RESEARCH ARTICLE

Norepinephrine versus Ephedrine for Hypotension Prophylaxis During Caesarean Section Under Spinal Anaesthesia

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ABSTRACT

Introduction: Spinal anaesthesia (SA) is the preferred technique for elective caesarean sections (CS) due to its safety and reduced maternal and neonatal risks compared to general anaesthesia. However, spinal anaesthesia-induced hypotension (SAIH) remains a frequent and significant complication. Vasopressors such as ephedrine and norepinephrine are commonly used for prophylaxis, but their comparative efficacy in maintaining haemodynamic stability and optimising neonatal outcomes remains under investigation.

Objective: This study aimed to compare the effectiveness of continuous norepinephrine (NE) versus ephedrine (EP) infusions in preventing hypotension during elective caesarean sections performed under spinal anaesthesia.

Methods: A prospective, randomised, single-blinded controlled clinical trial was conducted at Baghdad Teaching Hospital between January 2023 and December 2024. Sixty parturients undergoing elective CS under SA were randomly assigned to receive either norepinephrine (5 µg/mL at 0.1 µg/kg/min) or ephedrine (2 mg/mL at 2 mg/min) infusions immediately after spinal block administration. Maternal haemodynamic parameters—including systolic, diastolic, and mean arterial pressures—and heart rate were recorded at regular intervals. The primary outcome was the incidence of hypotension. Secondary outcomes included vasopressor requirements, maternal side effects, and neonatal parameters. Statistical significance was $p < 0.05$.

Results: The incidence of hypotension was significantly lower in the NE group than in the EP group (13.3% vs. 40.0%, $p = 0.02$). The mean number of hypotensive episodes per patient was also lower with norepinephrine (0.17 ± 0.38 vs. 0.63 ± 0.81, $p = 0.007$). Fewer patients in the NE group required rescue vasopressors (10.0% vs. 33.3%, $p = 0.03$), and their blood pressure remained within 20% of baseline throughout the procedure. The incidence of nausea and vomiting was lower with NE (10.0% vs. 30.0%, $p = 0.04$), while heart rate was significantly higher in the ephedrine group ($p < 0.05$ at most time points). Neonatal Apgar scores at 1 and 5 minutes were comparable; however, umbilical arterial pH was significantly higher with norepinephrine (7.31 ± 0.04 vs. 7.27 ± 0.05, $p = 0.002$).

Conclusion: Continuous norepinephrine infusion provides superior prophylaxis against spinal anaesthesia-induced hypotension compared to ephedrine in women undergoing caesarean section.

Keywords: Spinal anaesthesia, Caesarean section, Hypotension, Norepinephrine, Ephedrine, Vasopressors, Haemodynamics, Neonatal outcomes.

INTRODUCTION

Spinal anaesthesia has become the most popular method of anaesthesia for elective caesarean sections because it has many advantages over general anaesthesia. Some of these benefits are a lower risk of airway problems, a lower risk of maternal death, and very little exposure to drugs for newborns.[1] Despite these good things, spinal anaesthesia can cause significant changes in blood flow; the most common of which is low blood pressure, which happens in up to 80% of cases.[2] The most common cause of hypotension is due to the sympathetic blockade needed to get enough

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surgical anaesthesia at the T4 dermatome level for a caesarean delivery.

Maternal hypotension during Caesarian Section (CS) under spinal anaesthesia represents a significant clinical challenge with potential consequences for both mother and foetus. It is reported that hypotension induced by spinal anaesthesia occurs in nearly 80% of women who undergo CS under Spinal Anaesthesia (SA). [2] Hypotension presented as dizziness, nausea, vomiting, and, in severe cases, unconsciousness. [3] The foetal implications are more concerning when sustained maternal hypotension occurs, leading to reduced uteroplacental perfusion, potentially resulting in foetal hypoxia, acidosis, and compromised neonatal outcomes.[4] The threshold pH of the umbilical artery for adverse neurological outcomes is 7.10, with the ideal range being 7.26–7.30.[5] Low pH may cause hypoxic-ischemic encephalopathy and other neurological complications in the newborn, including cerebral palsy.

The primary physiological mechanism underlying post-spinal hypotension is a decrease in systemic vascular resistance secondary to small-artery vasodilation, accompanied by modest venodilation.[6] In a healthy parturient, a compensatory baroreceptor-mediated increase in heart rate and stroke volume typically occurs, thereby increasing cardiac output.[7] However, with high spinal blocks, the pre-ganglionic sympathetic cardiac accelerator fibres may be blocked, leading to a failure of compensatory tachycardia.

