Spinal Anaesthesia for Herniorrhaphy: A Comparison of Intrathecal Bupivacaine/Fentanyl; Bupivacaine/Saline and Bupivacaine Alone; In Respect of Motor/Sensory Characteristics.

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ABSTRACT

Background: Inguinal herniorrhaphy is the commonest surgery done in day-case settings, under local, spinal or general anaesthesia. The repair of inguinal hernias in our resource limited setting prior to this study was usually carried out under local infiltration plus sedation or general inhalational anaesthesia; which partly influence the need for this study. The aim of this study was to compare the effects of the addition of fentanyl, and saline on different doses of bupivacaine on spinal anaesthesia for herniorrhaphy. **Methods:** Forty ASA I-II adult patients were randomized to three groups, to have open inguinal herniorrhaphy under bilateral spinal anaesthesia; using 12.5mg bupivacaine plus 25µg fentanyl (BF group), 12.5mg bupivacaine plus 0.5mls 0.9% saline (BS group), 15mg bupivacaine only (BO group). The sensory block height, the bromage score, time to home readiness and patient satisfaction, were assessed and analyzed with spss 18.0. **Results:** There were statistically significant differences in the sensory block levels (P=0.027), and in requirements for rescue analgesia (P < 0.001), among the groups. There was no significant difference among the groups in the Bromage score (P =0.889), and patient satisfaction (P= 0.261). The criteria for home readiness in hours were fulfilled after, 6.16hours ± 1.33 for BFgroup; 5.8hours ± 1.24 for BS group; 9.80hours ± 3.65 for BO group. **Conclusions:** In inguinal hernia repair under bilateral spinal anaesthesia, 12.5mg intrathecal hyperbaric bupivacaine, with or without fentanyl will provide an effective/satisfactory surgical anaesthesia; increasing the dose further has no additional benefit, but delayed home readiness times.

Key-words: Home readiness, Patient satisfaction, Sensory/motor characteristics, Spinal anaesthesia

INTRODUCTION

Inguinal hernia repair remains the commonest operation performed by general surgeons all over the world,[1] and anaesthesia options include general, regional, or local anaesthesia; usually in day-case settings.[2]

The spinal anaesthesia is widely used for inguinal hernia repair, providing a fast onset and effective sensory/motor blockade.[3] The repair of inguinal hernias in our resource limited setting prior to this study was usually carried out under local infiltration plus sedation or general inhalational anaesthesia; which partly influence the need for this study. The methods of anaesthesia used for hernia repair do not affect the long-term outcome, but there is paucity of literature on this subject.[4]

Literature evidence suggests that regional anaesthesia was superior to general anaesthesia for reducing postoperative pain.[2-4]

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Spinal anaesthesia was associated with a higher incidence of urinary retention and increased time to home-readiness (especially large doses of bupivacaine) compared with local or field block.[5-7]

Mixing adjuvants with local anaesthetic solutions (L.A) usually reduces the density or baricity of the local anaesthetic, which is a major determinant of spread of the L.A in the CSF, and block height; in addition, to the gravitational effects of patient positioning, the clinical technique, and patient characteristics. In addition, opiods increases mean spread and delays regression.[8]

Low-dose mixtures of hyperbaric bupivacaine and fentanyl is commonly used in day-case spinal anaesthesia, it improves duration and quality of sensory block in adult surgical/obstetric population.[9-12]

Hyperbaric solutions are more predictable with greater spread in the direction of gravity, may be associated with increased incidence of cardio-respiratory side-effects, and requirement for treatment e.g. vasopressors.[8,13] In addition, studies on the effect of doses suggests that a change in dose will be accompanied by a change in either volume or concentration, others say there is no difference.[8]

The aim of this study was to compare the effects of the addition of 25 µg fentanyl or dilution with 0.5ml saline, and different doses of bupivacaine (12.5 or 15mg), on spinal anaesthesia for open inguinal hernia surgery.

