Recovery profile of low doses of hyperbaric bupivacaine for spinal anaesthesia in day case gynaecological procedures: a randomised controlled trial

Nweze Uchenna Onochie, Ebirim Longinus Ndubuisi & Alagbe-Briggs Olubusola Temitope

Authors' Addresses
Nweze Uchenna Onochie Senior Registrar
Ebirim Longinus Ndubuisi Consultant
Alagbe-Briggs Olubusola Temitope Consultant

Department of Anaesthesiology, University of Port Harcourt Teaching Hospital, Port Harcourt, Nigeria.

Correspondence: Dr L N Ebirim, Department of Anaesthesiology, University of Port Harcourt Teaching Hospital. Port Harcourt
Email: longinus.ebirim@uniport.edu.ng *Tel:* +2348033384198

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Abstract

Background: Use of spinal anaesthesia is gaining popularity for day-case gynaecological procedures which are of short duration. However, complications associated with use of lidocaine for spinal anaesthesia made an alternative necessary. This study compared the recovery profile and home readiness of patients using 12.5mg, 10mg, and 7.5mg of hyperbaric bupivacaine for subarachnoid block in day-case gynaecological procedures lasting not more than one hour.

Methods: Following ethical committee approval, ninety patients, aged 18–45 years with ASA class I or II scheduled for day case gynaecological procedures, who gave informed consent, were randomly allocated into 3 groups (K, Y or C). They received intrathecally, 2.5ml, 2.0ml and 1.5ml respectively of 0.5% hyperbaric bupivacaine made up to 3mls by adding 0.5ml, 1ml and 1.5ml each of normal saline. Intraoperative and postoperative monitoring till full recovery and discharge was observed. Data were analyzed using SPSS Version 20.

Results: The mean of maximum height of block was T5 in group K, and T6 in groups Y and C ($p<0.01$). The time until two segment regression, time to S2 regression, time to walk without support on a straight line and time to micturition decreased proportionally as the dose of bupivacaine reduced (group K>group Y>group C) ($p<0.01$).

Conclusion: Recovery and home readiness were significantly faster when 7.5mg of hyperbaric bupivacaine was used for spinal anaesthesia in day-case gynaecological procedures lasting not more than one hour compared to 10mg and 12.5mg doses.

Introduction

Ambulatory surgery is becoming popular in Nigeria because of its advantages to the patient, surgeon and the hospital. It is convenient, cost effective, reduces the demand on limited inpatient

facilities and shortens surgical waiting list[1].

The ideal anaesthesia for ambulatory procedures should provide a rapid and smooth onset of action, good intraoperative analgesia, good operating condition and short recovery time free from side effect[2]. Spinal anaesthesia is gaining popularity and acceptance in ambulatory setting because it is easy to administer, avoids airway manipulation, and provides continued post-operative analgesia. However, general anaesthesia with relaxation technique is the most commonly used anaesthesia in Nigeria.[3]

Recovery profile in spinal anaesthesia is a measure of the continual process of return of normal sensation following subarachnoid block which could be assessed using the following parameters; time to two segment regression of level of block, time to four segment regression of level of block or recovery of sensation to particular landmark segment such as T10,L1 or S2. Home readiness is when patient meets discharge criteria following anaesthesia and is usually determined by the following; ability to walk without support, ability to void, stable vital signs, and lack of side effects.

Most outpatient gynaecologic procedures are usually of short duration and lidocaine which has a short duration of action was widely used for spinal anaesthesia in such procedures[4,5]. However, lidocaine was associated with postoperative Transient Neurologic Symptoms (TNS) characterized by back pain that radiates to the buttock or lower extremities and this necessitated the need for an alternative[6,7].

Other local anaesthetics that have been used for ambulatory procedures include ropivacaine and bupivacaine[8]. Ropivacaine when compared with bupivacaine has a more rapid regression of sensory and motor block, earlier mobilization and shorter time to micturition[9]. Ropivacaine is preferred to other long acting local anaesthetics in ambulatory setting, but it is not readily available in our sub region. Bupivacaine is the readily available long acting local anaesthetic often used for spinal anaesthesia in Nigeria. It achieves very reliable block, is considered very safe in experienced hands and duration of action is known to be dose dependent. Low dose of hyperbaric bupivacaine has been used in ambulatory anaesthesia for different procedures with varying results10,11. To produce a reliable spinal anaesthesia with reasonable recovery time, it is essential to choose the optimal drug and adequate dose for specific procedures[2].

It was deemed necessary to determine if there would be a significant difference in recovery profile and time of home readiness when different low doses of hyperbaric bupivacaine that could provide adequate duration of intraoperative spinal anaesthesia are used. The purpose of this study was therefore to compare the recovery profile of low doses of hyperbaric bupivacaine in patients undergoing spinal anaesthesia for day-case gynaecological procedures.

