ORIGINAL ARTICLE

Comparison of the Duration and Quality of Epidural Analgesia between Plain Bupivacaine alone and Plain Bupivacaine with Tramadol in Lower Limb Orthopaedic Surgeries.

[1]Sambo YT,[2]Adamu SA,[1]Mahdi BM,[3]Esin A,[2]Nuhu AM

[1]Department of Anaesthesia, Federal Teaching Hospital Gombe, Gombe State, Nigeria
[2]Department of Anaesthesia and Intensive care, University of Maiduguri Teaching Hospital, Maiduguri, Borno State, Nigeria
[3]Department of Surgery, Federal Teaching Hospital Gombe, Gombe State, Nigeria

Correspondences and reprint request to Author: Dr Yusuf Tanimu Sambo, Department of Anaesthesia, Federal Teaching Hospital Gombe PMB 0037 Ashaka Road, Gombe, Gombe State, Nigeria Email: yusufsambo.ys@gmail.com

ABSTRACT

Background: This study was aimed at comparing the duration and quality of epidural analgesia between plain bupivacaine alone with plain bupivacaine and tramadol in lower limb orthopaedic surgeries. Method: This was a prospective randomized double blinded control study involving 74 ASA I and II patients scheduled for elective lower limb orthopaedic surgeries. Group A (n=37) received 19mls of 0.5% epidural plain bupivacaine with 1 ml of water for injection, while group B received 19mls of 0.5% epidural plain bupivacaine with 1ml (50mg) of preservative freetramadol. The duration of analgesia was from the time of epidural block to the time of rescue analgesia. While, the quality of block was measured with Visual Analogue Scale (VAS) and Bromage scale. Results: Thestudy ages were between 16-60years,consisting of 22(60%) male and 15(40%) female in group A, while in group B 20 (54%) were male and 17(46%) female. It showed the mean duration of analgesia were 189.05±21.92min and 254.19±32.78min in group A and B respectively with p <0.01.The intra-operative VAS scores between the two groups did not show any significant difference between study groups (P> 0.05).The differences of grades of motor block and maximum sensory block height were not statistically significant (P=0.26) among the study groups. Conclusion: The addition of 50mg (1ml) of tramadol to plain bupivacaine epidurally prolonged the duration of analgesia and improved the quality of analgesia when compared to the use of bupivacaine alone.

Key words: Duration, Quality of analgesia,Epidural Bupivacaine, Tramadol, Lower limb orthopaedic

INTRODUCTION

Epidural anaesthesia implies the deposition of local anaesthetic agent with or without adjuvant into the epidural space which results in the autonomic, sensory and motor blockades. There were various adjuvant drugs that have been added to bupivacaine for epidural anaesthesia. These include among others tramadol, morphine and fentanyl.[1] The epidural sensory blockade effect has been used for intra-operative and post-operative pain management involving the lower limbs, perineum, pelvis, abdomen and thoracic surgeries. Pain control remains the key to postoperative recovery of orthopaedic surgical patients.[2]Postoperative pain is often inadequately relieved and poor pain management is a common cause of distress and complaints.[3.]

Studies have shown the effectiveness of opioids like

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morphine, fentanyl and sufentanil as adjunct to bupivacaine for epidural anaesthesia while, the use of tramadol has not been explored extensively.[1,4] If tramadol would produce same epidural analgesic effect as other opioids, then it can replace the use of pure opioids because of its fewer side effects and prolonged duration of action with adequate postoperative analgesia.[4] Complications of intrathecal opioids like tramadol include pruritus, nausea,vomiting,urinary retention and respiratory depression.[4] Tramadol in contrast to a centrally acting opioid analgesic has minimal respiratory depressant effect because it has less affinity for u receptors.

Tramadol is also readily available and cheap in developing countries such as Nigeria.[4] If found to be effective as an additive to bupivacaine it will go a long way in providing prolonged analgesic effect and in reducing the dose of bupivacaine.

This study therefore, was aimed to verify the duration and quality of analgesia efficacy of the addition of epidural tramadol to plain bupivacaine for lower limb orthopaedic surgeries in Federal Teaching Hospital, Gombe.

