



# Efficacy of plain bupivacaine and hyperbaric bupivacaine in spinal anesthesia for elective cesarean section (Randomized control trials)

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## Abstract

**Objective.** Bupivacaine is a frequently utilized local anesthetic for spinal anesthesia, typically administered as a basic solution or a hyperbaric mixture. The ideal solution usage for regional intrathecal anesthesia preferable to has rapid onset & consistent duration, with fewer incidence of unpleasant effects.

**Methods.** Sixty patients who underwent cesarean section surgeries have been randomized into both groups. Group isobaric bupivacaine IB (number= thirty patients) received plain bupivacaine 10 mg + 20 mcg fentanyl. Group hyperbaric bupivacaine HB (n= 30 patients) hyperbaric bupivacaine 10 mg + 20 mcg fentanyl in spinal anesthesia for optional cesarean sections. Injection has been made intrathecally in sitting position or left lateral approach at L3-4 interspace.

**Results:** the commencement of motor blocks with hyperbaric bupivacaine has been sooner ( $1.8 \pm 0.6$ ) when assessed versus to isobaric ( $4.0 \pm 1.33$ ) minutes, respectively. The period of motor & sensory blocks has been longer in hyperbaric bupivacaine ( $201.03 \pm 19.694$ ) minutes when compared to isobaric bupivacaine ( $136.91 \pm 12.81$ ) minutes. In both groups, no significant differences in hemodynamic & the adversarial effects have been equivalent.

**Conclusion:** hyperbaric bupivacaine created more fast commencement & lengthier period when assessed to Isobaric but a good alternative.

**Keywords:** spinal anesthesia, plain bupivacaine, hyperbaric bupivacaine, elective cesarean section

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## Introduction:

Almost, cesarean section achieved under spinal anesthesia (SA) permits an efficient intraoperative anesthesia with good surgical conditions Bakshi et al 2021 (1). This leads to a motor & sensory blockade that is potent and rapidly onset, as well as a sympathetic blockade.

Bupivacaine hydrochloride (HCL) is a commonly utilized local anesthetic medicine for spinal anesthesia. It is to the amide class of local anesthetics. Loubert et al. 2019 (2). There are two commercially available forms: isobaric (IB), which has the same density as fluid of cerebrospinal & hyperbaric (HB), which has a higher compactness than CSF due to the addition of glucose (eighty milligrams per milliliter to plain bupivacaine. The variation in densities is supposed to impact the dissemination & spreading patterns following instillation into the subarachnoid region. Narejo et al. 2021 (3)

The diffusion pattern of bupivacaine, as determined by Sodhi et al. in 2020 (4) influences its effectiveness, spread (measured by dermatome height or block height), & potential adverse effects. The current research was conducted to assess & compare the impact of natural bupivacaine and hyperbaric bupivacaine in intrathecal anesthetic for elective cesarean sections. The investigation aimed to measure the effects on hemodynamics, as well as the onset, period, & offset of the block.

### Patients and Methods:

This investigation was a well-designed and controlled investigation that included a total of sixty cases classified as ASA I & II, aged between twenty and thirty-eight, who had cesarean section procedures at Al-Zahra University Hospitals. The study was done from July 2020 to June 2022. Following receiving oral and



written approval from the patients with ethical agency & obtaining a notification of authorization form.

The exclusion criteria encompassed anxious patient, coagulopathy, cutaneous infection at the systemic infection, puncture site, untreated hypovolemia, cardiomyopathy of class III or higher, grossly deformed vertebral column, severe aortic stenosis, failed block, & conversion to general anesthesia.

A routine preoperative evaluation was conducted on all cases, which included obtaining their medical history, doing a clinical examination, and performing laboratory investigations such as a CBC. Renal function and liver function include (prothrombin time, partial thromboplastin time, and INR), Serum electrolytes and electrocardiogram if necessary.

Upon arriving to the operation room, the case was equipped with monitoring devices, involving SPO<sub>2</sub>, NIABP, and a 5-lead electrocardiogram. The leads were attached & the baseline vital parameters have been documented.

