

# Hemodynamic changes under spinal anesthesia after elastic wrapping or pneumatic compression of lower limbs in elective cesarean section: A randomized control trial

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## Abstract

**Background and Aims:** In spite of adequate fluid loading and left lateral tilt, parturients develop hypotension under spinal anesthesia during cesarean section. Elastic crepe bandage (CB) or pneumatic compression device (PCD) can be utilized to prevent the pooling of blood in lower limbs and thereby it may reduce the incidence of hypotension in these patients. This study was formulated to analyze the hemodynamic effects of leg wrapping with elastic CB and PCD in parturients undergoing for cesarean section under anesthesia.

**Material and Methods:** Ninety term obstetric patients posted for elective cesarean section under spinal anesthesia were randomized into 3 groups: Group 1 (control), Group 2 (CB), and Group 3 (PCD). All the parturients had their legs wrapped with an elastic bandage and pneumatic sleeve applied over it. In Group 1 (Control), patients had their legs wrapped with CB loosely and pneumatic sleeve also applied was switched on. In Group 2, patients the CB was applied by stretching the bandage (15 cm width and 4 m stretched length). The PCD was not switched on in this group. In Group 3, the legs were wrapped with the CB loosely. The pneumatic sleeve was applied over the bandage, and the machine was switched on with a preset pressure of 40–50 mmHg after spinal anesthesia. Incidence of maternal hypotension and ephedrine requirement to maintain systolic blood pressure, neonatal Apgar score were recorded.

**Results:** The incidence of hypotension was significantly lower in Group 2 and 3 than the control group. Similarly, the requirement of ephedrine was significantly high in control group compared to CB and PCD. The incidence of hypotension was lower in group CB than group PCD. Meantime to receive the first dose of ephedrine was significantly low in control ( $7.37 \pm 4.94$  min) as compared to CB ( $10 \pm 2.8$  min) and PCD ( $13.88 \pm 9.23$ ).

**Conclusion:** Leg-wrapping with CB is cost-effective, non-invasive, non-pharmacological, and effective tool to reduce the incidence of hypotension after spinal anesthesia in a parturient.

**Keywords:** Hypotension, pneumatic compression device, spinal anesthesia

## Introduction

Spinal anesthesia is the most commonly used anesthetic technique for LSCS. Obstetric patients are more prone for

hypotension with spinal anesthesia in spite adequate fluid loading owing to aortocaval compression by gravid uterus before delivery of the baby, pooling of blood in lower limbs, and loss of vascular tone owing to sympatholysis caused by spinal anesthesia.<sup>[1]</sup> The left lateral tilt of gravid uterus can

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relieve the aortocaval compression.<sup>[2,3]</sup> A routine practice of treatment for hypotension after adequate fluid loading and left lateral tilt during spinal anesthesia is with vasopressors such as ephedrine, mephentermine, and phenylephrine.<sup>[3,4]</sup> These agents have their adverse effects such as tachycardia, headache with higher doses. By wrapping the legs with crepe bandage (CB), the pooling of blood in lower limbs can be prevented. CB is a simple, non-pharmacological, non-invasive, cost-effective tool.<sup>[5,6]</sup> Similarly, the utility of pneumatic compression device (PCD)<sup>[7]</sup> will propel the blood into the central circulation. PCD include the air pump and inflatable sleeves or boots. It is designed to improve the drainage and thereby prevents stasis.<sup>[5]</sup> It is commonly used in patients who are at risk for deep venous thrombosis (DVT) and pulmonary embolism (PE). Combining preloading, left lateral tilt and leg wrapping with CB or PCD may bring down the incidence and severity of hypotension. There were studies that compared leg wrapping with either CB or PCD with the control group<sup>[8-11]</sup> and found that the incidence of hypotension was lesser in the leg wrapping group. In this study, effects of CD, PCD, and control group on hemodynamics in parturient were evaluated after spinal anesthesia.

The current study intends to study the hemodynamic changes during spinal anesthesia in three groups of parturients, one in which the patients have their lower extremities wrapped in CB, the other with a PCD, and the third a control group. The primary objective of the study was to evaluate the incidence of hypotension and requirement of vasopressors in all the groups. The secondary objectives of this study were to study the hemodynamic effects in all the groups, Apgar score of the baby, and any adverse events.

