The minimum sample size (n) for this study was calculated using the formula by Charan et al. [6] The Standard deviation of the duration of the pain-free period was 72.64 in Dexamethasone group, using the study by Bani-Hashem et al. [7]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 patients for the entire study.

Sampling Technique

Simple random sampling technique was used to recruit patients and were allocated to a group according to the drugs to be injected by balloting: picking a paper from a sealed envelope which carried an equal number of BA and BD. BA (who received 10 mg of 0.5% intrathecal heavy bupivacaine 2ml with 1ml of normal saline) and BD (who received 10 mg of 0.5% intrathecal heavy bupivacaine 2ml with 1ml of dexamethasone) in the pre-anaesthetic room. It was a double blinded technique: prepared by a trained research assistant who was not involved in other perioperative management of the patients. The medication was also prepared by the research assistant. All the drugs were in 5ml syringe containing 3ml of prepared drugs. Neither the patient nor the researcher knew the group to which the patient belonged.

Data Collection Method

The hospital has four (4) Orthopaedic Surgeons that operate three times a week. An average of three (3) ORIF was done per week. The duration of the data collection was six (6) months, while the data cleaning, analysis and report writing lasted for about five (5) months. Questionnaire which was obtained from Bani-Hashem[7] and modified, were administered to the patients.

Pre-Anaesthetic Management

All patients booked for ORIF, whose names were on surgery list were seen a day before surgery, rapport was established, anxiety was allayed, the diagnosis was confirmed, the clinical condition was assessed, optimization done, pre-medication was prescribed, fasting guideline was established and informed consent was obtained. The socio-demographic data included age, sex, height, weight and BMI. The height and weight were measured using tape and bed scale respectively.

The patients were examined. Baseline vital signs were obtained; pulse rate, blood pressure, respiratory rate, temperature and oxygen saturation. 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 physical status was assigned according to the American Society of Anaesthesiologists (ASA) and physical status

classification. 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 diazepam5-10 mg was prescribed based on the patient's anxiety. Patient was educated how to use Visual Analogue Scale (VAS). On the day of surgery, 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 which carried an equalnumber of BA and BD in the pre-anaesthetic room (balloting).

It was prepared by an informed anaesthesia 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 the anaesthetic machine, suction machine, multi-parameter monitor, appropriate sizes of oropharyngeal airways, and endotracheal tubes was done. Facilities for resuscitation drugs and general anaesthesia were made available in case of any complications that might arise. 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 SPO_2, temperature and ECG. Intravenous access was secured using a size 18 Gcannula and Ringer's lactate was given at 15 mls per kilogram body weight over 20 minutes as pre-loading 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 to position the patient well without much pain. The researcher was responsible for the lumbar puncture and sub-arachnoid injection.

Patients were placed in lateral position with the limb to be operated on in the dependent position. The vertebral column position is 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 L_3/L_4 inter-vertebral 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 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 injectionof 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 or 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 L_3 on the dependent side. The motor block was evaluated using the Bromage scale at the time reaching peak sensorylevel on both the limbs, and time to complete recovery of motor block was noted. Heart rate (HR), non-invasive blood pressure (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 is defined as the time interval between the end the of injection of the drug into theintrathecal 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.

Pain Assessment

Visual Analogue Scale (VAS) is widely used for measurements of pain intensity, [8] it consists of a 10 cm line marked at one end with "no pain" and the other with "worst pain ever". The patient is asked to indicate where on the line he or she rates the pain, and a numerical value was then givento it, simply by measuring the length between no pain and worst pain as the patient's mark.[9]

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; age, height, weight, haemodynamic changes and the onset time. While Chi-squared (X^2) test was used to compare the qualitative variables; sex and ASA. Results were presented in the form of tables and $p < 0.05$ was regarded as statistically significant.

Ethical Considerations

Ethical approval was obtained from the Research and ethics committee of the Federal Teaching Hospital Gombe. An informed written consent was obtained

from each patient after adequate counselling and an information note was given to a patient and his relations for clarity.

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. A larger population 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.

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, none of them opted out and the study lasted for seven months. 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).

Table 1: Comparison of Socio-Demographic Characteristics of The Patients Amongst the Study Groups

Variable	Group BA Mean ± SD	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	23(35.30%)	26(38.20%)	0.58
ASA II	09(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 2: Comparison of Mean Preoperative Haemodynamic Parameters of the Subjects Amongst The Study Groups

Variable	Group BA Mean ± S.D	Group BD Mean ± S.D	p-value
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

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.

The mean weight was 62.74 ± 10.20 and 64.68 ± 8.25 kg in groups BA and BD respectively with no statistically significant difference (p=0.39).

Table 3: Comparison of Mean Onset Time for Both Sensory and Motor Blockage Amongst Study Groups

Onset (minute)	Group BA Mean ± S.D	Group BD Mean ± S.D	p-value
Sensory	4.48 ± 1.44	4.44 ± 0.88	0.92
Motor	7.24 ± 2.09	6.59 ± 1.56	0.16

BA: Bupivacaine Alone, BD: Bupivacaine with Dexamethasone, SD: Standard Deviation, P-Value <0.05 StatisticallySignificant

The mean heights were 1.8 ± 0.1 and 1.7 ± 0.0 m in groups BA and BD respectively and were not statistically significant (p=0.70). The body mass index (BMI) was 22.85 ± 3.55 and 23.35 ± 3.79 kg/m^2 in groups BA and BD respectively and was not statistically significant (p=0.58). The ASA health status classification; twenty-four patients, 24 (35.30%) in group BA, 26 (38.20%) in group BD were ASA I, 10 (14.70%) in group BA and 8 (11.80%) in group BD were ASAII which was not statistically significant (p=0.58), as shown above, in Table 1.