Early approaches focused heavily on giving intravenous fluids before or during the procedure. However, multiple studies have shown that just giving fluids alone doesn't reliably prevent hypotension.[8] As a result, attention turned to using medications that constrict blood vessels, vasopressors, as a preventive measure.[9] Others include mechanical interventions such as left uterine displacement to reduce inferior vena cava compression, leg compression to minimise venous pooling, and fluid management strategies.[10] Despite these measures, vasopressor administration remains the cornerstone of managing maternal haemodynamic stability.

Many strategies have been studied to reduce or prevent Spinal Anaesthesia Induced Hypotension (SAIH) during CS. In addition to prophylactic infusions, investigators have examined colloid and crystalloid co-loading, leg wrapping/compression stockings, left-lateral tilt and whole-body elevation, lower-limb compression before spinal injection, combination vasopressors like ephedrine plus phenylephrine or norepinephrine with or without phenylephrine, and computer-controlled closed-loop feedback infusions. All aim to reduce the incidence and severity of SAIH, yet none has displaced early, titrated vasopressor administration as the primary measure. [11]

Historically, ephedrine was considered the vasopressor of choice in obstetric anaesthesia, supported by the results of animal studies that showed preservation of uteroplacental blood flow compared with pure α-adrenergic agonists.[12] Ephedrine exerts its effects through both direct and indirect mechanisms on α- and β-adrenergic receptors, resulting in positive inotropic and chronotropic effects. However, its efficacy diminishes with repeated administration due to tachyphylaxis, and it has been associated with foetal acidosis when used in large doses.[13]

For the prevention and management of SAIH during caesarean delivery, norepinephrine has recently been recognised as a viable substitute. Being a strong α-adrenergic receptor agonist and a weak β-adrenergic receptor agonist, norepinephrine may help maintain maternal blood pressure while reducing adverse effects on heart rate and cardiac output.[14] The β-adrenergic effects of norepinephrine may help maintain cardiac output. In contrast, its α-adrenergic effects restore systemic vascular resistance, potentially providing more stable haemodynamics than pure α-agonists, such as phenylephrine.

The ideal vasopressor for obstetric use would effectively maintain maternal blood pressure without compromising uteroplacental

perfusion or causing significant maternal or fetal side effects.

Despite extensive research, the optimal agent and administration protocol remain subjects of debate.[3] The choice between ephedrine and norepinephrine represents a balance between efficacy in preventing hypotension, effects on maternal cardiac output, and potential foetal implications. This study aims to measure the effectiveness of continuous infusions of norepinephrine (NE) compared to ephedrine (EP) in preventing a drop in blood pressure in women who underwent elective C-sections under spinal anaesthesia. In addition to measuring its effect on maternal haemodynamics and neonatal outcomes.

METHODS

Study design and setting: This prospective, controlled, randomised interventional clinical trial was conducted at Baghdad Teaching Hospital. The research was conducted in the operating rooms of Baghdad Teaching Hospital, a major tertiary care centre in Baghdad, Iraq, from January 1, 2023, to December 1, 2024.

Ethical considerations: Ethical approval was obtained from the Iraqi Scientific Medical Council of Specialisations in Anaesthesia and Intensive Care. An agreement for the research was obtained from the hospital administration. Written informed consent was obtained from all participants before their enrollment in the study. Each patient was given the option to withdraw at any time, without condition. The confidentiality of data throughout the study was ensured, and patients were assured that their data would be used solely for research purposes.

Case definition; inclusion and exclusion criteria: Sixty parturients scheduled for elective CS under spinal anaesthesia were enrolled in this study based on the recommendations of the American Society of Anaesthesiologists (ASA) which are physical status II, singleton pregnancy, term gestation (37-42 weeks), and scheduled for elective CS delivery. Exclusion criteria were pre-existing hypertension, preeclampsia, cardiovascular or cerebrovascular disease, known foetal abnormalities, multiple gestations, placenta previa, contraindications to spinal anaesthesia, allergy to local anaesthetics or study medications, and patient refusal.