## Material and Methods

Full-term parturients with singleton uncomplicated pregnancies scheduled for elective LSCS) under spinal anesthesia formed the study population. Institute ethics committee permission was obtained to perform the study. Informed consent was taken from all patients. Patient refusal, parturient for emergency LSCS, known case of DVT and contraindication to spinal anesthesia were criteria for exclusion from the study.

The *primary objectives* of the study were to compare the incidence of hypotension and requirement of vasopressors (ephedrine) in the respective groups. *Secondary objectives* were the hemodynamic effects between the groups and Apgar score of the baby. The sample size was calculated taking into consideration the incidence of hypotension as our primary outcome. On the basis of the previous study by Rout *et al.*, which reported a 35% difference in the incidence of hypotension

between groups, with an alpha error of 0.05 and beta error of 80%, the sample size was calculated as 30 patients per group by the following derivation:

$$2(z\alpha+z1-\beta)^2 \times (p1 \times q1) + (p2 \times q2)/d^2$$

$$[2 (1.96 + 0.842)^2 \times (0.7 \times 0.3)] + (0.5 \times 0.5) / (0.35)^2 = 28.95$$

where  $Z\alpha = 1.96$  (0.05 P value),  $Z1-\beta = 0.842$  corresponding to 80% power.

$p1 = 70\%$  (Incidence of hypotension in prior control group).

$(1 - p1) = q1 = 30\%$  (Incidence of no hypotension in prior study group).

$p2 = 50\%$  (Incidence of hypotension in present control).

$(1 - p2) = q2 = 50\%$  (incidence of no hypotension in present study).

$d2 = 35\%$  difference we expected in our study. Additional 10% parturient were recruited keeping a possibility of exclusion owing to failed block after randomization.

Elastic stretchable bandage (CB) is used to create localized pressure [Figure 1]. It provides high resting compression and low active compression. It does not permit blood to pool in the peripheral compartment thus improving central blood volume. Commercially available CBs at our Institute measure 15 cm in width and 4 m in stretched length. It is stretchable, cost-effective, easily available, and has no major reported adverse effects. PCD is an intermittent compression device that includes an air pump and inflatable auxiliary sleeves, gloves, or boots in a system designed to improve venous circulation



**Figure 1:** Showing crepe bandage and pneumatic compression device (a) Crepe Bandage (b and c) Pneumatic compression device

in the limbs of patients who suffer edema or are prone to the risk of DVT or PE. NEOMEDIC (USA)<sup>[11]</sup> PCD pump was used in this study [Figure 1]. The pneumatic pump prevents pooling of blood in the lower limbs by producing circumferential compressions and decompressions at preset pressures. The compression cycles have been timed to the patient's venous refilling. This makes it more efficient in moving the peripherally pooled blood to the central compartment, and thus gives it a major advantage over the other pumps. Graduated sequential compression was done by keeping a set pressure of 50 mmHg with continuous mode timer, which gives 36 s of inflation and 24 s of deflation. The primary functional aim of the device is to squeeze the blood from the underlying deep veins assuming that the valves are competent and thereby blood will be displaced proximally. When the inflatable sleeves deflate, the veins will replenish with blood. The intermittent compressions of the sleeves will ensure the movement of venous blood.

Patient characteristics including age, weight, and gestational age were recorded after recruiting them into the study. They were randomized into three groups namely Group 1 (Control), (CB) crepe Bandage Group 2 (group CB), and Group 3 (group PCD) by a computer-generated random number allocation technique. All patients who participated in the study were kept fasting for a period of at least 6 h and premedicated with ranitidine 150 mg orally on the night before and on the morning of surgery. Baseline blood pressure (BP) and heart rate (HR) were measured in the supine posture with 15° left lateral tilt given by a wedge, measuring 10 cm in height. Baseline HR, systolic blood pressure (SBP), mean arterial pressure (MAP), and SpO<sub>2</sub> were noted down. Intravenous fluid preloading was done with 20 ml/kg of warm Ringer's lactate solution over 15–20 min just prior to the administration of spinal anesthesia. All the parturients had their legs wrapped with an elastic bandage and pneumatic sleeve applied over their legs. CB was applied by stretching the bandage (15 cm width, 4 m stretched length) for parturients belonged to Group 2 (CB). It was applied from the ankle to the mid-thigh in both legs and wrapped tightly enough that the parturient felt the tightness but was comfortable. Legs were raised 45° during wrapping. Care was taken to avoid compressing the legs to a greater extent than the mean arterial pressure by checking for capillary pulsation in the toes. The PCD was not switched on in this group. In Group 3 (PCD), the legs were wrapped with the CB loosely. The pneumatic sleeve was applied over the bandage from ankle to mid-thigh, and the machine was switched on after administering spinal anesthesia with a preset pressure of 40–50 mmHg and a cycle of 36 s sequential compression and followed by decompression for 24 s as described earlier. The