MATERIALS AND METHOD

This is a prospective, randomized, double- blinded, controlled study in adult patients aged between 16-60 years of American Society of Anaesthesiologists (ASA) health status I and II scheduled for elective lower limb orthopaedic surgeries with use of pneumatic tourniquet for one hour.Patients excluded from the study are those with bleeding disorders, hypovolaemia, infection at the site of procedure, raised intracranial pressure, anticoagulant therapy, failed epidural,patient's refusal and patients which pneumatic tourniquet was not use.

The sample size was determined using the formula byCharan et al.[5]

$$n = \frac{2(Z_{\alpha} + Z_{\beta})^2 S^2}{d^2}$$

The sample size was calculated to be 34.

Considering an attrition of 10% of the calculated sample size, 3 were added to each group, hence, the total sample size of thirty-seven (37) patients per group were recruited.

The patients were randomly divided into twogroups (A and B) by sealed envelope method. Group A (received plain bupivacaine 19mls with 1ml of water for injection) and B (received plain bupivacaine 19mls with 1ml of 50mg tramadol).

The approval of the Ethical committee was obtained, as well as informed consent from all the patients. The patients were taught how to use the visual Analogue scales (VAS)during preoperative assessment

In the theatre monitors were attached to the patient and baseline vital signs were obtained and documented.The Patient's peripheral vein was cannulated and preloaded with crystalloids (0.9%saline solution) 10mls/kg body weight over 20 minutes before epidural block. Subsequently fluid was administered as maintenance at 4 mls/kg/hr and ongoing losses were replaced accordingly.

Epidural anaesthesia was performed under aseptic condition by the blinded researcher, after assembling the epidural catheter. In a sitting position the back of the patient was cleaned and draped under aseptic condition and the L2-L3 intervertebral space was located by the used of the posterior superior iliac crest as a guide and skin weal was raised with 2mls of 2% plain lidocaine.The epidural space was identified using 16 gauge Touhy needle with loss of resistance to air technique and the epidural catheter was threaded into the epidural space. A test dose of 3mls of 2% lidocaine with adrenaline (1:100000) was injected through the epidural catheter and signs of intravascular or intrathecal injection was sought for. After confirming correct placement of epidural catheter the patients were re-positioned supineand the drug of the balloted group, either group A or group B was given foronward activation of the epidural anaesthesia. Time of activation was taken as time zero in minute.

The vital signs were monitored regularly. The relevant observations were made when the surgical procedure continues which include: onset of analgesia; successful epidural block (loss of pinprick sensation at T10 sensory level) and complete motor block with Bromage grade 4was

regarded as onset of analgesia. Degree / quality of analgesia which was judged as excellent (no discomfort or pain), good (mild pain or discomfort without need for additional analgesics), fair (pain that require additional analgesics), or poor (moderate or severe pain that required analgesics or general anaesthesia).The level of sensory anaesthesia defined as the loss of pain sensation to pin prick in mid-clavicular line was measured every minute until it reaches the T10 dermatome level and then every 5min during surgery.

The intra-operative VAS score was done at 15 min interval following epidural injection until the end of surgery. The VAS Score was also assessed immediately the patient was received in the Recovery room and at 30 mins interval till discharge from recovery room or administration of analgesics and up to 6 hours from the end of surgery. The time of first post-operative analgesic requestor when VAS >4.0 were noted and rescue analgesia given. Duration of analgesia which was calculated from the time of administration of the drug to the time of rescue analgesiaNo other analgesic or opioid was given during the surgery and the end point of the study was when a rescue analgesic was given.

A standard questionnaire was used to collate the following parameters: demographic characteristics of the patients, intra-operative events, duration of epidural analgesia, duration of surgery, quality of epidural analgesia and block, intra-operative and post-operative VAS scores.

Data was analyzed using Statistical Package for Social Sciences (SPSS, Chicago, USA) IBM Version 20 statistics. $P< 0.05$ was considered statistically significant.

