

Prophylactic Intravenous Phenylephrine 100, 150, and 200 Micrograms on Vasopressor Consumption, Bradycardia and Other Side Effects After Spinal Anesthesia in Obese Parturients During Cesarean Section: A Randomized, Single-Blind Study

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Abstract

Background: Obese parturients require a higher effective dose at 50% of phenylephrine (P) for prophylactic infusion than non-obese parturients after combined spinal-epidural anesthesia. There has been no study on the optimal dose of P administered in obese parturients using slow injection with a smart pump imitation injection technique (SPIIT) to prevent spinal hypotension (SH).

Objectives: To compare vasopressor consumption, bradycardia, and other side effects between prophylactic P at doses of 100, 150, and 200 µg intravenous slow injections after spinal anesthesia (SA) in obese parturients.

Methods: Participants were 369 obese parturients undergoing elective cesarean section (C-section) from December 2022 to June 2024 were randomized into P100, P150, and P200 (n = 123 per group). After completing SA, 3 groups were administered P at doses of 100, 150, and 200 µg over 30, 45, and 60 seconds, respectively, by opening 3 ways of a 3-way stopcock to imitate the function of a smart pump. SH (systolic blood pressure [SBP] < 90% of baseline) was treated with P100 µg.

Results: Mean rank of P were 201.0, 185.8, and 168.2 µg in the P100, P150, and P200 groups, respectively ($P = .03$). Reactive hypertensions (HTs) (SBP > 110% of baseline) were 59 (48.0%), 61 (49.6%), and 87 (70.7%) in P100, P150, and P200, respectively ($P < .001$). Subgroup analysis showed SBPs higher than 130% of baseline were 2 (1.6%), 16 (13.0%), and 25 (20.3%) in P100, P150, and P200, respectively ($P < .001$). No significant differences were observed in other side effects.

Conclusions: The optimal prophylactic dose of P for management of SH with a SPIIT considering an acceptable incidence of bradycardia and reactive HT is 100 µg after SA for C-section in obese parturients.

Keywords: Cesarean section, Hypotension, Obese parturient, Prophylactic phenylephrine, Spinal anesthesia

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Introduction

Spinal hypotension (SH) is a very common consequence of the sympathetic vasomotor block caused by spinal anesthesia (SA) for cesarean section (C-section). According to international guidelines,¹ the use of vasopressors has been recommended for all normal

pregnancies to prevent hypotension following SA for C-section. The preferred drug is phenylephrine (P), an alpha-adrenergic receptor agonist, as it has been supported by extensive researches demonstrating its safety. The administration should utilize single-dilution techniques and/or prefilled syringes. The goal is to maintain systolic blood pressure (SBP) at more than 90% of baseline values and to prevent it from dropping below 80% of baseline. The use of a smart pump has been recommended, starting at a rate of 25 to 50 µg per minute, administered immediately after completing the SA injection. The dosage should be adjusted based on BP levels and heart rate (HR), with the option to administer additional bolus doses as needed. In cases where a smart pump is unavailable and staff are more familiar with manual drug administration, a slow injection with a smart pump imitation injection technique by opening three ports of a 3-way stopcock system could be employed.² Administering P at 100 µg through this method had been shown to effectively raise BP and reduce the incidence of bradycardia more efficiently than direct intravenous (IV) bolus injections in normal body mass index (BMI) parturients. Furthermore, a study comparing prophylactic doses of P immediately after SA had found that 100 µg was more effective in preventing hypotension than 50 µg.³