equipment was covered by the drapes such that the attending anesthesiologist was blinded to the functioning of the pump. In Group 1 (Control), patients had their legs wrapped and pneumatic sleeve applied, but both were not activated. The same person responsible for group allocation had done the wrapping and applied the sleeve in about 3 min to eliminate bias. The person who recorded the physiological variables was blinded to the group allocation.

Spinal anesthesia was performed in the left lateral position using a 25G Quincke' tip needle in the L3-L4 interspace through midline approach under all aseptic precautions. All parturients received 1.8 ml (9 mg) of 0.5% hyperbaric bupivacaine intrathecally. Thereafter, the parturients were placed supine with 15° left lateral tilt. Lactated Ringer's solution was used for maintenance and replacement. HR, SBP, diastolic blood pressure, MAP, and SpO<sub>2</sub> were recorded every 2 min till the delivery of the baby and every 5 min after the baby delivery. Hypotension was defined as fall in SBP to ≤90 mmHg or >20% fall from the baseline and intravenous ephedrine sulphate initially 3 mg followed by total of 6 mg bolus was administered to treat hypotension in all the three groups. Duration of surgery and any intraoperative complications were also recorded. During the procedure, the highest level of sensory block was noted. Neonatal outcome was assessed using Apgar score at 1 and 5 min. Other parameters observed were an induction-incision interval (min), incision delivery interval (min), nausea, vomiting, lowest SBP (mmHg), spinal to 1<sup>st</sup> dose ephedrine time (min), ephedrine dose pre-delivery, and post-delivery (mg). All data were entered into a data collection proforma sheet and were entered into Excel (MS Excel 2010).

Statistical analysis was carried out using SPSS version 16.0 (IBM SPSS, US) software. Quantitative data were reported as mean ± standard deviation, median (range), and qualitative data with percentage. Incidence of hypotension and requirement of ephedrine among the groups were analyzed by using Chi-square test, and serial hemodynamic measurements were analyzed by one-way ANOVA.

## Results

Ninety full-term obstetric patients posted for elective LSCS were recruited in the study. Demographic characteristics were comparable among the groups [Table 1]. Baseline HR, SBP, and level of spinal anesthesia were comparable between the groups [Tables 2 and 3] Out of 30 parturients in each group, twenty developed hypotension in Control group (66.7%), two in the CB group (6.7%), and eight in the PCD group (26.6%) [Figure 2]. The incidence of hypotension was significantly higher in the

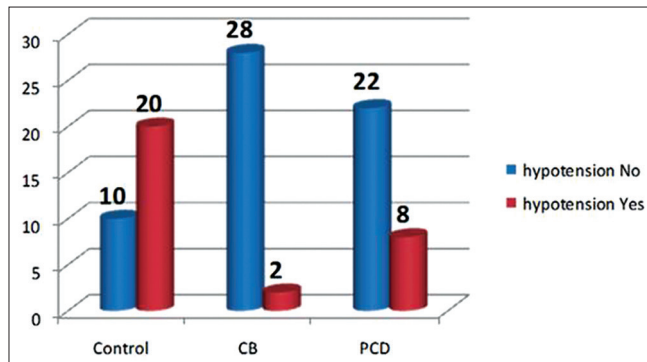
Control group than the group CB and group PCD ( $p < 0.0001$ ). The incidence of hypotension was higher in the PCD group than the group CB ( $p < 0.038$ ). Analysis of SBP between Group 1 and Group 2 following administration of spinal anesthesia revealed that there was statistically significant difference at the 8<sup>th</sup> ( $P = 0.002$ ), 10<sup>th</sup> ( $P = 0.005$ ), 12<sup>th</sup> ( $P = 0.026$ ), and 14<sup>th</sup> min ( $P = 0.018$ ) before delivery of the baby [Figure 3]. There was no statistically significant difference in SBP between Group 1 and Group 3 at any point of time before delivery of the baby. While comparing SBP between Groups 2 and 3, a statistically significant difference was noted at the 6<sup>th</sup> (0.022) and 8<sup>th</sup> min ( $P = 0.037$ ) before delivery of the baby. Statistically significant differences in SBP were noted between Groups 1 and 2 only at the 10<sup>th</sup> min ( $P = 0.038$ ) following delivery of

