International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 20s, 2025
https://www.theaspd.com/ijes.php

A Randomised Prospective Study For Clinical Comparison Of 0.5 % Hyperbaric Bupivacaine Vs 0.5% Hyperbaric Levobupivacaine For Patients Undergoing Cesarean Section Under Spinal Anesthesia

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Abstract
Background: *Subarachnoid block (spinal anesthesia) is a commonly used anesthetic technique for lower abdominal surgeries including abdominal hysterectomy. Bupivacaine 0.5% hyperbaric solution is a standard drug used due to its profound sensory and motor blockade. However, its R(+) isomer has been associated with cardiotoxicity. Levobupivacaine, the pure S(-) enantiomer of bupivacaine, offers similar anesthetic effects with improved safety and a reduced risk of cardiovascular and central nervous system toxicity.*
Aim: *To clinically compare 0.5% hyperbaric bupivacaine and 0.5% hyperbaric levobupivacaine in patients undergoing abdominal hysterectomy under spinal anesthesia, focusing on anesthetic efficacy, hemodynamic stability, and side effect profile.*
Methods: *This prospective, randomized, double-blind clinical study involved 120 female patients aged 30–60 years, ASA physical status I and II, undergoing elective abdominal hysterectomy. Patients were randomly allocated into two equal groups. Group B received 3.5 mL of 0.5% hyperbaric bupivacaine (17.5 mg), and Group L received 3.5 mL of 0.5% hyperbaric levobupivacaine (17.5 mg) intrathecally. Sensory and motor block onset, duration, regression, hemodynamic changes, and adverse events were monitored.*
Results: *Both groups achieved effective sensory and motor block suitable for surgery. Levobupivacaine exhibited better hemodynamic stability with a lower incidence of hypotension and bradycardia. It also showed faster motor recovery with minimal side effects.*
Conclusion: *0.5% hyperbaric levobupivacaine is a clinically effective and safer alternative to 0.5% hyperbaric bupivacaine for spinal anesthesia in abdominal hysterectomy. It offers comparable anesthetic efficacy with improved cardiovascular safety and shorter motor blockade duration, making it a favorable option for regional anesthesia.*
Keywords: *Subarachnoid block, Hemodynamic stability, Motor blockade, Sensory blockade.*

INTRODUCTION

A growing body of evidence suggests that spinal and epidural anesthesia are associated with reduced morbidity and mortality compared to general anesthesia. Subarachnoid (spinal or intrathecal) and epidural anesthesia are essential techniques that every anesthesiologist should master. Spinal anesthesia involves the subarachnoid injection of a small dose of local anesthetic, usually in the lumbar region below the termination of the spinal cord, which produces rapid and dense surgical anesthesia.

This technique is especially effective for surgeries involving the lower abdomen, pelvis, and lower limbs. Most spinal anesthetics are administered as a single injection and typically last for 2 to 3 hours. Spinal or epidural anesthesia is often preferred over general anesthesia for cesarean sections due to more stable hemodynamics, smoother recovery, and lower maternal mortality.

Spinal anesthesia for cesarean delivery commonly utilizes local anesthetics, opioids, or both, to block pain and induce muscle relaxation. Widely used local anesthetics include lidocaine, bupivacaine, ropivacaine,

prilocaine, etidocaine, and levobupivacaine. Among these, 0.5% hyperbaric bupivacaine is frequently used due to its long duration of action and suitability for procedures lasting 2–2.5 hours. However, bupivacaine is known for higher cardiotoxicity and more pronounced hemodynamic effects.

Levobupivacaine, a newer amino amide local anesthetic, is the S-enantiomer of bupivacaine. It acts by inhibiting sodium ion influx and has demonstrated a lower risk of cardiotoxicity and neurotoxicity. Studies suggest it offers a better pharmacokinetic profile, milder cardiovascular and central nervous system effects, and more predictable sensory blockade.

This prospective randomized study compares the clinical effects of 0.5% hyperbaric bupivacaine and 0.5% hyperbaric levobupivacaine in patients undergoing cesarean section under spinal anesthesia, aiming to evaluate their efficacy and safety profiles.