The prevalence of obese parturients has been increasing worldwide.⁴ There has been a lack of data specifically addressing the use of P in pregnant women with obesity who were those with a body mass index (BMI) of 30 kg/m² or greater.⁵ This population required further research to evaluate the safety, efficacy, and optimal dosing of P for preventing SH during SA for C-section. Previous study on pregnant women with obesity had demonstrated a higher incidence of SH compared to women with a BMI below 25 kg/m² and those with a BMI between 25 and 30 kg/m². Additionally, obese pregnant women required higher doses of ephedrine for treatment, indicating a greater susceptibility to SH and a potentially increased demand for vasopressor support in this population.⁶ There had been no studies in resource-limited hospitals to determine the optimal dose of P for preventing SH using a smart pump imitation injection technique at a rate of 100 µg over 30 seconds by opening 3 ports of a 3-way stopcock system (connecting the IV fluid bottle, P syringe, and the pregnant woman's IV line). This method, was designed to mimic the continuous infusion function of a smart pump, which had not been evaluated in pregnant women with obesity following SA.

The objectives were to compare the required doses of vasopressors (vasopressors consumption) for treating SH, incidence of bradycardia, reactive hypertension and other side effects among groups receiving P at doses of 100, 150, and 200 µg, administered using a smart pump imitation injection technique over 30, 45, and 60 seconds, respectively. The P was administered immediately after SA for C-section in pregnant women with obesity.

Methods

Study Design, Setting, and Participants

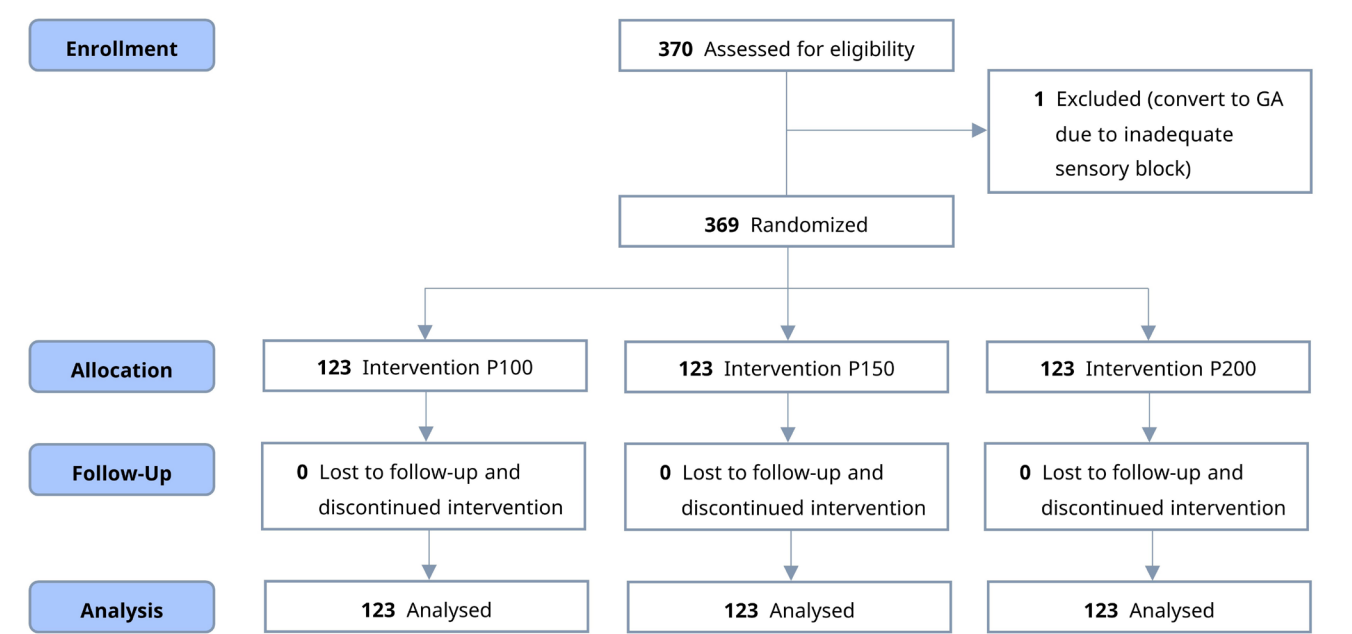
A randomized, single-blind, parallel-arm trial was conducted at Chaophrayayommarat Hospital, Suphan Buri, Thailand. Participants were 369 obese parturients (BMI ≥ 30 kg/m²) undergoing elective C-sections from December 2022 to June 2024 were assigned randomly in equal proportions (1:1:1) into 3 groups; P100, P150, and P200 (n = 123 per group) to compare the vasopressor consumption, the incidence of bradycardia and other side effects (Figure 1). The data collection was done after obtaining the approval of the research ethical committee of Chaophrayayommarat Hospital (YM002/2565), registration