the baby delivery. Ephedrine boluses of 6 mg were required for 17 parturients in Group 1, 1 parturient Group 2, and for 7 in Group 3 before delivery of the baby [Figure 4]. One parturient required a repeat dose of ephedrine, total of 9 mg (6 mg + 3 mg) in Group 1. None of the other study groups required repeated (second) doses of ephedrine prior to delivery of the baby. After delivery of the baby, 10 patients in Group 1, 2 in Group 2, and 4 in Group 3 required ephedrine 6 mg. Further, after the delivery of the baby, two patients in Group 1 required repeated doses of ephedrine 12 mg (6 + 6) followed by another 3 mg. Groups 2 and 3 required no repeat (second) doses of ephedrine after delivery of the baby. Number of patients requiring ephedrine were statistically significant among the groups. There were significantly more number of patients required ephedrine in Group- 1 when compared with Group 2 ( $p < 0.0001$ ); Group 1 and 3 ( $p < 0.0001$ ), and Group 2 and 3 ( $p < 0.038$ ). Meantime to receive the first dose of ephedrine was  $7.37 \pm 4.94$  min in Group 1,  $10 \pm 2.8$  min in Group 2, and  $13.88 \pm 9.23$  min in Group 3 [Figure 5]. It had shown that mean time to receive first dose of ephedrine was less in the control as compared to CB and PCD, and this difference was found to be statistically significant ( $p < 0.036$ ).

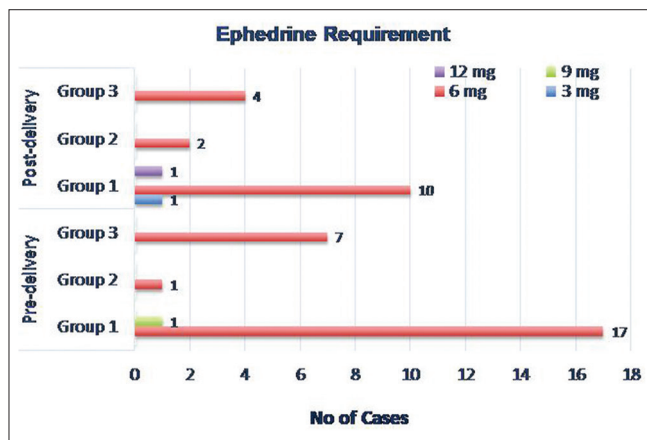
**Table 1: Demographic Data**

Parameters	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	P
Age*	26.83±3.53	25.73±3.75	25.27±3.23	0.43
BMI*	22.53±1.925	22.17±2.245	21.93±2.116	0.539
ASA* 1 & 2	24 & 6	25 & 5	26 & 4	0.563
Gestational Age*	39.23±0.971	39.23±0.971	39±0.756	0.526
Duration of surgery**	55 min (35-84)	55.5 min (45-84)	52 (35-65)	0.438