**Anesthetic Technique:** The cases given spinal anesthesia. During the surgical procedure, a cannula with a gauge size of 18-G was used to provide vascular access. To ensure proper hydration, intravenous fluids were administered at a rate of ten milliliters per kilogram of body weight over a period of twenty to thirty minutes. Subsequently, the cases received a preparation of intravenous midazolam at a dosage of 0.03 milligrams per kilogram. We employed a computer-generated sequence of numbers to randomly select the participants & utilized the sealed envelope method to allocate them into two groups. Group I, consisting of thirty cases, received plain bupivacaine 0.5 percent ten milligrams along with twenty micro grams fentanyl. Group II, which includes thirty cases, received hyperbaric bupivacaine 0.5 percent ten milligrams in addition to twenty micro grams fentanyl for spinal anesthesia during optional cesarean sections. A patient was assisted in maintaining a comfortable sitting position by an assistant. The process of sterilization involved carefully scrubbing the area with an antiseptic solution while wearing gloves, followed by cleansing the case's back with swabs & the same antiseptic solution. The case had spinal anesthesia at the lumbar vertebra (L3-4 or L4-5) intervertebral area. The procedure was carried out while the case in a sitting, using a midline or left lateral approach & a 21 or 24 G needle. Following the confirmation of the drift of pure CSF, the organized solution has been administered into the intrathecal space within fifteen seconds. Following the injection, the cases were maintained in a supine position as per the completion of the procedure. During the procedure, a

nasal cannula was used to give one hundred percent oxygen at a flow rate of four liters per minute. Next, evaluate the hemodynamic parameters including pulse, mean arterial blood pressure, & oxygen saturation. Evaluate the start, length, & offset of the block. Cases were directed to utilize the visual analogue scale to evaluate pain levels after surgery. The most prevalent VAS is a ten-centimeter providing efficient, simple, & insignificantly invasive measures of pain strength.

### Chief consequences

1. Inadequate pain regulator with conversion to general anesthesia.
2. Unsatisfactory control of discomfort demanding usage of complementary analgesics.
3. Time onset of the block to the fourth thoracic vertebra and regression of the block
4. Requirement for ephedrine and amount of ephedrine utilized.
5. Complications as nausea & vomiting, headache within seven days from spinal anesthesia, and occurrence of great dermatomal sensory block (above the cervical vertebra 8)

**Statistical analysis:** Data will be analyzed using SPSS (statistical package for social sciences) version 22. Qualitative data will be presented as number and percent, Quantitative data will be tested for normality by Shapiro-Wilk test then described as mean and standard deviation for normally distributed data and median and range for non-normally distributed. The appropriate statistical test will be applied according to data type with the following suggested tests: Chi-Square for categorical variable and Independent-samples t-test of significance was used when comparing between two means. & Mann Whitney U test: for two-group comparisons in non-parametric data. Probability (P-value)

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### RESULTS

In attendance statistically insignificant variations was observed among the examined groups in terms of their socio-demographic characteristics (weight, age, height, & BMI) ( $P > 0.05$ ). As mentioned in Table 1. Regarding saturation, heart rate, & MABP across the analyzed groups, there statistically insignificant variations was observed ( $P > 0.05$ ), as indicated in figures (1) and (2). The examined groups had inadequate pain control, which required either the utilize of general anesthesia or the administration of IO analgesia. Statistically significant variations were observed across the groups that were tested, as indicated by a p-value of less than 0.05. These variations are presented in table 2. Time-onset of dermatomal block at the fourth thoracic vertebra