with the Thai Clinical Trials Registry (TCTR20221024005), and written informed consent from participants. The inclusion criteria were American Society of Anesthesiologists (ASA) physical status classification II or III, age at least 18 years, singleton pregnancy, term pregnancy (gestational age [GA] at least 37 weeks) and the exclusion criteria were high BP (chronic HT, gestational HT, and preeclampsia), cerebrovascular disease, complicated pregnancy (abruptio placenta and placenta previa totalis), fetal abnormalities, history of maternal use of monoamine oxidase inhibitor (MAOI) or drug-induced bradycardia and other drugs except spinal bupivacaine and morphine administration after SA and before baby delivery.

Interventions and Methods of Analysis

Preoperative demographic data, including age, body weight, height, BMI, GA, ASA physical status, indication for C-section, and underlying diseases, were recorded. Baseline values for average BP and HR were calculated from previous medical records. In the operating room, monitoring and routine SA were performed according to standard guidelines. A fluid coload of 0.9% NaCl solution, 10 mL/kg IV, was administered during the SA procedure. The patient was positioned on their left side (lateral decubitus), and the anesthesia was administered using a 27-gauge Quincke spinal needle at the L2 to L3 or L3 to L4 vertebral interspace. Once the free flow of cerebrospinal fluid was confirmed, 2.2 mL of 0.5% hyperbaric bupivacaine and 0.2 mg of preservative-free morphine were injected intrathecally. Following the injection, the patient was placed in the supine position with left uterine displacement at a 15° angle, achieved by using a champagne-shaped pillow under the right hip. After completing the SA, the patients were randomly assigned

Figure 1. Consort Diagram



Abbreviations: GA, gestational age; P, phenylephrine.

into 3 groups using a computer-generated method: P100, P150, and P200. Three groups received prophylactic IV slow injections of P at doses of 100, 150, and 200 µg by anesthesiologists who were not blinded to the P doses, as they needed to be well-trained in this specific injection technique. Additionally, the limited number of anesthesiologists made blinding impractical. These injections were administered over 30, 45, and 60 seconds, respectively, by opening 3 separate ports of a 3-way stopcock. This approach was employed to simulate the functionality of a smart pump.² The patients were blinded to the P doses, making this a single-blind study. Patients with a HR below 60 beats per minute (bpm) before P administration were excluded. One-minute automatic interval noninvasive blood pressure (NIBP), HR, and oxygen saturation (SpO₂) monitoring commenced immediately after the completion of the spinal medication injection (referred to as time 0) and continued until the delivery of the baby. The dermatomal level of anesthesia was assessed by evaluating the loss of cold sensation discrimination at the 1st and 5th minutes following the completion of SA. An adequate sensory block extending to the T5 level was considered sufficient for C-section.

