

Novel Obstetric Air Cushion for the Prevention of Hypotension During Spinal Anesthesia for Cesarean Section: A Randomized Controlled Clinical Trial

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Purpose: Intravenous administration of large doses of vasopressors to treat hypotension due to spinal anesthesia can adversely affect the fetus and the mother. We assessed the effect of a novel obstetric air cushion pretreatment on the incidence of hypotension after spinal anesthesia.

Patients and Methods: Eighty parturients were randomly assigned to the air cushion or blank control group (Group A or B, respectively). The air cushion was placed in the lumbar area between the lower border of the costal arch and the iliac crest. The primary endpoint was the incidence of hypotension, while the secondary endpoints included norepinephrine dosage, success rate of maternal hypotension management, and adverse reactions like bradycardia.

Results: Hypotension occurred in 50% of the participants in Group A and 75% of those in Group B ($P=0.035$). Group A (median 4 μ g, range 0–8 μ g) required a lower norepinephrine dose than Group B (median 4 μ g, range 0–12 μ g; $P=0.015$). The success rate of hypotension management was significantly higher for Group A at 97.4% than for Group B at 83.3% ($P=0.035$). Bradycardia was less frequent for Group A than for Group B (10.5% vs 30.6%, $P=0.032$). Group A also showed a higher umbilical artery blood pH than Group B ($P=0.026$).

Conclusion: The novel air cushion pretreatment reduces the incidence of hypotension after spinal anesthesia in pregnant women, reduces the dose of single intravenous norepinephrine, improves the success rate of hypotension management, and increases the pH of fetal umbilical artery blood.

Keywords: caesarean delivery, hypotension, norepinephrine, obstetric anaesthesia, prevention, uterus lift

Introduction

Spinal anesthesia has been the most commonly used for elective cesarean sections in most countries, accounting for approximately 78% of total surgeries.^{1,2} Since 1970, ephedrine has been regarded as the gold standard for resolving hypotension after spinal anesthesia for cesarean section.^{3–5} However, increased attention has been paid to the potential of ephedrine to reduce fetal pH. Ephedrine improves maternal hypotension, but it has a direct effect on fetal acid–base balance.^{6–9} Norepinephrine had the least effect on fetal acid–base balance, and ephedrine was the least desirable vasoactive agent other than bradycardia.¹⁰ Therefore, vasoactive drugs alone are not the best treatment for hypotension after spinal anesthesia for cesarean section.

In a previous clinical study, Lee SW et al¹¹ observed that placing pregnant women in the left-leaning position was equally effective in reducing the incidence of hypotension after spinal anesthesia. Studies suggest that the left decubitus position or left shift of the uterus of more than 30° can effectively relieve the compression of the inferior vena cava.¹² Therefore, the authors invented a novel air cushion that simultaneously lifts the uterus upward from both sides of the waist of a pregnant woman to relieve the compression of the inferior vena cava in the abdomen by the uterus (Figure 1A, China Patent No.

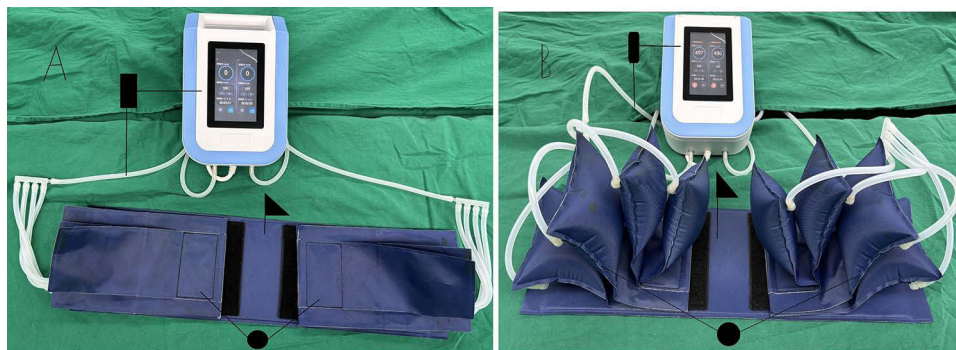


Figure 1 State of the novel air cushion before (A) and after (B) inflation.

Notes: Black rectangle: air supply device; Black Triangle: rigid support plate; Black Circle: multi-layer air cushion.

CN201810378168.4, Application Date: 2018-04-25). The advantage of the air cushion used in this study is the distribution of pressure on both sides of the abdomen. The uterus is lifted by applying pressure to both sides of the abdomen. With changes in inflation pressure, the impact of uterine compression on the inferior vena cava can be minimized (Figure 1B). This study was a randomized controlled clinical study to observe the effect of pretreatment with a new obstetric air cushion on the incidence of hypotension after spinal anesthesia.

Material and Methods

Ethics

This study was approved by the Ethics Committee of Fengxian District Central Hospital of Shanghai (2019-KY-10). A randomized, unblinded, parallel controlled study was conducted from December 2020 to June 2021. The trial was registered before patient enrollment in the Chinese Clinical Trial Registry and conducted in accordance with the Declaration of Helsinki (registration No. ChiCTR2000033991; principal investigator, Hao Weng; date of registration, July 1, 2020). All patients provided written informed consent before recruitment.