Sampling and sample size calculation: The sample size and sampling method were based on previous studies. A convenient sample was used in this study. The sample size was determined based on the primary outcome measure of the incidence of hypotension. Previous studies have reported hypotension rates of approximately 40% with ephedrine prophylaxis. Assuming a 10% reduction with norepinephrine, with a two-sided alpha of 0.05 and a power of 80%, a minimum of 27 patients per group was required. To account for potential dropouts and protocol violations, 30 patients were enrolled in each group. This sample size was also adequate to detect clinically significant differences in secondary outcomes such as vasopressor requirements and haemodynamic stability.

Randomisation: Block Randomisation were used by creating blocks of a fixed size of 4 to ensure that an equal number of participants are assigned to each group over time to help maintain balance throughout the recruitment process. An independent statistician prepared sealed envelopes. Allocation concealment ensured balance across groups. Participants were randomly allocated into two equal groups: The Norepinephrine group (N = 30) and the Ephedrine group (E = 30). The demographic characteristics of both groups were comparable in terms of age, weight, height, and gestational age.

Blinding: Patients and outcome assessors were blinded. The researcher anaesthesiologists administering infusions were not blinded due to visible differences in syringe labelling.

Procedure: All participants in both groups underwent a comprehensive preoperative assessment, which included a medical history, physical examination, and routine laboratory investigations. Patients were instructed to fast

for at least 6 hours before surgery and received oral ranitidine 150 mg the night before and on the morning of surgery as aspiration prophylaxis.

Upon arrival in the operating room, standard monitoring was applied, including non-invasive blood pressure measurement, electrocardiography, and pulse oximetry. Baseline vital signs were recorded before the administration of spinal anaesthesia.

Data Collection: The primary outcome measure was the incidence of hypotension, defined as a decrease in systolic blood pressure (SBP) >20% from baseline or SBP <90 mmHg. Secondary outcomes included the number of hypotensive episodes, total vasopressor consumption, incidence of bradycardia (heart rate <60 beats/min), incidence of nausea and vomiting, and neonatal outcomes (Apgar scores at 1 and 5 minutes and umbilical arterial blood gases). Maternal haemodynamic parameters, including systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate, were recorded at baseline (before spinal anaesthesia), immediately after spinal anaesthesia, and then at 2-minute intervals for the first 20 minutes, followed by 5-minute intervals until the end of surgery. Hypotensive episodes and vasopressor requirements were recorded throughout the procedure.

Neonatal assessment included Apgar scores at 1 and 5 minutes after delivery, assessed by a paediatrician who was blinded to the group allocation. Umbilical arterial blood samples were collected immediately after delivery for blood gas analysis, including pH, partial pressure of oxygen (PaO2), partial pressure of carbon dioxide (PaCO2), base excess, and bicarbonate levels.

All adverse events, including nausea, vomiting, bradycardia, and other side effects, were recorded throughout the procedure and in the immediate postoperative period.

Technical Procedures: All spinal anaesthesia procedures were performed by experienced anaesthesiologists using a standardised technique. With the patient in the sitting position, after skin disinfection and local anaesthesia with lidocaine 2%, a 25-gauge Quincke spinal needle was inserted at the L3-L4 or L4-L5 interspace using a midline approach. After confirmation of correct needle placement by free flow of cerebrospinal fluid, hyperbaric bupivacaine 0.5% was administered. The dose was calculated by multiplying 0.06 mg of hyperbaric bupivacaine by the parturient's height (in cm).[14]

Immediately after the administration of the spinal anaesthetic, patients were positioned supine with left uterine displacement using a wedge under the right hip. The sensory block level was assessed by loss of pinprick sensation and targeted the T4 dermatome bilaterally. Motor block was assessed using the modified Bromage scale.

In the norepinephrine group, norepinephrine was infused at a concentration of 5 µg/ml and an initial rate of 0.1 µg/kg/min (60 ml/hour). In the Ephedrine group, an ephedrine infusion was prepared at 2 mg/ml and administered at an initial rate of 2 mg/min (60 ml/hour). After delivery, the infusion rate was reduced to 40 ml/hour in both groups. The infusion rates were adjusted based on haemodynamic responses to maintain systolic blood pressure within 20% of baseline values.

