

PROPHYLACTIC EFFECTIVENESS OF PHENYLEPHRINE 100 MCG AND EPHEDRINE 10 MG ON THE INCIDENCE OF SPINAL ANESTHESIA INDUCED HYPOTENSION IN PATIENTS UNDERGOING CESAREAN SECTION

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ABSTRACT

Introduction: Birth by cesarean section (C-section) has increased significantly, with a high risk of maternal hypotension due to spinal anesthesia.

Objective: This study aims to compare the prophylactic effectiveness of phenylephrine 100 mcg and ephedrine 10 mg in preventing spinal anaesthesia induced hypotension in C-section patients. With a focus on safety and reducing the incidence of fetal acidosis, the results of the study are expected to provide clinical insights that can improve the safety and quality of care for pregnant women undergoing this procedure.

Methods: This study compared the effectiveness of phenylephrine 100 mcg and ephedrine 10 mg in preventing hypotension due to spinal anesthesia in cesarean section patients in four hospitals in Medan, Indonesia. Using a double-blind design, 40 patients aged 18-40 years were randomly selected, and blood pressure and heart rate were measured before and after anesthesia. Data were analyzed using SPSS, and ethical aspects were taken care of through informed consent.

Results: This study found that phenylephrine 100 mcg was more effective than ephedrine 10 mg in preventing spinal anaesthesia induced hypotension in cesarean section, with more stable blood pressure and mean arterial pressure (MAP) at the 5th, 10th, and 15th minutes (p-value < 0.05). Although ephedrine remained above 100 mmHg for systolic blood pressure (SBP), the incidence of nausea and vomiting was slightly higher in the ephedrine group. Results support phenylephrine as the primary choice for hypotensive management.

Conclusion: Phenylephrine 100 mcg is more effective than ephedrine 10 mg in preventing hypotension due to spinal anesthesia, without increasing heart rate. Despite causing nausea, ephedrine has a higher incidence of vomiting. Ephedrine is recommended if phenylephrine is not available, with further studies needed for lower doses of phenylephrine.

Keywords: Cesarean section; Ephedrine; Hypotension; Phenylephrine; Spinal Anaesthesia

ABSTRAK

Pendahuluan: Kelahiran melalui seksio sesarea (C-section) mengalami peningkatan signifikan, dengan risiko hipotensi maternal yang tinggi akibat anestesi spinal.

Tujuan: Penelitian ini bertujuan untuk membandingkan efektivitas profilaksis fenilefrin 100 mcg dan efedrin 10 mg dalam mencegah hipotensi yang dipicu oleh anestesi spinal pada pasien C-section. Dengan fokus pada keamanan dan pengurangan insiden asidosis janin, hasil penelitian diharapkan memberikan wawasan klinis yang dapat meningkatkan keselamatan dan kualitas pelayanan bagi ibu hamil yang menjalani prosedur ini.

Metode: Penelitian ini membandingkan efektivitas fenilefrin 100 mcg dan efedrin 10 mg dalam mencegah hipotensi akibat anestesi spinal pada pasien seksio sesarea di empat rumah sakit di Medan, Indonesia. Dengan desain *double-blind*, 40 pasien berusia 18-40 tahun diambil secara acak dan diukur tekanan darah serta denyut jantung sebelum dan sesudah anestesi. Data dianalisis menggunakan SPSS, dan aspek etika dijaga melalui informed consent.

Hasil: Penelitian ini menemukan bahwa fenilefrin 100 mcg lebih efektif daripada efedrin 10 mg dalam mencegah hipotensi akibat anestesi spinal pada seksio sesarea, dengan tekanan darah dan tekanan darah rata-rata (MAP) yang lebih stabil pada menit ke-5, ke-10, dan ke-15 (p-value < 0,05). Meskipun tekanan darah tetap di atas 100 mmHg untuk tekanan darah sistolik (SBP), kejadian mual dan muntah sedikit lebih tinggi pada kelompok efedrin. Hasil mendukung fenilefrin sebagai pilihan utama untuk manajemen hipotensi.

Kesimpulan: Fenilefrin 100 mcg lebih efektif daripada efedrin 10 mg dalam mencegah hipotensi akibat anestesi spinal, tanpa meningkatkan denyut jantung. Meskipun menyebabkan mual, efedrin memiliki insiden muntah lebih tinggi. Penggunaan efedrin disarankan jika fenilefrin tidak tersedia, dengan penelitian lebih lanjut diperlukan untuk dosis fenilefrin yang lebih rendah.