SH characterized by a SBP below 90% of the baseline, was recorded and promptly rescued with the administration of P at a dose of 100 µg. Additional doses of P were administered every 2 minutes if SH persisted. Bradycardia was treated with atropine 0.6 mg. Other side effects were also documented. The following timestamps were recorded: completion of SA, skin incision, uterine incision, and delivery of the baby. Nausea was evaluated using a 4-point ordinal scale (0: no nausea, 1: mild nausea not requiring pharmacological intervention, 2: nausea requiring pharmacological intervention, 3: nausea resistant to pharmacological treatment). Vomiting was graded on a 3-point ordinal scale (0: no vomiting, 1: single vomiting event, 2: repeated vomiting events requiring pharmacological intervention, 3: vomiting resistant to pharmacological treatment). These symptoms were recorded and managed with an antiemetic drug, typically metoclopramide 10 mg administered intravenously. Oxytocin, at a concentration of 20 units, was diluted in 1000 mL of 0.9% NaCl solution and administered to the patient. The Apgar scores for the baby were recorded at 1 and 5 minutes after birth.

Statistical Analysis

To calculate the sample size for the study, data were collected from a pilot study involving 20 participants per group, totaling 3 groups. Pairwise comparisons were performed, focusing on the primary objective (the required doses of vasopressors for treating SH). The sample size calculation followed the formula for randomized controlled trials (RCTs) with continuous data, using the n4Studies version 1.4.2 application (μ_1 , the mean of P in P100 group [100]; σ_1 , the standard deviation [SD] of P in P100 group [85.84]; μ_2 , the mean of P in P150 group [70]; σ_2 , the SD of P in P150 group [47.02]; μ_3 , the mean of P in P200 group [70]; σ_3 , the SD of P in P200 group [65.70]; ratio $n_2:n_1:n_3$, 1:1:1; $\alpha = 0.05$, and $\beta = 0.2$).

The sample size calculation based on the pilot data yielded a requirement of 102 cases per group. To account for a potential dropout rate of 20%, an additional number of participants was added, resulting in a final sample size of 123 cases per group. Continuous data with a normal distribution were reported as mean (SD) and compared across the 3 groups using a one-way analysis of variance (ANOVA) test. For data with a nonnormal distribution, results were presented as mean rank, and the Kruskal-Wallis test was applied for group comparisons. Categorical data were summarized as frequency and percentage, with comparisons made using either the chi-square test or Fisher exact test,

as appropriate. A *P* value of less than .05 was considered statistically significant. All statistical analyses were performed using SPSS version 20.0 (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp; 2011).

Results

A total of 369 patients were recruited during the study period and divided into 3 groups (P100, P150, and P200). No patients were excluded after random allocation. Baseline characteristics and demographic data were determined, there were no statistically significant differences in any variables between the 3 groups (Table 1).

Mean ranks of P required for treatment of SH were 201.0, 185.8, and 168.2 µg in the P100, P150, and P200 groups, respectively (*P* = .03). Bradycardias, treated with atropine showed 5 (4.1%) in both the P100 and P150 groups, and 7 (5.7%) in the P200 group, respectively (*P* = .86). Reactive hypertensions (defined as SBP > 110% of baseline) were 59 (48.0%), 61 (49.6%), 87 (70.7%) in P100, P150, and P200, respectively (*P* < .001). Subgroup analysis showed SBPs higher than 130% of baseline were 2 (1.6%), 16 (13.0%), and 25 (20.3%) in P100, P150, and P200, respectively (*P* < .001). The duration of reactive hypertension was a few minutes, and no hypertensive urgency or hypertensive emergency occurred, such as cerebrovascular or cardiovascular complications. No clinically significant difference was observed in the duration from completing SA to skin incision. No statistically significant differences were found among the three groups in terms of the duration from completing SA to uterine incision and baby delivery, maternal cardiac arrhythmia, nausea, and vomiting. Normal baby Apgar scores were observed in all 3 groups (Table 2).

