

Sequential compression device with thigh-high sleeves supports mean arterial pressure during Caesarean section under spinal anaesthesia

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Background. This study investigated the use of a Sequential Compression Device (SCD) with thigh-high sleeves and a preset pressure of 50 mm Hg that recruits blood from the lower limbs intermittently, as a method to prevent spinal hypotension during elective Caesarean section. Possible association of arterial pressure changes with maternal, fetal, haemodynamic, and anaesthetic factors were studied.

Methods. Fifty healthy parturients undergoing elective Caesarean section under spinal anaesthesia were randomly assigned to either SCD ($n=25$) or control ($n=25$) groups. A standardized protocol for pre-hydration and anaesthetic technique was followed. Hypotension was defined as a decrease in any mean arterial pressure (MAP) measurement by more than 20% of the baseline MAP. Systolic (SAP), MAP and diastolic (DAP) arterial pressure, pulse pressure (PP), and heart rate (HR) were noted at baseline and every minute after the spinal block until delivery.

Results. A greater than 20% decrease in MAP occurred in 52% of patients in the SCD group vs 92% in the control group ($P=0.004$, odds ratio 0.094, 95% CI 0.018–0.488). There were no significant differences in SAP, DAP, HR, and PP between the groups.

Conclusion. SCD use in conjunction with vasopressor significantly reduced the incidence of a 20% reduction of MAP.

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Subarachnoid block is the preferred anaesthetic for elective Caesarean section.^{1,2} The advantages are simplicity, rapid onset, reliability, dense motor block, and avoidance of the potential airway complications associated with general anaesthesia. However, hypotension occurs frequently following spinal block despite the use of standard preventive measures such as pre-hydration and left uterine displacement.^{1,3} This is distressing to the mother who often develops nausea and vomiting, and may also endanger the fetus as changes in maternal arterial pressure affect uteroplacental blood flow.⁴

There is good evidence that the strategy of recruiting blood from the lower extremities under spinal anaesthesia for Caesarean sections is clinically beneficial.^{5–8} For example, a systematic review evaluating the efficacy of

increasing the central blood volume on the incidence of hypotension following spinal anaesthesia for Caesarean section concluded that leg wrapping and colloid preload decreased the incidence of hypotension. A significant reduction in the incidence of hypotension by wrapping the patient's legs with an Esmarch bandage has been reported.^{6–9} However, the use of an Esmarch bandage application in this setting is not ideal because it exerts a constant lower extremity pressure that can neither be measured nor regulated, thus potentially impeding overall venous return.

In contrast to an Esmarch bandage, the thigh-high intermittent sequential compression device (SCD) (Kendall Health Care Products, Mansfield, MA, USA) prevents pooling of blood in the lower limbs by producing a

12-s period of compression at a preset pressure followed by a 60-s period of decompression. The SCD pressure is sequentially applied from the ankle to the thigh to produce a milking action. The SCD has been shown to be superior to single chamber compression by producing a high average and peak velocity of flow in the femoral veins, moving a greater volume of blood.^{10 11} SCD is safe and routinely used for the prevention of deep venous thrombosis.¹¹

In this study, we tested the hypothesis that intermittent compression by SCD decreases the incidence of hypotension in conjunction with routine vasopressor therapy following spinal anaesthesia for Caesarean section. We also studied the possible association between the magnitude of maternal arterial pressure changes and maternal/fetal anaesthesia-related variables and the duration of various intra-operative events.

Methods

The Institutional Research Review Board approved the study protocol, and written informed consent was obtained from each patient.

Fifty pregnant patients at term, ASA class I or II, undergoing elective Caesarean section were randomly assigned by opening sealed envelopes to either the SCD group ($n=25$) or the control group ($n=25$) when they arrived in the labour and delivery suite. Formal sample size was not calculated because there was no prior experience with the use of SCD. The study period was between October 1996 and December 1997. We excluded subjects who had chronic hypertension, multiple pregnancy, pregnancy-induced hypertension, diabetes mellitus, body weight greater than 110 kg, and contraindications to a spinal anaesthetic. All patients fasted for 10–14 h. On arrival to the labour and delivery suite the patients received 30 ml sodium citrate 0.3 M orally. Subsequently, the patients were positioned with left side tilt or left lateral displacement on the operating table. A 3-lead EKG monitor, pulse oximeter, and an automated non-invasive oscillotonometric arterial pressure monitor attached to a printer were applied. The same dedicated arterial pressure monitor was used in all the patients. Baseline systolic (SAP), diastolic (DAP), mean (MAP) arterial pressures were noted before proceeding with the protocol. The SCD group had appropriate size sleeves applied to the lower limbs.

Intermittent compression started with a preset pressure of 50 mm Hg. Pre-hydration with 20 ml kg^{-1} lactated Ringer's solution was administered over a period of 20–40 min. Spinal anaesthesia was performed in the sitting position using a 24 G Sprotte needle in the L3–4 or L2–3 interspace. All patients received bupivacaine 0.75% with dextrose 1.6 ml, 0.2 mg preservative free morphine and 10 μg fentanyl (total volume=2 ml). Thereafter, the patients were placed supine with a 20° left lateral tilt.