Kata kunci: *Cesarean section*; Efedrin; Hipotensi; Fenilefrin; Anaestesi spinal



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INTRODUCTION

Births by cesarean section (C-section) have seen a significant increase in recent decades. In England and Wales, data from the National Sentinel Caesarean Audit shows that C-section rates increased from 4% in the early 1960s to 21% in 2001, accounting for 32,222 births out of a total of 150,139 deliveries (1). The Indonesian Basic Health Research (*Riset Kesehatan Dasar*/RISKESDAS) 2018 recorded that the C-section delivery rate was 17.6%, with North Sumatra province recording the highest rate at 23.9% (2).

The safety of anesthesia for C-sections has improved considerably, with a decrease in anesthesia-related maternal mortality. However, the incidence of hypotension remains a significant problem, with the incidence reaching 25-75% in patients undergoing spinal anesthesia, and approximately 60-70% in C-section patients (3,4). Maternal hypotension can affect uteroplacental perfusion, potentially leading to serious complications such as fetal asphyxia and impaired acid-base status (4,5).

Spinal anesthesia is the primary choice for C-section, but side effects such as hypotension need to be well managed. Various approaches have been considered to prevent this problem, including intravenous fluid administration and the use of vasopressors. Ephedrine and phenylephrine are two commonly used vasopressors, each with a different mechanism of action and side effect profile (4,6). Phenylephrine, in particular, shows better potential in reducing the incidence of foetal acidosis compared to ephedrine, thus, it is increasingly recommended as the first choice in hypotensive management (5,7).

Some studies suggest that phenylephrine is more effective in preventing hypotension after spinal anesthesia. Research conducted by Veaser et al. found that the use of ephedrine increased the risk of fetal acidosis five-fold compared to phenylephrine (8). In addition, the study by Muneer et al. also indicated that phenylephrine

has a better safety profile with a lower incidence of fetal acidosis (9,10).

This study aims to compare the effectiveness of phenylephrine 100 mcg prophylaxis with ephedrine 10 mg in preventing the incidence of spinal anaesthesia induced hypotension in patients undergoing C-section. The results of the study are expected to provide new insights that are useful in clinical practice and improve the safety and quality of service for pregnant women undergoing C-sections.

METHODS

In this study, a cross-sectional observational analytic design was used. During July to August 2024, this study was conducted to evaluate the relationship between pain assessment with delirium using the critical-care pain observation tool (CPOT) scale and the confusion assessment method for the intensive care unit (CAM-ICU) in intubated patients. The study has been done in the Intensive Care Unit (ICU) of 4 hospitals in Medan, Indonesia, namely H. Adam Malik General Hospital, Prof. Dr. Chairuddin P. Lubis Hospital Medan, Haji Hospital Medan, and Dr. Pirngadi Hospital Medan City, after obtaining ethical clearance from the Universitas Sumatera Utara ethics committee for the implementation of health research No. 811/KEPK/USU//2024 dated 04th July 2024. This study also obtained ethical clearance and research permits from each multi-center institution with the following ethical research permit number information:

1. H. Adam Malik General Hospital, No. DP.04.03/D.XXVIII/6822/2024, dated 01st August 2024
2. Prof. Dr. Chairuddin P. Lubis Hospital, No. 3056/UN5.5.6.D2/PPM/2024, dated 24th July 2024
3. Haji Hospital Medan, No. 196/PSDM/RSUHM/VII/2024, dated 16th July 2024
4. Dr. Pirngadi Hospital Medan City, No. 161/B.LitBang/2024, dated 17th July 2024

The sample was drawn based on the predetermined inclusion and exclusion criteria, and the sample size was calculated using the formula for the relationship test (11). Inclusion criteria were intubated adult patients aged 18-40 years old who underwent elective cesarean section with spinal anesthesia technique and were admitted to the ICU. Exclusion criteria were vegetative patients, patients or patients' families who refused to participate in the study. The sample size estimate is calculated according to the sample formula for the relationship test:

$$n_1 = n_2 = 2 \left\{ \frac{(1,96+0,84)11,32}{117,2-106,43} \right\}^2$$

$$n_1 = n_2 = 2 \left\{ \frac{31,696}{10,77} \right\}^2$$

$$n_1 = n_2 = 16,82$$

$$n_1 = n_2 = 17$$

The results of the sample formula calculation obtained $n_1 = n_2 = 17$ samples. To anticipate drop out, 10% of the 17 samples needed were added. This resulted in each group requiring 19 samples, with a minimum total sample requirement of 38 samples. The sampling technique was performed using the simple random sampling method, ensuring that all subjects met the specified criteria.