MATERIALS AND METHODS

The approval of the Research and Ethics Committee of the Ekiti State University Teaching Hospital (EKSUTH), and informed consent was obtained from each patient. The aim of this interventional study was designed to compare the effects of the addition of 25µg fentanyl or dilution with 0.5ml saline and different doses of bupivacaine (12.5 or 15mg) on spinal anaesthesia for open inguinal hernia surgery.

The objectives are: 1) To compare among the groups, the effectiveness of analgesia by the absence of pain, and the need for intraoperative rescue fentanyl using, Verbal Rating Scale (VRS) 0 to3. 2) To compare among the groups sensory and motor block characteristics; based on sensory dermatomal levels, and modified bromage score; assessing patient's ability to flex knees and ankles respectively. (On a scale of 0 to 3): 0 = no motor block, full flexion of knees and feet; 1=partial block, just able to move knees and feet; 2=almost complete block, only able to move feet; 3=complete block, unable to move feet and knees. 3) To compare among the groups the patients' level of satisfaction, and times of home-readiness.

Design: This was a comparative prospective randomized double blind interventional study.

Settings/participants: Forty ASA I-II adult patients scheduled for open inguinal herniorrhaphy participated in the approved study. Excluded from the study were patients < 18 and >80 years, ASA class > II, emergent cases and patients with full stomach. Pre-operative evaluation, results of routine investigations and the patient's weights were documented in the case notes. Informed consent was obtained following detailed explanation of the study; including patient's familiarization with the pain assessment tool-Verbal Rating Scale –VRS; (0= no pain on prompting, 1=Mild pain, 2=Moderate pain, 3=Severe pain), which was used for the study. On arrival in the operation theatre, vital signs monitoring was instituted using multi-parameter patient monitor (Gima-model B3). All the patients received 500mls normal saline pre-hydration, before measuring the baseline values of Diastolic (DBP), Systolic (SBP) Arterial Pressures, Heart rate (HR), ECG, and SPO_2- that were recorded every five minutes until the end of surgery. The patients were randomly allotted by secret ballot to three groups (BF, BS, BO); BF group-received 12.5mg intrathecal bupivacaine(2.5mls) plus 25µg fentanyl(0.5mls); BS group-received 12.5mg bupivacaine(2.5mls) plus 0.5mls (0.9%) saline-placebo, BO group-received 15mg bupivacaine(3mls) only; prepared by a research assistant according to the group assignment, before instituting the spinal block. The volume of the injected solution was kept constant at 3mls, including addition of fentanyl or saline as required. A 25gauge Quincke spinal needle was inserted aseptically at L3- L4 intervertebral space, midline-sitting position, and the study drug was injected slowly after confirmation of free flow of cerebrospinal fluid. Thereafter, sterile back dressings applied and all patients maintained in supine position. Patients were adjudged ready for surgery when complete loss of pinprick sensation at T10 was reported, and concomitant inability to lift the lower limbs. Times from the end of the spinal injection to readiness for surgery (onset time), as well as maximal level of sensory block, and times of home readiness were recorded. The criteria for home readiness were stable vital signs, ability to tolerate liquid by mouth and pass urine, with no nausea or pain. Clinically relevant hypotension was defined as SBP less than 30% of baseline, and treated with ephedrine injection, as appropriate. Rescue analgesia (graded 0 or 1) with i.v 1µg /kg fentanyl, was offered for ineffective analgesia in the intraoperative period (VRS>1; assessed every 5 minutes after skin incision until the end of the operation). The patients' level of satisfaction with the anaesthetic technique was graded using a 3point scale: 0-dissatisfied (I would prefer a different anaesthetic technique for future operations), 1-undecided, 2- satisfied (I will accept the same procedure if required in the future). In the recovery room, pain was assessed using the VRS 0-3, every 15minutes for 2 hours; IV 30mg pentazocine was given for pain control when required. In addition, analgesic tablets (diclofenac 50mg twice daily for 72 hours and Paracetamol 500mg twice daily for one week) was given to all patients to take home. Post-operatively, the time of urine voiding, block resolution, ambulation, and home readiness were observed.