Interventions: All patients received a co-load of 10 ml/kg of lactated Ringer's solution, administered over 10-15 minutes, starting immediately before spinal anaesthesia. Oxygen was administered via face mask at 4 L/min throughout the procedure. In cases of hypotension despite the prophylactic infusion, rescue boluses of the respective vasopressor were administered: norepinephrine 5 µg or ephedrine 5 mg. Bradycardia was treated with atropine 0.5 mg intravenously if the heart rate decreased below 50 beats/min. Nausea and vomiting were treated with ondansetron 4 mg intravenously if necessary.

Statistical analysis: it was performed using SPSS version 25 (IBM Corp., Armonk, NY, USA). Continuous variables were presented as mean ± standard deviation or median (interquartile

Table 1 | Demographic Characteristics of Study Participants

Parameter	Norepinephrine Group (n=30)	Ephedrine Group (n=30)	P-value
Age (years)	29.5 ± 4.2	30.1 ± 3.8	0.56
Weight (kg)	78.3 ± 8.7	77.9 ± 9.1	0.86
Height (cm)	162.4 ± 5.3	161.8 ± 4.9	0.65
BMI (kg/m²)	29.7 ± 3.2	29.8 ± 3.5	0.91
Gestational age (weeks)	38.6 ± 1.2	38.4 ± 1.3	0.53

Values are presented as mean ± standard deviation. BMI: Body Mass Index.

Table 2 | Incidence of Hypotension and Related Parameters

Parameter	Norepinephrine Group (n=30)	Ephedrine Group (n=30)	P-value
Incidence of hypotension, n (%)	4 (13.3%)	12 (40.0%)	0.02*
Number of hypotensive episodes per patient	0.17 ± 0.38	0.63 ± 0.81	0.007*
Need for rescue vasopressor, n (%)	3 (10.0%)	10 (33.3%)	0.03*
Time to first hypotensive episode (min)	8.5 ± 2.1	5.2 ± 1.8	0.01*

Values are presented as mean ± standard deviation or number (percentage). *Statistically significant (p<0.05).

range), depending on distribution normality, as assessed by the Shapiro-Wilk test. Categorical variables were presented as numbers and percentages. Comparisons between groups for continuous variables were performed using the independent t-test for normally distributed data or the Mann-Whitney U test for non-normally distributed data. Categorical variables were compared using the chi-square test or Fisher's exact test as appropriate. Repeated-measures analysis of variance (ANOVA) was used to analyse changes in haemodynamic parameters over time, with post hoc Bonferroni correction for multiple comparisons. A p-value <0.05 was considered statistically significant.

RESULTS

The demographic characteristics of the study participants were comparable between the two groups, with no significant differences in age, weight, height, body mass index, or gestational age (Table 1).

The incidence of hypotension was significantly lower in the Norepinephrine group compared to the Ephedrine group (13.3% vs. 40.0%, p=0.02). Similarly, the number of hypotensive episodes per patient was significantly lower in the Norepinephrine group (0.17 ± 0.38 vs. 0.63 ± 0.81, p = 0.007), as shown in Table 2.

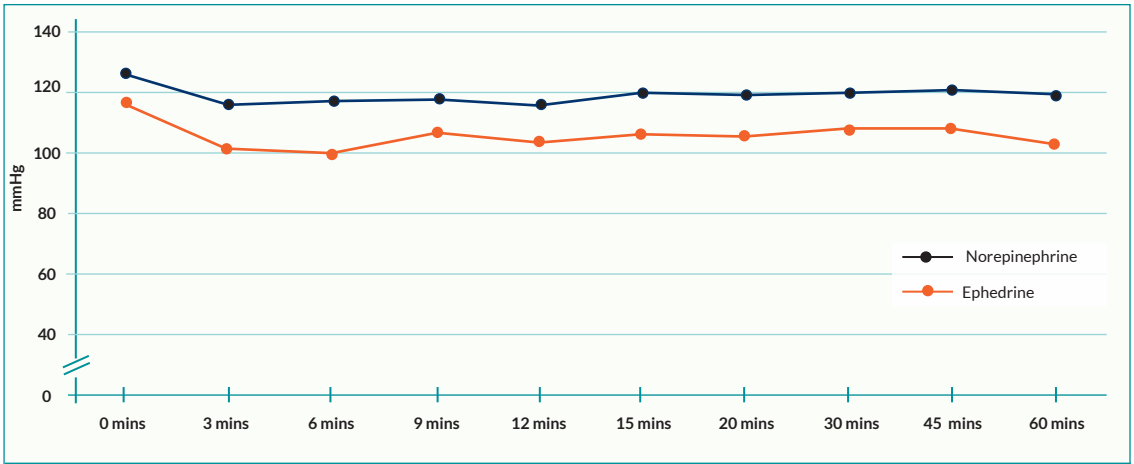

Figure 1 | Difference between the mean systolic blood pressure measurements between the Norepinephrine and Ephedrine group over time.