Table 1. Baseline Characteristics and Demographic Data

Variable	No. (%)			P Value
	P100 (n = 123)	P150 (n = 123)	P200 (n = 123)	
Age, mean (SD), y	29.3 (5.1)	29.8 (29.8)	29.5 (5.6)	.74
Weight, mean (SD), kg	88.1 (11.8)	89.9 (11.9)	89.8 (11.7)	.44
Height, mean (SD), cm	160.9 (5.7)	161.2 (5.1)	160.5 (5.4)	.64
Baseline systolic blood pressure, mean (SD), mmHg	121.6 (8.6)	122.0 (9.7)	121.3 (9.8)	.84
Baseline diastolic blood pressure, mean (SD), mmHg	75.8 (6.6)	76.1 (7.6)	75.1 (7.4)	.55
Baseline mean blood pressure, mean (SD), mmHg	91.0 (7.2)	91.3 (7.6)	90.3 (7.7)	.55
Baseline heart rate, mean (SD), bpm	85.0 (8.6)	86.0 (8.5)	84.6 (8.8)	.41
BMI, kg/m ²				
30.0-34.9	80 (65.0)	78 (63.4)	71 (57.7)	.73
35.0-39.9	33 (26.8)	33 (26.8)	35 (28.5)	
40.0-44.9	10 (8.1)	10 (8.1)	16 (13.0)	
45.0-50.0	0	1 (0.8)	1 (0.8)	
> 50.0	0	1 (0.8)	0	

Table 1. Baseline Characteristics and Demographic Data (Continued)

Variable	No. (%)			P Value
	P100 (n = 123)	P150 (n = 123)	P200 (n = 123)	
Gestation age, wk				
37	5 (4.1)	6 (4.9)	9 (7.3)	.80
38	83 (67.5)	77 (62.6)	73 (59.3)	
39	29 (23.6)	34 (27.6)	34 (27.6)	
40	4 (3.3)	6 (4.9)	6 (4.9)	
41	2 (1.6)	0	1 (0.8)	
ASA II	123 (100.0)	123 (100.0)	123 (100.0)	NA
Indication for C-section				
Cephalopelvic disproportion	58 (47.2)	52 (42.3)	58 (47.2)	.83
Oligohydramnios	7 (5.7)	6 (4.9)	5 (4.1)	
Previous C-section	52 (42.3)	58 (47.2)	51 (41.5)	
Breech presentation	3 (2.4)	4 (3.3)	6 (4.9)	
Nonreassuring FHS	1 (0.8)	0	0	
Unprogressive labor	0	1 (0.8)	0	
Fetal macrosomia	1 (0.8)	0	1 (0.8)	
Postterm	0	0	1 (0.8)	
Uterine mass	1 (0.8)	0	0	
Placenta previa (low lying)	0	2 (1.6)	0	
PROM	0	0	1 (0.8)	
Underlying disease				
Diabetic mellitus	1 (0.8)	0	3 (2.4)	.33
Asthma	1 (0.8)	3 (2.4)	1 (0.8)	
Thalassemia	0	0	1 (0.8)	
Migraine	0	0	1 (0.8)	

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; C-section, cesarean section; FHS, fetal heart sound; NA, not applicable; PROM, premature rupture of membrane.

Table 2. Relevant Data Pertaining to Anesthesia and Neonatal Outcome

Variable	No. (%)			P Value
	P100 (n = 123)	P150 (n = 123)	P200 (n = 123)	
Duration from completing SA, mean (SD), min				
To skin incision	3.5 (1.0)	3.9 (1.1)	3.4 (1.0)	.002
To uterine incision	6.3 (1.7)	6.7 (2.2)	6.1 (1.9)	.08
To baby delivery	7.6 (1.8)	8.0 (2.3)	7.5 (2.1)	.12

Table 1. Baseline Characteristics and Demographic Data (Continued)