REVIEW OF LITERATURE

The first documented case of spinal anesthesia in humans was performed by August Bier in 1898 using cocaine. This marked the beginning of neuraxial anesthesia. Subsequently, different local anesthetics were introduced for spinal use: procaine by Braun (1905), tetracaine by Sise (1935), lidocaine by Gordh (1949), chloroprocaine by Foldes and McNall (1952), mepivacaine by Dhunér and Sternberg (1961), and bupivacaine by Emblem in 1966. The 1980s saw the introduction of ropivacaine and levobupivacaine for spinal anesthesia.

The first intrathecal use of morphine was reported in 1901 by Racoviceanu-Pitesti. That same year, Cathleen described caudal anesthesia. Lumbar epidural anesthesia was first introduced by Pagés in 1921, followed by Dogliotti's loss-of-resistance technique in the 1930s, and continuous caudal anesthesia in obstetrics by Hingson in 1941. In 1947, Curbelo described lumbar epidural catheterization for surgery. Epidural morphine analgesia was first reported by Behar in 1979.

Despite the growing experience with neuraxial techniques, setbacks occurred, such as the Woolley and Roe case of paraplegia following spinal anesthesia in 1954. Additionally, adhesive arachnoiditis was reported with spinal chloroprocaine in the 1980s, and cauda equina syndrome was observed with continuous spinal lidocaine anesthesia in the early 1990s. More recently, concerns about epidural hematoma have arisen with the use of newer anticoagulants like LMWH and antiplatelet agents such as clopidogrel.

Spinal anesthesia is often preferred for non-emergent cesarean deliveries. It is faster, easier to administer, provides denser sensory block, and is more cost-effective compared to epidural anesthesia. However, it has a higher risk of maternal hypotension. This risk can be mitigated by left uterine displacement, appropriate fluid therapy, and vasopressors. Colloids have been found to be superior to crystalloids in preventing spinal-induced hypotension.

Hyperbaric bupivacaine is widely used in lower abdominal surgeries, including cesarean sections. However, due to its cardiotoxicity, newer agents like levobupivacaine are gaining popularity.

Singh A et al. (2018) compared levobupivacaine and bupivacaine in inguinal hernia surgeries. They concluded that levobupivacaine produced shorter sensory and motor blocks, allowing faster recovery and lower intraoperative hypotension—making it a viable alternative in day care surgeries.

Thakore S et al. (2018) compared low-dose hyperbaric 0.5% levobupivacaine and bupivacaine with fentanyl in MTP with sterilization. They found that 7.5 mg levobupivacaine provided better analgesia and sensory blockade with minimal motor block, suggesting it may be more suitable for day care surgeries.

Leong B et al. (2016) found that hyperbaric bupivacaine had superior anesthetic effects compared to isobaric bupivacaine in cesarean sections.

Sanansilip V et al. (2011) conducted a double-blind study comparing hyperbaric and isobaric 0.42% levobupivacaine in gynecological surgeries. Hyperbaric levobupivacaine demonstrated more predictable sensory block levels and better surgical efficacy.

Kaya M et al. (2010) evaluated hyperbaric vs. hypobaric levobupivacaine in unilateral spinal anesthesia for knee arthroscopy. Both provided satisfactory results, but hyperbaric levobupivacaine yielded more consistent unilateral block and hemodynamic stability.

Luck J et al. (2008) compared hyperbaric bupivacaine, levobupivacaine, and ropivacaine in spinal anesthesia. All agents were effective; however, ropivacaine offered a shorter duration of action. No significant differences were found between bupivacaine and levobupivacaine groups.

Aims And Objectives

The aim of present randomized prospective study is to compare the effect of 0.5% hyperbaric bupivacaine and 0.5% hyperbaric levobupivacaine in cesarean section under spinal anesthesia with following objectives.