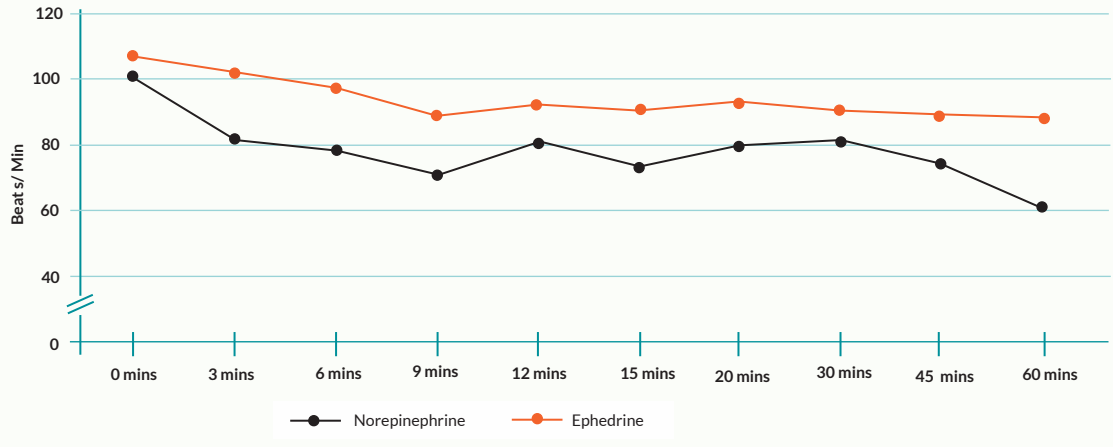

Figure 2 | Difference between the mean Pulse rate measurements between the Norepinephrine and Ephedrine groups over time.

Risk for Norepinephrine Group 4/30 = 13.3%. Risk for ephedrine group 12/30 = 40 %. So the relative risk would be 13.3/40 = 0.3, 95 % CI: 0.12-0.92 and the number needed to treat: 0.4- 0.13, nearly 4.

Haemodynamic parameters showed significant differences between the groups. The Norepinephrine group maintained a more stable systolic blood pressure throughout the procedure than the Ephedrine group (Figure 1).

Heart rate was significantly higher in the Ephedrine group compared to the Norepinephrine group at multiple time points after spinal anaesthesia (Figure 2). The incidence of bradycardia was significantly lower in the Ephedrine group compared to the Norepinephrine group (3.3% vs. 16.7%, p=0.04). However, the incidence of tachycardia (heart rate >100 beats/min) was significantly higher in the Ephedrine group (26.7% vs. 6.7%, p=0.03).

Regarding maternal side effects, the incidence of nausea and vomiting was significantly lower in the Norepinephrine group compared to the Ephedrine group (10.0% vs. 30.0%, p=0.04). No significant differences in the incidence of other side effects, such as shivering or pruritus, were observed between the groups.

Neonatal outcomes were comparable between the groups, with no significant differences in Apgar scores at 1 and 5 minutes. However, umbilical arterial pH was significantly higher in the Norepinephrine group compared to the Ephedrine group (7.31 ± 0.04 vs. 7.27 ± 0.05, p=0.002) (Table 3).

DISCUSSION

This study demonstrates that prophylactic norepinephrine infusion is more effective than ephedrine infusion in preventing hypotension during caesarean delivery under spinal anaesthesia. The incidence of hypotension was significantly lower in the Norepinephrine group compared to the Ephedrine group (13.3%

Table 3 | Neonatal Outcomes

Parameter	Norepinephrine Group (n=30)	Ephedrine Group (n=30)	P-value
Apgar score at 1 min	8.7 ± 0.6	8.5 ± 0.7	0.24
Apgar score at 5 min	9.8 ± 0.4	9.7 ± 0.5	0.38
Umbilical arterial pH	7.31 ± 0.04	7.27 ± 0.05	0.002*
Umbilical arterial PaO2 (mmHg)	18.6 ± 3.2	17.9 ± 3.5	0.42
Umbilical arterial PaCO2 (mmHg)	48.3 ± 4.1	50.2 ± 4.5	0.09
Umbilical arterial base excess (mmol/L)	-2.1 ± 1.8	-3.4 ± 2.1	0.01*