Variable	No. (%)			P Value
	P100 (n = 123)	P150 (n = 123)	P200 (n = 123)	
Anesthetic level at 1 min				
L1-T11	15 (12.2)	23 (18.7)	16 (13.0)	.40
T10-T5	87 (70.7)	86 (69.9)	92 (74.8)	
T4-T1	21 (17.1)	14 (11.4)	15 (12.2)	
Anesthetic level at 5 min				
T10-T5	11 (8.9)	17 (13.8)	19 (15.4)	.54
T4-T1	110 (89.4)	103 (83.7)	102 (82.9)	
C level	2 (1.6)	3 (2.4)	2 (1.6)	
Hypotension				
No	35 (28.5)	46 (37.4)	52 (42.3)	.10
Yes	88 (71.5)	77 (62.6)	71 (57.7)	
1 Episode	66 (53.7)	56 (45.5)	60 (48.8)	
2 Episodes	19 (15.4)	19 (15.4)	11 (8.9)	
3 Episodes	3 (2.4)	1 (0.8)	0	
4 Episodes	0	1 (0.8)	0	
Phenylephrine for treatment of SH, mean rank, µg	201.0	185.8	168.2	.03
HR before phenylephrine, mean (SD), bpm	96.3 (14.1)	96.6 (12.6)	93.9 (13.2)	.23
Bradycardia (treated with atropine)	5 (4.1)	5 (4.1)	7 (5.7)	.86
Reactive HT based on SBP of baseline				
SBP >110%	59 (48.0)	61 (49.6)	87 (70.7)	< .001
SBP >110-120%	53 (43.1)	51 (41.5)	68 (55.3)	.06
SBP >120-130%	21 (17.1)	30 (24.4)	44 (35.8)	.003
SBP >130%	2 (1.6)	16 (13.0)	25 (20.3)	< .001
Cardiac arrhythmia	5 (4.1)	2 (1.6)	2 (1.6)	.52
Type of cardiac arrhythmia				
Premature atrial contraction	1 (0.8)	0	0	.33
Premature ventricular contraction	3 (2.4)	2 (1.6)	0	
Sinus pause	0	0	1 (0.8)	
Sinus arrhythmia	1 (0.8)	0	1 (0.8)	
Nausea				
No nausea	120 (97.6)	121 (98.4)	120 (97.6)	.90
Mild nausea not requiring pharmacological intervention	1 (0.8)	1 (0.8)	2 (1.6)	
Nausea requiring pharmacological intervention	2 (1.6)	1 (0.8)	0	
Nausea resistant to pharmacological treatment	0	0	1 (0.8)	

Table 2. Relevant Data Pertaining to Anesthesia and Neonatal Outcome (Continued)

Variable	No. (%)			P Value
	P100 (n = 123)	P150 (n = 123)	P200 (n = 123)	
Vomit				
No vomiting	123 (100.0)	122 (99.2)	122 (99.2)	1.00
Single vomiting event	0	0	0	
Repeated vomiting events requiring pharmacological intervention	0	1 (0.8)	1 (0.8)	
Vomiting resistant to pharmacological treatment	0	0	0	
Apgar score at 1 min				
8	17 (13.8)	7 (5.7)	14 (11.4)	.10
9	103 (83.7)	109 (88.6)	107 (87.0)	
10	3 (2.4)	7 (5.7)	2 (91.6)	
Apgar score at 5 min				
8	0	0	0	NA
9	0	0	0	
10	123 (100.0)	123 (100.0)	123 (100.0)	

Abbreviations: HT, hypertension; NA, not applicable; SA, spinal anesthesia; SBP, systolic blood pressure; SH, spinal hypotension.

Discussion

The prevalence of obese parturients is increasing worldwide. Neuraxial blocks are the ideal anesthetic methods and gold standard techniques for C-section in pregnant women with obesity. Single-shot SA is the most common type of anesthesia used for C-section.⁴ The present study showed that SH was absent in 28.5%, 37.4%, and 42.3% of cases in the P100, P150, and P200 groups, respectively. However, SH could occur up to 3 to 4 times despite the administration of prophylactic P. It was similar to the previous study by Ituk et al,⁷ which observed that severe hypotension was more common in mothers with a higher BMI. This might be due to uterine compression of the aorta.⁸ Furthermore Vats et al⁹ conducted a systematic review and meta-analysis of 86 studies involving 20 328 777 pregnant women to examine the impact of maternal BMI on maternal and neonatal complications globally. The study found that overweight and obese pregnant women had higher rates of cesarean delivery (both emergency and elective), gestational diabetes, hypertension, postpartum hemorrhage, preterm birth, premature rupture of membranes, and macrosomia. Neonates from these pregnancies were more likely to require the neonatal intensive care unit (NICU) admission, have lower 5-minute Apgar scores, and be very low birth weight compared to those born to mothers with normal BMI.