The outcome measures are maximal height of block, bromage score, haemodynamic effects, rescue analgesia, postoperative pain scores, time of home-readiness, and patient satisfaction were determined. Data entry and analysis was performed with SPSS 18.0 statistical package (Inc. Chicago, Illinois). Data was assessed for normal distribution of variance using Kolmogorow- Smirnow and Shapiro-Wilk. Levene statistic for Homogeneity of variances was done. Demographic data, onset times of surgical block, and surgery times were analysed with the analysis of variance. The Tukey and Tamhane, "Post Hoc" Tests for multiple comparisons were done. Categorical variables were analyzed using Chi-square test. A P-value of 0.05 would be significant.

RESULTS

Forty patients (14 in group BF, 12 in group BS, 14 in group BO) completed the study according to protocol and were included in the analysis. The demographic data and other categorical variables were compared among the groups, using Chi-square analysis; there was no significant differences in median age=55.00 ± 16years, (P=0.263), sex (P=0.386), weight (p=0.330) and ASA physical status classification (P=0.526), among the groups. There were differences in the onset time of surgical anaesthesia among the 3groups, BF=12.14 ±4.33; BS=17.58 ± 6.83; BO=8.93 ±2.95minutes (P<0.001).

The mean duration of surgery were 61.86 ± 21.81; 61.50 ± 15.61; and 63.93 ± 26.55 minutes for groups BF, BS, BO respectively, P= 0.954. The differences in the sensory level recorded among the groups were compiled in Table 1. The maximal sensory block was obtained in group BO with 50% of patients having sensory block level >T8 (n=7); group BS 8.3% (n=1); group BF 0% (n=0).There were differences in the maximal sensory block recorded for the groups; P=0.027.

The differences in the motor block according to the Bromage score among the groups were compiled in Table 2 (p=0.889). The differences among the groups in their requirement for intraoperative rescue analgesia were as shown in Table 3. (p < 0.001)

Haemodynamic values were stable among the groups: SBP, P=0.643; DBP, P=0.643. There was no significant difference in postoperative pain scores (VRS) P=0.083. The difference among the groups in the level of patient satisfaction is as shown in Table 4. (p=0.261)

The criteria for home readiness were fulfilled after;
6.16hours ± I.33, CI 5.39-6.93 in group BF;
5.8hours ± I.24, CI 4.97-6.55 in group BS;
9.80hours ± 3.65, CI 7.69-11.91 in group BO.
Overall, mean of 7.32 ± 2.98, CI 6.36-8.27. (Using One-way Anova). Significant level by Kolmogorow Smirnow and Shapiro-Wilk <0.001. Levene statistic was significant 0.002; Anova between groups <0.001. Post Hoc Tests for multiple comparisons are compiled in Tables 5&6

Table 1: Sensory Block Level

Number (n) group. %.	Sensory block level					Total
	T12	T10	T8	T6	T4	
BF.n %	0 (0%)	1 (7.1%)	13 (92.9%)	0 (0%)	0 (0%)	14 (100%)
BS.n %	0 (0%)	2 (16.7%)	9 (75.0%)	1 (8.3%)	0 (0%)	12 (100%)
BO.n %	1 (7.1%)	2 (14.3%)	4 (28.6%)	5 (35.7%)	2 (14.3%)	14 (100%)

Table 2: Motor Block Level

Number (n) group %.	Bromagescore			Total
	1	2	3	
BF.n %	1 (7.1%)	3 (21.4%)	10 (71.4%)	14 (100%)
BS.n %	2 (16.7%)	3 (25.0%)	7 (58.9%)	12 (100%)
BO.n %	2 (14.3%)	2 (14.3%)	10 (71.4%)	14 (100%)

Table 3: Requirement for Intraoperative Rescue Analgesia

Group/Number (n) %	Rescue Analgesia		Total
	None	Yes	
BF.n %	12 (85.7%)	2 (14.3%)	14 (100%)
BS.n %	4 (33.3%)	8 (66.7%)	12 (100%)
BO.n %	14 (100%)	0 (0%)	14 (100%)

Table 4: Level of Patient Satisfaction

Number (n) group %	Patients' Satisfaction			Total
	Dissatisfied	Undecided	Satisfied	
BF.n %	0 (0%)	3 (21.4%)	11 (78.6%)	14 (100%)
BS.n %	1 (8.3%)	6 (50.0%)	5 (41.7%)	12 (100%)
BO.n %	0 (0%)	5 (35.7%)	9 (64.3%)	14 (100%)

Table 5: Home Readiness Times-Comparisons.