Patients and Randomization

This study included pregnant women aged 20–40 years who had weights of 50–90 kg, heights of 145–180 cm, and American Society of Anesthesiologists grades I–II; had a single pregnancy that was full-term; and underwent planned cesarean section at the Fengxian Hospital. The exclusion criteria were multiple pregnancy, suspected fetal damage, hypertension or diabetes during pregnancy, cardiovascular and cerebrovascular diseases, coagulation dysfunction, and spinal anesthesia failure, among others.

Before starting the study, a randomized sequence of 80 codes was generated using the PASS15 software, which were divided into two equally sized groups. The decision to make an air cushion inflation during this procedure was based on the envelope code. A research assistant placed a code for each patient into a sealed, opaque, numbered envelope. The assistant was not involved in patient management or data collection and was only responsible for opening envelopes for each patient in the study. The decision to inflate the air cushion during the procedure was made according to the patient code. The patients were divided into the air cushion and blank control groups according to the code. When hypotension occurred, 4 µg of norepinephrine was injected intravenously (Shanghai Hefeng Pharmaceutical Co., LTD., 1mL: 2mg, normal saline diluted to 500mL, 4ug/mL). The intravenous dose of norepinephrine was based on previously published literature and our clinical experience.¹³ The single dose was set at 1 mL (4ug). The air cushion is a patented Chinese invention. Unlike other lumbar cushion designs, this air cushion uses multiple layers of balloons for quick inflation and deflation. The position on both sides of the balloon can be individually adjusted according to the waist circumference of the patient. The actual clinical use of the patented cushion is shown in Figure 1.

Procedures

The patient received no medication before surgery. An uninflated air cushion was placed between the waist of the patient and the operating bed after entering the operating room. The venous access of the upper limbs was opened, and lactated Ringer's solution was injected to keep it open. The mean systolic blood pressure and heart rate readings at three consecutive 5-min intervals obtained after the patient was calm and before lying on the side were selected as the baseline values. The patient underwent subarachnoid puncture in the right lateral position after routine disinfection and local skin infiltration anesthesia. The L3–4 gap was selected, and a 25G lumbar puncture needle was used for the puncture. The lumbar puncture needle guide core was pulled out while gently aspirating after feeling two breakthroughs, and the reflux of cerebrospinal fluid was observed. After confirming the smooth reflux of cerebrospinal fluid, 1.5 mL of cerebrospinal fluid was extracted and mixed with 1.5 mL of 1% ropivacaine. This was injected into the subarachnoid space at a rate of 1 mL every 7 seconds. Cerebrospinal fluid was gently aspirated with a syringe to confirm its smooth reflux and ensure successful subarachnoid administration before withdrawing the lumbar puncture needle. The patient was excluded from the study if three punctures were unsuccessful.

The patient was returned to the supine position immediately after completion of the neuraxial anesthesia. In the supine position, the air cushion was adjusted below the waist to make sure it was between the iliac spine and the rib edge. The group A immediately inflated the air cushion according to the preliminary clinical trial observations, and the internal inflation pressure was set to 500 mmHg and maintained until the fetus was removed. The Group B air cushions were not inflated. According to the preliminary clinical trial observation, the inflation pressure inside the air cushion was set at 500 mmHg and maintained until the fetus was removed. All patients were not administered an intravenous infusion load.

The sensory blockade plane was measured by evaluating the loss of needle pain using an 18-gauge epidural needle, and surgery was considered feasible when the sensory blockade plane reached the T6 level. The sensory block level at 3 and 10 minutes after the subarachnoid injection was recorded for comparison.

During the subarachnoid injection, the blood pressure measurement interval was adjusted to once every minute until the fetus was delivered and changed to once every 5 minutes until the end of the surgery. The systolic blood pressure, diastolic blood pressure, and heart rate were measured at the end of each blood pressure measurement cycle. A single dose of 4 µg of norepinephrine was administered intravenously if the systolic blood pressure decreased below 90 mmHg, and the blood pressure was measured after the administration of pressors. The intravenous infusion of 4 µg of norepinephrine was continued if the systolic blood pressure remained below 90 mmHg. Ten milligrams of ephedrine had to be administered when the systolic blood pressure was still below 90 mmHg after three doses of 4 µg of norepinephrine. When the heart rate is less than 60 beats per minute. Atropine was administered intravenously at a dose of 0.5 mg atropine. The umbilical cord blood was extracted as follows. Three vascular forceps were used to clamp the umbilical cord connection between the mother and the fetus with the assistance of the surgeon. Two vascular forceps were left near the fetal end, and one vascular forceps was left at the maternal end. The umbilical cord connection between the mother and the fetus was cut. The umbilical cord was retrieved after the remainder was cut from the infant, and the umbilical artery and umbilical vein blood that had not been exchanged with the infant since removal was drawn between the two vascular forceps. The accuracy of umbilical artery and vein blood gas measurements was assessed, and relevant measures such as PaO₂, pH, BE, Lac were obtained using a blood gas analyzer. The time window for hypotension and related indicators in this study was from the time of spinal anesthesia to fetal delivery. The flow chart of patient enrollment is shown in [Figure 2](#).