In the course of the study, patients will be randomly divided into two groups: the phenylephrine group, receiving 100 mcg of phenylephrine and ephedrine group, receiving 10 mg of prophylactic ephedrine. The procedure begins with the measurement of blood pressure and heart rate before and after spinal anesthesia, at predetermined times. The data obtained from the measurements will be analyzed using SPSS software version 29, where descriptive and inferential analyses will be performed to assess the differences between the two groups.

The ethical aspects of the study were maintained by providing informed consent to each participant, explaining the purpose, benefits, and risks of the study. During the study, emergency

management procedures were also in place to ensure patient safety. The results of this study are expected to provide significant information regarding the effectiveness of both prophylactic drugs in preventing spinal anaesthesia induced hypotension.

RESULTS AND DISCUSSION

This study was conducted from July to August 2024 in 40 people. The sample was divided into two groups of 20 people each. Subject characteristics showed that in the phenylephrine group, the mean age was 30.8 ± 5.1 years. This study utilizes body weight in kilograms as a reference, as the dosage of medication administered to pregnant women is adjusted according to their weight. Additionally, the study does not employ Body Mass Index (BMI) as a reference, considering that the subjects are pregnant women. This decision is based on concerns that BMI calculations for all subjects may indicate obesity. Mean body weight was 65.65 ± 8.5 kg, and the mean height was 157.45 ± 3.9 cm. In contrast, in the ephedrine group, the mean age was 30 ± 5.04 years, the mean body weight was 67.45 ± 6.8 kg, and the mean height was 159.4 ± 5.38 cm.

Table 1. Characteristics of research subjects

Characteristics	Group		p-value*
	Phenylephrine (n=20)	Ephedrine (n=20)	
Age (years) [mean \pm SD]	30.8 ± 5.1	30 ± 5.04	0.464*
Body Weight (kg) [mean \pm SD]	65.65 ± 8.5	67.45 ± 6.8	0.613*
Height (cm) [mean \pm SD]	157.45 ± 3.9	159.4 ± 5.38	0.612*
Gravida [n (%)]			
1st pregnant	11 (27.5)	5 (12.5)	0.974**
2nd pregnant	4 (10)	6 (15)	
3rd pregnant	4 (10)	7 (17.5)	
4th pregnant	1 (2.5)	2 (5)	
Pregnancy Age [n (%)]			
37-38 weeks	8 (20)	7 (17.5)	0.526**
38-39 weeks	5 (12.5)	5 (12.5)	
39-40 weeks	2 (5)	13 (32.5)	

*Results of the Independent T-test, it is significant if $\alpha < 0.05$

**Results of the Chi-square test, it is significant if $\alpha < 0.05$

Analysis based on gravida and gestational age showed that in the phenylephrine group, the majority of patients were first gravida, with 11 people (40%) and a gestational age of 38-39 weeks, as many as 10 people (50%). In the ephedrine group, most patients were 3rd gravida, with 7 individuals (35%) and a gestational age of 39-40 weeks, including 13 individuals (65%). These data show that both groups had no statistically significant differences between the two groups for age, body weight, height, gravida status, and pregnancy age, as all p -values are greater than the significance level of $\alpha < 0.05$ [Table 1].

Table 2 shows the results of systolic blood pressure measurements, which show that phenylephrine is more effective than ephedrine in maintaining systolic blood pressure (SBP). At the 5th minute (T1), 10th minute (T2), and 15th minute (T3), the phenylephrine group showed higher blood pressure values with statistically significant differences (p -value < 0.05). Although the ephedrine group experienced a decrease in blood pressure over time, they were still able to maintain SBP above 100 mmHg.

Table 2. Comparison of Systolic Blood Pressure in the Phenylephrine 100 mcg and Ephedrine 10 mg Prophylaxis Groups

SBP	Group		p-value*
	Phenylephrine (n=20)	Ephedrine (n=20)	
0th minute (T0)	126.75 \pm 11.77	122.25 \pm 7.8	0.188
5th minute (T1)	125.35 \pm 7.0	115.95 \pm 6.86	0.001
10th minute (T2)	123.6 \pm 7.64	110.5 \pm 9.13	0.001
15th minute (T3)	124.05 \pm 5.57	108.15 \pm 9.58	0.0001

*Results of the Unpaired T-test, it is significant if $\alpha < 0.05$

Table 3 presents the results of diastolic blood pressure measurements between phenylephrine and ephedrine, which found that both drugs can maintain diastolic blood pressure (DBP) starting from the 5th minute (T1), 10th minute (T2), and 15th minute (T3) with statistically significant results, p -value < 0.05 . The DBP measurement in

the phenylephrine group was higher than in the ephedrine group.