Methods

Following approval from the Ethics and Research Committee of the University of Port Harcourt Teaching Hospital and patients' informed consent, 90 patients aged 18 – 45 years with ASA class I or II scheduled for day case gynaecological procedures were recruited into the study. Ninety ballot papers with 30 labelled with the letter K, another 30 labelled with the letter Y, and the remaining 30 each labeled with the letter C, were neatly folded and placed in an opaque envelope. After shuffling the ballot papers, each patient picked one and was subsequently allocated to the group (K, Y or C) written on the paper. The patients in group K received 2.5ml (12.5mg) of 0.5% hyperbaric bupivacaine (Duracaine Astra-Zeneca/PR Vademecum Uruguay) made up to 3ml by adding 0.5ml of

injection water. The group Y patients received 2ml (10mg) of 0.5% hyperbaric bupivacaine made up to 3ml by adding 1 ml of injection water. Group C patients received 1.5ml (7.5mg) of 0.5% hyperbaric bupivacaine made up to 3ml by adding 1.5ml of injection water.

In the theatre, equipment check was conducted, the resuscitation tray (comprising drugs atropine, adrenaline, ephedrine, suxamethonium, propofol, 0.9% sodium chloride infusion) and airway maintenance devices were set up. Baseline vital signs (pulse rate, non-invasive blood pressure, oxygen saturation and temperature) were measured and recorded. Intravenous access was secured on the non-dominant hand using size 18G cannula, and intravenous fluid preload of 10ml/kg of 0.9% normal saline over 10- 15 min given. Subsequently, the patient was placed in sitting position with the lower limb stretched in the long axis of the operating table (Hamstring stretch position). The researcher scrubbed and was appropriately gowned. While observing aseptic technique, the skin of the patient's back region was prepared with chlorhexidine and 70% alcohol and draped. The area of puncture (L3-L4 interspace) was infiltrated with 2ml of 1% plain lidocaine. The dural puncture was performed using a 26G Sprotte needle with the opening in the cephalad direction and correct placement of the spinal needle was confirmed by a backflow of the cerebrospinal fluid. Another anaesthetist wore sterile gloves and used sterile syringes to draw the local anaesthetic from the single use ampoule. Based on the patient's group, the study agent was handed to the researcher who was blinded to the study agent. The researcher then injected it into the subarachnoid space, the needle was withdrawn and a light sterile dressing placed over the puncture site before immediately returning patient to the supine position. The time of injection of drug was noted. The sensory block level was tested using alcohol swab. The sensory level was tested bilaterally along the midclavicular line every 2 min until the level was stabilized for three consecutive tests which was noted as the highest dermatomal level. Thereafter, the patient was placed in lithotomy position and procedure commenced. Patient was excluded from further participation in the study when the level of sensory block was not adequate for the procedure (less than T10). The intraoperative heart rate and blood pressure (SBP, DBP &MAP) were monitored every 2 min for the first 10 minutes then every 5 minutes until the end of procedure. Hypotension was taken as a decrease in systolic blood pressure below 20% of baseline and was treated with intravenous ephedrine, 5mg bolus which was repeated every 5 min until the desired response was obtained.

At the end of the procedure, patients were transferred to PACU and handed over to PACU staff who did not know what study agent the patients received. The researcher continued sensory level testing every 20 minutes, and motor block assessment was also done every 20 min using the Bromage Score (1= able to raise legs above the table, 2= able to flex knee, 3= able to move feet only, 4= no movement in the leg or feet). When a sensory level S2 and Bromage score of 1 were achieved, which was the point when sensation was expected to have returned to the legs, patient was asked every 10 min to ambulate and void urine. The time until two segment regression, time to walk without support on a straight line and time of first postoperative micturition was noted. The patient was assumed to be ready for discharge when the following criteria were met: stable vital signs, walk without support in a straight line, successful voiding, absence of nausea, vomiting and dizziness. Before discharge, patient was given a phone number to communicate with in case of any complication and asked to have a good rest for the day. On the 2nd post-operative day, the patient was contacted by the researcher. Based on a uniform questionnaire, patient was asked if they had headache especially when in upright position, Back pain radiating to the buttock or

legs, or pain at the injection site. Those with headache were encouraged to lie in supine position, rehydrate adequately and take analgesics. If it did not resolve after 48 hours, they were readmitted for epidural blood patch treatment. Any patient with complication was contacted daily until resolution of the complication. Also patient's satisfaction with the anaesthesia was obtained using the following scales: (1) Very satisfied (2) Satisfied (3) Not satisfied

Data analysis: Analysis of the results of this study was performed on an intention to treat basis. Data was entered into a spreadsheet and analyzed using the statistical package for social sciences (SPSS) version 20 for windows. Tables were used to present results, and expressed as median, proportion, range, and mean ± standard deviation. Data was assessed for normal distribution of variance using Shapiro-Wilk. Parametric data (time of Maximum block height, time until two segment regression, time to S2 segment, time to walk without support on straight line and time of micturition) were analysed using analysis of variance (ANOVA). The Turkey 'Post Hoc" test for multiple comparisons was done. Categorical variables such as complications, level of satisfaction, Type of procedures done were analyzed using chi-square test. A p-value of <0.05 was considered statistically significant.