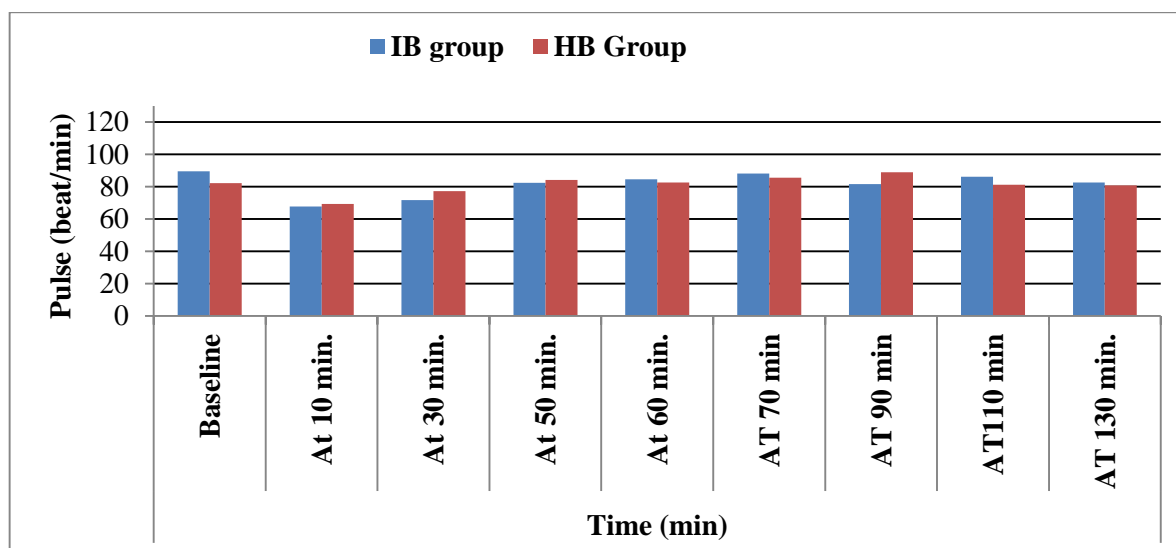
level and subsequent block regression. Significant statistical variations were observed amongst the groups ( $P < 0.05$ ). Comparison of the intraoperative and postoperative Visual Analog Scale among the groups under study. The post-operative VAS scores at ten minutes, twenty minutes, forty minutes, one hour, two hour, three hours, and six hours did not exhibit any statistically significant variations among the groups, as shown in table (3). Request for ephedrine. Significant

variations were seen among the groups ( $P < 0.05$ ), particularly in the amount of ephedrine. These variations were very significant among the 3 groups that were tested ( $P < 0.05$ ), as indicated in table (4). Complications such as low blood pressure, slow heart rate, nausea, vomiting, & a high level of blockage above the eighth cervical vertebra (C8 level). Statistically insignificant variations were observed among the groups analyzed, as seen in table (5).

**Table (1). demonstrates demographic features of the examined groups.**

	IB Group n=30	HB Group n=30	test of significance	Paired comparison
Age/years mean± SD	28.60±2.78	28.95±2.95	0.473	0.638
Weight (kg)	69.10± 3.73	70.70±3.42	1.473	0.201
Hight (cm2)	150.9±50.3	148.4± 49.46	-0.194	0.846
BMI (Weight kg/hight2 m)	27.75± 6.94	28.75±5.30	1.254	0.214

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**Figure 1: Comparison of postoperative heart rate, saturation between examined groups: There were no statistically significant differences ( $P < 0.05$ ).**