Measurements

The primary outcome was the incidence of hypotension, defined as systolic blood pressure less than 90 mmHg or greater than a 20% reduction in systolic blood pressure from baseline. The outcomes included the dose of intravenous norepinephrine, blood pressure measured every minute after subarachnoid anesthesia until after fetal cesarean section, need for intravenous norepinephrine 4 µg for each hypotensive occurrence, and the total dose and number of doses calculated. Successful management of maternal hypotension was defined as the need for no more than three intravenous infusions of norepinephrine before fetal delivery. Ephedrine was administered if the maternal blood pressure was less

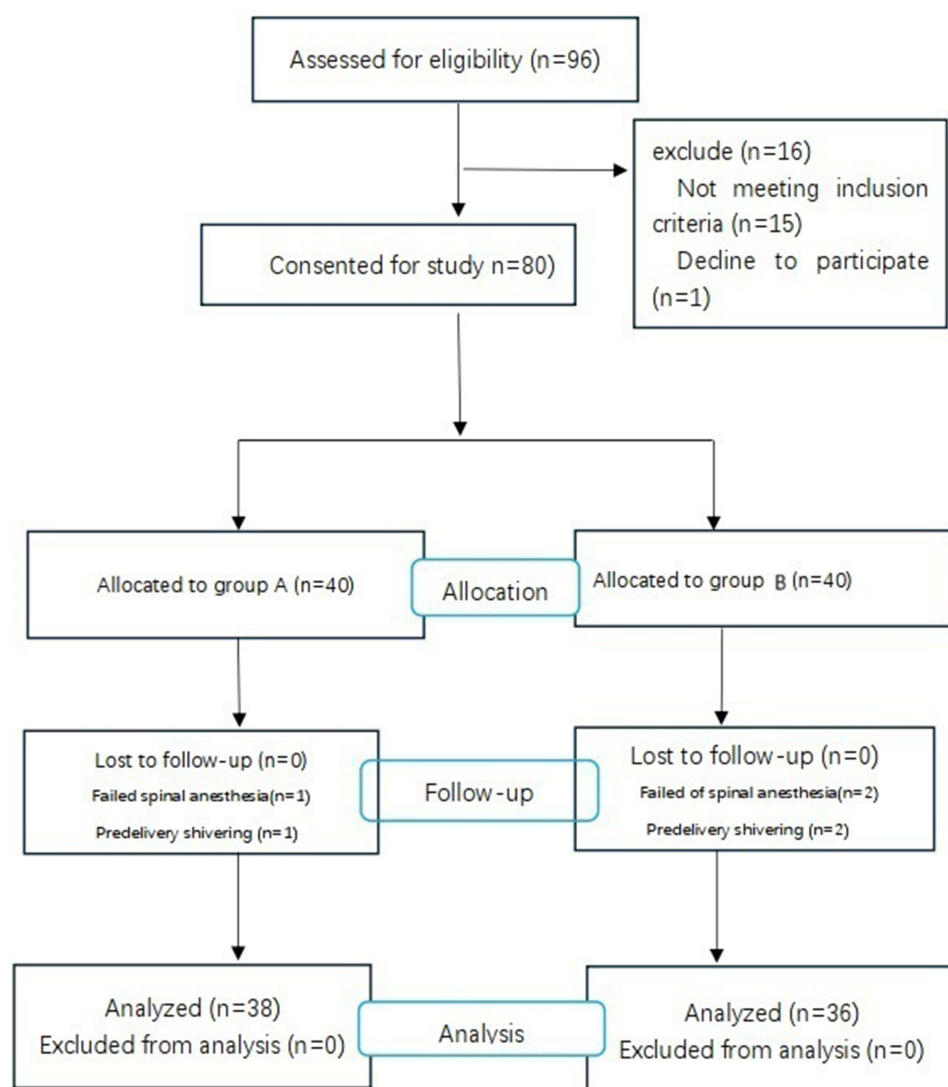


Figure 2 The clinical procedures for the study followed the CONSORT flow. Group A was given the air cushion after spinal anesthesia, while Group B not was given.

than 90 mmHg after the administration of three doses of norepinephrine. Bradycardia was defined as a heart rate of less than 60 beats per minute. Nausea and vomiting occurring between spinal anesthesia and fetal retrieval in pregnant women are categorized as follows: Grade 1, only mild nausea without vomiting; Grade 2, mild vomiting accompanied by 1–2 episodes; and Grade 3, 3 or more instances of vomiting. The secondary indicators also included neonatal Apgar score, umbilical artery, and venous blood gases.

Sample Size Calculation

PASS15 statistical software and the Cochrane Armitage proportional trend test were used to calculate sample size. This calculation was based on the preliminary results of our preliminary study conducted in 2020, where the incidence of hypotension was 42% for the air cushion group and 75% for Group B. We expect a sample size test efficiency of 80% for each group of 32 participants, with an alpha value of 0.025. Considering a dropout rate of 20%, the sample size was increased to 80 participants.