Results

A total of 90 patients were recruited for the study. All of them participated throughout the study and intraoperative analgesia was adequate in all the 3 groups. The mean of maximum height of block was T5 in group K, then T6 in groups Y and C ($p<0.01$).

The time until two segment regression, time to S2 regression, time to walk without support on a straight line and time to micturition showed similar pattern, decreasing as the dose of bupivacaine reduced (group K>group Y>group C).

The time until two segment regression in group K was 71.23±10.89 minutes, in group Y it was 64.80±6.84 min and in group C it was 60.73±15.36 minutes. Significant difference existed only between groups K and C ($p=0.003$).

The time until S2 regression reduced from group K to group Y and from group Y to group C. There was significant difference between groups K and C, and between groups Y and C, but no significant difference between groups K and Y.

Time to walk without support on a straight line was highest in group K and lowest in group C. There was significant difference when group K was compared with group Y and group C, and also between groups Y and C ($p<0.01$).

Time to micturition was 346.87±23.62 minutes in group K, 320.20±38.38 minutes in group Y and 313.40±27.57 minutes in group C. There was significant difference when group C was compared with groups K and Y, but no significant difference between groups K and Y.

When level of satisfaction of the patients following spinal anaesthesia was assessed, 54(60%) were very satisfied, 34 (37.8%) were satisfied, while 2 (2.2%) were not satisfied. Among the very satisfied were 16 (29.6%) in group K, 23 (42.6%) in group Y and 15 (27.8%) in group C. Among the satisfied patients 13 (38.2%) were in group K, 7 (20.6%) were in group Y while 14 (41.2%) were in group C. Only one patient each from group K and group C were not satisfied.

Table I Patient's Characteristics.

Variable	GP K (n=30)	GP Y (n=30)	GP C (n=30)	p = value
Age (years)				
Mean ± SD	34.83±4.46	35.13±5.16	35.13±5.16	
BMI (kg/m²)				
Mean± SD	25.93±2.7	26.00±2.13	26.13±3.80	0.965
Weight (kg)				
Mean± SD	69.10±6.67	69.87±6.67	69.60±11.83	0.942
Height (m)				
Mean±SD	163.80±4.17	163.40±6.28	162.73±5.84	0.751
ASA I/II	24/6	22/8	22/8	0.786
SD – Standard Deviation n – Number				

p<0.05 is considered significant

Table II Block Characteristics.

Variables	Group K (n=30)	GP Y (n=30)	GP C (n=30)	p = value
Maximum block Level				
Mean ± SD	T5 ± 1.51	T6 ± 0.81	T6 ± 0.86	<0.01
Time Until maximum block level (min)				
Mean ±SD	14.17± 1.93	13.73± 1.59	11.87± 2.73	<0.01
Time to 2 segment Regression (min)				
Mean ±SD	71.23± 10.89	64.80± 6.84	60.73±15.86	0.003
Time until S2 Regression (min)				
Mean ±SD	237.20± 29.61	196.33± 30.55	172.93± 32.03	<0.01
Time to walk without support on straight line(min)				
Mean ±SD	281.07±26.95	243.53±23.32	201.27±28.05	<0.01
Time until Micturition (min)				
Mean ±SD	346.87±23.62	320.20±38.38	313.40±27.57	<0.01

p<0.05 is considered significant

Discussion

This study demonstrated that decreasing the dose of intrathecal bupivacaine employed for spinal anaesthesia decreased the time for recovery and home readiness in day case gynaecological surgical procedures. The time until two segment regression from maximum block level, the time of regression of block to S2 segment, time to walk without support on a straight line and time of micturition were significantly longer in 12.5mg group than 10mg group and 7.5mg group in that order. These findings are supported by previous studies[11,12]. However, the doses of intrathecal hyperbaric bupivacaine studied were all effective for outpatient gynaecological procedures lasting less than 1 hour.

Previous studies by Ben-Davies et al11 and Veena et al[12] demonstrated a similar pattern with the present study and suggested that higher block levels were achieved with higher doses of hyperbaric bupivacaine and significant difference was not found when comparing low doses. These findings were also in line with suggestions by Hockings and Wildsmith[13] that a higher dose of intrathecal local anaesthetics produces higher maximum block height compared to a lower dose and the difference is more obvious with wide difference between the doses being studied.