RESULTS

A total of Seventy-four (74) ASA I and II patients between the ages of 16-60years, were recruited in this study consisting of 22(60%) male (M) and 15(40%) female (F) with M: F ratio of 3:2 in group A, while in group B 20 (54%) were male and 17(46%) female with M: F ratio of 1.2:1. There were no statistical significant differences with regard to the gender, age, height, weight, body mass index, surgical procedures(lower limb amputations, open reduction and internal fixation, arthroscopy, sequestrectomy, hemi arthroplasty etc) and ASA classification between the two groups

The mean onset of action of analgesia were 37.03±3.43min and 24.32± 3.76min in groups A and B respectively which was statistically significant ($p<0.01$), as shown in table 1.The mean durations of surgery were not statistically significant ($p= 0.22$) as shown on table 2. The mean durations of analgesia were 189.05±21.92 min and 254.19 ±32.78 min in groups A and B respectively. This was statistically significant ($p< 0.01$) as represent on table2. The patients' assessments on the quality of analgesia were found to be excellent in 21 (56%) patients and good in 16 (44%) patients in group A. While, in group B 27 (73%) patients had excellent and 10 (27%) patients had good quality of analgesia.This showed no significant difference in the quality of analgesia in the two groups $p=0.31$ and $p=0.17$ for excellent and good analgesia respectively, as shown in Table 1.

The mean VAS scores at the time of first analgesic request were 3.78±0.71 and 2.86±0.85 in groups A and B respectively, which was statistically significant ($p<0.01$) as shown in figure 1.The time before first request of rescue analgesia were 180± 20min and 280.33±40min in group A and B respectively which was statistically significant ($p<0.01$).Requirement for total number of analgesic doses in 24 hours were 3.65±0.5 and 2.5±0.6 in groups A and B respectively which was statistically significant ($p<0.01$). The effectiveness of Bromage motor block ($p=1.00$) and the maximum height of block($p=0.26$)were not statistically significantly in both groups A and B as shown in table 3 and fig 2 respectively.The common side effects observed were bradycardia, hypotension and; nausea and vomiting. However, the incidence was not statistically significant between the two groups, Hypotension was observed in 6 (16.2%) patients and 9 (24.3%) patients in group A and B respectively, ($p=0.47$). While, bradycardia was observed in 5 (13.5%) patients and 7 (18.9%) patients in group A and B respectively ($p= 0.68$), nausea and vomiting was observed in 5 (13.5%) patients and 7 (18.9%) patients in group A and B respectively, ($p= 0.68$).

TABLE 1: Onset of action of analgesia and quality of block in group A and B.

Variables	Group A	Group B	p-value
Onset of analgesia (Mean± SD)(min)	37.03±3.43	24.32±3.76	<0.01
Quality of block no (%)			
Excellent	21(57%)	27(73%)	0.31
Good	16(43%)	10(27%)	0.17

TABLE 2: Duration of surgery and analgesia in group A and B.

Variable	Group A	Group B	p-value
Duration of surgery (Mean± SD) (min)	140.76±39.37	143.92±32.46	0.22
Duration of analgesia (Mean± SD) (min)	189.05±21.92	254.19±32.78	<0.01

TABLE 3: Motor Block in Groups A and B.

TIME(min)	Bromage scale	Group A	Group B	P-value
20	I	7	7	1.00
	II	30	30	
30	II	12	9	0.61
	III	25	28	
40	III	2	1	A
	IV	35	36	
50	IV	37	37	A
60	IV	37	37	A
End of study	III	32	33	1.00
	IV	5	4	

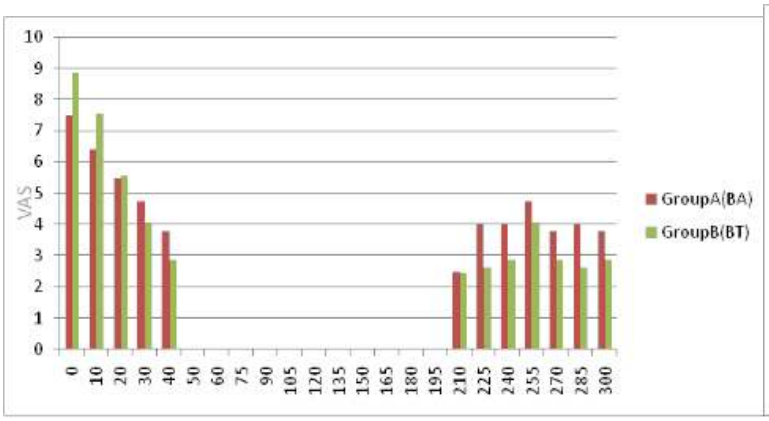

Fig 1: Presentation of VAS scores among the study groups.