Statistical Analysis

The Shapiro Wilk method was used for normality testing of continuous data, which were presented as the mean as needed. Normally distributed data were analyzed using an independent sample *t*-test to compare the means of the two groups. Nonnormally distributed data were analyzed using the Mann–Whitney *U*-test. The chi-squared test was used to analyze the incidence of hypotension and severe hypotension in both groups. Ordered hierarchical data were analyzed using a two independent sample rank sum test. The continuous hemodynamic data for the first 10 minutes after spinal anesthesia were analyzed, and the differences in systolic blood pressure per minute between the two groups were compared using repeated measures analysis of variance (ANOVA). The linear trend analysis was used to test the linear trend between the two groups. IBM SPSS 26.0 was used for analysis. Statistical significance was set at $P < 0.05$.

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Results

The recruitment of participants is shown in [Figure 2](#). Ninety-six pregnant women who underwent elective cesarean section were included in the study. Sixteen patients were not included in the study: fifteen did not meet the inclusion criteria, and one refused to participate in the clinical study. In group A, two patients were excluded: one patient underwent epidural anesthesia after spinal anesthesia failure, and one patient had shivering after spinal anesthesia that affected blood pressure measurement. In group B, four patients were excluded: two patients changed to other anesthesia methods after the failure of spinal anesthesia, and one patient had shivering and difficulty in blood pressure monitoring. The baseline systolic blood pressure, baseline diastolic blood pressure, baseline heart rate, and sensory blockade levels of the two groups were similar ([Table 1](#)). No subjects required intravenous medication to treat intraoperative pain.

The characteristics of the patients at baseline are shown in [Table 1](#). There were no statistically significant differences in height, weight, parity, gestational age, maternal age, basal blood pressure, BMI before cesarean section, and anesthesia block plane. [Table 2](#) summarizes the hemodynamic changes, side effects, neonatal outcomes, and incidence of hypotension and severe

Table 1 Characteristics of the Patients at Baseline

| | Group A | Group B |
|---------------------------|------------|------------|
| Patient (n) | 38 | 36 |
| Height (cm) | 160.2±4.3 | 160.2±5.4 |
| Weight (kg) | 74.8±9.9 | 74.3±8.8 |
| Gestational weeks (week) | 38.2±0.8 | 38.2±0.6 |
| Age (years) | 30.5±5.0 | 31.6±5.6 |
| Baseline SBP (mmHg) | 122.4±12.8 | 126.4±13.7 |
| Baseline DBP (mmHg) | 77.3± 8.1 | 78± 10.8 |
| Baseline heart rate (bpm) | 93.8±13.8 | 94.8±10.1 |
| Feeling blocked segment | 4(4–4) | 4(4–4) |

Notes: Value are express as mean ± standard deviation, Group A= air cushion, Group B=blank control. No statistical difference was observed in this table.

Abbreviations: SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure.

Table 2 Indicators Associated with Hypotension in Pregnant Women

| | Group A (n=38) | Group B (n=36) | P-Value |
|---|-------------------|-------------------|---------|
| SBP<100mmHg (n[%]) | 31[81.6%] | 32[88.9%] | 0.377 |
| SBP<90mmHg (n[%]) | 19[50.0%]* | 27[75.0%] | 0.027 |
| SBP<80mmHg (n[%]) | 9[23.7%]* | 17[47.2%] | 0.034 |
| SBP<70mmHg (n[%]) | 3[7.9%]* | 10[27.8%] | 0.025 |
| Success rates of hypotension treatment (n[%]) | 37[97.4%]* | 30[83.3%] | 0.035 |
| No hypotension occurred (n[%]) | 19[50.0%]* | 9[25.0%] | 0.027 |
| Reactive hypertension (n[%]) | 0[0%] | 0[0%] | – |
| Bradycardia (n[%]) | 4[10.5%]* | 11[30.6%] | 0.032 |
| Nausea and vomiting grading [median (IQR)] | 0(0–1)* | 1(1–2) | 0.001 |
| Apgar [median (IQR)] | 10.0(10.0–10.0)* | 10.0(9.3–10.0) | 0.006 |
| Umbilical artery pH | 7.310±0.029* | 7.292±0.038 | 0.021 |
| Umbilical vein pH | 7.362±0.034 | 7.345±0.046 | 0.086 |
| Umbilical vein PaO ₂ (mmHg) | 24.87± 6.25 | 23.40± 6.15 | 0.337 |
| Umbilical vein Lac (mmol/L) | 2.67±0.95 | 3.31±1.74 | 0.078 |
| Umbilical vein BE (mmol/L) | –1.84±1.74 | –2.02±2.42 | 0.746 |
| Norepinephrine usage (μg) | 4(0–8)* | 4(0–12) | 0.015 |
| Epinephrine use times (rate) | 0.5(0–2)* | 1(0–3) | 0.019 |

Notes: Value are express as mean ± standard deviation or number of patients (%), Group A= air cushion, Group B=blank control. *P < 0.05 vs group B.