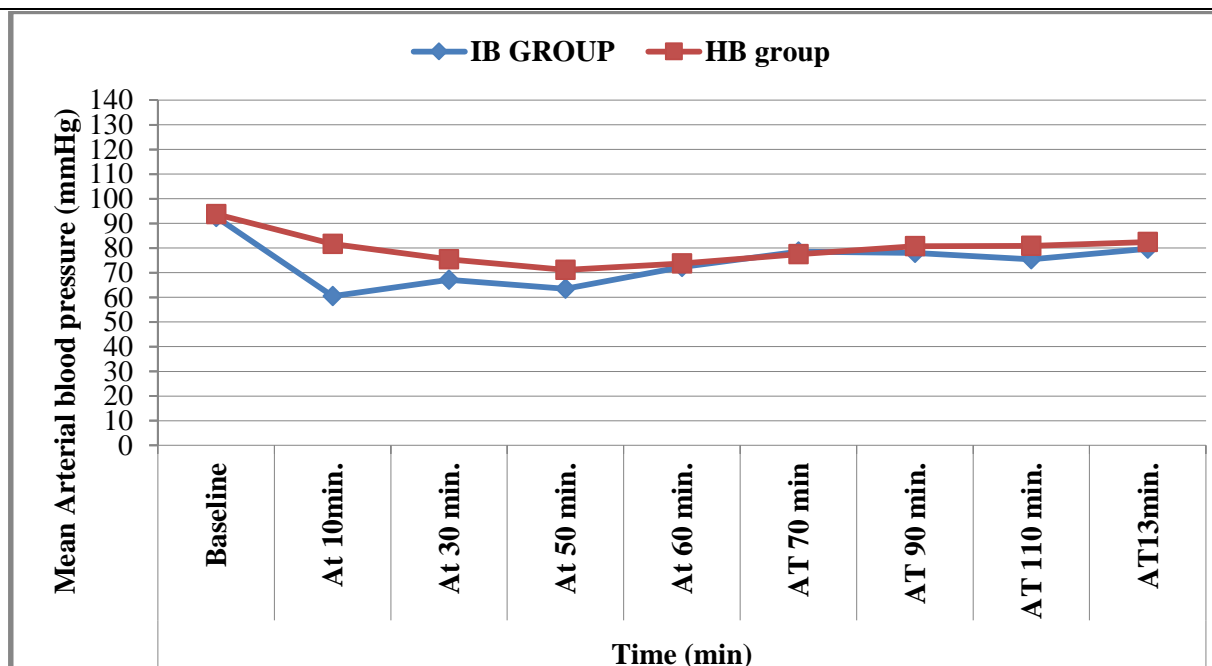


Figure 2; Comparison of postoperative MAP between studied groups (P>0.05).

Table 1: Insufficient pain control requiring alteration to general anesthesia or required IO analgesia characters among the studied groups (P< 0.001\*\*).

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	IB Group n=30	HB Group n=30	T-test of significance	Paired comparison test
Number of conversions to general anesthesia Mean ± SD	11.66 ± 3.88	5.0 ± 1.66	-8.644	<0.001**
Number of patients required IO analgesia. Mean ± SD	16.66 ± 5.55	10.33 ± 3.44	-5.310	<0.001**



**Table 3: Time onset of the block up to (T4) level and regression of the block (P < 0.05).**

	IB n=30	HB n=30	T-test of significance	Paired comparison test
Time onset of dermatomal block at T4 level (minutes)	4.0±1.33	1.8±0.6	-8.259	<0.001**
Time regression of the block (minutes)	136.91±12.813	201.03±19.694	14.948	<0.001**

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**Table (4) Comparison of VAS score between studied groups. (P>0.05).**

VAS score	IB n=30	HB n=30	T-test of significance	Paired of comparison
10 min	0.750±0.44 1.0(0-1)	0.850±0.36 1(0-1)	1.670	0.199
20 min	0.45±0.51 1(1-2)	0.95±0.37 1(1-2)	1.796	0.108
40 min	2.10±0.64 1(1-2)	0.75±0.64 1(1-2)	1.748	0.146
1 hour	2.65±0.49 1(1-2)	2.65±0.48 1(1-2)	0.265	0.565
2 hours	3.50±0.51 1(1-2)	3.55±0.69 1(1-2)	1.003	0.313
3 hours	2.40±0.50 2(2-3)	2.60±0.50 3(2-3)	0.719	0.426
6 hours	2.80±0.41 3(2-3)	2.70±0.47 3(2-3)	0.859	0.367



**Table (5) Requirement for ephedrine (P < 0.05), and amount of ephedrine there were highly significant differences among the studied groups (P < 0.001\*\*)**

	IB n=30	HB n=30	T-test of significance	Paired of comparison
Requirement for ephedrine	18.0 ± 6.0	16.05 ± 5.35	-1.329	0.189
Dose of ephedrine Used mg/person.	29.03 ± 9.676	12.12 ± 0.706	-9.547	<0.001**

**Table (6): Complications among the studied groups: P > 0.05.**

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Complications	IB n=30	HB n=30	test of significance	Paired comparison
Hypotension	5 (16.7%)	5 (16.7%)	0.000	1.000
Bradycardia	3 (10.0%)	2 (6.7%)	0.210	0.646
Nausea and vomiting	8 (26.7%)	5 (16.7%)	0.868	0.351
High block (above the cervical vertebra 8 (C8 level))	2 (6.7%)	1 (3.3%)	0.359	0.549

### Discussion

Regarding all socio-demographic features (age, weight, height, and BMI) Yurtlu et al. 2012 (5) demonstrating that socio-demographic data statistically insignificant variations along with the examined groups (P > 0.05).