ECG and oxygen saturation were monitored continuously, and the arterial pressure was measured every

minute until delivery of the infant and every 3 min thereafter. The baseline pressure was defined as the average of three consecutive recordings with less than 10% variation over 10 min before pre-hydration. Baseline heart rate (HR) was defined as the average value recorded during the same time period. In our study, hypotension was defined either as a decrease in any MAP measurement to less than 80% of the baseline MAP. Hypotension was also studied and treated according to the conventional definition, that is, an SAP below 100 mm Hg or 80% of baseline. Hypotension was treated by an anaesthetist, who was blinded to the assigned study group, with ephedrine i.v. in 5 mg increments every minute until corrected. If a total of ephedrine 30 mg did not correct the hypotension, phenylephrine 0.05 mg i.v. was given. Simultaneously, the i.v. infusion rate and the left uterine tilt were increased.

The following variables were also recorded for each patient:

Maternal. Height, weight, gestational age, and number of previous Caesarean sections.

Haemodynamic data. SAP, DAP, MAP, PP (PP was calculated), and HR baseline and every minute after spinal anaesthesia until the birth.

Fetal. Presentation, birth weight (BWT), Apgar at 1 and 5 min, and umbilical cord blood gases.

Spinal. Level of sensory block of the highest thoracic dermatome (T) assessed at 15 min after initiation of the block.

Duration of events. Time taken for pre-hydration (min), pre-hydration to the administration of spinal anaesthesia (min), initiation of the spinal to the delivery (min), and uterine incision to the delivery (UD interval) (s).

Miscellaneous. Volume of the fluid infused after pre-hydration until the birth (ml) and the total dose of ephedrine and phenylephrine.

The change in arterial pressure was expressed as per cent change from the baseline. Statistix 7 (Analytical Software, Tallahassee, FL, USA) was used for data analysis. Measurement of all patient characteristics and clinical variables were compared between using either the χ^2 -test, Fisher exact test, or Wilcoxon's rank sum test. The incidence of hypotension was compared using the χ^2 -test or Fisher's exact test. Although variables other than the study variables were expected not to differ between the groups because of randomization, logistic regression was used to check for possible confounding. Percentages, means and SD were consistently used to describe the data. Odds ratios and their 95% CI were used as assessments of association. The study objective calls for testing group differences in incidence of hypotension based on measurements of SAP, DAP, and MAP. To test for significance at the $\alpha=0.05$ level, Sime's method for controlling for multiple comparisons was used. Thus, the P -values for significance were less than 0.017, less than 0.033, and less than 0.050.

Table 1 Patient characteristics; mean (SD). No significant differences. EGA=estimated gestational age; *n*=number of patients; SAP=systolic arterial pressure; MAP=mean arterial pressure; DAP=diastolic arterial pressure

Variable	SCD (<i>n</i> =25)	Control (<i>n</i> =25)
Weight (kg)	83.96 (16.14)	78.80 (10.84)
Height (cm)	164.72 (7.31)	161.30 (6.60)
EGA (week)	38.83 (1.04)	38 (0.97)
SAP baseline (mm Hg)	122.52 (10.32)	120.80 (9.46)
MAP baseline (mm Hg)	93.84 (8.9)	94.76 (9.1)
DAP baseline (mm Hg)	77.52 (8.59)	75.72 (8.3)

Table 2 Clinical variables. No significant differences. Data expressed as mean (1 SD) or median (25%, 75%). *n*=number of patients, T=thoracic dermatome

Variable	SCD (<i>n</i> =25)	Control (<i>n</i> =25)
Ephedrine dose (mg)	5 (0, 15)	10 (0, 15)
Fluid infused after pre-hydration (ml)	373.7 (104)	428 (170)
Birth weight (g)	3525 (486)	3422 (523)
Upper level of sensory block median (25%, 75%)	T3 (3, 4) range T1–5	T4 (3, 5) range T1–5
Pre-hydration time (min)	22.65 (4.99)	22.5 (5.4)
Pre-hydration-spinal interval (min)	3.15 (3.31)	3.54 (5.5)
Spinal-delivery interval (min)	24.9 (10.62)	25.09 (7.74)

Results

There was no significant difference between the groups with respect to height, weight, gestational age, number of previous Caesarean sections, baseline SAP, DAP, MAP, HR, vasopressor therapy, fluid infused after pre-hydration until the delivery, duration of events, BWT, presentation, and Apgar 1 and 5 min (Tables 1 and 2). All neonatal Apgar scores were greater than 8 at 1 and 5 min after delivery. Umbilical artery pH was greater than 7.25 in all samples. Clinical variables are described in Table 2 and results of the study variables are shown in Table 3.

All our patients had a baseline SAP above 100 mm Hg. A total of 32 patients, 14 from the SCD and 18 from the control group ($P=0.54$), had a decrease of SAP below 100 mm Hg. There was no significant difference between the groups in DAP, PP, and HR. However, the MAP decreased by more than 20% from baseline in 23 (92%) patients in the control group ($P 0.004$, Fisher exact test) vs only 13 (52%) in the SCD group. Controlling for other factors the SCD was independently associated with less hypotension ($P=0.004$, logistic regression).