Abbreviation: SBP, Systolic Blood Pressure.

hypotension. The proportion of patients experiencing hypotension decreased with the use of an air cushion ($P=0.027$). Additionally, the dosage of norepinephrine showed a significant difference between the air cushion and control groups ($p=0.025$). Likewise, there was a statistically significant difference in the proportion of severe hypotension between the two groups. Further, the number of participants requiring physician interventions related to blood pressure was significantly different for the groups ($P=0.019$). Finally, a significant difference in the management success rate of hypotensive patients after spinal anesthesia-induced cesarean section was observed between the two groups ($P=0.035$).

Figure 3 shows a series of changes in systolic blood pressure during the first 10 minutes after spinal anesthesia. The results of repeated measures analysis of variance showed statistically significant differences in systolic blood pressure at

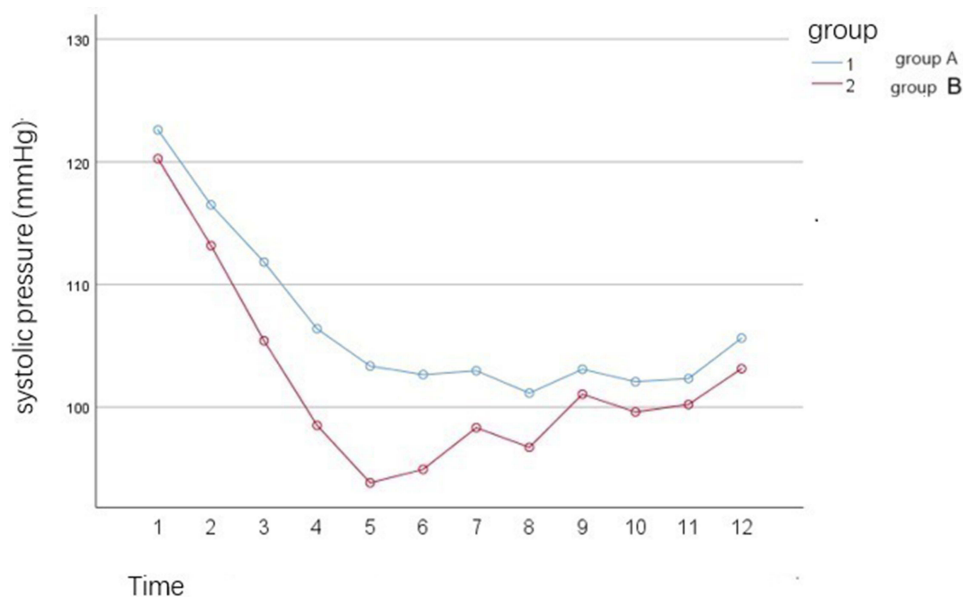


Figure 3 Dynamic systolic blood pressure from spinal anesthesia to fetal retrieval. Group A= air cushion; Group B= Blank control, the air cushion was not inflated. Abbreviations: T0, spinal anesthesia onset time; T1, 1min after spinal anesthesia, And so on.

Table 3 Hemodynamic Changes per Minute in the First 10 minutes After Spinal Anesthesia

| | Group A | Group B | F | P |
|--------------------------|-------------|------------|-------|-------|
| Initiation of anesthesia | 122.7±11.8 | 120.3±9.9 | 0.893 | 0.348 |
| First minute SBP (mmHg) | 116.8±8.7 | 113.2±11.0 | 2.523 | 0.117 |
| 2nd minute SBP (mmHg) | 112.7±15.7* | 105.4±13.5 | 4.589 | 0.036 |
| 3rd minute SBP (mmHg) | 107.5±17.8* | 98.5±20.0 | 4.221 | 0.044 |
| 4th minute SBP (mmHg) | 104.1±18.4* | 93.8±20.4 | 5.155 | 0.026 |
| 5th minute SBP (mmHg) | 102.8±19.0 | 94.9±18.3 | 3.277 | 0.074 |
| 6th minute SBP (mmHg) | 102.8±18.1 | 98.3±17.7 | 1.157 | 0.286 |
| 7th minute SBP (mmHg) | 101.4±15.4 | 96.7±14.5 | 1.792 | 0.185 |
| 8th minute SBP (mmHg) | 103.5±16.7 | 101.1±15.8 | 0.410 | 0.524 |
| 9th minute SBP (mmHg) | 102.7±13.0 | 99.6±16.0 | 0.837 | 0.363 |
| 10th minute SBP (mmHg) | 102.8±9.7 | 100.2±13.1 | 0.967 | 0.329 |
| F | 34.083 | 39.066 | | |
| P | <0.01 | <0.01 | | |

Notes: Value are express as mean ± standard deviation, Group A= air cushion, Group B=blank control. *P < 0.05 vs group B.

Abbreviation: SBP, Systolic Blood Pressure.

different time points within the group. The results of repeated measures analysis of variance (ANOVA) showed that there were statistically significant differences in systolic blood pressure at different time points within the group ($P<0.05$). There was also a statistically significant difference in continuous systolic blood pressure between the groups ($P<0.05$). There was no statistically significant difference in the interaction effect. The results of the simple effect analysis showed significantly different systolic blood pressures at 2, 3, and 4 minutes after spinal anesthesia, as shown in Figure 3 and Table 3 ($P<0.05$). This highlighted the difference between the air cushion and the control groups, as illustrated in Figure 3 and Table 3.