The present study found a decreasing trend in the mean rank of P required for the treatment of SH as the prophylactic dose of P increased ($P = .03$). Bradycardiac parturients, treated with atropine showed 5 (4.1%) in both the P100 and P150 groups, and 7 (5.7%) in the P200 group, respectively ($P = .86$). Reactive hypertensive parturients (defined as SBP > 110% of baseline) were 59 (48.0%), 61 (49.6%), and 87 (70.7%) in P100, P150, and P200, respectively ($P < .001$). Subgroup analysis showed SBPs higher than 130% of baseline parturients were 2 (1.6%), 16 (13.0%), and 25 (20.3%) in P100, P150, and P200,

respectively ($P < .001$). The results of this study have clearly shown that the group that received a lower dose of P for prevention experienced more cases of SH and required a higher dose of P for treatment. However, when considering the side effects of P that lead to reactive hypertension, it was found in up to 70.7% of cases in the P200 group (SBP $> 110\%$ of baseline). Additionally, SBP higher than 130% of baseline was observed in 13% and 20.3% of cases in the P150 and P200 groups, respectively, while only 1.6% of cases in the P100 group showed this. There were no statistically significant differences in maternal bradycardia, cardiac arrhythmia, nausea and vomiting. Normal baby Apgar scores were found in all 3 groups. The acceptable incidence of bradycardia and reactive hypertension was determined based on clinical considerations, aiming to balance the effectiveness of SH prevention with hemodynamic stability while ensuring maternal safety and minimizing excessive vasopressor effects. Therefore, 100 μg of P was more suitable than 150 and 200 μg for preventing SH. In some studies, P doses used for preventing hypotension during SA in obese pregnant women undergoing C-section typically range from 50 to 100 mcg, with adjustments made depending on the individual patient's response. The dose might vary based on factors like the patient's BMI and the severity of hypotension, with higher doses sometimes used for more significant hypotension.⁴ Effective dose at 50% (ED50) of phenylephrine needed to prevent hypotension after SA was 2 times greater in parturients with a BMI higher than 30 kg/m^2 than in parturients with a BMI lower than 30 kg/m^2 .¹⁰ Consistency with the study of Xiao et al¹¹ incidence of reactive hypertension was significantly high in higher dose of P, although however the incidences of bradycardia, cardiac arrhythmia, nausea and vomiting, were not significantly associated with increasing P dose.

A limitation of this study was the exclusion of parturients with hypertension, as obese pregnant women are at an increased risk of chronic hypertension, gestational hypertension, and preeclampsia. Determining the optimal SBP range by administering appropriate doses of P to prevent SH in obese pregnant women with hypertension is both challenging and important, in order to maintain adequate blood flow to the uterus and fetus.

Conclusions

The optimal prophylactic dose of P for management of SH with a smart pump imitation injection technique considering an acceptable incidence of bradycardia and reactive hypertension is 100 μg , compared to 150 and 200 μg , after SA for C-section in obese parturients. Further research should focus on obese pregnant women with high BP to determine the optimal dose of P for preventing SH with this injection technique.

Additional Information

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Ethics Approval: The study was approved by the Ethics Committee of Chaophrayayommarat Hospital (YM002/2565) on 20 January 2022.

Clinical Trial Consideration: The study was registered with the Thai Clinical Trials Registry (TCTR20221024005) on 24 October 2022.

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