Table 3. Comparison of Diastolic Blood Pressure in the Phenylephrine 100 mcg and Ephedrine 10 mg Prophylaxis Groups

DBP	Group		p-value*
	Phenylephrine (n=20)	Ephedrine (n=20)	
0th minute (T0)	80.15 \pm 6.25	77.05 \pm 7.3	0.186
5th minute (T1)	76.95 \pm 6.5	76.85 \pm 7.56	0.001
10th minute (T2)	77.8 \pm 1.04	68.85 \pm 7.44	0.001
15th minute (T3)	75.1 \pm 1.7	67.4 \pm 7.92	0.006

*Results of the Unpaired T-test, it is significant if $\alpha < 0.05$

Mean Arterial Pressure (MAP) between phenylephrine and ephedrine was found to increase MAP in the phenylephrine group higher than ephedrine at the 5th minute (T1), 10th minute (T2), and 15th minute (T3) with a statistically significant difference p -value < 0.05 . MAP in the phenylephrine group remained > 90 mmHg while in the ephedrine group > 80 mmHg [Table 4].

Table 4. Comparison of Mean Arterial Pressure in the Phenylephrine 100 mcg and Ephedrine 10 mg Prophylaxis Groups

MAP	Group		p-value*
	Phenylephrine (n=20)	Ephedrine (n=20)	
0th minute (T0)	96.55 \pm 7.9	86.3 \pm 13.63	0.092
5th minute (T1)	91.8 \pm 5.5	85.95 \pm 5.8	0.006
10th minute (T2)	91.75 \pm 5.92	82.75 \pm 7.61	0.001
15th minute (T3)	93 \pm 5.56	82.45 \pm 10.15	0.001

*Results of the Unpaired T-test, it is significant if $\alpha < 0.05$

Table 5 shows the results of measuring the average heart rate between the phenylephrine and ephedrine groups. There was an increase in the average heart rate in the ephedrine group starting at minute 10 (T2) and minute 15 (T3).

Table 5. Comparison of Heart Rate in the Phenylephrine 100 mcg and Ephedrine 10 mg Prophylaxis Groups

Heart Rate	Group		p-value*
	Phenylephrine (n=20)	Ephedrine (n=20)	
0th minute (T0)	86.8 ± 6.13	80.6 ± 6.9	0.007
5th minute (T1)	82.35 ± 7.52	85.9 ± 5.47	0.124
10th minute (T2)	79.9 ± 7.6	92.5 ± 7.4	0.0001
15th minute (T3)	74.05 ± 6.21	98.9 ± 5.92	0.0001

*Results of the Unpaired T-test, it is significant if $\alpha < 0.05$

Table 6 presents the results of observations on the incidence of nausea and vomiting in the phenylephrine and ephedrine groups. Where in the phenylephrine group there were 5 people who were nauseous and 2 people who experienced vomiting. In the ephedrine group, 7 people were nauseated and 2 people were vomited.

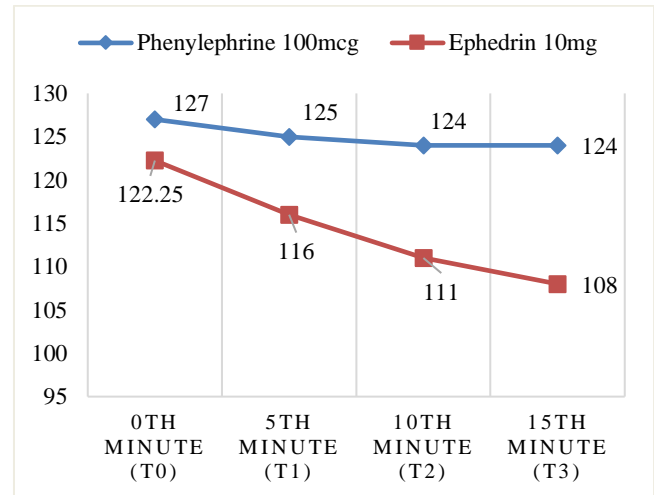
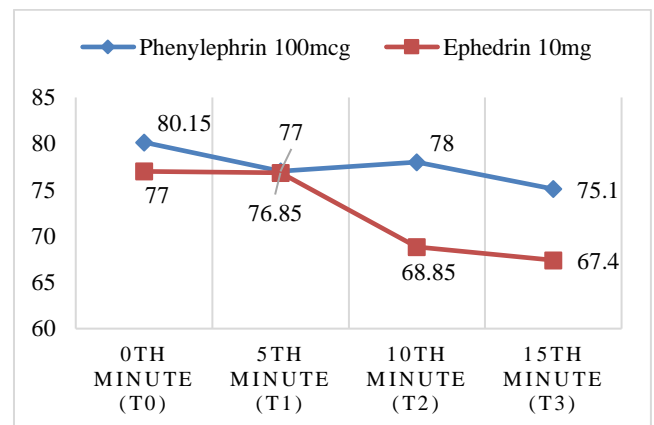
Table 6. Frequency of Nausea and Vomiting in the Phenylephrine 100 mcg and Ephedrine 10 mg Prophylaxis Group