The mean pre-operative haemodynamic parameters PR, MAP, RR and SpO2 were compared in both groups and there was no statistically significant difference between the two groups. The mean pre-operative pulse rate was 85.13 ± 5.51 b/min for group BA and 85.36 ± 4.60 b/min for group BD (p=0.84), mean preoperative MAP was 94.13 ± 17.06 mmHg for group BA and 93.18 ± 5.63 mmHg for group BD (p=0.76), mean RR was 18 ± 0.92 cycles/min for group BA and 18.24 ± 1.12 cycle/min for group BD (p=0.34), while the mean SpO_2 was 99.18 ± 0.99% for BA and 99.71 ± 0.72% for group BD (p=0.80). There was no statistically significant difference (p<0.05) in the pre-operative haemodynamic parameters (PR, MAP, RR and SpO2) as shown above in Table 2.

The mean onset time for the sensory block was 4.48 ± 1.44 minutes and 4.44 ± 0.88 minutes in groups BA and BD respectively, there was no statistically significant difference between the two groups with p=0.92, while the mean onset time for the motor block was 7.24 ± 2.09 minutes and 6.59 ± 1.56 minutes for groups BA and BD respectively, which was not statistically significant: p=0.16 as shown in Table 3

DISCUSSION

In this study, the mean onset time of sensory block was found to be 4.48 ± 1.44 minutes and 4.44 ± 0.88 minutes in groups BA and BD respectively and there was no statistically significant difference between the two groups with p=0.92, while the mean onset time for the motor block was 7.24 ± 2.09 minutes and 6.59 ± 1.56 minutes for groups BA and BD respectively, which was also not statistically significant p=0.16. Thus, the addition of intrathecal dexamethasone 4mg to

0.5% heavy bupivacaine for unilateral spinal block did not affect the onset time of action of anaesthesia when compared to 0.5% heavy bupivacaine alone.

This finding was similar to that of Shourbagy et al, [10] which their result showed that the addition of intrathecal dexamethasone to bupivacaine showed no statistically significant difference in the onset time of action between heavy bupivacaine with dexamethasone, p=0.14. The reason for the similarity in the onset time of action might be due to the addition of dexamethasone to the local anaesthetic agent and the use of the same drugs at the same dosage and same route of administration of the drugs. Similarly, the findings of Kaur et al,[11] showed that addition of intrathecal dexamethasone to 0.5% heavy bupivacaine for spinal anaesthesia in lower limb orthopaedic surgery showed no significant difference in the onset time of anaesthesia with p=0.05 in their study.

The mean time of onset of motor block was also not significant, p=0.16. Bani-Hashem et al,[7] also reported that, there was no statistically significant difference in the onset time of the sensory block between the bupivacaine containing dexamethasone and the heavy bupivacaine alone groups in spinal anaesthesia for orthopaedic surgery. Though they found a relatively longer onset of sensory block in their study which might be due to the variation in the definition of the onset time; they defined onset of action of the sensory block as time from of injection of drugs into the intrathecal space to the time of peak sensory and motor block, and the highest dermatomal level with the highest frequency was T6 in their study, while in this study it was defined as the time from the injection of the drug to time to reach T10 level.

Furthermore, a study by Nashwa et al,[12] also revealed that there was no statistically significant difference when dexamethasone was added to 0.5% heavy bupivacaine intrathecally for both sensory and motor blocks. The rapid onset time revealed in both sensory and motor blocks may be due to the smaller sample size and difference in number of the patients among the study groups in their study; twenty (20) patients that received dexamethasone in addition to heavy bupivacaine while thirty-four (34) patients received dexamethasone in this study.

In contrast to the findings of this study, Vaidya et al 13 found out that the addition of dexamethasone to bupivacaine provides faster onset of sensory and motor blocks. In an experimental study they recruited forty patients undergoing surgery of the elbow, forearm, and hand under supraclavicular brachial plexus block, with 0.25% bupivacaine with normal saline (n=20) in the Group I versus 0.25% bupivacaine with dexamethasone (n = 20) in Group II with an equal volume of 30 ml in each group, p<0.001.

The similarity with this study was the addition of dexamethasone to local anaesthetic agent during nerve block. However, significant decrease in the onset time of both sensory and motor blocks may be due to the use of higher dose of dexamethasone, 8 mg compared to 4 mg used in this study and their study was peripheral nerve block compared with central neuroaxial nerve block in current study.

The sample size they used in their study was forty, which is relatively small and may affect the strength of the study. In a similar way, Esmat et al,[14] also found out that there was a significant difference between the dexamethasone group and control group in the onset time of sensory block with, $p < 0.01$. The difference may be due to different methodology used. Lumber puncture was at different levels among the patients and onset time was defined as from the time drug was deposited to time to reach peak sensory level, which may also be different among the patients thereby affecting the level of the block. Also, the volume of the drug was not the same amongst the patients 2.5–3.5 ml (12.5–17.5 mg) of 0.5% hyperbaric bupivacaine.

CONCLUSION

This study revealed that, addition of 4mg dexamethasone to 10 mg of 0.5% heavy bupivacaine in unilateral spinal anaesthesia for lower limb ORIF does not affect both sensory and motor onset of action anaesthesia. We therefore encouraged the addition of 4 mg dexamethasone to 10 mg of 0.5% heavy bupivacaine in unilateral spinal anaesthesia in unilateral lower limb ORIF for other purposes but not for faster onset of action.

Declaration

This study has not been previously presented in a conference or previously published in another journal

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Author's Contributions

Concept and design of study; IN, ASA and WIM. Review of manuscript: ASA, PSU, SA and BIA

Competing Interest

The authors declare no conflicts of interest

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