\*Mean ± SD, \*\*Median and range

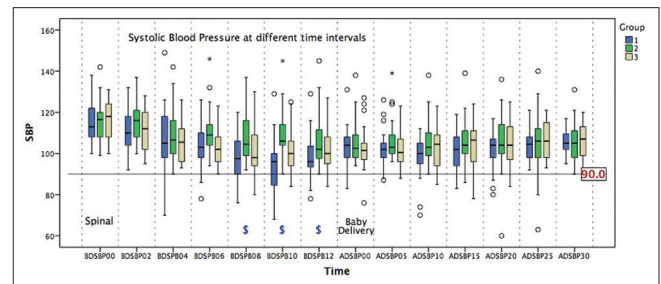


**Figure 2:** Incidence of hypotension among the groups

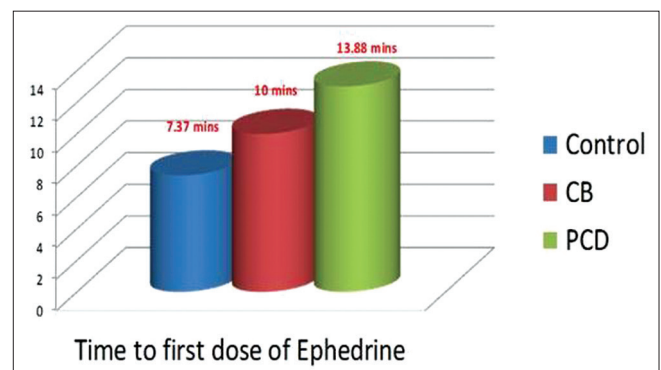


**Figure 4:** Number of patients received ephedrine before and after delivery

Analysis of MAPs had shown that there was statistically significant difference in Group 1 compared to Group 2



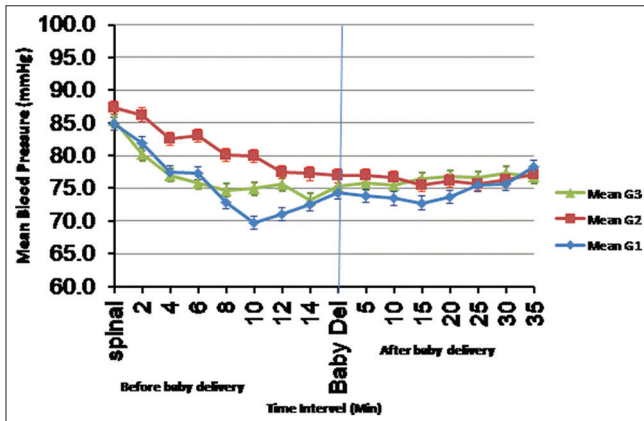
**Figure 3:** SBP change before and after baby delivery among the groups. Horizontal line denotes Median. Box denotes 25–75 percentile. Bottom whisker denotes 0–25 percentile and top whisker denotes 75–100 percentile. Circle denotes out layer and star denotes extreme values. Dollar (\$) denotes highly significant values. The horizontal long line shows SBP of 90 mmHg, down to that indicates parturient developed hypotension with  $P < 0.05$



**Figure 5:** Mean time to first dose of ephedrine

**Table 2: Spinal anesthesia to incision & Incision to delivery time**

Parameters	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	P
Spinal anaesthesia-incision interval (min)	4.9±1.45	4.7±1.26	4.48±1.32	0.443
Incision-delivery interval (min)	9.5±2.89	9.2±3.38	9.4±2.49	0.889



**Figure 6:** MAP change before and after baby delivery among the groups

**Table 3: Baseline heart rate, SBP, spinal level achieved in all the groups**

Parameters	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)
Heart rate (per min)	91±4	93±5	90±4
SBP (mmHg)	118±10	116±8	122±5
Spinal level (T4 & T6)	6 & 24	10 & 20	8 & 22

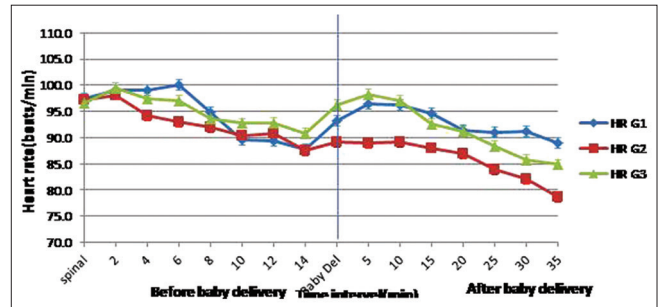
at the 8<sup>th</sup> min ( $P = 0.007$ ), 10<sup>th</sup> min ( $P = 0.005$ ), and 14<sup>th</sup> min ( $P = 0.040$ ) before delivery of the baby [Figure 6]. There was no statistically significant difference in MAPs between Group 1 and 3 at any point of time. The significant difference between Group 2 and 3 was seen at 2<sup>nd</sup> min (0.005) before the delivery of baby. There was no statistically significant difference in MAP after the delivery of baby among the groups.