As regards measurements (SPO2, HR and MAP), in the present study, Huang and Han. 2017 (6) It was found that there was no significant change in the parameter being evaluated between the groups before, during, and up to twelve hours after the operation. (P > 0.05).

Parallel conclusions are conveyed by Jabalameli et al 2012 (7) collected from ten investigations (614 patients) providing data to the principal consequences of this examination proved that insufficient pain alleviation needing alteration to general anesthesia & supplemental analgesia presented no variance among hyperbaric & isobaric bupivacaine.

On distinguish 3 investigations Chung et al. 2014 (8) participated to the result of change to general anesthesia

& two investigations. Altman et al. 2021 (9) participated to the consequence of necessity for supplemental analgesia with study isobaric bupivacaine.

Five conclusions done by Higgins 2019, 2012, 2021(10, 11, 12) provided that the results of more speedy beginning of sensory block with hyperbaric form of bupivacaine at the level T4 than isobaric form. Other investigations confirmed no differences in adding up; the sample sizes our results should be treated with caution, as more studies may alter these outcomes.

Transition to general anesthesia was an uncommon result in the 11 investigations. Most investigations by Lumbiganon et al. 2013 (13) didn't exhibit any report conversions to full general anesthesia and did not show any important differences and any suggested superiority of hyperbaric form of bupivacaine Odlind 2003 et al. (14). The research performed by Tsen et al. in 2018 (15) discovered that the use of a combination of spinal epidural method with low-dose hyperbaric & isobaric bupivacaine



resulted in a greater rate of supplemental analgesia. Sia and Tan 2013, 2015 (16,17).

Arai et al. 2006 (18), Kamaya et al. 2013 (19) show that usage of ephedrine was lowest as the dose 7 mg of bupivacaine either hyperbaric or isobaric with utilizing the combined spinal epidural practice, matched to a greater consumption of ephedrine 10, 12.5 mg isobaric or hyperbaric bupivacaine using spinal anesthesia alone Litz et al. 2005 (20).

Faust et al. 2003 (21) anesthesia level for caesarean delivery is up to T4 has been the guideline to allow discomfort free infant delivery evaluated the suggested time starting of T4 blockade, the upper limit sensory level realized throughout intrathecal block or decline of sensory blockade, Higuchi et al. 2014 (22) various processes used to assess sensory level either swabs, pinprick or sensation of cold.

The dosage of bupivacaine administered in the studies ranged from seven milligrams to fifteen milligrams (McLeod, 2004) (23). Some investigations additionally included intrathecal adjunct medication such as morphine & fentanyl. There has been also changeability observed in the method of regional block, which affected the duration of the block, post-delivery pain, and the ability to walk around Taivainen et al. 2019 (24), Vichitvejpaisal et al. 2012 (25).

Factors that increase duration of the block showed by Solakovic et al. 2010 (26) that dose of the drug, drugs adjuvant, and method of management impact the spread of local anesthetic in the intrathecal space. Martin et al. 2009 (27) shows however, the procedure is difficult to get definitive conclusion.

king 2019 (28), shows there is no good deed proof of the utilize of bupivacaine hyperbaric or isobaric for spinal anesthesia throughout caesarean section. because the indicative proof of quicker onset to fourth thorathic sensory block, intrathecal hyperbaric bupivacaine may have some benefits Jankowski and Villette 2010 (29).

### Conclusion:

The discoveries of the exhibit important impacts in transforming use of hyperbaric bupivacaine by isobaric one as local intrathecal anesthetic may be an appropriate alternative in case of absence or for financial causes. The review determined that intrathecal

hyperbaric bupivacaine resulted in a faster beginning of sensory blocking at the T4 level and had a longer duration. Nevertheless, there were little needs for converting to general anesthesia and additional pain relief that varied among the isobaric & hyperbaric bupivacaine groups. This is mostly because of to the infrequency of these consequences, variations in the method utilized for regional anesthesia, variability in the dose, & the use of adjuvant medications.

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