Significant differences were observed in several outcomes of the two groups. The incidence of nausea and vomiting were significantly different ($P=0.001$), as were umbilical artery pH ($P=0.026$) and bradycardia ($P=0.032$). However, no statistically significant differences were found in other neonatal outcomes, as indicated in Table 2. This suggests a specific impact on these adverse events in the context of the comparison of the two groups.

Discussion

The use of a novel air cushion pretreatment significantly reduced the incidence of hypotension and amount of norepinephrine after spinal anesthesia, improved the success rate of hypotension management, reduced the incidence of bradycardia, and increased the pH of fetal umbilical artery blood to promote placental blood supply relative to that of the blank control group.

A large body of literature has demonstrated that adjusting the position to relieve the pressure of the uterus on the inferior vena cava can effectively reduce the incidence of supine hypotension syndrome in women with mid- and late-stage pregnancies. In 2019, Allison Lee et al¹⁴ noted that a 30° left tilt in pregnant women can significantly alleviate inferior vena cava occlusion. However, this angle may be difficult to achieve in clinical practice. Xiao et al¹⁵ demonstrated that the use of stents to lift the uterus from both sides of the abdomen at the same time can reduce the incidence of post-spinal hypotension. However, the application method is complex and limits the free adjustment of the position of the patient. The new air cushion used in this study can be rapidly compressed or dilated, which is convenient for rapid lifting

of the uterus and relieves the pressure of the inferior vena cava without affecting the adjustment of the position of the patient, procedure of the anesthesiologist, and surgery. Moreover, the air cushion pressure adjustment was flexible and convenient for clinical medical workers.

This study observed a 25% reduction in the incidence of systolic blood pressure of <90 mmHg in pregnant women with prophylactic use of the novel air cushion after spinal anesthesia from 75.00% to 50.00%. The incidence of hypotension (SBP <80 mmHg) decreased by 24% from 47.2% to 23.7%. As shown in Figure 3, the reduction in systolic blood pressure within 10 minutes after spinal anesthesia in the air cushion group was lesser than that of the blank control. The systolic blood pressure of the air cushion group was higher than that of the blank control group at the second, third, and fourth minutes after spinal anesthesia. Xiao Tianke et al¹⁵ showed that hypotension after spinal anesthesia was reduced by 24.5% after using preventive lumbar pad in pregnant women. Yi Chen et al¹⁶ conducted a prophylactic intravenous continuous pumping of norepinephrine to prevent hypotension in pregnant women after spinal anesthesia, with a success rate of 82.5%, which was similar to our experimental results. Neither of the above two methods of preventing hypotension can completely prevent hypotension. The main cause of hypotension after spinal anesthesia in pregnant women is not just a decrease in bilateral venous return and cardiac output due to uterine compression of the inferior vena cava. The incidence of bradycardia in the air cushion group was significantly lower than that in the control group, and it decreased from 30.6% to 10.5%. Ngan¹³ observed that the incidence of bradycardia during prophylactic use of norepinephrine was 26%. The incidence of prophylactic phenylephrine-induced bradycardia was 37.5%.¹⁷ A review of the results of several studies suggests that norepinephrine is a strong alpha-adrenergic agonist and a weak beta-adrenergic agonist that induces maternal reflex bradycardia with decreased cardiac output at high doses. The use of norepinephrine was further supported by studies by Chinese anesthesiologists, which reported significantly reduced incidence of bradycardia. It was associated with higher CO compared with equivalent doses of phenylephrine.¹⁸ In addition to drug-induced maternal reflex bradycardia, an additional cause of bradycardia in this study was uterine compression of the inferior vena cava. Poor venous return in both lower limbs resulted in a sharp decrease in effective circulating blood volume, a stretch reflex at the junction of the vena cava and the right atrium, vagal inhibition, enhancement of the sympathetic nervous system, and a compensatory increase in cardiac output. With the sharp decrease in return blood volume and decrease in cardiac output, coronary blood supply decreases, ventricular relaxation time increases, and vagus nerve excitation causes bradycardia, resulting in the Bainbridge reflex.^{19,20} The lumbar pad reduces uterine pressure on the inferior vena cava, increases cardiac blood volume, and decreases the Bainbridge reflex.

Compared with the control group, air cushions may enhance the effectiveness of norepinephrine in managing hypotension. Six patients in the blank control group did not have an increase in systolic blood pressure above 90 mmHg after intravenous norepinephrine. Six patients in the blank control group did not have an increase in systolic blood pressure above 90 mmHg after intravenous norepinephrine. Six patients in the blank control group did not demonstrate an increase in systolic blood pressure above 90 mmHg after intravenous norepinephrine. In this study, prophylactic use of air cushions relieved obstruction of uterine compression of the inferior vena cava and increased effective circulating blood volume in pregnant women. The success rate of norepinephrine treatment of the air cushion group was 97.4% for the air cushion groups but could not be completely corrected for 87.3% of the patients in the control group. The prevalence of refractory hypotension was 13.7%, and it could not be maintained by vasopressors. None of the groups had a case of reactive hypertension caused by vasoactive drug. Hassabelnaby et al²¹ found that the incidence of reactive hypertension after prophylactic use of 6 and 8 μ g of intravenous infusion of norepinephrine was approximately 9%. In this study, the success rate of hypotension treatment after using the new air cushion significantly improved, and the dosage of norepinephrine was reduced. No case of reactive hypertension was reported in both groups. Therefore, the treatment of hypotension in pregnant women after spinal anesthesia requires the use of air cushions to relieve inferior vena cava obstruction and use of vasopressors to constrict peripheral blood vessels. This combined approach offers an effective strategy for managing hypotension in pregnant women after spinal anesthesia by using air cushions to relieve inferior vena cava obstruction and vasopressors to constrict peripheral blood vessels. This improved the success rates of preventing hypotension and minimizing the risk of reactive hypertension.