HR was comparable in all the groups before the delivery of the baby [Figure 7]. There was a statistically significant difference in HR at 10<sup>th</sup> min between Group 1 and 2 after the delivery of baby ( $p 0.0005$ ).

The Apgar score was comparable among the groups. The mean Apgar score at 1 min was found to be 8 in all the three groups, and mean Apgar at 5 min was 9 in all the three groups.

## Discussion

The primary objective of the study was to investigate the effectiveness of leg wrapping with CB and PCD in the prevention of hypotension following administration of spinal anesthesia in parturients. This study revealed that patients who were allocated to CB and PCD group developed less incidence of hypotension when compared with the control group. This



**Figure 7:** Heart rate change before and after baby delivery among the groups

finding is in accordance with the previous studies.<sup>[12-15]</sup> Rout *et al.* had done a study in 97 parturients who were randomized into three groups; one group received leg elevation and wrapping, second group received leg elevation alone, and third group received none. Authors found that leg elevation and wrapping reduced the incidence of hypotension following spinal anesthesia.<sup>[10]</sup> The requirement of vasopressors was also lower in parturients who received leg wrappings'. This is comparable to the study done by Singh K *et al.*<sup>[6]</sup>

The secondary objectives of the study were to evaluate the hemodynamic changes among the study groups, any adverse events, and neonatal APGAR score. The incidence of hypotension and requirement of vasopressors was lower in Group 2 than Group 3 and 1; further, it was lower in Group 3 than Group 1 [Figures 3 and 4]. The incidence of hypotension and requirement of vasopressors were lower in Group 2 than the Group 3 probably owing to sequential compression with PCD causing blood volume in the leg to be propelled up to the central compartment. With relaxation, the blood probably returned back to the peripheral circulation thereby it failing to maintain central blood volume in a sustained manner.<sup>[7]</sup> There was no statistically significant difference in Apgar at 1 and 5 min among the groups. There were no statistically significant differences in time from administration of spinal anesthesia to delivery and from delivery till the end of surgery among the three groups. Level of blockade was comparable between the groups. None of the patients had dermatomal levels more than T4 or less than T6.

Mean time to receive the first dose of ephedrine after spinal anesthesia was statistically significant in the control group as compared to Group 2 and 3 ( $p 0.0001$ ) [Figure 5]. It was observed that the incidence of hypotension was more in the control group than in PCD and CB before the baby delivery. This shows the requirement of vigilant monitoring

and institution of effective measures to be taken to prevent the development of hypotension before delivery of the baby in a patient undergoing LSCS.

We combined fluid pre-loading, left lateral uterine tilt with the wedge, and wrapping the legs to improve the venous return to reduce the incidence of hypotension in this study. Hartley *et al.* studied the effects of lateral position with the wedged supine position on the development of hypotension following spinal anesthesia.<sup>[16]</sup> They did not find a significant difference in ephedrine requirements between the groups, but a trend toward reduced ephedrine requirements in the latter group. Kundra *et al.* studied the manual displacement of the uterus during cesarean section to prevent post-spinal hypotension owing to aortocaval compression, and they found that it effectively reduced the incidence of hypotension and requirement of ephedrine when compared to 15° left lateral tilt.<sup>[3]</sup>

The advantages of raising or compressing the legs following spinal anesthesia are that it increases venous return at the time that this is required and at a rate faster than can be achieved by intravenous infusion.<sup>[10]</sup> However, leg elevation alone has not been shown to reduce the incidence of hypotension.<sup>[10]</sup>

Singh K *et al.* in their study in 60 parturients undergoing LSCS observed that 43.3% developed hypotension in parturients who did not have leg wrapping done compared to those who had their legs wrapped (10%).<sup>[6]</sup> Goudie *et al.* found the usefulness of inflatable splints in reducing the incidence of hypotension.<sup>[17]</sup> Sujata N *et al.* studied the effect of sequential compression mechanical pump with thigh-high sleeves with compression cycles timed to venous refilling.<sup>[15]</sup> In their study, they found that the incidence of hypotension was lower (25.5%) than controls (50%) ( $P < 0.0001$ ). They concluded that the use of a sequential compression mechanical pumps that detect venous refilling and cycles accordingly, reduced the incidence and severity of hypotension after spinal anesthesia for cesarean sections. Similarly, our PCD group showed a lower incidence of hypotension, i.e., 23.70% than the controls, i.e., 67.70% ( $p < 0.0005$ ). It was found that in spite preloading with 20 ml/kg crystalloids and wedging, the incidence of hypotension was higher in the control group, whereas leg wrapping with CDs and PCD caused significant reduction in the incidence of maternal hypotension without any maternal and fetal side effects.