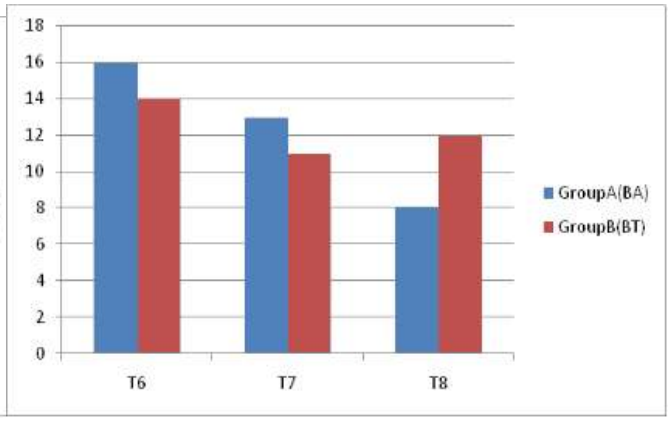

Fig 2: Maximum sensory block heights among the study groups.

DISCUSSION

This study demonstrated that the use of a combination of bupivacaine and tramadol provides superior analgesia when compared with bupivacaine alone for epidural anaesthesia in lower limbs orthopaedic surgeries. This was manifested by lower VAS scores and prolonged duration of pain relief in the immediate post-operative period. It is documented that epidural anaesthesia is associated with better postoperative analgesia and faster recovery of patients when compared to the use of systemic opioids.[6]

In the present study, the mean onset of action of analgesia was found to be statistically significant ($p < 0.01$). This shows that addition of tramadol to bupivacaine for epidural anaesthesia tend to shorten the mean onset of action of analgesia compared to plain bupivacaine alone. This finding was similar to the result obtained by Sutariya et al,[7] where they found a statistically significant difference ($p<0.001$) between the use of bupivacaine alone and bupivacaine with tramadol for epidural anaesthesia, this similarity may not be unconnected with the use of similar methodology as used in this study. However, the result contradicts the findings by Javid et al, [8] where they found that the onset of action of analgesia in bupivacaine alone group and bupivacaine with tramadol for epidural anaesthesia was statistically in-significant ($p=0.27$) despite the used of similar methodology, this may be due to the smaller sample size (50 patients) by Javid et al, [8] could be responsible for missing / masking the detection of a small difference in onset of action of analgesia between the study groups.

In this present study, there was a longer mean duration of analgesia in group Bcompared togroup A. This finding was similar to the previous studies. [8, 7,9,10,11]Thepossible reason for the longer duration of analgesia in the studies could be connected with similar selection of the ages of the patients and sample size as in this study.

In the present study, it was observed that the mean standard deviation of VAS score at the time of rescue analgesia was lower in group Bcompared with group A ($p<0.01$). This shows that addition of tramadol for epidural analgesia reduces the mean VAS. This was similar to the previous studies. [8, 9, 12]This similarity may be due to the used of the similar dosages of bupivacaine and tramadol as used in this study. However, this contradicts the findings of Jitendra et al,[10] and Saxena et al,[11] where they found a statistically in-significant differences between the study groups.In the study by Saxena et al,[11]they used verbal rating scale (VRS) as a tool for pain assessment instead of VAS that was used in the present study. It was documented by Soyanwo et al,[14] that VAS was usually more comprehended by Nigerians and the reason for it used in this study.

In the study the difference in Bromage motorblock was not statistically significant ($p = 1.00$) which is contradictory to the study by Paranjpe JS et al,[15] which foundhigher motor blockadein the tramadol group that was statistically significant than in group A.This may be because Paranjpe et al use only ASA III patients in their study instead of ASA I and II as was done in our study.

CONCLUSION:

The result of the study shows that the addition of 50mg of tramadol to 0.5% plain bupivacaine for epidural anaesthesia was associated with prolonged duration of analgesia and also improved quality of analgesia based on the VAS scores at the first analgesic request.

The following limitations were observed during this study:

1. We may not rule out the possibility of tramadol abuse / addiction among our patients therefore, this may invariably affect the duration of analgesia in such patients.
1. Some of the patients cannot stand upright and therefore we have some challenges in weighing such patients.

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