Veena and colleagues[12] reported similar findings with present study on two segment regression; their result showed that the time of two segment regression reduced with decreasing doses however they observed a longer time of two segment regression than equivalent doses used in this study. The methods used in testing for sensation in the two studies were however noted to be different; while pain sensation test with needle prick was used by Veena et al[12], cold and warm sensation test with alcohol swab was used in present study. Cold/Hot testing of sensation along dermatomes is often more sensitive than Pin prick testing of sensation because the needle has a small area of stimulation and can miss pain spots giving wrong interpretation. Unlike the needle, the cold alcohol swab is rolled over the skin across the area of the dermatome giving a wide area of stimulation. Huffnagle et al[14] observed significant difference in time of two segment regression when undiluted 0.5% hyperbaric bupivacaine 5mg, 7.5mg, 10mg and 12.5mg were given for post-partum tubal ligation. The use of undiluted concentration of 0.5% hyperbaric bupivacaine in their study may be the reason for the observation of significant difference even in very low doses. Dilution of hyperbaric local anaesthetics reduces the baricity and concentration thereby making the spread and recovery less predictable compared to the undiluted local anaesthetic.

The time until S2 segment regression equally decreased across the groups as the dose decreased and there was significant difference in the values between all the groups. This result is comparable to equivalent doses of hyperbaric bupivacaine used by Veena et al and it is not surprising as both studies used constant volumes while varying the concentration of the intrathecal bupivacaine. S2 segment (medial half of calf) regression was used in this study to assess block regression because of the convenience to the patients compared to S3, S4 or S5 where sensation is assessed in the perineal region.

Time to walk without support on a straight line indicated complete motor block recovery in the present study and there was significant difference across the groups ($p<0.01$). The motor block is achieved by blocking the $A\alpha$ myelinated nerve fibres. These motor fibres are large and less sensitive compared to the sensory nerve fibres (C unmyelinated nerve fibres). Higher doses of local anaesthetics therefore achieve a denser and more prolonged block compared to lower doses due

to above stated characteristics of motor nerve fibres. Low doses of local anaesthetics can achieve sensory block while sparing the motor nerve block. This may explain why patients who were given lower doses of hyperbaric bupivacaine had a shorter time to walk without support in the present study. This result is similar to what was observed in other studies.[11,15,16]

The addition of opioid does not prolong the motor block and therefore does not affect the time to walk without support. Opioids bind to opioid receptors in the spinal cord and act at the synapses of sensory nerves to inhibit the transmission of nociceptive information from Aδ and C fibres without affecting the dorsal root axon and somatosensory evoked potentials. This ensures that it prolongs analgesia without affecting the motor block. To corroborate this, Unal D et al[17] did not find differences in motor recovery when they compared 4mg of bupivacaine alone group with 4mg bupivacaine plus 25µg fentanyl group. However, the diffusion of opioid into the cerebrospinal fluid and its rostral bulk flow could cause respiratory depression and PONV by affecting the respiratory centre and chemoreceptive trigger zone respectively these being unacceptable in ambulatory anaesthesia settings. These side effects therefore limit opioid use in ambulatory spinal anaesthesia.

Micturition was the last discharge criterion reached by all the participants in the present study, and therefore time to micturition was regarded to be the same as the time of home readiness in this study. The time to micturition was found to have reduced with decreasing doses. Significant difference was observed when 12.5mg group was compared with the 7.5mg group, and also between 10mg group and 7.5mg group but not between 12.5mg group and 10mg group. Most gynaecological procedures require bladder emptying intraoperatively and this may explain the longer time to micturition observed postoperatively compared to previous studies.11The first urge to void is usually at a bladder urine volume of 150ml. At a volume of 300ml, the tension receptors in the bladder are activated to create a sense of fullness. Therefore catheterizing a patient will delay the urge to urinate and hence increase time of micturition relative to those not catheterized. Urinary retention was not observed in any of the patients.

Conclusion

This study shows that diluted low doses of hyperbaric bupivacaine can be used for spinal anaesthesia in day-case gynaecological procedures lasting less than 1 hour. Recovery and home readiness is significantly faster when 7.5mg dose is used compared to 10mg dose and 12.5mg dose. The incidence of complications such as urinary retention was very low with the doses employed in this study. This could result in high levels of satisfaction with spinal anaesthesia for day-case gynaecological procedures. Therefore, for day-case gynaecological procedures of less than 1 hour duration, 7.5mg of hyperbaric bupivacaine provides early recovery and satisfactory anaesthesia, while increasing the dose further will delay recovery and home readiness.

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