The results of this study showed that the decrease of the systolic blood pressure of the air cushion group after spinal anesthesia was slower and more stable than that of the control group. The systolic blood pressure of the air cushion group was significantly higher than that of the control group at 4 min after spinal anesthesia. The incidence of bradycardia in the air cushion group was significantly lower than that in the control group (10.5% vs 30.6%). The possible reason is that the air

cushion immediately inflates and lifts the uterus after the women receives spinal anesthesia to relieve the pressure on the inferior vena cava and prevent hypotension. At the same time, intermittent intravenous injection of vasopressor drugs after the women suffer from hypotension can improve peripheral vascular resistance and increase returned blood volume, which plays a role in the treatment of maternal hypotension. This was clearly expressed in the results of this study, showing that the air cushion has a good effect on the prevention of maternal hypotension and enhances the therapeutic effect of a single intravenous injection of norepinephrine on hypotension after spinal anesthesia.

Maternal nausea, vomiting, bradycardia, and fetal acidosis are common adverse reactions during cesarean section under spinal anesthesia [(median 0, range 0–1) vs (median 1, range 1–2; $p=0.001$)]. The results of this study showed that the grades of nausea and vomiting for the air cushion group were lower than those for the control group. The pH value of fetal umbilical artery blood was also higher than that of the control group, and fetal umbilical artery blood had a better outcome. This may be attributed to the reduction of the incidence of hypotension by the air cushion, which can lead to nausea and vomiting. The air cushion also reduces the amount of vasopressor during cesarean section under spinal anesthesia, reduces the effect of norepinephrine on placental vasoconstriction, and is more conducive to fetal blood supply, which may yield better maternal and infant outcomes. There are some limitations to our study. First, we only measured intermittent noninvasive blood pressure and heart rate as the main indicators and did not monitor maternal cardiac output changes. Second, our sample size was limited, and Class II errors were probable. The effects of air cushion lifting on lower extremity vein diameter, blood flow rate, and pressure were not observed.²² Furthermore, we included only low-risk patients with elective cesarean section. We need to further investigate the mechanism of the novel obstetric air cushion in preventing hypotension after spinal anesthesia.

Conclusion

In summary, the use of novel air cushion pretreatment after spinal anesthesia reduced the incidence of hypotension after cesarean section, dose and frequency of norepinephrine, incidence of bradycardia, and severity of nausea and vomiting in pregnant women. It also improved the success rate of hypotension management and increased the pH of fetal umbilical artery blood relative to that of the blank control group.

Abbreviations

SBP, Systolic Blood Pressure; BP, blood pressure; HR, heart rate; PH, pondus hydrogenii; CO, cardiac output; ASA, American Society of Anesthesiologists physical status.

Data Sharing Statement

The data that support the study findings are available from the corresponding author upon reasonable request. Original data are required to contact corresponding author Ding-ding Huang (huangdingding1984@163.com).

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Disclosure

The authors report no conflicts of interest in this work.