Post Hoc Tests	Multiple Comparisons	Significance
Tam hane	BF versus BO	0.008
	BF versus BS	0.004
	BO versus BO	0.008
	BO versus BS	0.004
	BS versus BF	0.823
	B S versus BO	0.004

Table 6: Home Readiness Times Significance.

A, B, C	N	Subset for alpha=0.05	
		1	2
Tukey BF	14	6.1600	-
BS	12	5.7625	-
BO	14	-	9.8021
Sig.	-	0.905	1.000

DISCUSSION

The present study demonstrates that, 12.5mg intrathecal hyperbaric bupivacaine produces an effective bilateral anesthesia for open inguinal herniorrhaphy, with or without fentanyl or saline dilution(s).

The mean duration of surgery, haemodynamic variables, motor block, and post-operative pain scores (VRS); the reported level of patient satisfaction, and number of doses of analgesics needed during the postoperative period was similar in all groups.

There were differences in the onset time of surgical anaesthesia among the 3groups; BO had the fastest onset of block, BF was intermediate, and BS was the longest. Which agrees with the findings of Critchley and colleagues; who reported the occurrence of early onset of sensory blockade in the hyperbaric group compared with the mixed group.[9-13] Thus, hyperbaric injectate and increasing dose enhances intrathecal spread and therefore the onset times of spinal anaesthesia,[8] but with drawbacks.[13]

There were statistically significant differences in the maximal sensory block levels among the groups-table I; group BO had a significantly higher spread of sensory analgesia (2 to 4 dermatomes) than groups BS and BF, this disparity in sensory levels was similar to the findings of Ben-David and colleagues[14] who compared hyperbaric 0.5% bupivacaine with serial saline dilutions of bupivacaine. In our study, group BO had 50% of patients with cephalad spread to T6-T4, and over 90% in BF and BS had restricted spread to T10-T8. Group BO had higher cranial spread, probably because of interplay of dose/concentration, and baricity; suggesting that the height of block is proportional to the concentration of the local anaesthetics according to the review of literature by Hocking and Wildsmith.[8] In addition, our study showed that fentanyl did not exact any influence on the maximal cephalad spread of intrathecal bupivacaine.

There was no significant difference among the groups in the Bromage score-Table 2. BF and BO had the greatest score (more dense motor block). In day-case surgery, it is desirable to avoid profound motor block, in other to ensure early mobilisation and discharge.[14]

We achieved 100% success rate for surgical readiness (T10 spinal block, end-point) in each group. Our study fail to observe significant CVS side-effects requiring treatment, which contradicts the expected CVS changes with large doses of hyperbaric bupivacaine (15mg), which was reported in some studies.[8,13]

There were significant differences among the groups in requirement for rescue analgesia Table 3. Intraoperative fentanyl requirement was higher in groups BF and BS, probably because of dilutional effect; which was more in Group BS, which has no active analgesic adjunct. The fentanyl group had improved analgesia compared with the saline group, but both groups were inferior to hyperbaric bupivacaine only. Higher concentration of hyperbaric bupivacaine in Group BO gave better analgesia; therefore, no patient in Group BO required any rescue analgesia intraoperatively.

Group's BF and BS had shorter-times to home-readiness than Group BO [Tables 5&6], which confirms the findings of Santos and colleagues that spinal anaesthesia with a dose of 15mg hyperbaric bupivacaine leads to delays in the discharge times/home readiness;[15] which also agreed with the observation of Nair and colleagues that increasing the dose of bupivacaine delayed recovery times.[5]

Group BO spent longer time at the recovery room, nearly 10hours; similar to the findings in a previous study by Santos et al.[15] Group BF and BS had significantly reduced home readiness times (nearly half), and did not require overnight hospital stay; similar to the findings of Ben-David.[14] Therefore BF and BS provided acceptable depth of anaesthesia and much early home-readiness times.

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