Discussion

The main finding of this study is the 50% higher incidence of significant MAP reduction (greater than 20% of baseline) in the control group compared with the SCD group. By definition, the MAP is the timed average pressure that determines and maintains continuous blood flow to the organs and is quantitatively dependent on arterial blood volume and peripheral arteriolar resistance. However, in our

Table 3 Haemodynamic variables. Number of patients with more than 20% decrease from the baseline. Data are expressed as the per cent. Comparison using Fisher's exact test, accounting for multiple comparisons with significance at the 0.05 level. SCD=sequential compression device; SAP=systolic arterial pressure; DAP=diastolic arterial pressure; MAP=mean arterial pressure

Haemodynamic variables	Control	SCD	<i>P</i> -value	Odds ratio	95% CI
SAP	72%	64%	0.54	0.69	(209, 2.285)
DAP	76%	80%	0.73	1.26	(0.330, 4.837)
MAP	92%	52%	0.004	0.09	(0.018, 0.488)

study, because of the spinal anaesthesia-induced sympathetic block to dermatomal level T4 or higher causing loss of peripheral arteriolar resistance, the MAP becomes primarily dependent on the magnitude of arterial blood volume. Therefore, we conclude that the lower incidence of MAP decreases in the SCD group is a consequence of an overall higher arterial blood volume achieved by lower extremity intermittent compression with SCD. The automated arterial pressure monitor that was used is based on the oscillotonometric principle and measures primarily MAP as the maximum amplitude of the pulse and applies an algorithm to calculate the SAP and DAP. In contrast, when manual sphygmomanometers are used MAP is calculated according to the formula ($\text{MAP}=\text{DAP}+1/3\text{PP}$). The oscillotonometric MAP measurement is accurate and correlates well with the pressure in the ascending aorta.¹²

However, the changes in SAP and DAP were not significantly different between the groups. The following rationale might explain the differences in the steady and pulsatile components of arterial pressure. Vasodilatation induced by spinal anaesthesia increases the proportion of blood that runs to the periphery (systolic run off) during systole. This not only decreases the systolic pressure but also decreases the proportion of the blood volume in the arteries during diastolic phase resulting in decreased stretch, faster recoil, pressure decay, and diastolic pressure. We hypothesize that the recruited blood volume was not sufficient to maintain the systolic pressure and diastolic pressures.

SCD provides intermittent pressure in a sequential manner from the ankles upwards. Studies in normal volunteers have shown that during the compression phase SCD can move approximately 125 ml of blood.¹⁰ Although no studies have compared SCD blood volume recruitment in non-pregnant vs pregnant women, it is well known that parturients at term have more blood trapped in the lower extremities, and spinal anaesthesia-induced vasodilatation will increase the pooling even more. Thus, theoretically, the SCD might move an even greater blood volume centrally in this patient population. Moreover, in our study, we used thigh-high sequential compression sleeves, which are known to produce greater venous emptying and greater venous return than a single chamber device.

The typical clinical utility of the SCD is to prevent thrombosis by its intermittent squeezing action and there are

no controlled studies yet to determine its value in increasing the central blood volume. However, in one study, Unger and Feiner¹³ observed that the SCD was associated with increased central venous, pulmonary artery, and pulse pressures (PP) and they concluded that the increased PP reflected an increased stroke volume. They also observed that these changes were most prominent at a wedge pressure of 6 mm Hg and completely disappeared at 15 mm Hg, in accordance with the notion that, at a low preload, a small increase in central blood volume produces a larger increase in stroke volume and PP compared with similar changes in blood volume at higher preload. Horiuchi and colleagues¹⁴ also indirectly demonstrated increased venous return with intermittent lower extremity pneumatic compression by observing short, marked decreases in the temperature of pulmonary artery blood at times corresponding to inflation of the stockings. In our study, the calculated mean PP of the two study groups was found to be within the same range, probably secondary to the sympathetic block higher than T4.

In spite of the higher incidence of reduced MAP in the non-SCD treated control group, vasopressor therapy was not quantitatively different between the two groups, probably because it was used to sustain SAP at or greater than 100 mm Hg according to the protocol. However, despite clinically adequate vasopressor therapy, 92% of subjects in the control group decreased their MAP. Interestingly, others also did not demonstrate any significant difference in the ephedrine requirement despite a significantly smaller decrease in the SAP in the leg-wrapped group.^{7,8} This could be because interventions have occurred before the arterial pressure had a chance to reach its nadir.⁷ We speculate that additional variability in an individual's response to ephedrine and rapidly developing tachyphylaxis could also be contributing factors.¹⁵

The neonatal condition, as assessed by Apgar scores and umbilical cord blood gases, was excellent in both groups in spite of the maternal group difference in MAP. However, this finding is based on a healthy parturient study population with uncomplicated pregnancies. SCD may be clinically valuable in pregnancies with sub-optimal uteroplacental blood flow. By improving the central blood volume and preload, it may also be valuable in parturients with cardiac problems.

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