Side effects	Phenylephrine (n=20)	Ephedrine (n=20)	Total
Nausea	5 (41.6)	7 (58.3)	12 (100)
Vomiting	2 (50)	2 (50)	4 (100)

Vasopressors play a key role in managing spinal anesthesia induced hypotension, which is caused by sympathetic blockade and loss of arteriolar tone. Ephedrine has long been considered the best vasopressor to manage maternal hypotension. However, studies have shown that ephedrine may increase the risk of fetal acidosis by up to five times compared to phenylephrine. Nowadays, phenylephrine is gaining popularity as the primary choice in preventing and managing spinal anesthesia induced hypotension in cesarean section surgery, despite its potential to decrease heart rate and cardiac output due to its non-beta-mimetic mechanism of action.

In this study, blood pressure measurement results showed the prophylactic effectiveness of phenylephrine and ephedrine in preventing spinal

anesthesia induced hypotension. Figures 1 and 2 provide a clear picture of the comparison, which supports the use of phenylephrine as a safer alternative despite the possible side effects. These results suggest that appropriate selection of vasopressors is essential to minimize risks to both mother and fetus during surgical procedures (6).

**Figure 1.** Comparison of Systolic Blood Pressure in the Phenylephrine 100 mcg and Ephedrine 10 mg Prophylaxis Groups**Figure 2.** Comparison of Diastolic Blood Pressure in the Phenylephrine 100 mcg and Ephedrine 10 mg Prophylaxis Groups

Phenylephrine and ephedrine were effective in maintaining systolic blood pressure in spinal anesthesia patients, with significant results at minutes 5, 10, and 15 (p-value < 0.05). Phenylephrine was superior in maintaining systolic blood pressure compared to ephedrine, following the findings of Dusitkasem et al. (7) and Chauhan et al. (8) who noted an increase in

blood pressure after prophylactic administration. Phenylephrine works as an α_1 adrenergic receptor agonist, whereas ephedrine functions as an agonist at α and β adrenergic receptors, which increases heart rate and cardiac output.

Both drugs also successfully maintained mean arterial pressure (MAP) significantly (p -value < 0.05) during the measurement. These results suggest that they can be effectively used to prevent spinal anaesthesia induced hypotension, as illustrated in [Figure 3](#). The selection of appropriate prophylaxis is important to minimize the risk of complications during surgical procedures.

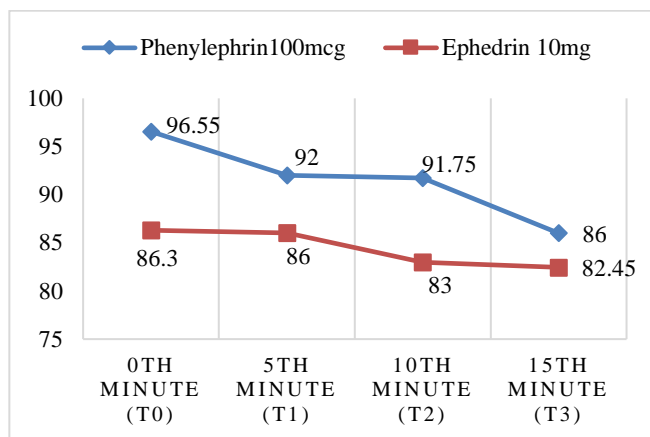


Figure 3. Comparison of Mean Arterial Pressure in the Phenylephrine 100 mcg and Ephedrine 10 mg Prophylaxis Groups

The results showed that both phenylephrine and ephedrine were effective in maintaining mean arterial pressure (MAP) during the prevention of spinal anesthesia induced hypotension, with p -value < 0.05 in all measurements. However, phenylephrine was superior, giving higher results. As an α -adrenergic agonist, phenylephrine increases systemic vascular resistance through sympathomimetic effects, while ephedrine has no major beta-mimetic effect but increases MAP through arteriolar vasoconstriction (6). These findings are in line with the study by Muneer et al. (12) which states that both drugs are effective in maintaining MAP, although phenylephrine shows superiority in this regard.