Primary Objectives

1. To compare the onset and duration of sensory blockade after administration of 0.5% hyperbaric bupivacaine and 0.5% hyperbaric levobupivacaine.
2. To compare the onset and duration of motor blockade after administration of 0.5% hyperbaric bupivacaine and 0.5% hyperbaric levobupivacaine.
3. To compare the time taken for two dermatome sensory regression to S1 after administration of 0.5% bupivacaine and 0.5% hyperbaric levobupivacaine.

Secondary Objectives

1. To compare the haemodynamic changes of systemic blood pressure and heart rate.
2. To observe any side effects due to bupivacaine or levobupivacaine during the study period.

MATERIAL AND METHOD

After approval from the institutional ethical committee of Swami Vivekanand Subharti University, Meerut the present randomised double blind prospective study for clinical comparison of intrathecal 0.5% hyperbaric Bupivacaine and intrathecal 0.5% hyperbaric Levobupivacaine in patients undergoing cesarean sections under spinal anesthesia will be conducted.

Place Of Study- The present study will be conducted at Chhatarpati Shivaji Subharti hospital of Subharti medical college affiliated to Swami Vivekanand Subharti university Meerut, UP.

Duration Of Study- This study will be conducted over a period of 24months from October 2022 to September 2024.

Study Design- A single centre prospective randomized double blind clinical study.

Inclusion Criteria-

The present prospective double blind randomized study shall be done on 116 patients of :

- Physical status ASA grade I , II & III
- pregnant females undergoing cesarean section
- Weighing 55-85kg
- Scheduled for cesarean section of 60-80 minutes duration at Department of Anesthesiology and Critical Care of C.S.S. Hospital associated to Subharti Medical College Meerut.

Exclusion Criteria-

- Uncooperative patient.
- Refusal to technique or enrolment for study.
- Patients with physical status of ASA grade IV or greater.
- Patients with history of severe cardiac or pulmonary disease, poorly controlled hypertension.
- Morbidly obese patients, neurologic or psychological disease, hepatic or renal dysfuction, endorcrinal or metabolic disorders.
- Deformity/Abnormality of spinal column.
- Bleeding or coagulation disorder.
- Known hypersensitivity to study drugs or using any drug that modifies pain perception.
- Infection at site of lumbar puncture.

Written Informed Consent- A written informed consent will be taken from each patient or her

legally authorised relative after explaining the research protocol and all the possible complications related to the procedure in the language patient understands. Patient will be assured that she is free to ask any question regarding the study at any stage and can continue or dropout from the study. The informed consent will be signed by the subject, the investigator and a witness unrelated to the research study.

Study Population Size

Preliminary sample size is decided in consultation with a statistician and is based in order to detect a 30minute difference in mean duration of sensory and motor blockade between the groups for type 1 error of 0.01 and power of 90% which indicated that approximately 58 patients should be included in each group. Assuming a 5% drop out rate, the final sample size is set at 116patients.

Randomization Of Study Groups

The total 116 adult consented patient will be divided into two equal groups of 58 patients each, according to computer generated random number table.

Group 1 (n=58)- Patients will be receiving intrathecal 2.5ml of 0.5% hyperbaric bupivacaine (12.5mg)

Group 2(n=58)-Patients will be receiving intrathecal 2.5ml of 0.5% hyperbaric levobupivacaine (12.5mg)

Blinding Of Study Groups

- Group allocation and study drug preparation in group labelled envelopes will be done by first anesthesiologist who will be unaware of the study and drug will be given by second anesthesiologist.
- Observation will be done by another resident who is unaware of the study.
- Data will be collected by resident who will be blinded about the group allocation.
- Even patient will also not be aware about the group allocation.

ANESTHETIC TECHNIQUE

Pre-anesthetic evaluation of the patients will be done before surgery with their clinical history, physical examination and routine investigations.

After arrival in the operation theatre, standard monitors for heart rate, electrocardiogram, pulse oximetry and non-invasive arterial blood pressure will be attached to continuous monitoring of vital parameters. Sedatives and hypnotics inclusive of opiods will be avoided in premedication as well as intra-operatively.