HRs were comparable among the groups before the delivery of the baby [Figure 7]. Goudie *et al.* observed that HR changes were inconsistent owing to physiological body adaptation and sympathectomy.<sup>[17]</sup> Further, their study population was small and probably underpowered to address this issue. In our study,

HRs were more stable in the CB group when compared with the other two, probably owing to more pooling of blood in peripheral venous compartments in Group 1 and 3, which was shown in graph trend [Figure 7].

Mean SBP was statistically significant before the delivery of the baby at 8<sup>th</sup>, 10<sup>th</sup>, 12<sup>th</sup>, and 14<sup>th</sup> min among the groups. There was a significant reduction in SBP in the control group at 8<sup>th</sup> and 14<sup>th</sup> min when compared with Group CB. Significant reductions in SBP at 6<sup>th</sup> and 8<sup>th</sup> min in the PCD group were also noted when compared with Group CB. However, there was no significant change in SBP between control and PCD groups. MAP changes before the baby delivery were found to be significant among the groups at 4<sup>th</sup>, 6<sup>th</sup>, 8<sup>th</sup>, 10<sup>th</sup>, and 14<sup>th</sup> min. MAP was significantly lower in the PCD group than the CB group at 2<sup>nd</sup> and 6<sup>th</sup> min. After the delivery of the baby, there were no significant differences in MAP between PCD and CB groups.

The decreased venous return caused by aortocaval compression during the gestational period is exacerbated by sympatholysis because of spinal anesthesia causing venous pooling of blood in the lower limbs and profound hypotension in spite preloading. The effect of aortocaval compression can be obviated by left uterine tilt or wedge and to offset the effects of sympatholysis on venous pooling the legs need to be wrapped. Preloading, left lateral tilt with the wedge, and wrapping, as in the CB or PCD groups were combined to alleviate the aforementioned effects of caval compression and sympatholysis by spinal anesthesia. The adverse effects of hypotension on maternal and fetal hemodynamics, adverse effects of vasopressors, etc., can be safely avoided by these non-pharmacological methods. In our study, elastic leg wrapping was much more effective in providing stable hemodynamics without much BP fall.

In our study, elastic leg wrapping was much effective in providing stable hemodynamic without much BP fall. Ephedrine requirement was also less in CB and PCD groups. In patient with leg wrapping, the incidence of hypotension was only 6.7%, which implies that in developing countries like India, many rural areas where the drug availability is limited; it could be used as a non-pharmacological measure to prevent hypotension. CB could be used safely for preventing hypotension. These methods such as leg wrapping and PCD are safe in applying to parturients that we have observed in the groups. Non-pharmacological methods are always safe to use compared to pharmacological methods in view of drug-induced side effects can be avoided.

In comparisons of control to PCD, incidence of hypotension and requirement of vasopressor were more in the control

group, whereas comparing with CB and PCD, incidence of hypotension and requirement of vasopressor were more in PCD. It might be owing to sequential compression cause blood volume in the leg propelled up to central compartment, when it relaxes blood goes to peripheral circulation and again cause vasodilatation; thus, it fail to maintain central blood volume in a sustained manner.<sup>[14,15]</sup>

In our study, no adverse events were noted both maternal and neonatal.

## Conclusion

This study has shown that using CDs or PCD reduce the incidence of hypotension in parturients undergoing elective LSCS. The requirement of vasopressors was lower in groups CB and PCD than the control groups. It has been revealed that CB was more effective in reducing the incidence of hypotension in parturients undergoing elective LSCS under spinal anesthesia. We recommend applying CB in a parturient undergoing elective LSCS under spinal anesthesia as a cost-effective, non-invasive, non-pharmacological, and effective tool in the prevention of venous pooling of blood in lower limbs, whereby we can reduce the incidence of hypotension in these patients.

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Institutional.

## Conflicts of interest

There are no conflicts of interest.

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