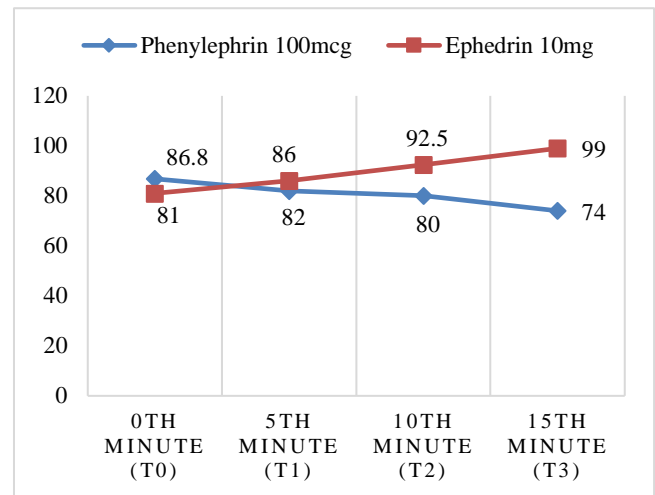


Figure 4. Comparison of Heart Rate in the Phenylephrine 100 mcg and Ephedrine 10 mg Prophylaxis Groups

The results showed that the heart rate in the group receiving phenylephrine prophylaxis decreased below 80x/min, while in the ephedrine group, it increased to above 90x/min. This can be seen in [Figure 4](#). This finding is in line with Chauhan et al. (8), which noted that phenylephrine did not cause an increase in heart rate, while 19 out of 40 samples in the ephedrine group experienced an increase. The increase in heart rate caused by ephedrine was primarily due to its predominant effects on β_1 receptors, whereas phenylephrine did not influence those receptors, resulting in a decrease in cardiac output. Although the decrease in cardiac output with phenylephrine may raise concerns regarding placental perfusion, the study suggests that higher cardiac output is needed in high-risk pregnant women (5,6).

Regarding side effects, the incidence of nausea and vomiting was higher in the ephedrine group, as also found by Chauhan et al. (8). Nausea and vomiting occurred even though systolic blood pressure did not fall below 100 mmHg, probably because no antiemetic was given as premedication. The study by Muneer et al. (12) found no significant difference in the incidence of nausea and vomiting between phenylephrine and ephedrine, and the study by Jaitawat et al. (5) showed that the incidence was not related to the dose of phenylephrine administered. A meta-

analysis by Chao et al. (13) also showed that the incidence of intraoperative nausea and vomiting was lower in the phenylephrine group.

This study found that prophylactic phenylephrine 100 mcg is more effective than ephedrine in preventing spinal anesthesia induced hypotension, mainly because phenylephrine does not increase heart rate excessively. This finding contradicts the meta-analysis by Dusitkasem et al (7) which stated that both drugs are equally effective in maintaining hemodynamics. Similar results were also found by Chao et al. (13), indicating that the effectiveness of both drugs is still a matter of debate.

Limitations in this study include the unavailability of phenylephrine at the sampling sites and the lack of data regarding the timing of the occurrence of adverse events of nausea and vomiting. Further studies are needed to elucidate the relationship between vasopressor administration and the incidence of adverse events and their impact on pregnant patients.

CONCLUSION

Phenylephrine 100 mcg is more effective as prophylaxis in preventing spinal anesthesia induced hypotension than ephedrine 10 mg, without excessively increasing heart rate. There were significant differences in systolic, diastolic, mean arterial pressure and heart rate between the two groups. Although phenylephrine caused nausea in some patients, ephedrine showed a higher incidence of vomiting. It is suggested that ephedrine should be used if phenylephrine is not available, and further studies are needed to compare lower doses of phenylephrine with ephedrine, taking into account cost-benefit aspects.

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Conflict of Interest

There is no conflict of interest in this study.

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Authors' contributions

All authors have contributed to all processes in this research.

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