Values are presented as mean ± standard deviation. *Statistically significant (p<0.05).

vs. 40.0%, p = 0.02), with fewer hypotensive episodes per patient and a lower need for rescue vasopressor administration. Our findings align with those of Ngan Kee et al., [13] who reported that norepinephrine has superior efficacy compared to phenylephrine in maintaining cardiac output during spinal anaesthesia for CS delivery. Similarly, Vallejo et al. [14] observed that norepinephrine was associated with a lower incidence of hypotension compared to ephedrine in their randomised controlled trial. The superior efficacy of norepinephrine may be attributed to its balanced α- and β-adrenergic effects, which help maintain both systemic vascular resistance and cardiac output.

In contrast to our results, Mohta et al.[15] found no significant difference in the incidence of hypotension between norepinephrine and ephedrine groups. This discrepancy might be explained by differences in dosing regimens and definitions of hypotension across the studies.

The haemodynamic profiles observed in our study reveal important differences between the two vasopressors. Norepinephrine maintained a more stable blood pressure with less fluctuation compared to ephedrine. This stability is clinically important as it may reduce the risk of uteroplacental hypoperfusion and subsequent foetal compromise. The higher heart rate observed in the Ephedrine group is consistent with its known β-adrenergic effects and has been reported in previous studies.[16]

The lower incidence of nausea and vomiting in the Norepinephrine group (10.0% vs. 30.0%, p = 0.04) is likely related to the more stable haemodynamics and reduced incidence of hypotension, as these symptoms are often associated with reduced cerebral perfusion during hypotensive episodes. This finding is consistent with the results reported by Wang et al.,[17] who also observed fewer episodes of nausea and vomiting with norepinephrine compared to ephedrine.

Regarding neonatal outcomes, while Apgar scores were comparable between the groups, the significantly higher umbilical arterial pH in the Norepinephrine group (7.31 ± 0.04 vs. 7.27 ± 0.05, p = 0.002) suggests a better foetal acid-base status. This finding is consistent with previous studies reporting lower umbilical arterial pH values with ephedrine than with other vasopressors.[18] The mechanism is thought to be related to ephedrine's ability to cross the placenta and increase foetal metabolism, leading to increased carbon dioxide production and subsequent respiratory acidosis.

Our study has several strengths, including its prospective randomised design, standardised anaesthetic technique, and comprehensive assessment of both maternal and neonatal outcomes. However, certain limitations should be acknowledged. First, the open-label design may have introduced bias, although the outcome assessors were blinded to group allocation. Second, although the sample size was adequate for the primary outcome, it may have been insufficient to detect differences in some secondary outcomes. Finally, we did not measure cardiac output directly, which would have provided more detailed information about the haemodynamic effects of the two vasopressors.

CONCLUSION

Prophylactic norepinephrine infusion is more effective than ephedrine infusion in preventing hypotension during caesarean delivery under spinal anaesthesia. Norepinephrine is associated with more stable maternal haemodynamics, a lower incidence of nausea and vomiting, and a better neonatal acid-base status. These findings suggest that norepinephrine may be preferred over ephedrine for hypotension prophylaxis during caesarean section under spinal anaesthesia. Future studies should focus on optimising the norepinephrine dosing regimen and on investigating its effects on maternal cardiac output and uteroplacental blood flow.

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Abbreviations list: American Society of Anaesthesiologists (**ASA**), Blood Pressure (**BP**), Caesarean Sections (**CS**), Cardiac Output (**CO**), Diastolic Blood Pressure (**DBP**), Electrocardiogram (**ECG**), Ephedrine (**EP**), Heart Rate (HR), Hyperbaric Bupivacaine (**HB**), Norepinephrine (NE), Post-Dural Puncture Headache (**PDPH**), Post-Spinal Hypotension (**PSH**), Spinal Anaesthesia (**SA**), Spinal Anaesthesia Induced Hypotension (**SAIH**), Subarachnoid Block (**SAB**), Systolic Blood Pressure (SBP), Umbilical Artery (**UA**), United States Food and Drug Administration (**US FDA**).

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