References

1. Massoth C, Töpel L, Wenk M. Hypotension after spinal anesthesia for cesarean section: how to approach the iatrogenic sympathectomy. *Curr Opin Anaesthesiol.* 2020;33(3):291–298. doi:10.1097/ACO.0000000000000848
2. Mhyre JM, Sultan P. General Anesthesia for Cesarean Delivery: occasionally Essential but Best Avoided. *Anesthesiology.* 2019;130(6):864–866. doi:10.1097/ALN.0000000000002708
3. Birnbach DJ, Soens MA. Hotly debated topics in obstetric anesthesiology 2008: a theory of relativity. *Minerva Anesthesiol.* 2008;74(7–8):409–424.
4. Burns SM, Cowan CM, Wilkes RG. Prevention and management of hypotension during spinal anaesthesia for elective Caesarean section: a survey of practice. *Anaesthesia.* 2001;56(8):794–798. doi:10.1046/j.1365-2044.2001.02058-5.x
5. Campbell JP, Stocks GM. Management of hypotension with vasopressors at caesarean section under spinal anaesthesia - have we found the Holy Grail of obstetric anaesthesia? *Anaesthesia.* 2018;73(1):3–6. doi:10.1111/anae.14114
6. JL Apfelbaum, JL Hawkins, M Agarkar, et al. Practice Guidelines for Obstetric Anesthesia: an Updated Report by the American Society of Anesthesiologists Task Force on Obstetric Anesthesia and the Society for Obstetric Anesthesia and Perinatology. *Anesthesiology.* 2016;124(2):270–300. doi:10.1097/ALN.0000000000000935
7. Cooper DW, Carpenter M, Mowbray P, Desira WR, Ryall DM, Kokri MS. Fetal and maternal effects of phenylephrine and ephedrine during spinal anesthesia for cesarean delivery. *Anesthesiology.* 2002;97(6):1582–1590. doi:10.1097/00005542-200212000-00034
8. Lee A, Ngan Kee WD, Gin T. A quantitative, systematic review of randomized controlled trials of ephedrine versus phenylephrine for the management of hypotension during spinal anesthesia for cesarean delivery. *Anesth Analg.* 2002;94(4):920–926. doi:10.1097/00005539-200204000-00028
9. Ngan Kee WD, Khaw KS, Tan PE, Ng FF, Karmakar MK. Placental transfer and fetal metabolic effects of phenylephrine and ephedrine during spinal anesthesia for cesarean delivery. *Anesthesiology.* 2009;111(3):506–512. doi:10.1097/ALN.0b013e3181b160a3
10. Singh PM, Singh NP, Reschke M, Ngan Kee WD, Palanisamy A, Monks DT. Vasopressor drugs for the prevention and treatment of hypotension during neuraxial anaesthesia for Caesarean delivery: a Bayesian network meta-analysis of fetal and maternal outcomes. *Br J Anaesth.* 2020;124(3):e95–e107. doi:10.1016/j.bja.2019.09.045
11. Lee SW, Khaw KS, Ngan Kee WD, Leung TY, Critchley LA. Haemodynamic effects from aortocaval compression at different angles of lateral tilt in non-labouring term pregnant women. *Br J Anaesth.* 2012;109(6):950–956. doi:10.1093/bja/aes349
12. Higuchi H, Takagi S, Zhang K, Furui I, Ozaki M. Effect of lateral tilt angle on the volume of the abdominal aorta and inferior vena cava in pregnant and nonpregnant women determined by magnetic resonance imaging. *Anesthesiology.* 2015;122(2):286–293. doi:10.1097/ALN.0000000000000553
13. Ngan Kee WD, Lee SWY, Ng FF, Lee A. Norepinephrine or phenylephrine during spinal anaesthesia for Caesarean delivery: a randomised double-blind pragmatic non-inferiority study of neonatal outcome. *Br J Anaesth.* 2020;125(4):588–595. doi:10.1016/j.bja.2020.05.057
14. Lee A, Ngan Kee W. Effects of Vasoactive Medications and Maternal Positioning During Cesarean Delivery on Maternal Hemodynamics and Neonatal Acid-Base Status. *Clin Perinatol.* 2019;46(4):765–783. doi:10.1016/j.clp.2019.08.009
15. Xiao T, Li W, Zhang K, JJJJoC W, Medicine E. Clinical study of air pressure uterus bracket in preventing supine hypotensive syndrome during C-section under combined spinal-epidural anesthesia. *Int J Clin Exp Med.* 2017;10(9):13598–13606.
16. Chen Y, Guo L, Shi Y, et al. Norepinephrine prophylaxis for postspinal anesthesia hypotension in parturient undergoing cesarean section: a randomized, controlled trial. *Arch Gynecol Obstet.* 2020;302(4):829–836. doi:10.1007/s00404-020-05663-7
17. Sharkey AM, Siddiqui N, Downey K, Ye XY, Guevara J, Carvalho JCA. Comparison of Intermittent Intravenous Boluses of Phenylephrine and Norepinephrine to Prevent and Treat Spinal-Induced Hypotension in Cesarean Deliveries: randomized Controlled Trial. *Anesth Analg.* 2019;129(5):1312–1318. doi:10.1213/ANE.0000000000003704
18. Wang X, Mao M, Zhang SS, Wang ZH, Xu SQ, Shen XF. Bolus norepinephrine and phenylephrine for maternal hypotension during elective cesarean section with spinal anesthesia: a randomized, double-blinded study. *Chin Med J.* 2020;133(5):509–516. doi:10.1097/CM9.0000000000000621
19. Comito C, Bechi L, Serena C, et al. Cardiac arrest in the delivery room after spinal anesthesia for cesarean section: a case report and review of literature. *J Matern Fetal Neonatal Med.* 2020;33(8):1456–1458.
20. Kinsella SM, Tuckey JP. Perioperative bradycardia and asystole: relationship to vasovagal syncope and the Bezold-Jarisch reflex. *Br J Anaesth.* 2001;86(6):859–868. doi:10.1093/bja/86.6.859
21. Hassabelnaby YS, Hasanin AM, Adly N, et al. Comparison of two Norepinephrine rescue bolus for Management of Post-spinal Hypotension during Cesarean Delivery: a randomized controlled trial. *BMC Anesthesiol.* 2020;20(1):84. doi:10.1186/s12871-020-01004-y
22. Goulart VB, Cabral AC, Reis ZS, et al. Anatomical and physiological changes in the venous system of lower limbs in pregnant women and findings associated with the symptomatology. *Arch Gynecol Obstet.* 2013;288(1):73–78. doi:10.1007/s00404-013-2728-9

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