Intravenous line 18G intracath shall be secured in the non-dominant forearm and all the patients will be preloaded with 10ml/kg Ringer Lactate solution before initiation of subarachnoid block. Before the commencement of spinal anaesthesia, all patients shall be instructed on the methods of sensory and motor assessments.

The subarachnoid block will be carried out under all aseptic precaution. Patients will be asked to sit on operating table with elbows resting on thighs. The skin of back will be cleaned with aseptic savlon solution (40% cetrimide) followed by iodine containing sterilizing solution(5% povidone iodine), then with alcohol containing solution and will be draped with sterile sheets.

The operator will take full sterile precautions, including wearing the gown, mask and gloves. The L2-L3 or L3-L4 intervertebral space will be identified using Tuffier's line as a bony landmark and a narrow gauze 25G Quincke's spinal needle will be inserted in the identified space through midline approach. After identification of the correct placement by the free flow of spinal fluid from the needle, study drug solution will be injected slowly at the rate of about 0.1ml/sec into the subarachnoid space according to group selection. Immediately after intrathecal injection,the patient will be made to lie supine.

Sensory And Motor Block Characteristics

The sensory and motor block characteristics will be assessed after the intrathecal injection of study drug solution at 2 minutes interval till the surgical anesthesia is achieved. The segmental level of sensory block will be assessed by pin prick test bilaterally along the mid clavicular line by using short beveled 26G hypodermic needle.

The motor block of the lower extremities will be evaluated bilaterally by MODIFIED BROMAGE

SCALE(0-3)
0=Full movement and able to raise straight leg against resistance 1=Unable to raise extended leg at the hip but able to flex knee.
2=Unable to flex the knee but able to move ankle joint 3=Unable to move hip, knee, ankle(no motor activity)
The surgical anesthesia will be considered when at least T6 dermatome level is anesthetized.
The onset time of both sensory and motor blockade, maximum cephalic dermatome level of sensory blockade and total time of both sensory and motor blockade will be recorded. Side effect of nausea, vomiting, sedation, itching and shivering will also be noted and shall be managed accordingly.

Hemodynamic Parameters

After institution of subarachnoid block, the hemodynamic parameters of systemic arterial blood pressure, heart rate, pulse oximetry and electrocardiography shall be monitored at every 5minutes interval till 30minutes then at 10 mins interval till the end of surgery and followed by at every 30 minutes interval postoperatively till 4 hours.
For the present study hypotension will be defined as systolic arterial blood pressure of less than <100mm Hg and will be treated primarily by increasing the intravenous crystalloi infusion rate and additionally with mephentermine 6mg IV if required. Bradycardia is defined as heart rate <60beats/minute and shall be treated with IV Atropine 0.6mg.
Intraoperative requirement of any analgesic medication, respiratory depression (defined as respiratory rate of less than 10breaths/minute or SpO2<95% on room air), shivering, nausea and vomiting or any drug induced side effects will also be recorded. Respiratory discomfort will be managed by administration of oxygen @2-3L/min by face mask. Nausea and vomiting will be treated by injection ondansetron(4-8mg)

STATISTICAL ANALYSIS

The results obtained in the study shall be presented in a tabulated manner as Mean ±SD and will be analyzed using Microsoft excel and SYSTAT(Version 13.2). The demographic data for categorical variables will be compared using Chi square test and statistical significance in mean difference will be done by using student Anyalysis of Variance(ANOVA).Block characteristics will be compared using Mann Whitney U test. A p value of <0.05 will be considered statistically significant. And <0.001 will be considered statistically highly significant.

CONCLUSION

This study highlights that 0.5% hyperbaric bupivacaine remains a widely used agent for spinal anesthesia due to its strong sensory and motor blockade and prolonged analgesia. However, 0.5% hyperbaric levobupivacaine, at equipotent doses, provides effective anesthesia with stable hemodynamics, fewer side effects, and shorter motor block—facilitating early mobilization, which is especially beneficial in geriatric patients undergoing hysterectomy.
Thus, hyperbaric levobupivacaine is a safe and efficient alternative to bupivacaine for spinal anesthesia in total abdominal hysterectomy.

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